# SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 1999

Commission file number 0-26224

INTEGRA LIFESCIENCES HOLDINGS CORPORATION (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

51-0317849 (I.R.S. Employer Identification No.)

105 Morgan Lane Plainsboro, New Jersey (Address of principal executive offices)

08536 (Zip code)

(609) 275-0500

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or  $15\,\mathrm{(d)}$  of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

[x] - Yes [ ] - No

As of August 10, 1999 the registrant had outstanding 15,802,976 shares of Common Stock, \$.01 par value.

### INTEGRA LIFESCIENCES HOLDINGS CORPORATION

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#### PART I. FINANCIAL INFORMATION

### Item 1. Financial Statements

INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands, except per share amounts)

	June 30, 1999	December 31, 1998
ASSETS Current Assets:		
Cash and cash equivalents	\$ 12,020	\$ 5,277
Short-term investments	11,177	14,910
Accounts receivable, net	8,048	3,106
Inventories	11,218	2,713
Prepaid expenses and other current assets	706	921
Total current assets	43,169	26,927
Property and equipment, net	9,395	6,291
Intangible assets and goodwill, net	13,650	1,446
Other assets	588	43
Total assets	\$ 66,802	\$ 34,707
10141 455015	======	======
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Short-term loans (including current maturities on long-term		
loan)	\$ 1,763	
Accounts payable, trade	1,739	573
Accrued expenses and other current liabilities	7,900	2,456
Income taxes payable	594	
Total current liabilities	11,996	3,029
Long-term loan	8 <b>,</b> 875	
Deferred revenue	5,964	
Deferred tax liability	1,343	
Other liabilities	424	312
Total liabilities	28,602	3,341
Stockholders' Equity: Preferred stock, \$.01 par value (15,000 authorized shares; 500 Series A Convertible shares issued and outstanding at June 30, 1999 and December 31, 1998, \$4,000 liquidation preference; 100 Series B Convertible shares issued and outstanding at June 30, 1999, \$10,000 with a 10% compounded annual cumulative dividend liquidation preference)	6	5
Common stock, \$.01 par value (60,000 authorized shares; 15,785 shares issued and outstanding at June 30, 1999 and December 31,		
1998)	158	158
Additional paid-in capital	130,068	120,046
Other	(84)	(183)
Accumulated other comprehensive loss	(132)	(40)
1998)	(286)	(286)
Accumulated deficit	(91,530)	(88,334)
Total stockholders' equity	38,200	31,366
Total liabilities and stockholders' equity	\$ 66,802	\$ 34,707
	======	======

The accompanying notes are an integral part of the condensed consolidated financial statements

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(In thousands, except per share amounts)

	Three Months Ended June 30,		Three Months Ended June 30, Six Months En		Six Months Ende	nded June 30,	
	1999 	1998	1999 	1998			
REVENUE							
Product sales	\$12,133 417	\$ 3,367 460	\$16,738 780	\$ 6,530 1,857			
Total revenue	12,550	3,827	17,518	8,387			
COSTS AND EXPENSES							
Cost of product sales	7,689 2,307	1,604 2,074	10,383 4,304	3,330 4,216			
Selling and marketing	2,927 4,459	1,519 2,744	4,506 6,685	3,079 5,566			
Total costs and expenses	17,382	7,941	25,878	16,191			
Operating loss	(4,832)	(4,114)	(8,360)	(7,804)			
Gain on disposition of product line Other income, net	 9	 889	4,161 262	1,279			
Loss before income taxes	(4,823) 1,241	(3,225)	(3,937) 781	(6,525)			
Net loss	\$(3,582)	\$ (3,225)	\$(3,156)	\$(6,525)			
Basic and diluted net loss per share	\$ (0.23)	\$ (0.20)	\$ (0.21)	\$ (0.41)			
Weighted average number of common and common share equivalents outstanding	16,785	15,944	16,785	15,948			

The accompanying notes are an integral part of the condensed consolidated financial statements

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(In thousands)

	Six Months Ended June	
		1998
OPERATING ACTIVITIES:		
Net loss	\$ (3,156)	\$ (6,525)
acquisitions		1,115
operating activities	(4,119)	707
Net cash provided by (used in) operating activities	1,621	(4,703)
INVESTING ACTIVITIES:		
Proceeds from sale of product line and other assets  Purchase of restricted securities		47 (500)
Purchases of available-for-sales investments		(16,450)
Proceeds from sale/maturity of investments	15,000	20,920
Cash used in a business acquisition, net of cash acquired	(14,161)	
Purchases of property and equipment	. (776)	(606)
Net cash (used in) provided by investing activities		3,411
FINANCING ACTIVITIES:		
Net proceeds from revolving credit facility	. 13	
Repayments of term loan		
Proceeds from exercise of stock options		8
Treasury stock purchases		(89)
Proceeds from sale of preferred stock		4,000
Preferred stock dividends paid	. (40)	
Net cash provided by financing activities	. 9 <b>,</b> 522	3,919
Net increase in cash and cash equivalents		2,627
Cash and cash equivalents at beginning of period	5 <b>,</b> 277	2,083
Cash and cash equivalents at end of period		\$ 4,710 =====
Supplemental disclosure of non-cash investing and financing activities:		
Assumption of term loan in connection with the acquisition of		
NeuroCare	\$ 11,000	\$

The accompanying notes are an integral part of the condensed consolidated financial statements

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued (UNAUDITED)

#### l. General

In the opinion of management, the June 30 unaudited condensed consolidated financial statements contain all adjustments (consisting only of normal recurring accruals) which the Company considers necessary for a fair presentation of the financial position and results of operations of the Company. Operating results for the periods ended June 30, 1999 are not necessarily indicative of the results to be expected for the entire year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosures of contingent assets and liabilities and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 1998 included in the Company's Annual Report on Form 10-K.

#### 2. Strategic Alliance

On June 15, 1999, the Company and Johnson & Johnson Medical, Division of Ethicon, Inc. ("JJM") signed an agreement (the "JJM Agreement") providing JJM with exclusive marketing and distribution rights to INTEGRA(TM) Artifical Skin ("INTEGRA Skin") worldwide, excluding Japan, for a minimum of ten years. JJM may extend the JJM Agreement for successive ten-year periods solely at its discretion. Under the JJM Agreement, the Company will continue to manufacture INTEGRA Skin and will collaborate with JJM to conduct research and development and clinical research aimed at expanding indications and developing future products in the field of skin repair and regeneration.

Upon signing the JJM Agreement, the Company received a payment from JJM of \$5.3 million for the exclusive use of the Company's trademarks and regulatory filings related to INTEGRA Skin and certain other rights. This amount has been recorded as deferred revenue and will be amortized over the ten-year term of the JJM Agreement. Additionally, the JJM Agreement requires JJM to make non-refundable payments to the Company each year based upon minimum purchases of INTEGRA Skin. As a result, the Company received a \$1.2 million prepayment upon signing the JJM Agreement for minimum purchases in 1999, which was recorded in current liabilities as customer advances.

The JJM Agreement also provides for annual research funding beginning in 2000 and additional payments upon achieving certain clinical and regulatory milestones and for funding expansion of the Company's INTEGRA Skin production capacity as certain sales targets are achieved.

#### 3. Acquisition

On March 29, 1999 the Company acquired the business, including certain assets and liabilities, of the NeuroCare group of companies ("NeuroCare"), a leading provider of neurosurgical products. The \$25.4 million acquisition price was comprised of \$14.0 million of cash, \$11.0 million of assumed indebtedness under a term loan from Fleet Capital Corporation ("Fleet"), and \$0.4 million of contingent purchase price adjustments. Fleet is also providing a \$4.0 million revolving credit facility to fund working capital requirements, of which \$13,000 was drawn down as of June 30, 1999. The cash portion of the purchase  $\frac{1}{2}$ price was financed in part by affiliates of Soros Private Equity Partners LLC, through the sale of \$10 million of Series B Convertible Preferred Stock and warrants. The convertible preferred shares are convertible into 2,617,801 shares of the Company's common stock, have a liquidation preference of \$10.0 million with a 10% compounded annual return and are senior to all other equity securities of the Company. The warrants issued are for the right to acquire 240,000 shares of the Company's common stock at an exercise price of \$3.82 per share. The acquisition has been accounted for under the purchase method of accounting. The purchase price has been preliminarily allocated based on estimated fair values at the date of acquisition. This preliminary allocation has resulted in acquired intangibles and goodwill of approximately \$13.5 million, which is being amortized on a straight-line basis over 15 years. The following is a summary of the preliminary allocation (in thousands):

Cash	Ş	285
Accounts receivable		4,958
Inventory		10,803
Property and equipment		3,654
Other assets		559
Intangibles and goodwill		13,456
Accrued expenses and other liabilities		(8,312)
Term loan		(11,000)
	\$	14,403
	==	

The following unaudited pro forma financial information assumes that the acquisition had occurred as of the beginning of each period (in thousands):

	For the Six Ended June	
	1999	1998
Total revenue	\$ 24,690	\$ 24,306
Net loss	(6,624)	(5,969
Basic and diluted loss		
per share	\$ (0.43)	\$ (0.41

The pro forma amounts for the six months ended June 30, 1999 exclude the \$3.7 million aftertax gain (\$0.22 per share) from the sale of the Panafil(R) product line (see Note 4). The pro forma amounts are based upon certain assumptions and estimates, and do not reflect any activities that might have occurred as a result of the acquisition. The pro forma results do not necessarily represent results that would have occurred if the acquisition

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

had taken place on the basis assumed above, nor are they indicative of the results of future combined operations.

#### 4. Panafil(R) Product Line Disposition

In January 1999, the Company sold the Rystan Panafil(R) product line, including the brand name and related production equipment, to Healthpoint, Ltd. for \$6.4 million in cash. The Company recognized a pre-tax gain of \$4.2 million after adjusting for the net cost of the assets sold and for expenses associated with the divestiture, including the closing of the Rystan facility.

#### 5. Loss per share and comprehensive loss

Basic and diluted net loss per share and comprehensive loss for the three and six months ended June 30 were as follows (in thousands):

	Three Months En	ded June 30,	Six Months End	
	1999 	1998	1999 	1998
Basic and diluted loss per share:				
Net loss  Dividends on Series A preferred stock  Dividends on Series B preferred stock	\$ (3,582) (20) (250)	\$ (3,225)  	\$ (3,156) (40) (250)	\$ (6,525) (7) 
Net loss applicable to common stock	\$ (3,852)	\$ (3,225)	\$ (3,446)	\$ (6,532)
Average number of shares outstanding	16,785	15,944	16,785	15,948
Basic and diluted loss per share	\$ (0.23) ======	\$ (0.20) =====	\$ (0.21) ======	\$ (0.41) ======
Comprehensive loss:				
Net loss Unrealized (loss) gain on investments	\$ (3,582) (108)	\$ (3,225) 6	\$ (3,156) (92)	\$ (6,525) (45)
Comprehensive loss	\$ (3,690) ======	\$ (3,219) ======	\$ (3,248) ======	\$ (6,570)

Options and warrants to purchase 4,018,077 and 2,275,000 shares of common stock and preferred stock convertible into 2,867,801 and 250,000 shares of common stock at June 30, 1999 and 1998, respectively, were not included in the computation of diluted loss per share because their effect would be antidilutive.

#### 6. Inventory

Inventories consist of the following (in thousands):

	June 30, 1999	December 31, 1998
Finished goods	\$ 4,877	\$1,433
Work-in-process	2,622	802
Raw materials	3,719	478
	\$11,218	\$2,713
	======	=====

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### 7. Current Liabilities

Accrued expenses and other liabilities consist of the following (in thousands):

	June 30, 1999	December 31, 1998
Customer advances	\$1,715	\$ 249
Acquisition costs	1,325	
Legal fees	826	591
Provision for facility closing	828	
Contract research	499	401
Vacation	582	260
Other	2,125	955
	\$7,900	\$2,456
	=====	=====

#### 8. Segment Reporting

The Company's reportable business segments are outlined in the Company's 1998 audited financial statements. As a result of the NeuroCare acquisition, the Company operates its neurosurgical business activities as a separate business segment. The majority of the Company's neurosurgical activity was previously included in the medical products business segment. Additionally, subsequent to the transfer of all INTEGRA Skin sales and marketing activities to JJM under the JJM Agreement signed in June 1999 (see Note 2) and the sale of the Panafil(R) product line in the first quarter of 1999, the results of the former skin repair and burns segment are now included in the medical products segment (which will now be referred to as the surgical products segment), as these products are now sold under OEM arrangements.

(In thousands)		Surgical	Reportable Segments	Corporate and All	
Business Segment	Neurosurgical	_	-		Total
Three months ended June 30,					
1999					
Total revenue	\$ 8,265 10,318 (2,053)	\$ 4,255 5,339 (1,084)		1,725	\$ 12,550 17,382 (4,832)
1998					
Total revenue	\$ 582 (582)	\$ 3,772 4,651 (879)	\$ 3,772 5,233 (1,461)		\$ 3,827 7,941 (4,114)
Six months ended June 30,					
1999					
Total revenue	\$ 8,786 11,205 (2,419)	\$ 8,591 11,315 (2,724)	22,520		\$ 17,518 25,878 (8,360)
1998					
Total revenue	\$ 1,000 1,188 (188)	,		\$ 107 5,378 (5,271)	\$ 8,387 16,191 (7,804)

INTEGRA LIFESCIENCES HOLDINGS CORPORATION AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### 9. Legal Matters

In July 1996, the Company filed a patent infringement lawsuit against three parties: Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps. The complaint charges, among other things, that the defendant Merck KGaA willfully and deliberately induced, and continues to willfully and deliberately induce, defendants Scripps Research Institute and Dr. David A. Cheresh to infringe on one of the Company's patents. This patent is one of a group of five patents granted to The Burnham Institute and licensed by the Company that are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid (known as "RGD") peptide sequence found in many extracellular matrix proteins. The defendants have filed a countersuit asking for an award of defendants' reasonable attorney fees.

The ultimate liability of any litigation matter cannot be determined because of the considerable uncertainties that exist. The Company's financial statements do not reflect any significant amounts related to possible unfavorable outcomes of the matter above. However, it is possible that the Company's results of operations, financial position and cash flows in a particular period could be materially affected by an unfavorable outcome of the above matter.

# Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with the Company's consolidated financial statements, the notes thereto and the other financial information included elsewhere in this report and in the Company's 1998 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

#### General

The Company has developed principally by combining existing businesses, acquiring synergistic technologies and forming strategic business and technological alliances. As a result of the Company's acquisition of Rystan Company, Inc. ("Rystan") in September 1998 and the acquisition of the NeuroCare Group of companies ("NeuroCare") in March 1999, the Company's consolidated financial results for the three and six months ended June 30, 1999 and 1998 may not be directly comparable. In addition, the Company's financial information discussed below should be considered in light of the Company's sale of the Panafil(R) product line on January 5, 1999.

#### Results of Operations

Three Months Ended June 30, 1999 Compared to Three Months Ended June 30, 1998

Total revenues increased significantly to \$12.6 million for the three months ended June 30, 1999 from \$3.8 million for the three months ended June 30, 1998 due to the acquisitions of NeuroCare and Rystan. Excluding the effects of the NeuroCare and Rystan acquisitions, total revenues decreased to \$3.6 million for the three months ended June 30, 1999, primarily from a decrease in product sales. Product sales, excluding the NeuroCare and Rystan acquisitions, decreased from \$3.4 million for the three months ended June 30, 1998 to \$3.2 million for the three months ended June 30, 1999. This decrease resulted from a decrease of \$0.4 million in sales of INTEGRA(TM) Artificial Skin ("INTEGRA Skin"), which was partially offset by an increase of \$0.2 million in sales of other surgical products. On June 15, 1999, the Company and Johnson & Johnson Medical, Division of Ethicon, Inc. ("JJM") signed an agreement (the "JJM Agreement") providing  $\rm JJM$ with exclusive marketing and distribution rights to INTEGRA Skin worldwide, excluding Japan, for a minimum of ten years. Under the JJM Agreement, the Company will continue to manufacture INTEGRA Skin and will collaborate with JJM to conduct research and development and clinical research aimed at expanding indications and developing future products in the field of skin repair and regeneration. The Company believes that growth in the use and sale of INTEGRA Skin will depend on JJM's ability to market the product for reconstructive and other additional indications.

Excluding the NeuroCare and Rystan acquisitions, sales of the Company's other surgical products increased to \$2.1 million for the three months ended June 30, 1999 from \$1.9 million for the three months ended June 30, 1998. This increase was related a \$0.4 million increase in sales of infection control products, offset by a \$0.2 million decrease in sales of other OEM products. Because significant portions of the Company's surgical products segment sales are made to marketing partners and distributors, quarter-to-quarter sales in the segment can vary significantly depending on the timing of shipments to these partners and distributors.

Product sales from NeuroCare and Rystan were \$8.9 million in the current quarter, with the Panafil(R) product line providing \$0.5 million of sales. Although under the terms of the Panafil(R) disposition agreement the Company is entitled to revenue based on identified sales into the podiatry and burn care markets (less certain fees), the Company currently anticipates a decline in Panafil(R) revenue in future periods.

Export sales for the three months ended June 30, 1999 were \$3.2 million, compared to \$0.7 million for the three months ended June 30, 1998, primarily due to the acquisition of NeuroCare.

Other revenue, which includes grant revenue, license fees, product development revenue and royalties, was approximately \$0.4 million for the three months ended June 30, 1999 compared to \$0.5 million for the three months ended June 30, 1998. The Company continues to seek research grants, licensing arrangements and development funding for several of its technologies, although the timing and amount of such revenue, if any, can not be predicted.

Cost of product sales increased significantly to \$7.7 million (63% of product sales) for the three months ended June 30, 1999 from \$1.6 million (48% of product sales) for the three months ended June 30, 1998 because of the effects of the NeuroCare and Rystan acquisitions. The significant increase in cost of product sales as a percentage of product sales is primarily attributable to \$1.8 million of fair value purchase accounting adjustments related to NeuroCare and Rystan inventory sold in the second quarter of 1999 and \$0.5 million of inventory reserves related to certain slow-moving products within the neurosurgical business where the Company is reducing its sales and marketing efforts. Excluding purchase accounting adjustments, cost of product sales would have been 49% of product sales in the second quarter of 1999. Excluding the NeuroCare and Rystan acquisitions, cost of product sales increased to \$1.8 million (53% of product sales) for the three months ended June 30, 1999. The Company anticipates that the inclusion of INTEGRA Skin sales in the surgical products segment and the lower gross margin percentage associated with sales of INTEGRA Skin under the JJM Agreement will adversely affect the gross margin percentage within the surgical products business. The impact on gross margin percentage will depend on capacity utilization and product mix within the surgical products business. The Company's consolidated gross margin should improve in the fourth quarter of 1999 after all inventory affected by the fair value purchase accounting adjustments has been sold.

Research and development expense increased to \$2.3\$ million for the three-month period ended June 30, 1999 from \$2.1 million for the three-month period ended June 30, 1998 because of the effect of the NeuroCare acquisition. Excluding the NeuroCare acquisition, research and development expense decreased to \$1.6 million for the three months ended June 30, 1999. This decrease resulted from the elimination of several collaborative research programs in non-core development programs. The Company anticipates adjusting the allocation of research and development resources as it combines NeuroCare's development activities. The JJM Agreement will provide the Company with research funding for INTEGRA Skin beginning in 2000. Additional funding to support the Company's research and development programs will be available if certain clinical and regulatory milestones related to INTEGRA Skin are achieved. The amount and allocation of resources to fund research and development will vary depending upon a number of factors, including the progress of development of the Company's technologies, the timing and outcome of pre-clinical and clinical results, changing competitive conditions, continued program funding levels, potential funding opportunities and determinations with respect to the commercial potential of the Company's technologies.

Selling and marketing expense increased to \$2.9 million for the three-month period ended June 30, 1999 from \$1.5 million for the three-month period ended June 30, 1998 because of the effect of the NeuroCare acquisition. Excluding the NeuroCare acquisition, selling and marketing expense decreased to \$1.3 million for the three months ended June 30, 1999. This decrease resulted from the reduction of INTEGRA Skin selling and marketing activities, which was partially offset by increased expenses relating to the Company's DuraGen(TM) dural graft matrix ("DuraGen") product pre-launch activities. In July 1999, the Company received FDA 510(K) clearance in the United States for DuraGen as a dura substitute for the repair of the dura mater of the brain. In February 1999, the Company received CE Mark Certification for DuraGen which allows the Company to market this new neurosurgical implant throughout the 18 member countries of the European Union. In the future, selling and marketing expenses related to INTEGRA Skin are expected to decrease, as these activities will be assumed by JJM.

General and administrative expense increased to approximately \$4.5 million for the three-month period ended June 30, 1999 from \$2.7 million for the three-month period ended June 30, 1998 primarily due to the effect of the NeuroCare and Rystan acquisitions. Included in the amount for the three months ended June 30, 1999 is \$0.8 million of employee severance costs relating to NeuroCare's recently closed Wisconsin facility. Excluding these charges and the remainder of the effect of the NeuroCare and Rystan acquisitions, general and administrative costs decreased to \$2.3 million for the three months ended June 30, 1999. This decrease is primarily the result of decreased legal fees, as the Company resolved various litigation matters in 1998.

While the Company believes that the consolidation of its corporate and distribution facilities will result in an overall cost reduction, the Company is anticipating a short-term increase in operating costs related to the NeuroCare acquisition, including additional severance costs, the transfer and installation of distribution and telecommunication equipment and other transition and training costs required as a result of the Wisconsin facility closing.

Other income, net, decreased from \$0.8 million for the three months ended June 30, 1998 to \$9,000 for the three months ended June 30, 1999. This decrease is primarily the result of a \$0.5 million litigation settlement gain recorded in the second quarter of 1998 and interest expense of \$0.2 million in the current quarter on the Fleet term loan assumed in the NeuroCare acquisition.

The income tax benefit of \$1.2 million for the three months ended June 30, 1999 is due to the deferred tax benefits recognized on the consolidated post-acquisition losses to the extent of the deferred tax liability recorded in the NeuroCare acquisition. Additional income tax benefit is expected through the remainder of 1999 as anticipated additional consolidated losses are incurred and the deferred tax liability is further reduced.

Six Months Ended June 30, 1999 Compared to Six Months Ended June 30, 1998

Total revenues increased significantly to \$17.5 million for the six months ended June 30, 1999 from \$8.4 million for the six months ended June 30, 1998 as a result of the NeuroCare and Rystan acquisitions. Excluding the effects of the NeuroCare and Rystan acquisitions, total revenues decreased to \$7.5 million for the six months ended June 30, 1999, primarily from a decrease of \$1.1 million in other revenue. Excluding the effects of the NeuroCare and Rystan acquisitions, product sales increased to \$6.7 million for the six months ended June 30, 1999 from \$6.5 million for the six months ended June 30, 1998. This increase was the result of a \$0.8 million increase in sales of other surgical products, which was offset by a \$0.6 million decrease in sales of INTEGRA Skin. Excluding the

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NeuroCare and Rystan acquisitions, sales of the Company's other surgical products increased to \$4.4 million for the six months ended June 30, 1999 from \$3.6 million for the six months ended June 30, 1998. This increase was primarily related to increased sales of the Company's dental and other OEM products. Product sales from NeuroCare (post-acquisition) and Rystan were \$10.0 million in the six months ended June 30, 1999, with the Panafil(R) product line providing \$0.9 million of sales. Export sales for the six months ended June 30, 1999 increased to \$4.2 million from \$1.3 for the six months ended June 30, 1998.

Other revenue was \$0.9 million for the six months ended June 30, 1999 compared to \$1.9 million for the six months ended June 30, 1998. The decrease related primarily to a non-refundable \$1.0 million licensing fee from Century Medical, Inc. in the first quarter of 1998. The Company continues to seek research grants, licensing arrangements and development funding for several of its technologies, although the timing and amount of such revenue, if any, can not be predicted.

Cost of product sales increased significantly to \$10.4 million (62% of product sales) for the six months ended June 30, 1999 from \$3.3 million (51% of product sales) for the six months ended June 30, 1998 because of the effects of the NeuroCare and Rystan acquisitions. The significant increase in cost of product sales as a percentage of product sales is primarily attributable to \$2.0 million of fair value purchase accounting adjustments related to NeuroCare and Rystan inventory and \$0.5 million of inventory reserves related to certain slow-moving products within the neurosurgical business. Excluding purchase accounting adjustments, cost of product sales would have been 50% of product sales for the six months ended June 30, 1999. Excluding the NeuroCare and Rystan acquisitions, cost of product sales increased to \$3.8 million (57% of product sales) for the six months ended June 30, 1999, compared to \$3.3 million (51% of product sales) for the six months ended June 30, 1998, largely due to lower utilization of the INTEGRA Skin manufacturing capacity in the first quarter of 1999.

Research and development expense increased to \$4.3 million for the six months ended June 30, 1999 compared to \$4.2 million for the six months ended June 30, 1998 due to the NeuroCare acquisition. Excluding the NeuroCare acquisition, research and development expense decreased to \$3.6 million for the six months ended June 30, 1999. This decrease resulted from the elimination of several collaborative research programs in non-core development programs.

Selling and marketing expense increased to \$4.5 million for the six-month period ended June 30, 1999 from \$3.1 million for the six-month period ended June 30, 1998 because of the effect of the NeuroCare acquisition. Excluding the NeuroCare acquisition, selling and marketing expense decreased to \$2.8 million for the three months ended June 30, 1999. This decrease resulted from the reduction of INTEGRA Skin selling and marketing costs, which was partially offset by increased expenses relating to the Company's pre-launch activities for DuraGen.

General and administrative expense increased to \$6.7 million for the six-month period ended June 30, 1999 from \$5.6 million for the six-month period ended June 30, 1998 due primarily to the effects of the NeuroCare and Rystan acquisitions. Included in the amount for the six months ended June 30, 1999 was \$0.8 million of employee severance costs relating to NeuroCare's recently closed Wisconsin facility. Excluding these charges and the remainder of the effect of the NeuroCare and Rystan acquisitions, general and administrative costs decreased to \$4.3 million for the three months ended June 30, 1999. This decrease is primarily the result of a significant decrease in legal fees in 1999, as the Company resolved various litigation matters in 1998, and a \$0.2 million asset impairment charge recorded in the first quarter of 1998.

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Other income, net increased to \$4.4 million for the six months ended June 30, 1999 from \$1.3 million for the six months ended June 30, 1998. This increase is primarily the result of a \$4.2 million gain (\$3.7 million net of taxes) related to the sale in January 1999 of the Panafil(R) product line along with certain other assets related to the product. Offsetting this gain is a \$0.5 million litigation settlement gain recorded in the second quarter of 1998 and interest expense of \$0.3 million in the six months ended June 30, 1999 on the Fleet term loan assumed in the NeuroCare acquisition.

The income tax benefit of 0.8 million for the six months ended June 30, 1999 included 0.5 million of taxes associated with the gain on the sale of the Panafil(R) product line, offset by a 1.2 million deferred tax benefit discussed above.

#### Liquidity and Capital Resources

The Company has funded its operations to date primarily through private and public offerings of equity securities, product revenues, research and collaboration funding, borrowings under a revolving credit line and cash acquired in connection with business acquisitions. At June 30, 1999, the Company had cash, cash equivalents and short-term investments of approximately \$23.2 million and \$10.6 million in short and long-term debt. The Company's principal uses of funds during the six-month period ended June 30, 1999 were \$14.1 million in the acquisition of NeuroCare, \$0.8 million in purchases of property and equipment and \$0.4 million in repayments of term loans. Cash flows provided by operations for the six months ended June 30, 1999 were \$1.6 million, which included \$6.5 million received from the JJM Agreement. During the six months ended June 30, 1999, the Company also raised \$10.0 million with the sale of Series B Preferred Stock and warrants to Soros Private Equity Partners LLC, assumed \$11 million of term debt in connection with the NeuroCare acquisition and received \$6.4 million in connection with the sale of the Panafil(R) product line.

The Company anticipates that it will continue to use its liquid assets to fund operations until sufficient revenues can be generated through product sales and collaborative arrangements. With the acquisition of NeuroCare, the Company has approximately \$2.4 million in liabilities related to the acquisition that will need to be funded over the remainder of 1999, including \$0.4 million of a contingent purchase price adjustment. As part of the assumption of the NeuroCare term loan, the Company obtained a \$4.0 million revolving credit facility to fund working capital needs of NeuroCare, of which \$13,000 was drawn down at June 30, 1999. The Company anticipates that NeuroCare will utilize the revolving credit facility to fund its capital needs. In the short-term, the Company believes that it has sufficient resources to fund its operations. However, in the longer-term, there can be no assurance that the Company will be able to generate sufficient revenues to obtain positive operating cash flows or profitability.

#### Year 2000 Disclosure

As is true for most companies, the potential for problems involving existing information systems as we approach and pass January 1, 2000 creates a risk for the Company. These potential problems are the result of the inability of certain date-sensitive computer programs and embedded controls to recognize a two-digit date field designated as "00" as the year 2000 instead of the year 1900, the consequences of which could lead to system failures or miscalculations causing disruptions to operations and normal business activities. This is a significant issue with far reaching implications, some of which cannot be anticipated or predicted with any degree of certainty and is commonly referred to as a Year 2000 (Y2K) compliance issue.

#### The Company's Businesses

The Company has completed its initial assessment as well as its correction plan for all areas previously identified as potentially compromised by the advent of Y2K. This correction plan was comprised of (i) the assessment of information technology systems ("IT systems") and non-IT systems for Y2K compliance, (ii) the modification and/or replacement of non-compliant systems, (iii) the testing of modified and/or replaced systems, and (iv) the deployment of Y2K compliant systems. Actions taken to achieve Y2K compliance included upgrading current hardware and software as well as purchasing additional hardware and software to enhance current IT systems. The majority of the capital expenditures and operating costs associated with these upgrades and purchases would have occurred in the normal course of business regardless of the Y2K issue, although a portion of such expenditures and costs is attributable to the Company's Y2K correction plan. The Company's upgrades and purchases for all critical systems have been implemented and tested. We have tested and confirmed that all critical systems are fully Y2K compliant or only require a simple manual update on the first of the new year to be compliant. The few remaining non-critical systems will be made Y2K compliant before December 31, 1999 as part of regularly scheduled system upgrades.

The only business division of the Company that makes and sells products that contain computer processors is Integra NeuroCare. The Company has determined that the Camino line of intracranial pressure monitors does not include a dating function, and therefore will not be affected by Y2K considerations. The Neuro Navigational line of neuroendoscopy products does contain certain dating functions that will be affected by Y2K considerations, but the substantive performance of the devices will not be affected. The Company is providing its customers with instructions for resetting the dating function to overcome effects of the Y2K considerations. No other products manufactured by the Company contain any materials that would make such products susceptible to disruptions relating to the Y2K.

#### Suppliers

The Company has been reviewing and has requested assurances on the status of the Y2K readiness of its critical suppliers. Many of these suppliers, however, have provided limited assurances on the status on their Y2K readiness. The Company plans to continue to monitor critical suppliers during 1999. As a precaution, Integra LifeSciences is beginning to build inventories of both raw materials and finished goods so that temporary shortages or an increase in product demand will not negatively effect the companies operations. The Company has also reviewed information regarding its major customers to assess their readiness for Y2K. If a significant number of suppliers and customers experience disruptions as a result of the Y2K issue, this could have a material adverse effect on the financial position and results of operations of the Company. Although the Company is formulating contingency plans to deal with Y2K problems of key business partners and major customers, there can be no assurance that these plans will address all Y2K problems or that the implementation of these plans will be successful.

Given the information available at this time, the Company currently anticipates that the amount that will be spent to complete its Y2K correction plan will not have a material adverse impact on the Company's business, results of operations, financial position and cash flow. Furthermore, Integra does not expect that the effects of any Y2K non-compliance on its systems will have any material adverse impact on the Company's business, results of operations, financial positions or cash flows. However, there can be no assurance that Integra will not incur additional expenses or experience business disruption as a result of systems problems associated with the century change, including system and equipment problems with third parties with which Integra does business.

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#### Item 4. Submission of Matters to a Vote of Security Holders

The Company's Annual Meeting of Stockholders was held on May 17, 1999 and in connection therewith, proxies were solicited by management pursuant to Regulation 14 under the Securities Exchange Act of 1934. An aggregate of 15,730,933 shares of the Company's common stock ("Common Stock"), 500,000 shares of Series A Preferred Stock (which are convertible into 250,000 shares of Common Stock) and 100,000 shares of Series B Preferred Stock (which are convertible into 2,617,801 shares of Common Stock) (collectively, "Shares") were outstanding and entitled to a vote at the meeting. At the meeting the following matters (not including ordinary procedural matters) were submitted to a vote of the holders of Shares, with the results indicated below:

1. Approval of Company Name Change. The proposal to approve and adopt an amendment to the Company's Amended and Restated Certificate of Incorporation to change the name of the Company to "Integra LifeSciences Holdings Corporation" was approved. The tabulation of votes was as follows:

For	Against	Abstentions
14,068,244	34,806	18,591

2. Approval of the Company's 1999 Stock Option Plan. The Company's 1999 Stock Option Plan was approved. The tabulation of votes was as follows:

For	Against	Abstentions
10,470,286	1,729,929	1,976,752

3. Approval of the Company's Deferred Compensation Plan. The Company's Deferred Compensation Plan was approved. The tabulation of votes was as follows:

For	Against	Abstentions
13,971,862	123,118	17,110

4. Election of directors to serve until the 2000 Annual Meeting. The following persons, all of whom were serving as directors, except for Mr. Moszowski, and were management's nominees for election, were elected. There was no solicitation in opposition to such nominees. The tabulation of votes was as follows:

Nominee	For	Withheld
Keith Bradley	14,069,091	50 <b>,</b> 950
Richard E. Caruso	14,066,800	53,241
Stuart M. Essig	14,069,941	50,100
George W. McKinney, III	14,069,091	51,292
Neil Moszkowski	14,068,749	52 <b>,</b> 750
James M. Sullivan	14,069,263	50 <b>,</b> 778
Edmund L. Zalinski	14,066,889	53,152

5. Ratification of independent auditors. The appointment of PricewaterhouseCoopers LLP as the Company's independent auditors for the current fiscal year was ratified. The tabulation of votes was as follows:

For	Against	Abstentions
13,276,727	11,458	4,275

Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits

10.1 Supply, Distribution and Collaboration Agreement between Integra LifeSciences Corporation and Johnson & Johnson Medical, a Division of Ethicon, Inc. dated as of June 3, 1999, certain portions of which are subject to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

27 Financial Data Schedule

#### (b) Reports on Form 8-K

On April 13, 1999, a Report on Form 8-K dated March 29, 1999 was filed relating to the acquisition of certain assets and stock held by Heyer-Schulte NeuroCare, L.P. and its subsidiaries, Heyer-Schulte NeuroCare, Inc., Camino NeuroCare, Inc. and Neuro Navigational, LLC (collectively, the "NeuroCare Group") on March 29, 1999.

On June 14, 1999, a Report on Form 8-K/A was filed to present and disclose the financial statements and pro forma financial information required to be filed in connection with the acquisition of the NeuroCare Group.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

Date: August 16, 1999 By: /s/ Stuart M. Essig

Stuart M. Essig

President and Chief Executive Officer

Date: August 16, 1999 By: /s/ David B. Holtz

David B. Holtz

Vice President, Finance and Treasurer

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## Exhibit Index

## Exhibit No.

10.1 Supply, Distribution and Collaboration Agreement between Integra LifeSciences Corporation and Johnson & Johnson Medical, a Division of Ethicon, Inc. dated as of June 3, 1999, certain portions of which are subject to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

27 Financial Data Schedule

EXECUTION COPY

### SUPPLY, DISTRIBUTION AND COLLABORATION AGREEMENT

between

### INTEGRA LIFESCIENCES CORPORATION

and

JOHNSON & JOHNSON MEDICAL (Trademark), A DIVISION OF ETHICON, INC.

Dated as of June 3, 1999

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THIS SUPPLY, DISTRIBUTION AND COLLABORATION AGREEMENT, dated as of June 3, 1999, is made and entered into by and between Integra LifeSciences Corporation, a Delaware corporation, having offices at 105 Morgan Lane, Plainsboro, New Jersey 08536, U.S.A. ("Integra") and Johnson & Johnson Medical(Trademark), a Division of Ethicon, Inc., a New Jersey corporation, having offices at 2500 Arbrook Blvd., Arlington, Texas 76014, U.S.A. ("JJM").

WHEREAS, Integra has developed the Integra(Trademark) Dermal Regeneration Template(Trademark) for use as a skin implant that provides a matrix structure to facilitate the orderly regeneration of human tissue on wound sites; and

WHEREAS, Integra desires to engage JJM as its exclusive distributor to market, distribute and sell the Integra(Trademark) Dermal Regeneration Template(Trademark) and other Products within the Territory and JJM desires to serve in such capacity; and

WHEREAS, both parties recognize that Integra will continue to develop, market, distribute and sell Integra(Trademark) Dermal Regeneration
Template(Trademark) for dental/gingival use under a different trademark, as well as any other products Integra may develop, purchase or in-license outside the Field; and

WHEREAS, JJM wishes to provide financial and other support for Integra in its ongoing research, development and clinical efforts relating to the Integra(Trademark) Dermal Regeneration Template(Trademark) to facilitate Integra's development of improvements to such product and its development of additional approved indications for such product; and

WHEREAS, JJM and Integra wish to define various elements of their collaboration regarding the Integra(Trademark) Dermal Regeneration Template(Trademark) and its related improvements;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the parties hereto, intending to be legally bound, hereby agree as follows:

#### ARTICLE I.

#### DEFINITIONS

Section 1.1. Certain Defined Terms. As used in this Agreement, the following terms shall have the following meanings.

(a) "Affiliate" means, with respect to any specified Person (as hereinafter defined), any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such specified Person. "Control", with respect to an entity, shall be deemed to include but not be limited to the power to vote or direct the

voting (by reason of ownership of securities, contractual rights or otherwise) of 50% or more of the voting securities of such entity. Any references in this Agreement to the Affiliates of JJM shall hereby be deemed to include JJM's Parent and the Affiliates of JJM's Parent.

- (b) "Annual Plan" means the written plan describing the research goals, clinical trials (other than the Excisional Wound and Chronic Wound Trials), specific budgets and priorities to be carried out pursuant to this Agreement during a calendar year by Integra and JJM, whether utilizing Integra or JJM personnel, or both, or utilizing third party providers, as annually approved by the Joint Steering Committee.
- (c) "Business Day" means a day other than a Saturday, Sunday or other day on which banks in the State of New Jersey are not required or authorized to close.
- (d) "Calendar Quarter" means the three month periods commencing on January 1, April 1, July 1 and October 1 in each year.
- (e) " [\*\*] Wound Trials" means the first two completed clinical research studies conducted under an IDE with the intent of obtaining regulatory approval for indications for the treatment of [\*\*] Wounds, the results of which will be included in a PMA and other submissions for Regulatory Approval of the Products for such [\*\*] Wound indications.
  - (f) "[\*\*] Wounds" means [\*\*]
- (g) "Competitive Products" means products in the Field that are marketed by or approved for marketing in the United States or any country of the European Union and that are regulated by the FDA (or foreign agency) as medical devices or biologics (or regulated by a Tissue Banking Authority).

  Notwithstanding the foregoing, no pharmaceutical product which has or is expected to have an NDA (or foreign equivalent) classification and no product which is or is expected to be sold through retail distribution channels or otherwise sold to consumers shall be deemed a "Competitive Product".
- (h) "Competitive Transaction" means a transaction in which a Person obtains rights from a non-Affiliate to manufacture, market or sell a Competitive Product.

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

- (i) Information is "Confidential Information" to the party receiving it if it is presented in writing by one party to the other party and identified in such writing as confidential, or if it is disclosed orally by one party to the other party and outlined and identified as confidential in writing to the other party within thirty (30) days of the oral disclosure. By way of example, Confidential Information shall include, without limitation, all information relating to existing and potential customers, suppliers, markets, contracts, prices, products, personnel, strategies, policies, systems, procedures, technologies, know-how, information, data, processes, inventions, research, developments, formulations, applications, methods of manufacture and any other information relating to either party or any of its Affiliates.
- (j) "Complaint" means any oral, written or electronic communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a Product that has been manufactured by Integra after it is released for distribution.
  - (k) "Effective Date" means June 15, 1999.
- (1) "Encumbrance" means any security interest, pledge, mortgage, lien (including, without limitation, environmental and tax liens), charge, encumbrance, option, adverse claim, preferential arrangement or restriction of any kind, including, without limitation, any restriction on the use, transfer, receipt of income or other exercise of any attributes of ownership.
  - (m) "[\*\*] Wounds" means [\*\*]
- (n) "Existing Distributor Countries" means the countries set forth on Schedule 1.1(n) hereto for so long as Integra maintains distributors other than JJM in such countries.
- (o) "FDA" means the United States Food and Drug Administration, or any successor body.

<sup>- -----</sup>

 $<sup>[\ ^{**}]\</sup>mbox{Confidential Information omitted}$  and filed separately with the Securities and Exchange Commission.

- (p) "Field" means all devices, products and biologics, regardless of physical form, that (A) are comprised of a matrix which is implanted as a dermal or epidermal replacement, (B) are integrated, resorbed or remodeled to resemble native tissue, (C) have a mode of action which is primarily dependent upon the three-dimensional matrix or matrix elements [\*\*] and (D) are intended to facilitate the repair and/or regeneration of human skin (which includes dermis, epidermis, epidermal and dermal basal laminas, and skin appendages (excluding all endodermis and dental and gingival tissues)).
- (q) "Governmental Authority" means any relevant national, federal, state, provincial, or local governmental, regulatory or administrative authority, agency or commission or any court, tribunal, or judicial or arbitral body, in each case wherever located.
- (r) "Integra Change of Control" means (i) the sale of all or substantially all of the assets of Integra's Parent to any Person, (ii) the merger or consolidation of Integra's Parent with or into any other Person in which Integra's Parent does not retain a majority of the voting power of the corporation or entity surviving the merger of consolidation or (iii) the acquisition by any Person of shares of Common Stock of Integra's Parent representing a majority of the issued and outstanding shares of Common Stock then outstanding.
- (s) "Integra Dental/Endodermis Product" means a product which is intended to facilitate the repair, healing and/or regeneration of endodermis or dental or gingival tissues and which would have been a "Product" had it been intended to facilitate the repair, healing and/or regeneration of human skin (which includes dermis, epidermis, epidermal and dermal basal laminas, and skin appendages).
- (t) "Integra's Parent" means Integra LifeSciences Holdings Corporation, a Delaware corporation.
- (u) "Invention" means the Patents and all copyrights, inventions (patentable or otherwise), developments, designs, applications, improvements, trade secrets, formulae, concepts, ideas, know-how, methods or processes, discoveries and techniques necessary or desirable for the development, manufacture, sale or distribution of, or otherwise relating to, Products, whether owned as of the date hereof or hereafter acquired or licensed pursuant to the terms of this Agreement.
- (v) "Joint Steering Committee" shall have the meaning attributed to such term in Section  $16.1\ \mathrm{of}$  this Agreement.

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

- (w) "JJM's Parent" means Johnson & Johnson, a New Jersey corporation.
- (x) "JJM's Wound Care Business" means JJM's business comprising all medical devices or biologics that are used to treat diseased or damaged skin, as well as any other products sold by JJM in the Field, but specifically does not include (i) wound or skin care products which are or are expected to be sold through retail distribution channels or otherwise sold to consumers or (ii) pharmaceutical products which have an NDA classification.
- (y) "Licensed Trademark" means the trademark identified in Schedule 1.1(y) hereto.
- (z) "Manufacturing Yield" shall mean, with respect to any manufactured lot of Products, a percentage equal to the number of units of such Product produced in such lot available for shipment to customers divided by the maximum number of units of such Product that could have been produced given the raw materials and processes deployed in such manufactured lot.
- (aa) "Net Sales" means the revenue received by JJM and its Affiliates from sales of Products to non-Affiliated purchasers, less cash discounts, refunds, rebates, group fees, duties, freight charges, replacements or credits allowed to purchasers for return of such Products or as reimbursement for damaged Products, sales and use taxes, customs, and any other governmental tax or charge (except income taxes) imposed on or at the time of production, importation, use, or sale of Products. If such Products are sold in combination with other components (a "Combination"), Net Sales for purposes of determining the payments to be made by JJM to Integra on such Combination shall be calculated as follows:

  - 0 = the other component price in such Combination when separately sold, or if not sold separately the price of an equivalent component that is sold separately
  - T = the total net revenues from the Combination sold during the applicable quarter

Net Sales for Combinations shall be calculated as follows:

Net Sales = 
$$C * [P / (P + O)]$$

In instances where more than one Combination is sold as to which all elements (namely P, O and C) are known, the above described fraction shall be calculated for each such Combination, the

results will be weighted for unit sales of each such combination and added, the resulting number will then be divided by the number of units of such Combinations, and the resulting fraction shall be used in calculating Net Sales for Combinations.

- (bb) "Other Wound Care Product" means a product which would have been a "Product" insofar as it is intended to facilitate the repair, healing and/or regeneration of human skin (which includes dermis, epidermis, epidermal and dermal basal laminas, and skin appendages (excluding all endodermis and dental and gingival tissues)), including the treatment of Chronic Wounds and Excisional Wounds, but which is outside the Field (and thus not a "Product") because it lacks one or more of the characteristics defined in clauses (A), (B) or (C) of the definition of the Field.
- (cc) "Patent" means (i) the U.S. and foreign patent applications and patents owned or licensed by Integra that are directly related to or have application in the Field, (ii) U.S. and foreign patent applications and patents owned solely by Integra, that claim inventions that are directly related to or have application in the Field (and that are conceived or reduced to practice as part of the research and development program contemplated by this Agreement) and (iii) all divisions, continuations, continuations—in—part, and substitutions thereof, and all extensions, reissues and re—examinations of any of the foregoing. Exhibit A hereto sets forth each patent described in (i) above; provided that failure to include a patent or an application on Exhibit A shall not affect its status as a Patent.
- (dd) "PMA" means a Pre-Market Approval application filed with the FDA or a Pre-Market Approval Supplement.
- (ee) "Person" means any individual, partnership, firm, corporation, Limited Liability Company, joint venture, association, trust, unincorporated organization or other entity, as well as any syndicate or group acting in concert.
- (ff) "Producer Price Index" means the final annual Producer Price Index for Finished Goods without any seasonal adjustment as reported by the Bureau for Labor Statistics of the U.S. Department of Labor or its successor agency.
- (gg) "Products" means any product in the Field which is or will be manufactured by or on behalf of Integra, including, without limitation, the INTEGRA(Trademark) Dermal Regeneration Template(Trademark) and approved indications and all future Product Improvements and expanded indications in the Field. Products only include those products which are regulated by the FDA (or foreign agency) as medical devices or biologics and specifically excludes pharmaceutical products which have or are reasonably expected to have an NDA (or foreign equivalent) classification ("NDA Drug") and products which are or are expected to be sold through retail distribution channels or otherwise sold to consumers. Any

determination that a product is a Product by virtue of its regulation by the FDA (or a foreign agency) as a medical device or biologic, or that it is not a Product by virtue of its regulation by the FDA (or a foreign agency) as an NDA Drug, shall be made with reference to the Food, Drug and Cosmetic Act, rules and regulations thereunder, and authoritative interpretations thereof (or foreign equivalents thereof, as the case may be), in each case as the same prevailed on the date of this Agreement. Notwithstanding the foregoing, (i) enhancements to the Integra Artificial Skin planned by the Joint Steering Committee shall be considered Products regardless of their classification by applicable regulatory authorities, and (ii) products owned or sold by Integra, other than the INTEGRA(Trademark) Dermal Regeneration Template (Trademark), which have received regulatory clearance or approval in the United States or Europe as of the date hereof shall not constitute Products hereunder.

- (hh) "Product Improvements" means any improvement to the Products that are conceived or reduced to practice by Integra (or to which Integra acquires rights) or as part of the research and development program contemplated by this Agreement, together with any additional approved indications within the Field for such Products or Product Improvements. For the avoidance of doubt, any improvements to the Products incorporating the RGD peptide technology shall be included in Product Improvements.
- (ii) "Regulatory Approval" in any country means a PMA approval, European approvals or registration and other international regulatory approvals, including CE mark approvals or any other regulatory approval to commence commercial sale of a Product for one or more indications in such country.
- (jj) "Research Payments" shall have the meaning ascribed to such term in Section 12.1 below.
- (kk) "Termination Date" means the expiration date of the Term, as defined in Section 29.1 hereof, or any earlier date on which termination of provisions of this Agreement become effective pursuant to Article XXIX hereof.
- (11) "Technology" means: (a) inventions (whether or not patentable, reduced to practice or made the subject of a pending patent application or applications), (b) ideas and conceptions of potentially patentable subject matter, including, without limitation, all patent disclosures (whether or not reduced to practice or made the subject of a pending patent application or applications), (c) patents, patent registrations and patent applications (including all reissues, divisions, continuations, continuations—in—part, extensions and reexaminations thereof) and all rights therein and improvements thereto, (d) computer software, including, without limitation, source code, operating systems and specifications, data and data bases and files, and (e) know how and trade secrets.

(mm) "Territory" means all of the countries or other geographical areas in the world except (i) Japan and (ii) any of the Existing Distributor Countries, provided that the exception relating to Existing Distributor Countries shall apply to a particular country only so long as it shall remain an Existing Distributor Country as contemplated by Section 2.2 of this Agreement.

#### ARTICLE II.

#### APPOINTMENT AND SCOPE OF DISTRIBUTORSHIP

Section 2.1. Appointment and Acceptance of Appointment. Integra hereby appoints JJM for the term of this Agreement, and JJM hereby accepts Integra's appointment, as Integra's exclusive distributor to market, promote and sell the Products in the Territory, pursuant to the terms and subject to the conditions set forth in this Agreement. In furtherance of the foregoing, Integra shall not sell Products in the Territory or appoint any other Person as a distributor to distribute or sell Products in the Territory.

#### Section 2.2. Extent of Territory.

- (a) In countries where the Products are approved for sale and there is not an Integra appointed distributor ("Direct Countries"), each of Integra and JJM shall use its commercially reasonable efforts to transition sales of the Products to JJM commencing on the Effective Date. In Direct Countries, all sales shall be credited to JJM commencing on the Effective Date. Integra shall work diligently to ensure an orderly and efficient transition of sales and related support activity to JJM.
- (b) If JJM has requested that Integra terminate its existing distributor in one of the Existing Distributor Countries and Integra so terminates such distributor pursuant to Section 2.2(c) below, then JJM shall use its commercially reasonable efforts to commence selling the Products within four months of such termination.
- (c) Integra shall diligently seek to (i) terminate its current distribution agreements for Products in [\*\*] and (ii) at JJM's discretion to terminate or assign its current distribution agreements for Products in the other Existing Distributor Countries within four months of the Effective Date, provided, however, that Integra shall not be obligated to terminate any agreements if such termination cannot be achieved at a Reasonable Termination Cost (as defined below). Integra shall not renew any such distribution agreement upon the expiration of its term, provided, however, that Integra may renew

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

any such agreement if failure to renew such agreement is reasonably expected to result in Damages (as defined in Section 10.1 below) to Integra(\*\*)

Following the termination of any such distribution agreement, the relevant country shall automatically no longer be deemed an Existing Distributor Country, but rather shall be deemed to be a part of the Territory, and the adjustments to the Minimum Prepayments (as defined in Section 6.7 below) pursuant to Section 6.8 hereof shall no longer be made with respect to such country. Nothing herein shall require, or be deemed to require, either Integra or JJM to breach any of its current distribution agreements for Products.

- (d) "Reasonable Termination Cost" means, for each Existing Distributor Country, [\*\*] of the Net Sales of Products achieved by Integra's distributor in such country in the twelve month period prior to the Effective Date, provided that such cost shall not exceed (a) [\*\*] for [\*\*] (b) [\*\*] for [\*\*] and (c) [\*\*] for [\*\*]
- (e) Integra shall seek to enforce the geographic restrictions of its current distribution agreements for Products in the Existing Distributor Countries; provided that Integra may determine not to initiate an action for the enforcement of such geographic restrictions if [\*\*]
- (f) JJM shall have up to [\*\*] from the Effective Date to elect whether it wants Integra to assign an existing distribution agreement to JJM rather than to have Integra seek to terminate such agreement. Other than [\*\*] Integra shall not terminate any distributor within the first [\*\*] from the Effective Date. Those countries, other than the Core Countries, as to which existing distribution agreements are assignable, and as to which JJM elects to have the applicable distribution agreement assigned to it, shall be subject to the [\*\*] such distribution agreement is either terminated or expires in accordance with its original term and without regard to any extension to which JJM may subsequently agree, [\*\*], and such countries shall no longer be deemed Existing Distributor Countries once such assignment has been effected.
- (g) If Integra has not terminated a distribution agreement with respect to a [\*\*] within [\*\*] of the

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 $<sup>[\ ^{**}]\</sup>mbox{Confidential Information omitted}$  and filed separately with the Securities and Exchange Commission.

Effective Date, Integra will, to the extent the same is assignable, assign such distribution agreement to JJM. On [\*\*] Integra will transfer to JJM, to the extent the same is assignable, any distribution agreements covering an Existing Distributor Country that has not been terminated or assigned prior to that date.

(h) Integra represents and warrants that annexed hereto on Schedule 1.1(n) is a true, complete and accurate list of the countries in which Integra maintains or might be alleged to maintain a distributor for the Product as of the date hereof, whether Integra has a signed agreement in place with any such distributor, and whether or not the terms of any such signed agreements prohibit or otherwise restrict their assignment by Integra.

Section 2.3. JJM's [\*\*] Commitment.

- (a) Neither JJM nor any of its Affiliates shall engage in the distribution, marketing, promotion or sale of any Competitive Product in any country in the Territory in which Integra has obtained or has filed for Regulatory Approval, [\*\*]
- (b) Notwithstanding Section 2.3(a) above, JJM and its Affiliates may design, develop, manufacture, distribute, market, promote and sell any Competitive Product which is based on (i) Technology owned or licensed by JJM or one of its Affiliates on the date hereof or (ii) Technology (other than Jointly-Owned Inventions or Funded Inventions) internally developed by JJM or one of its Affiliates after the date hereof. In addition, JJM and its Affiliates shall have the right, notwithstanding Section 2.3(a) above, to design, develop, manufacture, distribute, market, promote and sell any Competitive Product which is based on Early Stage Technology licensed or acquired by JJM or one of its Affiliates from a third party other than Integra after the date hereof. "Early Stage Technology" shall mean Technology in the Field which, at the time of its acquisition or licensing by JJM or such Affiliate, has not yet been incorporated into a Competitive Product which (i) has received Regulatory Approval from the FDA or comparable foreign regulatory
- (c) JJM shall keep Integra reasonably informed of any significant advances it makes regarding the design, development or manufacture of Competitive Products resulting from its own efforts or from acquired/in-licensed Technology after the date hereof, and shall (i) report the status of any such progress at all meetings of the Joint Steering Committee (as defined in

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

Section 16.1 below) and (ii) promptly notify Integra in writing of any Competitive Transaction which JJM has entered into and any material development milestones (i.e. patent filings, prototype developments, completion of Phase I and II studies, etc.) with respect to any Competitive Product of JJM.

[\*\*] (d)

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

(e) [\*\*]

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 $[**]\mbox{Confidential Information omitted and filed separately with the Securities and Exchange Commission.$ 

(f) Nothing herein contained in this Section 2.3 shall be construed to require JJM or its Affiliates to violate any confidentiality agreement to which they may be a party. JJM shall, however, use reasonable efforts to structure any confidentiality agreement to which it may become a party after the date hereof and that relates to a transaction that, if consummated, would constitute a Competitive Transaction, in such a manner as to permit full compliance with the provisions of this Section 2.3.

Section 2.4 Integra's Commitment to JJM on Other Wound Care Products.

(a) If Integra intends to commercialize an Other Wound Care Product internally developed by Integra or arising from Early Stage Technology acquired by Integra, then Integra shall identify such Other Wound Care Product to JJM in writing. JJM shall have [\*\*] to determine whether or not to undertake marketing and distribution of such Other Wound Care Product. [\*\*]

If JJM does not elect within the [\*\*] period to undertake the marketing and distribution of such Other Wound Care Product or, if in good faith negotiations a supplemental agreement has not been executed within a further period of [\*\*] following receipt of JJM's election, then Integra shall be free to commercialize such Other Wound Care Product on its own or with another distributor [\*\*]

(b) Notwithstanding the foregoing, Integra shall not be required to comply with the provisions of Section 2.4(a) with respect to any Other Wound Care Product which Integra may have acquired in connection with an Extraordinary Transaction nor shall Integra be required to comply with such provisions as to any Other Wound Care Product if compliance would constitute a breach of any agreement to which it is a party.

Section 2.5. Integra Dental/Endodermis Products. In the event that Integra shall intend to sell, market, distribute or promote, or license or authorize any Person to sell, market, distribute or promote, any Integra Dental/Endodermis Product in the Territory, the following provisions shall apply:

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 $<sup>[\ ^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

- (a) Such Integra Dental/Endodermis Product shall clearly be marketed, promoted and labeled as indicated solely for endodermis, dental or gingival use, as the case may be, and expressly not for facilitating the repair, healing and/or regeneration of human skin (which includes dermis, epidermis, epidermal and dermal basal laminas, and skin appendages). Such Integra Dental/Endodermis Product shall be contained in packaging different from packaging used in connection with the Products.
- (b) Integra shall not market or promote, or allow its sales representatives, licensees or distributors to market or promote such Integra Dental/Endodermis Product as similar or comparable to the Products, nor shall Integra allow any of its sales representatives, licensees or distributors to market, promote, distribute or sell any Integra Dental/Endodermis Product in contravention of the terms of this Section 2.5.
- (c) In the event that  $\ensuremath{\mathsf{JJM}}$  has evidence that the provisions of this Section 2.5 are being violated or that, notwithstanding such provisions,  ${\tt JJM}$ shall establish that there shall have been use of Integra Dental/Endodermis Products to facilitate the repair, healing and/or regeneration of human skin (which includes dermis, epidermis, epidermal and dermal basal laminas, and skin appendages), the Joint Steering Committee shall convene promptly, following written notice from one party to the other, to discuss such matter. If the Joint Steering Committee cannot resolve such matter to the satisfaction of both parties within thirty (30) days of when such written notice is delivered, then either party shall have the option of appointing an independent auditor (an "Auditor") to examine and investigate the matter. The Auditor shall be selected from one of the six largest certified public accounting firms in the United States at such time (excluding any of such certified public accounting firms which shall have served as the independent auditor of either of the parties in the prior three years). The parties shall cooperate fully with, and make available all books and records to, the Auditor. The Auditor shall be directed to (i) examine and audit all alleged cross-over use of the Integra Dental/Endodermis Products, as described above, (ii) discuss the alleged cross-over use with each of the parties and (iii) within ninety (90) days, issue a written report of its findings to the parties. If the Auditor determines that such cross-over use has occurred, then the Auditor shall set forth in such report the Auditor's conclusion as to the equitable compensation for profits and expenses associated with such cross-over use which shall be paid from one party to the other party in connection therewith. Within thirty (30) days of the date such report is issued, the party directed by the Auditor to make such payment shall make such payment to the other party. The expenses of the Auditor shall be borne equally by the parties.

### ARTICLE III.

## JJM's MARKETING OBLIGATIONS AS DISTRIBUTOR

Section 3.1. Purchase of Products; Minimum Effort. JJM shall purchase Products from Integra on the terms and conditions hereinafter set forth, and shall use commercially reasonable efforts to maximize Net Sales of the Products in the Territory taking into account the operating profit (margin) objectives of JJM derived from the sales of such Products across the entire line of Products over the Term, and shall, in any event, make the Minimum Prepayments for each calendar year during the Term as set forth in Section 6.7 hereof.

Section 3.2. Certain Duties of JJM as Distributor.

- (a) JJM shall, at its expense, be responsible for:
- (i) all marketing decisions regarding the Products including, but not limited to, labeling, packaging, advertising, pricing, and professional education;
- (ii) carrying finished inventory, invoicing, processing orders and physical distribution; and
- (iii) compliance with all Regulatory Approvals and with all applicable statutes, laws, rules, regulations, ordinances and decrees of Governmental Authorities from the time it receives the Products from Integra, including but not limited to those relating to (A) the labeling, finished packaging, advertising, import, export, re-export, promotion, sale, distribution and use of Products in the Territory, and (B) foreign exchange and health, safety and environmental matters.
- (b) Without limiting the obligations set forth in Section 3.2(a), in promoting, marketing, distributing and selling the Products in the Territory, JJM shall, at its expense:
  - (i) detail the Products and any Product Improvements with equal prominence to the lesser of: (a) the greatest detailing effort on behalf of a product in JJM's Wound Care Business in the Territory or (b) [\*\*]

(for purposes of this Agreement "detailing efforts" shall be measured as a percentage of direct time spent promoting, marketing and selling such products in the most recently completed four fiscal quarters); provided that this clause

 $<sup>[\ ^{**}]\</sup>mbox{Confidential Information omitted and filed separately with the Securities and Exchange Commission.}$ 

- (i) shall remain effective only if the Products and any Product Improvements [\*\*]; and
- (ii) to the extent required by law, establish and maintain a system of record keeping, with the diligent support and assistance of Integra, including a register of lot numbers and individual Product numbers and customer names and addresses for all Products sold by JJM in order to assist Integra with traceability in the event of a Product recall and require any customer that is not the end user of Products, to maintain a similar register, including names and addresses of its end users.
- (c) Except as permitted pursuant to Section 2.3 hereof (and upon the terms and subject to the conditions thereof), JJM and its Affiliates shall not, directly or indirectly, solicit orders for Products from any prospective purchaser having a principal place of business located outside the Territory.

Section 3.3. Marketing Plan. As soon as practicable, and in no event later than sixty (60) days, after the date hereof, JJM shall prepare a transition marketing plan for the calendar year ended December 31, 1999 and submit it to Integra for its review and comment. For each calendar year thereafter, JJM shall prepare a marketing plan and submit it to the Joint Steering Committee for review and comment not later than December 1 of the calendar year prior to the calendar year to which such plan relates. The Joint Steering Committee shall review the Forecasts (as defined in Section 4.1(a) below) on a quarterly basis.

# ARTICLE IV.

# SUPPLY OF PRODUCTS

#### Section 4.1. Orders.

(a) Orders shall be submitted to Integra by JJM on a monthly basis on JJM's regular purchase order forms; provided, however, that any term or condition on such purchase order form which is inconsistent with the terms of this Agreement shall be null and void. Prior to the first day of each Calendar Quarter, JJM shall prepare in good faith and deliver to Integra a rolling twenty-four month forecast of each type and size of Product to be purchased by JJM (a "Forecast"); provided, however, that a new Forecast shall be prepared within 10 days of receiving a positive recommendation from an advisory panel convened by the FDA to consider any application for an expanded indication for any Product. JJM shall be committed to purchase (i) the aggregate dollar amount of Products forecast to be purchased during the first three months of each such Forecast and (ii) at least eighty

 $<sup>[\</sup>ensuremath{^{**}}]\xspace$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

percent (80%) of the amount of Products to be purchased during the fourth, fifth and sixth month of such Forecast. The balance of such Forecasts shall be non-binding. Without the prior consent of Integra, no such Forecast shall call for Integra to supply in any twelve month period a number of Products the Net Sales of which would exceed the greater of (x) two times the Minimum Net Sales for such period or (y) four times the Net Sales of the preceding six month period. Integra shall maintain or place in service sufficient production capacity to meet the Forecasts, with available excess capacity to meet periodic fluctuations in purchase orders relating to the fourth, fifth and sixth months of the Forecast of at least 125% of the amount Forecast. All Products ordered pursuant to this Section 4.1 shall be delivered by Integra within sixty (60) days of receipt of the purchase orders.

- (b) JJM may supplement the Forecast from time to time by delivering additional purchase orders, which Integra shall fill on a timely basis to the extent such orders in respect of the fourth, fifth and sixth months of the then current Forecast are 125% or less of the previously forecasted amounts, and shall use all reasonable efforts to fill in a timely basis to the extent such orders exceed 125% of the forecast amounts.
- (c) Upon JJM's request, Integra shall reasonably cooperate in the implementation of integrated demand planning and deployment, at JJM's expense; provided that nothing in such implementation shall derogate in any manner any other provisions of this Agreement.
  - Section 4.2. Supply Difficulties; Supply Default.
- (a) If Integra fills less than [\*\*] of any monthly order from JJM, JJM shall have the right to convene a meeting of the Joint Steering Committee to discuss with Integra the reasons for the shortfall. If Integra fills less than [\*\*] orders, Integra shall provide to JJM within ten (10) days after the end of such second consecutive month a Management Action Plan ("MAP") setting forth in detail a time and responsibility schedule for resolving the supply difficulty. JJM shall have 10 days to provide written endorsement or required changes to the MAP. Integra shall thereafter diligently carry out the agreed upon MAP to resolve any such supply difficulties.
- (b) If Integra fills (x) [\*\*] of orders from JJM [\*\*] out of any twelve month period or (y) [\*\*] of orders from JJM for any [\*\*] period, which orders are consistent with the provisions of Section 4.1 and do

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 $<sup>[\ ^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

not exceed forecasted amounts by more than 125% (a "Supply Default"), JJM shall provide Integra with written notice of such default. Following such notification, the Joint Steering Committee shall promptly meet to discuss the Supply Default. If the Joint Steering Committee is unable to agree upon a MAP or other mechanism to resolve such Supply Default within forty-five (45) days of such notice, and if the Supply Default has not been cured and is continuing (a "Supply Default, Not Cured"), then

(i) [\*\*]; or

(ii) [\*\*]

 $[\ ^{**}]\mbox{Confidential Information omitted and filed separately with the Securities and Exchange Commission.}$ 

During the period of any such contract manufacturing arrangement or during the pendency of a Supply Default, Not Cured, Integra shall use all commercially reasonable efforts, to remedy, as quickly as possible, any issues that may have caused the Supply Default and to develop, as quickly as possible, the capacity sufficient to meet forecasted requirements of JJM going forward, and JJM shall use reasonable efforts to help Integra to achieve such objectives.

- (c) During the pendency of a Supply Default, Not Cured: (i) JJM shall pay a reasonable royalty rate to Integra in consideration for such license, which rate shall in no event exceed [\*\*] % of Net Sales of Products in the Territory; and (ii) Integra shall provide JJM or its designee with access to any technology and know-how necessary or useful for JJM or its designee to produce Products or arrange an alternative supplier of Products in a reasonable time frame and provide advice and consultation in connection therewith.

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- (d) Integra and JJM shall each bear 50% of the out-of-pocket costs incurred by both parties in transferring the manufacturing of the Products from Integra to JJM (or other third party) and back to Integra pursuant to Section 4.2(b) (ii). Integra shall reimburse JJM for the amounts it owes pursuant to this Section 4.2(d): (x) during the License Period by reducing the royalty rate specified in Section 4.2(c) and (y) after the License Period by reducing the Supply Price of the Products, in each case by 50% until such amounts are repaid in full.
- (e) A Supply Default or a Supply Default, Not Cured shall not provide JJM with a right to terminate this Agreement under Section 29.2(e)(i) hereof. Moreover, if JJM elects to accept the license contemplated by Section 4.2(b)(ii), the failure by Integra to deliver all or any portion of the Products ordered by JJM during the License Period shall not provide JJM with a right to terminate this Agreement under Section 29.2(e)(i) hereof. Only if JJM elects not to accept such license, shall a Supply Default, Not Cured provide JJM with a right to terminate this Agreement under Section 29.2(e)(i) hereof.
- (f) Following the occurrence of (i) a Force Majeure event, (ii) an Integra Change of Control or (iii) the tenth anniversary of the Effective Date, the thresholds in clauses (x) and (y) of Section 4.2(b) shall be replaced by the following single testing criterion: "less than [\*\*] of orders from JJM for [\*\*] consecutive months".

[\*\*]Confidential Information omitted and filed separately with the Securities and Exchange Commission.

(g) During the pendency of a Supply Default, or if a JJM backorder results from Integra's failure to supply Products to JJM consistent with the then prevailing Forecasts and the requirements of Sections 4.1(a) and 4.1(b), Integra shall not (i) commence production of any Integra Dental/Endodermal Products or (ii) ship Products to any other distributor in the Existing Distributor Countries or Japan until JJM's backorders are filled.

## Section 4.3. Expansion of Production Capacity.

- (a) To assist Integra in expanding its production capacity, both in terms of capital improvements and working capital for larger volumes of business, JJM shall make the following non-refundable payments to Integra:
  - (i) \$5,000,000 by wire transfer in immediately available funds to the account designated by Integra within 30 days after the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales exceed \$ [\*\*];
  - (ii) \$5,000,000 by wire transfer in immediately available funds to the account designated by Integra within 30 days after the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales exceed \$[\*\*];
  - (iii) \$5,000,000 by wire transfer in immediately available funds to the account designated by Integra within 30 days after the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales exceed \$[\*\*]; and
  - (iv) \$10,000,000 following the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales exceed \$[\*\*]\$; to be paid, at JJM's election, either (a) within 30 days after the completion of such first twelve month period or (b) in the manner specified in Section 6.2(a) hereof.
- (b) To ensure Integra has sufficient capacity and capability to supply Products as set out by the Forecast and to facilitate and coordinate the sharing of resources and expertise between JJM and Integra, Integra will submit a Manufacturing Status Report and Plan ("Manufacturing Plan") at the following intervals: (i) within thirty (30) days of receipt of each Forecast and (ii) within thirty (30) days of receipt of the first Forecast which exceeds \$ [\*\*] million in Net Sales. The Manufacturing Plan shall include, but not be limited to (i) yield trend, current programs to improve, plans to improve, target

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

yield, and factors limiting or contributing to the yield; (ii) estimated capacity (taking the then current yield and trend into account), plans to increase capacity and associated costs and potential for downtime to make changes to facilities; and (iii) quality systems.

# Section 4.4. Shipping and Delivery.

- (a) Products shall be delivered, and title and risk of loss or damage to the Products shall pass to JJM upon delivery, ExWorks (as defined in Incoterms 1990) Integra's place of manufacture or distribution in Plainsboro, New Jersey or other warehouse location as may reasonably be determined by Integra.
- (b) At JJM's expense, Integra shall ship the Products to designated warehouses of JJM located in the United States (or outside the United States) as may reasonably be specified by JJM. JJM shall, at its expense, ship the Products from such warehouse to any other locations in the Territory including warehouses of JJM or any of its Affiliates not located in the United States or to JJM's customers. The sale and shipment of Products to JJM shall be subject to receipt of all applicable licenses and permits and compliance with all applicable statutes, rules, regulations and decrees of the Territory and agencies thereof in effect currently or at any time hereafter.
- (c) Until December 31, 2001, Integra shall, at JJM's expense, ship Products directly to JJM customers at JJM's request for all orders up to  $\{[**]$  million in Net Sales in any calendar year. JJM shall reimburse Integra for any shipping costs, costs of packaging materials, labor costs, plus overhead not to exceed 30% of such labor costs, in each case attributable to the shipment of Products to JJM customers.
- (d) JJM shall be permitted to return, and Integra shall accept for full invoice credit, all Products which Integra acknowledges do not meet the applicable specifications for the Product as set forth on Schedule 4.4(d) hereto at the time of delivery, provided that, in the case of Products returned because of defects or damage that could have been detected by visual inspection of the labeling or packaging of the Product, such returns are reported to Integra within 15 days following delivery of the Products by Integra in accordance with Section 4.4(a), and when possible returned Products shall be still in original factory packaging. JJM shall only return Products pursuant to a Returned Goods Authorization issued by Integra. Integra's obligations under this Section 4.4(d) shall not extend to any Products that are abused, misused, or tampered with outside its facilities or control.

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 $<sup>[\,{}^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

- (a) In order to assist  $\ensuremath{\mathsf{JJM}}$  in promoting and selling the Products, Integra shall, at its expense:
  - (i) review all marketing and labeling information (including package inserts) and education material for compliance with Regulatory Approvals and other applicable law or regulation;
  - (ii) update JJM with information available to Integra which is necessary or useful for JJM to market the Products effectively;
  - (iii) provide JJM with prompt updates on all regulatory issues known to Integra that are reasonably likely to affect the sale and marketing of the Products by JJM;
  - (iv) provide JJM with such information in Integra's possession and control as may be required by JJM to obtain import permits from the appropriate Governmental Authorities to distribute the Products in the Territory;
  - (v) promptly refer to JJM all orders and inquiries for the Products in the Territory received by Integra;
  - (vi) notify JJM in advance of any manufacturing process changes with respect to the Products, comply with design control standard operating procedures with respect to such changes, and obtain consent of JJM prior to implementing product specification changes or material changes, which consent shall not be unreasonably withheld;
  - (vii) provide JJM, prior to each shipment of the Products, with a certificate stating that the Products included in that shipment meet all applicable specifications;
  - (viii) maintain Product order fulfillment, packaging and shipping capacity to meet its obligations hereunder; and
  - $\mbox{\ensuremath{\mbox{(ix)}}}$  provide JJM with prompt notice if any delays or shortfalls in deliveries seem imminent.

Section 4.6. Sampling. To achieve the objectives of this Agreement, both parties recognize that, to the extent allowable by law, it may be necessary to distribute a nominal quantity of the Product as samples to health care personnel and the trade on an ongoing basis (a "Sampling Program"). The development of any Sampling Program shall be solely JJM's responsibility. JJM shall keep Integra informed of meaningful changes to the Sampling Program. Integra shall provide JJM with a reasonable quantity of Products (as agreed to by the Joint Steering Committee, which in

no event shall exceed 5% of the aggregate units of a particular size and type of Product purchased by JJM hereunder) for use in the Sampling Program at a cost to JJM equal to 50% of the then applicable Supply Price (as defined and adjusted in Article VI below), but in no event at a price less than \$ [\*\*] for a [\*\*] dermal template, \$ [\*\*] for a [\*\*] dermal template, or \$ [\*\*] for an [\*\*] dermal template.

> Section 4.7. Supply for [\*\*] and [\*\*] Trials.

- (a) Integra shall supply, at no cost to JJM, all reasonable quantities of Products for use in connection with the [\*\*] Trials as contemplated by Article XIV hereof and for quality control and regulatory testing in connection therewith; provided, however, that  ${\tt JJM}$  shall pay to Integra 50% of the revenue earned by JJM for any such Products for which JJM receives any payment from a third party.
- (b) Integra shall supply to JJM, at Integra's actual cost, all reasonable quantities of Products or prototype Products for use in connection with any pre-clinical or scientific studies conducted, provided that such studies are accepted by the Joint Steering Committee.

Regulatory and Quality Audits; Integra Obligations. Section 4.8.

JJM shall have the right to conduct a regulatory and quality control audit of Integra's facilities and quality systems relating to the Products or Product Improvements at intervals no more frequent than semi-annually. At JJM's election it may engage a third party consultant to conduct such audit. JJM shall cover any fees and expenses for such consultant. Integra will provide access to requested documentation and its employees to assist in all such audits. The audit report shall be provided by  ${\tt JJM}$  to Integra promptly after it shall have been delivered to JJM management. As to all critical observations of such report that Integra does not dispute, Integra shall provide written responses to JJM in the form of a MAP within 10 days. In the event Integra disputes any observations contained in such report, Integra shall have the right, at its expense, to engage its own third party consultant to conduct an additional audit. Integra shall promptly deliver to JJM the results of such third party audit. As to all critical observations upon which the JJM audit and the third party audit are in agreement, Integra shall promptly provide written responses to JJM in the form of a MAP (or if a prior MAP has already been delivered with respect to some of the observations in the original JJM report, a amended and

[\*\*]Confidential Information omitted and filed separately with the Securities and Exchange Commission.

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supplemented MAP). As to any critical observations that are disputed between the JJM report and the third party audit that cannot be resolved by discussion within the Joint Steering Committee, the Joint Steering Committee shall select an additional independent consultant to whom both sets of observations shall be delivered who shall, after having conducted its own audit or such other procedures as it deems appropriate, resolve the disputed items. As to any critical observations resulting from such dispute resolution process, Integra shall promptly provide a MAP or amended and supplemented MAP.  $\mathsf{JJM}$  shall have 10 days from the delivery to it of a MAP or amended and supplemented MAP to provide written endorsement or required changes to such MAP. Integra shall diligently complete the agreed upon MAP and permit close-out visits by JJM or such third party consultants to confirm implementation of the MAP. The MAP for the first calendar year of the term of this agreement is set forth in Schedule 4.8.

## ARTICLE V.

# INITIAL PAYMENTS; TRADEMARK LICENSE

Section 5.1. Initial Payments. In consideration for the exclusive use of Integra's trademarks and regulatory filings related to the Products (including PMA P900033 and all supplements and amendments thereto related to the Integra(Trademark) Dermal Regeneration Template(Trademark)) in the Field and the Territory and other rights granted to JJM under this Agreement, JJM shall make the following payments to Integra upon the terms and subject to the conditions set forth below:

- \$5,280,000 by wire transfer in immediately available funds to (a) the account designated by Integra on the Effective Date;
- (b) [\*\*] by wire transfer in immediately available funds to the account designated by Integra within five (5) Business Days of receipt of notice from Integra that it has [\*\*]
- (c) [\*\*] by wire transfer in immediately available funds to the account designated by Integra within five (5) Business Days of receipt of notice from Integra that it has [\*\*]; and

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<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

(d) \$ [\*\*] by wire transfer in immediately available funds to the account designated by Integra, within five (5) Business Days of receipt of notice from Integra that it has [\*\*];

provided, that as to Sections 5.1(b), (c) or (d), if the applicable [\*\*] for the [\*\*] to which such clause relates shall have been assigned to JJM pursuant to the provisions of Section 2.2 of this Agreement, then the payments called for by such clause shall be made upon expiration of such assigned distribution agreement, in accordance with the term of such distribution agreement as of the date hereof and without regard to any extension to which JJM may subsequently agree.

Section 5.2. Limited License to Integra's Trademarks.

- (a) Upon the terms and subject to the conditions of this Agreement Integra hereby grants JJM an exclusive in Direct Countries and a co-exclusive (with Integra and its distributors) in Existing Distributor Countries, royalty-free, nontransferable license in the Field to reproduce the Licensed Trademark within the Territory during the Term with the standards employed by Integra for the protection of such Licensed Trademark. Such license is granted solely for the purpose of assisting JJM in promoting the sale and use of the Products in the Territory under this Agreement.
- (b) JJM's use of the limited license granted in Section  $5.2\,(a)$ , and any goodwill arising therefrom, shall inure to the sole benefit of Integra and shall not give rise to any compensation to JJM in the event of the expiration or termination of this Agreement.

# ARTICLE VI.

PRODUCT SUPPLY PRICE; MINIMUM PREPAYMENTS AND ADJUSTMENTS

Section 6.1. Supply Price.

- (a) JJM shall pay Integra a supply price for each Product unit (the "Supply Price") equal to the greater of:
  - (i) \$ [\*\*] \$ for a 4x5 dermal template, \$ [\*\*] \$ for a 4x10 dermal template, or \$ [\*\*] \$ for an 8x10 dermal template (the "Minimum Supply Price Per Unit", which Minimum Supply Price Per Unit shall be adjusted upward annually beginning in the calendar year 2001 by an amount corresponding to the

 $<sup>[\</sup>star\star]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

change between January 1, 2000 and the start of each such calendar year in the Producer Price Index, provided, that it shall not exceed  $\$  [\*\*] for a 4x5 dermal template,  $\$  [\*\*] for a 4x10 dermal template, or  $\$  [\*\*] for an 8x10 dermal template. In 2008 and thereafter, the parties shall mutually agree on any increase in such Minimum Supply Price Per Unit; or

(ii) the applicable percentage set forth below of the selling price for such Product actually charged by JJM based upon the Net Sales of Products in the Territory during the given calendar year, subject to adjustment as set forth in Section 6.2 below:

The Supply Price as a Percentage of Net Sales shall be:

			For
If Net Sales	For	For	Calendar
during the year	Calendar	Calendar	Years
are	Years	Years	2008 and
(in \$,000):	1999-2001	2002-2007	thereafter
Less than [**]	[**] %	[**] %	[**]%
[**] - [**]	[**] %	[**] %	[**] %
[**] - [**]	[**] %	[**] %	[**] %
[**] - [**]	[**] %	[**] %	[**] %
Over [**]	[**] %	[**] %	[**] %

(b) The Supply Price will be calculated on a tiered discount basis in each calendar year without any carry-over to the next calendar year. For example, in the calendar years 1999 through 2001, if Net Sales of Products in the Territory for a given year were \$ [\*\*] , the aggregate Supply Price would equal \$ [\*\*] (the sum of (x) \$ [\*\*] (i.e) [\*\*] % for first \$ [\*\*] of such Net Sales), (y) \$ [\*\*] (i.e. [\*\*] % for the second \$ [\*\*] of such Net Sales) and (z) [\*\*] % for the last \$ [\*\*] of such Net Sales)).

(c) Notwithstanding Section 6.1(a) hereof, following the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales of Products in the Territory exceed [\*\*] and the receipt by Integra of

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JJM's \$ [\*\*] payment pursuant to Section 4.3(a) hereof, the Supply Price shall be equal to the greater of:

> (i) the Minimum Supply Price Per Unit, as adjusted pursuant to Section 6.1(a)(i); or

(ii) the applicable percentage set forth below of the selling price for such Product actually charged by JJM based upon the Net Sales of Products in the Territory during the given calendar year, subject to adjustment as set forth in Section 6.2 below:

> The Supply Price as a Percentage of Net Sales shall be:

If Net Sales during the year are (in \$,000):Less than [\*\*]

For Calendar Years 2008 and 1999-2007 and thereafter

For Calendar Years

[\*\*] % [\*\*] %

Over [\*\*]

[\*\*] %

[\*\*] %

(d) JJM shall promptly notify Integra when the amount of Net Sales of Products in the Territory exceeds one of the threshold levels set forth in Section 6.1(a) or (c) resulting in a downward adjustment to the Supply Price.

> Section 6.2. Supply Price Adjustments.

- (a) If following the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales of Products in the Territory exceed [\*\*] , JJM elects not to make the requisite [\*\*] payment owing pursuant to Section 4.3(d) hereof within 30 days after the completion of such first twelve month period, the percentage of Net Sales of Products in the Territory used to calculate the Supply Price (as set forth in Section 6.1 hereof) shall be increased by [\*\*] ([\*\*]) percentage points until the aggregate amount paid to Integra as a result of such increase of [\*\*] ([\*\*]) percentage points in the Supply Price equals the requisite [\*\*] at which point the Supply Price shall revert back to the percentage of Net Sales of Products in the Territory set forth in Section 6.1 hereof.
- (b) If the actual increase in the cost to manufacture (in dollars) any Product Improvements (the "Incremental Costs") is not greater than the corresponding increase in Supply Price as calculated in Section 6.1, the method of calculating the Supply Price shall not be changed upon the development of any Product

<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

Improvements pursuant to the collaboration of parties hereunder. If the Incremental Cost is greater than the corresponding increase in Supply Price, the parties shall negotiate in good faith a new method of calculating the Supply Price to result in an increased (but in no event a decreased) Supply Price solely to reflect any demonstrated material increase in Integra's production costs (taking into account both increases and decreases in manufacturing costs, including the costs of raw materials and the costs of any royalties to third parties on Net Sales payable in respect of any Product Improvements, deriving from the change) that result from Product Improvements.

## Section 6.3. Invoicing/Payment.

- (a) Prior to the first day of each calendar year during the Term, the parties shall agree upon an estimate of Net Sales of Products in the Territory to be achieved by JJM for such calendar year (the "Net Sales Estimate"). Integra shall invoice the Products for each shipment at a Supply Price calculated based on the Net Sales Estimate and the tiering concept described in Section 6.1(b). Each such invoice shall also reflect amounts credited to JJM based on its Minimum Prepayments pursuant to Section 6.7 hereof and shall indicate (i) the Minimum Prepayment Amount which remains to be credited against future invoices and (ii) the amount of Excess Prepayments, if any. JJM shall pay Integra for each shipment of Products at the invoiced price within thirty (30) days from the receipt of such shipment.
- (b) The prices for the Products as specified in Section 6.1 are ExWorks Integra's place of manufacture or distribution in Plainsboro, New Jersey or other warehouse locations. Invoices shall not be dated prior to the date of delivery of the Products ExWorks Integra's place of manufacture or distribution in New Jersey or other warehouse location. All shipments of Products shall be billed to JJM at the price in effect for each Product at the time of acceptance by Integra of JJM's order for such Products. JJM shall alone bear any costs of shipment of the Products to its warehouse as well as the amount of any and all domestic, foreign, state, or local sales, use, value added, or other taxes (other than income or franchise taxes of Integra), custom duties, tariffs, levies, fees, or other charges which may be required to pay or collect on the sale, delivery, or transportation of the Products. If any such shipment cost, tax, duty, tariff, levy, fee, or charge shall be made or imposed on Integra, JJM shall reimburse Integra therefor.
- (c) Acceptance and endorsement by Integra of any instrument for less than the full amount that Integra claims to be due and payable to it under a purchase order or hereunder shall not be deemed to be an admission of payment in full, and any conditions to the contrary that are noted on such instrument shall not be binding on Integra.

Quarterly Adjustment. Within thirty (30) days after the end of each Calendar Quarter during the Term, JJM shall prepare and deliver to Integra a certificate with supporting data in reasonable detail (the "Net Sales Certificate"), setting forth (i) the Net Sales of Products in the Territory during the preceding Calendar Quarter -- in the aggregate and broken down by each type and size of Product and country within the Territory, (ii) the Estimated Net Sales which were used to calculate the Supply Price for such Calendar Quarter; (iii) the number of Products sold during such Calendar Quarter -- in the aggregate and broken down by each type and size of Product and country, (iv) the price actually paid based on the Estimated Net Sales for such Calendar Quarter -- in the aggregate and broken down by each type and size of Product and country, (v) the Supply Price owing pursuant to this Agreement based on the Net Sales for each Product sold in the Territory during such Calendar Quarter  $\operatorname{\mathsf{--}}$  in the aggregate and broken down by each type and size of Product and country and (vi) the amount of any "true-up" payment due to either JJM or Integra resulting from the difference between the Supply Price paid and the Supply Price owing. If JJM is obligated to make any payments to Integra pursuant to this Section 6.4, it shall do so simultaneously with the delivery of the Net Sales Certificate. If Integra is obligated to refund any amounts to JJM pursuant to this Section 6.4, it shall do so by crediting such amounts against the next succeeding invoices issued to JJM until fully applied.

Section 6.5. Accounting. All amounts payable hereunder shall be payable in United States Dollars; provided, however, that if any payment on account of Net Sales by JJM or its Affiliates is received in a foreign currency, such amount shall be converted monthly to United States funds at the rate set monthly by JJM's international finance department from Reuters wire service (providing international spot exchange rates) on or about the 25th day of the each month (unless such date falls on a Saturday, Sunday or holiday, in which case the date shall be the closest business day thereto). To the extent required, JJM shall estimate Net Sales in foreign countries based upon the deductions from the corresponding gross sales. JJM shall use its reasonable diligent efforts to minimize discrepancies between such estimated Net Sales and corresponding actual Net Sales, and, bi-annually, or upon the request of Integra, JJM shall reconcile estimated Net Sales in foreign countries with actual Net Sales and promptly make any additional payment (or request reimbursement or credit) from Integra. JJM shall notify Integra on a monthly basis of the exchange rates used by JJM for the preceding month in calculating Net Sales. Upon written notice to Integra, JJM may elect a different recognized independent wire service providing international spot exchange rates.

Section 6.6. Records. During the term of this Agreement, JJM shall keep, and shall cause its Affiliates to keep, complete and accurate records of Net Sales of Products in the Territory in sufficient detail to enable Integra to determine payments owed to

it under this Agreement for a period of three (3) years after such payments are due. JJM shall permit a certified public accountant, acceptable to JJM and appointed by Integra and at Integra's expense, to examine its books, ledgers and records covering Net Sales of Products in the Territory during regular business hours for the purpose of verifying, and only to the extent necessary to verify, the payments due pursuant to the provisions of this Agreement, but in no event more than once per calendar year. The accountant shall maintain all information received during such examination in confidence, and shall report to Integra only with respect to the accuracy of any report. Any report not examined within three (3) years of its having been made shall be deemed true and accurate. In the event the records examined reveal that JJM has paid less than ninety-five percent (95%) of the amount due Integra, JJM shall pay the reasonable costs of the audit and shall pay the additional amount due plus accrued interest at the average prime rate in effect for the period covered by the audit as set by Citibank, N.A.

## Section 6.7. Annual Minimum Prepayments.

- (a) Each calendar year during the Term, JJM shall make non-refundable minimum prepayments to Integra equal to the product of (x) the Minimum Net Sales (defined below) and (y) the applicable Supply Price as a percentage of Net Sales calculated in accordance with this Article VI for the Products (such prepayments, the "Minimum Prepayments"). Integra shall apply the Minimum Prepayments as an advance against actual payments due on Net Sales. If in any calendar year, the Minimum Prepayments actually paid by JJM for such calendar year exceeds the actual payments due on Net Sales (such excess amount referred to herein as "Excess Prepayments"), the Excess Prepayments shall be carried over as an advance on actual payments due on Net Sales from JJM for the subsequent calendar year, provided that in no event shall such Excess Prepayments (i) be applied as a deduction against any future Minimum Prepayment due pursuant to this Agreement, or (ii) be refunded by Integra.
- (b) "Minimum Net Sales" means, for each of the periods specified below, the aggregate Net Sales of Products in the Territory set forth opposite such period, subject to adjustments as provided in Section 6.8 hereof:

Calendar Year	Minimum Net Sales (\$, 000)
1999	[**]
2000	[**]
2001	[**]
2002	[**]
2003 and thereafter	[**]

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 $<sup>[\</sup>ensuremath{^{**}}]\xspace$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

- (c) JJM shall make the Minimum Prepayments to Integra no later than the following dates by wire transfer in immediately available funds to an account designated by Integra:
  - (i) for the calendar year 1999, the entire Minimum Prepayment shall be made on the Effective Date,  $\,$
  - (ii) for the calendar year 2000, the entire Minimum Prepayment shall be made prior to December 31, 1999, and
  - (iii) for the calendar year 2001 and each calendar year thereafter during the Term, the Minimum Prepayments shall be made in equal quarterly installments payable on or prior to the first day of each Calendar Quarter by wire transfer in immediately available U.S. dollars to a U.S. bank account specified by Integra.
- (d) JJM's obligation hereunder to make Minimum Prepayments shall cease upon the completion of the first twelve month period (calculated on a rolling monthly basis) in which Net Sales of Products in the Territory exceed  $\$  [\*\*] and the receipt by Integra of JJM's  $\$  [\*\*] payment pursuant to Section 4.3 [\*\*] hereof.
- (e) For purposes of this Agreement, the purchase of a Product shall be deemed to occur during the calendar year in which the Product is scheduled for delivery pursuant to a firm purchase order received and accepted by Integra.

Section 6.8. Adjustments.

- (a) General Principles of Adjustments.
- (i) Upon the occurrence of any of the events specified in Sections 6.8(b) and (c) which trigger an adjustment to Minimum Net Sales (such an event, an "Adjustment Event"), Integra shall promptly notify JJM and the adjustment shall take effect on the first day of the calendar month following the date of the Adjustment Event. Notice of the Adjustment Event shall specify any corresponding adjustment to the Minimum Prepayments.
- (ii) In no event shall the cumulative reduction in Minimum Net Sales for any calendar year made pursuant to Sections 6.8(b) and (c) hereof (without including any upward adjustment pursuant to Section 6.8(d)) exceed [\*\*] ([\*\*]%) of Minimum Net Sales set forth in Section 6.2 above.
- (iii) "PMAF" (Per Month Adjustment Factor) means the quotient Z/12, where Z is the integer equal to the number of

 $<sup>[\ ^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

months remaining in the calendar year in which the Adjustment Event occurred, not including the month in which the Adjustment Event occurred.

- (iv) From and after the last date on the calendar month in which an Adjustment Event no longer continues, the Reduction Factors applied pursuant to Sections  $6.8\,(b)$  and  $6.8\,(c)$  below shall no longer be applied.
- (b) Failure to Terminate Other Distributors. Commencing January 1, 2000, if Integra continues to maintain distribution agreements other than this Agreement for the Products in the Existing Distributor Countries, Minimum Net Sales shall be reduced by multiplying (x) the amount of Minimum Net Sales set forth in Section 6.7(b) and (y) (100-X)/100 where X equals the "Reduction Factor" set forth in the following chart for the respective countries:

Country	Reduction	n	Factor
[**]	[**]	X	PMAF
[**]	[**]	X	PMAF
[**]	[**]	X	PMAF
[**]	[**]	X	PMAF
[**]	[**]	X	PMAF
[**]	[**]	X	PMAF
[**]	[**]	X	PMAF

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For those countries as to which existing distribution agreements are assignable, and as to which JJM elects to have the applicable distribution agreement assigned to it, [\*\*].

(c) Failure to Achieve Certain U.S. [\*\*] Wound Indications. Commencing January 1, 2001, if the Products have not received Regulatory Approval from the FDA for the indications set forth in the chart below, Minimum Net Sales shall be reduced

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 $<sup>[\</sup>star\star]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

by multiplying (x) the amount of Minimum Net Sales set forth in Section 6.7(b) and (y) (100-X)/100 where X equals the "Reduction Factor" set forth in the following chart for the respective indications:

[\*\*] x PMAF

 Indication
 Reduction Factor

 [\*\*]
 [\*\*] x PMAF

For the avoidance of doubt, permission by the FDA to distribute articles describing the use of the Products for [\*\*] Wound Indications shall not be deemed as obtaining Regulatory Approval for [\*\*] Wound Indications for the purpose of the calculations set forth above.

(d) Receipt of Certain [\*\*] Wound Labeling. Commencing twelve months from date (the " [\*\*] Wound Approval Date") on which the Products receive Regulatory Approval from the FDA for a [\*\*] Wound indication [\*\*] Minimum Net Sales set forth in Section 6.7(b) shall be increased by an amount equal to [\*\*] Wound Net Sales. For the avoidance of doubt, permission by the FDA to distribute articles describing the use of the Products for [\*\*] Wound indications shall not be deemed as obtaining Regulatory Approval for [\*\*] Labeling. For purposes of this Agreement, the following terms have the following meanings:

" [\*\*] Wound Net Sales" means the product equal to (x) [\*\*] Wound Market Size and (y) the Applicable Percentage of Market Size.

"Comparable Competitive Products" means Competitive Products which have [\*\*] Wound Labeling, assuming that on the [\*\*] Wound Approval Date no more than two other Competitive Products have both (i) [\*\*] Wound Labeling and (ii) net sales per annum in excess of \$10 million (excluding the Products).

"Applicable Percentage of Market Size" means the percentage set forth in the chart below which is a factor of (x) the number of years since the [\*\*] Wound Approval Date and (y) whether or not the [\*\*] Wound Labeling of the Products is, on the [\*\*] Wound Approval Date, inferior, comparable or superior to the [\*\*] Wound Labeling of the

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## Comparable Competitive Products:

CLAIMS OF [**] WOUND LABELING	NET SALES FOR TWO YEARS AFTER [**] WOUND APPROVAL DATE TO EXCEED	NET SALES POST TWO YEARS AFTER [**] WOUND APPROVAL DATE TO EXCEED
Inferior	[**] %	[**] %
Comparable	[**] %	[**] %
Superior	[**] %	[**] %

For purposes of this definition, the inferiority, comparability and superiority of the [\*\*] Wound Labeling of a Product versus that of a Comparable Competitive Product will be determined with reference to, among other factors, the products' respective approved indications, package inserts, allowed label claims, supporting peer-reviewed published clinical research regarding efficacy relative to competing products and treatment modalities. In the event there are no competing products with net sales per annum in excess of \$10 million, then the Product shall be deemed to be Comparable.

" [\*\*] Wound Market Size" means the amount expressed in U.S. dollars of aggregate sales of Comparable Competitive Products sold to treat the indications covered by [\*\*] Wound Labeling in either the United States or the European Union, respectively, for the twelve month period prior to the [\*\*] Wound Approval Date, as adjusted by multiplying such market size by the ratio of (x) the average price of the Products to be sold in the United States or the European Union, respectively, to (y) the average price of the Comparable Competitive Products then being sold in the United States or the European Union, respectively. Such adjustments shall take into account (i) actual materials purchased for a procedure, (ii) the actual price per procedure and (iii) the number of procedures to reach clinical endpoint as established by actual clinical usage data.

In the absence of agreement between the parties regarding clinical usage data, the relevant Comparable Competitive Products and their average prices, the inferiority, comparability or superiority of the [\*\*] Wound Labeling of any Comparable Competitive Products, the net sales per annum of any Comparable Competitive Products or any other matter necessary to determine the [\*\*] Wound Market Size, prior to taking action in accordance with Section 28.2 or 28.3 hereof, the parties will try to resolve such disagreements first in the Joint Steering Committee, then in the Executive Committee and then by engaging a mutually acceptable consulting firm to resolve such

 $[\ ^{**}]\mbox{Confidential Information omitted}$  and filed separately with the Securities and Exchange Commission.

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dispute. The Joint Steering Committee, Executive Committee and any such consulting firm may each refer to the published data of the Competitive Persons (in reports filed with the Securities and Exchange Commission or press releases), data published by securities analysts at nationally recognized investment banks or HPIS or IMS data. Prior to obtaining Regulatory Approval, the two companies, through the Joint Steering Committee and the Executive Committee shall agree on the data source and/or model to be used to track Competitive Sales for [\*\*] Wound use. In the event incremental costs are incurred to obtain such data or model, the parties shall split such costs 50%/50%.

#### ARTICLE VII.

#### COMPLAINTS/RECALLS OF PRODUCTS

Section 7.1. Complaints. To the extent that it has knowledge thereof, each party shall promptly (and in any event within three Business Days) notify the other in writing of (i) any third party complaint, whether written or oral, and (ii) any defect in, or condition of, the Products or any other fact or circumstance which may result in a violation or alleged violation of any applicable statutes, laws, rules, regulations, ordinances and decrees of Governmental Authorities of any country in the Territory, including those referenced in Section 3.2(a)(iii) hereof. Integra and JJM shall share with each other all data on Complaints respecting the Products, including Complaints or information regarding performance or allegations or reports of any effects on a patient from use of such Products, as soon as such data is available. In connection with any such Complaints, JJM shall secure for Integra the lot number of the Product in question and the name of the health care professional, patient, and institution where the Complaint occurred. Each party shall cooperate with the other party to the extent reasonably necessary to resolve outstanding complaints, and Integra shall have primary responsibility to file all Medical Device Reports ("MDRs") required to be filed with the FDA. Either party may file an MDR, provided that, if permitted by the circumstances, it has conferred with the other party before doing so (and the parties shall use all reasonable diligent efforts to so confer), but the responsibility to follow up with the FDA regarding such MDR shall be Integra's alone. At such time as Integra develops or revises its procedures for filing MDRs in accordance with the MAP, JJM shall have the right to approve such revisions (such approval not to be unreasonably withheld).

Section 7.2. Recall.

(a) In the event that either party has reason to believe that one or more lots of Products should be recalled or withdrawn

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<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

from distribution or that an advisory letter should be issued regarding reliability or defects in the Products, such party shall immediately notify the other party in writing. If permitted by the circumstances, the parties, through the Joint Steering Committee, will confer before initiating any recall (and the parties shall use all reasonable diligent efforts to do so), but either party may initiate a recall of Products in any country in the Territory or issue any such advisory letter and report such letter to appropriate Governmental Authorities without the consent of the other party. JJM shall maintain adequate sales and service records to enable it to conduct any Product recall and shall take all actions to assist in promptly executing any Product recall as directed by Integra. If the recall is required because of a modification of the registrations, permits or licenses for the Products or a failure of a Product to conform to its specifications as provided to the health authorities in any specific country in connection with the registration of the Product, Integra shall reimburse JJM for the costs and expenses of such recall, and, at  $\mathsf{JJM's}$ option, Integra shall replace recalled Products or credit or refund the purchase price of recalled Products. If the recall is required because of a negligent act or omission of JJM in handling, storage or distribution of the Product, then such recall shall be conducted by JJM at its sole cost and expense and JJM shall not be entitled to any such credits, replacements or refunds from Integra. If such recall is required because of a joint act or omission, JJM shall conduct the recall and the parties shall negotiate in good faith an appropriate allocation of the costs and expense of such recall.

(b) In the event that a recall of the Products precludes Integra from shipping products for a one-month period, then all Minimum Prepayments and Minimum Net Sales requirements shall be suspended until such time as Integra recommences the shipment of Products. In the event that a recall of the Products is initiated because the Products caused manifest and publicized harm to patients, then all Minimum Prepayments and Minimum Net Sales requirements shall be suspended for a period of three (3) months from the date such recall commences.

## ARTICLE VIII.

## TRADEMARK/TRADE DRESS OF PRODUCTS

Section 8.1. General.

(a) Except as expressly provided in this Agreement, neither party shall use any trademarks, service marks or trade names which are confusingly similar to or which constitute an imitation of the other party's trademarks, service marks or trade names used in connection with the sale of the Products, nor shall either party assert any rights therein.

- (b) JJM shall provide Integra, at Integra's request, with copies of all advertising and promotional materials used for the Products. At Integra's request, JJM shall be obligated to remove Licensed Trademark from its packaging and promotional materials. Any incremental costs required to implement such request will be shared equally between the two parties.
- (c) Nothing contained herein (including, without limitation, in Section 29.3(v)) shall be interpreted as to grant Integra any rights in any trademarks, trade dress, copyrights or other intellectual property rights owned by JJM or its Affiliates.

## Section 8.2. Use of Trademarks.

- (a) The trademarks INTEGRA(Trademark) Dermal Regeneration
  Template(Trademark) or INTEGRA(Trademark) Regeneration Template(Trademark) shall appear on all packaging, promotional material developed particularly for the Products (including professional advertising but excluding mere listings of products and consumer advertising), and package inserts. The words "Manufactured by Integra LifeSciences Corporation" shall appear on the outside of the box, the container and the package insert. In order to protect the goodwill in the Licensed Trademark, JJM shall submit to Integra, for its written approval, specimens of labels, advertising, and other materials bearing the Licensed Trademark. Integra shall communicate its approval or disapproval of JJM's use of the Licensed Trademark within five (5) Business Days following receipt of such specimens. Failure of Integra to respond within such five (5) Business Day period shall constitute approval of such use. Integra's approval of JJM's use of the Licensed Trademark shall not be unreasonably withheld.
- (b) Integra or its distribution partners shall not be permitted to use "Integra" as part of the brand, trademark or product name for (i) any Other Wound Care Product, (ii) any product that would have been an Other Wound Care Product but for the fact that it is intended to facilitate the repair and/or regeneration of endodermis or dental or gingival tissues or (iii) any product made with GAG incorporated into a collagen matrix. Nothing herein shall be construed to limit Integra's right to use the "Integra" trademark in its corporate name or to limit the use of the phrase "Manufactured by Integra LifeSciences Corporation" (or derivatives thereof or similar phrases with respect to Affiliates of Integra) on any Product or product.
- (c) JJM shall not remove, conceal, alter or deface any of Integra's trademarks, service marks or trade names on the Products and shall not display Integra's trademarks, service marks or trade names on any Products not purchased, or manufactured under the license granted under certain circumstances following a Supply Default, Not Cured pursuant to Section 4.2(b) (ii), from Integra. JJM may add additional

trademarks or brand names to the Products in its sole discretion at any time.

Section 8.3. Promotional Materials. At JJM's request, Integra shall provide to JJM original copies of any promotional and physician training materials (the "Promotional Materials") currently in use by Integra, including any photos used in the Promotional Materials. Integra shall provide to JJM any original or master copies of such photos, slides, videos required for replication. Furthermore, Integra shall diligently pursue obtaining written relinquishment from patients for use of photos, video, audio, etc. in existing Promotional Materials.

## ARTICLE IX.

#### PRODUCT WARRANTY

Section 9.1. Product Warranty. Integra warrants that any Products supplied to JJM under this Agreement will, at the time of delivery, (i) meet the Product Specifications incorporated in Schedule 4.4(d), (ii) be free from defects in material, workmanship and design, (iii) comply in all material respects with all applicable statutes, laws, ordinances and regulations of the country of manufacture and of the country in which it will be distributed and (iv) conform in all material respects to the release specifications of the applicable United States or foreign Regulatory Approvals. Integra further warrants that it shall maintain the manufacturing facilities used to manufacture the Products in compliance in all material respects with GMP/ISO requirements and with the reasonable Corporate Quality Assurance Guidelines of JJM set forth in Schedule 9.1 hereto.

SECTION 9.2. Disclaimer of Warranties. INTEGRA MAKES NO WARRANTIES OTHER THAN THOSE STATED IN THIS AGREEMENT. INTEGRA DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, USAGE OF TRADE OR OTHERWISE. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN ARTICLE X, THE LIABILITY OF INTEGRA FOR A BREACH OF THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS ARTICLE IX SHALL BE LIMITED TO THE REPLACEMENT OF THE SPECIFIC SHIPMENTS OF PRODUCTS AS TO WHICH A CLAIM IS MADE, AND INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, LOSS OF PROFIT, OR LOSS OF USE.

### ARTICLE X.

## INDEMNIFICATION

# Section 10.1. Indemnity.

- (a) Integra shall indemnify and hold harmless JJM and its Affiliates against and from and shall compensate and reimburse JJM for costs and expenses and claims and governmental proceedings and fines, and costs and expenses reasonably incurred in defending against such claims (including expenses related to product recalls and reasonable attorneys' fees and disbursements of counsel) (collectively, "Damages") incurred by  $\overline{\text{JJM}}$  and its Affiliates, which Damages arise out of, or are based on any claim related to (i) defects in materials, workmanship, or design of any Product sold to JJM hereunder, (ii) promotional material distributed by Integra prior to the date hereof, (iii) a breach by Integra of its express warranty set forth in Section 9.1 hereof, (iv) a breach by Integra of its express warranty regarding no infringement of third party rights set forth in Section 23.4 below, (v) willful, reckless or negligent acts of Integra or its Affiliates or their respective employees, directors, consultants, sublicensees, agents or subcontractors or (vi) acts or omissions of Integra in breach of this Agreement, provided that Integra shall have no indemnification obligation regarding and shall not be liable for Damages which arise out of, or are based on, any claim related to JJM's use, marketing, distribution or sale of the Products for unauthorized indications or in any other manner in violation of the Regulatory Approval and applicable laws of the country in the Territory in which such acts occur. The indemnity rights conferred by this paragraph do not apply to Damages to the extent that such Damages result from willful, reckless or negligent acts of JJM or its Affiliates or their respective employees, directors, consultants, sublicensees, agents or subcontractors or acts or omissions of JJM in breach of this Agreement.
- (b) JJM shall indemnify Integra and hold Integra harmless against and from and shall compensate and reimburse it for, any Damages arising out of, or based on, any claim related to (i) a breach by JJM of its negative covenant set forth in Section 3.2(c) hereof, (ii) JJM's use, marketing, distribution or sale of the Products in violation of any applicable statutes, laws, rules, regulations, ordinances and decrees of Governmental Authorities of any country in the Territory, including those referenced in Section 3.2(a) (iii) hereof, willful, reckless or negligent acts of JJM or its Affiliates or their respective employees, directors, consultants, sublicensees, agents or subcontractors or (iii) acts or omissions of JJM in breach of this Agreement. The indemnity rights conferred by this paragraph do not apply to Damages to the extent that such Damages result from willful, reckless or negligent acts of Integra or its Affiliates or their respective employees, directors, consultants,

sublicensees, agents or subcontractors or acts or omissions of Integra in breach of this Agreement.

Section 10.2. Notice and Procedures. An indemnified party (the "Indemnified Party") shall give notice to the indemnifying party ("Indemnifying Party") of any Damages for which such Indemnified Party seeks indemnification, stating the amount claimed, if known, and method of computation thereof. Such notice shall be delivered promptly and in time reasonably to permit the Indemnifying Party to assume without prejudice or adverse effect the defense of any third party claim that could give rise to Damages. The obligations and liabilities of an Indemnifying Party under this Article X with respect to Damages arising from claims of any third party ("Third Party Claims") shall be governed by and contingent upon the following additional terms and conditions: the Indemnifying Party shall be entitled to assume and control the defense of such Third Party Claim if it gives prompt notice of its intention to do so to the Indemnified Party; provided, however, that if there exists or is reasonably likely to exist a conflict of interest that would make it inappropriate in the reasonable judgment of the Indemnified Party for the same counsel to represent both the Indemnified Party and the Indemnifying Party, then the Indemnified Party shall be entitled to retain its own counsel at the expense of the Indemnifying Party. The Indemnified Party shall cooperate with the Indemnifying Party in such defense and make available to the Indemnifying Party, at the Indemnifying Party's expense, all witnesses, pertinent records, materials and information in the Indemnified Party's possession or control relating thereto as is reasonably required by the Indemnifying Party. In the event that the Indemnified Party is conducting the defense against any such Third Party Claim, the Indemnifying Party shall similarly cooperate with the Indemnified Party. No such Third Party Claim may be settled by the Indemnifying Party without the written consent of the Indemnified Party unless such settlement includes a complete and unconditional release of the Indemnified Party.

Section 10.3. Insurance.

(a) Integra will maintain (i) product liability insurance with respect to the Products sold hereunder with minimum annual limits of [\*\*] per occurrence and [\*\*] in the aggregate and (ii) property insurance in an amount reasonably expected to be sufficient to replace its facility and obtain all necessary machinery and equipment. Such insurance shall (i) name JJM and Integra as insured parties thereunder as their interests may appear, (ii) provide that there shall be no recourse against JJM for payment of premiums or other amounts with respect thereto and (iii) provide that at least thirty (30) days prior notice of cancellation or lapse shall be given to JJM by the insurer. The additional insured status afforded to JJM under Integra's

 $<sup>[\ ^{**}]\</sup>mbox{Confidential Information omitted and filed separately with the Securities and Exchange Commission.}$ 

insurance shall not extend coverage beyond the indemnification provisions of this Agreement. Integra shall, if so requested by JJM, furnish a certificate of insurance evidencing the insurance required hereunder.

(b) JJM will maintain commercial general liability insurance providing coverage for liability arising from JJM's activities under this Agreement. JJM shall maintain the liability insurance required hereunder with minimal annual limits of [\*\*] per occurrence and [\*\*] in the aggregate. Such insurance shall provide that at least thirty (30) days prior notice of cancellation or lapse shall be given to Integra by the insurer. JJM shall, if so requested by Integra, furnish a certificate of insurance evidencing the insurance required hereunder.

#### ARTICLE XI.

### RESEARCH & DEVELOPMENT PROGRAM

Section 11.1. Product Improvement Research. Subject to the terms and conditions of this Agreement, Integra shall conduct an ongoing program of research and development, including clinical testing, directed to improving existing Products, expanding the approved indications for the Products within the Field and developing future Products with improved performance and efficacy. Such research and development efforts shall be carried out under the direction of the Joint Steering Committee and pursuant to Annual Plans developed and agreed upon as contemplated by Section 11.3 below.

Section 11.2. JJM Collaboration. Subject to the terms and conditions of this Agreement, JJM shall provide assistance, consultation and advice to Integra in the conduct and assessment of such research and development efforts. In addition, as contemplated by the Annual Plans, JJM shall collaborate with Integra and undertake certain aspects of the development and clinical testing programs.

Section 11.3. Annual Plan. The Annual Plan for the period between the Effective Date and December 31, 1999 shall be prepared by Integra and distributed for review to the Joint Steering Committee within sixty (60) days of the Effective Date. For each calendar year thereafter, Integra shall prepare a draft of the Annual Plan for submission to, and approval by, the Joint Steering Committee not later than September 1 of the calendar year prior to the calendar year to which such plan relates. Once approved by the Joint Steering Committee, the Annual Plan for each calendar year shall be appended to and made part of this Agreement. The members of the Joint Steering Committee shall seek in good faith to resolve any disagreements with respect to any Annual Plan. In connection with the approval of each Annual Plan, the Joint Steering Committee shall annually agree upon the

 $<sup>[\ ^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

number of individuals from Integra's research and development staff that will be dedicated to the performance of research under this Agreement.

#### ARTICLE XII.

#### RESEARCH FUNDING

Section 12.1. Funding Through 2004. JJM shall contribute to Integra's research, development and clinical programs by making periodic payments to Integra to be utilized to fund such programs, including (subject to the approval of the Joint Steering Committee) in conjunction with grants (such as NIH, NIST) received by Integra (the "Research Payments"). JJM shall pay to Integra [\*\*] million as Research Payments in each of calendar years 2000 through 2004. Such Research Payments shall, in each case, be made by JJM in four equal installments of [\*\*] ([\*\*]) payable on or prior to the first day of each Calendar Quarter by wire transfer in immediately available U.S. dollars to a U.S. bank account specified by Integra.

Section 12.2. Funding After 2004. Commencing January 1, 2005 and each calendar year of the Initial Period (as defined herein) thereafter, JJM shall pay to Integra as an aggregate annual Research Payment an amount equal to [\*\*] of Net Sales for the previous calendar year. There shall be no maximum amount to the aggregate Research Payments made by JJM to Integra in any calendar year commencing January 1, 2005. Such Research Payments shall, in each case, be made by JJM in four equal quarterly installments payable on or prior to the first day of each Calendar Quarter by wire transfer in immediately available U.S. dollars to a U.S. bank account specified by Integra.

Section 12.3. Funding for Extension Period. For each of the first five calendar years of the Extension Period (as defined in Article XXIX, JJM shall make Research Payments to Integra in amounts equal to the percentage of Net Sales of the Products in the Territory for the previous calendar year specified in the following table, which percentage shall decrease each year by 0.5 percentage points until it is zero as follows:

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<sup>[\*\*]</sup>Confidential Information omitted and filed separately with the Securities and Exchange Commission.

Research Payments
(as % of Net Sales for the previous calendar year)

Year of Extension Period

1
2
3
4
5
6, and thereafter

[\*\*] %
[\*\*] %
[\*\*] %
[\*\*] %
[\*\*] %

There shall be no maximum amount to the aggregate Research Payments made by JJM to Integra in any calendar year during the Extension Period. Such Research Payments shall, in each case, be made by JJM in four equal quarterly installments payable on or prior to the first day of each Calendar Quarter by wire transfer in immediately available U.S. dollars to a U.S. bank account specified by Integra.

Section 12.4. Utilization and Allocation of Research Payments. In connection with the approval of each year's Annual Plan, the parties, through their representatives on the Joint Steering Committee, shall agree on the allocation of Research Payments to research, development and clinical uses within the Annual Plan. In any calendar year, at least \$ [\*\*] of the Research Payments for such year shall be allocated in the Annual Plan by the Joint Steering Committee to the salaries of Integra's research and development personnel in support of the research program contemplated herein unless otherwise mutually agreed by the parties. Commencing with the calendar year beginning January 1, 2005, the parties intend that approximately 20% of Research Payments shall be utilized for research, development and clinical programs in the Field conducted by JJM, with the remainder of such amounts to be conducted by Integra. Integra shall not apply any of the Research Payments to research or development outside the Field unless it shall have received express written approval for such expenditure from JJM. [\*\*]

At the conclusion of each calendar year during the Term, Integra shall provide JJM with a certificate duly executed by its chief executive officer certifying that the Research Payments were used substantially in accordance with the Annual Plan or as otherwise directed by the Joint Steering Committee.

Section 12.5. Additional Technology Acquisition Funding. In the event JJM and Integra agree to seek to acquire or in-license third party technologies useful in the Field, the cost of which is beyond the scope of the Research Payments, given other

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 $<sup>[\ ^{**}]</sup>$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

allocated uses within the Annual Plan, the parties shall negotiate in good faith a mechanism for acquiring such technologies and reimbursing the party that pays for the in-license or acquisition of such technologies. Notwithstanding the foregoing, under no circumstances shall either party be able to compel the other party to expend for such acquisition or in-licensing funds in excess of the Research Payments, nor shall one party be able to block the other party from acquiring such Technology (subject to the provisions of Section 2.3).

Section 12.6. Utilization of Animal Testing Facility. Upon the agreement of the Joint Steering Committee, Integra may request that JJM provide services and resources, if available, at the Johnson & Johnson Wound Healing TRC ("TRC") located in Skillman, New Jersey in connection with the research, development and clinical program, provided that the rate which Integra shall pay for such services shall not exceed the average rate charged by TRC to JJM. Integra shall make payments to JJM to offset the corresponding inter-company cross-charge.

Section 12.7. Development of [\*\*] Product. The parties may mutually agree, through the Joint Steering Committee, to conduct a separate research, development and clinical program for a [\*\*] Product. [\*\*]

Until the parties agree to conduct such a program, neither party shall be obligated to allocate or spend any resources on such program. If the Joint Steering Committee recommends that the parties conduct such a program, and the cost of such program exceeds the available Research Funding, the parties will determine how to jointly fund it.

Section 12.8. Reports and Exchange of Information.

- (a) Reports. Each party shall communicate to the other the status of its work pursuant to each Annual Plan, its findings and all results in a manner and at such intervals as the Joint Steering Committee shall reasonably determine, but no less frequently than a written report every Calendar Quarter. Each such quarterly report shall summarize the progress and results during the previous quarter in implementing the Annual Plan and achieving the goals and shall provide such other related information as the Joint Steering Committee shall reasonably request.
- (b) Access to Facilities. Each party shall permit personnel of the other party to visit the facilities that are utilized in connection with the research and development contemplated by the Annual Plan, at mutually agreed upon times,

 $<sup>[\,{}^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

during normal business hours, to observe the activities being conducted under the Annual Plan.

(c) Books and Records. Each party shall keep and maintain detailed and accurate books and records, consistent with its current accounting procedures, with regard to its expenditures under the Annual Plan. Each party shall be entitled to review and audit such books and records of the other from time to time (but not more frequently than twice per calendar year) during normal business hours upon reasonable notice to verify the application of Research Payments in accordance with the Annual Plan. All information received by a party (or its representatives) during such an audit shall be considered Confidential Information.

#### ARTICLE XIII.

## CLINICAL AND REGULATORY EVENT PAYMENTS

Section 13.1. Clinical and Regulatory Event Payments. Upon the first occurrence of each of the events set forth below, Integra shall promptly notify JJM in writing of the achievement of such event, along with any related documentation reasonably requested by JJM (a "C&R Notice"). Within thirty (30) days following the delivery of any C&R Notice, in further consideration for the exclusive use of the PMA P900033 and all amendments and supplements thereto relating to the Products in the Field and the Territory, JJM shall pay directly to Integra in addition to the Research Payments contemplated by Article XII, the corresponding C&R Event Payment set forth below (a "C&R Event Payment"). Until Manufacturing Yield exceeds [\*\*]% for three consecutive lots of [\*\*] size Product, JJM shall withhold 50% of C&R Event Payments of \$1 million or more, payment of such withheld amount to be subsequently paid out in full upon notification of achieving such Manufacturing Yield. C&R Event Payments shall be paid directly to Integra by wire transfer in immediately available U.S. dollars to a U.S. bank account specified by Integra.

C&R Event Payment

C&R Event

(i) \$0.25 million:

Upon publication of part of or the entire " [\*\*] study" with data equivalent to or better than the pivotal study data (minimum of one-hundred patients) in a U.S. peer-reviewed iournal [\*\*].

<sup>[\*\*]</sup> Confidential Information omitted and filed separately with the Securities and Exchange Commission.

In no event shall such publication be made prior to completion of the [\*\*] study.

(ii) \$0.75 million:

Upon the filing of the FDA [\*\*] Burn Study satisfying the original conditions of PMA approval [\*\*]

(iii) \$0.50 million:

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(iv) \$0.50 million:

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provided, that if this shall be the first PMA supplement approval granted since the Effective Date, and  ${\sf JJM}$  shall not then have previously paid the C&R Event Payment set forth under (iii) above, then JJM shall make such payment at such time.

(v) \$0.50 million:

Upon receipt of PMA supplement approval from the FDA for  $[\,^{\star\star}\,]$ 

indication; provided, that if this shall be the first  ${\tt PMA}$ supplement approval granted since the Effective Date, and JJM shall not then have previously paid the C&R Event Payment set forth under (iii) above, then JJM shall make such payment at such time.

(vi) \$0.50 million:

Upon publication [\*\*]

<sup>[\*\*]</sup> Confidential Information omitted and filed separately with the Securities and Exchange Commission.

of a [\*\*] study [\*\*] including those patients used in obtaining the [\*\*] and/or those patients used in applying for the PMA supplement for [\*\*] indication; such payment not to be paid until and unless the PMA supplement is approved.

(vii) \$5.00 million:

Upon receipt of first FDA approval for
[\*\*] indication [\*\*]

For the avoidance of doubt, permission from the FDA to distribute a peer-reviewed article describing the use of the Product for [\*\*] is not sufficient.

(viii) \$2.00 million:

Upon CE mark approval (whether such mark is held in Integra's name or in JJM's name) and publication of a prospective clinical study for [\*\*]

allowing sale to that indication with CE mark (whether such mark is held in Integra's name or in JJM's name) in Europe, including as an extension of Integra's (or JJM's if the mark is held in its name) current design dossier, and receipt of a Regulatory Approval for such indication in at least

(if required, including any required product registration).

(ix) \$3.00 million:

Upon receipt of subsequent FDA approval for any one additional [\*\*] indication [\*\*]

; to be paid simultaneously with the payment set forth under (vii) above if the first and second [\*\*] indications receive approval simultaneously.

 $<sup>[\ ^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

[\*\*] In the event that the Joint Steering Committee decides to adopt a different [\*\*] that no longer contemplates the achievement of one or more events set forth above (an "Abandoned Event"), the Joint Steering Committee shall reallocate the C&R Event Payment for such Abandoned Event to another existing event or a new event, in either case in favor of the existing event or new event that is closest in scope and expected timing to the Abandoned Event.

Section 13.2. C&R Event Payments Upon Termination. From and after the Termination Date, JJM shall no longer be obligated to make any C&R Event Payment, except with respect to any C&R Event Payment as to which a C&R Event (as described in Section 13.1) has occurred prior to the Termination Date.

### ARTICLE XIV.

## CLINICAL RESEARCH

Section 14.1. Responsibilities of the Parties. Except for any clinical research studies ongoing as of the Effective Date, JJM shall design, manage, coordinate, implement, monitor and administer the [\*\*] Wound Trials, [\*\*] Wound trials and any other clinical research studies with its clinical research group or any third party JJM elects as its agent (such as a clinical research organization). JJM shall bear (i) all third party clinical trial costs for the [\*\*] Wound Trials and, except as set forth in the next sentence, any such [\*\*] Wound trials required to support the regulatory submissions for product registrations in the United States and Europe and (ii) its internal personnel costs in connection with such trials. Integra shall bear its internal personnel costs in connection with such trials and 100% of the prospective per patient fee for the [\*\*] Wound trials up to a maximum of \$500,000 per year, and Integra shall have the right to utilize Research Payments (described in Article XII above) to defray any of its non-personnel costs associated with the [\*\*] Wound Trials or such Wound trials (excluding the production of Products as contemplated by Section 4.7 hereof).

In a manner comparable to Section 11.3, JJM shall prepare an annual plan for such clinical trials for review and approval by the Steering Committee. JJM shall use reasonable commercial efforts (i) to initiate such trials within three (3) months after agreement between the parties regarding the clinical protocols and selection of sites, as contemplated by Section 14.2 and (ii) to complete such trials within two (2) years, subject to the requirements of the relevant regulatory authorities and reasonable prudent medical and commercial practices. JJM shall

 $[\,{}^{\star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

be responsible for preparing the necessary IDE and PMA filings related to the trials with the FDA and any other regulatory submissions in the Territory, and shall use reasonable commercial efforts to make the necessary filings required for initial Regulatory Approval within six (6) months of completion of such trials. At its sole discretion, JJM may also support clinical advocacy programs in connection with [\*\*] Wound and [\*\*] Wound indications. Integra shall provide any documentation, information, or advice required by JJM to Wound Trials or any such [\*\*] support the [\*\*] Wound trials. Notwithstanding the foregoing, Integra shall have responsibility for completing the Post-Approval Burn study. Integra will diligently and expeditiously complete the study in accordance with the Post-Approval Burn study protocol and objectives, perform all monitoring and administration of the study, cover all costs associated with the study including, without limitation, investigator fees and CRO fees. Prior to filing any reports or submissions with respect to the study, Integra shall present draft copies to JJM and seek consultation from  $\tt JJM$ to prepare the final study report and any associated submission documents. At JJM's sole discretion, it may offer to assist Integra to compile the study.

The obligations and responsibilities of JJM under this Section 14.1 shall be performed by JJM hereunder at the request of Integra, and shall remain subject to the supervision and control of the Joint Steering Committee. In the event of any disagreement or dispute between JJM and Integra arising under this Section 14.1, which the Joint Steering Committee is unable to resolve, then such disagreement or dispute shall be resolved by the chief executive officer of Integra, after and based upon consultation and discussion with the Executive Committee member designees of JJM.

Section 14.2. Clinical Protocol; Selection of Sites. JJM shall follow a mutually agreeable clinical protocol and selection of sites, and shall consult with Integra and provide Integra with an opportunity to amend (subject to JJM's approval) such protocol or selection of sites for the [\*\*]Wound Trials and any [\*\*] Wound trials (such approval not to be unreasonably withheld or delay trial initiation). If Integra seeks to amend the protocol or selection of sites, and JJM disagrees with Integra's amendment; then, the parties shall assemble an ad-hoc panel of four (4) relevant external experts with no financial ties to either party. As a process, each of the parties shall recommend three (3) people for the ad-hoc committee and each party shall have the right to disqualify one of the other's proposed members. The committee's recommendation shall be binding on the parties. To the extent that to do so would in no way prejudice or jeopardize the [\*\*] Wound Trials or any such [\*\*]

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 $<sup>[\ ^{**}]</sup>$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

Wound trials, a representative of Integra's Medical Department and its Regulatory Department shall have reasonable access to information developed during such trials and shall participate in appropriate reviews during the establishment of the trial program and review of results.

Section 14.3. Japan Studies. To the extent allowable, Integra shall provide clinical protocols for its Japan Studies, in order for JJM to review and advise on any consequences of such Studies on the Products in the Territory or the PMA.

## ARTICLE XV.

### REGULATORY APPROVALS

Section 15.1. General Responsibilities. Integra shall be responsible for obtaining all regulatory approvals for the Products and Product Improvements. Unless otherwise agreed by Integra and JJM, all product registrations and applications for approval shall be filed in Integra's name and Integra shall own all rights under such approvals and registrations. Except as otherwise provided in Section 15.2 and 15.3 below, any regulatory costs associated with such filings shall be borne by Integra. Prior to any submission to any regulatory authority or strategic discussions with the FDA, Integra shall consult with, and provide a final draft copy of the proposed regulatory submission to JJM, which shall, within twenty (20) days of receipt of the draft, provide any written comments to Integra. Integra shall consider in good faith and consult with JJM regarding any such comments, but Integra shall have final decision making authority with respect to all such regulatory filings. Integra shall, to the extent permitted by the FDA, permit JJM to participate in FDA meetings and phone calls surrounding regulatory approvals. Integra shall make appropriate arrangements to permit JJM representatives to participate in all meetings between Integra and the FDA or comparable foreign regulatory authority relating to the Regulatory Approvals for the Products or Product Improvements. In all such meetings, Integra shall defer to JJM and permit JJM to take the lead in making presentations relating to the [\*\*]Wound Trials or any [\*\*] Wound trials and in seeking regulatory guidance or concurrence with the procedures to be followed or the scope of approvals to be sought. Integra and JJM shall jointly approve any material compromises and changes from the initial submission documents, decisions not to file a PMA supplement, and the content of the PMA annual report. Upon the expiration or termination of this Agreement, or at such earlier time as Integra shall request in its sole discretion, JJM shall promptly transfer to Integra or Integra's designee any and all ownership rights in product registrations,

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 $<sup>[\</sup>star\star]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

applications for approval and Regulatory Approvals which the parties had agreed to file in  ${\tt JJM's}$  name.

Section 15.2. Responsibilities in Specific Countries. With respect to jurisdictions within the Territory other than the United States or the European Union, JJM shall cooperate with Integra, in preparing product registrations, applications for approval and all other filings required under applicable laws to obtain all regulatory approvals for the Products and Product Improvements, including, without limitation, translating all such filings. All regulatory filing fees, translation costs and local consultant costs related to such regulatory filings shall be borne by JJM; in addition, at JJM's expense, JJM shall make its employees reasonably available to assist Integra in making such filings and obtaining such regulatory approvals. JJM shall only ask Integra to seek Regulatory Approvals in jurisdictions in which it reasonably determines that there is a commercial benefit to doing so; provided, that in so doing, Integra shall not be obligated to incur fully loaded costs per annum in excess of \$75,000, and provided further, that Integra may use the Research Payments to pay for such costs.

Section 15.3. JJM Regulatory Participation. Prior to the next submission of a PMA supplement pursuant to the Annual Plan, Integra shall file a PMA supplement with the FDA whereby Integra appoints JJM as the submission correspondent with the FDA on all PMA matters with respect to such submission, and with respect to each subsequent submission in accordance with the direction of the Joint Steering Committee. To the extent reasonable and practical, JJM will consult with Integra on all oral communications, shall submit in advance to Integra drafts of all submissions and written correspondence to the FDA, and shall provide copies of all actual correspondence within 5 Business Days of sending or receiving any such correspondence. In the event JJM's performance as the submission correspondent is not exceeding the standard as established by Integra, or such performance is not consistent with the regulatory strategy agreed upon by the parties, then Integra shall have the right to notify JJM of its dissatisfaction, which notice shall list the performance deficiencies and cite the relevant standards. Upon receipt of such notice, the Joint Steering Committee shall review the deficiencies and recommend an action plan. JJM shall then have 60 days to address such deficiencies in accordance with the recommended action plan. If JJM is unable to address the deficiencies, then at Integra's sole discretion. Integra can change the submission correspondent back to itself. but not without the chief executive officer of Integra first consulting and discussing its decision with the Executive Committee member designees of JJM. In the event JJM is no longer designated the submission correspondent, JJM's regulatory participation shall be in accordance with the provisions of Sections 15.1 and 15.2:

#### ARTICLE XVI.

## JOINT STEERING COMMITTEE

Section 16.1. Appointment of Members. Promptly after the date hereof, the parties shall form a committee (the "Joint Steering Committee") to coordinate their efforts and activities under this Agreement. The Committee shall be composed of four designees of JJM and four designees of Integra. The designees of Integra and JJM shall include a representative from each of the following divisions of Integra: (i) Regulatory/Clinical, (ii) Research/Product Development, (iii) Marketing/General Management (iv) Operations/Other. Members of the Executive Committee shall be permitted to attend meetings of the Steering Committee from time to time at their discretion as ex officio members. Each of JJM and Integra shall designate one of their designees on the Committee to act as co-chairman.

Section 16.2. Role of Committee. The Joint Steering Committee shall be responsible for (1) monitoring all aspects of the collaboration between the parties, and (2) discussing issues and advising each party prior to making certain decisions including: (i) regulatory strategy and review of progress of regulatory filings, (ii) review of the Manufacturing Plan, (iii) establishing Annual Plans, (iv) prioritizing research and development and clinical trials, (v) consideration of external in-licensing opportunities, (vi) consideration of opportunities to use technologies of JJM or its Affiliates, (vii) intellectual property strategy, and (viii) publications and other public disclosures such as posters and presentations at scientific and industry meetings. The Joint Steering Committee shall also review product pricing, manufacturing, and other business issues. More generally, the Joint Steering Committee shall serve as a forum in which each of the parties will in good faith seek to resolve issues or disagreements under, or regarding the interpretation of, this Agreement.

Section 16.3. Designation of Members. Each party shall designate its members on the Committee and shall promptly advise the other parties if it substitutes any of its members; provided that notice as to the substitution or replacement of either party's co-chairman shall be given in writing. If one or more members of the Committee are unable to attend any meeting, the party that appointed such non-attending member may designate a substitute to participate in replacement of the absent member. Other non-members may attend as deemed necessary or appropriate.

Section 16.4. Meetings. The Joint Steering Committee shall meet at such times as mutually agreed and at such places as it may select, but in any event shall meet at least quarterly. The first meeting of the Joint Steering Committee shall occur within forty-five (45) days of the Effective Date. No meeting of the Joint Steering Committee shall, for purposes of this Agreement,

be validly constituted unless at least two members representing each party shall be in attendance (a quorum of the Committee), and no action shall be taken or deemed validly taken by the Committee unless such action shall have been approved by unanimous vote (each party collectively having one vote) of the members of the Committee participating at a meeting at which a quorum is present. All actions validly taken by the Committee shall be duly recorded in minutes of the Committee prepared by a member of the Committee selected for that purpose at any given meeting, shall be furnished to each party by its respective co-chairman, and shall be retained by each party (after corrections, if any, are made) as part of its records of actions taken with respect to this Agreement. Unless otherwise determined by all parties, the meetings shall take place at the offices of JJM's Parent in New Brunswick, New Jersey. At JJM's request, one meeting a year will take place at JJM's headquarters in Arlington, Texas. All reasonable costs of participation by each member in the activities of the Committee shall be borne by the party appointing such member.

Section 16.5. Disputes. In the absence of a unanimous decision on any matter introduced before the Joint Steering Committee for a vote, either co-chairman may refer such matter to the Executive Committee for resolution. In addition, in the event the Joint Steering Committee is unable to obtain a vote required to approve, or take other action on, any matter referred to it, or is otherwise engaged in a deadlock on any matter, then the matter may be approved or settled in accordance with Article XXVIII.

#### ARTICLE XVII.

## EXECUTIVE COMMITTEE

Section 17.1. Executive Committee. Integra and JJM shall also form an executive committee (the "Executive Committee") whose role shall be to oversee the Joint Steering Committee and the collaboration between the parties contemplated by this Agreement. The Executive Committee shall consist of Integra's President and Chief Executive Officer and JJM's Group Company Chairman, plus as many as two additional members from each party. The Executive Committee shall meet at the request of either party, but in any event shall meet no less than two times per calendar year. One member of the Executive Committee from each party shall attend meetings of the Joint Steering Committee but shall have no authority to vote on matters that come before the Joint Steering Committee. Any decision of the Executive Committee must be unanimous.

#### ARTICLE XVIII.

## PERSONNEL; CONSULTANTS

Section 18.1. Liaison Officers. Integra and JJM shall each designate one of its Joint Steering Committee members as its principal liaison officer, who shall function as the principal person responsible for the resolution of day-to-day issues which may arise under this Agreement and who shall also function as the principal point of contact with representatives of the other party. To the extent that the respective principal liaison officers must meet face-to-face, such meetings shall occur in New Jersey.

Section 18.2. Salespeople. Integra shall make available for transfer to JJM, at JJM's expense, Integra's five U.S. salespeople and three European salespeople (collectively, the "Salespeople") to support JJM's marketing and distribution efforts pursuant to this Agreement. On or about the date hereof, JJM will make employment offers, to such of the Salespeople as it so desires. Upon written acceptance of such employment offer, but not before the Effective Date, JJM shall be responsible for paying all expenses associated with such Salespeople (which shall accrue from and after the later of the Effective Date and the commencement of employment with JJM) including, without limitation, base salary, benefits, travel expenses, commissions and bonuses, all in accordance with the employment offer. Integra and JJM shall cooperate, to the extent necessary, in effecting the transition of the Salespeople from Integra to JJM, provided that such transition shall be completed prior to the Effective Date. Integra shall use its best efforts to transfer Salespeople to JJM. If any of the Salespeople does not accept the offer of employment with JJM, Integra may retain such Salesperson and utilize his or her services in any aspect of Integra's business at Integra's discretion other than the marketing, promotion, distribution or sale of the Products in the Territory, provided that Integra shall cause any such employee to be available for up to 50% of his or her time for six months to support the transition of the business to JJM. Such activities shall include, but not be limited to sales training, professional education, development of sales aids, and customer calls. JJM shall pay all out of pocket expenses (not including salary and benefits) incurred by these employees and any other employee that Integra uses, at the express and specific request of JJM, to assist in the transition of the promotion, marketing, distribution and sales of the Products to JJM, including Integra's Medical Director and Reimbursement Director. For the avoidance of doubt, Integra shall cause the Medical Director and Reimbursement Director to be available for 50% of their time for the twelve months following the Effective Date.

Section 18.3. Assignment and Assumption of Consultant and Other Contracts. To the extent permitted by their terms, Integra

shall assign to JJM and JJM shall assume the contracts set forth in Schedule 18.3 hereto (the "Assumed Contracts") as of the Effective Date. To the extent that such assignment and assumption cannot be done prior to the Effective Date, JJM and Integra shall cooperate and use their reasonable commercial efforts for Integra to assign and JJM to assume the Assumed Contracts as promptly as practicable following the Effective Date and JJM shall reimburse Integra for any expenses incurred in connection with the Assumed Contracts from the Effective Date until the Assumed Contracts are either assumed by JJM or terminated; provided that Integra shall not pay any termination fee, liquidated damages or similar penalty in connection therewith, without the prior written consent of J.TM.

#### ARTICLE XIX.

#### NON-SOLICITATION

Section 19.1. Non-Solicitation. JJM covenants and agrees that during the term of this Agreement and for a period of one year thereafter, JJM will not, and will use all reasonable efforts to ensure that its Affiliates do not solicit, endeavor to entice away or otherwise directly interfere with the relationship of Integra with, any of the individuals listed on Schedule 19.1 hereto, the "Restricted Employees"), except to the extent that such offer of employment is specifically provided for under this Agreement, or the employee has responded to a general advertisement of employment.

## ARTICLE XX.

#### STANDSTILL

Section 20.1. Standstill. By its countersignature of this Agreement, JJM's Parent covenants and agrees on behalf of itself and its Affiliates that for a period ending upon the later of seven (7) years from the date hereof or two (2) years following the termination of this Agreement: (i) such entities shall not acquire "beneficial ownership" (as defined under Section 13(d) of the Securities Exchange Act of 1934) of any securities of Integra's Parent without the prior consent of Integra's Parent's Board of Directors, and (ii) such entities shall refrain from forming or participating in a "group" (as defined under Section 13(d) of the Securities Exchange Act of 1934) for the purpose of influencing the direction or management of Integra's Parent. JJM's Parent shall be released from the foregoing restrictions if: (a) any Person (other than (i) existing stockholders of Integra's Parent, (ii) JJM's Parent or one of its Affiliates or (iii) a Person acting on behalf of a "group" which includes JJM's Parent or one of its Affiliates) shall acquire 15% or more of the then outstanding shares of Common Stock of Integra's Parent in any transaction other than the issuance to

such Person of newly issued shares as approved by the Board of Directors of Integra's Parent or (b) any person (other than JJM's Parent or one of its Affiliates or a Person acting on behalf of a "group" which includes JJM's Parent or one of its Affiliates) shall commence a tender offer seeking to acquire 50% or more of the then outstanding shares of Common Stock of Integra's Parent.

Section 20.2. Shareholder Rights Plan. Integra's Parent shall not implement a shareholder rights plan with a feature that would discriminate specifically against JJM or its Affiliates, as distinct from any other adverse party. Notwithstanding the foregoing, nothing contained in this Agreement shall prevent Integra's Parent from implementing a shareholder rights plan in response to a proposal or offer from JJM or its Affiliates.

### ARTICLE XXI.

## INTELLECTUAL PROPERTY

Section 21.1. Ownership of Inventions. Title to all Inventions related to any Product existing as of the date of this Agreement, will be retained by the current holder. Integra shall own title to all Inventions made solely by employees of Integra during the term of this Agreement. Title to all Inventions made solely by JJM employees during the term of this Agreement shall be owned by JJM. Title to all Inventions made jointly by employees of Integra, on the one hand, and employees of  ${\tt JJM}$ , on the other hand ("Jointly-Owned Inventions"), shall be jointly owned by Integra and JJM. Each of the parties shall have the right to use such Jointly Owned Inventions for use not only with the Products, but also in any other areas within or outside the Field. Any Inventions of either party hereto arising from research conducted by such party during the term of this Agreement and funded by Research Payments shall be deemed to be a "Funded Invention." Each of Integra and JJM shall receive a royalty free non-exclusive license to each such Funded Invention for use in the Field and neither party may sublicense such rights to a third party without the prior written consent of the other party. Each party shall notify the other upon filing a patent application with respect to any Funded Invention, except to the extent that such notification would impair the validity of such application.

Section 21.2. Out-licensing of Funded Inventions. In the event that Integra desires to out-license Funded Inventions outside of the Field, [\*\*]

 $[\,{}^{\star\,\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

Section 21.3. Product Improvements to Distributors. Integra shall have the right to sell any Product Improvements developed pursuant to this Agreement to (i) its distributor in Japan, without any further conditions, and (ii) its other distributors, provided that Integra is (x) obligated pursuant to its agreements with such distributors to include Product Improvements and [\*\*]. To the extent that any Product Improvements which arose from research or clinical development which was funded pursuant to this Agreement are sold by Integra to its distributor in Japan, Integra shall pay a reasonable royalty rate on such Product Improvements to JJM, which rate shall be agreed upon by JJM and Integra.

## ARTICLE XXII.

#### PATENT/FILING/MAINTENANCE

Section 22.1. Prosecution. JJM and Integra shall select those countries where they wish to have patent applications filed or patents maintained on the Patents and other patentable Inventions (whether held solely by Integra or jointly by Integra and JJM). Upon such selection, Integra shall, represented by patent counsel of its choice, reasonably acceptable to JJM, take all necessary steps to file, prosecute and maintain the requested patent protection on such Patents and other Inventions. Integra shall be the client of any counsel engaged for such purpose. Either party shall have the right upon thirty (30) days prior written notice to the other party, at its sole cost and expense, to file and prosecute a patent application or maintain a patent covering all or a part of any such jointly-held Invention in any country which such other party does not select under the first sentence of this Section, unless upon receipt of such notice and before the end of the notice period, such other party selects such country. In all events concerning patent prosecution of the application under this Article, JJM and Integra agree to cooperate with each other.

Section 22.2. Costs. All patent attorney fees and all patent registration, patent filing, patent translation and patent maintenance fees, costs and expenses with respect to (a) the Patents and the Inventions solely owned by Integra shall be borne by Integra and (b) the Inventions jointly owned by Integra and JJM shall be shared equally by Integra and JJM, in each of those countries or patent offices selected by the parties pursuant to Section 22.1.

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 $<sup>[\ ^{**}]</sup>$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

## ARTICLE XXIII.

## REPRESENTATIONS AND WARRANTIES OF INTEGRA

Integra represents and warrants to JJM as follows:

Section 23.1. Organization, Standing, Etc. Integra is a corporation duly organized, validly existing and in good standing under the laws of Delaware, and has all necessary power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as it has been and is currently conducted. Integra is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the properties owned or leased by it or the operation of its business makes such licensing or qualification necessary or desirable, except where the failure to be so licensed, qualified or in good standing would not have a material adverse effect on Integra and its subsidiaries taken as a whole.

Section 23.2. Authorization, Noncontravention. Integra has all necessary power and authority to enter into this Agreement, to carry out its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by Integra, the performance by Integra of its obligations hereunder and the consummation by Integra of the transactions contemplated hereby have been duly authorized by all requisite action on the part of Integra, and do not contravene or constitute a default (or an event which with notice or lapse of time or both will constitute a default) under (i) any provision of applicable law or regulation, (ii) the Certificate of Incorporation or the Bylaws of Integra or (iii) any material agreement, judgment, injunction, order, decree or other instrument binding upon Integra, or result in the creation or imposition of any Encumbrance on any asset of Integra.

Section 23.3. Binding Effect. This Agreement has been duly authorized, executed and delivered by Integra and (assuming due execution and delivery by each of the other parties thereto) constitutes a legal, valid and binding obligation of Integra enforceable against Integra in accordance with its terms.

Section 23.4. No Infringement of Third Party Rights. To the best of its knowledge, the manufacture, use and sale of Products do not infringe the rights of any third party.

## ARTICLE XXIV.

## REPRESENTATIONS AND WARRANTIES OF JJM

JJM represents and warrants to Integra as follows:

Section 24.1. Organization, Standing, Etc. JJM is a division of a corporation duly organized, validly existing and in good standing under the laws of New Jersey, and has all necessary power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as it has been and is currently conducted. Ethicon, Inc. is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the properties owned or leased by it or the operation of its business makes such licensing or qualification necessary or desirable, except where the failure to be so licensed, qualified or in good standing would not have a material adverse effect on Ethicon, Inc. and its subsidiaries taken as a whole.

Section 24.2. Authorization, Noncontravention. JJM has all necessary power and authority to enter into this Agreement, to carry out its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by JJM, the performance by JJM of its obligations hereunder and the consummation by JJM of the transactions contemplated hereby have been duly authorized by all requisite action on the part of JJM, and do not contravene or constitute a default (or an event which with notice or lapse of time or both will constitute a default) under (i) any provision of applicable law or regulation, (ii) the Certificate of Incorporation or the Bylaws of Ethicon, Inc. or (iii) any material agreement, judgment, injunction, order, decree or other instrument binding upon JJM or Ethicon, Inc., or result in the creation or imposition of any Encumbrance on any asset of JJM or Ethicon, Inc.

Section 24.3. Binding Effect. This Agreement has been duly authorized, executed and delivered by JJM and (assuming due execution and delivery by each of the other parties thereto) constitutes a legal, valid and binding obligation of JJM enforceable against JJM in accordance with its terms.

#### ARTICLE XXV.

## PATENT INFRINGEMENT

Section 25.1. Third Party Infringement.

Section 25.1.1. Enforcement by Integra. If either party becomes aware that any of the Patents are being or have been infringed by any third party, such party shall promptly notify

the other party hereto in writing describing the facts relating thereto in reasonable detail. Integra shall have the initial right, but not the obligation, to institute, prosecute and control any action, suit or proceeding (an "Action") with respect to such infringement, including any declaratory judgment action, at its expense, using counsel of its choice. JJM shall cooperate with Integra and provide such non-monetary assistance as Integra may reasonably request in connection with any such Action. Any recovery of damages by Integra for any such suit shall be applied (i) first in satisfaction of any costs incurred by Integra and JJM relating to the Action (including attorneys' and expert fees), (ii) second to Integra in the amount of any damages awarded for out-of-pocket costs and expenses incurred by Integra and (iii) the balance remaining from any recovery shall be divided as follows: (a) Integra shall recover seventy-five percent (75%), and (b) all the remaining damages shall be recovered by JJM.

Section 25.1.2. Joint Enforcement. In the event that Integra institutes an Action relating to the Field pursuant to Section 25.1.1 above, JJM shall have the right to intervene in such Action and Integra shall not oppose such intervention, provided that (i) JJM notifies the court of its intention to intervene within one hundred twenty (120) days of the commencement of such Action, and (ii) JJM shares equally with Integra the total costs incurred by Integra (including, without limitation, attorneys' and expert fees) of conducting such Action. The parties shall cooperate and provide each other such assistance as either may reasonably request in connection with any such Action, provided, Integra shall retain the control of the conduct and settlement of any such Action. Any recovery of damages for any such suit shall be applied first in satisfaction of any out-of-pocket costs and expenses incurred by the parties relating to the Action (including, without limitation, attorneys' and expert fees), and the balance shall be equally divided by the parties.

Section 25.1.3. Enforcement by JJM. In the event that Integra fails to initiate or defend any Action involving the Patents in the Field within one hundred eighty (180) days of receiving notice of any alleged infringement, JJM may, at its option, initiate and control such an Action, and Integra shall cooperate with JJM and provide such non-monetary assistance as JJM may reasonably request in connection with any such Action. Any recovery of damages by JJM for any such suit shall be applied: (i) first in satisfaction of any costs incurred by JJM or Integra relating to the Action (including attorneys' and expert fees), (ii) second to JJM in the amount of any damages awarded for out-of-pocket costs and expenses incurred by JJM, and (iii) the balance remaining from any recovery shall be divided as follows: (a) Integra shall recover twenty-five percent (25%) and (b) all remaining amounts shall be retained by JJM.

Section 25.2. Costs. The costs of litigation referred to in this Article XXV shall include but not be limited to any royalty payments which either party is required to make as a result of such litigation and such out-of-pocket expenses as court costs and court fees, reasonable travel expenses, reasonable charges for the professional services of outside counsel and experts, and shall exclude only the time that JJM's or Integra's regular employees devote to such litigation.

Section 25.3. Assistance. Integra agrees, in the event that JJM chooses to prosecute an action for infringement of a Patent under Section 25.1.3 herein but cannot do so in its own name, to sign and give to JJM, within thirty (30) days after request by JJM, all necessary documents in order for JJM to prosecute such infringement in the name of Integra. Integra also agrees to cooperate with JJM, at JJM expense for out-of-pocket costs, in the prosecution of such infringement.

#### ARTICLE XXVI.

# CONFIDENTIALITY, DISCLOSURE AND PUBLICATION

Section 26.1. Confidentiality. During the term of this Agreement and thereafter, each party shall maintain in confidence all Confidential Information disclosed by the other party or which such party knows is or contains Confidential Information, and shall not use such Confidential Information for any purpose except as permitted by this Agreement or disclose the same to anyone other than those of its Affiliates, employees, sublicensees, consultants, agents or subcontractors as are necessary in connection with such party's activities as contemplated in this Agreement. Each party shall obtain a written or oral agreement from any employees, sublicensees, consultants, agents and-subcontractors, prior to disclosure, to hold in confidence and not make use of such Confidential Information for any purpose other than those permitted by this Agreement. Each party shall be responsible for any breach of

this Section 26.1 by any of its employees, sublicensees, consultants, agents or subcontractors. Nothing herein contained shall be deemed to limit the obligations of either of the parties hereto (or any of their Affiliates) with respect to any confidentiality agreements executed by each of the parties (or by any one or more of their Affiliates) prior to the date hereof.

Section 26.2. Exceptions. The obligation of confidentiality contained in this Agreement shall not apply to the extent that (a) any receiving party (the "Recipient") is required to disclose information by order or regulation of a governmental agency or a court of competent jurisdiction, provided that the Recipient shall not make any such disclosure (other than a filing of information or materials with the U. S. Securities and Exchange Commission made with a request for confidential treatment for portions of such material for which such treatment may reasonably be expected to be granted or a similar filing of information or materials with the National Association of Securities Dealers, in either case, subject to Section 27.3) without first notifying the other party and allowing the other party a reasonable opportunity to seek injunctive relief from (or protective order with respect to) the obligation to make such disclosure or (b) the Recipient can demonstrate that (i) the disclosed information was at the time of such disclosure to the Recipient already in (or thereafter enters) the public domain other than as a result of actions of the Recipient, its Affiliates, employees, consultants, sublicensees, agents or subcontractors in violation hereof, (ii) the disclosed information was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient or was independently developed by the Recipient or its Affiliates (as shown by its written records) subsequent to the date of disclosure and without access to any related disclosed information, or (iii) the disclosed information was received by the Recipient or its Affiliates on an unrestricted basis from a source unrelated to any party to this Agreement and not reasonably believed to be under a duty of confidentiality to the other party or (c) disclosure is made to a government regulatory agency as part of such agency's product license approval process.

Section 26.3. Publications. Prior to public disclosure or submission for publication of a manuscript describing the result of any aspect of the research or other scientific or clinical activity or collaboration between Integra and JJM contemplated by this Agreement, the party disclosing or submitting such a manuscript ("Disclosing Party") shall send the other party ("Responding Party") a copy of the manuscript to be submitted and shall allow the Responding Party not less than thirty (30) calendar days in which to determine whether the manuscript contains subject matter for which patent protection should be sought prior to publication of such manuscript for the purpose of protecting an invention of commercial value to the Responding Party, or whether the manuscript contains confidential

Information belonging to the Responding Party. After the expiration of such thirty (30) calendar day period, if the Responding Party has not objected, the Disclosing Party may submit such manuscript for publication and publish or otherwise disclose to the public such research results. If the Responding Party believes the subject matter of the manuscript contains Confidential Information or a patentable invention of commercial value to the Responding Party, then prior to the expiration of such thirty (30) calendar day period, the Responding Party shall notify the Disclosing Party in writing of its determination. Upon receipt of such written notice from the Responding party, the Disclosing Party shall delay public disclosure of such information or submission of the manuscript for an additional period of sixty (60) calendar days to permit preparation and filing of a patent application on the disclosed subject matter. The Disclosing Party shall thereafter be free to publish or disclose such information, except that the Disclosing Party may not disclose any Confidential Information of the Responding Party in violation of Section 26.1 without the prior written consent of the Responding Party. Determination of authorship for any paper or inventorship of any patent shall be in accordance with accepted scientific or legal practice, respectively. Should any questions on authorship arise, this will be determined by good faith consultation between the parties. In the event that Integra wishes to disclose information that is not deemed as strictly confidential or patentable, but JJM believes to be potentially harmful to its commercial efforts, regulatory approvals, clinical studies under this Agreement, or such disclosure would put it at a competitive disadvantage, then such information shall not be released.

## ARTICLE XXVII.

## PUBLIC STATEMENT AND PRESS RELEASES

Section 27.1. Public Statements and Press Releases. The parties hereto covenant and agree that, except as provided for herein below, each will not from and after the date hereof make, issue or release any public announcement, press release, statement or acknowledgment of the existence of, or reveal publicly the terms, conditions and status of, the transactions contemplated by this Agreement, without the prior written consent of the other party as to the content and time of release of and the media in which such statement or announcement is to be made; provided, however, that (i) either party may at any time and in any media repeat verbatim any announcements, statements, acknowledgments or revelations which were previously approved by the other party, including without limitation those contained in the transaction press release described in Section 27.2 below and (ii) in the case of announcements, statements, acknowledgments or revelations which either party is required by law to make, issue or release, the making, issuing or releasing of any such announcement, statement, acknowledgment or revelation by

party so required to do so by law shall not constitute a breach of this Agreement if such party shall have given, to the extent reasonably possible, not less than two (2) Business Days prior notice to the other party, and shall have attempted, to the extent reasonably possible, to clear such announcement, statement, acknowledgment or revelation with the other party. No party shall use the name of the other party or any of its Affiliates for advertising or promotional purposes without the prior written consent of such other party.

Section 27.2. Transaction Press Release. Promptly following the signing of this Agreement, Integra and JJM's Parent shall issue the joint press release which shall be approved by each party prior to release and which shall include a statement by James T. Lenehan endorsing the collaboration.

Section 27.3. SEC Filing. Prior to filing with the SEC, Integra will provide JJM with a redacted version of this Agreement which it intends to file, will give due consideration to any reasonable comments thereto provided promptly by JJM and will use reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by JJM.

## ARTICLE XXVIII.

#### DISPUTE RESOLUTION

Section 28.1. Executive Resolution. In the event of any dispute or deadlock arising from the Joint Steering Committee, or any other dispute arising under this Agreement, such matter shall be referred to the Executive Committee for resolution, prior to any further action being taken to resolve such dispute in accordance with the terms of this Article Twenty Eight. In addition, any strategic issues in connection with the collaboration of the parties may be referred by the Executive Committee to be decided at this level. The determination of the Executive Committee on any matter, as provided in this Section, shall be made as promptly as practicable, but in any event no later than twenty (20) Business Days following the referral of such matter to the Executive Committee; provided, however, that all parties shall provide to the Executive Committee all supporting information, data and documentation as may be available with respect to any such matter in the time limit specified. In the event the Executive Committee is unable to resolve any matter presented to it within applicable time limits, then any of the parties to this Agreement may refer the matter for outside dispute resolution in accordance with the terms of the remaining provisions of this Article Twenty Eight.

Section 28.2. Mediation. Any dispute, controversy or claim arising out of or related to this Agreement, or the breach, termination or validity hereof, including any claim of inducement by fraud or otherwise, shall, before submission to litigation

pursuant to Section 28.3 hereof, first be mediated through non-binding mediation in accordance with the Model Procedures for the Mediation of Business Disputes promulgated by the Center for Public Resources ("CPR") and in effect as of the date of this Agreement. The mediation shall be conducted in New Jersey. The mediator shall be an attorney who has at least 20 years of experience as a lawyer or judge and who shall be appointed from the list of neutrals maintained by CPR. The parties shall promptly confer in an effort to select a mediator by mutual agreement. In the absence of such an agreement, the mediator shall be selected from a list generated by CPR with each party having the right to exercise two peremptory challenges within forty-eight (48) hours of receiving the CPR list. The mediator shall confer with the parties to design procedures to conclude the mediation within no more than forty-five (45) days after initiation including limited discovery between the parties at the discretion of the mediator. The parties agree to toll all applicable statutes of limitation during the mediation process and not to use the period or pendency of the mediation to disadvantage the other procedurally or otherwise. All discussions and proceedings in preparation for or during the mediation shall be deemed Confidential Information hereunder and not distributed to any third party or used for any other purpose whatsoever. Either side may pursue provisional relief from any court, such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm even though mediation has not been commenced or completed.

Section 28.3. Court Resolution of Claims. Any dispute, claim or controversy, arising from or related to this Agreement, or the breach, termination or validity thereof, including any claims asserting inducement of this Agreement by fraud or otherwise, will be submitted for resolution to the U. S. District Court for the District of New Jersey. Each party hereby consents to the jurisdiction of the above courts with respect to any such matter. EACH PARTY HERETO WAIVES ITS RIGHTS TO TRIAL OF ANY ISSUE BY JURY. EACH PARTY HERETO WAIVES ANY CLAIM TO PUNITIVE, EXEMPLARY, SPECIAL OR CONSEQUENTIAL DAMAGES FROM THE OTHER.

## ARTICLE XXIX.

#### TERM AND TERMINATION

Section 29.1. Term. The initial term of this Agreement (the "Initial Period") shall commence on the date hereof and shall expire on the ten (10) year anniversary of the date hereof unless sooner terminated as herein provided. JJM, at its sole option, may extend this Agreement for successive ten (10) year periods following the Initial Period (the "Extension Periods"), provided that during such Extension Periods, the Minimum Supply Price Per Unit shall be adjusted annually up or down in accordance with the percentage change in the Producer Price Index in the manner set forth in Section 6.1(a)(i) hereof. This

Agreement shall be automatically extended, unless JJM shall notify Integra in writing of its election to allow this Agreement to expire not less than one year prior to the end of the Initial Period or any such Extension Period. For purposes of this Agreement, the "Term" shall refer to the Initial Period and any Extension Periods thereof in accordance with this Section.

Section 29.2. Termination. Notwithstanding Section 29.1 hereof, this Agreement may be terminated as follows:

- (a) By JJM, at any time for any reason, by giving Integra one year's prior written notice thereof. Any termination pursuant to this Section 29.2(a) shall take effect on the one-year anniversary of the date on which Integra receives such notice.
- (b) By Integra, if JJM breaches its obligations to make the Minimum Prepayments pursuant to this Agreement, provided that JJM may cure any such breach within thirty (30) calendar days after receipt of written notice from Integra of such breach by making the Minimum Prepayments then due to Integra plus interest calculated at a rate per annum equal to 2.0% over the rate of interest publicly announced by Citibank N.A. (or its successor) from time to time in New York, New York as its "base" or "prime" rate, provided, however, that if JJM breaches its obligations to make the Minimum Prepayments pursuant to this Agreement more than three times in any rolling two year period, it shall no longer maintain this right to cure. Any termination pursuant to this Section 29.2(b) shall take effect thirty (30) calendar days after receipt by JJM of written notice from Integra of the breach.
- (c) (i) By JJM in accordance with Section 2.3(e)(ii) hereof. Any termination pursuant to this Section 29.2(c)(i) shall take effect upon the receipt by Integra of written notice from JJM of its intent to terminate this Agreement in accordance with Section 2.3(e)(ii) hereof.
  - (ii) By Integra in accordance with Section 2.3(e) (iii) hereof. Any termination pursuant to this Section 29.2(c) (ii) shall take effect upon the receipt by JJM of written notice from Integra of its intent to terminate this Agreement in accordance with Section 2.3(e) (iii) hereof.
- (d) By Integra, upon notice given to JJM at any time within ninety (90) days following the consummation of a JJM Change of Control (as defined below) of JJM if (i) the Person or Persons acquiring control of JJM's Wound Care Business, or their respective Affiliates, had Net Sales of Competitive Products during the twelve month period ending immediately prior to the effective date of the JJM Change of Control equal to or greater than 50% of Net Sales of the Products during the comparable period, or (ii) following such JJM Change of Control such Person or Persons could not or would not be able to fulfill JJM's

obligations under this Agreement. Any termination pursuant to this Section 29.2(d) shall take effect upon JJM's receipt of the requisite notice.

For purposes of this Agreement, "JJM Change of Control" shall mean (i) the sale of all or substantially all of the assets of JJM's Wound Care Business to any Person other than an Affiliate of JJM controlled by JJM's Parent, (ii) the merger or consolidation of JJM's Wound Care Business with or into any other Person in which JJM's Parent does not retain a majority of the voting power of the corporation or entity surviving the merger of consolidation or (iii) the acquisition by any Person (other than an Affiliate of JJM controlled by JJM's Parent) of shares of Common Stock of Ethicon, Inc. or its successor or the corporate entity in which JJM is spun-off representing a majority of the issued and outstanding shares of Common Stock then outstanding (unless JJM's Wound Care Business is transferred to a different Affiliate of JJM prior to such acquisition, in which case this clause (iii) shall relate to the acquisition of shares of such Affiliate), provided that a spin-off of JJM to the stockholders of JJM's Parent shall not constitute a JJM Change of Control. JJM shall give prompt notice to Integra upon any such JJM Change of Control and shall furnish the data necessary for Integra to determine if such JJM Change of Control triggers the provisions contained in Section 29.2(d) above.

(e) By either party, upon the occurrence and at any time during the continuance of any of the following events:

(i) the failure by the other party in any material respect to perform or fulfill, at the time and in the manner provided herein, any material covenant, agreement, obligation or condition required to be performed or fulfilled by such party, which failure shall not be cured within sixty (60) calendar days after receipt of written notice from the other party specifying such failure, or in the case of payments due (other than JJM's failure to pay to Integra the Minimum Prepayments pursuant to this Agreement) hereof, which breach shall be governed solely by Section 29.2(b) above), within thirty (30) calendar days after receipt of such notice; or

(ii) the insolvency, dissolution or liquidation of the other party, the making by the other party of a general assignment for the benefit of its creditors, the filing by or against the other party of a petition in bankruptcy, or the appointment of a receiver for a substantial part of the assets of the other party.

Any termination pursuant to Section 29.2(e)(i) hereof shall take effect immediately upon the conclusion of the cure period provided for in such Section. Any termination pursuant to Section 29.2(e)(ii) hereof shall take effect immediately upon the

receipt of written notice from the non-defaulting party of the breach.

Section 29.3. Effect of Termination or Expiration.

- (a) Upon the expiration or termination of this Agreement:
- (i) JJM shall return to Integra all Confidential Information pertaining to Products or this Agreement, including without limitation all information relating to existing and potential customers of the Products;
- (ii) neither Integra nor JJM shall, in any way, interfere with the transfer of any personnel who were located on the site of the other party during the Term back to the party with which such individual is employed;
- (iii) to the extent permitted under applicable law, JJM shall diligently and expediently take the necessary steps to transfer all product registrations and applications for approval that were filed with respect to the Products and Product Improvements in JJM's name (including, without limitation, any CE marks) and all other permits, licenses, approvals, consents and clearances of Governmental Authorities related to the Products (collectively, the "Registrations and Permits") to Integra or its designated Affiliate in a commercially reasonable time frame. To the extent that such transfers are not permitted under applicable law, JJM shall use reasonable and practical efforts to cooperate with Integra in its efforts to resubmit such Registrations and Permits in Integra's or Integra's designee's name and shall provide any existing data and documentation requested by Integra to achieve the same;
- (iv) the responsibilities of the Joint Steering Committee shall be limited to planning and coordinating the orderly transitions of the Excisional Wound Trials and the Chronic Wound Trials from JJM to Integra, and JJM shall promptly transfer to Integra any data produced in connection with the Excisional Wound Trials and the Chronic Wound Trials, which data shall be the property of Integra and may be utilized by Integra in the submission of its regulatory filings;
- (v) the license to reproduce the Licensed Trademark granted by Integra to JJM pursuant to Section 5.2 hereof shall terminate automatically upon the later of (A) the date which is six months from the Termination Date or (B) the date on which JJM completes its distribution of any Products purchased pursuant to this Agreement; JJM shall not use any other trademark developed by it expressly for use with the Products for a period of three years beginning on the date on which the license to reproduce the Licensed Trademark terminates in accordance with this Section 29.3(a)(v)

(provided that this Section 29.3(a)(v) shall not apply to any trademarks used by JJM generally in JJM's Wound Care Business);

- (vi) any rights and interests to the Funded Inventions (other than Jointly-Owned Inventions) in the Field shall automatically revert to Integra, including the royalty free non-exclusive license granted to JJM pursuant to Section 21.1 hereof, any rights of JJM pursuant to sublicenses granted to third parties and any additional licenses or rights of first refusal previously obtained by JJM;
- (vii) JJM shall retain any rights and interests pursuant to the terms of any licenses to the Funded Technology outside the Field, including any royalties due pursuant to Section 21.2 hereof and any other payments due to it;
- (viii) any Jointly-Owned Inventions shall remain jointly owned by Integra and JJM;
- (ix) JJM shall not be entitled to recover any prior payments or funding made to Integra pursuant to this Agreement;
- (x) JJM shall cease to be obligated to pay any ongoing costs of the R&D Funding or Chronic Wound Trials or Excisional Wound Trials, other than such costs incurred prior to the Termination Date; and
- (xi) JJM shall continue to provide, at Integra's expense, any services it was providing at the time of termination in connection with the Excisional Wound Trial and/or Chronic Wound Trials until the earlier of (x) the date which is six months from the Termination Date or (y) an orderly transition to Integra or to a third party vendor for such trials was completed.
- (b) JJM SHALL BE ENTITLED TO NO COMPENSATION OR OTHER PAYMENT FROM INTEGRA AS A RESULT OF THE EXPIRATION OF THIS AGREEMENT OR DUE TO THE EARLY TERMINATION HEREOF IN ACCORDANCE WITH THE TERMS HEREOF; PROVIDED THAT NOTHING IN THIS SECTION 29.3(b) SHALL PREVENT JJM FROM PURSUING CLAIMS FOR WRONGFUL TERMINATION OR, IN THE EVENT THAT JJM TERMINATES THIS AGREEMENT PURSUANT TO SECTION 29.2(e), FOR DAMAGES.
- (c) Sections 5.2, 8.1(a), 8.1(c), 13.2, 20.1, 21.1, 21.3, 29.3 and 29.4 and Articles VII, IX, X, XI, XXV, XXVI, XXVIII and XXXI of this Agreement shall survive the termination of this Agreement, to the extent applicable, notwithstanding any breach by Integra or JJM of their respective obligations hereunder or thereunder.

(d) Termination of this Agreement shall be in addition to any other remedy available to the terminating party at law or equity.

Section 29.4. Additional Effects of Termination Pursuant to Sections 29.2(a), 29.2(b) or 29.2(c). In addition to the effects of termination specified in Section 29.3, in the event of the termination of this Agreement pursuant to Sections 29.2(a), 29.2(b) or 29.2(c):

- (i) JJM shall pay to Integra the Minimum Prepayments (or those Minimum Prepayments which would be payable to Integra were it not for the provisions of Section 6.7(d)) for the twelve (12) month period beginning on the date on which JJM provides its notice of termination to Integra, pro-rated for actual calendar months, provided, however, that the following Sections of the Agreement shall survive for the duration of such period contemplated in Section 29.3(a)(v) above: Sections 4.1, 4.4, 4.5 and 4.8 and Article VI, each to the extent applicable;
- (ii) any of JJM's outstanding prepaid purchases of Products (including any outstanding Minimum Prepayments) may be used by JJM as credit to continue to purchase Products at the applicable Supply Price and to sell Products in the Territory on a non-exclusive basis until the earlier of (x) the second anniversary of the Termination Date or (y) the time at which such credits have been exhausted; and
- (iii) JJM shall pay up to \$3,000,000 of Integra's reasonable out-of-pocket expenses incurred in connection with the transferring or restoring to Integra of any functions provided by JJM pursuant to this Agreement including, without limitation, (1) severance costs, (2) out-of-pocket expenses incurred in connection with the rehiring of the equivalent number of sales, marketing and/or distribution personnel for the Products as Integra transfers to JJM on the Effective Date and (3) expenses incurred in connection with the transfer of Regulatory Approvals and other product registrations, licenses and applications for approval and legal expenses. Integra shall not solicit any employees of JJM or its Affiliates regarding the rehiring contemplated in this Section 29.4(iii) until the later of (x) the date on which JJM has sold or otherwise disposed of all of the Products or (y) six months from the Termination Date.

## ARTICLE XXX.

## FORCE MAJEURE

Section 30.1. Force Majeure. Neither Integra nor  ${\tt JJM}$  shall be liable for, or be considered to be in breach of or default

under this Agreement (including Section 4.2 hereof) on account of, any delay or failure to perform as required by this Agreement when, and to the extent that, its performance is delayed or prevented by any cause which is reasonably beyond the party's control, including, but not limited to, acts of God or of the public enemy, fire, storm, explosion, earthquake, riots, wars or similar hostilities, civil commotion, strikes and labor disputes, interruption of supply, inability to obtain power, raw materials or freight or transportation services, or voluntary or involuntary compliance with any law or governmental order put into effect after the date hereof (each a "Force Majeure Event"). Such non-performance will be excused for the earlier of three (3) months or as long as the Force Majeure Event shall be continuing; provided, that the party excused from performance under this Section 30.1 promptly gives notice to the other party advising of the Force Majeure Event and the steps it will take to remedy the same and exercises all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable.

## ARTICLE XXXI.

## GENERAL PROVISIONS

Section 31.1. Relationship of the Parties. In the performance of this Agreement and with respect to all matters relating hereto, JJM's relationship to Integra will be that of an independent contractor only. Except as may be otherwise stated in this Agreement, (i) this Agreement does not create any agency, joint venture, or partnership relationship between Integra and JJM, (ii) this Agreement does not grant, and neither party hereto or thereto shall have, any right or authority, express or implied, to incur, create or assume any liability or obligation, enter into any agreement, make any representation or warranty, file any document with any Governmental Authority, or serve or accept any legal process on behalf of the other party, or to settle any claim by or against the other party hereto, or to bind or otherwise render the other party liable in any way in the Territory or anywhere else in the world, without the prior express written consent of the other party, (iii) each party hereto shall be responsible for the selection, training and supervision of, and the payment of compensation and benefits to, its employees who assist it in the performance of its obligations hereunder and in no event shall either party have any obligation to, or authority over, such employees of the other party and (iv) each party shall be solely responsible for all costs and expenses incurred by it in connection with this Agreement and its performance of its obligations thereunder.

Section 31.2. Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS PERFORMANCE OR NONPERFORMANCE OF THIS AGREEMENT.

Section 31.3. Assignment. Except as expressly contemplated in Section 29.2(d), neither party shall assign this Agreement, in whole or in part, directly, by operation of law, or otherwise, except with the prior written consent of the other party which may be withheld in the discretion of such other party; provided that JJM shall be permitted to assign this Agreement to one of its Affiliates without Integra's prior written consent. No such assignment by JJM, with or without Integra's consent, will relieve JJM of the JJM's responsibilities under this Agreement.

Section 31.4. Entire Agreement; Amendments. This Agreement and the Exhibits and Schedules thereto contain the entire agreement and supersede any and all prior oral and written agreements and understandings between the parties with regard to the subject matter hereof and thereof. This Agreement may not be waived, amended or rescinded except by a writing signed by the party to be charged thereby. Neither course of performance, nor course of dealing, nor usage of trade, shall be used to qualify, explain, supplement, or otherwise modify any of the provisions of this Agreement.

Section 31.5. Successors and Assigns; No Third-Party Beneficiaries. This Agreement shall be binding upon and inure solely to the benefit of the parties thereto and their respective successors and permitted assigns. Nothing herein, express or implied, is intended or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

Section 31.6. Specific Performance. The parties to this Agreement agree that irreparable damage would occur in the event any material provision of this Agreement was not performed in accordance with the terms thereof and that the parties shall be entitled to specific performance of the material terms hereof, in addition to any other remedy at law or equity.

Section 31.7. Nonwaiver. The failure of either party to insist upon or enforce strict performance of any of the provisions of this Agreement or to exercise any rights or remedies under this Agreement will not be construed as a waiver or relinquishment to any extent of such party's right to assert or rely upon any such provisions, rights or remedies in that or any other instance; rather, the same will be and remain in full force and effect.

Section 31.8. Governing Law. This Agreement will be governed by and interpreted in accordance with the laws of the State of New Jersey without regard to conflicts of law provisions thereof.

Section 31.9. Severability. If any term or provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law or public policy, all other provisions of this Agreement shall nevertheless remain in full force and effect.

Upon such determination that any term or provision of this Agreement is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in order that the transactions contemplated hereby, including limitations on liability, may be consummated as originally contemplated to the greatest extent possible.

Section 31.10. Notices. All notices, requests, claims, demands and other communications under this Agreement shall be in writing and shall be given (and shall be deemed to have been duly given upon receipt) by delivery in person, by facsimile, or by registered or certified mail (postage prepaid, return receipt requested) to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 31.10):

#### If to Integra:

Integra LifeSciences Corporation 105 Morgan Lane Plainsboro, NJ 08536 Facsimile (609) 275-1082 Attention: President

with a copy to

Willkie Farr & Gallagher 787 Seventh Avenue New York, New York 10019-6099 Facsimile (212) 728-8111 Attention: Peter H. Jakes

If to JJM:

Johnson & Johnson Medical(Trademark), a division of Ethicon, Inc. 2500 East Arbrook Blvd.
Arlington, Texas 76014-3130
Facsimile (817) 472-9534
Attention: President

with a copy to

Johnson & Johnson Law Department One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 Facsimile (732) 524-2788 Attention: Michael Ullmann

Any party may change its address for notices by giving notice to the other party as heretofore provided.

Section 31.11. Counterparts. This Agreement may be executed and delivered (including by facsimile transmission) in

one or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

Section 31.12. U.S. Accounts. All payments to Integra hereunder or in connection herewith shall be in U.S. Dollars and paid to a U.S. bank account.

Section 31.13. Rights Upon Insolvency. Any license which may be granted under Section 4.2(b)(ii) of this Agreement by Integra to JJM shall be, for all purposes of Section 365(n) of Title 11 of the U.S. Code ("Title 11"), a license of rights to intellectual property as defined in Title 11. If a case is commenced by or against Integra under Title 11, then, unless and until this Agreement is rejected as provided in Title 11, Integra (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall perform all of the obligations provided in this Agreement to be performed by Integra.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.  $\,$ 

# INTEGRA LIFESCIENCES CORPORATION

By: /s/ Stuart M. Essig
----Name:Stuart M. Essig
Title:President and CEO

JOHNSON & JOHNSON MEDICAL (Trademark), A DIVISION OF ETHICON, INC.

By: /s/ Jan H. Egberts
----Name: Jan H. Egberts
Title: Vice President - Worldwide

ACCEPTED AND AGREED FOR PURPOSES OF SECTION 20.1

JOHNSON & JOHNSON

Sy: /s/ Russ Deyo
----Name:Russ Deyo
Title:Vice President

EXHIBIT A

# INTEGRA PATENTS

1.	U.S.	Patent	No.	4,060,081
2.	U.S.	Patent	No.	4,252,759
3.	U.S.	Patent	No.	4,280,954
4.	U.S.	Patent	No.	4,350,629
5.	U.S.	Patent	No.	4,418,691
6.	U.S.	Patent	No.	4,448,718
7.	U.S.	Patent	No.	4,458,678
8.	U.S.	Patent	No.	4,505,266
9.	U.S.	Patent	No.	4,522,753
10.	U.S.	Patent	No.	4,787,900
11.	U.S.	Patent	No.	4,902,289
12.	U.S.	Patent	No.	4,947,840
13.	U.S.	Patent	No.	4,955,893

# SCHEDULE 1.1(n)

# EXISTING DISTRIBUTOR COUNTRIES

Is the agreement Country signed?	Do the terms of the agreement prohibit or otherwise restrict assignment by Integra?
1. [**] (**)	(**)
2. (**)	(**)
3. (**)	(**)
4. (**)	(**)
5. (**)	(**)
6. (**)	(**)
7. (**)	(**)
8. (**)	(**)
9. (**)	(**)
10.(**)	(**)
11.(**)	(**)
12.(**)	(**)
13.(**)	(**)
14.(**)	(**)
15.(**) (**)	(**)
16.(**)	(**)
17.(**)	(**)
18.(**)	(**)
19.(**)	(**)
20.(**)	(**)
21.(**)	(**)
22.(**) (**)	(**)
23.(**)	(**)
24.(**)	(**)
25.(**) (**)	(**)
26.(**)	(**)
27.(**)	(**)
28.(**)	(**)

<sup>------[\*\*]</sup> Confidential Information omitted and filed separately with the Securities and Exchange Commission.

SCHEDULE 1.1(y)

# LICENSED TRADEMARK

INTEGRA(Trademark) Dermal Regeneration Template(Trademark)

# SCHEDULE 4.4(d)

# PRODUCT SPECIFICATIONS

See attached.

[\*\*]

## SCHEDULE 4.8

## INITIAL MAP

Integra agrees to diligently execute the MAP contained in this Schedule 4.8. It may, at its discretion, request assistance from JJM and JJM, to the extent reasonable and practical, will provide such assistance. In the event Integra is more than fifteen (15) days delinquent on any item contained in the MAP, (i) the Joint Steering Committee shall meet to discuss such delinquency and (ii) JJM may require Integra to hire a consultant, at Integra's expense, to assist in Integra's execution of the MAP. The Joint Steering Committee shall make the final determination as to whether or not any item contained in the MAP has been completed.

MAP is attached hereto.

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 $[\,{}^{\star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

# SCHEDULE 9.1

# CORPORATE QUALITY ASSURANCE GUIDELINES OF JJM

See attached.

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 $[\ensuremath{}^{**}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

# SCHEDULE 18.3

# ASSUMED CONTRACTS

- 1. Consultant Agreement dated the 15th of March, 1996 between Integra LifeSciences Corporation and John F. Burke, M.D.
- 2. Research Support Agreement dated the 26th of January, 1999 between [\*\*] and Integra LifeSciences I Ltd.

<sup>[\*\*]</sup> Confidential Information omitted and filed separately with the Securities and Exchange Commission.

# SCHEDULE 19.1

# RESTRICTED EMPLOYEES

Name	Location	Function
[**]	 NJ	Scientist
(**)	NJ	MD
(**)	CA	Scientist
(**)	NJ	Reimbursement
(**)	NJ	Scientist
(**)	NJ	Customer Service
(**)	NJ	Clinical Affairs
(**)	NJ	Manufacturing
(**)	CA	Scientist
(**)	CA	Scientist
(**)	NJ	Manufacturing
(**)	NJ	Corporate Marketing
(**)	NJ	Corporate QA/QC
(**)	NJ	Regulatory
(**)	NJ	Manufacturing
(**)	NJ	COO
(**)	NJ	Manufacturing
(**)	NJ	Scientist
(**)	NJ	Manufacturing
(**)	NJ	Regulatory
(**)	NJ	Corporate Sales
(**)	CA	Scientist
(**)	CA	Asia/Pacific
(**)	NJ	Manufacturing
(**)	NJ	Corporate QA/QC
(**)	CA	Scientist

 $<sup>[\,{}^{\</sup>star\star}]$  Confidential Information omitted and filed separately with the Securities and Exchange Commission.

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<sup>[\*\*]</sup> Confidential Information omitted and filed separately with the Securities and Exchange Commission.

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and Exchange Commission.

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JUN-30-1999
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