



Integra's DuraSeal® Dural Sealant Saves Healthcare Costs According to an Economic Evaluation Published in the Journal of Comparative Effectiveness Research

Nov 13, 2024

The health economic analysis, conducted in five European countries, shows that hospitals can reduce costs of cerebrospinal fluid leaks after posterior cranial fossa surgeries by using DuraSeal dural sealant instead of fibrin glue

CE Mark



CE Mark

PRINCETON, N.J., Nov. 13, 2024 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (Nasdaq: IART), a leading global medical technology company, today announced the publication of a new economic study, "PEG hydrogel sealant versus fibrin glue in posterior fossa surgery: An economic comparison across five European countries."¹

The purpose of this evaluation was to assess the budget-impact of switching patient treatment from fibrin glue to DuraSeal Polyethylene Glycol (PEG) hydrogel in five major European countries: Belgium, France, Germany, Italy, and the United Kingdom. The evaluation demonstrates an average cost savings of €419 to €1,279 per patient, when using Integra's DuraSeal PEG dural sealant hydrogel instead of fibrin glue. Depending on the country, consistent cost reduction per procedure averaged around 22%, except for Italy where the analysis resulted in 15% consistent cost reduction per procedure.

Cerebrospinal fluid (CSF) leaks after posterior cranial fossa (PCF) surgery are a significant cause of longer hospital stays, hospital readmissions and other costly post-surgical interventions. Current practice to seal the operative site after primary closure aid the healing process and protect the patient from CSF leaks widely relies on either fibrin glue or PEG hydrogel.²

The analysis, published in the *Journal of Comparative Effectiveness Research* in February 2024, was conducted by Giuseppe Talamonti³, Jorn-Andre Horaczek⁴, Rafael Torrejon Torres⁵, Lisa Da Deppo⁶ and Marissa J Carter⁷. This economic analysis is based on a peer-reviewed prospective observational study of 200 patients that found PEG hydrogel was associated with positive clinical outcomes of PEG-based hydrogels⁸ compared to fibrin glue in PCF surgeries. A decision tree was developed on a previous U.S. model⁹ and input costs that were derived from European country-specific published sources. The results demonstrated that the clinical effectiveness of Integra's DuraSeal Dural Sealant at preventing CSF leaks compared to fibrin glue after PCF surgery may help hospitals reduce costs.

Marissa Carter, PhD, MA, president of Strategic Solutions, a consultancy specializing in clinical trials and real-world data health economic studies, said "This follow-up health economics study in the use of PEG hydrogel as a dural sealant to prevent CSF leaks and other complications resulting from PCF surgery is very timely. Most of all, it is gratifying to see the original model developed in the United States now successfully applied to five European countries in which cost savings are also demonstrated. Thanks to this collaboration between the manufacturer and clinicians, it is hopeful that these results will enable greater access to DuraSeal for patients undergoing surgery."

DuraSeal can be a viable, cost-effective alternative to fibrin glue in PCF surgery in Europe. As a direct consequence of the decreased occurrence of adverse CSF leaks and related complications, DuraSeal, despite its higher up-front cost, reduces overall PCF operative spend.

"This recently published economic evaluation supports DuraSeal in the management of PCF surgery to our customers, providing strong evidence for healthcare professionals to reduce CSF leaks and cost-saving improvement for hospitals and healthcare systems," said Harvinder Singh, Integra's executive vice president and president, International. "This study outcome reinforces our commitment to our neuro access & repair strategy, innovating new treatment pathways, and restoring patient lives through technologies that transform surgical care."

Abstract of the analysis and the full analysis can be found [here](#)

About Integra LifeSciences

At Integra LifeSciences, we are driven by our purpose of restoring patients' lives. We innovate treatment pathways to advance patient outcomes and set new standards of surgical, neurologic and regenerative care. We offer a comprehensive portfolio of high quality, leadership brands. For the latest news and information about Integra and its products, please visit www.integralife.com

About Integra DuraSeal® Dural Sealant System

The DuraSeal® Dural Sealant System is intended for use as an adjunct to standard methods of dural repair as sutures to provide watertight closure.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. All the medical devices mentioned on this document are CE marked in accordance with the applicable European laws, unless specifically identified as "NOT CE MARKED".

DuraSeal® cranial sealant system is CE class III devices in Europe.

Consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions.



2787

Legal manufacturer: Integra LifeSciences Corporation also dba Integra NeuroSciences, 1100 Campus Rd., Princeton, New Jersey 08540, USA

EC REP : Integra LifeSciences Services (France) Immeuble Séquoia 2 - 97, allée Alexandre Borodine, Parc technologique de la Porte des Alpes 69800 Saint-Priest France

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ from predicted results. Forward-looking factors that may be discussed include, but are not limited to, the improved clinical effectiveness and cost savings of Integra's DuraSeal PEG hydrogel in PCF surgery. There can be no assurance that the clinical benefits and cost savings described herein will be replicated. The actual effect of the use of this product can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that this product will be commercially successful or achieve any level of sales for use in PCF surgery. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Integra's business and market, particularly those identified under the heading "Risk Factors" included in item 1A of Integra's Annual Report on Form 10-K for the year ended December 31, 2023, and information contained in subsequent filings with the Securities and Exchange Commission. These forward-looking statements are made only as the date thereof, and Integra undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Contact:

Media (Europe)

Marion Vincent
00 33 (0)6 47 84 64 82
marion.vincent@integralife.com

Media (U.S.)

Laurene Isip
+1 609 208 8121
laurene.isip@integralife.com

Investor Relations

Chris Ward
+1 609 772 7736
chris.ward@integralife.com

¹ Talamonti G, Horaczek JA, Torres RT, Deppo LD, Carter MJ. PEG hydrogel sealant versus fibrin glue in posterior fossa surgery: an economic comparison across five European countries. *J Comp Eff Res.* 2024 Apr;13(4):e230047.

² Wright NM, Park J, Tew JM, et al. Spinal sealant system provides better intraoperative watertight closure than standard of care during spinal surgery: a prospective, multicenter, randomized controlled study. *Spine.* 2015;40(8):505-513.

³ Neurosurgery Ospedale Niguarda Ca' Granda

⁴ International Neurosurgical Practice

⁵ Coreva Scientific GmbH & Co. KG

⁶ Integra LifeSciences

⁷ Strategic Solutions, Inc.

⁸ Than KD, Baird CJ, Olivi A. Polyethylene glycol hydrogel dural sealant may reduce incisional cerebrospinal fluid leak after posterior fossa surgery. *Neurosurgery.* 2008 Jul;63(1 Suppl 1).

⁹ Carter MJ. A Cost-benefit Analysis of Using Polyethylene Glycol Hydrogel Sealant versus Fibrin Glue as a Dural Sealant for Posterior Fossa Surgery in the United States. *J Health Econ Outcomes Res.* 2017 Aug 9;5(2):125-139.

A photo accompanying this announcement is available at

<https://www.globenewswire.com/NewsRoom/AttachmentNg/c007cf36-2739-41bf-b669-9f5059c00358>