



Integra LifeSciences Announces Positive Clinical Outcomes for PriMatrix® Dermal Repair Scaffold for the Management of Diabetic Foot Ulcers

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Data Shows a Single Application of PriMatrix Closed More Wounds Than Standard of Care Alone

PRINCETON, N.J., July 19, 2021 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holding Corporation](#) (Nasdaq: IART), a leading global medical technology company, today announced positive clinical outcomes for [PriMatrix® Dermal Repair Scaffold](#) for the management of hard to heal diabetic foot ulcers (DFUs). This study is one of the largest DFU randomized controlled trials (RCTs) ever completed with more than 100 patients per treatment group and demonstrated that in most cases, one application of PriMatrix plus standard of care (SOC) healed 60% of DFUs in 12 weeks versus 35% of DFUs that healed in 12 weeks with SOC for the per protocol analysis.

This data was recently published by lead investigator, John Lantis, M.D., FACS, from Mount Sinai Health System in New York, in the *Journal of Wound Care*, the definitive wound-care journal and leading source of up-to-date research and clinical information on everything related to tissue viability.

Diabetic foot ulceration is a major health and economic problem that significantly impacts both patients and the health care system. According to the 2020 National Diabetes Statistics Report, 34.2 million Americans have diabetes.¹ Estimates suggest that as high a number as 15% of patients with diabetes may develop a DFU in their lifetime.^{2,3} An estimated 40% of patients with DFUs experience a recurrence within one year and 65% within five years, with 15% of patients undergoing an amputation during a 10-year follow-up period.⁴

"The hallmark of this study, which was designed to prove the clinical efficacy and safety of PriMatrix in managing DFUs, shows that PriMatrix has demonstrated statistically and, most importantly, clinically significant results against standard of care," said John Lantis, M.D., FACS, principal investigator, professor and site chief of surgery, Mount Sinai West Hospital, Icahn School of Medicine. "The differentiating result is that, in most cases, only one application of PriMatrix is needed, underscoring the potential cost-effectiveness of using PriMatrix in managing DFUs. This marks the second prospective PriMatrix DFU study, which represents Integra's continued commitment to addressing the significant unmet needs associated with patients suffering from chronic wounds."

PriMatrix is a unique scaffold for the management of wounds that includes diabetic foot ulcers. Derived from fetal bovine dermis, this novel acellular dermal matrix provides an ideal environment to support cellular repopulation and revascularization processes critical in wound healing. PriMatrix is particularly rich in Type III collagen, a collagen found in fetal dermis that is active in developing and healing tissues.

"Diabetic foot ulcers are one of the most significant and devastating complications of diabetes that leave surgeons and patients with a critical need for effective solutions beyond standard of care," said Robert T. Davis, Jr., executive vice president and president, Tissue Technologies. "This recently published clinical data demonstrates that PriMatrix is an adaptable solution to address the most challenging DFUs in a single application. It also further supports PriMatrix's clinical and economic value to our customers who are treating patients in hospitals and wound care clinics, providing strong evidence for payors to expand reimbursement coverage."

For more information, please visit [PriMatrix® Dermal Repair Scaffold](#) or www.integralife.com.

¹Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2020.

²Reiber, G. E. The epidemiology of diabetic foot problems. *Diabet. Med. J. Br. Diabet. Assoc.* 13 Suppl 1, S6-11 (1996).

³Singh, N. Preventing Foot Ulcers in Patients with Diabetes. *JAMA* 293, 217 (2005).

⁴Rayman, G. *et al.* Guidelines on use of interventions to enhance healing of chronic foot ulcers in diabetes (IWGDF 2019 update). *Diabetes Metab. Res. Rev.* 36, e3283 (2020).

Summary of Study Results

This prospective, multi-center randomized controlled trial of 226 patients with chronic DFUs used a 2-week run-in period, 12-week treatment phase, and 4-week follow up phase to determine the safety and efficacy of PriMatrix Dermal Repair Scaffold plus SOC compared to SOC only, which consisted of sharp debridement, infection elimination, use of dressings and offloading. The results of the study showed patients receiving PriMatrix were found to be significantly more likely to achieve complete wound closure compared with SOC with a median number of one application of the product. The study conclusion states that "these results indicate that in many cases a single application of PriMatrix in conjunction with SOC offer a safe, faster and more effective treatment of DFUs than SOC alone."

[Click here](#) for the full study results published in the *Journal of Wound Care*.

About Integra LifeSciences

Integra LifeSciences is a global leader in regenerative tissue technologies and neurosurgical solutions dedicated to limiting uncertainty for clinicians,

PriMatrix Dermal Repair Scaffold



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so they can focus on providing the best patient care. Integra offers a comprehensive portfolio of high quality, leadership brands that include AmnioExcel®, Bactiseal®, CerebroFlo®, CereLink® Certas® Plus, Codman®, CUSA®, Cytal®, DuraGen®, DuraSeal®, Gentrax®, ICP Express®, Integra®, MatriStem® UBM, MAYFIELD®, MediHoney®, MicroFrance®, MicroMatrix®, PriMatrix®, SurgiMend®, TCC-EZ® and VersaTru®. For the latest news and information about Integra and its products, please visit www.integralife.com.

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