MIMEDX Announces FDA 510(k) Clearance for HELIOGEN® AMS

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MIMEDX's First 510(k) Clearance Expands Portfolio of Solutions for Surgical Applications

Built-In Antimicrobial Protection Designed to Help Guard Against Bacterial Contamination

MARIETTA, Ga., Nov. 23, 2026 (GLOBE NEWSWIRE) -- MIMEDX Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company") today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for HELIOGEN AMS (Antimicrobial Sheet), a device formulated from bovine collagen, chondroitin sulfate, and polyhexamethylenebiguanide hydrochloride (PHMB).

"Today's news is a significant accomplishment for MIMEDX and aligns with our ambition to deliver an innovative, differentiated and expansive product portfolio," stated Joseph H. Capper, MIMEDX Chief Executive Officer. "510(k) clearance for HELIOGEN AMS is another step in our diversification strategy to support the expansion of our surgical product offering. HELIOGEN AMS is our first ever antimicrobial collagen matrix solution that can be used to manage complex surgical wounds, a significant unmet clinical need. In response to customer feedback, we are building a comprehensive, evidence-backed portfolio to partner with surgeons in our mission to improve patient outcomes. I applaud the members of our world-class R&D team for developing this product."

HELIOGEN AMS is intended for use in the management of:

- Full-thickness and partial-thickness wounds
- Chronic wounds (pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Partial-thickness burns
- Trauma wounds (abrasions, lacerations, skin tears)
- Draining wounds

HELIOGEN AMS is an absorbent, conformable, three-dimensional matrix supplied in sheet form. Its patent-pending design incorporates PHMB, the antimicrobial agent, and chondroitin sulfate into bovine collagen. Testing demonstrates that PHMB is effective in reducing the growth of microbes within the dressing and acts as a chemical barrier to bacteria, preventing penetration through the matrix.

Bioburden and infection remain among the most persistent barriers to wound healing, and surgical site infections are a leading contributor to post-operative complications, readmissions and cost. HELIOGEN AMS was designed with this challenge in mind. By pairing a highly conformable collagen matrix with PHMB, a well-established antimicrobial agent with a long history of use in wound care, HELIOGEN AMS provides antimicrobial protection within the dressing against a broad range of microbes, including bacteria, yeast and mold, and creates a barrier to bacterial penetration. This helps protect the dressing from becoming a source of contamination while it manages exudate in complex, draining wounds. The result is a single, easy-to-use dressing that combines the familiar handling of collagen with built-in antimicrobial protection, giving surgeons and wound care clinicians another tool to help support healing in their most challenging cases.

About MIMEDX
MIMEDX is a pioneer and leader focused on helping humans heal. With more than a decade and a half of helping clinicians manage chronic and other hard-to-heal wounds, MIMEDX provides a leading portfolio of products for applications in the wound care, burn, and surgical sectors of healthcare. The Company's vision is to be the leading global provider of healing solutions through relentless innovation to restore quality of life. For additional information, please visit www.mimedx.com.

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