GMReis Achieves New FDA Milestone for Its U.S. Trauma Strategy

New 510(k) clearance expands GMReis' sterile plating platform and establishes the regulatory foundation for a comprehensive portfolio of single-use trauma solutions for the U.S. ASC market.

August 20, 2026 / GMReis has reached another important milestone in the execution of its U.S. orthopedic trauma strategy with FDA 510(k) clearance K262537 for the VersaLock® Sterile Plating System.

With this latest clearance, GMReis has established 510(k)-cleared sterile implant solutions across its upper and lower extremity plating portfolio, creating the foundation for the next phase of the company's strategy: developing comprehensive, procedure-specific sterile single-use trauma sets designed for Ambulatory Surgery Centers (ASCs).

The concept follows the philosophy already introduced by GMReis with its 510(k)-cleared single-use Distal Radius Plating Set—combining sterile implants and procedure-specific instrumentation into streamlined solutions intended to simplify preparation and support greater efficiency in the operating room.

GMReis plans to progressively expand this concept across upper- and lower-extremity trauma procedures, developing single-use platforms configured around the specific requirements of each surgery.

For ASCs, the strategy is designed to address several important operational challenges associated with traditional reusable trauma systems, including instrument reprocessing, sterilization logistics, tray management, inventory complexity and the infrastructure required to maintain large reusable instrument sets.

Rather than bringing multiple large trays into the operating room, the GMReis concept is to provide surgeons and ASCs with focused, ready-to-use procedural solutions containing the implants and instrumentation required for a specific procedure.

The latest FDA clearance therefore represents more than the addition of another product family. It provides an important regulatory building block for GMReis' broader objective of creating a comprehensive single-use trauma ecosystem for the U.S. market.

This initiative is part of GMReis' continued investment in the United States and its strategy to combine a broad orthopedic trauma portfolio with solutions specifically developed around the evolving needs of ASCs.

From comprehensive trauma fixation to procedure-specific single-use solutions, GMReis is building the next stage of its U.S. trauma platform.

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