SAM®
MEDICAL

June 5, 2026

RE: URGENT – Labeling Correction Required: SAM Pelvic Sling II Single-Use Device

Dear Valued SAM Medical Distributor Partner,

It has come to our attention that some materials currently in circulation incorrectly describe the SAM Pelvic Sling II as a reusable device. The SAM Pelvic Sling II is a single-use device and must not be represented otherwise in any digital or print materials.

SAM Medical's product labeling accurately reflects the single-use classification. This notice applies to distributor-owned digital and print marketing materials only and the device labeling on the product itself is not affected.

Misrepresentation of a single-use medical device poses a direct patient safety risk and constitutes a labeling violation. We ask that all distribution partners take immediate action to correct any outstanding materials.

Please review and update all product information, website content, and marketing materials for all SAM Pelvic Sling models to accurately reflect single-use labeling:

SAM® Pelvic Sling II	Small	Standard	Large	Military
Part Number	PS300-OB-EN	PS301-OB-EN	PS302-OB-EN	PS301-OD-EN

We request that digital and web updates be completed within 15 days of this notice. All remaining print and marketing materials should be corrected within 60 days. Forward this request to your marketing department and/or website developer as applicable.

Please reply to this notice confirming that corrections have been made or that no action was required because your materials already accurately reflect the single-use labeling. For questions, contact regulatory@sammedical.com.

Thank you for your follow-up on this matter and for being a valued SAM Medical partner.

Sincerely,

Siri Belur
Regulatory Affairs Manager
SAM Medical