SAM[®] Pelvic Sling II

SAM Pelvic Sling Product Family Technical Data Sheet

Finished Product Description

The SAM[®] Pelvic Sling II Product Family is available in three sizes to fit over 99% of patients and is composed of lightweight bonded fabrics and a polymer buckle with stainless steel springs. The SAM[®] Pelvic Sling II incorporates a rugged, clear vinyl slider to facilitate movement of a patient across surfaces. The SAM[®] Pelvic Sling II is provided with printed instructions for use attached under the slider and included in a zippered clear vinyl bag for easy storage.

The SAM[®] Pelvic Sling II is radiolucent allowing diagnostic, high quality x-rays to be taken with the Sling left in place. The **TRUFORCE™** buckle contains two stainless steel springs that are radiopaque and researchers have stated that "artifacts proved negligible and did not affect posterior fracture visualization." (Krieg clinical trial). The SAM[®] Pelvic Sling II products are MR conditionally safe up to 3 Tesla while firmly applied to the patient. Due to the presence of the springs in the buckle, MR images may be affected by artifacts if the imaging area of interest is near the buckle.

The SAM[®] Pelvic Sling II is reusable and can be washed or disinfected between uses. If the SAM[®] Pelvic Sling II fabric becomes stained with bodily fluids, replacement is strongly recommended. The SAM[®] Pelvic Sling II is extremely durable even when used or stored at extremes of temperature.

Material Technical Data

Belt Materials

- Strap: Webbing, Nylon, Black
- Handle: Webbing, Polypropylene (lightweight), Black
- Thread: Bonded Nylon Twist, Black
- Hook: Nylon, Black
- Hook and Loop Fastener: Nylon, Black

Laminate/Backpad Fabric

- Fabric: Nylon Tricot (Royal Blue or Olive Drab); Polyester Needle Punch, White; Polyester Backing, Black
- Binding: 200 Denier Nylon, Black, Bias Full Fold, Urethane Coated
- Thread: Bonded Nylon Twist, Black
- Slider: Vinyl, Clear, Flexible, 9mil
- Handle: Webbing, Polypropylene (lightweight); Civilian Orange, Military Olive Drab
- Loop: Nylon, Black

Buckle

- Frame and Slider: Acetal Copolymer, Orange (Military Olive Drab version Black)
- Springs: 17-7 Stainless Steel

Labeling

Instructions for Use: Included in Vinyl Bag and sewn to fabric under the Slider

Packaging

- Bag: 4 Gauge Clear PVC with nylon zipper, L: 7.25in (184.2mm) x W: 3.5in (88.9mm) x H: 5.5in (139.7mm)
- Weight Each: Small = 8.6oz. (244g); Standard = 8.8oz (250g); Large = 9.2oz (261g)
- Case Amount: 24

Compliance

- CE Marked, Self-Certified with Declaration of Conformity
- ISO 13485:2003 CMDCAS Certified
- EN ISO 13485:2012 Quality Management System Certified
- ASTM F2428-04 Standard Guide for Selection and Use for Pelvic Ring Circumferential Compression Stabilization Devices (PRCCSD)
- · Authorized Representative Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, NL
- NSN # 6515-01-509-6866 for Military Version
- Reusable following cleaning and disinfection
- · X-Ray Radiolucent, MRI Conditional up to 3 Tesla (ferromagnetic springs will result in buckle area artifact)

SAM[®] Pelvic Sling II

SAM[®] Pelvic Sling Product Family Listing

- SL556652-SM, SAM[®] Pelvic Sling II, Small 27 in. to 45 in. (68.6 cm to 114.3 cm) Hip Circumference, Overall Length 55 in. (139.7 cm) x Width 7 in. (17.8 cm)
- SL556652, SAM[®] Pelvic Sling II, Standard 32 in. to 50 in. (81.3 cm to 127.0 cm) Hip Circumference, Overall Length 60 in. (152.4 cm) x Width 7 in. (17.8 cm)
- SL556652-LG, SAM[®] Pelvic Sling II, Large 36 in. to 54 in. (91.4 cm to 137.2 cm) Hip Circumference, Overall Length 64 in. (162.6 cm) x Width 7 in. (17.8 cm)
- SL556652-OD, SAM[®] Pelvic Sling II, Standard Olive Drab 32 in. to 50 in. (81.3 cm to 127.0 cm) Hip Circumference, Overall Length 60 in. (152.4 cm) x Width 7 in. (17.8 cm)

SAM[®] Pelvic Sling Patents

United States 6,554,784 7,008,389 8,192,383

Europe

1487317 EP2,461,772

<u>Canada</u>

2478115 2803517

<u>Australia</u> 2010281689

<u>Japan</u> 5620489