

SAM Splints – Technical Data Sheet

Finished Product Description

The SAM[®] Splint Product Family is composed of lightweight, moldable splints in a variety of sizes built from a thin core of aluminum that is sandwiched between two layers of waterproof, hypoallergenic closed cell foam. The SAM[®] Splints are extremely pliable and soft enough to cut with ordinary household scissors. When bent into any of three simple curves, the SAM[®] Splint becomes rigid providing strong stabilization of injured limbs and joints. The SAM[®] Splints can be rolled or folded for easy storage.

The SAM[®] Splint is radiolucent allowing diagnostic, high quality x-rays to be taken with the splint left in place. SAM[®] Splints are MRI conditionally safe up to 3 Tesla with a minimal (10mm) artifact halo.

Material Technical Data

Aluminum

- Description: Al, 0.016" (0.4mm)
- Alloy: 1145 or 1350
- Temper: O

Polyethylene Foam

- Description: Cross-linked, closed-cell LDPE
- Waterproof / fluid proof: 100%
- Color(s): Orange, Blue, Charcoal, Olive Drab
- Compression Deflection: 25% @ 3.0 psi (20.7KPa)
- Density: 1.8 to 2.2 lb/ft³ (49,824 kg/m³)
- Tensile Strength: 40.0 psi (275.8 KPa) minimum
- Tear Resistance: 8.0 psi (55.2 KPa) minimum

Adhesive

- Description: Hot melt, non-latex rubber on PE carrier
- 180° Peel Adhesion: 8.0 lb/in minimum
- Shear Resistance: 1 in² (6.45cm²), 161.6°F (72°C), 10-pound (4.54 kg) load, 72 minutes
- Quick Stick: 9.0 minutes (lb/in) minimum

Labeling

- Ink: Screen printed, ink heat processed onto foam
- Instructions for Use: Printed on Splints, URL provided for additional information, SAM Splint User Guide

Packaging

- Wrapping: Individually with 60-gauge Medical Grade Polyolefin Shrink-wrap
- Case Amount: 36in (91.4cm) = 60 each; 18in (45.7cm) = 24 each; 9in (22.9cm) = 60 each

Compliance

- CE Marked, Self-Certified with Declaration of Conformity
- EN ISO 13485:2016/MDSAP Quality Management System Certificate
- Authorized Representative – Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, NL
- NSN # – 6515-01-494-1951
- Not manufactured with natural rubber latex
- X-Ray Radiolucent
- MRI Conditional up to 3 Tesla
- Reusable following cleaning and decontamination
- Made in the USA

Care and Maintenance

These Care and Maintenance Guidelines are recommendations for maximizing the service life of the SAM Splint. You should always follow the specific cleaning and disinfecting practices dictated by your Medical Director. The SAM Splint is a reusable malleable splint that can be properly cleaned and disinfected for additional field service.

Cleaning Procedure

NOTE: Utilize appropriate eye and skin protection whenever handling devices contaminated with blood/body fluids and when using bleach.

If you decide to re-use the SAM Splint, it should be initially cleaned using a cloth or sponge soaked with soap and water or a mild detergent to remove gross contamination. Any blood, body fluids, tissue or other soil materials should be completely removed prior to disinfection.

Next, prepare a dilution of sodium hypochlorite bleach (for example Clorox, White King) for a final concentration of 0.625% to 0.7%. This can typically be done with one-part bleach to 9 parts of water with normal household bleach, or one-part bleach to 11 parts of water for “concentrated” bleach.

Fully immerse the SAM Splint in the diluted bleach solution ensuring all air bubbles are removed from the Splint by wiping each of the surfaces (including the sides) with a clean cloth while in the bleach solution. Allow the SAM Splint to remain submerged in the bleach solution for 10 minutes following wiping.

ALWAYS rinse the SAM Splint thoroughly with running water following immersion then allow to air dry or towel dry before placing it back into service.

Reference: FR7073 (A) Cleaning and Disinfection Validation of SAM Splints

SAM[®] Splints Models

SP500-OB-EN (old PN SP1005F), SAM[®] Wrist Splint – 9in (22.9cm) Orange/Blue
SP500-CH-EN (old PN SP1007F), SAM[®] Wrist Splint – 9in (22.9cm) Charcoal
SP502-OB-EN (old PN SP1410F), SAM[®] Junior Splint – 18in (45.7cm) Orange/Blue
SP502-CH-EN (old PN SP1412F), SAM[®] Junior Splint – 18in (45.7cm) Charcoal
SP504-OB-EN (old PNSP1124F), SAM[®] Splint – 24in (61.0cm) Flatfold, Orange/Blue
SP506-CH-EN (old PN SP1109R), SAM[®] Splint – 36in (91.4cm) Rolled Charcoal
SP507-CH-EN (old PN SP1109F), SAM[®] Splint – 36in (91.4cm) Flatfold Charcoal
SP506-OB-EN (old PN SP1121R), SAM[®] Splint – 36in (91.4cm) Rolled Orange/Blue
SP507-OB-EN (old PN SP1121F), SAM[®] Splint – 36in (91.4cm) Flatfold Orange/Blue
SP507-OD-EN (old PN SP1110F), SAM[®] Splint – 36in (91.4cm) Flatfold Olive Drab
SP508-OB-EN (old PN SP1121FXL), SAM[®] Splint – 36in (91.4cm) Extra Large Orange/Blue
SP510-OB-EN (old PN SP1213L), SAM[®] Finger Splint – Orange/Blue