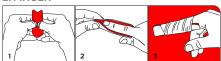
SAM Splint

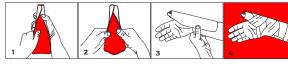


1. BASIC BENDS: MAKE CURVES FOR STRENGTH 2. FINGER





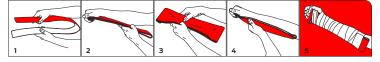
з. ТНИМВ



4. HAND



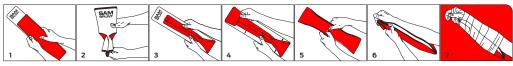
5. WRIST



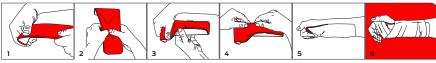
6. UPPER ARM



7. WRIST



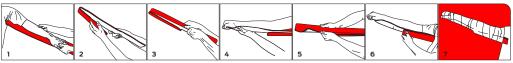
8. WRIST



9. WRIST / FOREARM



10. ELBOW



11. UPPER LEG



SAM*Splint

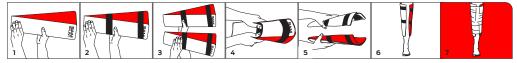


12. ANKLE





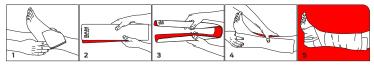
14. KNEE



15. LOWER LEG



16. ANKLE



CARE AND MAINTENANCE

The SAM® Splint is a reusable malleable splint that can be properly cleaned and disinfected for additional field service. These guidelines are recommendations for maximizing the service life of the SAM® Splint. Patients should follow the specific cleaning and disinfecting practices recommend by their medical practitioner.

CLEANING PROCEDURE

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.

INTENDED USE

The SAM Splint is intended to temporarily immobilize extremities following traumatic injury.

INDICATIONS FOR USE

The SAM Splint is a non-sterile, reusable device indicated for use in the short-term prehospital setting to treat acute trauma such as sprains, strains, contusions and fractures and to prevent further damage during transport to a definitive care facility.



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$oldsymbol{\Lambda}$ PRECAUTIONS

- If Splint is cut to shape, cover the cut end with protective tape and/or fold cut edge under
- Inspect device after use and discard if aluminum is exposed

MR CONDITIONAL

The SAM Splint is MR Conditional and this information applies to the entire family of SAM Splints that exist. Non-clinical testing and MRI simulations were performed to identify the worst-case conditions that were used to demonstrate that the SAM Splint is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 1.5- or 3-Tesla, only
- Maximum spatial gradient magnetic field of 10,000-Gauss/cm (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

Under the scan conditions defined, the SAM Splint is expected to produce a maximum temperature rise of 2.5 °C after 15-minutes of continuous scanning (i.e., per pulse

In non-clinical testing, the image artifact caused by the SAM Splint extends approximately 10-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Notice to Users and/or Patients:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Manufacturer	ш	MR Conditional	
Batch Code	LOT	Caution	Λ
Not Made With Natural Rubber Latex	M	CE Mark	CE
Catalog Number	REF	Authorized Representative in the European Community	EC REP
Medical Device	MD	Importer	1
X-Ray Radiolucent	X-RAY	Consult instructions for use. eIFU available at: sammedical.com/eIFU	elFU