



SAM® Chest Seal – Technical Data Sheet

Product Description

The SAM® Chest Seal Product Family is comprised of sterile dressings used to provide emergency treatment for open chest wounds. Chest seals provide an air-tight and water-tight seal around the open chest wound in order to convert an open pneumothorax into a closed pneumothorax. The one-way valve only allows air and fluids to leave the chest cavity and prevents pressure from increasing in the pleural space in turn preventing the development of a tension pneumothorax.

Guidelines issued by the United States Tactical Combat Casualty Care recommend that “all open and/or sucking chest wounds should be treated by immediately applying a vented chest seal to cover the defect. If a vented chest seal is not available, use a non-vented chest seal.”

The SAM® Chest Seal Product Family has the following Indications for Use:

- To be used as a temporary bandage to treat penetrating chest wounds that could compromise the pleural space of the chest cavity, such as: gunshot wounds, stab wounds and fragment wounds.
- To be used as an occlusive wound dressing.
- To be used in emergency situations and to be left in place only while the patient is transported to the hospital.

Material Technical Data

Dressing

- Description: Transparent, conformable polyurethane adhered to a strong hydrogel adhesive
- Use: Single Use Only, dispose of per healthcare facility biohazard protocol
- Adhesive: Water-based hydrogel
- Visibility: Night vision optimized
- Size: Large, oval dressing (7 in x 9 in / 17.8 cm x 22.9 cm) covering a surface area of 35.4 in² / 995 cm²
- Sterilization Method: Gamma irradiation
- Shelf Life: 6 years

Packaging

- Description: Polyester / aluminum / polyethylene laminate pouch with multiple peel/tear locations
- Size: 10 in (25.4 cm) x 6.3 in (16 cm)
- Weight: varies by model

Compliance

- CE₀₀₅₀ Marked
- MDD Certificate Registration Number – 252.820 issued by NSAI.
- ISO 13485:2016/MDSAP Quality Management System
- EN ISO 13485:2016 Quality Management System
- Authorized Representative – Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, NL
- Made in the USA

Device Models

Model/Catalog Numbers	Product
CS200-EN	SAM® Chest Seal with Valve, 1 dressing, 1 valve cap, 1 absorbent pad
CS201-EN	SAM® Chest Seal non-valved, 2 dressings, 1 absorbent pad (no valve)
CS202-EN	SAM® Chest Seal Valved 2.0, 1 dressing (no absorbent pad or valve cap)
CS203-EN	SAM® Chest Seal Combo – 1 SAM® Chest Seal Valved 2.0 and 1 SAM® Chest Seal (no absorbent pad or valve cap)