



## SAM<sup>®</sup> Chest Seal – Technical Data Sheet

### Product Description

The SAM<sup>®</sup> 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<sup>®</sup> 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 in<sup>2</sup> / 995 cm<sup>2</sup>
- 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

- CE<sub>0050</sub> Marked
- MDD Certificate Registration Number – 252.820 issued by NSAI.
- EU Authorized Representative – Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
- ISO 13485:2016/MDSAP Quality Management System
- EN ISO 13485:2016 Quality Management System
- Made in the USA

### Device Models

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