

ChitoSAM[®] 100

PRODUCT FAMILY TECHNICAL DATA SHEET

Finished Product Description

The ChitoSAM[®] 100 Product Family is a high-performance hemostatic dressing designed to control moderate to severe bleeding fast. ChitoSAM works independently of the body's normal clotting processes. The non-woven dressing is spun directly from chitosan which is derived from snow crab shells. Studies have demonstrated the safety of chitin-derived products in patients allergic to shellfish; including a published finding that "all subjects tolerated the (chitosan) bandage without reaction."¹ The dressing contains no cotton, rayon or polyester.

Indications for use

ChitoSAM[®] 100 products are for use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations.

Material Technical Data

Product Materials

- Description: 100% chitosan hemostatic dressing
- Sizes: Three options, | Single Ply: 4"x4" (10cm x 10cm), Z-Fold: 3"x4' (7.6cm x 122cm) and 3"x6' (7.6cm x 183cm)
- Sterilization Method: Gamma Irradiation
- Shelf Life: 5 years
- Does not contain natural rubber latex.

Instructions for use

- Printed on packaging. Visit sammedical.com for additional training materials and support.
- Complete product information and disclosures are listed in the Instructions for Use and available at sammedical.com/eIFU.
- Single Use Only. Dispose of used device per healthcare facility biohazard protocol. Reuse of device may cause illness or injury.
- Prescription Use Only.
- Do not place over eyes.
- Contains chitosan from shellfish. If shellfish allergy is a concern, please consult your doctor.
- Dressing must be removed within 24 hours.

Packaging

- Product is individually packaged; multiple units are packaged in a corrugated cardboard box.
- Individual pouch is designed to be easily opened on any edge, providing quick access.
- Case Packaged Size & Weight:

Catalog #	Height	Width	Depth	Weight	Quantity
CT101-A-EN	6.375 in 16.19 cm	5.375 in 13.65 cm	4.625 in 11.75 cm	1 lb. 453.6 g	40 Units
CT101-B-EN	7.375 in 18.73 cm	6.375 in 16.19 cm	5.625 in 14.29 cm	1 lb. 453.6 g	15 Units
CT101-C-EN	12.375 in 31.43 cm	6.375 in 16.19 cm	4.625 in 11.75 cm	1 lb. 453.6 g	15 Units

* Size and weight may vary by configuration and/or manufacturing process.

Compliance

- Manufactured by BenQ Materials Corporation, 29 Jianguo E. Rd., Guishan, Taoyuan, Taiwan
 +886.3.374.8800
 Certifications: Management System Certificate EN ISO 13485:2016
 248681-2017-AQ-RGC-NA-PS-Rev.2.0
 EC Certificate Full Quality Assurance System
 10778-2017-CE-RGC-NA-PS Rev 5.0
 EC Design Examination Certificate
 10529-2017-CE-RGC-NA-PS Rev 4.0
- European Union:** Class III medical device, CE Marked
- EU Authorized Representative:** Obelis s.a., Boulevard Général Wahis 53, 1030 Brussels, Belgium
- Notified Body:** DNV Product Assurance AS, Notified Body 2460
- GMDN Code:** 46922 (Chitosan hemostatic agent)

ChitoSAM[®] Product Family Listing

Catalog Number	Description	Case Box GTIN
CT101-A-EN	ChitoSAM 100 4"x4" (10cm x 10cm) Single Ply	14719745034401
CT101-B-EN	ChitoSAM 100 3"x4' (7.6cm x 122cm) Z-Fold	14719745034418
CT101-C-EN	ChitoSAM 100 3"x6' (7.6cm x 183cm) Z-Fold	14719745034425

¹ Kirk H. Waibel, Brian Haney, Merrideth Moore, Bonnie Whisman, Robert Gomez, Safety of Chitosan Bandages in Shellfish Allergic Patients, *Military Medicine*, Volume 176, Issue 10, October 2011, Pages 1153–1156