INVOTEC INTERNATIONAL, INC.®

# Silicone Sheeting

**Description**

Silicone sheeting is available in different sizes and forms and can used or trimmed into functional intra-operative geometries to meet the operational area and the specific patient anatomy.

**Indications**

Temporary splint and buttress device.

**Contraindications**

1. This product is shipped NON-STERILE.
2. Allergic reactions to the material used.
3. While the material used on this product has passed certain bio-compatibility screening tests that are applicable to products intended to be left in-situ for fewer than 29 days, Invotec makes no end use representation based on such tests. It is the user's responsibility to assure the safety and efficacy of this component for all intended uses. Invotec does not make any representation concerning the suitability leaving this material in-situ for 29 days or more. It's the user's responsibility to meet all FDA and ISO requirements for finished medical devices.
4. Not for permanent implantation.

**Sterilization**

**The following sequential steps are recommended to clean and sterilize:**

1. Scrub thoroughly with a clean, soft-bristled brush in a hot water soap solution to remove possible surface contaminates. Use a non-oily soap. Do not use synthetic detergents or oil-based soaps, as these may be absorbed and subsequently leached out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave by one of the following methods:
a. High Speed Instrument Sterilization: 10 minutes at 270°F (132°C).
b. Standard Gravity Sterilization: 30 minutes at 250°F (121°C).
c. Pre-vacuum High Temperature Sterilization: 10 minutes at 270°F (132°C).
4. Gas Sterilization is NOT recommended for silicone products.

**General Handling:**

1. This product is intended for single use only. Reuse of this device may expose the patient to infection or contamination risks.
2. When disposing the product, take all steps necessary to avoid risk of injury and infection. Contaminated products must be disposed of as hazardous waste and handled so as to avoid contamination of third parties.
3. Any serious incident that has occurred in relation to the device should be reported to Invotec International, Inc., MDSS GmbH, and the competent authority of the member state in which the user and/or patient is established.

**Warranty**

Invotec International, Inc. warrants that the product is free from defects in material and workmanship. Invotec will replace or provide a refund for any product found to be defective so long as the product is returned according to the Returned Goods instructions in the Sales Policy.

Invotec shall not be liable for any consequential loss, damage or expense directly or indirectly arising from the use of, or inability to use, this product. THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, HOWEVER ARISING, INCLUDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST INFRINGEMENT OR OTHERWISE. Invotec International neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product.

Invotec International, Inc.
6833 Phillips Industrial Blvd.
Jacksonville, FL 32256 USA
Tel: 904-880-1229 Fax: 904-886-9517 www.invotec.net