

VENAPORTA® Surgical Felt

Surgical Felt, Pledget, Strip, Tape Instruction For Use

Product

Materials Used:

The product is manufactured from Polytetrafluoroethylene (PTFE) or Polyester (PE/PES) fibers or Composite (Dual) materials, which is a combination of Polyester and ePTFE. Surgical Felts can be manufactured in different sizes, permeabilities and thicknesses. Frequently, the smallest sizes are called “Pledget”, flat strips are called “Strip”, and flat knitted strips are called “Tape”.

Product Groups

PTFE Felt, Pledget, Strip, Tape

Polyester Felt, Pledget, Strip, Tape

Composite Felt, Pledget, Strip, Tape

Pledget with Suture

Sterility: Surgical Felts are sterilized by Ethylene Oxide prior to delivery and remain sterile and nonpyrogenic unless the package is opened or damaged. The products are **single use** only. A second usage of this product may cause complications and contaminations that can lead to infection or even death.

Recommended Techniques

Product Care : Surgical Felts should be stored in a cool and dry environment. The expiration date exists on the label and box of the product. It is necessary to **use the product before the expiration date** to avoid possible complications. Remove the Surgical Felt gently from its package and handle it **using sterile gloves or atraumatic instruments** only. Do not use the product if the product and/or product package is damaged.

Intended use of the product : Surgical Felts, Pledgets and Strips are generally used as an implant in cardiac and vascular surgery. Felts can be used as pledget or to construct the segments of ventricular myocardium as a patch. Pledgets can be used for vascular or myocardial closure, septal or hepatic repair, or valvular suturing.

PTFE or polyester surgical tapes can be used for tissue approach, retraction, or as a ligature. Tapes can be used for the purpose of vascular retraction (separating, marking, lifting or pulling the vessels with forceps), nerve retraction and tendon retraction. Tapes should contact the body for less than 24 hours and must be discarded after surgery.

For all varieties of these products, misuse or use for the wrong purposes can cause **serious complications**.

Suturing: Use **only** non-resorbable suture and a suitable needle. The usage of resorbed suture is **not suitable** for this product and may cause serious complications.

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Probable Complications: A series of complications such as infection, inflammation, hematoma, thrombosis and excessive bleeding may occur if the following precautions are not applied.

Indications: Surgical Felt, Pledget and Strip products are generally used for cardiac and vascular surgery. Felts can be used as a suture buttress under the suture or as a patch. Tapes can be used for the purpose of vascular retraction (separating, marking, lifting or pulling the vessels with forceps), nerve retraction and tendon retraction.















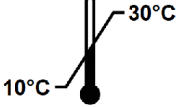
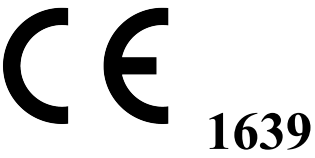




Contraindications: This product does not have any known contraindications.

Liability: The product should only be used by a professional surgeon with accepted cardiovascular surgical techniques. All precautions must be followed. VENAPORTA® is not responsible for the misuse of the product.



General Precautions

- Use only sterile gloves with atraumatic instruments.
- Do not use resorbable sutures.
- Do not use cutting needles.
- Do not contaminate the Surgical Felt.
- Do not excessively manipulate the surface of the Surgical Felt.
- Do not damage the Surgical Felt during handling.
- Do not use if the sterility of “Surgical Felt” has expired.
- Single use only.
- Do not resterilize.

 Single Use Only. Do Not Re-use.	 Sterilized Using Ethylene Oxide	 Keep Away From Sunlight	 Do Not Use If Package Is Damaged Or Opened
 Do Not Resterilize.	 Lot Number / Batch Code	 Keep Dry	 Caution, See Instructions For Use
 Single Sterile Barrier System	 Single Sterile Barrier System With Protective Packaging Inside	 Medical Device	 Unique Device Identifier
 Consult Instructions Before Use.	 Catalogue Number	 Store At Between 10°C and 30°C	
 Date of Manufacture	 Use-by Date	 Manufacturer	
 Quantity			

Venaporta

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