

INSTRUCTIONS FOR USE FOR:



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no

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se

Svenska

INSTRUCTIONS FOR USE FOR GORE-TEX® Expanded Polytetrafluoroethylene Cardiovascular Patch

INDICATIONS:

CARDIOVASCULAR PATCHING.

CONTRAINDICATIONS:

THERE ARE NO KNOWN CONTRAINDICATIONS.

STERILITY

The GORE-TEX® Cardiovascular Patch is supplied **STERILE** unless the package has been opened or damaged.

RECOMMENDED TECHNIQUES

HANDLING

To open the package, hold the base of the tray and peel back the lid so that the inner tray can be removed by grasping the sealed lip. Beginning at one corner, peel back the inner tray lid and gently remove the GORE-TEX® Cardiovascular Patch. Use clean gloves or atraumatic instruments when handling the GORE-TEX® Cardiovascular Patch. It is not necessary to preclot the GORE-TEX® Cardiovascular Patch.

SIZING

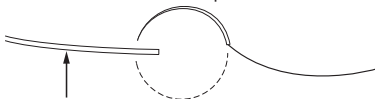
Trim the GORE-TEX® Cardiovascular Patch to the desired size using sharp surgical scissors. **Cutting to proper size is essential.** Cutting the GORE-TEX® Cardiovascular Patch too small may result in excessive tension on the suture line, which may add significantly to suture line bleeding. Do not suture GORE-TEX® Cardiovascular Patches together to form a larger GORE-TEX® Cardiovascular Patch. This is not part of the design criteria of this product and may result in a mechanically inadequate repair.

SUTURING

Do not use absorbable suture. Use only **nonabsorbable suture**, such as GORE-TEX® Suture, with a noncutting needle (such as taper or piercing point) of appropriate size. For best results, use monofilament sutures. Suture size should be determined by surgeon preference and the nature of the reconstruction.

Use a **minimum 2 mm suture bite** in cardiac and great vessel applications. For peripheral applications, use a minimum 1 mm suture bite.

Recommended suture technique:



GORE-TEX® Cardiovascular Patch

To avoid mechanical damage and suture hole elongation, smoothly pierce the material and follow the curve of the needle.

In cardiovascular reconstructions, suture line bleeding may be attributed to various sources, such as:

- gaps between the prosthetic material and the natural tissue
- suture holes in the prosthetic material
- suture holes in the natural tissue
- patient coagulopathy or platelet dysfunction

Significant suture line bleeding may occur if suture holes are elongated, torn, or if large gaps are allowed to form between the prosthetic material and the natural tissue. Use appropriate suture size and placement to prevent gaps. To minimize suture hole bleeding, use minimal tension when pulling up on the suture line or when placing a knot. Use the smallest needle that is appropriate for the repair. Follow the curve of the needle through the GORE-TEX® Cardiovascular Patch to avoid damaging the material and enlarging the suture holes. Topical hemostatic agents may be used to minimize anastomotic bleeding. The manufacturers' instructions for these hemostatic products should be observed.

VASCULAR ACCESS

When using the GORE-TEX® Cardiovascular Patch for vascular access applications or where repeated needle punctures of the GORE-TEX® Cardiovascular Patch may be necessary, ensure that needle puncture sites are spaced apart along the accessible subcutaneous length of the GORE-TEX® Cardiovascular Patch. Repeated needle puncture of the GORE-TEX® Cardiovascular Patch at the same site, or within the same immediate area, may cause mechanical damage to the GORE-TEX® Cardiovascular Patch which could lead to hematoma or false aneurysm formation. Patients should be carefully monitored.

WARNINGS

NOT FOR RECONSTRUCTION OF:

- HERNIAS
- SOFT TISSUE DEFICIENCIES
- SOFT TISSUE BIOLOGICAL MEMBRANES SUCH AS DURA MATER, PERICARDIUM, OR PERITONEUM

Use of this product in applications other than those indicated has the **potential for serious complications**, such as suture pullout, failure of the repair, or undesired healing to surrounding tissues.

PRECAUTIONS

- **DO NOT TAKE LESS THAN A 2 MM SUTURE BITE IN ALL CARDIAC AND GREAT VESSEL APPLICATIONS.**
- **DO NOT TAKE LESS THAN A 1 MM SUTURE BITE IN PERIPHERAL APPLICATIONS.**
- **DO NOT USE ABSORBABLE SUTURES.**
- **DO NOT USE A CUTTING NEEDLE.**
- **DO NOT HANDLE WITH UNGLOVED HANDS.**
- **DO NOT CUT THE PATCH TOO SMALL.**
- **DO NOT SEW TWO PATCHES TOGETHER.**

- **DO NOT** PLACE EXCESSIVE TENSION ON THE SUTURE LINE.
- **DO NOT** PUNCTURE THE PATCH REPEATEDLY AT THE SAME SITE OR WITHIN THE SAME IMMEDIATE AREA.
- **DO NOT** CONTAMINATE OR DAMAGE THE PATCH.

The GORE-TEX® Cardiovascular Patch is hydrophobic. Complete wetting through the GORE-TEX® Cardiovascular Patch wall prior to establishing blood flow may create a condition which could allow blood leakage and / or persistent plasma leakage. **To avoid wetting:**

- **DO NOT** allow the GORE-TEX® Cardiovascular Patch to contact organic fluids such as alcohol or BETADINE® solution.
- **DO NOT** excessively manipulate the GORE-TEX® Cardiovascular Patch when in contact with tissue fluids or blood.
- **DO NOT** generate syringe pressures sufficient to force fluids through the GORE-TEX® Cardiovascular Patch wall.

POSSIBLE COMPLICATIONS WITH THE USE OF ANY CARDIOVASCULAR PROSTHESIS:

Complications which may occur include but are not limited to: infection, inflammation, perigraft seroma formation, hematomas, thrombosis, prolonged bleeding, or formation of pseudoaneurysms.

STERILITY

The GORE-TEX® Cardiovascular Patch is supplied **STERILE**. Provided that the package is not compromised in any way, the package will serve as an effective sterile barrier until the “use by” (expiration) date printed on the box.

RESTERILIZATION

The GORE-TEX® Cardiovascular Patch may be resterilized up to three times using steam or gas techniques without compromising its mechanical or structural quality. **Do not sterilize the GORE-TEX® Cardiovascular Patch in the original packaging materials.** The Cardiovascular Patch must be repackaged in materials appropriate for sterilization. Sterility of repackaged product is the responsibility of the health care institution.

Clean, unused, and undamaged portions of the GORE-TEX® Cardiovascular Patch may be resterilized if handled with clean gloves or atraumatic instruments such as dry transfer forceps. Protect the GORE-TEX® Cardiovascular Patch from heavy or sharp objects during sterilization.

- Do not expose the GORE-TEX® Cardiovascular Patch to temperatures greater than 482°F (250°C).
- **Do not sterilize the GORE-TEX® Cardiovascular Patch using radiation.**

STEAM

Using a validated gravity displacement steam sterilizer, autoclave at or above these minimum requirements: 250°F (121°C) for 30 minutes or 270°F (132°C) for 15 minutes.

Using a validated pre-vacuum (also known as high vacuum) steam sterilizer, autoclave at or above these minimum requirements: 270°F (132°C) for 4 minutes.

ETHYLENE OXIDE

Due to the tremendous variation in gas sterilization equipment, the choice and validation of specific cycles and aeration parameters are the responsibility of the health care institution.

FOR OTHER PATCHING APPLICATIONS

The GORE DUALMESH® Biomaterial, GORE MYCROMESH® Biomaterial and GORE-TEX® Soft Tissue Patch are available for the reconstruction of hernias and soft tissue deficiencies.

The GORE PRECLUDE® Membrane is available for reconstruction or repair of the pericardium or peritoneum.

DEFINITIONS



Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.



Contents sterile unless enclosed package has been opened or damaged. Sterilized by steam.



AB0345-ML2



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For international contact and additional product information,
visit **www.goremedical.com**



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