

INSTRUCTIONS FOR USE FOR:



PRECLUDE®

V E S S E L G U A R D

en

English

cz

Čeština

dk

Dansk

nl

Nederlands

ee

Eesti

fi

Suomi

fr

Français

de

Deutsch

gr

Ελληνικά

hu

Magyar

it

Italiano

lt

Lietuvių

no

Norsk

pl

Polska

pt

Português

sk

Slovenčina

es

Español

se

Svenska

INSTRUCTIONS FOR USE FOR: GORE PRECLUDE® Vessel Guard

INDICATIONS

For use as a cover for vessels following anterior vertebral surgery to reduce the risk of potential vessel damage during a revision surgery by providing a plane of dissection.

CONTRAINDICATIONS

Not for reconstruction of cardiovascular defects. Use of this product in applications other than those indicated has the **potential for serious complications**, such as suture pullout or failure of the repair (aneurysm formation).

FOR OTHER PATCHING APPLICATIONS

The GORE-TEX® Cardiovascular Patch is available for cardiovascular patching reconstructions.

STERILITY

GORE PRECLUDE® Vessel Guard 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.

RECOMMENDED TECHNIQUES

HANDLING

Use clean, sterile gloves and / or atraumatic instruments when handling GORE PRECLUDE® Vessel Guard.

MAINTAINING ASEPSIS

To help maintain strict asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary.

SIZING

Proper sizing of GORE PRECLUDE® Vessel Guard is essential for optimal results. Size the material appropriately to completely cover the desired vessel area. GORE PRECLUDE® Vessel Guard should not be stretched to cover the vessels. If GORE PRECLUDE® Vessel Guard is cut too small, excessive stress may be placed on the tissue or material and suture pull out could occur. If the material is cut too large, excessive wrinkling may occur, possibly compromising results.

SUTURING

Use **nonabsorbable** sutures, such as GORE-TEX® Suture, with a noncutting needle (such as taper or piercing point) of appropriate size to anchor the material. Final suture selection should be determined by surgeon preference and the nature of the procedure. Use the smallest needle that is appropriate for the application.

After properly sizing GORE PRECLUDE® Vessel Guard to completely cover the desired vessel area, suture the material to adjacent non-vascular tissues using the minimum number of sutures to prevent material migration. To avoid mechanical damage and suture hole elongation, smoothly pierce GORE PRECLUDE® Vessel Guard and follow the curve of the needle through the material. Use minimal tension when pulling up on the suture line or when placing a knot.

WARNINGS

Strict aseptic techniques should be followed. If an infection develops, it should be treated aggressively. An unresolved infection may require removal of the material.

PRECAUTIONS

If GORE PRECLUDE® Vessel Guard is cut too small, excessive stress may be placed on the tissue or material and suture pull out could occur.

If the material is cut too large, excessive wrinkling may occur, possibly compromising results.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, seroma, hematoma, adhesions, and fibrous reaction. Additionally, non-indicated or contraindicated uses may result in material failure.

RESTERILIZATION

GORE PRECLUDE® Vessel Guard may be resterilized up to three times using steam techniques without compromising its mechanical or structural quality. Do not sterilize the device in the original packaging materials. The device must be repackaged in materials appropriate for sterilization. Sterility of the repackaged device is the responsibility of the health care institution.

Clean, unused, and undamaged portions of the device may be resterilized if handled with clean, sterile gloves and / or atraumatic instruments such as dry transfer forceps. Protect the device from heavy or sharp objects during resterilization.

- Do not expose the device to temperatures greater than 482°F (250°C).
- Do not resterilize the device using radiation.

STEAM RESTERILIZATION

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.

DEFINITIONS

 Use By

 Attention, See Instructions for 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.



AL0615-ML1



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For international contact and additional product information,
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