

INSTRUCTIONS FOR USE FOR:



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se

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INSTRUCTIONS FOR USE FOR GORE PRECLUDE® Spinal Membrane

INDICATIONS

FOR THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES FOLLOWING SPINAL SURGERY.

CONTRAINDICATIONS

Not for reconstruction of cardiovascular defects.

Use of this device in applications other than those indicated has the potential for serious complications, such as aneurysm formation or undesired healing to surrounding tissues.

STERILITY

GORE PRECLUDE® Spinal Membrane 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. There is no expiration date for device function or characteristics.

SURFACE ORIENTATION

Correct surface orientation is extremely important for GORE PRECLUDE® Spinal Membrane to function as intended. One surface of the device has been textured for identification. This textured surface should be placed adjacent to those tissues, such as the paraspinal muscles, where tissue ingrowth is desired. The smoother, non-textured surface should be placed adjacent to epidural structures where minimal tissue attachment is desired.

Textured surface for tissue ingrowth



Smooth surface for minimal tissue attachment

RECOMMENDED TECHNIQUES

HANDLING

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

MAINTAINING ASEPSIS

To help maintain strict asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary. When operative infection is suspected, dissection of involved tissues should be considered. Any postoperative infection should be aggressively treated at the earliest possible time. An unresolved infection may require removal of the device. Staged repairs should be considered when GORE PRECLUDE® Spinal Membrane will be subjected to gross contamination or infection.

SIZING

Proper sizing of the GORE PRECLUDE® Spinal Membrane is essential for optimal results. Use sharp surgical instruments to trim the device. The device should be positioned without tension and should overlap the entire border of the tissue defect by at least one centimeter. The material should drape into the defect, laying in direct contact with the dura.

Before securing the GORE PRECLUDE® Spinal Membrane, meticulous hemostasis should be achieved to minimize hemorrhage into the defect and to identify anchoring sites. Position the device over the defect so that wrinkles are minimized.

SUTURING

Use only **nonabsorbable sutures**, such as GORE-TEX® Suture, with a noncutting needle (such as taper or piercing point) of appropriate size to anchor the device. The use of absorbable sutures may lead to inadequate anchoring of GORE PRECLUDE® Spinal Membrane to the host tissue and necessitate reoperation.

For best results, use monofilament sutures. Suture size should be determined by surgeon preference and the nature of the reconstruction.

After properly sizing the GORE PRECLUDE® Spinal Membrane to cover the defect completely, use the minimum number of sutures required to attach the device in a non-watertight fashion with one centimeter overlap to the surrounding tissues to prevent device migration.

When used for laminectomy procedures, a fat graft placed on top of the membrane will minimize any tendency for the membrane to lift off the dura, creating a space that could fill with tissue or fluid.

WARNINGS

Strict aseptic techniques should be followed. If an infection develops, it should be treated aggressively. An unresolved infection may require removal of the device. Should cauda equina syndrome occur, device removal should be considered. Improper positioning of the textured surface adjacent to epidural structures may result in undesired tissue attachment.

Attachment of GORE PRECLUDE® Spinal Membrane to the defect margins in a watertight fashion may result in cauda equina syndrome due to postoperative fluid accumulation when used for laminectomy procedures. Immature granulation tissue may form under the membrane.

PRECAUTIONS

Do **not** use absorbable sutures or cutting needles to secure the device in place. Ensure the size of the device is adequate for the intended repair.

If the GORE PRECLUDE® Spinal Membrane is cut too small for the repair, excessive tension may be placed at the fixation points, which may lead to pullout. Inadequate overlap may expose the defect to possible adhesion formation. Inadequate fixation may allow the device to migrate and expose the defect.

The GORE PRECLUDE® Spinal Membrane must not be tucked into the spinal canal or wrapped around the spinal cord or nerve roots. Doing so may result in complications such as cauda equina syndrome.

ADVERSE REACTIONS

Possible adverse reactions with the use of any tissue deficiency prosthesis may include, but are not limited to, contamination, infection, inflammation, adhesion, fistula formation, seroma formation, and hematoma.

RESTERILIZATION

The GORE PRECLUDE® Spinal Membrane may be resterilized up to three times using steam or gas techniques without compromising its mechanical or structural quality. **Do not resterilize GORE PRECLUDE® Spinal Membrane in the original packaging materials.** GORE PRECLUDE Spinal Membrane 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 GORE PRECLUDE® Spinal Membrane from heavy or sharp objects during resterilization.

- Do not expose GORE PRECLUDE® Spinal Membrane to temperatures greater than 482 °F (250 °C).
- **Do not resterilize GORE PRECLUDE® Spinal Membrane 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

Because of 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.

DEFINITIONS

 Use By

 Attention, See Instructions for Use

 Do Not Re-Use

 Catalogue Number

 Batch Code

 European Authorized Representative


 STERILE

Contents sterile unless package has been opened or damaged.

 STERILE

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

 Smooth=Minimal Attachment

 Texture=Ingrowth



AB0348-ML2



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