

INSTRUCTIONS FOR USE FOR:



PRECLUDE®

D U R A S U B S T I T U T E

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English

INSTRUCTIONS FOR USE FOR GORE PRECLUDE® Dura Substitute

INDICATIONS

FOR USE AS A TEMPORARY OR PERMANENT PROSTHESIS FOR REPAIR OF DURA MATER DURING NEUROSURGERY.

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® Dura Substitute 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® Dura Substitute.

MAINTAINING ASEPSIS

To help maintain strict asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary. Any postoperative infection should be aggressively treated at the earliest possible time. An unresolved infection may require removal of the material.

SIZING

Proper sizing of the GORE PRECLUDE® Dura Substitute is essential for optimal results. Size the material appropriately to completely cover and overlap the defect. The GORE PRECLUDE® Dura Substitute should not be stretched to fit the dural defect. Inadequate overlap may expose the defect to possible adhesion formation and may result in cerebrospinal fluid leakage. If the GORE PRECLUDE® Dura Substitute is cut too small, excessive stress may be placed on the tissue or material and suture line leakage or suture pull out could occur. If the material is cut too large, excessive wrinkling may occur, possibly resulting in undesired tissue attachment.

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. Bench testing with dura substitute materials indicates reduced needle hole fluid leakage when using GORE-TEX® Suture in dura mater repairs. Suggested GORE-TEX® Suture sizes with an approximate one-to-one needle to thread ratio include CV-5 (5K12, 5K08, 5M16) and CV-6 (6K02, 6K10). Final suture selection should be determined by surgeon preference and the nature of the dural repair.

After properly sizing the GORE PRECLUDE® Dura Substitute to completely cover and overlap the defect, suture the material in place using the appropriate number of sutures and uniform spacing. It is imperative that a watertight seal be achieved along the suture line to minimize cerebrospinal fluid leakage. Due to the non-elastic nature of the GORE PRECLUDE® Dura Substitute, achieving a watertight closure is technique dependent. In duraplasty procedures, cerebrospinal fluid leakage can 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

Significant suture hole fluid leakage can occur if suture holes are elongated, torn, or if large gaps are created between the prosthetic material and the natural tissue. Use appropriate suture size and placement to prevent gaps. To minimize suture hole leakage, 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. To avoid mechanical damage and suture hole elongation, smoothly pierce the GORE PRECLUDE® Dura Substitute and follow the curve of the needle through the material. If the needle falls out of the needle hole following membrane puncture, care must be taken to pass the suture back through this original needle hole.

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.

Spinal dura defects should be closed primarily when the size of the defect permits. Use of the GORE PRECLUDE® Dura Substitute as a covering, without primarily closing the defect, may result in continued cerebrospinal fluid leakage and possible pseudomeningocele formation. If the dural defect is of sufficient size that primary closure is not possible, the GORE PRECLUDE® Dura Substitute can be used in a full segmental repair.

A watertight seal of the duraplasty is essential to minimize cerebrospinal fluid leakage.

Do not place the Dura Substitute in contact with bone cement or organic solvents, such as alcohol or BETADINE® Solution. Otherwise, cerebrospinal fluid leakage may result.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, hematoma, leakage of cerebrospinal fluid, adhesions and fibrous reaction. Additionally, contraindicated uses may result in material failure.

RESTERILIZATION

GORE PRECLUDE® Dura Substitute can be resterilized up to three times using steam or gas techniques without compromising its mechanical or structural quality. Do not resterilize the Dura Substitute in the original packaging materials. The Dura Substitute 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 material may be resterilized if handled with clean, sterile gloves and/or atraumatic instruments such as dry transfer forceps. Protect the Dura Substitute from heavy or sharp objects during resterilization.

- Do not expose the Dura Substitute to temperatures greater than 482°F (250°C).
- Do not resterilize the Dura Substitute 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



Caution



Consult Instructions for Use



Do Not Reuse



Catalogue Number



Batch Code



CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.



Sterile



Sterilized using Steam or Dry Heat



Do Not Use if Package is Damaged



Manufacturer



AP3324-ML1

 Manufacturer



W. L. GORE & ASSOCIATES, INC.

Flagstaff, Arizona 86004 • USA

Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763

Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

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

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