

INSTRUCTIONS FOR USE FOR:



PRECLUDE® PDX

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

en

English

bg

Български

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

ro

Română

sk

Slovenčina

es

Español

se

Svenska

INSTRUCTIONS FOR USE FOR GORE PRECLUDE® PDX 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® PDX 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® PDX Dura Substitute.

MAINTAINING ASEPSIS

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

SIZING

Proper sizing of the GORE PRECLUDE® PDX Dura Substitute is essential for optimal results. Size the material appropriately to completely cover and overlap the defect. The GORE PRECLUDE® PDX 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® PDX 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. Final suture selection should be determined by surgeon preference and the nature of the dural repair.

After properly sizing GORE PRECLUDE® PDX 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. 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® PDX Dura Substitute and follow the curve of the needle through the material. Avoid unnecessary membrane puncture.

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.

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

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

The GORE PRECLUDE® PDX Dura Substitute 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



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.



AB0684-ML3



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**

CE
0459

GORE, GORE-TEX®, PRECLUDE®, PRECLUDE® PDX, and designs are trademarks of W. L. Gore & Associates.

© 1999, 2008 W. L. Gore & Associates, Inc.

Printed on recyclable paper.

NOVEMBER 2008