other synthetic and biological materials.

function or characteristics.

soaking or rinsing prior to use. Provided that the integrity of the
disease-transmission concerns of dural grafts derived from animal

Substitute using radiation.

cal or structural quality. Do not resterilize the PRECLUDE® Dura

ePTFE membrane is a safe and effective synthetic
dura

surface of the neural tissue without damage. The studies concluded

Substitute must be repackaged in material appropriate for steriliza-

greater than

°F (°C). Do not resterilize the PRECLUDE® Dura

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dura. Avond. Made to order. Does not resterilize the PRECLUDE® Dura

Substitute using radiation.

Suture Compatibility

With its three-layer construction incorporating an elastomeric fla-
nex, the PRECLUDE® Dura Substitute is compatible with any non-absorbable suture with a

suture is an ideal suture for duraplasty due to its excellent handling

stitching with a 4-0 or 5-0 PDS or PGL. Do not resterilize.

Sterilization/Resterylization

PRECLUDE® Dura Substitute is supplied sterile and requires no

ordering Information (United States)

For orders and overnight delivery, contact your Technical Sales Associate or a

Product Specialist at

800 / 437-8181.

W. L. Gore & Associates, Inc.

10 cm x 12 cm

1 cm x 2 cm

1 cm x 10 cm

1 cm x 5 cm

4 cm x 4 cm

2 cm x 5 cm

5 cm x 6 cm

1PDX303

1PDX306

1PDX302

1PDX304

10 cm x 12 cm

6 cm x 6 cm

4 cm x 4 cm

2 cm x 10 cm

2 cm x 5 cm

5 cm x 6 cm
Indications/Contraindications

PRECLUDE® Dura Substitute is indicated for use as a temporary or permanent patchwork for repair of dural tears during neurosurgery. It is contraindicated for cardiovascular defects.

Description

The Second Generation PRECLUDE® Dura Substitute combines the proven performance of inert expanded polytetrafluoroethylene (ePTFE) with a completely inert elastomer urethane polymer in a three-layer construct. The outer ePTFE layers have a node and fibril microstructure with an average porosity of less than one micron. This porosity provides excellent conformability and handling while minimizing tissue ingrowth. The elastomer layer facilitates a watertight seal at the tissue line. Supplied as a watertight membrane, PRECLUDE® Dura Substitute serves as a watertight, full thickness dural graft which minimizes tissue attachment between the neural tissues and other tissues.

Biocompatibility

Gore has conducted physicochemical and in vitro studies of ePTFE membranes to ensure the absence of significant amounts of phan- maceutical or active leachables and the absence of any adverse biological effects. Results have shown that the material is not system- ically toxic, carcinogenic, or mutagenic. The material was also found to be non-pyrogenic, non-hemolytic, non-wetting, and free of contaminants or heavy metals.

Independent experimental studies have confirmed the excellent biocompatibility of PRECLUDE® Dura Substitute. The material demonstrates that the material excels in minimal foreign-body reactions. Neither inflammatory cells nor non-collagenic proliferation are present in adjacent tissue. Histological analysis of explanted PRECLUDE® Dura Substitute has revealed the formation of a thin non-adherent adhesion to the surface of the membrane.

No Risk of Infectious Disease Transmission

In 1997, the World Health Organization issued a press release regarding superficial epidermolysis that recommended cadaver- ous dura mater grafts as no longer to be used, and “Whenever possible, a synthetic dura (bovine) source should be used for preservation of medical products and devices.” This clearly has implications for the use of cadaveric and bovine-derived grafts in drapeley. Because it is a synthetic material, PRECLUDE® Dura Substitute does not have the inherent disease transmission risk of biological materials. The biological safety of Gore’s ePTFE has been demon- strated in more than six million procedures since 1975.

Minimal Tissue Attachment

Independent experimental and clinical studies have proven that the tight microstructure of the ePTFE surface of PRECLUDE® Dura Substitute is effective at minimizing tissue attachment. With an average porosity of less than one micron, the microstruc- ture prevents penetration by fibroblasts and other myofibrocytes and thus minimizes dense fibrous ingrowth.

In a canine spinal dura reconstruction model, PRECLUDE® Dura Substitute was compared to glutaraldehyde fixed bovine peri- cardiurn and a polyester-urethane membrane. Following laminectomy at T-12, L-1, and L-3, dural defects 1 cm long were created, a dural patch was placed subdurally, and the dura was closed over the patch material. After 7 days, the specimens were retrieved and analyzed grossly and histologically. At time of retrieval, the vertebrae were opened and the spinal cord examined. There was a dense fibrous adhesion at the site of the polyester-urethane material and a dense fibrofatty adhesion at the site of the glutaraldehyde-fixed bovine pericardium. These dense adhesions obscured the patch material completely. In comparison, there was minimal tissue attachment to the PRECLUDE® Dura Substitute site which is clearly visible in the gross photograph. Histological analysis revealed extensive scarring and tethering associated with the polyester-ure- thane and bovine pericardium materials with extensive cellular infil- tration and inflammation. Minimal scarring and tethering was asso- ciated with the PRECLUDE® Dura Substitute.

Waferlight

PRECLUDE® Dura Substitute is a waferlight membrane which uses ePTFE technology similar to Gore-Tex® fabric. Because it is in- vert, non-absorbable, the membrane will maintain its waferlight character for the duration of its implantation. The Second Generation PRECLUDE® Dura Substitute now incorporates an elastomeric fluoropolymer winding layer that greatly facilitates the watertight closure by sealing tightly against the natural dural surface.

Clinical Experience

The initial use of ePTFE membranes for dural replacement occurred in Japan in the early 1980s. At that time, the T. i.e. thick GORE-TEX® Surgical Membrane was found to be quite effec- tive at preventing meningocentral adhesions. With this initial clinical success, further modifications and product refinements were made to produce PRECLUDE® Dura Substitute specifically tailored for dura repair applications.

In a series of independent clinical evaluations, Gore ePTFE mem- branes were used as a synthetic dural substitute in 162 patients undergoing neurosurgery for craniocerebral dural repair. Fourteen patients (8.1%) experienced a temporary postoperative subarachnoid or epidural CSF leak. Ten of these were with first generation membranes and four were operated with the Second Generation PRECLUDE® Dura Substitute but the leakage was not attributed to the membrane. In three cases resolution was achieved within two weeks of sheet placement. Infection was

Clear Plane of Dissection

After three to four months in vivo, the PRECLUDE® Dura Substitute becomes translucent.* This occurs through a healing process in which the air in the subdural space becomes displaced by a surrounding aqueous environment. As body fluid displaced the gas, the material becomes translucent because of the similar index of refraction of the fluid and the ePTFE. This is visual- ized in canine models. In cases requiring reoperation since it allows visualization of the underlying neural structures. The wetting process in six way compromises the watertight character of the membrane.

*data on file
PRECLUDE® Dura Substitute is indicated for use as a temporary or permanent patch for repair of dural defects during neurosurgery. It is contraindicated for cardiovascular defects.

**Description**

The Second Generation PRECLUDE® Dura Substitute combines the proven performance of ePTFE expanded polytetrafluoroethylene (ePTFE) with a comparably inert elastomeric fluoropolymer in a twophase construct. The outer ePTFE layers have a non-adherent microstructure with an average porosity of less than one micron. This provides excellent conformability and handling while minimizing fibrous tissue ingrowth. The elastomer layer facilitates a watertight seal at the outer layer. Supplied as a 0.3 mm thick membrane, PRECLUDE® Dura Substitute serves as a watertight, full thickness dural graft which minimizes tissue attachment between the neural structures and other tissues.

**Bladder**

Gore has conducted physiochemical and in vitro studies of ePTFE membranes to ensure the absence of significant amounts of phagocytes and active leukocytes and the absence of any adverse biological effects. Results have shown that the material is not systemically toxic, carcinogenic, or mutagenic. The material was also found to be non-pyrogenic, non-hemolytic, non-irritating, non-sensitizing, non-toxic, non-cytotoxic, non-carcinogenic, or non-mutagenic. The material was also found to be non-pyrogenic, non-hemolytic, non-irritating, non-sensitizing, non-toxic, non-cytotoxic, non-carcinogenic, or non-mutagenic. The material was also found to be non-pyrogenic, non-hemolytic, non-irritating, non-sensitizing, non-toxic, non-cytotoxic, non-carcinogenic, or non-mutagenic. The material was also found to be non-pyrogenic, non-hemolytic, non-irritating, non-sensitizing, non-toxic, non-cytotoxic, non-carcinogenic, or non-mutagenic.

**Indications/Contraindications**

PRECLUDE® Dura Substitute is indicated for use as a temporary or permanent patch for repair of dural defects during neurosurgery. It is contraindicated for cardiovascular defects.

**Clinical Evidence**

In a series of independent clinical evaluations, Gore ePTFE membranes were used as a synthetic dural substitute in 125 patients undergoing neurosurgery for craniotomy and spinal dural repair. Fourteen patients (11%) experienced a temporary postoperative subdural or epidural CSF leak. Ten of these were found to have fistulas which were repaired with the Second Generation PRECLUDE® Dura Substitute but the leakage was not attributed to the membrane. In three cases resolution was achieved within two weeks of start placement. Infection was
Transmission electron micrograph of the PRECLUDE® Dura Substitute at approximately four microns from the PRECLUDE® Dura Substitute surface. Organized fibrocollagenous stroma and portions of four fibroblasts can be seen within the micrograph.

**Implant Duration**

PRECLUDE® Dura Substitute (S) implanted on the cerebral cortex (CC) for three years, resulting in dense fibrous ingrowth and subsequent adhesion formation. Portions of four fibroblasts (and other mesenchymal cells) and thus minimizes toxic, carcinogenic, or mutagenic. The material was also found to prevent penetration by fibroblasts and other mesenchymal cells and thus minimizes dense fibrous ingrowth.

**Biocompatibility**

Independent experimental studies have confirmed the excellent biocompatibility of PRECLUDE® Dura Substitute. This porosity provides excellent conformability and handling while minimizing fibrous tissue ingrowth. The elastomeric layer facilitates a watertight seal at the caucus line. Supported by a 0.3 mm thick membrane, PRECLUDE® Dura Substitute serves as a watertight, full thickness dural graft which mimics tissue attachment between the neural structures and other tissues.

**Detachment**

PRECLUDE® Dura Substitute was compared to glutaraldehyde fixed bovine pericardium. These dense adhesions obscured the patch surface of the PRECLUDE® Dura Substitute. This porosity provides excellent conformability and handling while minimizing fibrous tissue ingrowth. A scanning electron micrograph reveals how the elastomeric inner layer permits durable integration with the host tissue and thus minimizes dense fibrous ingrowth.

**Clear Plane of Dissection**

The initial use of ePTFE membranes for dural replacement occurred in Japan in the early 1980s. At that time, the Dura-Gen® porous polytetrafluoroethylene was the preferred material for dural replacement. However, the porous nature of the material led to the development of a plane of separation between the graft and the dura mater. In some cases, this separation was significant enough to require reoperation for a recurrent meningioma in the left occipital region.

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reported in six cases (1.4%), but none of these were related to the aPTT membrane. There were no episodes of CSF shunts or other complications. Traces of resorption, no adhesions were found, and the aPTT membranes could be easily removed from the surface of the surgical tissue without damage. The studies concluded that aPTT membrane is a safe and effective dural substitute without the complications observed with other synthetic and biological materials. The case of PRECLUDE® Dura Substitute will obviate the immunogenicity and disease-transmission concerns of dural grafts derived from animal or human tissue.

Suture Compatibility

With its three-layer construction incorporating an elastomeric fluoropolymer membrane, the Second Generation PRECLUDE® Dura Substitute is compatible with any non-absorbable suture with a non-cutting needle such as a taper or piercing point. The Gore-TEX® Suture is an ideal suture for dural surgery due to its excellent handling characteristics and documented excellent biocompatibility. The PRECLUDE® Dura Substitute should be utilized as point using a tension-free technique. This can be achieved by appropriately positioning the membrane to slightly overlap the dural defect and putting minimal tension on the sutures. Avoid unnecessary needle punctures in the material.

Sterilization/Resteralization

PRECLUDE® Dura Substitute is supplied sterile and requires no soaking or rinsing prior to use. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective sterile barrier until the “Use By” (expiration) date. A soaked or damaged package must be repackaged in material appropriate for sterilization.

CONTRAINDICATIONS: Not for reconstruction of cardiovascular defects. Use of this product in applications other than the intended use may alter its performance characteristics and may cause the medical device to fail, with a possible serious injury or death.

To receive further information on available sizes and custom configurations for PRECLUDE® Dura Substitute, contact your Technical Sales Associate or a Product Specialist at 608/473-0181. For orders and overnight delivery, call 800/726-8743.

References:
Suture Compatibility

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ration layer, the Second Generation PRECLUDE® Dura Sub-
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Sterilization/Resterilization

PRECLUDE® Dura Substitute is supplied sterile and requires no
washing or rinsing prior to use. Provided that the integrity of 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 the product.

ADVERSE REACTIONS: Possible adverse reac-
tions 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.

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