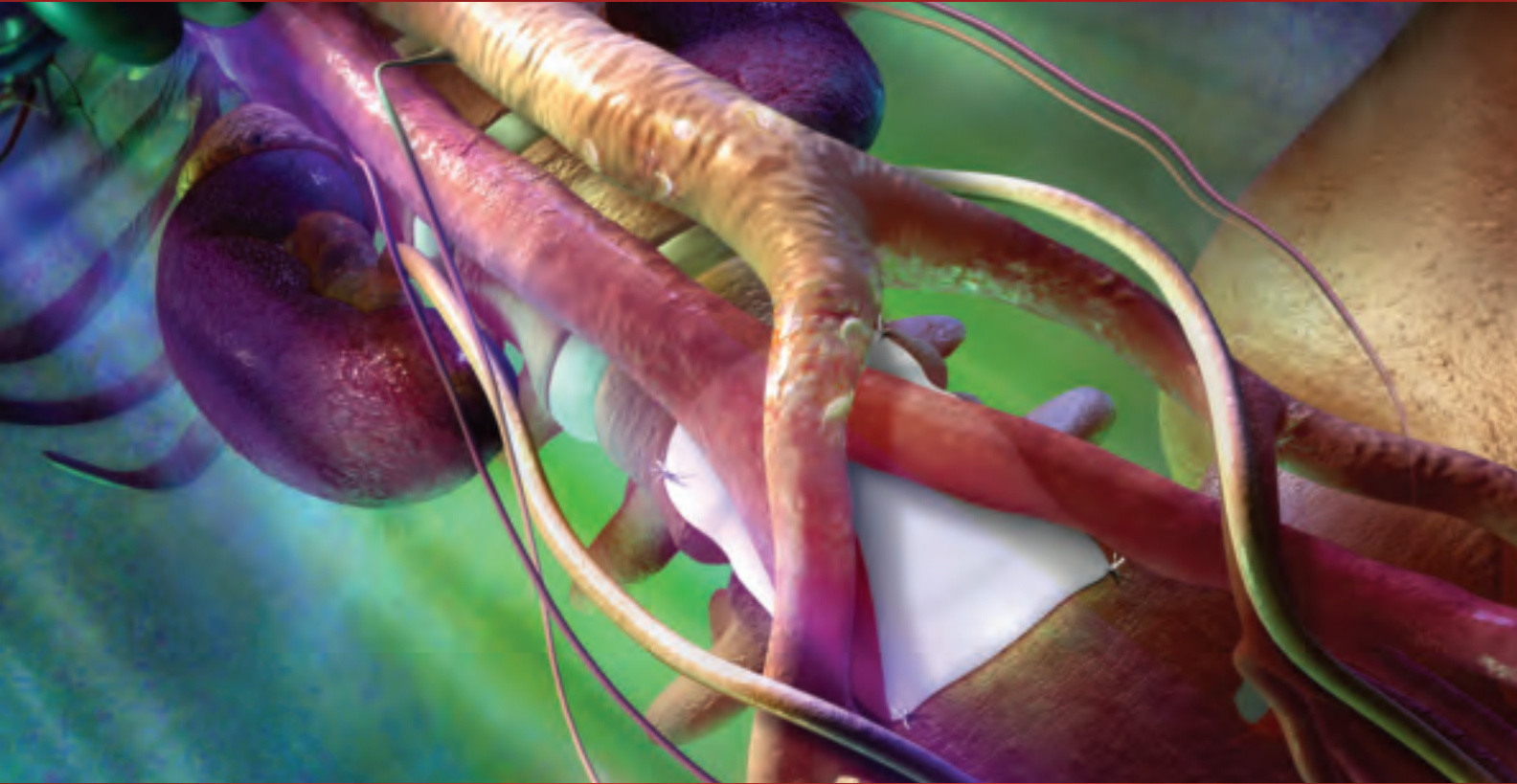


# *Permanent Vessel Protection*



**PERFORMANCE** through experience

**GORE**  
**PRECLUDE®**  
VESSEL GUARD



## The Science

### Simple, elegant design

GORE® PRECLUDE® Vessel Guard features three-layer construction for ease of placement and effective performance.

- Outer ePTFE layers feature tight microstructure (pore size <1 micron)
  - Prevents fibroblast penetration
  - Minimizes tissue attachment to the device
  - Permits safer anterior reoperations
- Elastomeric inner layer
  - Provides stiffness to prevent impingement
  - Enables accurate placement

### Easy to use

- 0.3 mm thickness conforms easily
- Elastomeric inner layer minimizes impingement and provides stiffness for placement
- Material may be trimmed and tailored without fraying
- No special handling or storage needed

### Biocompatible

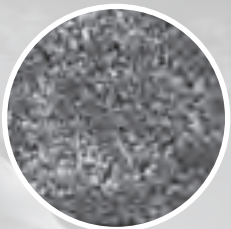
- Comprised of inert fluoropolymer (ePTFE and fluoroelastomer)
- Proven in more than 25 million implants for 35 years
- Non-biological material eliminates risk of animal-source disease transmission

### Bioinert

- No foreign body reaction
- Not systemically toxic
- Non-carcinogenic
- Non-mutagenic
- Non-pyrogenic
- Non-hemolytic
- Non-irritating
- Non-sensitizing
- Free of contaminants or heavy metals



GORE® PRECLUDE®  
Vessel Guard



GORE® PRECLUDE®  
Vessel Guard  
(SEM 2000x)

# The Surgeries

## The surgeries

GORE® PRECLUDE® Vessel Guard is appropriate for use in the following surgeries:

- Anterior lumbar interbody fusion
- Adjacent level disc treatment
- Total disc replacement
- Hardware removal
- Instrumented scoliosis reconstruction
- Corpectomy for tumor or trauma
- Open vascular treatment
- Staged procedures or reoperations for any of the above procedures

## Simple surgical technique

- Shape the patch: After the spinal hardware has been implanted, trim the GORE® PRECLUDE® Vessel Guard patch to completely cover the vessel area. Material may be trimmed and tailored without fraying.
- Suture the patch: Before placement, nonabsorbable sutures should be passed through the patch and then to the corresponding fixation site. Sutures can be attached to ligament, annulus or any other nonvascular tissue. Fixation sites should be along the edge of the patch on the side of vessel retraction.
- Release the retraction: Release the vessels, using a right angle or similar instrument to guide vessels over the patch.

See Instructions for Use and Surgical Technique for Sutured Fixation of GORE® PRECLUDE® Vessel Guard for further details.

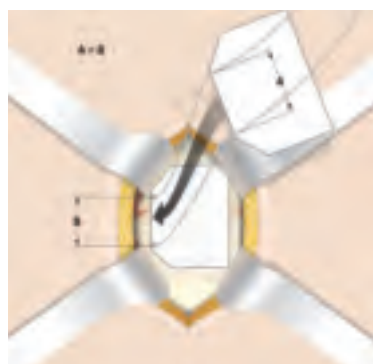
## Reoperations

- During a reoperation, GORE® PRECLUDE® Vessel Guard will serve as a clear plane of dissection<sup>2</sup> with minimal tissue attachment, thus allowing the vessels to be mobilized. In addition, the material becomes translucent, allowing visualization of the underlying structures.

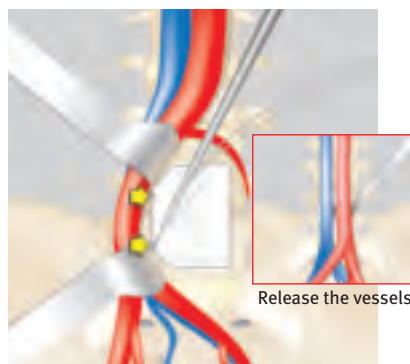
## 3-Step Procedure



Use nonabsorbable sutures along the edge of the patch.



Spacing of sutures on the patch and fixation points should be relatively equal to prevent wrinkling or stretching.



Release the vessels.

Fixation sites should be on the side of vessel retraction.\*

\*As the number of sutures needed is affected by multiple factors, including, but not limited to, the nature of the procedure, the number of operative levels, or the orthopedic hardware implanted, the final number of sutures should be determined by the surgeon's judgment. In addition, suture placement may not be limited to the side of vessel retraction.

# The Successes

## Documented performance

Benefits of anterior spine revisions with the use of GORE® PRECLUDE® Vessel Guard are documented\*\*. In a study of 21 reoperations, with average time to revision being nine months (range: two days to 30 months):

- More than 81% had an approximate surgical time to access the spine of only 30 to 60 minutes.
- More than 75% had an approximate blood loss during approach portion of procedure of less than 100 ml.

## Preserves future treatment options

- A permanent and identifiable plane of dissection may facilitate anterior spine reoperations for:
  - Adjacent level treatment
  - Hardware removal
  - Subsequent trauma treatment
  - Open vascular treatment

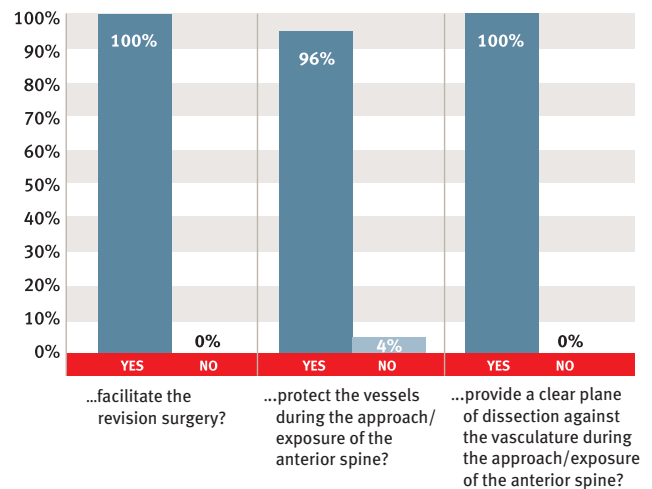
## Time-proven performance

Gore ePTFE technology has proven safe and effective over more than 35 years of use in more than 25 million clinical implants.

## Surgically proven

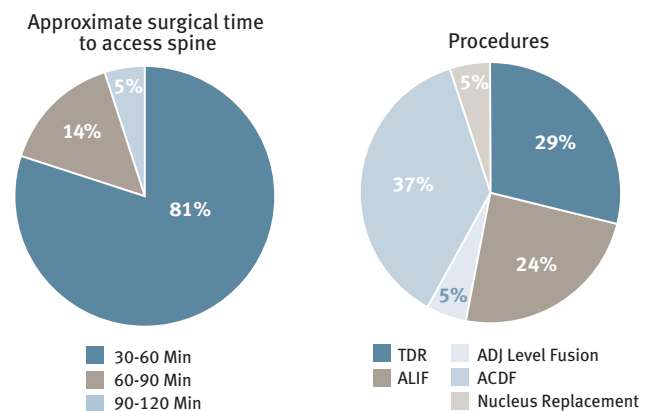
- The outcome of Gore’s ongoing registry program demonstrates the performance of GORE® PRECLUDE® Vessel Guard during anterior reoperation procedures.
- Minimal tissue attachment to the device

Surgeon Feedback – Did the GORE® ePTFE membrane...



## Total Reoperations: 21

Average Time to Revision: 9 Months (Range: 2 days to 30 months)

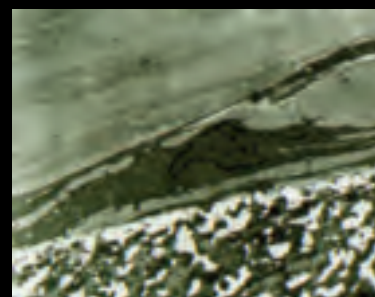


\*\*Data on file. Additional publications further substantiate the performance of GORE® PRECLUDE® Vessel Guard.

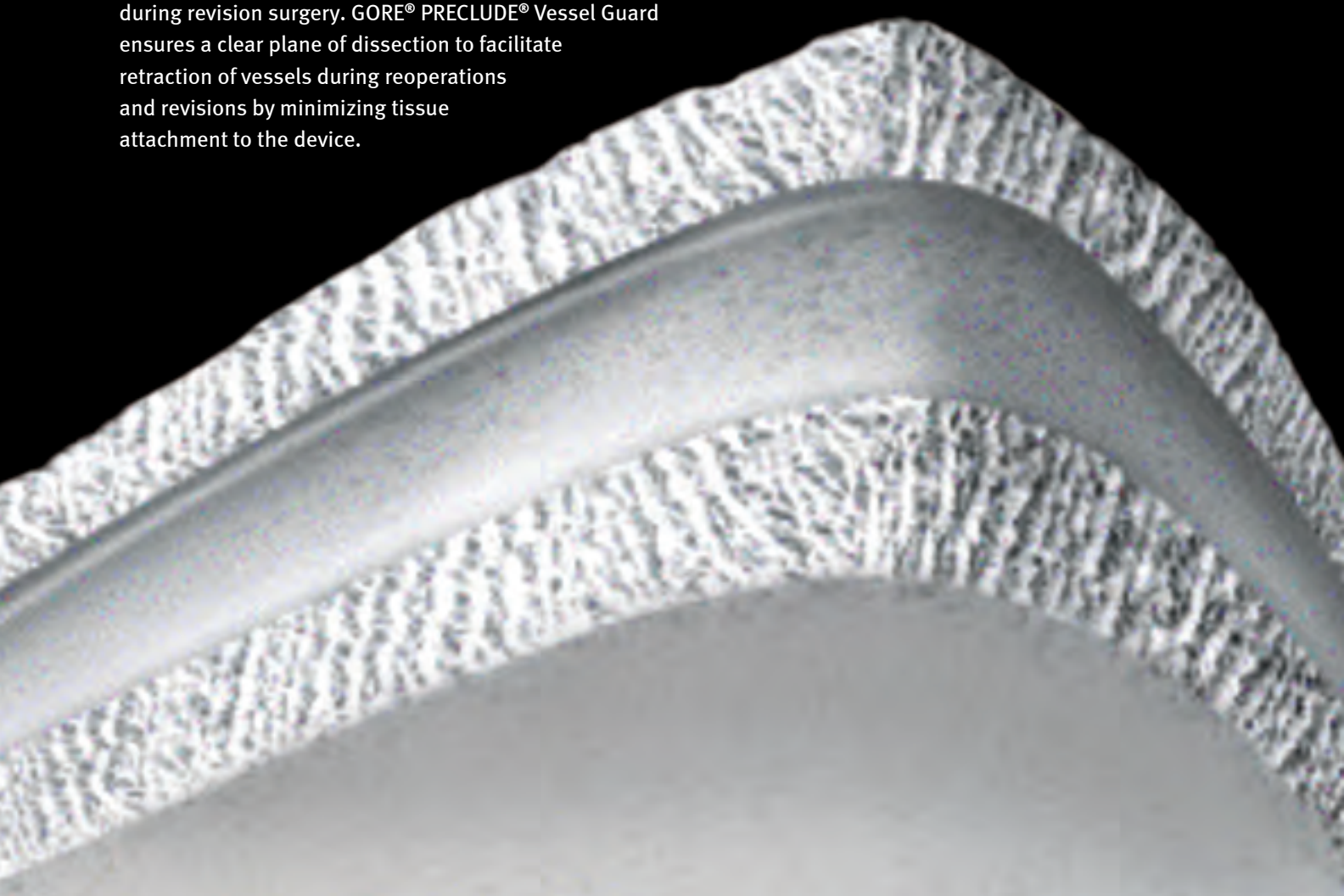
# *Permanent vessel protection for anterior spine reoperations*

While advances in spine surgery promote an anterior approach, the presence of the aorta and vena cava presents a particular challenge. Post-operative scarring can make retraction for subsequent surgeries difficult and time-consuming. The challenges of anterior spine revisions without the use of GORE® PRECLUDE® Vessel Guard have been documented<sup>1</sup>: 71% of patients had complications with anterior spine revisions, and 57% of complications were vascular injuries. While alternative approaches to the anterior spine may avoid the vessels, they entail a higher risk of nerve root damage and decreased access to the anterior spinal anatomy.

GORE® PRECLUDE® Vessel Guard is a cover for vessels following anterior vertebral surgery to reduce the risk of potential vessel damage during revision surgery. GORE® PRECLUDE® Vessel Guard ensures a clear plane of dissection to facilitate retraction of vessels during reoperations and revisions by minimizing tissue attachment to the device.



Electronic micrograph illustrating tight pore structure, which prevents fibroblast penetration.



Dear \_\_\_\_\_,

I have seen the clinical advantages of GORE® PRECLUDE® Vessel Guard and request the following catalogue number(s) and quantity(ies) stocked for usage on my anterior spine cases:

1PVG506 (5 cm x 6 cm) Qty: \_\_\_\_\_

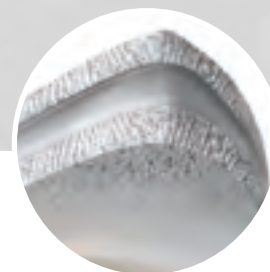
1PVG610 (6 cm x 10 cm) Qty: \_\_\_\_\_

\*Other \_\_\_\_\_ Qty: \_\_\_\_\_

Signed \_\_\_\_\_, MD

Date \_\_\_\_\_

\*Discounted 5-packs available in select markets.



For more information on GORE® PRECLUDE® Vessel Guard visit [goremedical.com/vesselguard](http://goremedical.com/vesselguard)

<sup>1</sup> Nguyen H-V, Akbarnia BA, van Dam BE, et al. Anterior exposure of the spine for removal of lumbar interbody devices and implants. Spine 2006; 31 (21): 2449–2453.

<sup>2</sup> Yamagata S, Goto K, Oda Y, Kikuchi H. Clinical experience with expanded polytetrafluoroethylene sheet used as an artificial dura mater. Neurologia Medico-Chirurgico 1993; 33 (80): 582–585.

Refer to Instructions for Use for a complete description of all warnings, precautions, and contraindications.

Ⓡ<sub>only</sub> Products listed may not be available in all markets.

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