

INSTRUCTIONS FOR USE FOR:



STAPLE LINE REINFORCEMENT

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement *Configured for Endoscopic Surgical Staplers*

en

English

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

sk

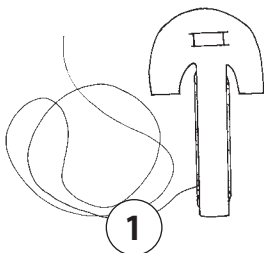
Slovenčina

es

Español

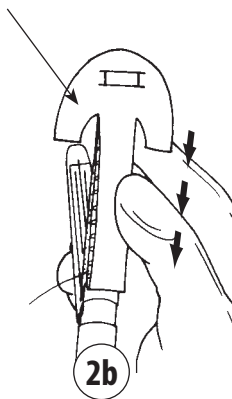
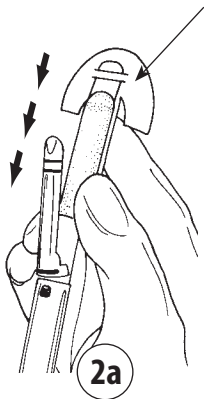
se

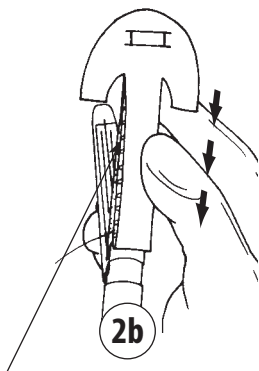
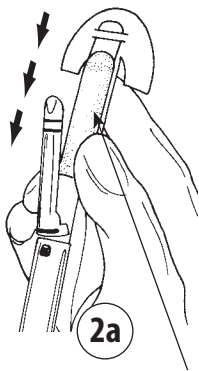
Svenska



- en** Cartridge Device
- cz** Zařízení se zásobníkem
- dk** Patron
- nl** Cassettedeel
- ee** Kassettseade
- fi** Makasiini
- fr** Dispositif pour cartouche
- de** Magazin-Vorrichtung
- gr** Συσκευή κασέτας
- hu** Patron
- it** Dispositivo per caricatore
- lt** Kasetinis prietaisas
- no** Ladeenhet
- pl** Kasetta
- pt** Dispositivo do cartucho
- sk** Zariadenie so zásobníkom
- es** Dispositivo de cartucho
- se** Magasinstycke

- | | | | |
|-----------|-------------------|-----------|------------------------------|
| en | TYVEK® Insert | hu | TYVEK® betét |
| cz | Vložka TYVEK® | it | Inserto in TYVEK® |
| dk | TYVEK® Indlæg | lt | TYVEK® įdėklas |
| nl | TYVEK® inzetstuk | no | TYVEK®-innlegg |
| ee | Paigaldaja TYVEK® | pl | Wkładka TYVEK® |
| fi | TYVEK®-sisäke | pt | Peça de encaixe de TYVEK® |
| fr | Insert en TYVEK® | sk | Vložka TYVEK® |
| de | TYVEK®-Einlage | es | Material de inserción TYVEK® |
| gr | Ένθετο TYVEK® | se | TYVEK®-insats |





en GORE SEAMGUARD®
Bioabsorbable Staple Line
Reinforcement

cz Biologicky absorbovatelný
zesilující materiál
mechanicky šitých stehů
GORE SEAMGUARD®

dk GORE SEAMGUARD®
Absorberbar Forstærkning
til hæftesøm

nl GORE SEAMGUARD®
Bioabsorbeerbare
verstevinging voor naden
met nietjes

ee Bioabsorbeeruv
klammerdusjoone
tugevdusmaterjal GORE
SEAMGUARD®

fi GORE SEAMGUARD®
-bioresorboituva
hakasrivin vahvike

fr Renforcement biorésorbable
des lignes de sutures GORE
SEAMGUARD®

de GORE SEAMGUARD®-
Klammernahtverstärkung
(bioresorbierbar)

gr Βιοαπορροφήσιμο
Ενίσχυσης Γραμμών
Συνδετήρων
GORE SEAMGUARD®

hu GORE SEAMGUARD® felszívódó
kapocssor-megerősítő anyag

it Rinforzo bioassorbibile
GORE SEAMGUARD® per linea
di sutura con punti metallici

lt GORE SEAMGUARD®
bioabsorbuojama siūlės
sutvirtinimo medžiaga

no GORE SEAMGUARD®
Bioresorberbar forsterkning
for klipslinjer

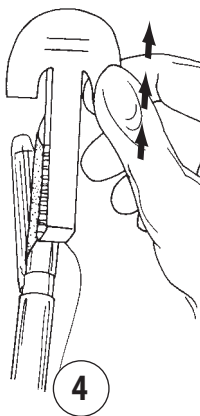
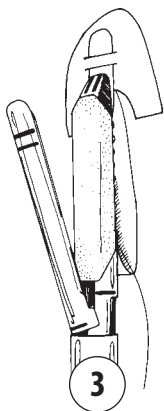
pl Biowchłaniany materiał GORE
SEAMGUARD® wzmacniający
linię zszywania

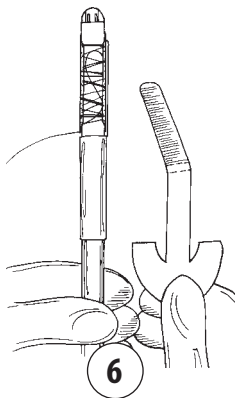
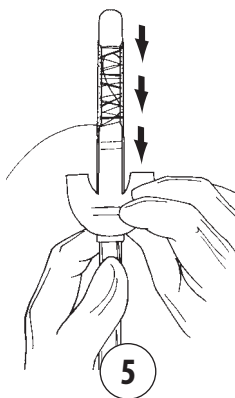
pt Reforço das Linhas de
Agrafos Bioabsorvível
GORE SEAMGUARD®

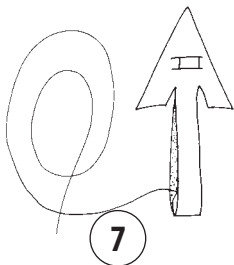
sk Biologicky absorbovatelný
spevňujúci materiál mechanicky
šitých stehov GORE
SEAMGUARD®

es Refuerzo bioabsorbible
de la línea de grapado
GORE SEAMGUARD®

se GORE SEAMGUARD®
Bioresorberbar förstärkning
för staplerad



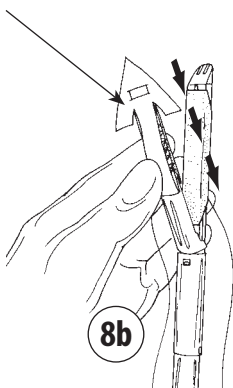
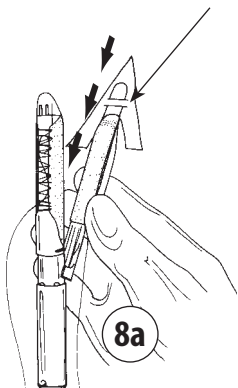


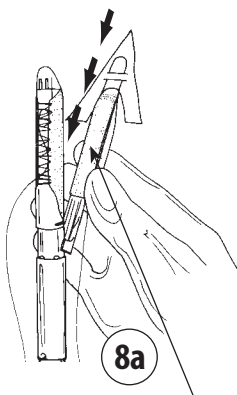


- en** Anvil Device
- cz** Kovadlinka
- dk** Ambolt
- nl** Slagdeel
- ee** Alasiseade
- fi** Alasin
- fr** Dispositif pour enclume
- de** Amboss-Vorrichtung
- gr** Συσκευή άκμονα
- hu** Űllő
- it** Dispositivo per incudine
- lt** Atraminis prietaisas
- no** Ambolt
- pl** Kowadełko
- pt** Dispositivo da matriz
- sk** Nákovka
- es** Dispositivo de yunque
- se** Motstålsstycke

- en** TYVEK® Insert
- cz** Vložka TYVEK®
- dk** TYVEK® Indlæg
- nl** TYVEK® inzetstuk
- ee** Paigaldaja TYVEK®
- fi** TYVEK®-sisäke
- fr** Insert en TYVEK®
- de** TYVEK®-Einlage
- gr** Ένθετο TYVEK®

- hu** TYVEK® betét
- it** Inserto in TYVEK®
- lt** TYVEK® įdėklas
- no** TYVEK®-innlegg
- pl** Wkładka TYVEK®
- pt** Peça de encaixe de TYVEK®
- sk** Vložka TYVEK®
- es** Material de inserción TYVEK®
- se** TYVEK®-insats





8a

en GORE SEAMGUARD®
Bioabsorbable Staple Line
Reinforcement

cz Biologicky absorbovatelný
zesilující materiál
mechanicky šitých stehů
GORE SEAMGUARD®

dk GORE SEAMGUARD®
Absorberbar Forstærkning
til hæftesøm

nl GORE SEAMGUARD®
Bioabsorbeerbare
versterking voor naden
met nietjes

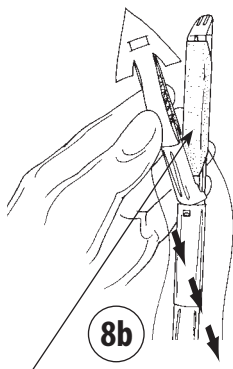
ee Bioabsorbeeruv
klammerdusjoone
tugevdusmaterjal GORE
SEAMGUARD®

fi GORE SEAMGUARD®
-bioesorboituva
hakasrivin vahvike

fr Renforcement biorésorbable
des lignes de sutures GORE
SEAMGUARD®

de GORE SEAMGUARD®-
Klammernahtverstärkung
(bioesorbierbar)

gr Βιοαπορροφήσιμο
Ενίσχυσης Γραμμών
Συνδετήρων
GORE SEAMGUARD®



8b

hu GORE SEAMGUARD® fel-
szívódó kapocssor-
megerősítő anyag

it Rinforzo bioassorbibile
GORE SEAMGUARD® per linea
di sutura con punti metallici

lt GORE SEAMGUARD®
bioabsorbuojama siūlės
sutvirtinimo medžiaga

no GORE SEAMGUARD®
Bioesorberbar forsterkning
for klipslinjer

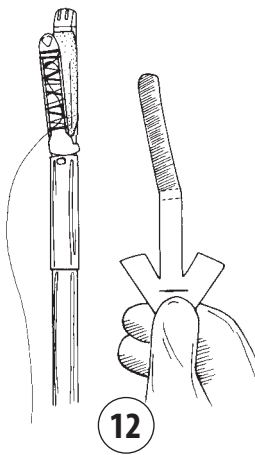
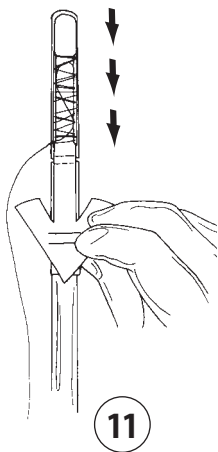
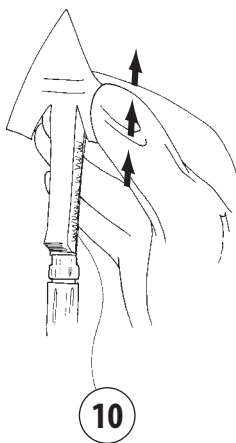
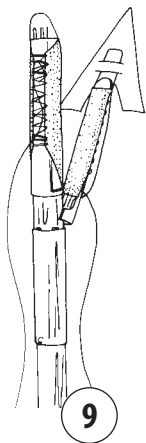
pl Biowchłaniany materiał
wzmacniający GORE
SEAMGUARD® stosowany przy
zakładaniu klamr

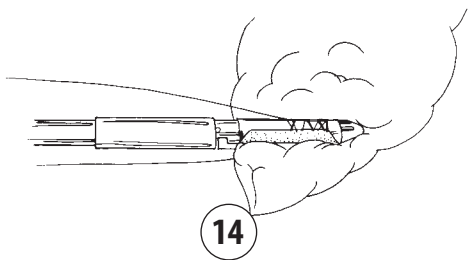
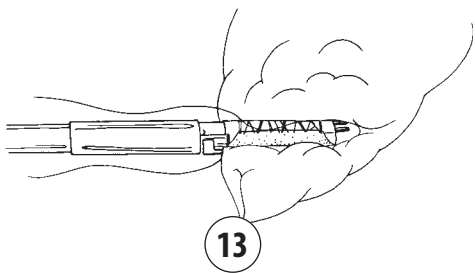
pt Reforço das Linhas de
Agrafos Bioabsorvível
GORE SEAMGUARD®

sk Biologicky absorbovatelný
spevňujúci materiál
mechanicky šitých stehov
GORE SEAMGUARD®

es Refuerzo bioabsorbible
de la línea de grapado
GORE SEAMGUARD®

se GORE SEAMGUARD®
Bioesorberbar förstärkning
för staplerad





INSTRUCTIONS FOR USE

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement

Configured for Endoscopic Surgical Staplers

DESCRIPTION

As packaged, GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement constitutes preformed porous bioabsorbable sheets held into the form of sleeves (one cartridge device, one anvil device) through the use of a non-absorbable polyester braided suture.

A TYVEK® insert, which is removed and discarded after positioning on the stapler, is included to facilitate the placement of the device onto the jaws of surgical staplers. After deployment of the stapler / reinforcement material combination, the non-absorbable suture component is removed and discarded. Desiccant paper and a MINIPAX® desiccant pack are included to preserve device integrity and are to be discarded.

The implanted GORE SEAMGUARD® Bioabsorbable Staple Line reinforcement is a porous fibrous structure composed solely of synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer. Degraded via a combination of hydrolytic and enzymatic pathways, the copolymer has been found to be both biocompatible and nonantigenic, with a history of use as bioabsorbable sutures, membranes and other implantable devices.¹

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement is provided STERILE for single use only. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement has been sterilized by gamma radiation. Provided the package is stored at room temperature and is not compromised in any way, it will serve as an effective barrier until the “use by” (expiration) date printed on the box.

INDICATIONS/INTENDED USE

GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement is also intended to be used for reinforcement of suture-lines and staple-lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

CONTRAINDICATIONS

Not for the patch reconstruction of cardiovascular defects such as cardiac, great vessel, and peripheral vascular arteries or veins.

WARNINGS

- Use of this product in applications other than those indicated has the potential for serious complications. Potential complications include: inadequate reinforcement strength, staple pullout, infection, abrasion, migration and erosion.
- The use of GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement will increase the thickness of the area to be stapled by a maximum of 0.5 mm. Selection of staple size should reflect

the thickness of the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement such that the total thickness of material to be stapled falls within the recommended range for the stapler (see stapler Instructions for Use). Use of staples with insufficient length for the procedure performed may lead to disruption of the staple line due to inadequate staple closure.

- The TYVEK® insert, desiccant paper, MINIPAX® desiccant pack and sutures are not for implantation and are to be discarded.
- Use of this product with stapler models other than those listed on the package labeling is not recommended.

PRECAUTIONS

- To avoid damage or contamination, always use clean gloves and atraumatic instruments when handling the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement. Always protect the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement from damage by heavy or sharp objects.
- Do not resterilize the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement.
- If the MINIPAX® desiccant pouch has been compromised, discard the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to: infection, inflammation, adhesions and hematoma.

INSTRUCTIONS

LOADING ONTO THE CARTRIDGE JAW

- The device with the **curved** TYVEK® insert (Figure 1) is configured for the **cartridge** jaw of the stapler.
- Slide the GORE SEAMGUARD® Sleeve onto the cartridge jaw of the stapler keeping the cartridge jaw between the bioabsorbable material and the TYVEK® insert (Figures 2a and 2b).
- Make sure that the bioabsorbable material is positioned on the inside of the stapler jaws.
- Slide the GORE SEAMGUARD® Sleeve over the cartridge jaw of the stapler until all of the staples are covered with the bioabsorbable material (Figure 3).
- To remove the TYVEK® insert, grasp the curved portion and pull it until the curved portion is separated from the underlying tab (Figure 4).
- Orient the TYVEK® insert parallel to the stapler shaft (Figure 5).
- Pull the insert to remove it from the device (Figure 6).

LOADING ONTO THE ANVIL JAW

- The device with the **arrowed** TYVEK® insert (Figure 7) is configured for the **anvil** jaw of the stapler.
- Slide the GORE SEAMGUARD® Sleeve onto the anvil jaw of the stapler keeping the anvil jaw between the bioabsorbable material and the TYVEK® insert (Figures 8a and 8b).
- Make sure that the bioabsorbable material is positioned on the inside of the stapler jaws.
- Slide the GORE SEAMGUARD® Sleeve over the anvil jaw of the stapler until all of the staples are covered with the bioabsorbable membrane (Figure 9).

- Remove the TYVEK® insert by grasping the arrowed edge and pull it until the arrowed portion is separated from the underlying tab (Figure 10).
- Orient the TYVEK® insert parallel to the stapler shaft (Figure 11).
- Pull the insert to remove it from the device (Figure 12).

COMPLETING THE PROCEDURE

Examine the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement on the stapler jaws. It should fully cover all of the staple holes. If it does not, reposition the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement so that it does cover all the staple holes. Close and lock the stapler jaws, ensuring that the polyester suture material is not inside the stapler jaws. Keep the stapler jaws locked while passing the stapler through the trocar (or chest incision). Unlock the stapler allowing it to return to its fully opened position. Place the stapler over the tissue to be resected (Figure 13). Make sure that the polyester suture material is not inside the jaws of the stapler. Close and lock the stapler jaws. Pull the suture to release the GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement from the stapler jaws (Figure 14). Fire the stapler. Discard the suture.

REFERENCE

- ¹ Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. *Surgery, Gynecology & Obstetrics* 1985;161(3):213-222.

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 irradiation.



Anvil



Cartridge



Circular



Endoscopic



Open



Stapler Type



AJ0203-ML4



*Creative Technologies
Worldwide*

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, SEAMGUARD®, and designs are trademarks of W. L. Gore & Associates.

MINIPAX® is a trademark of Multisorb Technologies, Inc.

TYVEK® is a registered trademark of E. I. du Pont de Nemours and Company.

© 2003, 2005-2008 W. L. Gore & Associates, Inc.

 Printed on recyclable paper.

MARCH 2008