

INSTRUCTIONS FOR USE FOR:

GORE

TUNNELER

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sk

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es

Español

sv

Svenska

INSTRUCTIONS FOR USE

GORE® TUNNELER

STERILITY

The GORE® Tunneler and replacement parts are supplied NON-STERILE. Clean and sterilize your GORE® Tunneler and replacement parts prior to use.

REPLACEMENT PARTS

To ensure the replacement parts are compatible with your GORE® Tunneler, assemble it upon receipt.

DESCRIPTION

The GORE® Tunneler is made from surgical-grade stainless steel and anodized aluminum. These materials are designed to withstand repeated use and resterilization.

INDICATION

The GORE® Tunneler aids in creating accurately placed and precisely sized tissue tunnels for the placement of vascular prostheses for vascular access, peripheral and extra-anatomic bypass.

PRECAUTIONS

Protect the GORE® Tunneler from mechanical damage.

1. DO NOT bend the rod or sleeve. Bending may cause metal fatigue and could lead to breakage. Misalignment or compression of the outer sleeve against the enclosed rod may damage the vascular prosthesis as it is drawn through the sleeve.
2. DO NOT use the tunneler handle rod without the compatible sleeve and tip.
3. DO NOT use the tunneler if it does not assemble properly.

CLEANING PRIOR TO STERILIZATION

The tunneler requires disassembly, cleaning, inspection, sterilization, and assembly before each use. Personnel should wear appropriate attire when handling the components. Immediately after use, disassemble the tunneler and rinse the components in cool running tap water to aid in the removal of visible debris. A mechanical cleaning system or manual cleaning method may be used to clean the GORE® Tunneler. Consult the mechanical cleaning system manufacturer's instructions for cleaning surgical instruments.

The following manual cleaning method is suggested:

1. Detergents of neutral pH (7) are usually recommended for cleaning surgical instruments. The manufacturer's directions for the cleaning agents should be consulted.
2. Immediately after washing components, rinse in fresh running water and/or distilled water to remove all traces of detergents and debris. Thoroughly dry all components.
3. Components should be inspected for cleanliness and damage.

STERILIZATION

DO NOT sterilize the GORE® Tunneler in the original packaging materials. Sterilizing the GORE® Tunneler with ethylene oxide is not recommended. Sterilization instructions are for wrapped items. Sterility of the product is the responsibility of the health care institution.

Using a validated gravity displacement steam sterilizer: Autoclave at or above 250°F (121°C) for 30 minutes or 270°F (132°C) for 15 minutes.

Using a validated pre-vacuum (also known as a high vacuum) steam sterilizer: Autoclave at or above 270°F (132°C) for 3 minutes.

ASSEMBLY AFTER STERILIZATION

The handle rod, compatible sleeve and tip must be properly assembled prior to use.

1. Wearing sterile gloves, grasp the handle of the tunneler and insert the rod into the sleeve following the curvature of the sleeve. DO NOT force the components to fit together.
2. Seat the hollow sleeve firmly onto the taper lock fitting at the base of the handle.
3. Use the appropriate tip with the compatible sleeve. Screw the tip onto the handle rod, making sure that the tip is centered on the sleeve, and hand tighten. The tip is adequately tightened when there is minimal movement of the hollow sleeve on the handle rod.
4. The tunneler is now ready for use.

OPERATIVE TECHNIQUES

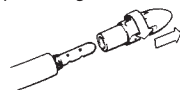
1. Standard surgical practice should be followed in creating proximal and distal incisions for the tunneling device. Use the assembled GORE® Tunneler to create a tissue tunnel between the incisions.



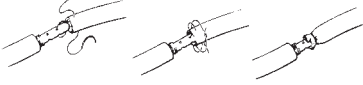
2. To facilitate the creation of the tissue tunnel, grasp the hollow sleeve at midpoint and insert the tunneler into an incision. Advance the tunneler through the tissue. Beyond the midpoint, grasp the handle and complete advancement of the tunneler to the opposite incision.



3. When a satisfactory tunnel has been created, unscrew and remove the bullet-tip from the end of the rod that is protruding from the incision.



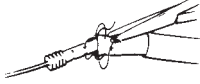
4. Place a suture through one pair of holes in the head of the rod. Next, place the suture through the end of the appropriately sized graft and draw the graft over the head of the rod, securing it by wrapping and tying the suture around the graft and rod.



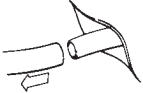
5. Holding the outer sleeve in place, carefully slide the rod and graft through the sleeve.



6. When an incision is reached, remove the graft from the rod by cutting the suture or graft.



7. Holding the graft at the incision site, carefully slide the sleeve out of the tissue tunnel by pulling on the end protruding from the incision site. The graft remains behind in a close fitting tunnel. Proceed with the vascular anastomosis.



DEFINITIONS



Caution



Consult Instructions for Use



Catalogue Number



Batch Code



Authorised Representative in the European Community



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



Store in a Cool Place



Keep Dry



Manufacturer



Non-Sterile



AN0307-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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