

INSTRUCTIONS FOR USE - MARINA VASCULAR TUNNELER

STERILITY

The Marina Tunneler and replacement parts are supplied NON-STERILE.

Clean and sterilize your Marina Tunneler and replacement parts prior to use.

REPLACEMENT PARTS

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

DESCRIPTION

The Marina Tunneler is made from surgical-grade stainless steel and anodized aluminum. These materials are designed to withstand repeated use and re-sterilization.

INDICATION

The Marina 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 tunneler from mechanical damage.

- 1. Do not bend the rod or sleeve. This will cause metal fatigue that can lead to breakage.
- 2. Do not use the tunneler 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, including the cap and any tip(s). Then rinse all 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 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. The manufacturer's directions for the cleaning agents should be consulted.
- 2. Immediate after washing components, rinse in fresh running water and/or distilled water to remove all traces of detergents and debris. Thoroughly dry all the components.
- 3. Components should be inspected for cleanliness and damage.

STERILIZATION

Using a validated pre-vacuum (also known as a high vacuum) steam sterilizer: Autoclave at or above 270°F (132°C) for 4 minutes.

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.

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

ASSEMBLY AFTER STERILIZATION

The entire Tunneler assembly, including the rod, compatible sleeve, tip and cap (where applicable), 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 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. If the tunneler includes a cap and handle storage compartment, the cap should also be threaded snugly prior to use.
- 5. The tunneler is now ready for use.

OPERATIVE TECHNIQUES (For reference only)

- 1. Standard surgical practice should be followed in creating proximal and distal incisions for the tunneling device. Use the assembled 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 the 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 the on the end protruding from the incision site. The graft remains behind in a close-fitting tunnel. Proceed with the vascular anastomosis.

Manufactured for Marina Medical Instruments, Inc.

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phone: 954.924.4418

fax: 954.924.4419