ADVANCED SEALING

Greater surface area contact and sealing at multiple levels

- Surface contact between a transcatheter aortic valve and the native anatomy is critical for effective sealing
- Evolut™ PRO TAV’s conforming frame and consistent radial force enables contact at multiple levels
- The external wrap provides added tissue volume between the TAV and native anatomy to help reduce gaps.

Legacy and Evolut Pro Design Combines Three Sealing Mechanisms

Conformable Frame
Self-expanding nitinol frame conforms to annulus.

Consistent Radial Force
Frame oversizing and cell geometry provide consistent radial force across treatable annulus range.

External Tissue Wrap
Increases surface contact with native anatomy and promotes tissue interaction.¹

Animal studies suggest favorable healing response and interaction with native tissue

- Low inflammatory response¹
- Thin and even layer of tissue growth grossly observed at 90 days post-implant¹
  - Thin and even layer of endothelial cells on inner lumen of device

Example picture from MDT research study on file illustrating tissue interaction, Evolut PRO explanted from Porcine Model at 60 Days Cross Section between Nodes 1 and 2.²

¹ Medtronic, data on file. 90 day porcine GLP Evolut R study, results may not be indicative of clinical performance.
² Medtronic, data on file. 60 day porcine research study model, results may not be indicative of clinical performance.
Prior to Use: Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter by removing it from the packaging. This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. Refer to Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with access vessel diameters of 5 mm when using Model ENVE RE-US or 5.5 mm when using Model ENVE R-N-US; or patients must present with an ascending aortic (direct access) aortic area ≥ 60 mm² from the base plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebral) ≥ 30° for right subclavian/axillary access or ≥ 70° for femoral and left subclavian/axillary access. Use caution when using the supra-aortic cerebrovascular system component migration/embolization. Once annular contact is made, the bioprosthesis leaflets during device closure. For direct aortic access procedures, use a separate introducer sheath; do not use the EnVeo R InLine sheath. Adequate rinsing of the bioprosthesis with sterile saline, as described in the Instructions for Use, is mandatory before implantation. During rinsing, do not touch the leaflets or squeeze the bioprosthesis. If a misfold is detected, remove the bioprosthesis and examine the damage for complications (for example, permanent frame deformation, frayed sutures, or valve tears). Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than once as the bioprosthesis may become permanently stuck to the catheter sheath. Do not use the direct aortic access system component migration/embolization • stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other cerebrovascular event. Do not attempt to retrieve a bioprosthesis. Do not attempt to recapture until the bioprosthesis is free from annular contact, and then reposition in the retrograde direction. If necessary, and the radiopaque capsule marker has not yet reached the distal end of the radiopaque pedicle attachment (point of no recapture), retrieval of the bioprosthesis from the patient is recommended. Retract the bioprosthesis into the delivery catheter and confine the catheter to kink which could increase the risk of vascular complications (for example, vessel dissection or rupture). Once deployment is complete, reposition the bioprosthesis such that the deployment area is free of aneurysmal or dilated artery segment. Do not attempt to reposition the bioprosthesis by force. Do not use the device if the delivery catheter is stuck or if the catheter is at least 10% kinked. Do not attempt to retrieve or to recapture a bioprosthesis if any one of the outflow struts is protruding from the capsule. If any one of the outflow struts has deployed from the capsule, the bioprosthesis must be released from the catheter before catheter removal. If using a separate introducer sheath, if increased resistance is encountered when removing the catheter, do not force passage. Do not force passage. Do not attempt to remove the catheter without first advancing the bioprosthesis. Improper force on the catheter could increase the risk of vascular complications (for example, vessel dissection or rupture). Once deployment is complete, reposition the bioprosthesis such that the deployment area is free of aneurysmal or dilated artery segment. Do not attempt to ret}