Medtronic

Evolut™ FX+ System

MR Evolut™ FX+ Transcatheter Aortic Valve

Evolut™ FX Delivery Catheter System

Evolut™ FX Loading System

Instructions for Use

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Explanation of symbols on package labeling

 Use-by date

 Consult instructions for use or consult electronic instructions for use

 Do not reuse

 Do not resterilize

 Size

 Serial number

 Sterile LC: Device has been sterilized using liquid chemical sterilants according to EN/ISO 14160

 Catalog number

 Lower limit of temperature

 Quantity

 Lot number

 Sterilized using ethylene oxide

 Nonpyrogenic

 MR Conditional

 Do not use if package is damaged and consult instructions for use

 Manufacturer

 Date of manufacture

 Model

 For US audiences only

 Keep dry

 Keep away from sunlight

 Manufactured in

 Maximum guidewire diameter

 Contains biological material of animal origin

 Single sterile barrier system

 Double sterile barrier system

UDI Unique Device Identifier

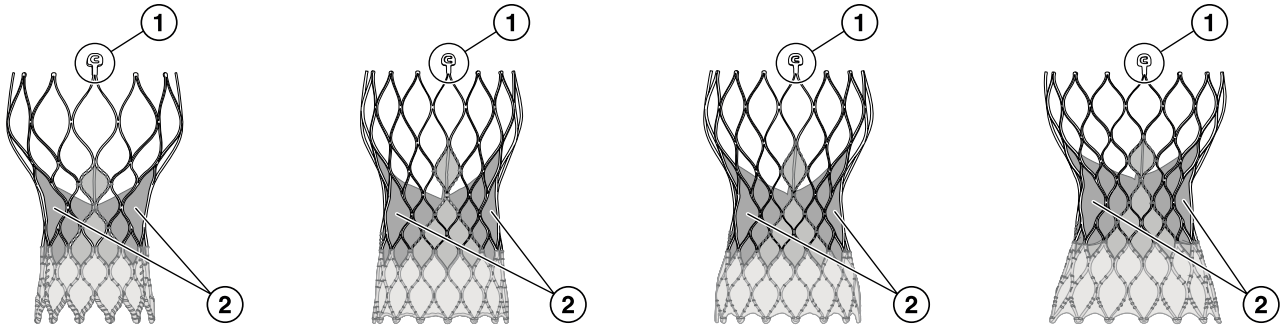
1 Device description

Caution: Implantation of the Medtronic Evolut FX+ system should be performed only by physicians who have received Medtronic Evolut FX+ training. These devices are supplied sterile for single use only. After use, dispose of the delivery catheter system and the loading system in accordance with local regulations and hospital procedures. Do not resterilize.

The Medtronic Evolut FX+ system is a recapturable transcatheter aortic valve replacement system, which includes the Evolut FX+ transcatheter aortic valve (bioprosthesis)[1], the delivery catheter system (catheter), and the loading system (LS).

1.1 Evolut FX+ transcatheter aortic valve (bioprosthesis)

Figure 1. Evolut FX+ transcatheter aortic valve (bioprosthesis)



1 "C" paddle
2 Windows

The bioprosthesis is manufactured by suturing 3 valve leaflets and an inner skirt, made from a single layer of porcine pericardium, onto a self-expanding, multi-level, radiopaque frame made of nitinol. The support frame includes three gold radiopaque markers approximately 3 mm from the inflow portion of the TAV frame, below the 3 tissue commissure pads. The support frame has expanded windows (*Figure 1*) behind each of the 3 valve leaflets for post implant access to the coronary ostia for potential future percutaneous coronary intervention (PCI). The bioprosthesis has a porcine pericardial tissue outer skirt (wrap), which is 1.5 cells in height and is sutured to the inflow section of the bioprosthesis. It is designed to replace the native, surgical bioprosthetic, or transcatheter bioprosthetic aortic heart valve without open heart surgery and without concomitant surgical removal of the failed valve.

Table 1. Heart valve materials

Component	Materials
Tissue	Processed porcine pericardium
Frame	Nitinol (a nickel titanium alloy)
Suture	Polyethylene[a]
Radiopaque markers	Gold

[a] The Evolut FX+ 23 mm valve also uses expanded polytetrafluoroethylene (ePTFE).

The bioprosthesis is processed with alpha-amino oleic acid (AOA™), which is a compound derived from oleic acid, a naturally occurring long-chain fatty acid. The bioprosthesis is available for a range of aortic annulus diameters (*Table 2*).

Table 2. Patient anatomical criteria

Bioprosthesis model	Size	Aortic annulus diameter[a]	Aortic annulus perimeter (π × aortic annulus diameter)[a]
EVFXPLUS-23	23 mm	17[b]/18 mm to 20 mm	53.4[b]/56.5 mm to 62.8 mm
EVFXPLUS-26	26 mm	20 mm to 23 mm	62.8 mm to 72.3 mm

[1] The terms "bioprosthesis" and "transcatheter aortic valve" are synonymous terms and are used interchangeably throughout the document to refer to the Evolut FX+ device.

Table 2. Patient anatomical criteria (continued)

Bioprosthesis model	Size	Aortic annulus diameter[a]	Aortic annulus perimeter (π × aortic annulus diameter)[a]
EVFXPLUS-29	29 mm	23 mm to 26 mm	72.3 mm to 81.7 mm
EVFXPLUS-34	34 mm	26 mm to 30 mm	81.7 mm to 94.2 mm

[a] For TAV in SAV and TAV in TAV, diameter and perimeter criteria are applicable to the failed SAV or TAV measured inner diameter.

[b] Applicable to surgical aortic valves (SAV) and failed transcatheter aortic valves (TAV) only.

1.2 Delivery catheter system (catheter)

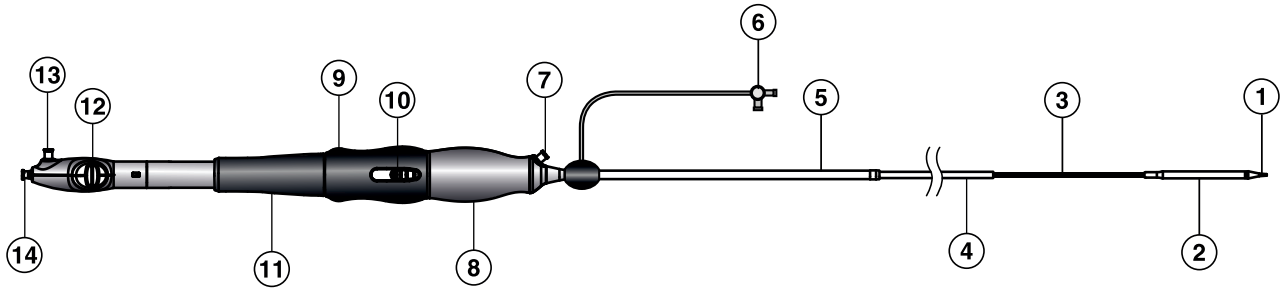
The catheter comes in different sizes. Refer to *Table 3* for system compatibility. Refer to *Figure 2* and *Figure 3* for catheter components.

The catheter facilitates the placement of the bioprosthesis within the annulus of the aortic valve. The catheter assembly is flexible and compatible with a 0.035 in (0.889 mm) guidewire. The distal (deployment) end of the system features an atraumatic, radiopaque catheter tip and a capsule that covers and maintains the bioprosthesis in a crimped position. The capsule includes a distal flare to enable the bioprosthesis to be partially or fully recaptured after partial deployment. A green stability layer is fixed at the handle and extends down the outside of the catheter shaft. It provides a barrier between the retractable catheter and the introducer sheath and vessel walls, thus enabling the catheter to retract freely. An Evolut FX inline sheath is assembled over the stability layer, which functions as a hemostatic introducer sheath and minimizes the access site size to the capsule diameter. The 23-29 mm catheter model is compatible with sheaths that can accommodate an 18 Fr (6.0 mm) device. The 34 mm catheter model is compatible with sheaths that can accommodate a 22 Fr (7.33 mm) device.

The delivery catheter system consists of a catheter with an integrated handle to provide the user with accurate and controlled deployment. The handle is on the proximal end of the catheter and is used to load, deploy, recapture, and reposition the bioprosthesis. The handle features a gray front grip used to stabilize the system. The deployment knob turns to deploy the bioprosthesis precisely. Arrows on the deployment knob indicate the direction of rotation required to deploy the bioprosthesis. If desired, the deployment knob can be turned in the opposite direction to partially or fully recapture the bioprosthesis if the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment. Once the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment, it is at the point of no recapture. The deployment knob also features a trigger, which can be engaged to make macro adjustments to the capsule position. A dark blue hand rest connects to the deployment knob. The end of the handle features a tip-retrieval mechanism, which can be used to withdraw the catheter tip to meet the capsule after the device has been fully deployed.

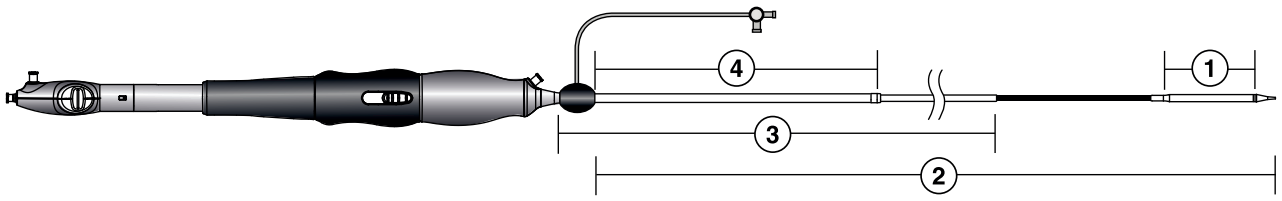
The catheter packaging contains an integrated loading bath and a removable tray with 3 rinsing bowls for loading and rinsing the bioprosthesis. The integrated loading bath features a mirror, which aids in accurate placement of the bioprosthesis frame paddles during loading. In addition to these features, the device packaging is swiveled and secured to facilitate the bioprosthesis loading procedure.

Figure 2. Catheter



1 Catheter tip
2 Capsule (Model D-EVOLUTFX-2329: 18 Fr [6.0 mm] outer diameter [OD]; Model D-EVOLUTFX-34: 22 Fr [7.33 mm] OD)
3 Catheter shaft
4 Stability layer
5 Model D-EVOLUTFX-2329: 14 Fr equivalent Evolut FX inline sheath (18 Fr [6.0 mm] OD); Model D-EVOLUTFX-34: 18 Fr equivalent Evolut FX inline sheath (22 Fr [7.33 mm] OD)
6 Evolut FX inline sheath flush port
7 Stability layer flush port
8 Gray front grip
9 Deployment knob
10 Trigger
11 Dark blue hand rest
12 Tip-retrieval mechanism
13 Capsule flush port
14 Wire lumen flush port

Figure 3. Catheter



1 7.6 cm (Model D-EVOLUTFX-2329); 7.7 cm (Model D-EVOLUTFX-34)
2 108 cm
3 90 cm
4 30 cm

Figure 4. Catheter distal tray

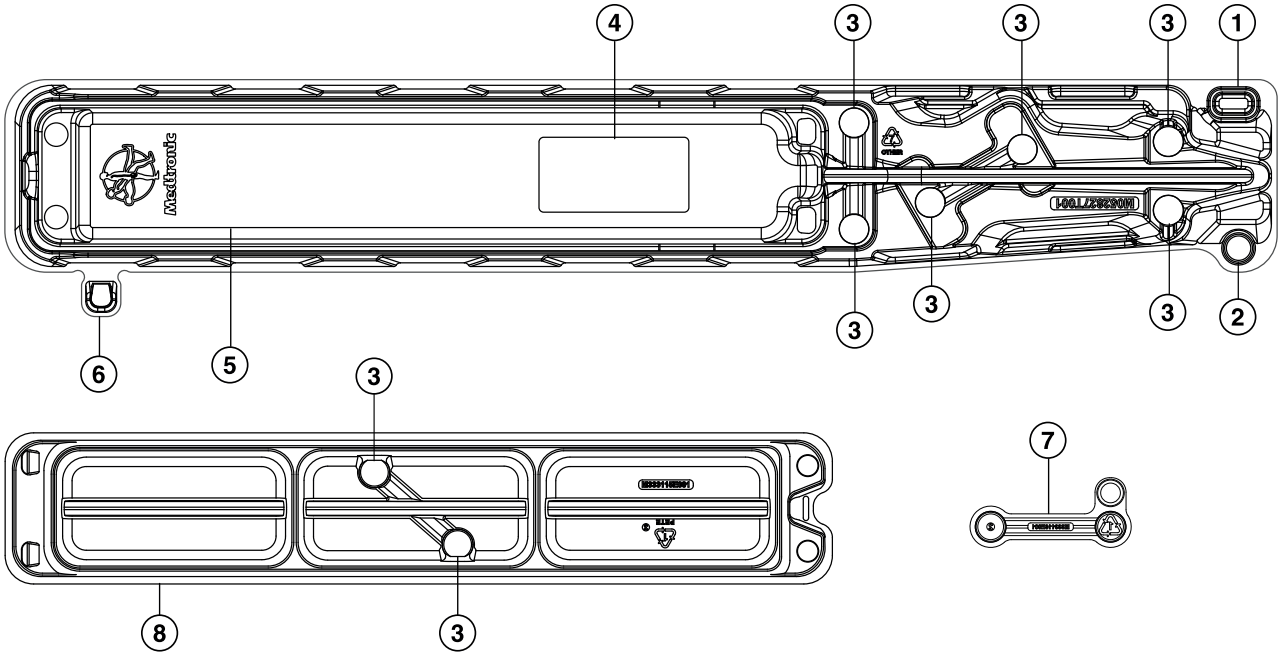
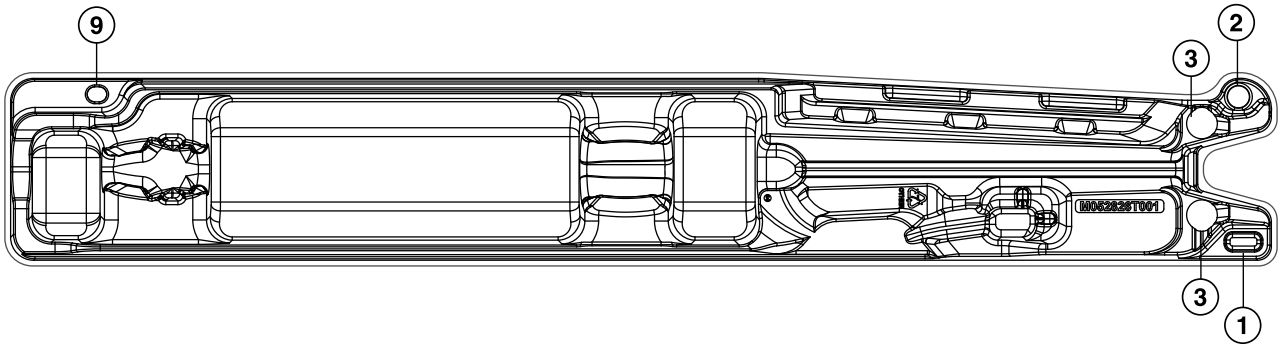


Figure 5. Catheter proximal tray

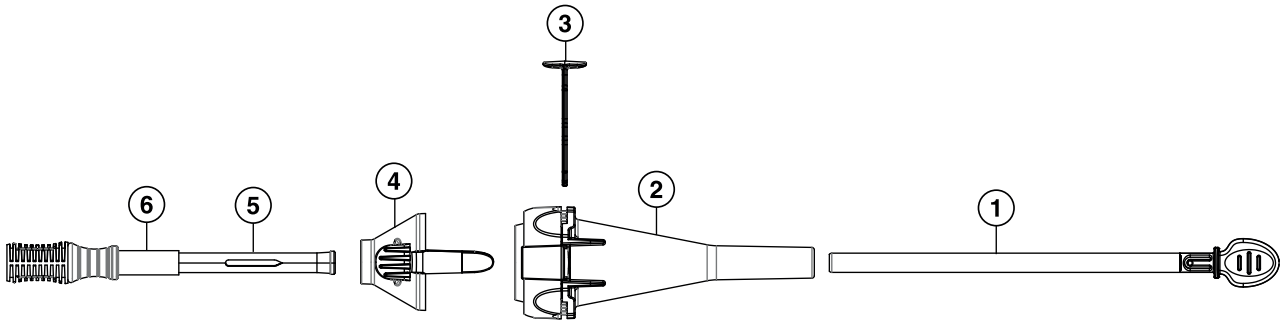


1 Tray connector
2 Swivel hinge
3 Clip holder
4 Mirror
5 Integrated loading bath
6 Tray tab
7 Locking clip
8 Rinsing bowls
9 Tray tab holder

1.3 Loading system (LS)

The loading system compresses the bioprosthesis into the catheter. The loading system comes in different sizes. Refer to *Table 3* for system compatibility. Refer to *Figure 6* for components.

Figure 6. Evolut FX loading system



1 Catheter tip guide tube
2 Inflow cone
3 Backplate
4 Outflow cone
5 Capsule guide tube
6 Locking collar

Table 3. System compatibility

Bioprosthesis model	Compatible loading system models	Compatible catheter models
EVFXPLUS-23	L-EVOLUTFX-2329	D-EVOLUTFX-2329
EVFXPLUS-26		
EVFXPLUS-29		
EVFXPLUS-34	L-EVOLUTFX-34	D-EVOLUTFX-34

2 Indications

The Medtronic Evolut FX+ system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Medtronic Evolut FX+ system is indicated for use in patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

3 Contraindications

The Evolut FX+ system is contraindicated in patients who cannot tolerate the device materials listed in *Table 1*, an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections.

4 Warnings and precautions

Carefully read all warnings, precautions, and instructions for use for all components of the system before use. Failure to read and follow all instructions or failure to observe all stated warnings could cause serious injury or death to the patient.

4.1 Warnings

General

- Implantation of the Medtronic Evolut FX+ system should be performed only by physicians who have received Medtronic Evolut FX+ training.
- The transcatheter aortic valve is to be used only in conjunction with the delivery catheter system and the loading system.
- System failure could occur if an incorrect combination of devices is used. Refer to *Table 3* for system compatibility.
- This procedure should only be performed where emergency aortic valve surgery can be performed promptly.
- **Do not** use any of the Medtronic Evolut FX+ system components if any of the following has occurred:
  - It has been dropped, damaged, or mishandled in any way
  - The Use By date has elapsed
- Mechanical failure of the delivery catheter system and/or accessories may result in patient complications.

Transcatheter aortic valve (bioprosthesis)

- **Do not** use the bioprosthesis if any of the following conditions is observed:
  - There is any damage to the container (for example, cracked jar or lid, leakage, particulate material, broken or missing seals or jar lid gasket)
  - The serial number tag does not match the container label
  - The freeze indicator in the secondary package has activated
  - The storage solution does not completely cover the bioprosthesis
- Accelerated deterioration of the bioprosthesis due to calcific degeneration may occur in:
  - Children, adolescents, or young adults
  - Patients with altered calcium metabolism (for example, chronic renal failure, or hyperparathyroidism)

4.2 Precautions

General

- **Do not** contact any of the Medtronic Evolut FX+ system components with cotton or cotton swabs.
- **Do not** expose any of the Medtronic Evolut FX+ system components to organic solvents, such as alcohol.
- **Do not** introduce air into the catheter.
- **Do not** expose the bioprosthesis to solutions other than the storage and rinse solutions.
- **Do not** add antibiotics or any other substance to either the storage or rinse solutions. **Do not** apply antibiotics or any other substance to the bioprosthesis.
- **Do not** allow the bioprosthesis to dry. Maintain tissue moisture with irrigation or immersion.
- **Do not** attempt to repair a damaged bioprosthesis.
- **Do not** handle or use forceps to manipulate the bioprosthesis leaflet tissue.
- **Do not** deform the bioprosthesis in excess of what is experienced during crimping, loading, and implantation.
- Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up.
- The safety and effectiveness of the Medtronic Evolut FX+ system have not been evaluated in the pediatric population.
- The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations:
  - Patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined below:

    - **Symptomatic severe high-gradient aortic stenosis:** aortic valve area ≤1.0 cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient ≥40 mmHg, or a peak aortic-jet velocity ≥4.0 m/s

    - **Symptomatic severe low-flow/low-gradient aortic stenosis:** aortic valve area ≤1.0 cm^2 or aortic valve area index ≤0.6 cm^2/m^2; a mean aortic valve gradient <40 mmHg; and a peak aortic-jet velocity <4.0 m/s
  - With untreated, clinically significant coronary artery disease requiring revascularization
  - With a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the preexisting prosthetic heart valve
  - Patients with liver failure (Child-Pugh Class C)
  - With cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support
  - Patients who are pregnant or breastfeeding
- Implanting the Evolut FX+ bioprosthesis in a degenerated surgical bioprosthetic valve (transcatheter aortic valve in surgical aortic valve [TAV in SAV]) should be avoided in the following conditions. The degenerated surgical bioprosthetic valve presents with a:
  - Significant concomitant paravalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (for example, wireform frame fracture)
  - Partially detached leaflet that in the aortic position may obstruct a coronary ostium
  - Stent frame with a manufacturer's labeled inner diameter <17 mm
- Before implanting the Evolut FX+ bioprosthesis in a degenerated transcatheter bioprosthetic valve (transcatheter aortic valve in transcatheter aortic valve [TAV in TAV]), additional factors regarding failed valve size and patient anatomy must be considered in order to ensure patient safety (for example, to avoid coronary obstruction). The potential need for future coronary access should be considered. TAV in TAV implantation should be avoided in the following conditions:
  - The degenerated TAV presents with a significant concomitant paravalvular leak (between the prosthesis and the native annulus),
  - The degenerated TAV is not securely fixed in the native annulus, or is not structurally intact (for example, frame fracture) or
  - The risk of coronary obstruction or sinus sequestration after Evolut FX+ bioprosthesis implantation is high

- The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patient populations presenting with the following:
  - Blood dyscrasias as defined: leukopenia (WBC <1000 cells/mm^3), thrombocytopenia (platelet count <50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states
  - Congenital unicuspid valve
  - Mixed native aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3–4+])
  - Moderate to severe (3–4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation
  - Hypertrophic obstructive cardiomyopathy
  - New or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation
  - Native aortic annulus size <18 mm or >30 mm per the baseline diagnostic imaging or a surgical or transcatheter bioprosthetic aortic annulus size <17 mm or >30 mm
  - Transarterial access not able to accommodate the following:
    - 22 Fr introducer sheath or the 18 Fr equivalent Evolut FX inline sheath
    - 18 Fr introducer sheath or the 14 Fr equivalent Evolut FX inline sheath
  - Prohibitive left ventricular outflow tract calcification
  - Sinus of Valsalva anatomy that would prevent adequate coronary perfusion
  - Significant aortopathy requiring ascending aortic replacement
  - Moderate to severe mitral stenosis
  - Severe ventricular dysfunction with left ventricular ejection fraction (LVEF) <20%
  - Symptomatic carotid or vertebral artery disease
  - Severe basal septal hypertrophy with an outflow gradient
  - A known hypersensitivity or contraindication to any of the following that cannot be adequately pre-medicated:
    - Aspirin or heparin (HIT/HITTS) and bivalirudin
    - Ticlopidine and clopidogrel
    - Nitinol (titanium or nickel)
    - Gold
    - Contrast media

Before use

- Accelerated deterioration due to calcific degeneration of bioprostheses may occur in:
  - Children, adolescents, or young adults
  - Patients with altered calcium metabolism (for example, chronic renal failure, or hyperparathyroidism)
- 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 *Table 2* for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed in *Chapter 5*.
- Patients must present with transarterial access vessels with diameters that are ≥5.0 mm when using Model D-EVOLUTFX-2329 or ≥6.0 mm when using Model D-EVOLUTFX-34, or patients must present with an ascending aortic (direct aortic) access site ≥60 mm from the basal plane.
- Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of >30° for right subclavian/axillary access or >70° for femoral and left subclavian/axillary access.
- For subclavian access, patients with a patent Left Internal Mammary Artery (LIMA) graft must present with access vessel diameters that are either ≥5.5 mm when using Model D-EVOLUTFX-2329 or ≥6.5 mm when using Model D-EVOLUTFX-34. Use caution when using the subclavian/axillary approach in patients with a patent Left Internal Mammary Artery (LIMA) graft (for left subclavian/axillary approach only) or patent Right Internal Mammary Artery (RIMA) graft (for right subclavian/axillary approach only).
- For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a preexisting patent RIMA graft.
- For transfemoral access, use caution in patients who present with multiplanar curvature of the aorta, acute angulation of the aortic arch, an ascending aortic aneurysm, or severe calcification in the aorta and/or vasculature. If ≥2 of these factors are present, consider an alternative access route to prevent vascular complications.
- Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.
- Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (minimum of 15 minutes). In the event of eye contact, flush with water for a minimum of 15 minutes and seek medical attention immediately.

- The bioprosthesis and the glutaraldehyde storage solution are **sterile**. The outside of the bioprosthesis container is **nonsterile** and must not be placed in the sterile field.
- Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when 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.
- Before catheter insertion, remove the loading stylet.

During use

- For direct aortic and subclavian access procedures, care must be exercised when using the tip-retrieval mechanism to ensure adequate clearance to avoid advancement of the catheter tip through the bioprosthesis leaflets during device closure.
- For direct aortic access procedures, use a separate introducer sheath; do not use the Evolut FX inline sheath. Maintain the Evolut FX inline sheath at the proximal end of the catheter throughout the procedure.
- Adequate rinsing of the bioprosthesis with sterile saline, as described in the Instructions for Use, is mandatory before implantation. No other solutions, drugs, chemicals, or antibiotics should ever be added to the glutaraldehyde or rinse solutions, as irreparable damage to the leaflet tissue, which may not be apparent under visual inspection, may result.
- During rinsing, do not touch the leaflets or squeeze the bioprosthesis.
- If a misload is detected during fluoroscopic (cine mode) inspection, do not attempt to reload the bioprosthesis. Discard the entire system. The valve, catheter, loading system, loading tray, and saline all must be replaced with new sterile components. A misload is defined as one or more of the following:
  - Inflow crown overlap (non-uniform shadow starting at the inflow) that has not ended before the 4th node from the inflow.
  - Outflow crown misalignment and/or not parallel to the paddle attachment.
  - Curved or bent capsule.
  - Direct load as detailed in *Section 9.1.4*, *Step 17*.
  - Shadow or outline in outflow indicating a bent strut.
- Inflow crown overlap that has not ended before the 4th node within the capsule, increases the risk of an infold upon deployment in constrained anatomies, particularly with moderate-severe levels of calcification and/or bicuspid condition.
  - Do not attempt to direct load the valve (for example, loading the valve without completing *Step 17* in *Section 9.1.4* and simply advancing the capsule to load the valve). This increases the likelihood of excessive inflow crown overlap. If a valve has been direct loaded, discard the entire system. The valve, catheter, loading system, loading tray, and saline all must be replaced with new sterile components.
- Prevent contamination of the bioprosthesis, its storage solution, the catheter, and the loading system with glove powder.
- If a bioprosthesis and catheter have been removed from a patient, dispose of both the bioprosthesis and catheter; do not attempt to reuse either component. Both the bioprosthesis and catheter must be replaced with new sterile components.
- While the catheter is in the patient, ensure the guidewire is extending from the proximal end of the catheter. Do not remove the guidewire from the catheter while the catheter is inserted in the patient.
- There will be some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and investigate the cause of the resistance (for example, magnify the area of resistance) before proceeding. Do not force passage. Forcing passage could increase the risk of vascular complications (for example, vessel dissection or rupture).
- Use the deployment knob to deploy and recapture the bioprosthesis. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis.
- From annular contact (or contact with the failed valve, for valve-in-valve procedures) to just before the point of no recapture, the bioprosthesis will occlude cardiac output. Promptly deploy or recapture the valve during this occlusive phase as prolonged obstruction or occlusion of blood flow may lead to hypotension, bradycardia, conduction disturbance, congestive heart failure, pulmonary edema, or death.
- If the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment, the bioprosthesis can be recaptured or repositioned. During deployment, the deployment knob provides a tactile indication as a notification before the point of no recapture.
- Infold detection steps are outlined in *Section 9.2.4*. An observation of any inward fold or crease in the valve, extending from the inflow, identified as a dark line under fluoroscopic (cine mode) inspection, may indicate an infold. If identified, and if the patient's condition allows, do not proceed and do not release the valve.
  - Recapture, remove and discard the entire system. The valve, catheter, loading system, loading tray, and saline all must be replaced with new sterile components.
  - Predilatation is strongly recommended prior to subsequent implantation attempts to minimize infold risk.
  - If initial predilatation does not prevent infolding, reassess valve sizing in the presence of complex anatomies.

  - If an infold is detected and the valve is removed, consider a slightly lower depth of implantation of the second valve to provide additional space for frame expansion.
- Implanting a valve with an unresolved infold increases the risk of PVL and need for post implant dilatation, which is associated with higher rates of adverse events such as dislodgement and dissection.

  Note: Predilatation may confer some risk to the patient (for example, liberation of embolic debris, damage to the tissue, or perforation of the aortic root). Patient anatomical characteristics (for example, bicuspid anatomy, excessive or asymmetric leaflet calcification, and possible leaflet fusion) should be considered by the heart team when evaluating and determining the risk/benefit of predilatation and treatment plan for each patient. For TAV in TAV procedures, the characteristics of the failed TAV (for example, under-expansion, depth of index implant) should be considered by the heart team when evaluating and determining the risk/benefit of predilatation and the treatment plan for each patient.
- Once the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment (point of no recapture), retrieval of the bioprosthesis from the patient (for example, use of the catheter) is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery.
- During deployment, the bioprosthesis can be advanced or withdrawn as long as annular contact (or contact with the failed valve, for valve-in-valve procedures) has not been made. Once annular contact is made, the bioprosthesis cannot be advanced in the retrograde direction; recapture until the bioprosthesis is free from annular contact, and then reposition in the retrograde direction. If necessary, and the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction.

  Note: For TAV in SAV or TAV in TAV procedures, fully recapture the bioprosthesis before repositioning to reduce risk of hang up or snagging on the failed bioprosthesis and to aid with positioning using the radiopaque capsule marker band.

  Caution: Use the handle of the delivery system to reposition the bioprosthesis. Do not use the outer catheter sheath.
- Physicians should use judgment when considering repositioning a fully deployed bioprosthesis (for example, using a snare, balloon, and/or forceps). Repositioning the bioprosthesis is not recommended, except in cases where imminent serious harm or death is possible (for example, coronary occlusion). Repositioning of a deployed valve may cause aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery.
- 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 the catheter can be withdrawn.
- Ensure the capsule is closed before catheter removal.
- When using a separate introducer sheath, if increased resistance is encountered when removing the catheter through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and/or harm to the patient. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter and confirm that it is complete.
- Postprocedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis.
- Postprocedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment.
- Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage.
- Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long-term.

Post-implant balloon dilatation considerations

If valve function or sealing is impaired due to excessive calcification or incomplete expansion, a post-implant balloon dilatation (PID) of the bioprosthesis may improve valve function and sealing. If the heart team determines that balloon dilatation is appropriate, consider all of the following factors when selecting the dilatation parameters to ensure patient safety:

- Balloon model
- Balloon size
- Balloon position
- Inflation pressure
- Patient anatomy

To mitigate trauma to the annulus or the Evolut FX+ TAV bioprosthetic leaflets, the maximum balloon size chosen for dilatation using a compliant, semi-compliant, or non-compliant balloon should not exceed the level set forth in *Table 4*, and the applied inflation pressure should be no greater than 2 atm.

Table 4. Post-implant balloon dilatation sizing

Evolut FX+ size	23 mm			26 mm				29 mm				34 mm				
Native annulus (failed SAV or TAV inner) diameter (in mm)	17[a]/18	19	20	20	21	22	23	23	24	25	26	26	27	28	29	30
TAV waist diameter (in mm)	20	20	20	22	22	22	22	23	23	23	23	24	24	24	24	24
Maximum balloon diameter (in mm) for compliant and semi-compliant balloons @ 2 atm	17[a]/18	19	20	20	21	22	23	23	24	25	25	26	27	28	28	28
Maximum balloon diameter (in mm) for non-compliant balloons @ 2 atm	16[a]/17	18	19	19	20	21	22	22	23	23	23	25	25	25	25	25

[a] Applicable to surgical aortic valves (SAV) and failed transcatheter aortic valves (TAV) only

Caution: Overexpansion of the narrowest portion (waist) of the Evolut FX+ TAV beyond the levels set forth in *Table 4* has been demonstrated through bench data to cause damage to the bioprosthetic leaflets. Complaints of damage to the bioprosthetic leaflets during post-implant balloon dilatation have been reported in some clinical cases, resulting in moderate to severe aortic insufficiency, which may be detected acutely or during follow-up.

It is important to note that the mechanical compliance properties of the selected balloon influence the dilatation dynamics.

Balloons should not be inflated beyond 2 atm of applied pressure.

The maximum balloon sizes in *Table 4* are derived from bench testing based on a single Evolut FX+ TAV dilation to 2 atm. Multiple dilations of the Evolut FX+ TAV increases the risk of damage to the bioprosthetic leaflets.

Compliant and semi-compliant (softer) balloons will more readily conform to the hourglass profile of the TAV bioprosthesis at lower pressures, but must be inflated at pressures that preserve the hourglass profile of the TAV.

Conversely, non-compliant (stiffer) balloons will achieve the nominal diameter during inflation irrespective of the underlying annulus or TAV resistance and should be downsized (see *Table 4*).

For additional instructions on the use of balloon catheter devices refer to the specific balloon catheter manufacturer's labeling.

In the event that larger balloon diameters than those listed in *Table 4* are required to expand the Evolut FX+ TAV due to clinically important residual aortic regurgitation or stenosis, using "bailout" intraventricular balloon positioning when performing PID avoids expansion of the narrowest portion (waist) of the Evolut FX+ TAV. This can mitigate the risk of leaflet damage. Dilatation with intraventricular balloon positioning should be performed with caution in the setting of a smaller ventricle cavity, presence of LVOT calcification, or wire positioning that interferes with mitral valve function, in order to avoid any unintended balloon interaction with anatomy. The balloon's length and diameter, along with the individual patient anatomy, must be considered. Care should also be taken not to exceed the annular diameters when performing PID with intraventricular balloon positioning (see *Table 4*).

In the event that a bailout PID with intraventricular balloon positioning is performed, the nominal diameter of the balloon should not exceed the annular diameter when using compliant or semi-compliant balloons; the nominal diameter of the balloon should be at least 1 mm smaller than the annular diameter when using non-compliant balloons.

4.3 Magnetic resonance imaging (MRI)

MRI may be used on the bioprosthesis only under specific conditions. See *Section 6.2*: MRI Safety Information for more information.

5 Potential adverse events

Potential risks associated with the implantation of the Evolut FX+ bioprosthesis may include, but are not limited to, the following:

- Death
- Myocardial infarction, cardiac arrest, cardiogenic shock, cardiac tamponade
- Coronary occlusion, obstruction, or vessel spasm (including acute coronary closure)
- Cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention)
- Emergent surgical or transcatheter intervention (for example, coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty)
- Prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement

- Prosthetic valve migration/embolization
- Prosthetic valve endocarditis
- Prosthetic valve thrombosis
- Delivery catheter system malfunction resulting in the need for additional re-crossing of the aortic valve and prolonged procedural time
- Delivery catheter system component embolization
- Stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits
- Individual organ (for example, cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure
- Major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding)
- Vascular access-related complications (for example, dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, stenosis)
- Mitral valve regurgitation or injury
- Conduction system disturbances (for example, atrioventricular node block, left-bundle branch block, asystole), which may require a permanent pacemaker
- Infection (including septicemia)
- Hypotension or hypertension
- Hemolysis
- Peripheral ischemia
- Bowel ischemia

General surgical risks applicable to transcatheter aortic valve implantation:

- Abnormal lab values (including electrolyte imbalance)
- Allergic reaction to antiplatelet agents, contrast medium, or anesthesia
- Exposure to radiation through fluoroscopy and angiography
- Permanent disability

6 Patient information

6.1 Registration information

! USA A patient registration form is included in each bioprosthesis package. After implantation, please complete all requested information. The serial number is located on both the package and the identification tag attached to the bioprosthesis. Return the original form to the Medtronic address indicated on the form and provide the temporary identification card to the patient prior to discharge.

! USA Medtronic will provide an Implanted Device Identification Card to the patient. The card contains the name and telephone number of the patient's physician as well as information that medical personnel would require in the event of an emergency. Patients should be encouraged to carry this card with them at all times.

6.2 MRI safety information

The MRI safety information for the Medtronic Evolut FX+ bioprosthesis is presented in *Table 5*.

Table 5. MRI safety information

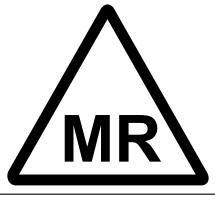
	A patient with the Medtronic Evolut FX+ bioprosthesis may be safely scanned under the following conditions, including immediately after placement of this device. Failure to follow these conditions may result in injury to the patient.
Name/Identification of the device	Evolut FX+ bioprosthesis
Nominal value of static magnetic field [T]	1.5 T or 3.0 T
Maximum spatial field gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil

Table 5. MRI safety information (continued)

Maximum whole body SAR [W/kg]	2 W/kg (Normal Operating Mode)
Maximum head SAR [W/kg]	3.2 W/kg (Normal Operating Mode)
Limits on scan duration	2 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR image artifact	The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter. The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters. For deployment of a Medtronic Evolut FX+ bioprosthesis inside of a failed surgical or transcatheter bioprosthetic valve, consult the MRI labeling pertaining to the failed valve for additional artifact information.	

7 How supplied

7.1 Packaging

The bioprosthesis is supplied **sterile** and **nonpyrogenic** in a glass container and a screw cap with a liner. The outside of the container is **nonsterile** and must not be placed in the sterile field. A freeze indicator is placed inside the labeled carton. If the freeze indicator has been activated, do not use the bioprosthesis.

The catheter is packaged in a single-pouch configuration and sterilized with ethylene oxide gas. The catheter is sterile if the package is undamaged and unopened. The outer surfaces of the pouch are **nonsterile** and must not be placed in the sterile field.

The loading system is packaged in a double-pouch configuration. The loading system is sterile if the pouches are undamaged and unopened. The outer surfaces of the outer pouch are **nonsterile** and must not be placed in the sterile field. The loading system is sterilized with ethylene oxide gas.

7.2 Storage

Store the bioprosthesis at room temperature (5 °C to 25 °C [41 °F to 77 °F]). Avoid exposing to extreme fluctuations of temperature. Do not freeze. Appropriate inventory control should be maintained so that bioprostheses with earlier Use By dates are implanted preferentially.

Caution: Do not use the bioprosthesis if the freeze indicator in the secondary package has activated. If the freeze indicator has activated, dispose of the bioprosthesis in accordance with applicable laws, regulations, and hospital procedures.

Store the catheter and loading system at room temperature in a dry environment.

8 Additional equipment

Note: While extensive, this equipment list is not meant to cover all possible scenarios.

Transesophogeal echocardiogram (TEE) or transthoracic echocardiography (TTE) on standby

Temporary pacer insertion

- Temporary pacemaker lead
- Sterile sleeve for pacemaker lead
- Hemostatic vessel introducer sheath
- Temporary pacemaker generator
- Sterile temporary pacemaker-to-generator cable

If indicated, pulmonary artery catheter insertion

- Standard pulmonary artery catheter
- Hemostatic vessel introducer sheath
- Saline flush line connected to pressure transducer

Baseline aortography via radial, brachial, or femoral approach

- 5 Fr or 6 Fr pigtail angiographic catheter
- 6 Fr hemostatic vessel introducer sheath
- 2-port manifold with saline flush line and pressure tubing or transducer
- Power injector syringe
- Contrast media
- High-pressure power injector tubing

Predilatation of implant site

- 2-port manifold with saline flush and transducer
- 9 Fr hemostatic vessel introducer sheath and a 14 Fr, 18 Fr or 22 Fr hemostatic vessel introducer sheath

  Note: The 23-29 mm catheter model is compatible with sheaths that can accommodate an 18 Fr (6.0 mm) device. The 34 mm catheter model is compatible with sheaths that can accommodate a 22 Fr (7.33 mm) device.
- Standard length 0.035 in (0.889 mm) straight guidewire
- Appropriate suture-mediated closure system, if applicable
- Angiographic catheter
- 0.035 in (0.889 mm) × 260 cm standard high support guidewire to be shaped with a pigtail loop
- Balloon valvuloplasty catheters, ≤4 cm length × 18 mm, 20 mm, 22 mm or 23 mm, and 25 mm, 28 mm, and 30 mm diameters
- Inflation device or syringe and diluted 1:5 contrast media

Bioprosthesis implantation

- 18 Fr or 22 Fr hemostatic vessel introducer sheath

  Note: The 23-29 mm catheter model is compatible with sheaths that can accommodate an 18 Fr (6.0 mm) device. The 34 mm catheter model is compatible with sheaths that can accommodate a 22 Fr (7.33 mm) device.

  Note: A separate introducer sheath is optional for transfemoral and subclavian access procedures.

Standby supplies (must be available in the room)

- Pericardiocentesis tray
- 35 mm × 120 cm single loop snare
- Standard percutaneous coronary intervention (PCI) equipment
- 14 Fr and 18 Fr hemostatic vessel introducer sheaths
- Standard cardiac catheterization lab equipment
- Intra-aortic balloon pump (IABP)

9 Instructions for use

9.1 Inspection and bioprosthesis loading procedure

Caution: Once the bioprosthesis is removed from its container and the catheter and loading system are removed from their packaging, ensure all subsequent procedures are performed in a sterile field.

Caution: Do not allow the bioprosthesis to dry. Maintain tissue moisture with irrigation or immersion.

9.1.1 Inspection before use and swivel tray setup

1. Before removing the bioprosthesis, catheter, or loading system from its primary packaging, carefully inspect the packaging for any evidence of damage that could compromise the sterility or integrity of the device (for example, cracked jar or lid, leakage, broken or missing seals, torn or punctured pouch).

   Caution: Do not use after the Use By date or if there is evidence of damage.

   Caution: Do not use the bioprosthesis if the freeze indicator has been activated.
2. Remove the product from the protective package.
3. Visually check that the product is free of defects. Do not use if any defects are noted.
4. Remove the locking clip attached to the rinsing bowls.
5. Remove the rinsing bowls from the integrated loading bath.
6. Remove the locking clips that connect the distal and proximal trays.
7. Lift the tray connector from the distal tray, and swivel the distal tray 180° counterclockwise.
8. Clip the tray tab on the distal tray to the tray tab holder on the proximal tray.
9. Fill the integrated loading bath with cold, sterile saline (0 °C to 8 °C [32 °F to 46 °F]).

9.1.2 Preparation of the catheter and loading system

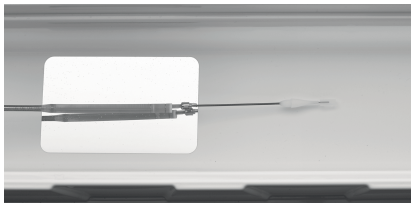
1. Attach a 10 mL syringe filled with sterile saline to the capsule flush port on the proximal end of the handle. Leave the syringe in place until loading is complete.
2. Carefully lift the distal end of the catheter to a near vertical orientation. To prevent kinking, do not bend the catheter severely.
3. Open the capsule and expose the paddle attachment.

   Note: Use the deployment knob to open the capsule completely until the paddle attachment is fully exposed.

4. With the capsule held vertically, flush the capsule flush port. Verify that no catheter leakage is observed during any of the flushing steps. If leakage is observed, use a new system.
5. Submerge the capsule completely in the cold saline bath while flushing the capsule flush port. Continue flushing the capsule until it is completely submerged in the bath to prevent air from entering the catheter (*Figure 7*).

   Note: After the bioprosthesis has been loaded into the capsule, the capsule flush port can no longer be flushed.

   Figure 7.



   Note: The bioprosthesis, catheter, and LS may look slightly different from the figures in *Chapter 9*. The functionality of the system is the same.
6. Secure a locking clip in the clip holder to angle the catheter tip into the integrated loading bath.
7. Place the loading system components in the integrated loading bath.

9.1.3 Bioprosthesis rinsing procedure

1. Fill each of the 3 rinsing bowls (provided within the packaging) with approximately 500 mL of fresh, sterile saline at ambient temperature (15 °C to 25 °C [59 °F to 77 °F]).

   Caution: Do not handle or manipulate the bioprosthesis with sharp or pointed objects. Use atraumatic forceps only.
2. Confirm the integrity of the primary bioprosthesis container. Do not use the bioprosthesis if there is any damage to the container (for example, cracked jar or lid, leakage, particulate material, broken or missing seals or jar lid gasket).
3. Remove the bioprosthesis from its container by carefully grasping one of the bioprosthesis frame paddles with a pair of blunt tipped forceps. Do not use the forceps to grasp the tissue portion of the bioprosthesis. Let any remaining solution drain from the bioprosthesis completely.

   Note: Retain the container with the original solution. It may be needed to store and return a rejected bioprosthesis.
4. Compare the serial number on the container with the serial number on the tag attached to the bioprosthesis.

   Caution: If the serial numbers do not match, do not use the bioprosthesis.
5. Carefully remove the serial number tag from the bioprosthesis and retain the tag.
6. Immerse the entire bioprosthesis in a sterile rinsing bowl.
7. Gently agitate the bioprosthesis by hand for 15 seconds to remove the glutaraldehyde from the bioprosthesis.
8. Repeat *Step 6* and *Step 7* in one of the remaining rinsing bowls.
9. Leave the bioprosthesis submerged in sterile saline in the third rinsing bowl until it is ready to be loaded.

9.1.4 Bioprosthesis loading procedure

Perform the bioprosthesis loading procedure while the distal end of the catheter is immersed in the integrated loading bath filled with cold, sterile saline (0 °C to 8 °C [32 °F to 46 °F]). The bioprosthesis should remain immersed in saline during the loading process to minimize the introduction of air into the loaded system.

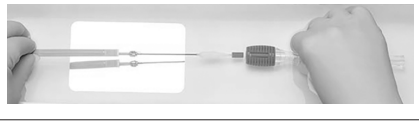
Note: Confirm the loading system and catheter sizes are compatible with the bioprosthesis size (*Table 3*).

Note: Refer to *Figure 6* for Evolut FX loading system components.

Caution: Rapid capsule advancement can contribute to difficulties with loading the valve and can increase the risk of damage to the catheter. Slowly advancing the capsule helps facilitate successful loading.

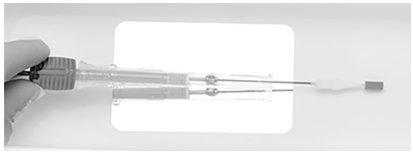
1. Submerge and cool the bioprosthesis in the integrated loading bath filled with cold, sterile saline.
2. Ensure that the capsule guide tube is fully open (unlocked) with the locking collar at the proximal end of the capsule guide tube (*Figure 8*).

   Figure 8.



3. Advance the capsule guide tube over the catheter shaft toward the handle and across the catheter tip (*Figure 9*).

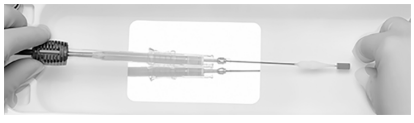
Figure 9.



4. Once the catheter tip has been crossed, fully advance the locking collar to the distal end of the capsule guide tube until it is closed (locked).
5. Continue to advance the capsule guide tube over the catheter shaft towards the handle until it contacts the distal end of the capsule (*Figure 10*).

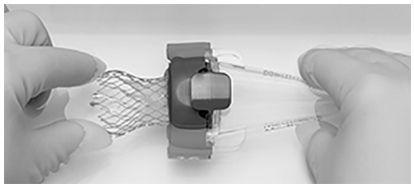
   Caution: Do not attempt to advance the capsule guide tube over the capsule; this will prevent the capsule flare from expanding fully and prevent proper loading.

   Figure 10.



6. Ensure that the backplate has been inserted into the inflow cone and the exposed part of the backplate is facing up.
7. Insert the inflow portion of the bioprosthesis frame into the inflow cone. Ensure that the bioprosthesis frame paddle marked with a “C” is facing up and that the paddles are aligned with the paddle attachment pockets (*Figure 11*). Ensure the paddles are presented straight and are not bent inwards prior to proceeding to the next step.

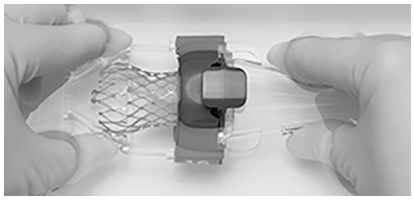
   Figure 11.



8. Secure the outflow cone onto the inflow cone (*Figure 12*) until it locks.

   Note: Ensure that the outflow cone is aligned with the inflow cone when attaching and crimping the valve.

   Figure 12.



9. Insert the catheter tip guide tube completely into the distal end of the inflow cone (*Figure 13*). Inspect the outflow struts of the bioprosthesis and, if needed, manually manipulate so that they are evenly spaced and the bioprosthesis frame paddles are approximately 180° apart.

   Note: Do not apply excessive force when inserting the tip guide tube. If resistance is encountered, stop and observe the paddle presentation.

   Figure 13.

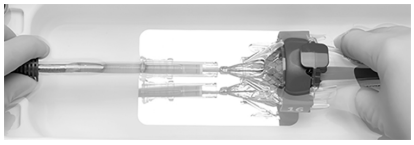
10. Insert the distal catheter tip into the catheter tip guide tube.

    Note: Allow the loading tool to rest on the loading bath floor to ensure coaxial alignment with the catheter to assist in seating the bioprosthesis frame paddles within the paddle attachment pockets.
11. Retract the catheter tip guide tube to set the bioprosthesis frame paddles into the paddle attachment pockets (*Figure 14*).

    Note: If the bioprosthesis frame paddles do not seat properly within the paddle attachment pockets upon retracting the catheter tip guide tube, slightly manipulate the position of the loading tool until paddle seating is achieved.

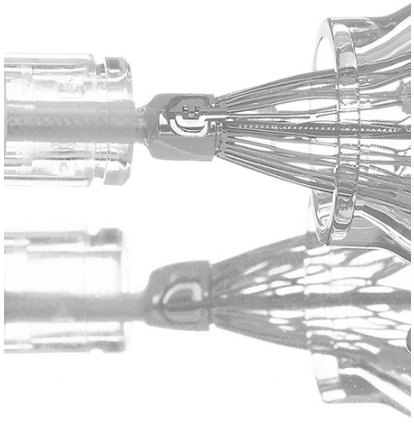
Note: If necessary, it is acceptable to manually compress the bioprosthesis frame paddles with fingertips to help seat the paddles within the paddle attachment pockets.

Figure 14.



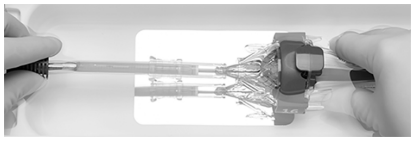
Note: Ensure both bioprosthesis frame paddles are completely seated within the paddle attachment pockets (*Figure 15*) before continuing to the next step.

Figure 15.



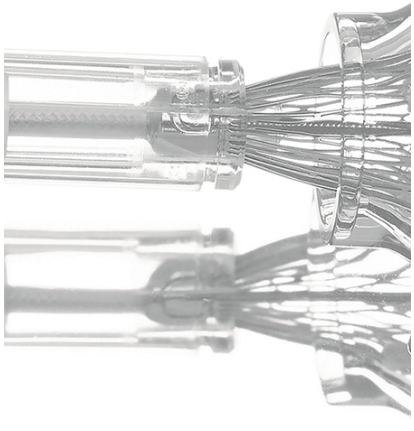
12. Hold the loading tool stationary with one hand, and with the other hand manually advance the capsule guide tube so that the distal section covers the paddle attachment pockets and the top portion of the outflow struts (*Figure 16*).

Figure 16.



Use the mirror to ensure that both bioprosthesis frame paddles are positioned correctly in the paddle attachment pockets and the outflow struts are within the distal tip of the capsule guide tube (*Figure 17*).

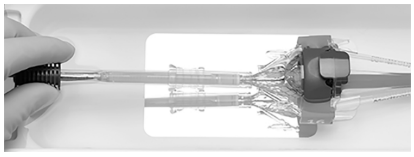
Figure 17.



13. Advance the capsule to cover the bioprosthesis frame paddles (*Figure 18*), pausing when the capsule covers the proximal half of the paddles to confirm the paddles are both still properly seated before advancing further.

    Use the mirror to ensure that both paddles are captured in the capsule.

Figure 18.

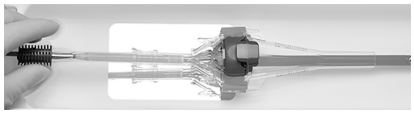


Caution: Do not advance the capsule over the bioprosthesis frame paddles unless they are fully seated in the center of the paddle attachment pockets. Advancing the capsule before the paddles are fully seated could damage the capsule and result in emboli.

14. Advance the capsule to capture the bioprosthesis outflow struts (*Figure 19*).

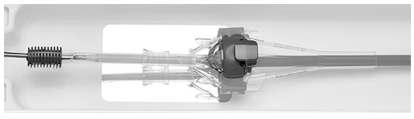
    Use the mirror to ensure that all bioprosthesis outflow struts are symmetrical and captured in the capsule.

    Figure 19.



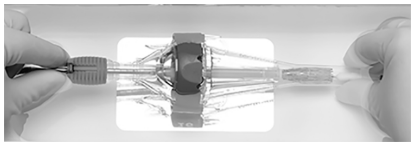
15. Continue to advance the capsule until the distal end of the capsule guide tube covers the distal end of the commissure pad of the bioprosthesis (*Figure 20*). The capsule guide tube should completely cover the commissure pad.

    Figure 20.



16. Remove the backplate and the catheter tip guide tube from the outflow cone.
17. While holding the capsule guide tube stationary, advance the inflow cone to crimp the inflow portion of the bioprosthesis frame until the outflow cone contacts the capsule guide tube (*Figure 21*). During this step, the outflow cone contacts the locking collar component and moves the locking collar to the proximal end of the capsule guide tube.

    Figure 21.



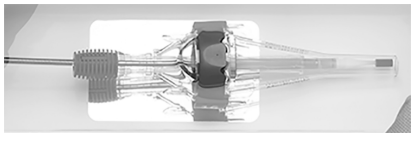
    Note: The capsule guide tube will be in the unlocked configuration after this step.

    Note: Ensure the bioprosthesis frame axis is visually aligned (coaxial) with the inflow cone axis during the insertion of the bioprosthesis into the inflow cone. Complete the insertion of the bioprosthesis into the inflow cone in one uninterrupted movement.

    Caution: Do not attempt to direct load the valve (for example, loading the valve without completing Step 17 and simply advancing the capsule to load the valve). This increases the likelihood of excessive inflow crown overlap. **If a valve has been direct loaded, discard the entire system.** The valve, catheter, loading system, loading tray, and saline all must be replaced with new sterile components.

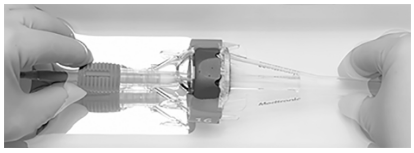
18. Advance the capsule over the bioprosthesis until the capsule comes within 5 mm of the catheter tip (*Figure 22*).

    Figure 22.



19. Remove the capsule guide tube together with the outflow cone and inflow cone from the catheter (*Figure 23*).

Figure 23.

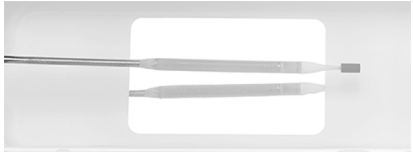


20. Slowly advance the capsule to close the gap between the capsule and catheter tip completely (*Figure 24*).

    Caution: Stop advancing the capsule once the gap to the catheter tip is closed. Advancing the capsule farther could damage the capsule.

    Note: If the deployment knob has reached the gray front grip and a gap exists between the capsule and the catheter tip, pause to allow any additional capsule movement to occur. If the gap remains, slowly continue rotating the deployment knob to advance the capsule one increment at a time, pausing between each increment.

Figure 24.



21. Slightly rotate the deployment knob in the direction of the arrows to relieve stress. Ensure that the capsule does not separate from the catheter tip.

    Note: After the bioprosthesis has been loaded into the capsule, the capsule flush port can no longer be flushed.
22. Visually and tactilely inspect the capsule for a misloaded bioprosthesis. The capsule should be straight, smooth, and free of any bends, protrusions, or discolorations. If any of these conditions are felt or observed, the bioprosthesis is likely to be misloaded.

    Note: If a misload is detected, do not attempt to reload the bioprosthesis. Discard the entire system. The valve, catheter, loading system, loading tray, and saline must all be replaced with new sterile components.
23. Attach a 10 mL syringe filled with sterile saline to the stability layer flush port on the distal end of the handle and flush.
24. Remove the loading stylet from the guidewire lumen at the capsule.
25. Attach a 10 mL syringe filled with sterile saline to the wire lumen flush port on the proximal end of the handle and flush.
26. Attach a 10 mL syringe filled with sterile saline to the Evolut FX inline sheath flush port and flush.
27. Before inserting into a patient, visually inspect the loaded bioprosthesis under fluoroscopy.

    Note: Complete fluoroscopy check under a magnified, high-resolution view over an area selected to not impede the clarity of the device.

    Note: Ensure the capsule is slowly rotated 360° during the fluoroscopy check.

    Note: If a misload is detected, do not attempt to reload the bioprosthesis. Discard the entire system. The valve, catheter, loading system, loading tray, and saline must all be replaced with new sterile components.
28. Leave the bioprosthesis submerged in sterile saline until implantation.

9.2 Bioprosthesis implantation

Note: Use systemic anticoagulation during the implantation procedure based on physician/clinical judgment. If heparin is contraindicated, consider an alternative anticoagulant.

9.2.1 Vascular access

Note: Vascular access should be achieved per standard practice (either percutaneously or via surgical cutdown).

Note: The primary access artery will be used to introduce the Evolut FX+ device and, if predilatation is performed, the balloon catheter; the secondary access artery will be used to introduce the reference pigtail.

1. Establish a central venous line. Insert a temporary pacemaker lead via the right internal jugular vein (or other appropriate access vessel) per physician/clinical judgment.
2. Insert an introducer sheath into the secondary access artery.
3. Insert an introducer sheath into the primary access artery.
4. Administer anticoagulant according to physician/clinical judgment. If heparin is administered as an anticoagulant, check activated clotting time (ACT) and monitor every 30 minutes after initial bolus of heparin. Maintain ACT ≥250 seconds.

    Note: Anticoagulant may be administered at any time prior to this point, but avoid delaying beyond this point.

9.2.2 Crossing the valve

1. Advance the graduated pigtail catheter to the ascending aorta and position the distal tip in the noncoronary cusp of the aortic valve.
2. Identify the ideal annular viewing plane using contrast injections at various angiographic angles.

   Note: It is recommended that a dedicated individual prepare and operate the contrast injector.
3. Insert an angiographic catheter over a standard J-tip guidewire into the primary access sheath and advance to the ascending aorta.
4. Exchange the J-tip guidewire for a 0.035 in (0.889 mm) straight-tip guidewire. Advance the straight-tip guidewire across the aortic valve into the left ventricle (LV).
5. After crossing the aortic valve with the guidewire, advance the angiographic catheter into the LV.
6. Exchange the straight-tip guidewire for an exchange length J-tip guidewire.
7. Exchange the angiographic catheter for a 6 Fr pigtail catheter.
8. Remove the guidewire and connect the catheter to the transducer. Using both catheters, record the aortic pressure gradient.
9. Using a right anterior oblique (RAO) projection, advance the previously pigtail-shaped, 0.035 in (0.889 mm) high support guidewire through the pigtail catheter and position in the apex of the LV.
10. Remove the pigtail catheter while maintaining guidewire position in the LV.

9.2.3 Predilatation of the implant site

Adequate predilatation can help reduce the need for post dilatation and may mitigate the occurrence of infolding.

Predilatation may also be useful to prepare the valve for crossing by the delivery catheter system and implantation of the transcatheter valve but may also confer some additional risk to the patient (for example, liberation of embolic debris, damage to the tissue, or perforation of the aortic root). Patient anatomical characteristics (for example, bicuspid anatomy, excessive or asymmetric leaflet calcification, and possible leaflet fusion) should be considered by the heart team when evaluating and determining the risk/benefit of predilatation and treatment plan for each patient.

The size and model of the predilatation BAV balloon should be selected such that it results in effective expansion and relief of the stenosis in the context of BAV to allow full expansion of the TAV upon implantation. Avoid balloon under sizing to ensure effective predilatation, therefore minimizing the risk of under expansion and infolding.

Notes:

- Predilatation is specifically recommended prior to implantation in the following situations:
  - Moderate-severe calcification
  - Bicuspid anatomy
  - Size 34 mm valve
- Utilize an adequate size balloon for effective predilatation, avoid under dilatation.

Information for failed surgical or transcatheter bioprosthetic valve: Balloon predilatation of a stenotic surgical or transcatheter aortic bioprosthetic valve has not been evaluated. In cases where there is severe stenosis, predilatation of the surgical or transcatheter aortic bioprosthetic valve may be done at the discretion of the heart team, and the steps used are identical to native valve predilatation.

1. Insert the valvuloplasty balloon through the introducer sheath in the primary access artery and advance it to the ascending aorta.
2. Reposition the angiographic equipment to the ideal viewing plane. Position the valvuloplasty balloon across the valve, while maintaining strict fluoroscopic surveillance of the distal tip of the guidewire in the LV.
3. Perform balloon valvuloplasty per standard practice and remove the valvuloplasty balloon while maintaining guidewire position across the aortic valve.

9.2.4 Deployment

1. Insert the device over the 0.035 in (0.889 mm) guidewire with the delivery catheter flush ports oriented at 3 o'clock (toward the left side of the patient) to better facilitate commissure alignment (flush ports shown in *Figure 2*, callouts 7 and 13). Insert the catheter tip and capsule through the access site, while maintaining the Evolut FX inline sheath tip against the proximal end of the capsule. Then, insert the Evolut FX inline sheath through the access site, maintaining contact with the capsule. When advancing the delivery system, allow the catheter handle to rotate freely after insertion of the system. Maintain strict fluoroscopic surveillance of the guidewire in the LV.

   Note: The 23-29 mm catheter model is compatible with introducer sheaths that can accommodate an 18 Fr (6.0 mm) device. The 34 mm catheter model is compatible with introducer sheaths that can accommodate a 22 Fr (7.33 mm) device.

   Note: For transfemoral and subclavian access procedures, a separate introducer sheath is optional. For direct aortic access procedures, use a separate introducer sheath; do not use the Evolut FX inline sheath. Maintain the Evolut FX inline sheath at the proximal end of the catheter throughout the procedure.

2. Under fluoroscopic guidance, advance the catheter over the guidewire to the aortic annulus. To assist capsule advancement or alignment, the capsule orientation may be adjusted by rotating the handle a quarter turn before the capsule crosses into the arch. If adjustment to capsule orientation is required after crossing the arch, withdraw the system until the capsule is in the descending aorta and rotate the handle a quarter turn before readvancing.

   Caution: Stop handle rotation if resistance is encountered or the capsule does not respond to rotation under fluoroscopic visualization. Do not rotate the handle when the capsule is at or beyond the arch. Continued attempts to rotate the capsule during resistance may result in product failure and/or patient harm.

   Caution: There will be some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and investigate the cause of the resistance (for example, magnify the area of resistance) before proceeding. Do not force passage. Forcing passage could increase the risk of vascular complications (for example, vessel dissection or rupture).

   Caution: Persistent force on the catheter can cause the catheter to kink, which could increase the risk of vascular complications (for example, vessel dissection or rupture).

   Note: When crossing the aortic arch, it is critical that the guidewire is controlled to prevent it from moving forward. Without proper management of the distal tip of the guidewire, the guidewire could move forward and cause trauma to the LV.
3. Advance the device through the valve. Perform an angiogram to confirm that the pigtail catheter is in position within the noncoronary cusp of the aortic root. Fluoroscopically identify the appropriate landmarks.
4. Position the catheter so that the bioprosthesis is at the recommended target depth of 3 mm relative to the valve annulus. Position the radiopaque markers at the valve annulus. If the implant depth is ≤1 mm or >5 mm, consider recapture (*Section 9.2.5*).

   Caution: Bioprosthesis implant depth ≤1 mm may contribute to an increased risk of prosthetic valve dislodgement during valve release, DCS retrieval, or post-implant dilatation. Bioprosthesis implant depth >5 mm may contribute to an increased risk of conduction disturbances, which may require a permanent pacemaker.

   Note: For surgical or transcatheter bioprosthetic valves, consider the features of the valve when determining the optimal placement of the bioprosthesis.

   Note: Physicians should consider patient anatomy when determining implant depth.
5. To deploy the bioprosthesis, rotate the deployment knob in the direction of the arrows. The capsule retracts and exposes the bioprosthesis. Continue deploying the bioprosthesis in a controlled manner, adjusting valve position as necessary and noting the position of the radiopaque capsule marker band and paddle attachment. Position the bioprosthesis so that the radiopaque markers are at the level of the native valve annulus. Note that the radiopaque markers are 3 mm from the inflow tip of the bioprosthesis.

   Warning: Use the deployment knob to deploy and recapture the bioprosthesis. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis.

   Note: Consider pacing to increase valve stability during deployment, especially in patients with larger anatomies. Pace at a rate sufficient to achieve a desired decrease in systolic pressure. If pacing at a high rate, consider stepping the pacing rate down incrementally.

   Note: Slight antegrade repositioning of a partially deployed bioprosthesis (before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment) can be achieved by carefully withdrawing the catheter.

   Caution: Use the catheter handle to reposition the bioprosthesis. **Do not** use the outer catheter shaft.
6. Before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment, evaluate the bioprosthesis position by assessing the position of the radiopaque markers.

   Note: When the bioprosthesis is approximately 2/3 deployed, the deployment knob provides a tactile indication as a notification before the point of no recapture. Once the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment, it is at the point of no recapture.
7. A right and left cusp overlap projection prior to deployment with a second radiographic view without parallax, may be useful to detect infolding, particularly in the presence of complex anatomies (bicuspid nature, severe calcification). An observation of **any** inward fold or crease in the valve, extending from the inflow, identified as a dark line under fluoroscopy inspection, may indicate an infold. If identified and if the patient's condition allows, do not proceed and do not release the valve.
   - Recapture, remove and discard the entire system. The valve, catheter, loading system, loading tray, and saline all must be replaced with new sterile components.
   - Predilatation is strongly recommended prior to subsequent implantation attempts to minimize infold risk.
   - If initial predilatation does not prevent infolding, reassess valve sizing in the presence of complex anatomies.
   - If an infold is detected and the valve is removed, consider a slightly lower depth of implantation of the second valve to provide additional space for frame expansion.
8. Either complete bioprosthesis deployment or initiate bioprosthesis recapture.

   Note: Shortly after annular contact, the blood pressure will be reduced until approximately the 2/3 deployment point, when the bioprosthesis leaflets are exposed and are functioning.

9.2.5 Bioprosthesis recapture (optional)

The bioprosthesis is recapturable during deployment before the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment. Deployment of the bioprosthesis can be attempted 3 times. If the bioprosthesis is recaptured a third time, it must be removed from the patient.

1. Rotate the deployment knob in the opposite direction of the arrows to recapture the bioprosthesis. A partially recaptured bioprosthesis can be repositioned or fully recaptured.

   Note: For TAV in SAV or TAV in TAV procedures, fully recapture the bioprosthesis before repositioning to reduce the risk of hang up or snagging on the failed bioprosthesis and to aid with positioning using the radiopaque capsule marker band.

   Warning: Use the deployment knob to deploy and recapture the bioprosthesis. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis.
2. To fully recapture the bioprosthesis, continue rotating the deployment knob until the gap between the capsule and catheter tip is closed.

   Caution: Stop advancing the capsule once the gap between the capsule and the catheter tip is closed. Advancing the capsule farther could damage the capsule.
3. Reposition the recaptured bioprosthesis at the recommended target depth of 3 mm relative to the valve annulus. Position the radiopaque markers at the valve annulus. If the implant depth is ≤1 mm or >5 mm, consider recapture.

   Caution: Bioprosthesis implant depth ≤1 mm may contribute to an increased risk of prosthetic valve dislodgement during valve release, DCS retrieval, or post-implant dilatation. Bioprosthesis implant depth >5 mm may contribute to an increased risk of conduction disturbances, which may require a permanent pacemaker.

   Note: For surgical or transcatheter bioprosthetic valves, consider the features of the valve when determining the optimal placement of the bioprosthesis.

   Note: Physicians should consider patient anatomy when determining implant depth.
4. Redeploy the bioprosthesis (*Section 9.2.4*, *Step 5* and *Step 6*).
5. Monitor frame during recapture to detect any presence of infolding. An observation of **any** inward fold or crease in the valve, extending from the inflow, identified as a dark line under fluoroscopy inspection, may indicate an infold. If identified and if the patient's condition allows, do not proceed and do not release the valve.
   - Fully complete the recapture, remove and discard the entire system. The valve, catheter, loading system, loading tray, and saline all must be replaced with new sterile components.
   - Predilatation is strongly recommended prior to subsequent implantation attempts to minimize infold risk.
   - If initial predilatation does not prevent infolding, reassess valve sizing in the presence of complex anatomies.
   - If an infold is detected and the valve is removed, consider a slightly lower depth of implantation of the second valve to provide additional space for frame expansion.
6. Either complete bioprosthesis redeployment or initiate bioprosthesis recapture. If the bioprosthesis has been recaptured 3 times, withdraw the recaptured bioprosthesis.

   Note: Shortly after annular contact, the blood pressure will be reduced until approximately the 2/3 deployment point, when the bioprosthesis leaflets are exposed and are functioning.

9.2.6 Postdeployment

1. Perform an angiogram to assess the location of the bioprosthesis.
2. Under fluoroscopic guidance, confirm that the catheter tip is coaxial with the inflow portion of the bioprosthesis.
3. Withdraw the catheter to the aorta while maintaining guidewire position.

   Note: For transfemoral access, withdraw the catheter until the catheter tip is positioned in the descending aorta. For direct aortic access and subclavian access, withdraw the catheter until the catheter tip is close to the distal tip of the introducer sheath.
4. Under fluoroscopic guidance, close the catheter capsule.

   Caution: Close the capsule until it is aligned with the catheter tip. Do not overcapture the catheter tip, because it could interfere with catheter withdrawal through the introducer sheath or cause vessel trauma upon removal.

   Caution: Ensure the capsule is closed before catheter removal.

   Caution: When using a separate introducer sheath, if increased resistance is encountered when removing the catheter through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and/or harm to the patient. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter and confirm that it is complete.
5. Withdraw the catheter until the capsule meets the distal end of the Evolut FX inline sheath.

   Note: For direct aortic access procedures, maintain the Evolut FX inline sheath at the proximal end of the catheter.
6. Withdraw the catheter and Evolut FX inline sheath together. Dispose of the catheter and loading system in accordance with the applicable laws, regulations, and hospital procedures, including those regarding biohazards, microbial biohazards, and infectious substances.

7. Advance a 6 Fr pigtail catheter over the guidewire into the LV.
8. Remove the guidewire and connect the pigtail catheter to the transducer.
9. Using both pigtail catheters, record aortic pressure gradient.
10. Remove the 6 Fr pigtail over a standard, J-tip guidewire.
11. Perform a post-implant aortogram with the reference pigtail to ensure coronary patency and assess aortic regurgitations.
12. Remove the introducer sheath (if used) and complete the puncture site closure per standard practice.
13. Perform contrast angiography to verify the absence of any vascular complications.
14. Remove the reference pigtail catheter over a standard guidewire. Remove the 6 Fr introducer sheath and close the access site per standard practice.
15. Administer anticoagulation and/or antiplatelet therapy as required according to physician/clinical judgment.

9.2.7 Post implant dilatation

If valve function or sealing is impaired due to excessive calcification, bicuspid nature, incomplete expansion or infolding, a post-implant balloon dilatation (PID) of the bioprosthesis may improve valve function and sealing.

1. **Cautions:**
   - Use caution when considering post dilatation in the presence of an infold to minimize dislodgement risk, particularly in the case of shallow implant depth. Consider pacing to increase valve stability, especially in patients with 34 mm valves. Pace at a rate sufficient to achieve a desired decrease in systolic pressure. If pacing at a high rate, consider stepping the pacing rate down incrementally.
   - Overexpansion of the narrowest portion (waist) of the Evolut FX+ TAV beyond the levels set forth in *Table 4* has been demonstrated through bench data to cause damage to the bioprosthetic leaflets. Complaints of damage to the bioprosthetic leaflets during post-implant balloon dilatation have been reported in some clinical cases, resulting in moderate to severe aortic insufficiency, which may be detected acutely or during follow-up. Multiple dilatations of the Evolut FX+ TAV increases the risk of damage to the bioprosthetic leaflets.
   - Snares should be available to stabilize the bioprosthesis in the event of dislodgement following post implant dilatation.
2. Consider the precautions outlined in *Chapter 4* Warnings and Precautions when selecting the post implant dilatation balloon model, size, and applied inflation pressure.

10 Return of explanted bioprostheses

Medtronic is interested in obtaining recovered bioprostheses. Specific pathological studies of the explanted bioprosthesis will be conducted under the direction of a consulting pathologist. A written summary of the findings will be returned to the physician. To obtain a product return kit, contact a Medtronic distribution center or a Medtronic Representative. If a kit is not available, place the explanted bioprosthesis in a container of glutaraldehyde or 10% buffered formalin immediately after excision. For further instructions on the return of an explanted device, contact a Medtronic Representative.

11 Clinical studies

Information regarding clinical studies and post-approval studies that are applicable to Evolut FX+ are available on the Medtronic Manual Library website:

1. Point your browser to www.medtronic.com/manuals.
2. Select the geography and language, and then search by product name for Evolut FX+. The instructions for use and premarket and post-approval study summaries are listed. The clinical study summaries include the following: study name, applicable device, patient population and indication, sample size, and follow-up duration.

If you do not have web access, you can order printed copies of the clinical study summaries from your Medtronic representative or by calling the toll-free number located on the back cover.

12 Disclaimer of warranty

The following disclaimer of warranty applies to United States customers only:

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ALTHOUGH THE MEDTRONIC EVOLUT™ FX+ TRANSCATHETER AORTIC VALVE (MODELS EVFXPLUS-23, EVFXPLUS-26, EVFXPLUS-29, AND EVFXPLUS-34), EVOLUT FX DELIVERY CATHETER SYSTEM (MODEL D-EVOLUTFX-2329 AND D-EVOLUTFX-34), EVOLUT FX LOADING SYSTEM (MODELS L-EVOLUTFX-2329 AND L-EVOLUTFX-34), HEREAFTER REFERRED TO AS "PRODUCT", HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR

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13 Patents

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Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000
LifeLine Technical Services, 24-hour consultation service:
1 877 526 7890

www.medtronic.com/manuals

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