Edwards 23F Guide Sheath

Instructions For Use

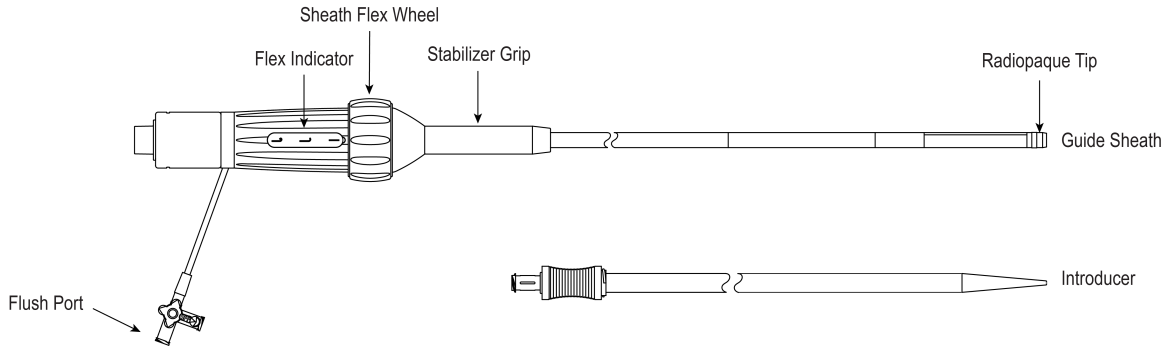
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

The product should only be used by physicians trained and experienced in interventional techniques. Standard techniques for placement of vascular access sheaths should be employed. **Please verify that you have the latest version of the instructions for use prior to using the device by visiting http://eIFU.edwards.com or by calling 1-800-822-9837.**

1.0 Device Description

The Edwards 23F guide sheath (also known as guide sheath and shown in Figure 1) is comprised of an articulating hydrophilic coated guide sheath and a hydrophilic coated introducer. The sheath provides venous vascular access to cardiac structures enabling the introduction and removal of SAPIEN M3 devices. The guide sheath has a radiopaque soft tip, and a flex wheel which flexes the guide sheath towards the flush port. The introducer is compatible with a 0.035 inch (0.89 mm) guidewire.

Figure 1: Edwards 23F Guide Sheath model 9880GS



Sheath I.D.	23 F (7.6 mm)
Sheath O.D.	29 F (9.6 mm)
Sheath Total Length	98 cm
Sheath Effective Length	77 cm
Introducer I.D.	0.89 mm (0.035 in)
Introducer O.D.	24 F (7.9 mm)
Introducer Total Length	106 cm
Introducer Effective Length	103 cm

2.0 Indication for Use

The Edwards 23F guide sheath is indicated to provide venous vascular access to cardiac structures enabling the introduction and removal of SAPIEN M3 transcatheter mitral valve replacement devices.

3.0 Contraindications

There are no known contraindications.

4.0 Warnings

Failure to abide by the warnings and precautions in this labeling could lead to damage to the device or device coating and may result in adverse events leading to additional intervention.

- The devices are designed, intended, and distributed for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, non-pyrogenicity, and functionality of the devices after reprocessing.
- Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (i.e., kinked or stretched, etc.), or the expiration date has elapsed.
- Procedures should be conducted under echocardiographic and fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting.

- The minimum ID of the guide sheath is 23F (7.6 mm). Characteristics of the device(s) to be inserted into the guide sheath should be evaluated to prevent damage to the interior liner of the guide sheath, damage to the device(s) being inserted, and/or injury to the patient.
- In the event of device malfunction or device damage during use (e.g. destructive deformation to the catheter) safely remove the device(s). If unable to safely remove the device(s), conversion to surgery is recommended.
- Patient injury could occur if the guide sheath is not unflexed prior to removal.

5.0 Precautions

- Abnormalities in the caval vein, the presence of an atrial septal occluder device, or presence of calcium may preclude safe transvenous femoral access.
- The sheath and introducer are coated with a hydrophilic lubricious coating. Failure to activate the hydrophilic coating with heparinized saline may result in difficulty with insertion.
- Use caution in tortuous or calcified vessels that would prevent safe entry of the guide sheath and introducer.

6.0 Potential Adverse Events

The following potential risks are associated with the device usage including potential access complications associated with standard cardiac catheterization, the potential risks of anesthesia, and the use of angiography.

- Death
- Stroke/TIA or nerve injury
- Cardiovascular injury – cardiac structure complications
- Cardiovascular injury – vascular complications
- Cardiovascular injury – access related complications
- Cardiac arrest
- Pericardial effusion or cardiac tamponade
- Thromboembolism including air, calcific valve material, or thrombus
- Arrhythmia
- Bleeding / Hematoma / Hemorrhage that may require transfusion or intervention
- Pleural effusion
- Emergency cardiac surgery
- Myocardial infarction
- Infection including septicemia and endocarditis
- Allergic reaction to anesthesia, contrast media, or device materials
- Deterioration of native valve (leaflet tear/tearing, leaflet retraction, or other)
- Atrial septal defect that may require intervention
- Conduction system defect which may require a permanent pacemaker
- Skin burn
- Vessel spasm
- Catheter entrapment
- Fever
- Inflammation
- Pain or changes at the access site

7.0 Directions for Use

7.1 Device Handling and Preparation

Step	Procedure
1	Verify expiration date, model number, and visually inspect for breaches in package integrity prior to opening sterile package.
2	Visually inspect guide sheath and introducer for damage.
3	While keeping distal tip raised, flush guide sheath with only heparinized saline.
4	Hydrate the length of the introducer with only heparinized saline.
5	Insert introducer into guide sheath partially.
6	While keeping distal tip raised, flush guide sheath with only heparinized saline.
7	Advance introducer and twist to lock to guide sheath.
8	Flush introducer with only heparinized saline. Hydrate the length of the guide sheath with only heparinized saline.

7.2 Device Use

CAUTION: Excessive device manipulation may result in cardiac structure damage requiring surgical repair or other intervention.

Step	Procedure
1	Access the common femoral vein using conventional percutaneous puncture methods.
2	Access the left atrium via transseptal puncture using conventional percutaneous methods and place a guidewire in the left atrium. **CAUTION: Inappropriate puncture may result in cardiac structure damage, requiring surgical repair or other intervention.**
3	Administer heparin to maintain the ACT at ≥ 300 sec.
4	Insert the guide sheath and introducer with the flushport oriented away from the operator. Advance until guide sheath tip is at the desired location.
5	Unlock introducer from guide sheath and slowly retract the introducer (and guidewire if applicable).

Step	Procedure
6	With the introducer and wire remaining across the guide sheath seals, aspirate and flush the guide sheath. Remove the introducer (and guidewire if applicable) slowly.
7	Insert the device(s) into the sheath. When inserting / removing device(s), aspirate and flush the guide sheath. **CAUTION: Ensure a 15F or larger catheter/device is across the guide sheath seals when aspirating and flushing the guide sheath to reduce the risk of air embolization.**
8	After the completion of the procedure and removal of device(s), fully unflex and retract the guide sheath. Retract guide sheath into the right atrium and assess the residual atrial septal defect. **CAUTION: Patient Injury could occur if the guide sheath is not unflexed prior to removal.**
9	Remove the guide sheath without torquing.
10	Close the access site per standard of care.

8.0 How Supplied

The Edwards 23F guide sheath is supplied sterilized with ethylene oxide.

9.0 Storage

The Edwards 23F guide sheath should be kept dry. Keep away from sunlight.

10.0 Device Disposal

Used devices may be handled and disposed of in the same manner as hospital waste and biohazardous materials in accordance with local regulations. There are no special risks related to the disposal of these devices.

Symbol Legend

	English
REF	Reorder Number
#	Model Number
cm	Usable length
	Do not re-use
LOT	Lot Number
	Consult instructions for use or consult electronic instructions for use
eifu.edwards.com + 1 888 570 4016	Consult instructions for use on the website
	Do not use if package is damaged and consult instructions for use
	Exterior Diameter

	English
	Inner diameter
	Keep dry
	Keep away from sunlight
UDI	Unique device identifier
STERILE EO	Sterilized using ethylene oxide
STERILIZE	Do not resterilize
	Single sterile barrier system with protective packaging inside
QTY	Quantity

	English
	Use-by date
	Manufacturer
	Date of manufacture
GWC	Guidewire compatibility
	Contents
	Non-pyrogenic
MD	Medical device
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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