



Edwards Expandable Introducer Sheath Set

Instructions for Use

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

Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System Instructions for Use for full prescribing information.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting <http://THVIFU.edwards.com> or by calling 1.800.822.9837. In order to access the instructions for use, an IFU Code will be required.

This product should be used by physicians trained and experienced in interventional techniques.

STERILE: Edwards Expandable Introducer Sheath Set catheter is supplied sterilized by ethylene oxide.

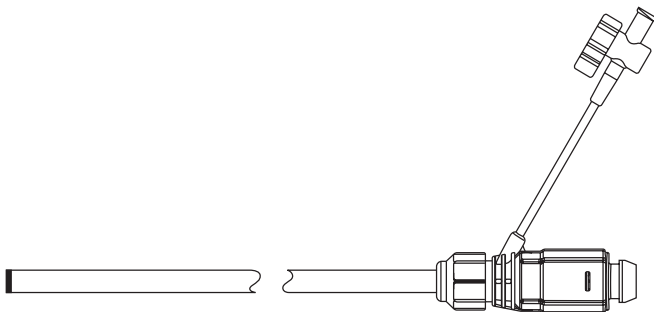
1.0 Device Description

The Edwards Expandable Introducer Sheath Set contains:

- an expandable sheath with a hydrophilic coating that provides access into the vasculature while maintaining hemostasis and temporarily enlarges in diameter to allow for passage of an Edwards SAPIEN XT transcatheter heart valve (THV).

Figure 1

THV209



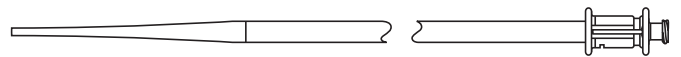
Model	Sheath I.D.	Largest Compatible THV
916ES23	16F (5.3 mm)	23 mm
918ES26	18F (5.9 mm)	26 mm
920ES29	20F (6.6 mm)	29 mm

Edwards Lifesciences, the stylized E logo, Edwards SAPIEN XT, NovaFlex+ and Edwards are trademarks of Edwards Lifesciences Corporation.

- an introducer with a hydrophilic coating to facilitate entry and trackability of the sheath into the vessel.

Figure 2

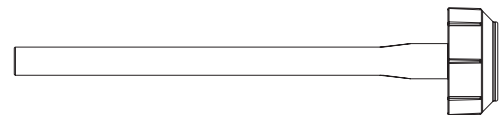
THV113



- a loader to aid insertion of the THV into the sheath, and which may be removed to utilize the full working length of the inserted delivery system.

Figure 3

THV197



Model	Loader ID
916ES23	21F
918ES26	21F
920ES29	23F

2.0 Indications

The Edwards Expandable Introducer Sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN XT Transcatheter Heart Valve.

3.0 Contraindications

This product is contraindicated for tortuous or calcified vessels that would prevent safe entry of the introducer and sheath.

4.0 Warnings

The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

The Edwards Expandable Introducer Sheath Set must be used with a compatible 0.035" guidewire.

5.0 Precautions

- Do not use the introducer sheath set if the packaging sterile barriers and any components have been opened or damaged.
- The Edwards Expandable Sheath temporarily enlarges to allow the passage of devices; ensure that the vasculature can accommodate the maximum diameter of the expanded sheath.

- When inserting, manipulating or withdrawing a device through the expandable sheath, always maintain sheath position.
- When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

6.0 Potential Adverse Events

Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis, and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, stroke, infection, and/or death.

7.0 Directions for Use

1. Visually inspect device components for damage.
2. Using standard catheterization techniques, gain access to the vessel and dilate as necessary to accommodate the sheath.
3. Flush the introducer using heparinized saline through the guidewire lumen.
4. Hydrate the length of the introducer and sheath with heparinized saline to activate the hydrophilic coating.
5. Flush the sheath using heparinized saline through the flush port; close the flush port.
6. Insert introducer completely into sheath.
7. Orient the sheath with the Edwards logo facing up and maintain orientation during the duration of the procedure. Fully insert the introducer and sheath using standard technique and advance into the vessel while following its progression on fluoroscopy.

NOTE: The proximal tapered end of the Edwards Expandable Sheath working length is larger in diameter.

8. Suture the sheath into place and remove the introducer from the sheath.
9. Insert the device into the sheath.
 - 9.1 If using the loader, immerse the loader in heparinized saline and insert the device into the loader.
 - 9.2 Advance the device into the proximal end of the sheath, ensuring that the loader cap is flush with the proximal sheath hub. Advance device through the loader and into the sheath.
 - 9.3 Retract the loader once the device is passed through the sheath hub. If additional working length is needed unscrew the cap from the loader and peel the loader from the shaft of the device.

NOTE: The sheath should be intermittently flushed with heparinized saline per standard technique.

10. After the completion of the procedure, remove sheath entirely without torquing and do not reinsert.

8.0 How Supplied

The Edwards Expandable Introducer Sheath Set is supplied pouched and sterilized by ethylene oxide.

9.0 Storage

The Edwards Expandable Introducer Sheath Set should be stored in a cool, dry place.

10.0 Device Disposal

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



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