



Edwards

Edwards eSheath+ Introducer Set

Instructions for Use

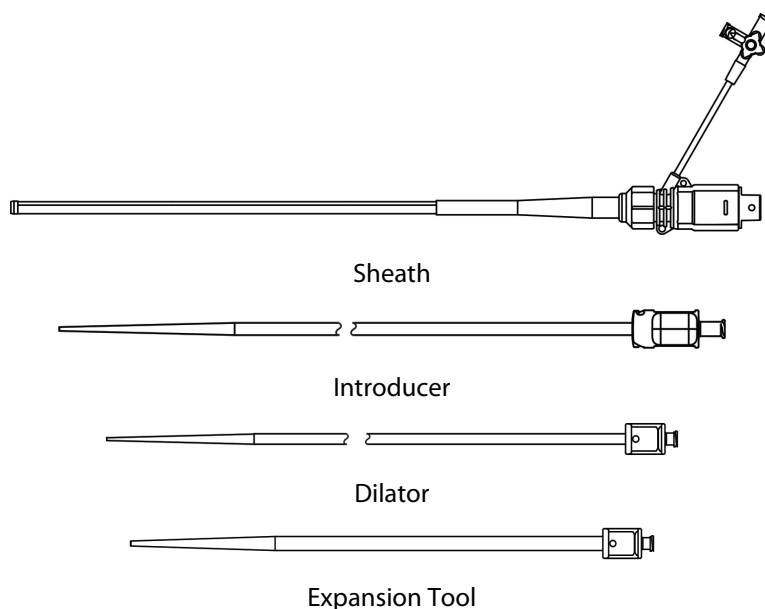
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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.

1.0 Device Description

The Edwards eSheath+ introducer set contains one introducer, one dilator, one expansion tool and a sheath, as well as a loader packaged with an Edwards delivery system. The working lengths of the introducer, dilator, and sheath contain a hydrophilic coating.



Model	Sheath I.D.	Sheath Working Length	Compatible THV	Introducer O.D.	Introducer Working Length	Dilator O.D.	Dilator Working Length
914ESP	14 F	36 cm	20 mm 23 mm 26 mm	14 F	57 cm	16 F	38 cm
916ESP	16 F	36 cm	29 mm	16 F	57 cm	18 F	38 cm

2.0 Indications

The Edwards eSheath+ introducer set is indicated for the introduction and removal of devices used with the Edwards transcatheter heart valves.

3.0 Contraindications

There are no known contraindications.

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 eSheath+ introducer set must be used with a compatible 0.035" (0.89 mm) guidewire to prevent vessel injury.

5.0 Precautions

- Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath+ introducer set respectively.
- Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set.
- Do not use the Edwards eSheath+ introducer set if the packaging sterile barriers and any components have been opened or damaged.
- When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position.
- When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.
- Expansion tool does not contain a hydrophilic coating. Do not use as a dilator.

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, hemorrhage, infection, and/or death.

7.0 Directions for Use

1. Inspect the length of the introducer, dilator, expansion tool and sheath for surface defects and damage prior to clinical use.
2. Flush the introducer and dilator using heparinized saline through the guidewire lumen.
3. Hydrate the length of the introducer, dilator, and sheath with heparinized saline to activate the hydrophilic coating. Wet the surface of the expansion tool.
4. Flush the sheath using heparinized saline through the flush port; close the flush port.
5. Use the expansion tool to pre-expand the partially expandable portion of the sheath prior to procedural use.

Note: After pre-expanding the sheath, inspect the length of the expandable portion for damage prior to use.

6. After removing the expansion tool, flush the sheath a second time using heparinized saline through the flush port; close the flush port.
7. Insert the introducer completely into the sheath and turn clockwise to lock the introducer hub to the sheath hub.
8. Using standard catheterization techniques, gain access to the vessel and dilate as necessary with the dilator to accommodate the sheath.
9. Orient the sheath appropriately and maintain orientation for the duration of the procedure. Insert the sheath assembly using standard technique while following its progression on fluoroscopy.

Note: The proximal tapered end of the sheath working length is larger in diameter.

10. If possible, suture the sheath into place.
11. Remove the introducer from the sheath by turning counterclockwise to unlock the introducer hub from the sheath.
12. Insert the device into the sheath (reference device specific instructions for use).
 - a. When using the loader, flush the loader with heparinized saline and insert the device into the loader.
 - b. Insert the loader into the sheath until the loader stops. Advance device through the loader and into the sheath.

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- c. Retract the loader once the device is passed through the sheath. If additional working length is needed unscrew the cap from the loader and peel the loader from the shaft of the device.

13. After the completion of the procedure, remove the device from the sheath.

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

14. Remove the suture (if necessary) and remove the sheath entirely without torquing. Do not reinsert the sheath.

8.0 How Supplied

The Edwards eSheath+ introducer set is supplied pouched and sterilized by ethylene oxide.

9.0 Storage

The Edwards eSheath+ introducer 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.

These products are manufactured and sold under one or more of the following US patent(s): US Patent No. 8,690,936; 8,790,387; 9,301,840; and 9,301,841; and corresponding foreign patents.



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Manufacturer

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500

800.424.3278

FAX 949.250.2525

Web IFU

