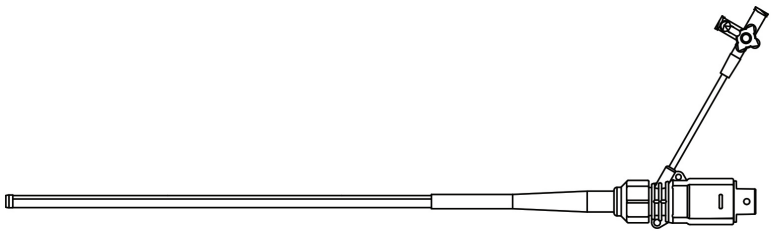
Edwards eSheath+ Introducer Set

Instructions for Use

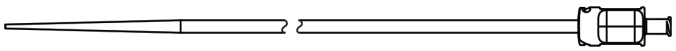
This product should be used by physicians trained and experienced in interventional techniques.

1.0 Device Description

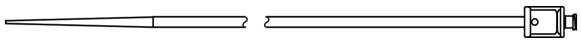
The Edwards eSheath+ introducer set contains one introducer, one dilator, one expansion tool and a sheath, as well as a loader packaged with an Edwards delivery system. The working lengths of the introducer, dilator, and sheath contain a hydrophilic coating.



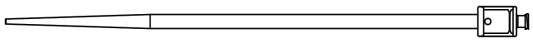
Sheath



Introducer



Dilator



Expansion Tool

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 SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve systems and the Alterra adaptive prestent system into the vascular system.

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.
    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.

11.0 Summary of Safety and Clinical Performance (SSCP)

The SSCP has been adapted in accordance with the clinical evaluation assessment by the Notified Body on which CE certification has been granted. The SSCP contains a relevant summary of the same information.

Refer to https://meddeviceinfo.edwards.com/ for a SSCP for this medical device.

After the launch of the European Database on Medical Devices/Eudamed, refer to https://ec.europa.eu/tools/eudamed for a SSCP for this medical device.

Symbol Legend

	English
REF	Reorder Number
#	Model Number
cm	Usable length
	Do not re-use
LOT	Lot Number
	Caution
	Consult 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
	Inner diameter
	Store in a cool, dry place
	Keep dry
	Keep away from sunlight
UDI	Unique Device Identifier
	Temperature limit
STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation

	English
STERILIZE	Do not resterilize
eSheath	eSheath compatibility
eSheath™	eSheath compatibility
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
QTY	Quantity
	Use-by date
SN	Serial Number
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community/European Union
GWC	Guidewire compatibility
NP	Nominal Pressure
RBP	Rated burst pressure
	Recommended guidewire length
Sheath	Minimum sheath size
Catheter	Catheter shaft size
	Importer

	English
	Balloon diameter
	Balloon working length
20 mm	For use with size 20 mm Edwards transcatheter heart valve
23 mm	For use with size 23 mm Edwards transcatheter heart valve
26 mm	For use with size 26 mm Edwards transcatheter heart valve
29 mm	For use with size 29 mm Edwards transcatheter heart valve
MR	MR Conditional
	Contents
	Non-pyrogenic
MD	Medical device
BIO	Contains biological material of animal origin
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Time & Temperature Sensitive
	Contains hazardous substances
SZ	Size
WO	Work Order

Note: Not all symbols may be included in the labeling of this product.

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Manufacturer
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone +1.949.250.2500
+1.800.424.3278
FAX +1.949.250.2525

Web IFU