Edwards eSheath Optima 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://eifu.edwards.com/ or by calling 1.800.570.4016.

The product is intended for use by physicians trained and experienced in interventional techniques. Standard techniques for placement of vascular access sheaths should be employed.

1.0 Device Description

The eSheath Optima introducer set contains:

- one expandable sheath (eSheath Optima) (Fig 1) with hydrophilic coating that provides access into the target vessel while maintaining hemostasis and temporarily enlarges its diameter to allow for passage of a device.
- one introducer (Fig 2) with hydrophilic coating that is used to facilitate entry and trackability of the sheath into the vessel.
- one vessel dilator (Fig 3) with hydrophilic coating that is used to dilate the vessel to accommodate the sheath.
- one in-sheath dilator (Fig 4) that can be used to expand the sheath during device use at the physician's discretion.

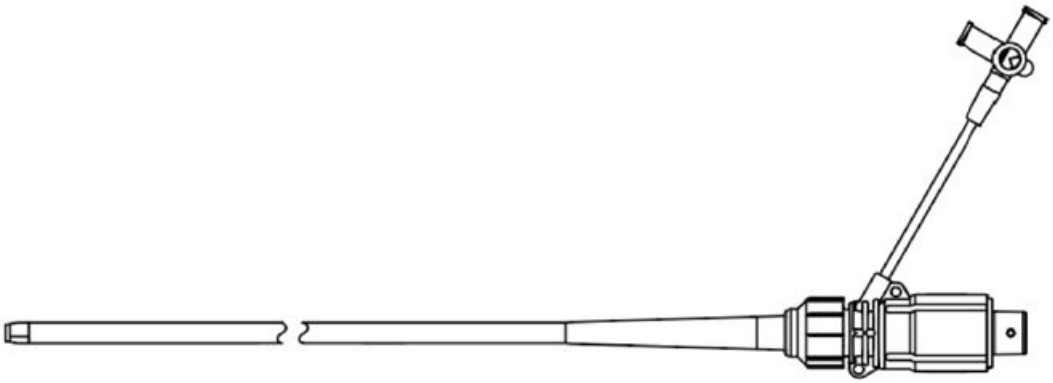

Figure 1: Sheath

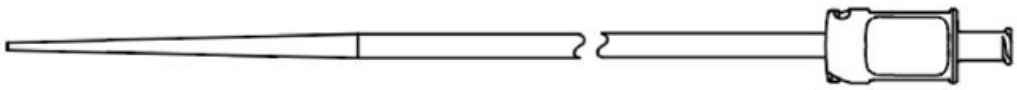

Figure 2: Introducer

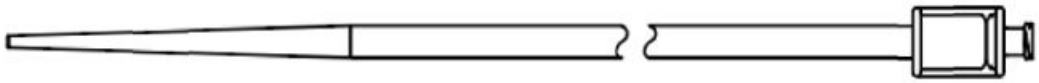

Figure 3: Vessel Dilator

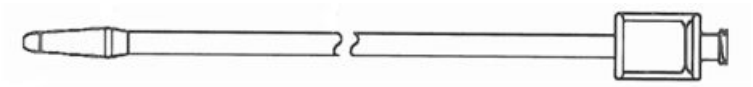

Figure 4: In-Sheath Dilator

Table 1: eSheath Optima Introducer Set

REF	14000ES14
Sheath I.D. (unexpanded)	14F (4.5 mm)
Sheath O.D. (unexpanded)	6.3 mm
Sheath Working Length	36 cm
Compatible THV	20 mm, 23 mm,26 mm
Introducer O.D.	14F (4.6 mm)
Introducer Working Length	57 cm
Vessel Dilator O.D.	16F (5.3 mm)
Vessel Dilator Working Length	38 cm
In-Sheath Dilator Maximum O.D.	21F (6.9 mm)
In-Sheath Dilator shaft O.D.	16F (5.3 mm)
In-Sheath Dilator Working Length	39 cm

2.0 Indications

The Edwards eSheath Optima introducer set is indicated for the introduction and removal of compatible devices used with 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 are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

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

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., cracked, bent, etc.), or the expiration date has elapsed.

Failure to abide by precautions and notes in this labeling that could lead to damage of device coating, may result in adverse events leading to additional intervention.

5.0 Precautions

- The In-sheath dilator does not contain hydrophilic coating. Do not use as a vessel dilator.
- Do not flush sheath with introducer inserted.
- When inserting, manipulating, or withdrawing a device through the sheath, always maintain orientation of the sheath position.
- When puncturing, suturing, or incising the tissue near the sheath, use caution to avoid damage to the sheath.
- The sheath temporarily enlarges to allow the passage of devices; ensure that the vasculature can accommodate the maximum diameter of the expanded sheath. Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F eSheath Optima introducer set.
- Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set.
- Avoid using surfactants and solvents such as isopropanol, or ethanol which could impact the coating of the device.
- Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: A known hypersensitivity or contraindication to heparin, which cannot be adequately premedicated.

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

Note: Refer to the provided delivery system instruction for use for all other preparation and procedural steps.

1. Inspect the length of the introducer, vessel dilator, in-sheath dilator, and sheath for surface defects and damage prior to clinical use.
2. Flush the introducer, vessel dilator and in-sheath dilator using heparinized saline through the guidewire lumen.
3. Hydrate the length of the introducer, vessel dilator, and sheath with heparinized saline to activate the hydrophilic coating. Hydrate the surface of the in-sheath dilator.

   Note: Avoid excessive wiping which may cause damage to the coating.
4. Flush the sheath using heparinized saline through the flush port; close the flush port.
5. Insert the introducer completely into the sheath and turn clockwise to lock the introducer hub to the sheath hub.
6. Using standard catheterization techniques, gain access to the vessel and dilate as necessary with the vessel dilator to accommodate the sheath.
7. Orient the sheath appropriately and maintain orientation throughout the procedure. Insert the sheath assembly as close to the hub as possible, using standard technique while following its progression under fluoroscopy.

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

Note: If a significant increase in resistance occurs when advancing the sheath through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications

8. Remove the introducer from the sheath by turning counterclockwise to unlock the introducer hub from the sheath.
9. At the physician discretion, insert the in-sheath dilator completely into the sheath to expand the sheath inside of the vessel prior to delivery system insertion.
10. Remove in-sheath dilator from sheath.
11. If possible, suture the sheath into place using the suture ring(s).
12. Insert the device into the sheath (reference device specific instructions for use).
    a) Insert the loader into the sheath until the loader stops. Advance device through the loader and into the sheath. Retract the loader once the device is passed through the sheath.

    Note: The sheath should be intermittently flushed with heparinized saline throughout the procedure, per standard interventional technique.
13. After completion of the procedure and removal of the device, remove the suture (if necessary), and then remove the sheath entirely. Do not reinsert.

8.0 How Supplied

The eSheath Optima introducer set is supplied in a pouch and sterilized with ethylene oxide.

9.0 Storage

The eSheath Optima 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.

2025-04
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