



Edwards Axela Sheath

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.

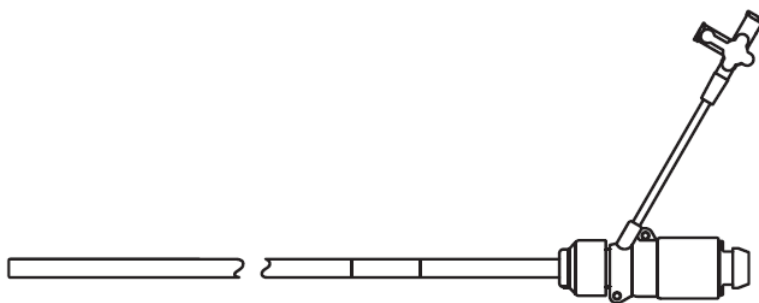
This product should be used by physicians trained and experienced in interventional techniques.

1.0 Device Description

The Edwards Axela sheath (Figure 1) contains two dilators, a sheath with hydrophilic coating, and a loader packaged with the Edwards SAPIEN 3 Ultra delivery system.

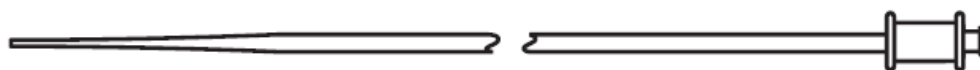
Figure 1

THV419



Sheath

THV252



Dilators (2)

Model	Sheath I.D.	Sheath Working Length	Compatible THV
9630ES14	14F	37 cm	20 mm 23 mm 26 mm 29 mm

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2.0 Indications

The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery 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 Axela sheath 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 as it may preclude safe placement of the 14F Edwards Axela sheath.
- For subclavian/axillary vessels with the 29mm SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath.
- Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath.
- Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed.
- 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.

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 dilators and sheath for surface defects and damage prior to clinical use.
2. Flush the dilators using heparinized saline through the guidewire lumen.
3. Hydrate the length of the dilators and sheath with heparinized saline to activate the hydrophilic coating.
4. Flush the sheath using heparinized saline through the flush port; close the flush port.
5. Insert one dilator completely into the sheath.

NOTE: Do not flush the sheath while the dilator is inserted to prevent additional expansion of the sheath.

6. Using standard catheterization techniques, gain access and dilate as necessary to accommodate the sheath.
7. Orient the sheath appropriately and maintain orientation for the duration of the procedure. Insert the sheath. The sheath assembly should be inserted beyond the proximal end of the insertion marker to maintain hemostasis. Use standard technique while following its progression on fluoroscopy.

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

8. If possible, suture the sheath into place.

9. Remove the dilator from the sheath.

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

10. Insert the device into the sheath (reference device specific instructions for use).

10.1. When using the loader, flush the loader with heparinized saline and insert the device into the loader.

10.2. 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.

NOTE: Do not flush the sheath while the device is inserted to prevent additional expansion of the sheath.

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

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

8.0 How Supplied

The Edwards Axela sheath is supplied pouched and sterilized by ethylene oxide.

9.0 Storage

The Edwards Axela sheath 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.

US and foreign patents are pending.



Edwards

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