Ascendra+ Introducer Sheath Set

Instructions for Use

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

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.

1.0 Device Description

The Ascendra+ Introducer Sheath Set (Figure 1) contains an introducer and sheath. The sheath has radiopaque markers for visualization of the tip and non-radiopaque depth markings on the distal end of the body of the sheath. The proximal end of the sheath includes a side port. The introducer has a radiopaque marker at the distal end where the taper begins.

Model	Minimum Sheath I.D.
9350IS23	24F (8.0 mm)
9350IS26	24F (8.0 mm)
9350IS29	26F (8.7 mm)

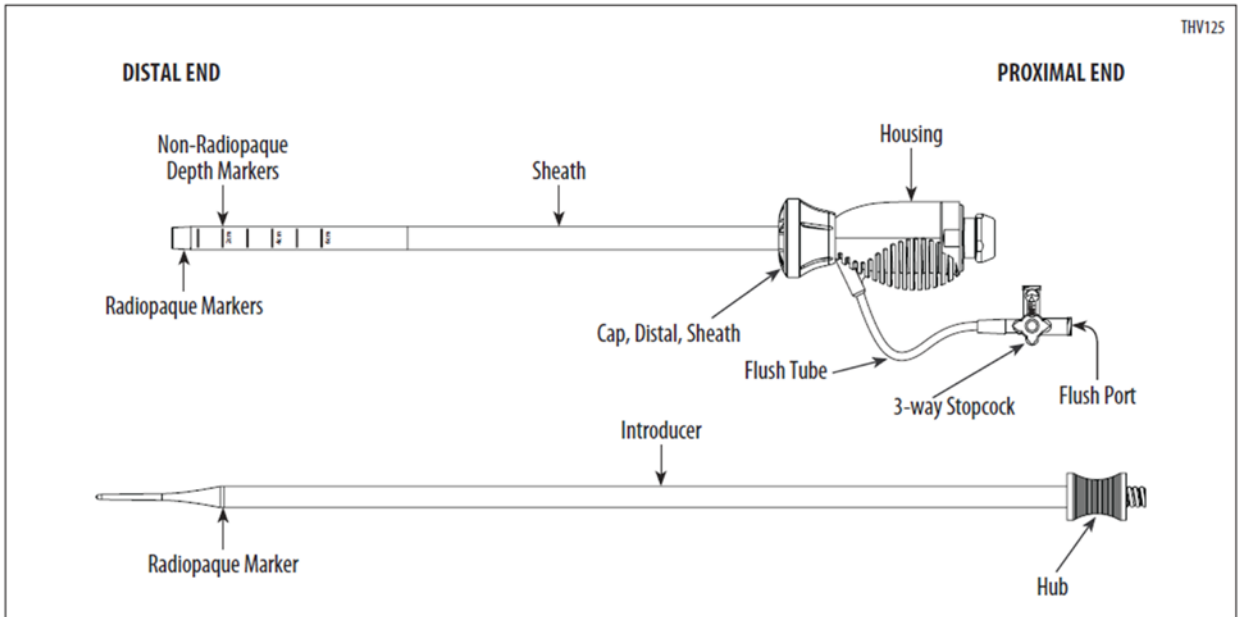

Figure 1. Ascendra+ Introducer Sheath Set

2.0 Indications

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

3.0 Contraindications

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.

Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed.

Should not be used in patients with left ventricular aneurysm.

The Ascendra+ Introducer Sheath Set must be used with a 0.035" guidewire.

5.0 Precautions

No known precautions.

6.0 Potential Adverse Events

Complications associated with cardiac surgical intervention and use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including myocardial injury, thrombus formation, and plaque dislodgement which may result in myocardial infarction, arrhythmia, stroke, and/or death. Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System Instructions for Use for a full list of potential adverse events.

7.0 Directions for Use

Step	Procedure
1	Once access has been gained, place at least two pledgeted sutures (e.g. purse-string or mattress) around the access site.
2	Hydrate the length of the introducer and sheath. Flush the sheath and introducer using heparinized saline.
3	Fully insert the introducer into the sheath and flush the sheath again. Close the stopcock to the sheath.
4	Insert an 18G needle within the sutures and insert a 0.035" soft guidewire through the needle. Exchange needle for a 6-8F introducer sheath and cross the native valve with soft guidewire. Exchange soft guidewire for exchange length extra stiff guidewire.
5	Using the sheath depth markers, advance the introducer sheath over the guidewire to the desired depth in the left ventricle while following its progression on fluoroscopy.
6	Remove the introducer from the sheath to provide access for entry and/or removal of a device. Continue to hold the guidewire centered relative to the introducer sheath.
7	Upon completion of the procedure, remove the sheath from the access site, close the access site and confirm hemostasis.

8.0 How Supplied

The Ascendra+ Introducer Sheath Set is supplied pouched and sterilized by ethylene oxide.

9.0 Storage

The Ascendra+ Introducer Sheath Set should be stored in a cool, dry place.

10.0 Device Disposal

Used introducer 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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