



AFX™ Introducer System

INSTRUCTIONS FOR USE

IMPORTANT NOTES:

Please read carefully all instructions contained in this packet before attempting to use the AFX™ Introducer System.

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.
AFX Introducer System is provided sterile and for single use only. Therefore, carefully inspect the package before use. If the product is opened, damaged or the label is illegible do not use the device.

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1. **DEVICE DESCRIPTION**

The AFX Introducer System consists of an outer sheath with hemostasis valve and sideport. It is available in two models S17-45 and S17-45DD. Model S17-45DD includes the AFX introducer sheath along with two inner dilators (single lumen and dual-lumen) with tapered tips. Model S17-45 includes the AFX introducer sheath and only the single lumen dilator.

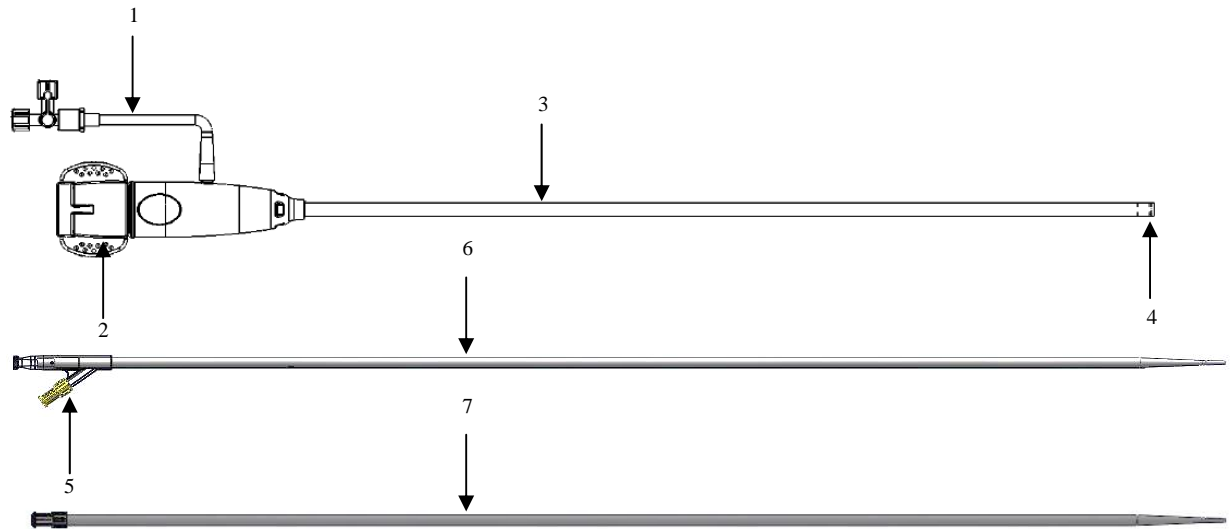
The outer sheath tubing has a platinum marker band at the distal tip and is connected at the proximal end to a hub consisting of a hemostasis valve with side port tubing which has a 3-way stopcock valve. The sideport may be used for flushing the sheath. The sheath is introduced into the vascular system with the aid of an inner dilator which has a luer at the proximal end and a tapered tip at the distal end. The hemostasis valve at the proximal end of the introducer sheath seals and conforms around catheters and guidewires to minimize blood leakage from the introducer sheath.

The single lumen dilator is used in conjunction with the introducer sheath and over a guidewire for purposes of insertion of the introducer sheath into the arteriotomy. It may also be used for purposes of repositioning the introducer sheath distally or proximally within the anatomy. A dual-lumen dilator, available with model S17-45DD, is used in conjunction with the introducer sheath and over a guidewire for purposes of placement of two parallel wires. Similar to the single lumen dilator, it may also be used for insertion of the introducer sheath into the arteriotomy and for repositioning of the introducer sheath distally or proximally within the anatomy.

2. **INDICATIONS FOR USE**

The AFX Introducer System (Figure 1) facilitates the introduction of guidewires, catheters, and other medical devices into the vasculature and minimizes blood loss associated with such introduction.

Figure 1. AFX Introducer Sheath System



- | | |
|---|---|
| 1) Sideport with flush valve | 5) Parallel wire lumen |
| 2) Hemostasis valve | 6) Dual-lumen dilator (available with model S17-45DD) |
| 3) Outer sheath (attached to handle) | 7) Single lumen dilator |
| 4) Radiopaque marker (on introducer sheath) | |

3. **WARNINGS AND PRECAUTIONS**

- The AFX Introducer System is designed for single patient use only. Do not reuse or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Examine packaging and device before use. Do not use if either the packaging or device is damaged or if sterile barrier has been compromised.
- The AFX Introducer System is supplied sterile. The package will serve as an effective barrier until the “use by” (expiration) date printed on the box.

- Individual patient anatomy and physician technique may require procedural variations.
- Do not alter this device as it may impair function.
- Do not attempt to use a guidewire with a maximum diameter larger than 0.035”.
- The AFX Introducer System for AAA should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.
- The AFX Introducer System should only be advanced or retracted under fluoroscopic guidance, and should only be advanced with the dilator fully inserted.
- Always maintain a fluoroscopic view of the introducer sheath to ensure location.
- Do not attempt to advance or withdraw guidewire, catheter, or other interventional medical device through introducer sheath and/or dilator if resistance is felt. Use fluoroscopy to determine cause. Continued advancement or retraction against resistance may result in damage to the vessel, or breakage of the guidewire, catheter or interventional medical device. Continued advancement or retraction against resistance may result in serious injury.
- Advance dilator/sheath assembly with a twisting motion to avoid damage to the sheath or vessel.
- Do not attempt to insert a catheter or other interventional medical device having a diameter larger than the introducer sheath size indicated. Device damage or breakage may occur.
- Use of this product with a metal cannula or metal dilator may cause damage to the PTFE coating.
- Do not use device with a power injector.

4. **DIRECTIONS FOR USE**

4.1 **Sheath Preparation**

- Verify sheath, device, catheter and accessory components size compatibility prior to use.
- Remove the Introducer Sheath from its packaging and examine for possible damage or defects. Do not use any damaged or defective devices.
- Flush the dilator, introducer sheath, and sideport with heparinized intravenous fluid.
- When the sheath will remain in a vessel for an extended period, consider using a continuous drip of heparinized intravenous fluid under pressure administered through the sideport connection.

4.2 **Sheath Use (Single Lumen Dilator)**

1. Insert the dilator tip through the valve and completely into the sheath until the dilator hub comes in contact with the hemostasis valve. This ensures that the tapered portion of the dilator is beyond the end of the sheath.

NOTE: When advancing the sheath, ensure that the dilator remains fully inserted into the sheath and that the dilator hub remains in contact with the hemostasis valve.

2. Follow normal accepted practice for vessel puncture or incision and guidewire insertion.
3. Using fluoroscopic guidance, advance the dilator/sheath over the guidewire as a unit; do not allow dilator to back out of the (separate) sheath while advancing. Stop advancement of the assembly if there is resistance. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is at the desired location. Advance dilator/sheath assembly with a twisting motion to avoid damage to the sheath or vessel.
4. Hold the sheath steady and maintain the guidewire position while withdrawing the dilator from the sheath, over the guidewire until it is completely removed from the guidewire.
5. While maintaining the position of the guidewire, advance the selected catheter or other interventional medical device over the guidewire into the sheath, taking care to keep the sheath assembly as straight as possible outside the body and avoid kinking.
6. When exchanging different catheters and devices through the introducer sheath care should be taken to maintain proper guidewire and sheath positions within the vascular system.
7. Carefully support all wires, catheters and devices while pushing across the hemostasis valve.
8. Upon removal of the sheath, precautions should be taken to prevent bleeding, vessel damage, or other serious injury.

4.3 **Sheath Use (Dual-Lumen Dilator; available with model S17-45DD only)**












1. Insert the dilator tip through the valve and completely into the sheath until the dilator hub comes in contact with the hemostasis valve. This ensures that the tapered portion of the dilator is beyond the end of the sheath.

NOTE: When advancing the sheath, ensure that the dilator remains fully inserted into the sheath and that the dilator hub remains in contact with the hemostasis valve.

2. Follow normal accepted practice for vessel puncture or incision and guidewire insertion.

3. Using fluoroscopic guidance, advance the dilator/sheath over the guidewire as a unit; do not allow dilator to back out of the (separate) sheath while advancing. Stop advancement of the assembly if there is resistance. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is at the desired location. Advance dilator/sheath assembly with a twisting motion to avoid damage to the sheath or vessel.
4. For placement of a parallel wire, insert wire into Parallel wire lumen and continue to feed it until at desired location.
5. Hold the sheath steady and maintain the guidewire position of both wires while withdrawing the dilator from the sheath until it is completely removed from the guidewire.
6. While maintaining the position of the guidewires, advance the selected catheter or other interventional medical device over the guidewires into the sheath, taking care to keep the sheath assembly as straight as possible outside the body and avoid kinking.
7. When exchanging different catheters and devices through the introducer sheath care should be taken to maintain proper guidewire and sheath positions within the vascular system.
8. Carefully support all wires, catheters and devices while pushing across the hemostasis valve.
9. Upon removal of the sheath, precautions should be taken to prevent bleeding, vessel damage, or other serious injury

5. SYMBOLS LEGEND

SYMBOL	DESCRIPTION
	Product expiration date "Use product by expiration date"
	Serial number for the product.
	Contents sterile unless package has been opened or damaged. Sterilized by ethylene oxide.
	Caution, Consult Instructions for Use
	Device is intended for use one time only. Do not re-use or re-sterilize.
	Consult Instructions for Use
	Keep Dry
	Do not use if package is damaged
	Keep away from sunlight
	Catalog number
	Manufacturer

6. RETURN GOODS

In the event an unused device must be returned for any reason, please place the AFX Introducer System into its original package and shipping box. Contact Customer Service at 800-983-2284 or +1 (949) 595-7200 to receive a return goods authorization number (RGA) and ship the device to the address provided by customer service.