AMPLATZER™ STEERABLE DELIVERY SHEATH

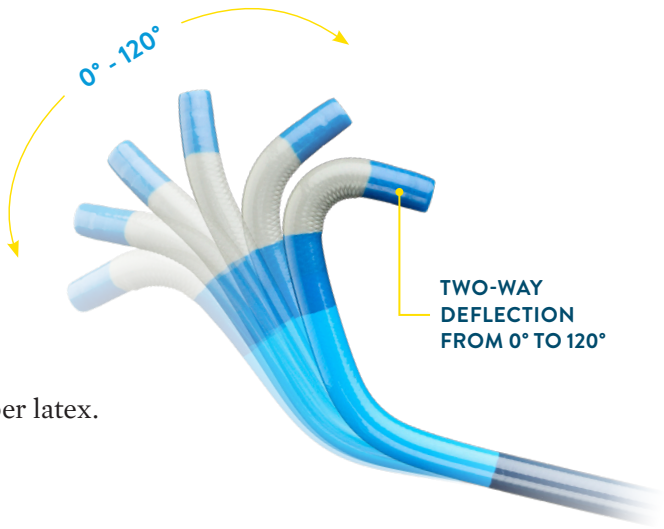
FOR IMPLANTING THE AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER DEVICE

The Amplatzer™ Steerable Delivery Sheath is designed to improve ease-of-use in both simple and challenging left atrial appendage anatomies. Designed specifically for the Amplatzer™ Amulet™ Left Atrial Appendage Occluder, it leverages the design of the Agilis™ NxT steerable introducer. The sheath features bidirectional deflection from 0° - 120° to enable coaxial alignment with the ostium.

The 14F Steerable Delivery Sheath is compatible with all Amulet device sizes. To use with smaller Amulet occluders (16mm, 18mm, 20mm, 22mm and 25mm), connect the adapter provided in the Amulet packaging.

INDICATIONS AND USAGE

The Steerable Delivery Sheath is indicated to facilitate the delivery of the Amulet device into the LAA in patients having non-valvular atrial fibrillation. The Steerable Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.



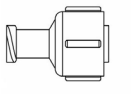
LATEX FREE INFORMATION

These Amplatzer™ products are not made with natural rubber latex.

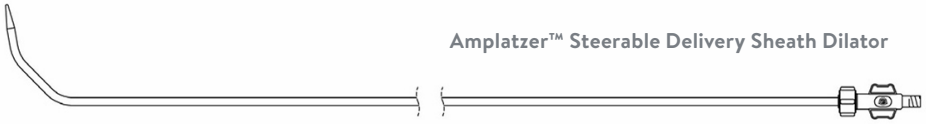
See Important Safety Information referenced within.

Abbott

PACKAGING INFORMATION

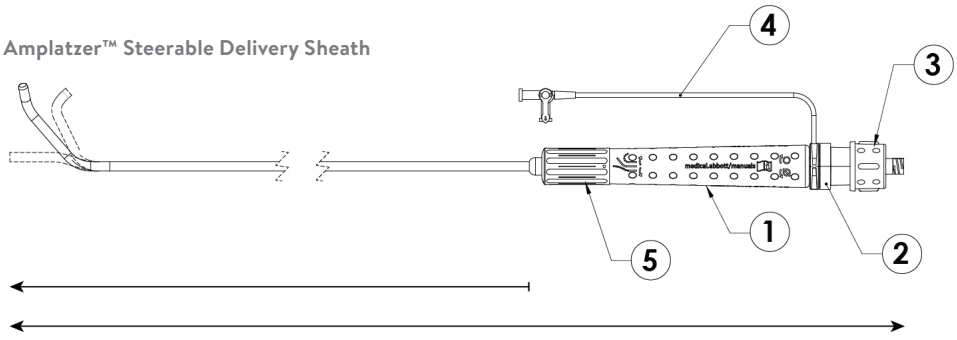


2X to 1X
Flush Adapter



Amplatzer™ Steerable Delivery Sheath Dilator

Amplatzer™ Steerable Delivery Sheath



STEERABLE SHEATH COMPONENTS:

1. Handle
2. Hemostasis Valve
3. Hemostasis Valve Knob
4. Flushing Port/Tube
5. Deflection Knob

AMPLATZER™ STEERABLE SHEATH ORDERING INFORMATION

REF					
Model / Reorder Number	Fr	mm (in) Inner diameter	mm (in) Outer diameter	cm (in) Usable Length	cm (in) Length
ASDS-14F-075	14	4.7 (0.184)	6.0 (0.238)	75.0 (29.5)	98.5 (38.8)

ASSOCIATED AMPLATZER™ PRODUCTS ORDERING INFORMATION

Amplatzer™ Amulet™ Left Atrial Appendage Occluder

Model/Reorder Number	Size/Lobe Diameter (mm)
9-ACP2-007-016	16
9-ACP2-007-018	18
9-ACP2-007-020	20
9-ACP2-007-022	22
9-ACP2-010-025	25
9-ACP2-010-028	28
9-ACP2-010-031	31
9-ACP2-010-034	34

Amplatzer™ Guidewire Specifications

Model / Reorder Number	Diameter (inch)	Body	Tip Description	Usable Length (cm)
9-GW-002	0.035	Super Stiff	1.5 mm, Modified J-tip	260

See Important Safety Information referenced within.

IMPORTANT SAFETY INFORMATION
STEERABLE SHEATH

INDICATION FOR USE

℞ ONLY

The Amplatzer™ Steerable Delivery Sheath is indicated to facilitate the delivery of the Amplatzer™ Amulet™ Left Atrial Appendage Occluder.

CONTRAINDICATIONS

The Amplatzer™ Steerable Delivery Sheath is contraindicated for patients with the presence of intracardiac thrombus with active infections including endocarditis. The Amplatzer™ Steerable Delivery Sheath is contraindicated for use with a power injection system.

WARNINGS

This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient. Do not use this device if the sterile package is open or damaged. Inspect all components before use. Do not use if the package or items appear to be damaged or defective. This device should be used only by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that use this device. Slowly remove the dilator and sheath from the patient to prevent an ingress of air. As this medical device uses an alternative small-bore connector (luer) design different from those of the ISO 80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonable, foreseeable risks. See call-out 6 in Figure 2 for an illustration of the small-bore connector (luer).

PRECAUTIONS

To prevent air ingress, maintain a continuous flush of saline to the flushing port throughout the procedure: The hemostasis valve in the closed position minimizes blood loss, but does not prevent air ingress. Capping of the bypass hub may not be sufficient to prevent air ingress. Do not aspirate from the sheath flushing port. DO NOT use the Amplatzer™ Steerable Delivery Sheath after the Use-by date stated on the package label. The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, or after the use of the Amplatzer™ Steerable Delivery Sheath. Use caution when advancing the steerable delivery sheath and dilator to avoid damaging tissue and vessels or interfering with previously implanted medical devices. If resistance is felt, determine the cause before proceeding. Continuing to advance, retract, or manipulate the catheter under this circumstance has the potential to result in patient injury or delivery sheath damage.

POTENTIAL ADVERSE EVENTS

Potential adverse events that can occur during or after a procedure using this sheath may include but are not limited to: air embolism, allergic reaction/toxic effects (due to anesthesia, contrast media, etc.), arrhythmia, arteriovenous fistulae, bleeding, cardiac tamponade, cardiac perforation, death, dissection, embolism, foreign material embolous, heart failure, hematoma, hypotension/hypertension, infection, myocardial infarction/ischemia, pericardial effusion, peripheral embolism, pseudoaneurysm, stroke, thrombosis, transient ischemic attack, vascular access site injury (such as arteriovenous fistulae, hematoma, pseudoaneurysm), vessel trauma/damage

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals or more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

Abbott
3200 Lakeside Dr, Santa Clara, CA 95054, USA, Tel: 1.800.227.9902
www.structuralheart.abbott

Abbott