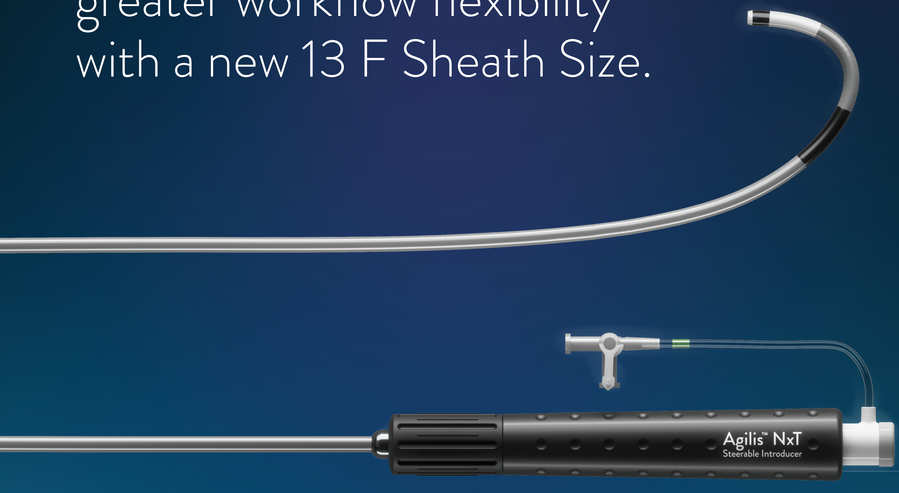
Abbott

CONSISTENT OUTCOMES WITH HANDLING AND CONTROL[1]

From PFA to RF to Cryo – greater workflow flexibility with a new 13 F Sheath Size.



Agilis™ NxT Steerable Introducer, Dual-Reach

1. Nair, D., Saliba, W., Santangeli, P., Palmeri, N. O., Gaeta, L., Hook, B. G., Sundaram, S., & Hussein, A A. (2025). Initial clinical experience with first FDA-cleared bidirectional 13F steerable sheath in PFA procedures. Abstract presented at AF Symposium 2025.

Rx Only. Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Indications: The Agilis™ NxT Steerable Introducer Dual-Reach™ is indicated for the introduction of various cardiovascular catheters into the heart, including the left side of the heart, during the treatment of cardiac arrhythmias. Contraindications: The Agilis™ NxT Steerable Introducer Dual-Reach™ is contraindicated for: Previous interatrial septal patch. Known or suspected atrial myxoma. Acute myocardial infarction. Unstable angina. Recent cerebral vascular accident (CVA). Patients who do not tolerate anticoagulation therapy. Patients with an active infection. Presence of an intracardiac thrombus. **Warnings:** Do not alter this device in any way. This device must be used by board-certified electrophysiologists, or EP fellows in training, in a fully equipped operational EP laboratory. This device is intended for one time use only; do not reprocess or reuse it. Note the product "Use by" date on the package. Any attempt to resterilize and reuse this system may compromise its integrity. Adverse effects of using nonsterile components may include, but are not limited to: Local or systemic infection or reaction, Mechanical damage, Inaccurate functionality. Always aspirate, insert and withdraw components, and exchange catheters slowly to minimize the risk of air emboli. Aspirate all air before fluid infusion from the sideport. Provide continuous heparinized saline infusion while the introducer remains in the vessel. Fibrin may accumulate in or on the introducer tip during the procedure. To prevent dislodgement of potential thrombus, aspirate when removing dilator or catheter. Before removing the steerable introducer, reinsert the guidewire through the introducer, reintroduce the dilator over the guidewire, straighten the steerable introducer, then remove the dilator, guidewire, and introducer as a unit. Maximum in-vivo time: 7 hours. Read the IFU carefully before using this device to help reduce the potential risks and complications associated with the transseptal technique, such as air emboli and perforation of the aorta and left atrium. Aspirate and saline flush the introducer frequently to minimize the potential for thrombus formation. Do not use the introducer without a catheter or dilator supporting the lumen. Use of the introducer directly over a wire without a catheter or dilator supporting the lumen may result in complications that can cause death. For both patients and laboratory staff, cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the x-ray beam intensity and duration of the fluoroscopic imaging. Carefully consider the use of this introducer in pregnant women. Persons with known history of allergies to any of the materials listed below may suffer an allergic reaction to this device. Before use, counsel the patient on the materials contained in the device and discuss a thorough history of allergies. This device contains: Polyether block amide (PEBAX), Polytetrafluoroethylene, ABS, Silicone rubber, DOW Corning 360 fluid , HDPE, MDX,/hexane solution, Nylon. Precautions: Federal law (U.S.) restricts this device to sale by or on the order of a physician. Only use this device with equipment that complies with international safety standards. Store in a cool, dark, dry place. Inspect all components before use. Do not use if the packaging or items in the kit appear to be damaged or defective. Conditions requiring special consideration when using this product may be, but are not limited to, small left atrium, marked right atrial enlargement, and marked distortion of the thorax configuration (example, kyphosis or scoliosis). Individual patient anatomy and physician technique may require procedural variations. **Potential Adverse Events:** The following potential complications may occur during the use of this device, but are not limited to: Arrhythmia, Bleeding Major; bleeding requiring surgery or transfusion, Hematoma or Anemia, Cardiac perforation: Cardiac tamponade, Pericardial complications, Pericardial effusion Hemopericardium, Pneumopericardium, Pericarditis. Cardiovascular injury: Atrial/ventricular trauma, Great vessel perforation, Valvular damage. Cerebral injury: Asymptomatic cerebral emboli (ACE), Stroke/cerebrovascular accident, Transient ischemic attack (TIA). Coronary artery injury, Embolism: Air embolism, Foreign body embolism, Pulmonary embolism, Thromboembolism, Thrombosis/thrombus. Hypotension: Vasovagal reaction. Immunological reaction: Anesthesia reaction, Anaphylaxis. Infection: Endocarditis, Pneumonia, Sepsis/shock. Organ injury: Esophageal injury, Pleural effusion. Pain: Groin. Peripheral vascular injury: Arteriovenous fistula, Dissection, Laceration, Pseudoaneurysm. Superficial tissue injury. Please consult the respective manufacturer's labeling for adverse events associated with the use of either cardiovascular catheters or endomyocardial biopsy devices.

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Abbott.com

MAT-2503012 v1.0 | Item approved for global use, with the exception of Finland.