COOK MEDICAL

Amplatz Support Wire Guide with Apex Curve

Instructions for Use

T_APEX_REV0

AMPLATZ SUPPORT WIRE GUIDE WITH APEX CURVE

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION

The Amplatz Support Wire Guide with APEX Curve is made with a stainless steel inner mandril and stainless steel outer coil. This device is provided with a PTFE coating to ease coaxial use with other devices. The product is manufactured with a double curve distal tip and is available in a diameter of 0.035 inches and 260 cm in length. Refer to product label for additional product specifications.

INTENDED USE

The Amplatz Support Wire Guide with APEX Curve is used to facilitate the placement of devices during diagnostic and interventional procedures.

INDICATIONS FOR USE

The Amplatz Support Wire Guide with APEX Curve is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart including those used within transcatheter aortic valve procedures.

CONTRAINDICATIONS

Not for use in the coronary arteries or cerebrovasculature.

WARNINGS

- This product is not intended for use in the coronary arteries.
- This product is a delicate instrument. Avoid forceful angulation.
- Do not attempt to torque the wire guide.
- Avoid manipulating or withdrawing the wire guide back through a metal needle or cannula. A sharp edge may scrape or shear material from the wire guide.
- Altering the tip's configuration or curve manually may damage the wire guide.
- This wire should only be introduced into or withdrawn from the ventricle through a catheter already positioned in the ventricle.
- The Amplatz Support Wire Guide with APEX Curve is manufactured with a double curve; attempts to modify may alter its performance and cause complications.
- These procedures are usually undertaken with therapeutic anticoagulation. Use extreme caution and careful judgment in patients for whom anticoagulation is not used or is contraindicated.
- If contrast agents are used, use extreme caution in patients who have had a severe reaction to contrast agents and who cannot be adequately pre-medicated.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of devices in angiographic procedures should be employed.
- Use medical imaging when you manipulate the wire guide. Do not advance or manipulate the wire guide without visual evidence of the corresponding movement of the distal tip.
- Do not advance or withdraw a wire guide when resistance is encountered as perforation may occur.
- When you use the wire guide with another device, consider the end-hole size and the length of the device in order to ensure a proper fit between the wire guide and the device.
- Expected device performance is based upon use in non-tortuous anatomy. Physicians should consider the anatomy of the patient before use.

POTENTIAL ADVERSE EVENTS

- Access site complication
- Additional surgical procedure
- Air embolism/thromboembolism
- Allergic reaction, aorta complications
- Arteriovenous (AV) fistula embolism
- Arrhythmia
- Cardiac and /or septal perforation
- Death
- Embolism
- Foreign body/wire fracture
- Hematoma
- Hemorrhage
- Infection or sepsis
- MACCE
- Mitral Valve Regurgitation
- Myocardial ischemia and/or infarction

- Pericardial effusion
- Pseudoaneurysm
- Stroke or other neurologic event
- Tamponade
- Thrombus
- Valve complications
- Vascular complication
- Vessel occlusion
- Vessel perforation
- Vessel dissection
- Vessel trauma or damage
- Vessel spasm
- Wire entrapment/entanglement

INSTRUCTIONS FOR USE

1. Flush the wire guide holder by attaching a syringe with heparinized saline or sterile water to the fitting of the wire guide holder. Inject enough solution to wet the wire surface entirely.
   NOTE: If flushing through the wire guide holder is not possible, remove the wire guide from the holder and place in a bowl of heparinized saline or sterile water, or wet the wire guide surface over the entire length using gauze moistened with heparinized saline solution.
2. Carefully remove the wire guide from the holder.
3. If needed, insert the included wire guide insertion tool through the valve assembly or hub of the guiding sheath or other interventional device. Insert the tip of the wire guide through the insertion tool.
4. Standard wire guide endovascular techniques may now be employed.
   NOTE: When utilizing this product within the heart, this wire should only be introduced into or withdrawn from the ventricle through a catheter already positioned in the ventricle.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information.

A symbol glossary can be found at https://cookmedical.com/symbol-glossary

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www.cookmedical.com

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