Amplatz Type Graduated Renal Dilator Set Prescriptive Information

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

Warning
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use
The Amplatz Type Graduated Renal Dilator Set is recommended for dilatation of the nephrostomy tract.

Contraindications
This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

Warnings
None known.

Precautions
A thorough understanding of the technical principles, clinical applications, and risks associated with nephrostomy dilatation is necessary before using this product. The recommendations given are meant to serve only as a basic guide to the utilization of this set. The performance of percutaneous nephrostomy should not be undertaken without comprehensive knowledge of the indications, techniques and risks of the procedure.

Adverse Events
The adverse events which may result from a dilatation procedure include:

- Tissue Trauma
- Tissue perforation