ASTER
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ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Amplatz Sheath

Device Description

The Amplatz Sheaths are firm renal sheaths designed to allow smooth passage of surgical instruments into the nephrostomy tract.
The configurations available include.

Family	Size (Fr.)	Length (cm)	Catalogue Number	Colors
Amplatz Sheath (AS)	18 20 22 24 26 28 30 32 34	17	AMPLGP001	Black Grey

Intended Purpose

Amplatz Sheaths is used as a working channel to maintain a previously established nephrostomy tract for introduction of instruments and catheters during urological procedures and during renal dilatation to provide atraumatic working track after removal of dilator.

Performance Characteristics of the Device

Amplatz Sheath is used as a working channel and helps in maintaining a previously established nephrostomy tract for introduction of instruments and catheters. It has a smooth surface and is radiopaque in nature for better visualization. Provides high radiopacity specification for easy X- ray Verification of position.

Intended Patient Population

- Amplatz Sheath is used in patients to allow smooth passage of surgical instruments into the nephrostomy tract.
- It is recommended for use in patients above the age of 18yrs.
- The above-mentioned Frenches is not recommended for use in infants and patients below the age of 18yrs.

Indications

Used during renal dilatation to provide and maintain a nephrostomy tract.

Contraindications

- Uncorrected Bleeding Diathesis, most commonly uncontrollable coagulopathy.
- Severe hyperkalemia
- Uncooperative patient.

Precautions & Warnings

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- The Intended User of the device must be a Urologist specialized in the treatment of urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

Warnings:

- All components of the Amplatz Sheaths are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient:
  Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Shelf-life and storage condition of the Product

The shelf life of Amplatz Sheath is 3 years (Indicated on product label with the following use-by date symbol).

Store the Amplatz Sheath at a temperature between 12-35^{0}C and a Humidity range of 30-75%.

Store in a dry, cool place. Avoid extended exposure to sun light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Amplatz Sheaths have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Amplatz Sheaths are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Open the package from the Chevron Side (‘V’ Notch) of the pouch.
- Suggested instructions for using Amplatz Sheaths:
- After puncturing the tract to the kidney and application of the guide wire, start dilatation with sequential dilation starting from smaller size to bigger size.
- Put the guiding catheter over the wire

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- Complete system dilatation over the catheter till requested size.
- Slide the Amplatz Sheath over the previously placed dilator. Remove the dilator and leave sheath in place.

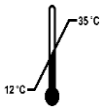
Removal Instructions

Retrieve the device slowly after the introduction of the catheter or other instruments during urology procedures.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

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Bibliography

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  https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical Devices – Symbols to be used along with Medical Device labels, labelling and information to be supplied- PART 1: General Requirements
- EN ISO 20417:2020- Medical Devices- Information to be supplied by the manufacturer.