

NEPHROCUTANEOUS DILATORS SET AND SHEATHS

Device Description:

AMECATH Nephrocutaneous Dilators Set and Sheaths is a sterile, single-use device for short-term use (60 minutes).

AMECATH Nephrocutaneous Dilators are made of medical grade polypropylene with radiopaque filler, the sheaths are made of radiopaque PTFE or Tecoflex Polyurethane, the guiding catheter and the introducer sheath are made of radiopaque Polyurethane.

AMECATH Nephrocutaneous Dilators are designed with taper short tip design for a traumatic placement and full tract dilation.

The dilator sizes 6, 8 and 10 Fr are designed to adapt 0.038" Guide wire while the dilator sizes from 12 Fr to 30 Fr are designed to adapt Guiding catheter 07 Fr.

Hydrophilic coating is applied on the 15 cm from Nephro-cutaneous dilators tip which covered by 18 cm renal sheath to facilitate the placement.

Range of size of dilators between 6 to 30 FR. And length 30cm.

Range of size of renal sheath between 12 to 30 FR. And length 18cm.

Target patient populations: Adults and children (Paediatric)

Intended user: Health Care Professionals

Device construction:

List of Accessories:

There are no accessories supplied with the device .

Intended Use:

Dilate the tract before endoscopic renal procedure to adapt the passage of Nephroscope and accessories.

Contraindications:

- Previous Renal Surgery.

Warnings and Precautions

- For single product and patient use only.
- Do not use the device if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection. Reprocessing or Re-sterilization may damage the device and affect its integrity which when re- used may lead to possible deterioration in health and safety of patients.
- It is not recommended to use antimicrobial ointments on devices as it may cause its degradation.
- Do not use absolute alcohol or acetone-based product on the device. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution.
- The proper size selection for the device size and length is the responsibility of the physician considering the patient's anatomy.

COMPLICATIONS:

- Injury of the Kidney if used by non-expert physician, and that may lead to severe Haemorrhage or kidney loss.

- Injury of adjacent organs as the colon or the lung.
- Hematuria.

How Supplied:

- **AMECATH Nephrocutaneous Dilators Set and Sheaths** is a sterile, single-use Medical device
- Each **AMECATH Nephrocutaneous Dilators Set and Sheaths kit** is packed in a PETG hard blister tray with blister cover then packed in Breathable bag (window bag).
- Each carton box includes 10 **AMECATH Nephrocutaneous Dilators Set and Sheaths kits**

***Note: When the sheath is packed separately with the dilator, it is packed in medical paper pouch W (7.5cm) then packed in medical paper pouch W (10cm).**

AMECATH Nephrocutaneous Dilators Set and Sheaths method of application

1. After puncturing the tract to the kidney and application of the guide wire, start dilatation with sequential dilation starting from 6 Fr. To 10 Fr.
2. Put the guiding catheter over the wire.
3. Complete system dilatation over the catheter till requested size (26, 28 or 30).
4. Slide the sheath of the requested dilator over it.
5. Remove the dilator and leave sheath in place.

*** N.B for further information on luer connections, please refer to latest version of BS EN ISO 80369-7 (If Applicable).**

Product Variants:

For variants of **AMECATH Nephrocutaneous Dilators Set and Sheaths**, Kindly refer to the catalogue, visit our website on : **“www.amecathgroup.com”** , or contact your nearest **AMECATH** representative.

1. Nephro-Cutaneous Dilator and Sheath Complete Set

Code Structure: NCD-SET:

NCD:	Nephro-Cutaneous Dilator and Sheath
SET:	Complete Set

Reference	Contents
NCD-SET	<ul style="list-style-type: none"> ● NEPHRO-CUTANEOUS DILATOR from 06 to 30 Fr 30 Cm. ● Renal Sheath from 24 to 30 Fr 18 Cm. ● Guiding Catheter 07 Fr 70 Cm. ● Introducer Sheath 10 Fr 25 Cm.
● In case of Dilators hydrophilic coating add (H) at the end of code (NCD-SET-H)	

2. Separate Renal Sheath

Code Structure: NCD-SHE-XX

NCD:	Nephro-Cutaneous Dilator and Sheath.
SHE:	Renal Sheath
XX:	Size in Fr (Inner Diameter).

Referencia	Contents
NCD-SHE-XX	<ul style="list-style-type: none"> Renal Sheath from 12 to 30 Fr 18 Cm with Nephro-Cutaneous Dilator XX Fr

3. Separate Nephro-Cutaneous Dilators

Code Structure: NCD-DIL-XX:

NCD:	Nephro-Cutaneous Dilator.
DIL:	Dilator
XX:	Size in Fr (Outer Diameter).

Reference	Contents
NCD-DIL-XX	<ul style="list-style-type: none"> Nephro-Cutaneous Dilator from 06 to 30 Fr 30 Cm.
<ul style="list-style-type: none"> In case of Dilators hydrophilic coating add (H) at the end of code (NCD-DIL-XX-H) 	

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
 - Do not expose to organic solvents, ionizing radiation or ultraviolet light.
 - Rotate inventory so that catheters are used prior to expiration date on the package label.
 - Used product should be disposed in sanitary container to prevent possible contamination and cross infection.
- In case of any questions or queries, kindly contact the local Authorized Representative or visit **AMECATH** website on : “ www.amecathgroup.com ”
- You can find a copy of this IFU in a PDF format on **AMECATH** website on : “www.amecathgroup.com”.
- In case of any Adverse event, Contact your local Health Authority immediately.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



AMECO MEDICAL INDUSTRIES
 Industrial Zone B4 - Plot 119 East.
 10th of Ramadan City - Egypt
 Tel: +20 5545 01321/2 - Fax: +20554501224
support@amecathgroup.com | www.amecathgroup.com



OBELIS S.A.
 Bd. Général Wabis, 53
 1030 Brussels - BELGIUM
 Tel: +322.732.59.54 | Fax: +32.2.732.60.03
mail@obelis.net | www.obelis.net