PACKAGING

Medical device delivered in a peelable pouch as inner packaging within a cardboard packaging box.
One (1) unit per box (one (1) access sheath with a dilator tubing).
Do not use if the packaging is open or damaged.
Use before the expiry date clearly indicated on the label.
Store in a dry place below 40ºC. Keep away from light.

LABELING SYMBOLS DEFINITION

	Manufactured by
REF	Device reference
LOT	Device Lot number/Serial Number
	Expiry date, Use before date, Use by
STERILE EO	Sterilized by Ethylene Oxide
	Device Intended for Single Use only. Do Not reuse
	Caution, consult accompanying documents
	Do not use if package has been opened or damaged
	Keep dry
	Keep away from sunlight
15°C 40°C	Temperature limitation
	Non pyrogenic
	Production date

Instructions for use ref. CO000853 – Rev 06/2015

Manufactured by:

NATEC Medical Ltd.
Maeva Centre Building,
Silicon Avenue,
Ebene Business Park,
Reduit 72201, Mauritius
www.natec-medical.com

Distributed by:

Envaste Ltd.
Maeva Centre Building,
Silicon Avenue,
Ebene Business Park,
Reduit 72201, Mauritius
www.envaste.com

CE 0459

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

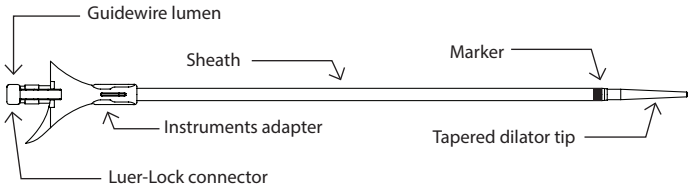
Manawa

URETERAL ACCESS SHEATH SET

INSTRUCTIONS FOR USE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS

CONTENTS: One (1) Ureteral Access Sheath Set sterilized with ethylene oxide gas. Non-pyrogenic.



These instructions apply to all sheath diameters and lengths.

PRODUCT INFORMATION

Maximum guidewire diameter: 0.038" (0.96 mm)
Maximum sheath internal diameter: 9.5Fr, 10.7Fr, 12.0Fr, 14.0Fr. Please refer to label information.
After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy related to product contaminated by blood.
For one time use only. Do not reuse. Do not re-sterilize.
Read instructions before to use.

I. DEVICE DESCRIPTION

The MANAWA Ureteral Access Sheath Set is composed of a reinforced proximal shaft surrounding an inner tapered dilator tubing. The shaft has a rounded distal end and a plastic molded hub with a locking mechanism at its proximal end. A radiopaque marker band on the distal end of the shaft allows accurate placement of access sheath under fluoroscopy.
The proximal end of the dilator tubing bears a molded Luer-Lock connector that latches onto the shaft hub. The tapered distal end of the dilator tubing permits gentle atraumatic insertion and dilation.
The sheath is designed to create a conduit allowing the insertion of urological procedure instruments.

The Access Sheath is available in lengths of 20, 28, 35 and 45 cm with internal diameter of 9.5Fr, 10.7Fr, 12.0Fr and 14.0Fr.
Maximum guidewire size is 0.038" (0.96mm).

II. INDICATIONS

The Manawa ureteral access sheath is indicated for use during ureteral access procedures to provide ureteral dilatation with continuous working channel for the introduction of urological instruments such as ureteroscopes and for the injection of fluids into the urinary tract.

III. CONTRAINDICATIONS

- Patients who are contraindicated for retrograde urologic procedures.
- Patients who are contraindicated for antegrade urologic procedures, including, but not limited to patients with blood clotting abnormalities due to coagulopathies or pharmacological anticoagulations.
- Patients who have the presence of tight strictures which would limit the device.
- Patients who have the presence of large obstructing distal ureteral calculi.

IV. WARNINGS

- The device is designed and intended for single use only.

DO NOT RESTERILIZE AND/OR REUSE. Reuse or resterilisation may 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. Reuse or resterilisation 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. The manufacturer will not be responsible for any direct, incidental or consequential damages resulting from resterilisation or reuse.

- Inspect the device, prior to procedure, to verify functionality and lack of damaged parts. Do not use the device if the outer or the inner package is damaged or opened.
- To minimize resistance during advancement, ensure the hydrophilic coating on the dilator and sheath is activated with saline or sterile water prior to placement.
- When the ureteral access sheath is in the body, it should be manipulated while under sufficient and/or high quality fluoroscopy. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- This device should be used only by physicians who are experienced and have a through understanding of the clinical and technical aspects of flexible ureteroscopy.
- Product and packaging should be disposed of in accordance with hospital, administrative and/or local government policy.
- Do not expose device to organic solvents, e.g. alcohol.
- Product should be used prior to 'use before' date (see label).

V. PRECAUTIONS FOR USE

- Access sheath should only be used by physicians who have comprehensive knowledge of the indications, techniques and risks of the procedure
- Do not use the flexible ureteroscopy access sheath if the packaging is damaged.
- Do not use the flexible ureteroscopy access sheath after its expiry date.
- Do not use the device if damaged or kinked either before or during use.
- The access sheath and dilatation catheter should be handled with the utmost precaution and care to avoid excessive or unnecessary handling especially when inserting the access sheath over the guidewire.
- Activate the hydrophilic coating of the access sheath by immersing in a recipient containing saline solution.
- Do not advance access sheath without dilator in place.
- If resistance is encountered, suspend progression of the access sheath or guidewire until the cause has been determined and corrective actions have been performed.
- In the event of a tight stenosis, consider ureteral balloon dilatation prior to insertion of the access sheath.

VI. POTENTIAL COMPLICATIONS

Complications that may result from this procedure include, but not limited to:
- Mucosal irritation, inflammation and edema
- Ureteral strictures
- Acute bleeding or hemorrhage
- Urethral, bladder, or ureteral perforation
- Other injury to the urinary tract

VII. SELECTION, DEVICE PREPARATION & DEVICE COMPATIBILITY WITH ACCESORIES

- Place a 0.035" (0.89mm) or 0.038" (0.96mm) guidewire of the desired length into the ureter to establish a working tract.
- Activate the hydrophilic coating by immersing the dilator/access sheath assembly in a container of saline solution or sterile water.

VIII. INTRODUCTION

- Grasp the sheath just below the instrument adapter and advance the dilator/sheath assembly over the guidewire to the desired location.

Note: Ensure the dilator is securely locked onto the instrument adapter, such that the dilator/sheath assembly can be placed as a single unit, allowing one-hand placement.

- Confirm the dilator/sheath assembly is properly placed via fluoroscopy.
- While holding the access sheath in position, pinch to detach the luer-lock connector and remove the dilator. Do not advance the sheath without the dilator in place.

Note: Suture may be utilized to secure the adapter externally. Suture holes are conveniently located on the instrument adapter.

- Introduce the desired ureteroscope or instruments as needed.
- After use, gently withdraw the access sheath and discard as per hospital procedures.
- To perform a retrograde pyelogram, reinsert the dilator into the sheath until the luer-lock connector snaps into the instrument adapter. Inject contrast through the fitting of the luer-lock adapter. Remove dilator as desired..
- Upon completion of the access procedure, gently withdraw the device.
- Discard device upon completion of procedure in accordance with hospital procedures.

IX. DISCLAMER OF WARRANTY AND LIMITATION OF REMEDY

The manufacturer has exercised reasonable care in the manufacture of this device. Both manufacturer and distributor excludes all warranties, whether express or implied by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device as well as factor relating to the patient, the diagnosis, treatment, surgical procedures, and other matters beyond our control directly affect this device and the results obtained from its use. Both manufacturer and distributor shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.