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CE 0344

Instructions for Use
of
Single Use Flexible Suction-Evacuation Ureteral Access Sheath

[Foreword]



[Name of Registrant/Manufacturer/After-sales Service Unit]
Anhui Happiness Workshop Medical Instruments Co., Ltd
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：3years

[Notified Body]
DEKRA Certification B.V. - NB0344

[European Representative]
Authorized Representative: Lotus NL B.V.
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[Date of Preparation and Revision of Instructions] 2026-04-01, 1.5

[Part No.] 01007001029

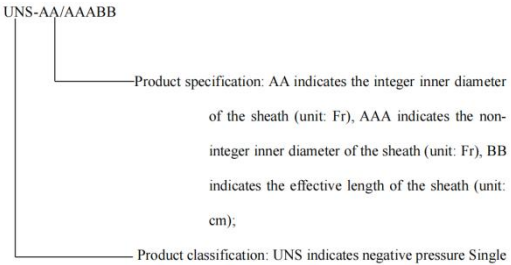
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[Marking instruction]

	Manufacturer		European Representative
	Catalogue number		Date of manufacture
	Use-by date		Sterilized with ethylene oxide
	Batch code		Serial number
	No secondary serialization		No secondary use
	Consult instructions for use or consult electronic instructions for use		Keep dry
	Importer		Medical device
	Unique device identifier		Single sterile barrier system with protective packaging outside
	Do not use if the package is damaged		Keep away from sunlight

[Product Name]
Single Use Flexible Suction-Evacuation Ureteral Access Sheath

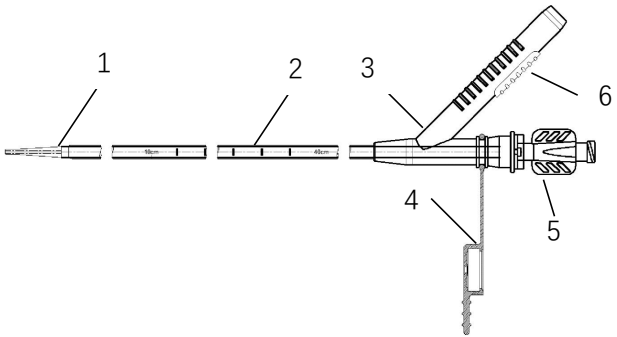
[Model]



Model	Fr	Length cm
UNS-10 (105, 11, 115, 12) 13 (20, 28, 30, 31, 35, 36, 40, 41, 44, 45, 46, 49, 50, 51, 54, 55)	10 10.5 11 11.5 12	13 20 28 30 31 35 36 40 41 44 45 46 49 50 51 54 55

[Product Performance]
The product is lubricated, with anti-compression and anti-twisting characteristics, effectively guaranteeing the smooth passage of instruments.

[Structure and composition]



1. Dilator 2. Sheath 3. Sheath hub 4. Sealing cap 5. Dilator hub 6. Pressure control vent
Figure 2 Schematic diagram of Single Use Flexible Suction-Evacuation Ureteral Access Sheath, type UNS.

[How to use]

UNS (negative pressure type)

1） The guide wire is placed into the ureter under surveillance to a predetermined position.
2） Sterile water or saline is wiped on the outer surface of the sheath to activate the hydrophilic coating function.
3） Push the tip of the dilator down along the guidewire to push the dilator and sheath into the ureter as a unit.
4） Fluoroscopy is used to confirm that the sheath is definitively in place.
5） Ensure that the sheath remains in position, the dilator centre seat is rotated anticlockwise and the dilator is withdrawn to complete the channel establishment.
6） Endoscopes or surgical instruments can be introduced for use through the sheath.
7） During surgery, the drainage fluid can flow out through the Y-shape co-tube or be used in connection with a negative pressure suction device.

[Intended purpose]

The product is intended to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

1) Indications

The product is designed to establish a conduit for the treatment of urinary stones during endoscopic procedures.

2) Contraindications

This product is contraindicated in patients who cannot tolerate urological endoscopic procedures, including:

- Urinary tract infection
- Uncorrected bleeding diathesis

3) Patient target group
Adult population requires the treatment of urinary stones.
4) Intended users
This product must be operated by the trained and qualified medical personnel.

[Clinical benefits to be expected]
The product is intended to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract so as to improve surgical efficiency. The flexible tip allows the endoscope to better access intrarenal areas. The suction evacuation function provides higher stone-free rates (SRF) and reduces post-operative complications compared to traditional ureteral access sheaths.

[Potential Side-effects]
• Ureteral injury
• Urinary tract infection

[Other devices to be used with]
Guide wire, endoscope and negative pressure suction device are the common devices to be used with Single Use Flexible Suction-Evacuation Ureteral Access Sheath, not accessories of the device.

- Guide wire: The diameter of the guidewire shall not be greater than 0.035inch.
- Endoscope: The maximum outer diameter of the endoscope shall not be greater than the inner diameter of sheath tube (3.3mm, 3.5mm, 3.7mm, 3.8mm, 4.0mm respectively).
- Negative pressure suction device: The suction tube's inner diameter of the suction device should be less than the outer diameter of Y-shape co-tube (9mm).

[Caution]
1） This product is for single use only, check the package integrity before use, and can not be used if the sterile package is broken or the product is damaged.
2） This product has been sterilized by ethylene oxide. It is strictly prohibited to use in case of damaged packaging, altered appearance and structure, or in case of breakage.
3） Use immediately once the package is opened, and destroy it after use.
4） The instructions for use must be read in detail before use and used before the expiry date according to clinical procedures.
5） This product must be used by professionals.
6） This product is intended for single patient, single use only.

[Warning]
1） To make the hydrophilic coating work and achieve the best lubrication, ensure that sterile water or saline is wiped on the outer surface of the sheath before use.
2） Before entering the urinary tract along the guide wire, confirm that the dilator hub and sheath hub are securely locked, and place the dilator and sheath as one unit.
3） Before entering the urinary tract, the sheath should not be bent or kinked to avoid damaging the integrity and causing urinary tract injury.

4） During being placed into the urinary tract, if the sheath encounters resistance which prevents its advancing,stop immediately and withdraw the sheath carefully. Do not force the sheath in place until the cause is identified.
5） After placing the sheath to a defined position, the operator holds the sheath in place with one hand while the other hand rotates the dilator to withdraw it.
6） The Y-shape lateral connection is for draining fluids only.

[Tips for Use]
1） Waste should be disposed of after use in accordance with the requirements of the hospital or environmental protection department.
2） This product is valid for three years, and the use of expired products is prohibited.
3） Before using, preoperative examination is required to assess the patient's condition and the dimensions of the cooperating instruments, in order to select the appropriate model size. For women or individuals with smaller body frames, a shorter specification should be selected. For men or those with larger body frames, a longer and wider specification is generally chosen. The above are only manufacturer recommendations; the actual selection should be determined by the physician based on clinical circumstances.

[Notice to user]
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.

[Date of manufacture & Expiry]
See label.

[Storage]
This product should be stored in a dry, light-proof, cool place.