

Stone basket
Instructions for use套石网篮
使用说明結石用バスケット
使用説明書Корзина для удаления камней
Istruzioniنطر راب الحوضي
سلة الحصواتTas sepeti
Instruções de utilização

IFU Nr. 25-D

Instructions for use
Stone basket

IFU Nr. 25-D Steinfangkörbchen EN 06/20.06.2016

Please note: This medical product may be obtained and used only by trained medical personnel.

1. Description

Nitinol stone basket with detachable handle.

2. Contents and packaging

- Nitinol stone basket with detachable handle; length 90 cm or 120 cm; basket with three, four, or six wires, straight or helical; basket type: standard, tipless, filiform
- Blister packaging, Instructions for use

3. Intended use

Stone extraction from the ureter and renal pelvis or renal calice under ureterorenoscopic visual guidance.

4. Indications

Stone baskets catch and eliminate kidney stones with a rigid or flexible endoscope during a transurethral intervention for the following indications:

- Removal of distal stones
- Removal of higher lying stones after consideration of other methods (e.g. shock wave lithotripsy or laser disintegration) or if a "wait and see" attitude does not lead to success.

5. Contraindications

Contraindications result from the restrictions for the uretero-renoscopy.

6. Possible side effects

- Injury of the kidney (bleeding)
- Urter injury during the procedure (perforation, bleeding)
- Local fibrosis from extravasation of urine
- Formation of a ureteral stricture
- Vesicoureteral reflux
- Urinary tract infection
- Pain

7. Instructions

The stone basket is inserted into the target organ using the uretero-renoscope. By withdrawing the tube covering, the basket is released at the tip of the instrument and unfolds. The operator manipulates the urinary stone into the open basket. The spring mechanism of the handle then automatically secures the stone in the basket, and the entire instrument is withdrawn from the body from which the stone was removed, and the instrument is re-inserted to retrieve additional stones.

In the event that the instrument gets stuck in the ureter, it is possible to release the handle from the basket and withdraw the endoscope, thereby unblocking the working channel. Then the endoscope can be re-inserted and the stone disintegrated by laser or mechanically.

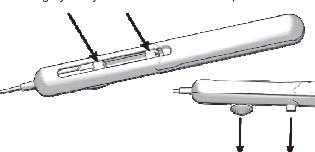
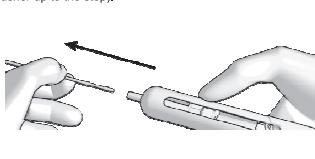
7.1. Releasing the basket

7.1.1. Remove the protective cover

Grasp with stone pincers or forceps in the provided perforation and remove the cover from the handle body.



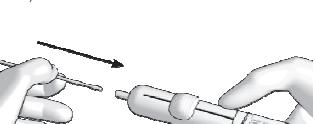
7.1.2. Push the gray and yellow fixation until the stop.

7.1.3. Withdraw basket.
(Should the basket get caught in the detachable handle, it can be released by pushing back with the pusher up to the stop.)

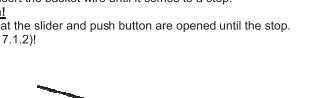
7.2. Fixing the basket in place

Note: For safety, only reconnect the basket outside of the body.

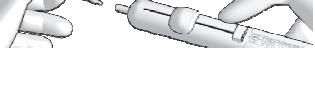
7.2.1. Insert the basket wire until it comes to a stop.

Attention!
Ensure that the slider and push button are opened until the stop.
(see step 7.1.2)

7.2.2. Push the slider down until it comes to a stop.



7.2.3. In the pressed state, pull the slider until it catches and hold in position.



7.2.4. At the same time, push down the gray push button.



7.3. Interaction with other drugs

- The stone basket or its components could potentially be discolored when applying urinary examination methods that use dye.
- 11. Transport and storage conditions**
The products may be transported and stored only in the packaging intended for this. There are no further specific requirements for transport.
Products must be stored dry and protected from direct sunlight, in the temperature range of 5 - 30 degrees Celsius.
- 12. Disposal**
After use, this product may pose a biological hazard. Handling and disposal must be carried out in accordance with recognized medical procedures and be completed pursuant to applicable legal regulations and guidelines of the respective country.

7.4. Possible complications and/or risks

- Very large kidney stones may be too large for removal using a stone basket and can get stuck in the kidney area or ureter.
- With very large stones, it may not be possible to remove the stone from the basket in some circumstances.
- Basket inverting
- Breakage of the basket during forced withdrawal despite resistance
- If the basket is strongly bent directly at the tube-basket connector, the advancement and withdrawal of the basket may be impeded or impossible. In this event, the entire stone basket should be advanced or withdrawn a few millimeters. Do not advance or pull back the basket against strong resistance, otherwise there is a risk of damage to the product.
- 9. Warnings / Precautions**
This product is only sterile if the packaging is undamaged and unopened.
- For single use only! Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the instrument and/or cause the instrument to malfunction, which may result in illness, injury or the death of a patient.
- Do not use products after the date of expiry has passed.
- Do not wipe the product and set components with alcohol/disinfectant agents. This may damage the surface.
- All components must be carefully checked for compatibility and integrity before use.
- The product is intended for a temporary service life of 5 minutes.
- Do not rotate the open basket in the Ureter. A kink in the tube prevents the mechanical operation of the basket.
- To prevent the basket from becoming stuck during withdrawal, it is recommended to expand the ureter before the endoscopy and stone removal.
- The size of the stone should be determined before the procedure using ultrasound or x-ray to prevent getting stuck in the urinary tract. Do not use the stone basket if the stone is too large.
- Push forward or remove the stone basket carefully to prevent damage to the mucous membrane or the urinary tract (trauma perforation).
- With the simultaneous use of laser lithotripsy, great caution is required, as the nitinol basket can be very easily damaged by the laser. The laser should under no circumstances be fired directly into the basket.
- 10. Interaction with other drugs**
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7.5. Notes

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7.6. Disposal

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7.8. Interaction with other drugs

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7.12. Interaction with other drugs

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7.16. Interaction with other drugs

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7.20. Interaction with other drugs

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7.21. Transport and storage conditions

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7.28. Interaction with other drugs

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7.32. Interaction with other drugs

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7.36. Interaction with other drugs

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7.44. Interaction with other drugs

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7.45. Transport and storage conditions