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EN

INSTRUCTIONS FOR USE

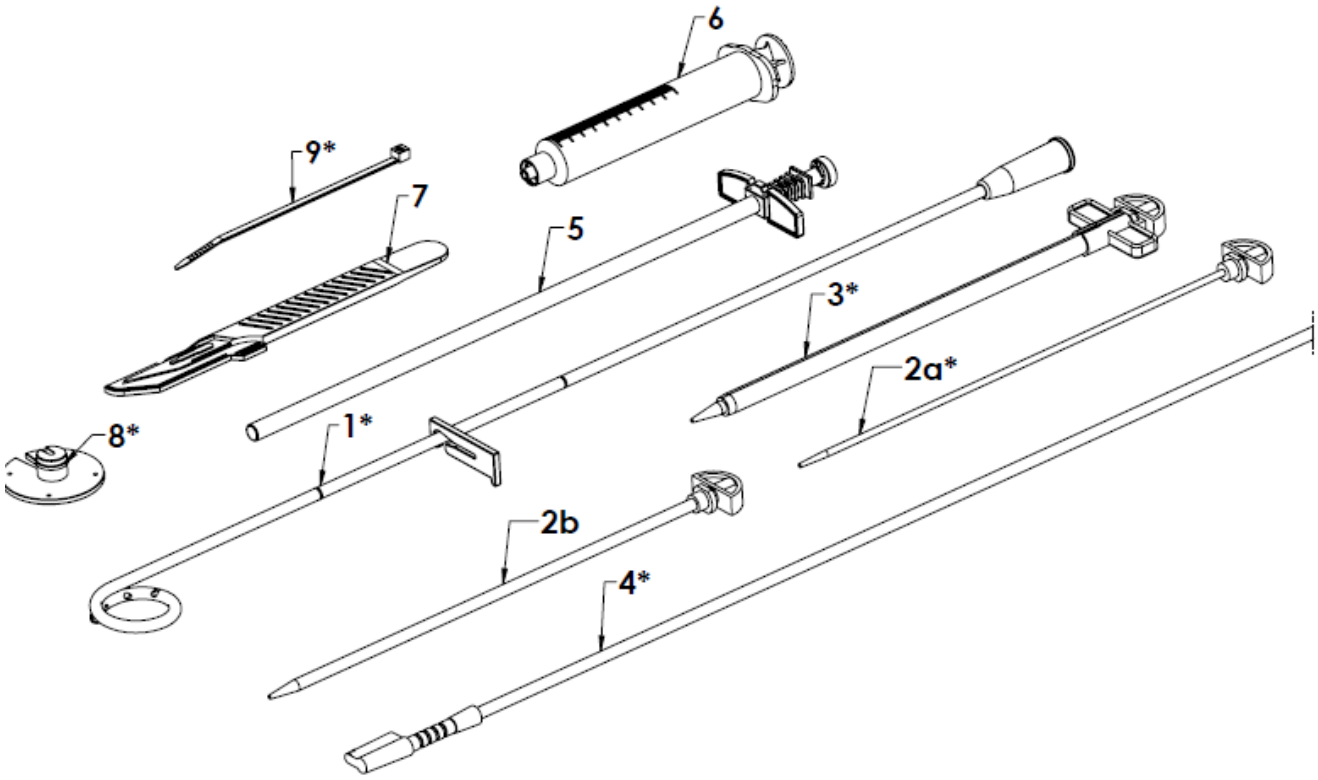
NEPHROSTOMY KIT

CE 0197

READ THESE INSTRUCTIONS BEFORE USE

1. DEVICE DESCRIPTION

The nephrostomy kit consists of a catheter with a clamp, a dilator, a dilator with peel away sheath (both radiopaque and with atraumatic tip), a guidewire, a two - or three-part needle, a syringe, a scalpel, a fixing collar and a band clip.
Polyurethane, radiopaque catheter comes in two configurations: with a pigtail curve with numerous holes inside the loop, and a straight tip with holes located spirally along the axis. The distal tip of the catheter is atraumatic. The catheter is available in many French (F) sizes with color-coded tips. The catheter has depth marks.



1. Pigtail type or straight catheter with a clamp (with pigtail catheter as an example)
2a. Dilator I
2b. Dilator II
3. Dilator with peel-away sheath
4. Guidwire
5. Two- or three-part needle
6. Syringe
7. Scalpel
8. Fixing colar
9. Band clip

Fig. 1. Elements of the kit

2. PRODUCT RANGE

All available configurations of this device are presented in Table 1.

Table 1. Parameters of nephrostomy kit elements

CATHETER			NEEDLE		DILATOR	GUIDEWIRE	
Size [F]	Length [cm]	Color coding	Size [G]	Length [mm]	Size [F]	Diameter [inch]	Length [mm]
5	45	blue	20*	190*	5, 6	0.035"	800
6		transparent green			7, 8		
8		blue	18**	200**	7, 10	0.038"	
9		transparent green					
10		red			7, 10, 13		
11		navy blue					
12		white					
14		green			10, 13, 15		
18		transparent red	Non - available				

* three-part needle
** two-part needle

The two-part needle is included in the nephrostomy kit containing catheters 8 F÷14 F.
The three-part needle is included in the nephrostomy kit containing catheters 5 F÷6 F.

3. INTENDED PURPOSE / INDICATIONS

The kit is intended for short-term (up to 30 days) urinary diversion and drainage when natural urine outflow from the kidney is not possible.

3.1. CONTRAINDICATIONS

The use of nephrostomy kit is usually contraindicated in the following cases:

- coagulation disorders or the use of anticoagulants;
- severe hypokalemia (K > 7 mmol/l);
- infection at the puncture site;
- allergy or hypersensitivity to polyurethane.

3.2. POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with use of the device include (in alphabetical order), but are not limited to:

- allergic reaction or hypersensitivity to polyurethane;
- bleeding;
- catheter fracture;
- catheter incrustation, malfunction and possible urinary retention;
- catheter migration;
- damage to surrounding organs (e.g. liver, spleen, colon, subcostal vessels);
- fever;
- hematuria;
- infection / pyuria;
- pain in the lumbar region;
- pneumothorax;
- septic shock;
- urine extravasation.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer at **reklamacje@balton.pl** and the competent authority of the country in which the user and/or patient is established.

3.3. INTENDED USER PROFILE

Intended users of this device are only physicians who have received appropriate training.

3.4. USE ENVIRONMENT

Use of this device is allowed only in healthcare facilities prepared for this kind of procedures.

3.5. PATIENT TARGET GROUP

Target group are patients qualified for nephrostomy. No known data restrict use of this device in patients of particular gender or race.
Before making decision concerning use of the device, potential benefits and risks should be considered individually for every patient.

4. WARNINGS

- The device is designed for single use in a single patient only. Do not resterilize or reuse. Reuse or resterilization 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. Reuse or resterilization may also create a risk of contamination of the product and cause patient infection including the transmission of infectious disease(s). Contamination of the product may lead to injury, illness or death of the patient.
- Do not use if the package is opened or damaged.
- Do not use after expiration date given on the package label.
- Do not use if labeling is incomplete or illegible.

5. PRECAUTIONS

- The procedure must be carried out after adequate preparation of the patient under conditions of operating room and under ultrasound or X-ray guidance.
- This product is intended for use by physicians trained in urological procedures.
- Nephrostomy catheter should be inspected regularly, as directed by the physician.
- The catheter should not indwell in the patient longer than 30 days. Leaving the catheter inside the patient's body for longer period may increase the risk of complications including: catheter incrustation, malfunction and urinary retention.
- Do not use excessive force while introducing, manipulating and removing the device. If resistance is felt, check the possible cause of resistance before deciding to continue the procedure.
- The patient should be given all information about the procedure and the correct conduct during and after the procedure.

6. HOW SUPPLIED

6.1. CONTENT OF THE PACKAGING

One (1) Nephrostomy kit in a blister, packed in a case box with Instructions for Use.

6.2. STERILITY

This product is supplied sterilized with ethylene oxide gas, in a blister. Only the content of the blister should be considered sterile. The device is only sterile if this packaging is not opened or damaged.

7. HANDLING AND STORAGE

Store at room temperature in a dry place, in the case box, as supplied.
Do not expose to temperatures outside the range: 10 ºC ÷ 30 ºC.

8. DISPOSAL INSTRUCTIONS

Used product shall be treated as medical waste. After use, dispose the product and packaging in accordance with healthcare facilities, administrative and/or local government policy.

9. WARRANTY

If delivered product is damaged or has any other defects, inform the manufacturer and keep the device with original packaging.

10. OPERATIONAL INSTRUCTIONS

Balton sp. z o.o. shall not be liable for any direct, incidental or consequential damages resulting from the misuse of this product.

1. Check the primary packaging (blister) for possible damage and expiry date.

If there is a suspicion that sterility may be compromised and/or the expiry date has been exceeded it must not be used.

2. Open the blister and take out the kit components.
3. Check if the kit components are not damaged.

If there is a suspicion that the device is damaged it must not be used.

4. Perform the ultrasound examination of the kidney to evaluate the urine retention in the pelvicalyceal system.
5. Disinfect the skin according to the local procedures and cover with sterile drapes.
6. Mark the puncture site.
7. Anesthetize the puncture site.
8. Remove the needle's protector.
9. Puncture the skin (under ultrasound guidance) with the two-part or three-part needle and introduce it into the pelvicalyceal system.
10. Withdraw the mandrin and check the needle for presence of urine.

In case of the three-part needle withdraw also the needle, leaving the sheath inside.

11. Remove the guidewire protector.
12. Check the correctness of needle position under ultrasound.

13. Under ultrasound guidance introduce the guidewire through the needle / sheath of the three-part needle, so its soft end gets into the renal pelvis.
14. Withdraw the needle / sheath of the three-part needle.
15. Confirm the correctness of guidewire position in the renal pelvis under ultrasound.
16. Incise the skin using the scalpel next to the introduced guidewire.
17. Introduce and withdraw (onto the guidewire) dilators provided in the kit, successively beginning with the smallest size and progressing to the biggest one (with a sheath), in order to dilate the channel for catheter introduction.

If a resistance is felt, withdraw the dilator, widen the incision and try reinserting with rotating movement.

18. Withdraw the biggest dilator under ultrasound guidance, leaving its sheath inside the renal pelvis.
19. Introduce the nephrostomy catheter into the renal pelvis through the peel-away sheath, paying attention to the marks on the catheter.

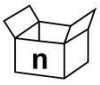
First mark informs that the tip of the catheter is at the outlet of the peel-away sheath. Second mark informs that the pigtail curve is fully deployed from the sheath.

20. Carefully withdraw the guidewire.
21. Close the catheter clamp.
22. Remove the sheath by gradually peeling it away when withdrawing, leaving the catheter inside the patient.

Make sure the sheath is peeled away simultaneously with removing it from the catheter, to prevent breaking it inside the patient.

23. Confirm the correct placement of the catheter under ultrasound, fluoroscopy or X-ray guidance.
24. Fix the catheter with the fixing collar and a band clip.
25. Connect the urine bag to the catheter fixing the bag below the patient's bladder.
26. Open the clamp to allow urine flow.

SYMBOLS GLOSSARY

CE	CE mark	MD	Medical device
UDI	Unique device identifier		Manufacturer
	Date of manufacture		Use-by date
REF	Catalogue number	LOT	Batch code
	Consult instructions for use or consult electronic instructions for use		Do not use if the packaging is damaged and consult instructions for use
	Caution	STERILE EO	Sterilized using ethylene oxide
	Do not resterilize		Do not re-use
	Single sterile barrier system		Single sterile barrier system with protective packaging outside
	Non-pyrogenic		Keep away from sunlight
	Fragile, handle with care		Temperature limit
Not made with natural rubber latex	Not made with natural rubber latex		Additional information facilitating proper use
	n units per package		Keep dry
	Recyclable packaging material		