



Catheters for infusion and drainage and accessories

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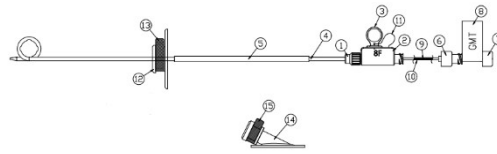
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REV.01/U



- 1- Drainage catheters fixing connector;
 - 2- Drainage catheters connector;
 - 3- Silk thread and clamp;
 - 4- Drainage tube;
 - 5- Straightener;
 - 6- Luer connector;
 - 7- Needle stylet cap;
 - 8- Paper card;
 - 9- Needle stylet;
 - 10- Needle cannula;
 - 11- Silk thread and Clamp;
 - 12- Straight fixing plate;
 - 13- Straight Clamp ;
 - 14- Oblique fixing plate;
 - 15- Oblique Clamp;
- Note: 4-14Fr drainage tube uses straight fixing plate, 16-18Fr uses slanted fixing plate.

Instructions for Use:

Catheters for infusion and drainage and accessories

INTENDED USE

The Catheters for infusion and drainage and accessories are determined for the use of diagnostic and therapeutic purposes and it is intended for the drainage of liquids from the human body and for the infusion of drugs. They are aimed for a long term use.

GENERAL INFORMATION

The product is provided single packed, sterile (EO sterilization). It is intended for single use only, and may not be re-sterilized.

The product must be stored in a cool, dry place and must be protected from daylight. Do not use this product, if the packaging or the product is damaged. Only physicians experienced with its application, corresponding interventional techniques and possible complications may use this product.

DESCRIPTION

The above mentioned products are designed for percutaneous direct puncture techniques.

The packaging contains one or more of the following components :

Drainage catheters fixing connector, Drainage catheters connector, Release button, Drainage catheters, Straightener, Luer connector, Needle stylet cap, Paper card, Needle stylet, Needle cannula, Silk thread, straight fixing plate, Clamp, Slanted fixing plate.

MATERIAL

TPU, PE, ABS, SUS 304 stainless steel

ABSOLUTE CONTRAINDICATION

- Untreatable coagulation disorder
- No safe percutaneous access

RELATIVE CONTRAINDICATIONS

- Only physicians experienced with its application, corresponding interventional techniques and possible complications may
- use this product. Possible complications can occur at any time pre-, intra- and post-operative.

POSSIBLE COMPLICATIONS

When using this product, the pre-, intra- and postoperative surgery of possible complications are as follows:

- Catheter Dislocation
- Infection, sepsis
- Embolisms, thromboses
- Occlusion and encrustation of catheter
- Pain
- Emphysema
- Pneumothorax
- Haematomas, bleedings
- Perforation or dissection of organs and vessels
- Bacteremia

PRECAUTIONS:

This instrument should be used by or under the supervision of a physician who is completely familiar with the use and limitations of this device.

Instructions of use accompanying the products has to be followed in the correspondent issues related to the compatibility, warnings, indications, usage, contraindications etc.

This product is intended for long-term use, but its indwelling time should not exceed 3 months.

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PRECAUTIONS:

Note: Do not use the product if the packaging and / or the product are damaged.

Note: Highly sterile working conditions during the complete procedure are absolutely mandatory to avoid infection.

Note: To avoid catheter problems please observe the following points:

- Adequate catheter fixation
- Regularly flushing of the catheter
- Regular checks on catheters and ward rounds
- If necessary, replace under fluoroscopic control e.g. dislocated or clogged catheters immediately

DIRECTIONS FOR USE

Handling

Note:

- a) In view of the overall condition of the patient, the indication for drainage must always been given
- b) Ensure sufficient anesthesia
- c) Adhere to legal hygienic standards
- d) Fluoroscopy is mandatory to work with
- e) Always remove the metal cannula prior removal or manipulation of the guide wire, to avoid possible damage
- f) Do not perforate drainage/nephrostomy catheter through manipulation
- g) Catheters should be fixed in place after positioning without kinks to avoid dislocation or insufficient drainage

Direct Puncture

1. Push the straightener to the taper of the front end of the pigtail ring until the pigtail ring becomes straight.
2. Remove the paper card, push the needle cannula forward to the end to tighten the connector, Insert the needle stylet until the tip of the needle is exposed at the front taper of the pigtail ring and then tighten the connector, do not perforate the drainage catheter.
3. Remove the straightener.
4. Puncture to reach the target site.
5. After reaching the target position, loosen the connector and take out the needle cannula and needle stylet. Pull the silk thread until desired pigtail is formed, twine the thread around the release button, then press the release button to fix the silk thread.
6. Pass the disposable drainage catheters through the

fixing plate and fix it to the exposed position of the human body (the large diameter is close to the human skin), and clamp the clamp. There are two ways of fixation: ①Using sutures to sew the fixation method: the fixation plate is attached to the skin of the human body, and the sutures pass through the 6 fixation holes. ②make fixing method with medical fixing stick: the fixing plate is attached to the human body skin, and the medical fixing stick is glued and fixed at the large diameter.

7. After fixing the disposable drainage catheters tube in a suitable position, connect other medical equipment, such as valves, connecting tubes, urine bags, etc.

To avoid problems with the disposable drainage catheters, please pay attention to: -Fully secure the drainage catheters. -Flush the drainage catheters frequently. -Check the disposable drainage catheters and conduct inspections at any time. -If there is displacement or blockage, it should be replaced immediately under X-ray or ultrasound guidance

8. Remove the catheter: after loosening the release button, the fixed silk thread is in a loose state. Try to pull out the drainage catheter. If the resistance is large, try to use a new set of inner cannula, straighten the catheter and pull it out slowly.

RECOMMENDED MEDICATION

Pre-, intra- and postoperative medication should be carried out according to current medical standards.

GENERAL PRECAUTIONS

The packed devices have to be stored in a dry place and room temperature.

The packed devices have to be protected from direct daylight.

Do not use devices if the expiry date on the sterile packaging is exceeded.

DISPOSAL AFTER USE

Medical devices, and accessories might pose a potential biohazard. Dispose them properly off according to approved procedures in medicine and in compliance with the statutory regulations for medical waste and recognized practices.

SHELF LIFE




















5 years

WARNING

The product must not be used if the packaging is damaged. The drainage catheters are for **Single Patient Use Only. Do Not Reuse. Do Not Reserialize.** Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient. After use this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose in accordance with applicable laws and regulations.

WARRANTY

- 1.German Medical Technology (Beijing) Co., Ltd. is responsible only for products manufactured, inspected, and packaged. This is the sole effective guarantee and supersedes any other stated guarantees.
- 2.German Medical Technology (Beijing) Co., Ltd. is not liable for treatment outcomes, complications, or treatment failures due to misuse or improper operation. Defective products from German Medical Technology (Beijing) Co., Ltd. will be replaced.
- 3.German Medical Technology (Beijing) Co., Ltd. are not authorized to deviate from these terms and conditions, nor to accept additional or supplementary responsibilities.

	Use-by date		Medical device
	Catalogue number		Date of manufacture
	Manufacturer		Batch code
	Do not resterilize		Consult instructions for use
	Do not re-use		Unique device identifier
	Sterilized using ethylene oxide		Keep away from sunlight
	Do not use if package is damaged		Unit quantity in packaging
	Authorized representative in the European Community		Caution
	Fragile, handle with care		Keep dry
	CE marking of conformity and Identification number of the notified body		