

Instruction for use

【Product name】 Wound drainage tube fixing device

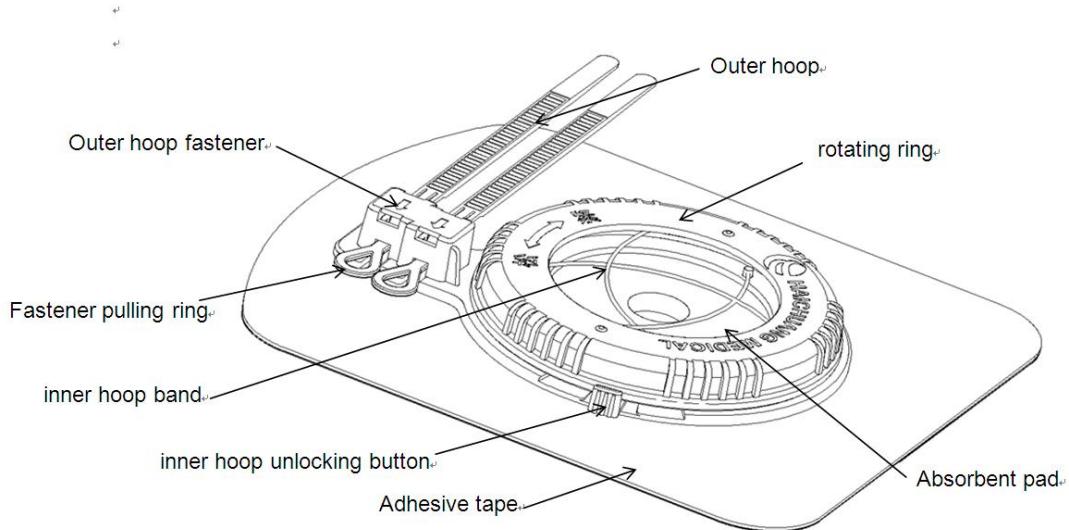
【Type】 GD8090

Product models :

| model | Inner diameter of rotating ring | Size of tube/catheter |
|----------|---------------------------------|-----------------------|
| GD8090-A | 30mm | Fr6~Fr28 |
| GD8090-B | 20mm | Fr4~Fr20 |
| GD8090-C | 50mm | Fr12~Fr36 |

【Scope of application】 The Wound drainage tube fixing device is designed to fix the drainage tube which can replace fixing with suture needles. And it can help minimize catheter movement and accidental removal to avoid secondary skin damage.

【Composition of product structure】 The device is composed of adhesive tape, absorbent pad(1-2 piece), rotating ring, Outer hoop, Outer hoop fastener, fastener pulling ring, inner hoop band and inner hoop unlocking button.



【Performance】

| | |
|---------------------|---|
| Size | Size of the Inner diameter of rotating ring should meet the requirement of the table mentioned above. Error within $\pm 2\text{mm}$ |
| Appearance | Should be neat and smooth with no foreign matter or damage. The package should seal tightly. |
| | The Inner hoop should hidden and remain no protruding or shedding before using. |
| Physical Properties | Thickness of non-woven adhesive tape should be not more than 2.5mm |
| | Peel strength of non-woven adhesive tape should be not less than 1N/cm |
| | The inner hoop should maintain catheters under 200g weight for 10s and the displacement should less than or equal to 0.5cm |
| | The inner hoop should not break when supporting a 5N force for 30min. |
| | The outer hoop should fix catheters under 3N cross pull for 5s and the displacement should be less than or equal to 0.5cm |

| | |
|-----------------------|---|
| | Water absorption of absorbent pad should be more than or equal to 6g/g |
| Chemical properties | PH of test liquid of absorbent pad :5-8 Heavy metal in absorbent pad should be not more than 10µg/mL |
| Biological properties | The product should be sterile after radiation sterilization. |

【Method of application】

1. Please select the appropriate type according to the size of the catheter;
2. Please clean the skin and keep the skin clean and dry before sticking and fixing.
3. Open packaging and take out the product. Pass the catheter through the center of the rotating ring. Aim at the center of these two dots based on the two symmetrical raised dots on the rotating ring, tear off the release paper behind of the tape, and then attach the product closely onto the skin.
4. Take out the absorbent pad and put the catheter into the c-type notch on absorbent pad, and make sure the absorbent pad is in rotating ring.
5. Rotate the rotating ring clockwise to keep the catheter fixed in the inner hoop band. Please use appropriate force to fix catheter with inner hoop band, then fix the catheter by outer hoop fastener according to different materials or specifications of clinical catheter.
6. If the catheter needs to be adjusted or dismantled, It can be realized by adjusting the inner hoop band and outer hoop
 - 1) Adjust the inner hoop band: Holding the unlock button on both sides of the rotating ring, and rotate anticlockwise the ring to loosen the inner hoop band. Otherwise, release the unlock button to tighten the inner hoop band clockwise.
 - 2) Adjust the outer hoop: Continuous pull the fastener pulling ring to adjust the outer hoop slowly. It can't be adjusted if the fastener pulling ring is released.
 - 3) Remove the product: After loosening the outer hoop and inner hoop band, remove the adhesive tape and the products. Then remove the catheter according to the clinical operation standard.
7. Replace the absorbent pad: If the exudate is too much and the absorbent pad is saturate (if the area discolored by exudates was less than 1 cm from the edge of the absorbent pad or if a leakage was apparent) .Loosen the inner hoop band to the initial position according to step 6. Remove the absorbent pad with tweezers, replace a new absorbent pad and fix the catheter again.

【Cautions】

1. This product is for single use only. Do not use if package is damaged. Do not reuse, reprocess or resterilize. Reuse, reprocessing 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. Please treat it as medical waste after use.
2. Prescription only, this product is sold and used by doctors or prescribed by doctors
3. Different size of catheters should fixed by different product types. Do not exceed the scope.
4. If you are allergic after use, clinician should decide whether to remove the product according to allergic condition.
5. Be sure to clean your skin surface before use. Remove the disinfectant residue and the exudate as far as possible. Do not use a solution with surfactant to achieve the best pasting effect.

6. When removing the product, if there is glue left or it's difficult to remove the tape, you can use some saline or alcohol on the adhesive place to remove it easier.
7. To fix the catheters safely and effectively and keep the drainage smoothly, please make sure that the rotating ring is fully rotated. Lack of compaction may lead to the movement of the catheter; however, excessive closeness may compress the catheter, hinder or block fluid drainage.
8. Please ensure that the catheter is fixed and without any bending which will result in poor drainage.
9. This product is for single use only. Please change the product regularly according to the indwelling time of catheters. The maximum should not exceed 7 days. If the fastener is loose for any reason within 7 days, replace it earlier.
10. Please contact the medical staff immediately if there is a large amount of exudate, or peripheral pain of the catheter outlet, or the loose of the catheter.
11. Armpit, groin or other bending parts in body surface should be used combine with clinical situations.
12. The absorbent pad is only use for absorb a small amount of blood exudate. If there is a large amount of exudate out of the drainage tube, please replace the absorbent pad in time to avoid the dropping off of the adhesive tape.

【Contraindications】

The Wound drainage tube fixing device is not intended to be used on vascular catheters. People with wound Infection, too much exudate, or have skin defect around the catheter are prohibited. People allergy to tape should use with caution.

【Storage】 -10°C~30°C ,Keep dry.

【Production date】 See packing label

【Shelf Life】 30 months

【Registrant and manufacturer】 Zhejiang HaiChuang Medical Device Co., Ltd.

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【after-sales service unit】 Zhejiang HaiChuang Medical Device Co., Ltd

【Tel】 0571-87178676、0571-87178683

【Symbols】

| Symbol | Explain |
|--------|----------------------------------|
| | Sterilized by radiation |
| | Do not re-use |
| | Read instruction prior to use |
| | Do Not use if Package is Damaged |
| | Caution |
| | Temperature limit |

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|---|---|
|  | Manufacturer |
|  | Authorized representative in the European Community |
|  | Use-by date |
|  | Batch code |
|  | Catalogue number |