Shunmei®

CE 0197

Angelkiss-A

【INSTRUCTION FOR USE 】

TR-CLOSURE BAND

(*air type*)

SCOPE OF APPLICATION

TR-closure Band is an auxiliary equipment used for radial artery oppression hemostasis after the radial artery puncture interventional surgery.

CONTRA-INDICATIONS

None known.

THE USE OF THE ENVIRONMENT AND STORAGE

The product should be stored in a cool, dry environment, avoid direct sunlight.

PLEASE PAY ATTENTION TO THE FOLLOWING POINTS

1. It must be operated by trained doctor.
2. The product is sterilized by ethylene oxide. If damaged packaging use is strictly prohibited.
3. The product is for single use only, do not repeat sterilization and use.
4. The product should not be used in the process of arbitrarily changing its structure.

THE PRODUCT STRUCTURE AND MATERIALS

1. The product is mainly composed of oppression balloon, fixed band, supporting plate, velcro, one-way valve, gas filling tube, syringe, etc. The oppression balloon is made from PU material. The fixing band, one-way valve and supporting plate are made from PC material. The syringe is silicone and PP material.

INSTRUCTIONS FOR USE

1. The product should be used in aseptic environment.
2. After checking the package and valid period, open the package and take out the product.
3. After implementing radial interventional surgery, pull out introducer sheath for 2~3cm or after radial puncture pressure monitoring to insert indwelling needle into puncture site.
4. Make the blue mark of TR-closure band aim at the punture site, fix the TR-closure band on patient's wrist punctured through the adjustable fixed band.
5. Use the specific syringe for TR-closure band to inject moderate air to dilate oppression balloon. (Note: the maximum volume of balloon is 18ml.)
6. Take out the sheath or indwelling needle, confirm the puncture site has no bleeding. If there is bleeding, inject more air but not over 18ml.
7. Check the hemostasis condition, and use the syringe to regulate the pressure correspondingly. (Note: It may lead to bleeding if there is looseness occurs for TR-closure band during compression process.)

WARNING

1. The duration of sterilization of the product is three years, please confirm the sterilization date before use, prohibited to use if expired.
2. The product is disposable, it is strictly prohibited to resterilization and reuse.
3. The product should be used in conjuction with a specific syringe to fill air and the syringe can not be used for other purpose.
4. The maximum filling volume of balloon is 18ml, do not over the limit.
5. After observing the end of hemostasis, do not extract all air immediately but use syringe to extract air of 2~5ml; after observe 3~5min, extract the left air and observe 5~10min; if there is no errhysis completely, remove the TR-closure band.

Do not reuse

STERILE EO
Sterilization using ehylene oxide

Attention, see instruction for use

Fragile

Keep away from sunlight

Consult instructions for use

Do not resterilize

40℃ 0℃
Store in cool place

Keep dry

damage to packing do not use

Use by

LOT
Lot Number

REF
Catalog Number

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SM-IFU-TRB -001 A.6
Effective date:2021.05.10