CE 0197

Brun Medical Co., Ltd.

GRA-405002,Rev.02

Radial Artery Tourniquet [INSTRUCTION FOR USE]

1. INTENDED USE

The device is intended for use with hemostasis after the radial arterial catheterization by professional physician

2. INTENDED USER

Intended users are the competent physicians who have the training in interventional treatment.

3. INTENDED PATIENT POPULATION

patients needing interventional treatment.

4. CONTRAINDICATION

Allergic to product ingredients
localized skin inflammation or ulceration
Platelet and coagulation disorders
Retroperitoneal bleeding

5. HANDING AND STORAGE

Stored in the relative humidity of not more than 80%, non-corrosive gases, a common, dry, well-ventilated and clean environment.

6. STRUCTURE AND SPECIFICATIONS

Snap-on(BR-RAT1) and Spiral(BR-RAT2) :The device is consist of the fastened panel, fixation band and elastomer.
(BR-RAT3):The device is consist of compression balloon and supporting board,inflatable pipe and inflatable syringe.
Specifications:

Specification
BR-RAT1
BR-RAT2
BR-RAT3A
BR-RAT3B
BR-RAT3C

7. PRODUCT PERFORMANCE

Designed with spiral slide to staunch bleeding,can adjust compression pressure.Suspending bracket design is able to avoid obstruction of venous reflux effectively.Pressure in air balloons is easily adjusted by specially designed syringe(RAT3).

8. INSTRUCTION FOR USE

1. Remove the packaging, do not use if the elastomer fall off or the package damaged.
2. Fixation band to assemble into the fastened panel, adjust the fixation band.(BR-RAT1)
3. Put the elastomer of the device on the puncture point, fix the fixation band, then rotary the knob to adjust the pressure.(BR-RAT2)
4. Inflatable syringe is connected with inflatable pipe and put the compression balloon on the puncture point,then inject gas to adjust the pressure(BR-RAT3)
5. Single use only, discards after use.

9. PRODUCT LABEL AND PACKAGING (See the label or packaging)

1.Product name, model and specification.
2.Production date, batch lot.
3.Sterilization expiry date.

10. CAUTION

●The product was sterilized and valid for three years, make sure the device is used in the period of validity.
●Do not use if elastomer fall off.
●Do not use if fixation band can't be fixed well.
●The device is designed and intended for SINGLE USE ONLY.
●Do not resterilize and/or reuse, otherwise patients could get the risk of infection. After use dispose of product and packaging in accordance with infectious medical waste disposal method.
● Sterilized by ethylene oxide. Do not use if the package damaged.


Caution


Use-by date


Keep dry


Keep away from sunlight

Catalogue number


Date of manufacture


Manufacturer


Do not re-use

Sterilized Using ethylene oxide


Do not use if package is damaged and consult instrction for use

Batch code

Unique device identifier

Authorized representative in the European Commutity/European Union


Consult instructions for use or consult electronic instructions for use

Do not resterilize

Medical device


Single sterile barrier system

Cnovate Medical B.V.
ADDRESS：Terminalweg 15, 3821AJ Amersfoort, The Netherlands
TEL：+31 850140404 E-mail：cs@cnovate.eu


Brun Medical Co., Ltd.
ADDRESS: Building B8, Entrepreneurship and Innovation Park.88 Changtang Road, Yunlong Demonstration Zone,Zhuzhou, 412000 Hunan ,P.R.China
TEL：+0731-22029666 WEB：www.brunmd.com

Date of issue：2024/05/13