CE 0197

Brun®

Brun Medical Co., Ltd.

GRA-404001,Rev.02

Introducer Sheath [INSTRUCTION FOR USE]

1. INTENDED PURPOSE

The product is intended to enlarge the incision of percutaneous intervention, which assists catheter into blood vessel 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

No absolute contraindications when used correctly by medical personnel.

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

The product is consist of introducer sheath and dilator.

Specifications:

Specifications	Introducer sheath Size (Fr.) x Length (cm)	Dilator Size (Fr.) x Length (cm)	Specifications	Introducer sheath Size (Fr.) x Length (cm)	Dilator Size (Fr.) x Length (cm)
BR-RA0407	4F X 7cm	4F X 13cm	BR-FA0409	4F X 9cm	4F X 15cm
BR-RA0507	5F X 7cm	5F X 13cm	BR-FA0511	5F X 11cm	5F X 18cm
BR-RA0607	6F X 7cm	6F X 13cm	BR-FA0611	6F X 11cm	6F X 18cm
BR-RA0707	7F X 7cm	7F X 13cm	BR-FA0711	7F X 11cm	7F X 18cm
BR-RA0411	4F X 11cm	4F X 18cm	BR-FA0811	8F X 11cm	8F X 18cm
BR-RA0511	5F X 11cm	5F X 18cm	BR-FA0911	9F X 11cm	9F X 18cm
BR-RA0611	6F X 11cm	6F X 18cm	BR-FA1011	10F X 11cm	10F X 18cm
BR-RA0711	7F X 11cm	7F X 18cm	BR-FA1211	12F X 11cm	12F X 18cm
BR-RA0416	4F X 16cm	4F X 23cm	BR-FA0419	4F X 19cm	4F X 26cm
BR-RA0516	5F X 16cm	5F X 23cm	BR-FA0523	5F X 23cm	5F X 29cm
BR-RA0616	6F X 16cm	6F X 23cm	BR-FA0623	6F X 23cm	6F X 29cm
BR-RA0716	7F X 16cm	7F X 23cm	BR-FA0723	7F X 23cm	7F X 29cm
BR-RA0423	4F X 23cm	4F X 29cm	BR-FA0823	8F X 23cm	8F X 29cm
BR-RA0523	5F X 23cm	5F X 29cm	BR-FA0923	9F X 23cm	9F X 29cm
BR-RA0623	6F X 23cm	6F X 29cm	BR-FA1023	10F X 23cm	10F X 29cm
BR-RA0723	7F X 23cm	7F X 29cm	BR-FA1223	12F X 23cm	12F X 29cm

7. PRODUCT PERFORMANCE

Zero clearance is realized when using a combination of the Sheath catheter and dilator, which can effectively reduce the damage of blood vessel. The special design and excellent technology can effectively prevent blood backflow and air enter as well.

8. INSTRUCTION FOR USE

1. Remove the introducer sheath components from the packing boxI and rinse the kit thoroughly with heparin saline.
2. Note: the intensity should be light and should be inserted from the center of the joint, otherwise it will damage the hemostatic valve that lead the sheath blood leak. Just as important, the dilator should be connected with the introducer sheath. Otherwise, the dilator will withdraw in the puncture of sheath kit and lead to the damage of the tip of the introducer sheath. It can cause damage to the blood vessels.
3. Insert the introducer sheath into the target vessel slowly along the guide wire.
4. The dilator and guide wire are slowly removed from the introducer sheath, but when the dilator is about to leave the introducer sheath, should quickly pull out the dilator, otherwise it will result in incomplete sealing and leakage of the hemostatic valve.
5. The catheter is inserted into the target vessel through the insertion of the sheath and is pushed into the desired location.
6. After the operation, the catheter is removed and then pulled out of the sheath and then compressed to stop bleeding after operation.
7. After use, destruction is performed according to scrap procedures for medical supplies.

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

1. Procedure must be performed by trained medical personnel.
2. Sterilization is valid for three years, please confirm date of sterilization before use,do not use if expiry.
3. Do not use if luer taper leakage.
4. The device is designed and intended for SINGLE USE ONLY.
5. Do not resterilize and/or reuse, otherwise patients could get the risk of infection.
6. 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

EC REP 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

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