

Brun Medical Co., Ltd.

GRA-401001,Rev.02

Introducer Needle [INSTRUCTION FOR USE]

1. INTENDED PURPOSE

The product is used for body puncture to collect human samples, inject liquid and gas, etc., or be a path for other devices entering the body 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 device is consist of needle hub,needle tube and protective sleeve.

I.V. cannula is consist of needle hub,needle tube , protective sleeve,catheter and catheter hub.

Specifications:

Specifications	Length
BR-IN-1770	70mm
BR-IN-1865	65mm
BR-IN-1870	70mm
BR-IVC-2032	32mm
BR-IN-2038	38mm
BR-IN-2138	38mm
BR-IN-2140	40mm
BR-IN-2150	50mm
BR-IN-2170	70mm
BR-INY-1865	65mm
BR-INY-1870	70mm
BR-INY-2038	38mm
BR-INY-2138	38mm
BR-INY-2150	50mm
BR-INY-2170	70mm

7. PRODUCT PERFORMANCE

The device has Well-cut Needle Tip , well-polished lumen surface and smooth transition between hub an lumen.

8. INSTRUCTION FOR USE

1.Remove the packaging, do not use if the package damaged.

2.Take off the protective cover, and advance the guide devices through introducer needle into human body, then pull out introducer needle.

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.



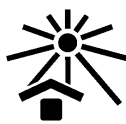
Caution



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 instruction for use



Batch code



Unique device identifier



Authorized representative in the European Community/European Union



Consult instructions for use or consult electronic instructions for use



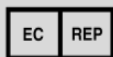
Do not resterilize



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