

Brun Medical Co., Ltd.

GRA-408002, Rev. 02

Dose-control Syringe [INSTRUCTION FOR USE]

1. INTENDED PURPOSE

The product is used for injecting solution or contrast medium by manual control in minimally invasive interventional therapy or diagnostic surgery 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 the luer connector, o-ring seal, piston, piston head, syringe barrel, syringe barrel lid, handle. Specifications: BR-DCS10, BR-DCS12

7. PRODUCT PERFORMANCE

The device has humanistic handle design, special spraying process and more smooth injection. Smooth and transparent injector with intuitive and clear scale, which is easy to observe and read. Anti -air design effectively prevent the air into the injector.

8. INSTRUCTION FOR USE

- 1.Remove the packaging, do not use if the package damaged.
- 2. Connect dose-control syringes to related device(s).
- 3.Inject the contrast agent by pushing the handle.
- 4. 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

- 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

REP

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