SYMBOL REFERENCE TABLE	
REF	Catalog number
LOT	Batch Code
EC REP	Authorized Representative in the European Community / European Union
Rx Only	Caution: US Federal law restricts this device to sale by or on the order of a physician
	Use-by-date
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not use if packaging is damaged
	Do not reuse
	Caution
	Consult instructions for use
	Manufacturer
GB	Country of Manufacture (Made in the United Kingdom)
QTY	Quantity
	Distributor

DTR Medical®
AN INNOVIA MEDICAL COMPANY

CERVICAL BIOPSY PUNCH WITH ROTATION

Instructions for Use

REF **CBR1041 | Cervical Biopsy Punch with Rotation**

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CE 2797

EC REP
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2514 AP, The Hague
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DTR.M.013 | Rev1.0 | OCT2021

EN

REF CBR1041 | Cervical Biopsy Punch with Rotation

DESCRIPTION
The Cervical Rotating Biopsy Punch has been designed specifically for use in Gynaecological procedures to obtain a Cervical Biopsy. Equipped with a pair of cupped jaws at the end of a metal rod with a handle and trigger. The long metal construction ensures better access to the Cervix for the jaws, whilst the handle is operated outside. When the trigger is pulled the sharp jaw closes, this action removes a segment of Tissue for the Biopsy.

360° rotation enables enhanced positioning and patient interaction.

It is a sterile single-use device which is disposed of once used.

MATERIALS OF CONSTRUCTION

Product Component	Details
Jaw	Stainless Steel
Tube	Stainless Steel
Handle	Polycarbonate (PC)
Trigger	Polycarbonate (PC)
Rotation Controller	Polycarbonate (PC)

INTENDED USE/INDICATIONS FOR USE
The Cervical Rotating Biopsy Punch is intended for use in gynaecological procedures to obtain a cervical biopsy and allows a biopsy to be taken from a hardened cervix.

The Cervical Rotating Biopsy Punch is indicated for patients requiring cervical biopsy, including patients with a hardened cervix.

INTENDED USER
The Cervical Rotating Biopsy Punch is intended to be used by suitably qualified clinicians and healthcare practitioners.

WARNINGS
- The device is for single use only. Do not resterilise or reuse.
- This device is intended for use by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device.

STERILITY
- The Cervical Rotating Biopsy Punch is provided STERILE, in a single sterile barrier with protective packaging inside. The instrument has been terminally sterilised by gamma irradiation.
- The package should be carefully inspected for punctures, tears, security of the seal or any other evidence of the sealed pouch having been compromised prior to placement of the contents in the sterile field.
- This product is sterile in an undamaged, unopened package.
- **DO NOT USE** if package is damaged.
- If sterility is compromised, do not resterilise.

OPERATING INSTRUCTIONS
Rotate the device as necessary using the purple rotational element to ensure optimal biopsy and patient interaction.
Pull the trigger to close jaws and remove a segment of tissue for biopsy.

DEVICE DISPOSAL
Used devices should be disposed of as clinical waste. If unused, product in original packaging which has exceeded the declared shelf life should be removed from packaging and disposed of as clinical waste.

STORAGE
Products must be stored in the original unopened packaging away from moisture, dust, insects, vermin and extremes of temperature and humidity.

SERIOUS INCIDENT REPORTING
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the FDA/competent authority of the Country/Territory/State in which the user and/or patient is established.

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES:
1. Single use devices have not been validated for re-use. If you re-use a device you may be held Legally Liable for the safe performance.
2. Cross-contamination and infection risks to patients, including transmission of:
    - CJD & Variant CJD.
    - Prion Diseases.
    - Bacterial Endotoxins.
    - Hepatitis B & Hepatitis C.
    - Risks posed by HIV and AIDS
3. Device failure through material fatigue or degradation caused by initial use and design:
    - Plastics: Can be weakened, warped or become brittle.
    - Metals: Can be damaged or subjected to rusting.
    - Other materials: May degrade, becoming unacceptable when compared to original manufacturing criteria.
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.