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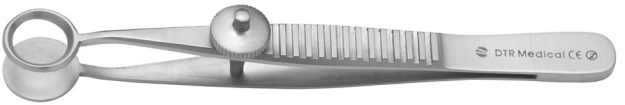
DTR.M.046
CYST FORCEPS
Instructions for Use

REF

TCB2013, TCB2016, TCL2928



EN

DESCRIPTION
The Cyst Forceps are single use, stainless steel devices. They are tweezer style forceps with a screw adjuster and a smooth circular plate at the tip against which the cyst can be incised.

MATERIALS OF CONSTRUCTION

Product Component	Details
Cyst Forceps	420 Stainless Steel

INTENDED USE
The Cyst Forceps are intended for use during ophthalmic procedures.

INTENDED USER
The device is intended to be used by appropriately trained surgeons.

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS
The Cyst Forceps are indicated for use during ophthalmic procedures to reduce bleeding and to provide a rigid surface against which a cyst can be incised.

These devices are made of Stainless Steel, which may cause an allergic reaction in patients with sensitivity to Nickel. The User should risk assess the use of the device in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to Nickel.

PATIENT POPULATION
Anyone of any age in the human population as determined by a suitably qualified surgeon.

WARNINGS AND PRECAUTIONS
- This device is supplied STERILE and ready to use.
- The device is for SINGLE USE ONLY. Do NOT re-sterilise or re-use.

- Do not use if the packaging has been opened or damaged.
- If the device accidentally becomes contaminated before use, do not use and dispose of accordingly.

SHELF LIFE AND STERILITY

The devices are sterilised by exposure to Ethylene Oxide, as indicated by the symbol on the label. They remain sterile as long as the package integrity has not been compromised.

The expiration date is printed on the label. Do not use devices after the expiration date. The shelf life is 5 years.

Devices are single use, transient devices. Therefore, the device lifetime in use is less than 60 minutes continuous use.

STORAGE AND HANDLING

Sterile, packaged devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, sunlight and temperature/humidity extremes.

Care must be exercised in handling of individual devices to prevent damage to the sterile barrier.

Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

TRANSPORTATION

The devices are supplied in their designated packaging. This packaging ensures that every device is kept in a way that they do not receive any damage and that their functionality is preserved during transportation.

OPERATIONAL USE

This is a standard device. For the operational use, please refer to the indications and intended use.

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. Handle and dispose this product in accordance with accepted medical practice

and with applicable local, state and national laws and regulations.

The Forceps do not contain:
- Substances of human origin
- Animal tissues
- Dangerous or hazardous substances
- Radioactive material
- Any substance that may be a Medicinal Product as defined in Article I of Directive 2001/83/EC

REPORTING PROBLEMS

Healthcare professionals, users and patients should report any suspected serious incident related to the device by informing the manufacturer at www.dtrmedical.com/contact and the competent authority, ministry of health, or delegated agency in which the suspected serious incident has occurred.

SYMBOL REFERENCE TABLE	
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the medical device is not to be used.
STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide.
	Indicates a medical device that is not to be re-sterilized.
	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Indicates a medical device that is intended for one single use only.
	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Indicates the need for the user to consult the instructions for use.
	Indicates Medical Device Manufacturer.
	To identify the country of manufacture of products (Made in the United Kingdom).
QTY	Indicates the packaged quantity.
MD	Indicates the item is a medical device.
UDI	Indicates a carrier that contains Unique Device Identifier Information.
	Indicates a medical device that needs protection from light sources.
	Indicates a medical device that needs to be protected from moisture.

UK CA 0086	Indicates that a product conforms to the Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 202 (SI 1478) and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified.
Rx ONLY	Caution: US Federal law restricts this device to sale by or on the order of a physician.
	Indicates the entity distributing the medical device into the locale.

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