SYMBOL REFERENCE TABLE	
REF	Indicates the manufacturer's catalog 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.
EC REP	Indicates the authorized representative in the European Community/European Union.
QTY	Indicates the packaged quantity.
CH REP	Authorized Representative in Switzerland.
	Indicates the date after which the medical device is not to be used.
	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 is intended for one single use only.
	Keep away from sunlight.
	Keep dry.
MD	Indicates the item is a medical device.
	Indicates Medical Device Manufacturer.
	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 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.

GB	To identify the country of manufacture of products (Made in the United Kingdom).
	Indicates the entity distributing the medical device into the locale.
UDI	Indicates a carrier that contains Unique Device Identifier Information.
2797	Indicates that the product conforms to EU Regulation 2017/745 and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified.
UK CA	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.

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DTR.M.055
SILICONE CLAMP COVERS
Instructions for Use

REF

CCR2031, CCW2041, CCB2051

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EN

DESCRIPTION
The Silicone Clamp Covers are disposable devices cut to size and used to cover the jaws of forceps and clamps to reduce trauma to vessels, nerves and tendons by cushioning the grip during surgical procedures

MATERIALS OF CONSTRUCTION

Product Component	Details
Silicone Clamp Covers	Medical Grade Silicone

INTENDED USE
Clamp covers are used on the jaws of forceps/clamps to reduce trauma to vessels, nerves and tendons by cushioning the clamp grip during surgical procedures.

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

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS
Clamp Covers are indicated for use within surgical procedures.
Do not use with in direct contact with the heart, central circulatory (areriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, ateria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pumonales, vena cava superior and vena cava inferior) and central nervous system (brain, meninges and spinal cord).

These devices are made of silicone which may cause an allergic reaction in patients with sensitivity to this material. Surgeons 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 silicone.

Devices are not implantable, or intended to be left in the body.

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.
- Placement of the knot to be kept away from fragile structures.

SHELF LIFE AND STERILITY
- Instruments are supplied in a sterile condition, packaged individually. The instruments are sterilized by exposure to Ethylene Oxide indicated by the symbol on the label. They remain sterile as long as the package integrity has not been violated.
- Packaging must be inspected before use. Do not use any component from an opened or damaged package. The expiration date is printed on the label. Do not use instruments after the expiration date. The shelf life is 5 years.

DEVICE LIFETIME
Clamp Covers are single use transient devices. Therefore, the device lifetime in use is less than 60 minutes continuous use.

STORAGE AND HANDLING
- Sterile, packaged instruments 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 wrapped cases or individual instruments to prevent damage to the sterile barrier.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

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

OPERATIONAL USE
Clamp Covers are to be placed on the jaws of forceps/ clamps in order to cushion the clamp grip of vessels, nerves and tendons.

DEVICE DISPOSAL
After use the device should be disposed of in accordance with the healthcare settings disposal procedure. The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination.

The Silicone Clamps 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.

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