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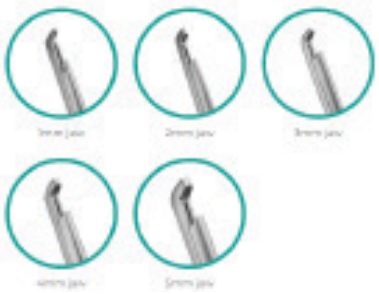
DTR.M.050
KERRISON RONGEUR PUNCHES
Instructions for Use

REF

KRU1101, KRU1201, KRU1301, KRU1401, KRU1501, KRUF11029, KRUF11039



EN

DESCRIPTION
Kerrison Rongeur are manually operated instruments with a handle which moves the jaw as it is closed.

MATERIALS OF CONSTRUCTION

Product Component	Details
Kerrison Rongeur Punch	410 Stainless Steel

INTENDED USE
The Kerrison Rongeurs are manually operated instruments intended for cutting, biting or removing bone and/or cartilage during surgery.

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

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS
The Kerrison Rongeurs are indicated to cut, bite or remove bone and/or cartilage during Otologic, Orthopaedic, Ophthalmic, ENT and Maxillofacial procedures.

These devices are made of stainless steel, which may cause an allergic reaction in patients with sensitivity to nickel. 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 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.
- Rongeurs are sharp. Caution should be exercised at all times when handling and using these devices.

SHELF LIFE AND STERILITY

- The instruments 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 instruments 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 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 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

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

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. Rongeurs are sharp and must be placed in a secure, puncture-resistant bin (conforming to appropriate regulations) which is suitable for incineration.

The products 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 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 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.

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DTR.M.050 | Rev1.0 | JAN2024

UK CA 0086