DTR MEDICAL® BY

innovia medical

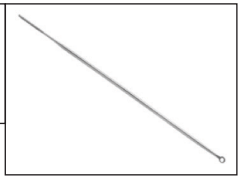
DTR.M.037
HOOKS, PROBES AND POINTS FOR ENT PROCEDURES

Instructions for Use

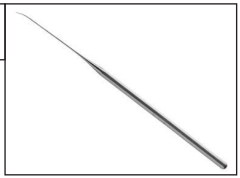
REF

JHPS5001-S, JHPS10001-S, JHPL5001-S, JHPL10001-S, FCH5001-S, CTH2901-D, CTP2001-D, SPS2001, RSN2016, RSNF2016

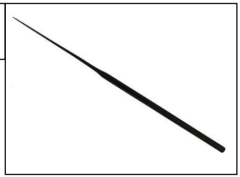
JHPS5001-S,
JHPS10001-S,
JHPL5001-S,
JHPL10001-S



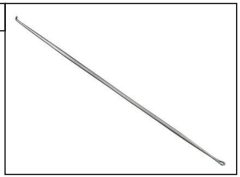
RSN2016
RSNF2016



CTP2001-D
CTH2901-D



FCH5001-S



SPS2001

DESCRIPTION
ENT Hooks, Probes and Points: The ENT Hooks, Probes and Points are devices that are indicated for use within the ear.

MATERIALS OF CONSTRUCTION

Product Component	Details
JHPS5001-S	410 Stainless Steel
JHPS10001-S	410 Stainless Steel
JHPL5001-S	410 Stainless Steel
JHPL10001-S	410 Stainless Steel
FCH5001-S	410 Stainless Steel
CTH2901-D	410 Stainless Steel
CTP2001-D	410 Stainless Steel
SPS2001	410 Stainless Steel
RSN2016	410 Stainless Steel
RSNF2016	410 Stainless Steel

INTENDED USE
Jobson Horne Ear probes are a combined ear curette and cotton wool holder used for ENT procedures.

Formby Cerumen Hook and Probe are double ended instruments with a blunt hook on one side and a scoop on the other, used to remove foreign objects from the ear.

Cawthorne Hook and Points are sharp, or hooked devices used in ENT procedures for the removal of ear wax.

Rosen Needles are designed to create a clean incision in the ear drum during ENT procedures.

Schuknecht Pick are sharp devices used in ENT procedures for the removal of ear wax and/or foreign objects.

INTENDED USER

The ENT Hooks, Probes and Points are intended to be used in appropriately trained healthcare professionals in a hospital / clinical environment.

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS

- The Jobson Horne Ear probes are indicated for use within ENT procedures.
- The Formby Cerumen Hook and Probes are to be used in ENT procedures to remove foreign objects or wax from the ear.
- The Cawthorne Hooks and Points are to be used in ENT procedures to remove ear wax.
- The Rosen Needles are to be used in ENT procedures.
- The Schucknecht Picks are to be used in ENT procedures to remove ear wax and/or foreign objects.

These devices are made of stainless steel which may cause an allergic reaction in patients with a 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

- The 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.
- Care should be taken when using the device to prevent damage to the tissue and structure of the ear canal and drum.
- The ENT Hooks, Probes and Points may be 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.

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.

ENT Hooks, Probes and Points may be 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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UK CA 0086