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FINE ENDS, CURVED ZOELLNER SUCTION FINE ENDS AND CURVED ENDOSCOPIC SUCTION TUBES

Instructions for Use

REF

74-2020, 74-2021, 74-2022, 74-2023, SM4018, SM4020, SM4022, SM4024, SM4026, SME4183, CES2183, CES2186

Fine Ends
(74-2020, 74-2021, 74-2022, 74-2023, SM4018, SM4020, SM4022, SM4024, SM4026)

Curved Zoellner Suction Fine Ends (SME4183)

Curved Endoscopic Suction Tubes (CES2183, CES2186)

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EN

DESCRIPTION

Fine Ends (including the Curved Zoellner Suction variety) and Curved Endoscopic Suction Tubes are attachments that can be used during suction within ENT (Ear, Nose and Throat) procedures.

Product Code	Product Description
CES2183	Curved Endoscopic Suction Tube, 3mm Bend Radius, 18 swg
CES2186	Curved Endoscopic Suction Tube, 6mm Bend Radius, 18 swg
SM4018	Fine Ends size 18 swg
SM4020	Fine Ends size 20 swg
SM4022	Fine Ends size 22 swg
SM4024	Fine Ends size 24 swg
SM4026	Fine Ends size 26 swg
SME4183	Curved Zoellner Suction Fine End, 3mm Bend Radius, 18 swg
74-2020	Fine End (Purple) 18G / 1.0mm
74-2021	Fine End (Orange) 20G / 0.8mm
74-2022	Fine End (Blue) 22G / 0.65mm
74-2023	Fine End (Green) 24G / 0.5mm

MATERIALS OF CONSTRUCTION

Product Component	Details
74-2020, 74-2021, 74-2022, 74-2023	304 Stainless Steel and Polypropylene Hub
SM4018, SM4020, SM4022, SM4024, SM4026, SME4183	304 Stainless Steel and Nickel Plated Brass
CES2183, CES2186	304 Stainless Steel

INTENDED USE

The Fine End range are tips which attach to Zoellner Suction Handles which are used during ENT procedures to remove ear wax, debris, bodily fluids and foreign bodies.

The Curved Endoscopic Suction Tubes attach via luer connection to suction regulators which are used during ENT procedures to remove ear wax, debris, bodily fluids and foreign bodies.

INTENDED USER

The devices are intended to be used by appropriately trained healthcare professionals.

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS

The devices are indicated for use in ENT procedures.

These devices are made of Stainless Steel and Nickel Plated Brass, which may cause an allergic reaction in patients with sensitivity to Nickel. 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 healthcare professional.

WARNINGS AND PRECAUTIONS

The devices are supplied STERILE and ready to use.

The devices are 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 tissues and structures of the nasal cavity, ear canal and drum.

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 the devices after the expiration date. The shelf life is 5 years.

Devices are single use, transient devices. The devices 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 instrument 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 instrument is kept in a way that they do not receive any damage and that their functionality is preserved during transportation.

OPERATIONAL USE

Fine Ends: Connect the Fine Ends by inserting the metal taper into the tip of the Zoellner Suction Handle. The Fine Ends can be removed from the Zoellner Suction Handle during procedures and if required, replaced by a different gauge Fine End.

The Curved Endoscopic Suction Tubes are standard devices. For the operational use, please refer to the indications and intended use.

DEVICE DISPOSAL

After use, the devices should be disposed of in accordance with the healthcare settings disposal procedure. The devices 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 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.
	Indicates the date after which the medical device is not to be used.
STERILE EO	Sterilised using Ethylene Oxide. Please check label for sterilisation method.
	Indicates a medical device that is not to be re-sterilised.
	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.

SYMBOL REFERENCE TABLE	
MD	Indicates the item is a medical device.
UDI	Indicates a carrier that contains Unique Device Identifier Information.
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
	Indicates a medical device that needs protection from light sources
	Indicates a medical device that needs to be protected from moisture

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