GB - INSTRUCTIONS FOR USE

Description

DTR Medical Suction Tubes, Aspiration Cannulae, and Fine Ends are 'single use only' tubes designed essentially for ENT applications and can be attached to all commonly available suction systems found in ENT theatres and Out Patient Departments.

The tubes are supplied in a variety of diameters and angles pertinent to the surgical application and can be further reduced in diameter down to 26G (0.4mm) by the use of Fine End inserts.

Intended Use

DTR Medical Suction Tubes, Aspiration Cannulae, and Fine Ends are designed particularly for ENT applications when excess fluids and debris need to be removed from the surgical site.

The tubes can be attached directly to any standard suction system commonly found in an ENT theatre or Out-Patient Departments. The aspiration tubes attach directly to the suction handle of a standard suction system and the fine end can reduce further the diameter of any standard suction tube.

CAUTIONS:

- 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.
- This device is intended for use by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device.
- 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.
- CAUTION: US Federal law restricts this device to sale by or on the order of a physician
- This product contains nickel which may cause allergic reaction in patients with sensitivity to nickel. Risk assess the use of the devices in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to nickel.
- Suction tubing can obstruct when viscous or particulate materials are suctioned, which has in some cases led to problems with airway management.
- Care should be taken that a tube with a sufficiently large diameter is used to remove any particulate. If the tube becomes blocked it should be detached and discarded, or a stylet used to remove the debris. The stylet should be passed through the whole length of the tube to remove the debris.
- There is a risk that aspiration during tympanostomy tube insertion can cause tympanosclerosis

Incident Reporting

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Sterilisation

- The device is a SINGLE USE ONLY device supplied sterile and ready for use. Sterilisation is by Ethylene Oxide (EO)

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES:

1. Single use devices have not been validated for re-use.

If you re-use a device you may be held **Legally Liable** for the safe performance.

2. Cross-contamination and infection risks to patients. Including but not limited to the transmission of:
- CJD & Variant CJD.
- Prion Diseases.
- Bacterial Endotoxins.
- Hepatitis B & Hepatitis C.
- Risks posed by HIV and AIDS

3. Device failure through material fatigue or degradation caused by initial use and design:
- **Plastics:** Can be weakened, warped or become brittle.
- **Metals:** Can be damaged or subject to rusting.

4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

SYMBOL REFERENCE TABLE	
LOT	Lot Number / Batch code
	Use by Date
	Do Not Re-use
	Do not use if product is opened or damaged
STERILE EO	Sterilised by Ethylene Oxide
	Manufacturer
QTY	Numerical count of contents
UK CA	0086 Product confomity to Medical Device Regulations 2002 (SI 628)
	Protect from light sources
REF	Catalogue Number

	Caution
	Sterile barrier system
Rx only	Caution: US Federal law restricts this device to sale by or on the order of a physician
	Do not resterilise
MD	Medical Device
UDI	Unique Device Identifier
	Protect from moisture

DTR Medical Ltd.,
17 Clarion Court, Enterprise Park,
Swansea SA6 8RF, UK
T: +44(0) 1792 797910
www.dtrmedical.com

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UK CA 0086

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PRODUCT NAME: SUCTION TUBES, ASPIRATING CANNULAE AND FINE ENDS

PRODUCT INFORMATION
AND INSTRUCTIONS FOR USE FOR THE
FOLLOWING PRODUCTS:

REF

74-1230 | 74-1231 | 74-1231A | 74-1232
74-1232A | 74-1233 | 74-1234 | 74-1236
74-1260 | 74-1262A | 74-1264 | 74-1265
74-1267 | 74-1268 | 74-1297 | 74-2009
74-2011 | 74-2012 | 74-2012P | 74-2013
74-2014 | 74-2014P | 74-2015 | 74-2016
74-2016P | 74-2017 | 74-2020 | 74-2021
74-2022 | 74-2023 | 74-2030 | 74-2033
74-2037 | 74-2050 | 74-2051 | 74-2052
74-2053 | 74-2057 | 74-2058 | 74-2060
74-2063 | 74-2077 | 74-2079 | 74-2080
74-2081 | 74-2082 | 74-2083 | 74-2087