DTR Medical®

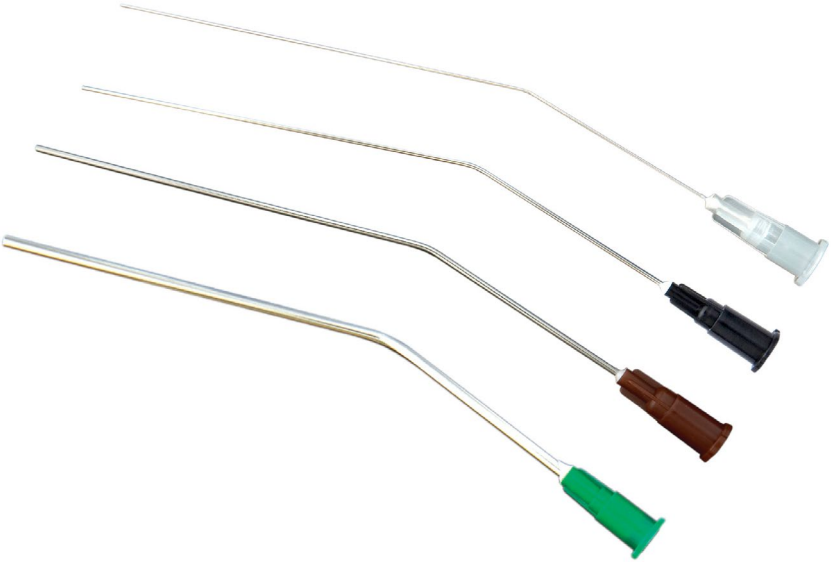
AN INNOVIA MEDICAL COMPANY

MICRO SUCTION HANDLES

Instructions for Use

REF

MSV50114 | MSV50117 | MSV50119 | MSV50122
MSV50214 | MSV508113| MSV508113R | MSV508114
MSV508114R | MSV508116 | MSV508117 | MSV508119



EN

DESCRIPTION
The Micro Suction Handles are small devices that can be used in a variety of procedures including dislodging particles during ENT procedures.

MATERIALS OF CONSTRUCTION

Product Component	Details
Tube	Stainless Steel
Hub	Bayer Markrolon 2856

INTENDED USE/INDICATIONS FOR USE
The Micro Suction Handles are indicated for use in ENT and general surgical procedures to aid the suction of bodily fluids.

INTENDED USER
The intended user of the Micro Suction Handle consists of qualified healthcare professionals and medical experts who have been trained in suction procedures, and in the use of aspirators. The product is intended solely for use in the medical sector and within a clinical environment.

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS
There are no absolute contraindications but there are risks associated with suctioning and this should be weighed against patient specific needs.

PATIENT POPULATION
No age restriction. As the devices were developed to support suction activities during a surgical procedure, the target population for this device is anyone, of any age, in the human population, that is identified as needing suction during an ENT or General Surgery procedure.

WARNINGS AND PRECAUTIONS
- Device is **single use only**.
- Device is provided **sterile**, in a single sterile barrier packaging. Do not sterilise or re-use.
- 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.
- Do not use if the packaging is damaged. Packaging should be carefully inspected for punctures, tears, security of the seal, and any other evidence of the sealed pouch having been compromised prior to the placement of the contents in the sterile field.
- Device should be used for suction only – it is not suitable for irrigation uses.
- Additional care should be taken if patients are suffering from bradycardia, hypoxia or other similar complaints / concerns.
- There is a risk of epistaxis if patient moves or struggles while the device is in use.
- Excessive suction can cause tissue damage.
- Suctioning is not entirely without risk, as with all medical interventions, healthcare workers must use clinical judgement to determine whether the benefit outweighs the risks.
- Do not use in the presence of magnetic fields such as those which occur during magnetic resonance imaging. The device has not been tested for magnetically induced torque, radiofrequency indued heating or image artefacts.
- Instruments made from Stainless Steel may contain Nickel. Although the contact between instruments and patient is transient, it may cause an allergic reaction in patients with sensitivity to this material. Users should risk assess the use of the instruments in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to nickel.

SHELF LIFE AND STERILITY
- Instruments are supplied in a sterile condition and are packaged individually. The instruments are sterilised by exposure to ethylene oxide indicated by the STERILE EO symbol on the label. They remain sterile as long as the package integrity has not been compromised.
- Packaging must be inspected before use. Do not use any component from an opened or damaged package.
- The expiry date is printed on the label. Do not use instruments after the expiry date.

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.
- 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.

POSSIBLE ADVERSE EFFECTS
- Complications such as discomfort, infection, hemorrhage, and hemodynamic changes could occur as a result of the procedure.
- The most frequently reported complications are reduced oxygenation. Hyper-oxygenating the patient before suctioning and allowing rest between suctioning attempts can reduce the chances of hypoxia.
- Injury to the mucosal membranes and bleeding can also occur.
- Using the appropriate vacuum level, a water-soluble lubricant and avoiding forcing the device can reduce the risk of tissue injury.

OPERATING INSTRUCTIONS
1. Aspirating procedures can begin after it has been explained to the patient and supplies have been collected. The use of PPE is highly recommended and should be in line with hospital /clinic processes. Sterile technique should always be used to reduce the risk of nosocomial infections.
2. Micro Suction Handles are intended to be used with silicone tubing and an aspirator.

DEVICE DISPOSAL
Used devices should be disposed of as clinical waste. If unused, product in original packaging which has exceeded the declared shelf life should be removed from packaging and disposed of as clinical waste. Handle and dispose this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES:
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.
Cross-contamination and infection risks to patients, including transmission of:

- CJD & Variant CJD.
- Prion Diseases.
- Bacterial Endotoxins.
- Hepatitis B & Hepatitis C.
- Risks posed by HIV and AIDS

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 subjected to rusting.
- Other materials: May degrade, becoming unacceptable when compared to original manufacturing criteria.

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

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.

- For patients in Australia please visit the Therapeutic Goods Administration (TGA) website: www.tga.gov.au.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

The words “Authorized Representative” and the name and address of the Authorized Representative if the legal manufacturer of the product and on the product label is from outside of the Member States of the EU.

“Swiss Representative” may also be present if the product is not legally manufactured in Switzerland.

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
CH REP	Authorized Representative in Switzerland
	Indicates the date after which the medical device is not to be used
STERILE EO	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 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
GB	To identify the country of manufacture of products (Made in the United Kingdom)
QTY	Indicates the packaged quantity
	Indicates the entity distributing the medical device into the locale
MD	Indicates the item is a medical device
UDI	Indicates a carrier that contains Unique Device Identifier Information
CE 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

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CE 2797

EC REP

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