DTR MEDICAL® BY

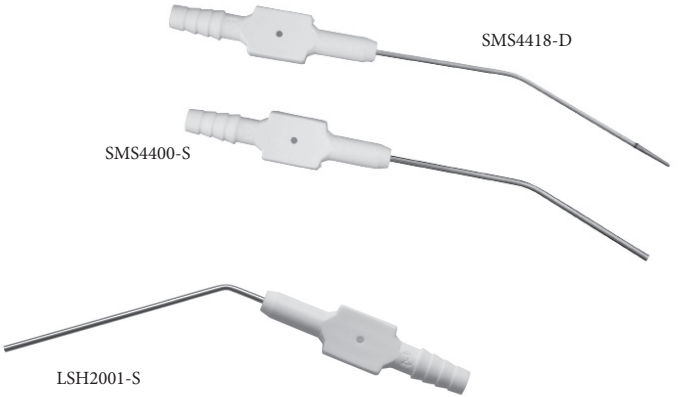
innovia medical

ENDOSCOPIC SUCTION HANDLES

Instructions for Use

REF

SMS4400-S, SMS4418-D, LSH2001-S, SMES4483-D, SMES4486-D



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EN

DESCRIPTION

The Endoscopic Suction range including Zoellner Suction Handles and Lempert Suction Handles are suction handles are devices with a polypropylene hub and stainless steel tube used within ENT (Ear, Nose and Throat) procedures.

MATERIALS OF CONSTRUCTION

Product Component	Details
Handle	Polypropylene hub
Tube	304 Stainless Steel
Fine Ends needle blank (SMES4483-D and SMES4486-D)	304 Stainless Steel
Fine Ends Taper	Nickel Plated Brass

INTENDED USE

The Endoscopic Suction range including Zoellner Suction Handles and Lempert Suction Handles are suction handles which can be 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

Devices are indicated for use within ENT procedures.

These devices are made of Stainless Steel, 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.

SMES4483-D and SMES4486-D contain Nickel Plated Brass, which may cause an allergic reaction in patients with sensitivity to Nickel. Users 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 devices after the expiration date. The shelf life is 5 years.

Devices are single use, transient devices. The device 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 device 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 device 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.

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).

SYMBOL REFERENCE TABLE	
QTY	Indicates the packaged quantity.
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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