

INSTRUCTIONS FOR USE

Sinus Suction Handle

Product Code(s): SSH2606, SSH2609, SSH2909, SSH2612 & SSH2912

READ INSTRUCTIONS BEFORE USE!

Sterile single-use device

Do not re-sterilise

Product Description

The Sinus Suction Handle is a sterile single-use device. Each device is double packed in a sealed pouch. The suction handle is supplied in a range of lumen diameter (6Fg, 9Fg and 12Fg) and a range of bend angles (65° and 90°).

Intended Use

The Sinus Suction Handle is used for removal of mucus and exudate from the sinus cavity.

Contraindications

- Do not use the Sinus Suction Handle in the presence of magnetic fields such as those that occur during magnetic resonance imaging. Although the cannula is made from chrome plated brass and should be non-ferromagnetic it has not been tested for magnetically induced torque, radiofrequency induced heating or image artefacts.

Warnings & precautions

- Do not attempt to bend or re-shape the device as this could cause stresses and fractures in the device and may render the device unusable.
- Use of appropriate surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the use of this device on a case by case based on their medical training, experience and surgical procedure employed.
- The clinical procedure must only be undertaken by suitably qualified personnel.
- Do not re-sterilize – this device is supplied single-use.
- Do not use if the packaging is damaged.

Complications

- Cannula misplacement
- Bleeding
- Intraorbital complications
- Voice changes
- Impaired smell or taste
- Infections leading to abscesses or meningitis
- Nasal dryness leading to pain

INSTRUCTIONS FOR USE

1. Check that the packaging is intact and not damaged. Do not use if the packaging is damaged.
2. Open the packaging onto sterile field.
3. Use the device as intended within the specialist area.
4. UDI traceable barcode is supplied to ensure traceability is maintained in theatre records and patient notes.

GRAPHICAL SYMBOLS USE ON LABELLING



"Sterilised using Ethylene Oxide"



"Use By date"



"Batch Code"



"Do not reuse"



"European Conformity assessment mark"

Manufacturer address:

DTR Medical Ltd
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