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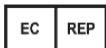
# Zoellner Suction Tip



## Product Information and Instructions for Use



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| SYMBOLS    |                         |               |   |                  |  |
|------------|-------------------------|---------------|---|------------------|--|
| <b>REF</b> | Catalogue Number        |               | Manufactured By                                     | <b>STERILE R</b> | Sterilisation by Gamma Irradiation         |
| <b>LOT</b> | Lot Number              | <b>EC REP</b> | Authorised Representative in the European Community |                  | Do Not Reuse                               |
|            | Use by date.            |               | Latex Free  |                  | Phthalate free                             |
|            | Keep Dry                |               | Manufactured Date                                   |                  | Do Not Use if Packaging is Open or Damaged |
|            | Keep away from Sunlight |               | Do Not Resterilize                                  |                  | Consult Instructions For Use               |
| <b>MD</b>  | Medical Device          |               | Sterile Barrier With inner non sterile Barrier      |                  |  |

### INSTRUCTIONS FOR USE

#### ➤ INTENDED USE:

The Medasil Zoellner Suction Tip is intended to provide fine suction during middle ear surgery and procedures involving the removal of foreign bodies/cerumen/dermal flakes/discharge from the external auditory meatus. The device is intended for transient use (continuous use for less than 60 minutes).

#### ➤ INTENDED PATIENT POPULATION

The Medasil Zoellner Suction Tip is intended for use on the general patient population applied on adults and children.

#### ➤ INTENDED USERS

Medasil Zoellner Suction Tip is intended to be used by Healthcare Professionals (HCP) with a clinical/healthcare setting only.

#### ➤ DEVICE DESCRIPTION:

Medasil Zoellner Suction Tip is manufactured from a stainless-steel tube with a tapered brass ferrule which is biocompatible, Latex and phthalate free.

Zoellner Suction Tip is designed to be compression fitted onto the distal end of a Zoellner or Frazier type suction tube, in order to provide fine suction at the aural cavity. A range of tip diameters are available to suit the requirements of the clinician.

#### ➤ INDICATIONS FOR USE:

- Fine suction during routine otolaryngologic evaluation of the ear canal and middle ear surgery.
- Fine suction during procedures involving the removal of foreign bodies/cerumen/dermal flakes/discharge from the external auditory meatus (e.g., Due to otorrhea).
- Use during other procedures in which fine suction is deemed appropriate by the surgeon.

#### ➤ PERFORMANCE CLAIMS

- Provision of fine suction at the aural cavity.

#### ➤ SAFETY CLAIMS

- Biologically Safe.

#### ➤ CONTRAINDICATIONS:

- Patients with active infections of middle ear or external auditory meatus.
- Patients who are sensitive to loud noises as this may cause pain and discomfort (suction noise may range from 80 to 101dB).

#### ➤ POSSIBLE ADVERSE EFFECTS:

- Excessive force placed on the suction tip may cause it to fracture.
- Excessive force placed on the suction tip may lead to ear canal or tympanic membrane trauma.
- Feeling of pain or discomfort during use, due to loud suction noise.
- Feeling of vertigo during use, due to cooling within the aural cavity.
- Potential for the suction tip to become blocked if the incorrect size is used.

#### ➤ WARNINGS AND PRECAUTIONS:

Prior to use the HCP should consider the following:

- Only a trained HCP should fit and use the device.
- Carefully select the size of suction tip for the requirements of each specific clinical condition, whilst minimising adverse effects.
- Carefully inspect the suction tip after fitting onto the suction handle.
- The device should fit snugly, leaving approximately 2-3 mm clearance from the end of the Zoellner/Frazier suction tube to the end of the brass ferrule. It should not dislodge with gentle pulling or shaking.
- Device is sterile only in a sealed, undamaged and unopened pouch.
- Must not be used if packaging has been compromised.
- Must not be used beyond expiry date on the label.
- Must be stored in the original unopened packaging.
- Must be stored away from moisture and direct sunlight.
- Zoellner Suction Tip is for single use only.
- Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.

#### ➤ STERILITY:

Device is supplied STERILE, having been terminally sterilised using Gamma Radiation. Do not resterilise.

#### ➤ SINGLE USE:

The Device has not been validated for reuse. Anyone reusing a single use device, may be held legally liable for the safe performance of the device.

#### ➤ DISPOSAL OF THE DEVICE:

Biohazardous related waste means related products which were in use and in direct contact with Human Body Fluids and Tissues.

Please note that the proper disposal of products protects the environment. It prevents possible harmful effects on humans and the environment which could be caused by improper handling of the waste.

Disposal of biohazardous waste shall follow local regulations and environmental requirements, taking different contamination levels into account.

Do not dispose biohazardous related waste as unsorted municipal waste.

Waste disposed of in biohazard waste accumulation sites must be collected by service provider for final off-site treatment/incineration/disposal through a biowaste vendor in accordance with local regulations and environmental requirements.

Table 1. Product REF Specifications:

| Box Ref       | Pouch Ref*    | Sizes  |
|---------------|---------------|--------|
| 112-3150-1018 | 112-3101-1018 | SWG 18 |
| 112-3150-1020 | 112-3101-1020 | SWG 20 |
| 112-3150-1022 | 112-3101-1022 | SWG 22 |
| 112-3150-1024 | 112-3101-1024 | SWG 24 |
| 112-3150-1026 | 112-3101-1026 | SWG 26 |

\*Pouch REF for individually packed product

#### ➤ LIABILITY AND WARRANTY:

Medasil declare that reasonable care has been applied in the design and manufacture of this product. In the event of any alleged damage, please contact Medasil or your supplier. The responsibility of Medasil or your supplier under this warranty is limited to the replacement of product if faulty. On no account may Medasil or your supplier be held responsible for damage, whether direct, indirect and/or incidental resulting from the misuse and/or the manipulation of this device.

#### ➤ NOTES:

This device:

- Does not contain any animal or human cells, tissues and/or derivatives thereof, rendered non-viable; cells, tissues and/or derivatives of microbial or recombinant origin; and/or irradiating components, ionizing or non-ionizing.
- Does not incorporate materials that lead to endocrine disrupting, carcinogenic, mutagenic, or toxic to reproduction or could result in sensitization or allergic reaction to the patient or user.
- Are not intended for use by lay persons.

Any serious incident that has occurred in relation to the Zoellner Suction Tip should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

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