

**SPOKE
MEDICAL**

ZEPHYRTM

OPERATION MANUAL

Micro-suction device



INSTRUCTIONS FOR USE

COMPONENTS

1. The Zephyr Sucker
2. The Zephyr Adapter

Zephyr Sucker comes with two plastic suction tips: Standard and small. It can be connected directly to standard suction tubes or used with the Zephyr Adapter, which is supplied separately as an accessory.

DEVICE COMPATIBILITY

The Zephyr Micro-suction Device is compatible with standard suction tubes with an internal diameter of 5-7 mm. Ensure that the suction tube used meets these specifications for optimal performance and safety.

INTENDED-USE

The Zephyr Micro-suction Device is a sterile, single-use instrument designed for connection to standard medical vacuum systems. It is intended for the removal of earwax, debris, and fluid from the external auditory canal under direct visualisation. It is also used for the controlled removal of debris and fluid from surgical fields.

INDICATIONS

The Zephyr Micro-suction device is indicated for use in a clinical setting where suction is required. Patient suitability is at the discretion of a trained healthcare professional.

INTENDED POPULATION

Adult and Children (5 years old and above)

INTENDED USERS AND NECESSARY QUALIFICATIONS

Healthcare professionals trained in surgical or micro-suction techniques.

CONTRA-INDICATIONS

Zephyr Micro-suction device is contraindicated for use in the following circumstances:

- Patient with active infection, tympanic membrane perforation, or significant patient anxiety.
- Patient with a history of distress or pain during previous cerumen removal.
- Patients with intrusive tinnitus or hyperacusis.
- Patients not able to remain still under procedure.

SPECIFICATION OF EXPECTED CLINICAL BENEFIT

Button-regulated suction flow limits noise exposure for the patient and user. Button-regulated suction flow controls suction strength which may help in reducing the risk of tissue injury. An internally widening bore reduces the risk of blockage during use. Zephyr Sucker and Zephyr Adaptor clip interface reduces rotational torque.



WARNINGS

1. Use in line with sterile practice guidelines.
2. Confirm device suitability prior to use.
3. Inspect the device for damage prior to use.
4. Do not use expired product.
5. Do not use the device if the sterile barrier is damaged.
6. Use with care in conjunction with devices such as power tools, electrosurgical devices, heat sources or lasers to prevent damage to the device or injury to the patient or user.
7. If the device becomes damaged, discontinue use.
8. Excessive vacuum on tissue may cause injury: bleeding, trauma to ear canal skin, trauma to ear drum, trauma to the Tympanic Membrane (TM) resulting in TM perforation.
9. Excessive noise in the ear canal may cause:
 - **Common minor complications:** pain, temporary hearing loss, temporary sensorineural hearing loss and temporary tinnitus, reduced hearing, Vertigo, unpleasant loudness during clinical use, dizziness, Nystagmus.
 - **Rare major complication:** permanent sensorineural hearing loss, permanent tinnitus, permanent hearing loss.
10. Excessive force applied to the device could result in:
 - tip breakage, and injury to the patient or user.
 - bleeding, trauma to ear canal skin, trauma to ear drum, TM perforation.
11. The device is for single use only. It cannot be reprocessed due to the risk of infection, cross-contamination, and device damage.
12. Do not use third party tip.

INSTRUCTIONS FOR USE

1. Read and understand the IFU before using the device.
2. Inspect the sterile packaging before removing the device from it. Dispose of the device if the sterile barrier is broken or damaged.
3. Inspect the label for expiry date. Do not use expired product.
4. Remove and handle the device from packaging in accordance with sterile practice.
5. Inspect the device for damage prior to use. Damaged devices should not be used.
6. Select the required Zephyr suction tip and connect it to the Zephyr Sucker.
7. Connect the Zephyr Sucker to the Zephyr adaptor.
8. Connect the Zephyr sucker adaptor to standard medical suction tubing.
9. Connect the suction tubing to the medical vacuum source with suction pressure of 60kPa.
10. Ensure that all connections are secure.
11. The device is ready for the intended use stated above.
12. Suction rate is controlled by the use of the finger button on the Zephyr Sucker.
13. Check that the device is intact after completing the procedure.
14. Dispose of the device as clinical waste or sharps in accordance with clinical waste guidelines.

SUCTION CONTROL MECHANISM

The Zephyr Sucker is equipped with a finger button that regulates the suction rate.

1. Maximum Suction Setting when medical vacuum pressure sat out at 60 kPa: When the button is in the open position, the device generates a suction pressure exceeding 50 KPa but not exceeding 60 KPa with noise level less than 50dBC
2. Adjusting Suction Rate: Gradually pressing the button down will decrease the suction rate.
3. Minimum Suction Setting when medical vacuum sat out 60 kPa: When the button is fully closed, the suction pressure stops and noise level drops to below 35dBC.
4. If button does not depress appropriately either flush or replace the device.

STORAGE & DESPOSAL










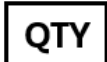









Dispose of the device as clinical waste or sharps in accordance with clinical waste guidelines.





MANUFACTURER DETAILS

Contact the manufacturer for Technical Support. Any serious incident involving the device should be reported to the manufacturer at vigilance@spokemedical.com and to the competent Authority of the Member State in which the incident occurred.

Symbol Key:

	Manufacturer		CE certification mark
	Catalogue number		Medical device
	Date of manufacture		Do not resterilize
	Authorised representative in the European community/European union		CAUTION: US Federal law restricts this device to sale by or on the order of the physician
	Batch code		Quantity of content
	Do not reuse		Latex Free
	Do not use if packaging is damaged and consult instructions for use		Consult instructions for use or electronic instructions for use
	Sterilised using ethylene oxide		Single sterile barrier system
	Keep away from sunlight		Keep dry
	Use-by-date		

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