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VorOtek ENT Speculums Instructions for Use



VorOtek

23 Point Henry Road Moolap VIC 3224 Australia

Device Description

The VorOtek range of ENT Speculums are non-sterile, reusable medical devices. VorOtek ENT Speculums are made of autoclavable polypropylene with an oval tip.



VPS-XXX speculum range



Carefully read these instructions before using VorOtek devices

Intended Use

VorOtek ENT Speculums are used during a wide range of Ear, Nose & Throat (E.N.T.) procedures.

Intended User

VorOtek's devices are intended to be used, handled and managed in a healthcare setting by appropriately trained and qualified health professionals.



The user is responsible for selecting the right speculum for the application or surgical procedure.

Contraindications

Before each use visually inspect each device for damage and do not use if any damage is identified. Discard damaged speculums.



Improper handling, application of excess force or misuse may cause device breakages.

Reprocessing Instructions



VorOtek ENT Speculums are delivered in non-sterile state.



It is the responsibility of the user to ensure reprocessing is performed using appropriate equipment, materials, and personnel to achieve the desired results.



Follow the instructions and warnings issued by the suppliers of any cleaning chemicals and equipment used.



The quality of water used to reprocess the devices is to conform to AS 5369:2023 or current relevant standard.

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Cleaning equipment and chemicals must have a proven efficiency e.g. FDA / CE mark.



Do not exceed 140 °C throughout reprocessing steps.

Initial treatment at Point of Use

Equipment	Disposable wipes (cloth or paper) / PPE Equipment
	Cleaning Brush (e.g. Soft Bristle Brush)
	Suitable plastic tray or sterilisation tray

Steps	Remove gross soiling with a disposable cloth or paper wipe promptly after any use. Do not allow organic debris to dry on speculums prior to cleaning
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Preparation for Cleaning

No disassembly is required for VorOtek's speculum range.

Manual Cleaning

Equipment	Enzymatic Detergent Cleaning Solution (e.g. Miltex EZ-Zyme)
	Cleaning Brush (e.g. Soft Bristle Brush) / PPE Equipment
	Ultrasonic Cleaning Bath / Bath for full immersion

Steps	Immerse in bath and soak the device in an Enzymatic Solution for 10 minutes in accordance with manufacturer's specifications. Ensure no air pockets
	Rinse the devices under running tap water to remove remaining debris
	Immerse the devices in an Ultrasonic Cleaning Bath with Enzymatic Solution in accordance with manufacturer's specifications for 10 minutes. Ensure no air pockets
	Check for remaining soiling. If required remove soiling and repeat Manual Cleaning steps if required

Automatic Cleaning

Equipment	Ultrasonic Cleaning Bath / PPE
	Alkaline Cleaner
	Batch type automatic cleaning device

Steps	Immerse the devices into Ultrasonic Bath with Alkaline Cleaner for 15 minutes at 40 °C.
	Load & arrange devices into the Automatic Cleaning Device. Note: cycle must be validated for load size including drying time and temp.
	Run cleaning cycle using cleaning solution as per machine manufacturer's instructions

Manual Disinfection

Equipment	Bath for full immersion / PPE
	Disinfectant solution
	Sterile water
	Sterile drying wipes and or medical compressed air

Steps	Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer.
	Place devices in the disinfectant bath and observe the specified soaking time & temperature

	Rinse the devices thoroughly with sterile water to remove residual disinfectant
	Dry with medical compressed air and or lint free sterile wipes

Automatic Disinfection

Equipment	Thermal disinfection machine / PPE
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Steps	Machine operated thermal disinfection must be carried out in regard to the A0 value (see ISO 15883)
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Packaging

Equipment	Sterilization Wraps
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Steps	Wrap speculums in accordance with local procedures and using standard techniques such as those described in ISO 11607
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Sterilization

Equipment	Steam or Gravity Sterilizer / PPE
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Steps	Load sterilizer. Ensure maximum load in not exceeded
	Run cycle according to manufacturers instructions. E.g.:
	Steam 134 deg C for 4 mins Gravity 134 deg C for 15 mins

Storage

Store the packaged devices in a normal environmental condition free from dust and fluctuations in temperature and humidity.

Used Symbols for IFU and Label

	Symbol for "Manufacturer"	VorOtek 23 Point Henry Road Moolap VIC 3224 Australia T: +61 03 52485809 E: office@vorotek.com.au W: www.vorotek.com
	Symbol for "Catalogue Number"	
	Symbol for "Lot Number"	
	Symbol for "Consult the Instruction for Use"	
	Symbol for "Non-Sterile"	
	Symbol for "Caution, consult accompanying documents"	