

1. Product Information

Product(group):	Ear Syringes
Basic UDI-DI:	896110285Syringes9H
Intended User:	To be used by qualified users in the medical field, e.g. doctors, specialists and nurses.
Intended Use:	Ear syringes are medical devices intended to be used for cleaning of the ear canal through lavage.













2. General Instructions

It is very important that all terms and conditions in this Instructions for Use are met, and that all information is carefully read and followed. If this is not the case, the ear syringes should not be used.

If you have any questions regarding these instructions, you can contact us regarding the (re-) use of ear syringes. Our contact details can be found under § 9 of this instruction.

 **Read all instructions carefully before use**

3. Symbols Used

	Article number / Article reference manufacturer		Indication that the product is a 'Medical Device'
	LOT-number		Indication that the product is delivered 'Non Sterile'
	Electronic Instructions for Use (accessible via e-ifu.nl)		Product complies with the applicable laws and regulations for medical devices
	UDI - Unique Device Identifier		Keep packaging dry
	Date of Manufacture		Manufacturer (details)
	Importer (details)		European Representative (details)

4. Processing Instructions

Before (first) use

Before first use the ear syringes must be cleaned and disinfected. In case of re-use the ear syringes should be cleaned, disinfected and sterilised in between usages.

Initial treatment at the point of use

Immediately after a procedure, debris should be removed from the ear syringes using distilled or demineralised water and a cloth intended for that purpose. This prevents deposits on the devices.

Preparations prior to cleaning and disinfection

Disassemble the ear syringes and its various parts (the syringe, nozzle and shield). Clean, disinfect and sterilise each of the parts individually.

Manual cleaning and disinfection

Step 1. Maintain humidity

Ear syringes should be placed directly in a designated tray or container after use. Cover the devices with a cloth moistened with distilled or demineralised water. Preservatives (foams) specifically suitable for this purpose are also available.¹

Step 2. Cleaning devices

For cleaning and disinfecting, choose a cleaning and disinfectant² suitable for use with medical device, and follow their instructions for use. When cleaning,

use a soft hand brush to remove dirt from all surfaces of the device. Brush the medical device while it is immersed in the solution. Do not use steel wool, wire brushes, scalpel blades, or highly abrasive cleaners in the cleaning and disinfection process to remove debris from ear syringes. These damage the passive layer of the devices, which makes a device more likely to show signs of corrosion.

Step 3. Rinse

Rinse the devices thoroughly after cleaning. Rinsing should be done with distilled water to prevent discoloration and deposits on the devices.

Step 4. Ultrasonic cleaning (optional)

Ultrasonic cleaning is seen as a good support during the cleaning process but should not be seen as a substitute for cleaning (step 2). When using ultrasonic cleaning, follow the instructions of the manufacturer of the ultrasonic cleaner. Follow the recommendations regarding cycle times, cleaners, placement of the devices and "degassing" of the cleaner.

Step 5. Rinse (if Step 4 is carried out)

After ultrasonic cleaning, rinse the devices thoroughly. You should also use distilled or demineralised water for this final rinse.

Step 6. Drying

The devices should be thoroughly dried after the final rinse. You can use lint-free disposable cloths for this. You may also use a drying gun with compressed air. Compressed air can be used to dry very carefully and efficiently. Good drying will reduce the risk of discoloration and deposition.

Step 7. Inspection devices

Within this step, the devices must be visually inspected. It should be ensured that the devices are clean, but also that they function correctly. Defective or malfunctioning devices should be withdrawn from use at all times. If devices are visually not (completely) clean, they should undergo further cleaning.

Step 8. Maintenance / Lubrication

Lubricating the ear syringe is an important step in making the devices suitable for reuse. The lubricant should be applied to the O-rings of the devices.

Mechanical cleaning and disinfection

Instead of manual cleaning and disinfection, the use of a disinfecting washing machine (Washer/Disinfector) can also be chosen. This form of cleaning is generally preferred over manual cleaning. When using the disinfectant washing machine, you must follow the manufacturer's recommendations at all times. Furthermore, it is important;

- The disinfecting washing machine has proven effectiveness (CE marking according to EN-ISO-15883-1).
- Use a proven thermal disinfection program (A0 value ≥ 3000).
- The program used contains sufficient rinse cycles and is suitable for cleaning reusable devices.
- Sterilisation trays must not be overloaded so that the devices can be rinsed properly.

Inspection

Before use, the devices must be visually inspected by the qualified user. Check the devices for fractures, cracks, deformations and damage. Particular attention should be paid to cut surfaces, ends, closures, locks, ratchets and all movable parts. Furthermore, it must be ensured that the devices are clean and that they function correctly;

- Defective or malfunctioning devices (worn, corroded, deformed, or otherwise damaged) should be always withdrawn from circulation.
- If devices are visually not (completely) clean, they should undergo further cleaning.
- Special attention should be paid to checking the screw threads of the device. If the thread shows signs of wear, the ear syringe should be always removed from circulation.

¹ E.g.: Neodisher® PreStop

² E.g.: Neodisher® Septo Plus

Maintenance

For maintenance of the device a maintenance product (lubricant) should be applied after the device has been cleaned and disinfected.³ The lubricant should be applied O-rings of the device (see below). These can therefore move freely and are better protected against deposits and wear (thus preventing frictional corrosion). Correct lubrication is an essential step for proper functioning and ensuring the long life of the device. The lubricant must be applied to the device before it is sterilised.



Important: For the correct functioning of the ear syringe, it is essential that this step is properly carried out. Proper lubrication prevents friction and allows the plunger to move freely (without too much friction) through the tube. If the syringe is not lubricated, it may eventually become so stiff that the O-rings (due to too much friction) will come off the piston during treatment. This can endanger the patient.

(Sterilisation) -Packaging

After the ear syringes have been cleaned and disinfected, they are ready for sterilisation. The devices must be packed in a laminate bag and / or sterilisation container (in accordance with EN-868-5 & EN-ISO-11607series). The sterilisation packaging should be suitable for steam sterilisation (resistant to temp. of $\geq 137^{\circ}\text{C}$ (279 °F)).

The packaging must also provide the possibility to state (label) certain information, including;

- Sterilisation date
- Best before date
- Packer / processor
- Content

Sterilisation

The last process is sterilisation, and the device can be sterilised through autoclaving. For the specific sterilisation process requirements, we additionally refer to the recommended International Standards (ISO 17665 series). For the steam steriliser requirements, we refer to EN-13060 and / or EN-285.

For ear syringes the following sterilisation cycle has been validated (in accordance with the test specifications EN-ISO 13402):

Sterilisation method	Pre-vacuum
Sterilisation temperature	134 °C (273°F)
Sterilisation time	3 minutes

⚠ Sterilisation is not a substitute for cleaning and disinfecting

Reassembly

Before the device can be used the ear syringes and its individual parts must be reassembled. Place the plunger back and guide the silicone O-rings into the cylinder so that they are not pushed out of their recess. Then carefully screw the cap (to prevent damage to the thread) on the tube. Finally, move the plunger up and down a few times to spread the lubrication equally and to check the functioning of the ear syringe.

5. Storage, Handling and Transport

Ear syringes should be stored and handled in a clean and dry environment. The devices should be stored, handled and transported in a manner that protects them against moisture, dust, extreme temperatures and humidity.

6. General Warnings

This Instruction for Use does not replace adequate training/education of the intended user. The responsibility for proper treatment of the patient and the presence of adequate training/education rests with the qualified intended user. The ear syringe should be used and operated by an intended user who is familiar with its use and how to disassemble and reassemble the device. The manufacturer is not responsible for any complications resulting from an incorrect diagnosis, incorrect product selection or improper use of the medical device.

- ⚠ This Instruction for Use cannot replace proper training**
- ⚠ To be used in contact with intact skin only**

7. Reusability / Product life

The ear syringes can be reused provided that they are not damaged and function properly. The life cycle is limited due to damage and normal wear and tear. We do not define the maximum number of times that a medical device can be used or that it can go through the preparation cycle. The life cycle depends on many factors, including the nature and duration of use, as well as the handling and storage of the devices. When visually inspecting ear syringes, close attention should be paid to the threads and movable parts. Defective or malfunctioning devices (worn, corroded, deformed, or otherwise damaged) should be always removed from circulation. Thorough examination and function testing before the next use is the best way to detect and sort non-functioning devices.

8. Warranty

Ear syringes from Expert International are free from defects in material and workmanship. All our ear syringes are manufactured to the highest quality standards. As a result, we give a five-year warranty on manufacturing and workmanship on all our ear syringes. A prerequisite for this is that the devices are cleaned, disinfected, and sterilised in the prescribed correct manner and that the devices are used for its intended purpose by a qualified intended user.

9. Company details



Medipharchem Nederland B.V.
Oude Blaauwweg 1A
1521RN Wormerveer
Netherlands



www.medipharchem.nl



+31 (0)75 62 12 363



info@medipharchem.nl



Expert International
62-C Ghalib Road
Small Industrial Estate
Sialkot 51340 Pakistan



KB International
Auróra utca, 13. al. 1
1084 Budapest
Hungary

10. Complaint handling

Immediately notify Medipharchem Nederland B.V. (importer) by telephone or e-mail of complaints, defects or incidents related to basic care items. If possible, keep the product in question and return it to Medipharchem Nederland B.V. Complaints about quality defects in the packaging, the instructions for use or in the product itself, should be reported to Medipharchem Nederland B.V.: info@medipharchem.nl

Should a serious incident occur (in which the product led to serious deterioration of a patient's state of health, or it could pose a public health threat), report it to the importer (Medipharchem Nederland B.V.) and to the competent authority in your country. Competent authority for the Netherlands: meldpunt@igi.nl

³ E.g.: Eks® Hi Tech Oil

