Medipharchem Netherlands BV

Instructions for Use

Reusable Surgical Instruments

Ear Syringes, Nozzle(s) and Shield

Instructions are subject to change. The most recent version of every manual is always available online.

1. General instructions

It is very important that all conditions included in this user manual are met and that all information is carefully studied. If this is not the case, these instruments should not be used (clinically).

If uncertainties, disagreements or questions arise, you can contact us regarding the (re-) use of the instruments. Our contact details can be found under point 17 of this instruction.

This instruction of use does not replace adequate user training and the availability of the best available technology. This instruction also does not replace device-specific instructions already included with the device. We assume that the legal provisions, standards and recommendations (e.g. of RIVM, RKI, NEN or AKI) are known to the user (see "Standards/References under point 19) and are followed.

⚠ READ THE FULL INSTRUCTIONS for use CAREFULLY BEFORE FIRST USE

2. Gebruikte symbolen

MD	Medical Device	LOT	LOT-number
	Electronic Instructions for Use (study before use)	CE	Product complies with Directive 93/42/EEC for class 1 medical devices
	Manufacturer	NON STERILE	Indication that product is Non Sterile

3. Description and Product-Specific Instruction

The products covered by this instruction are Medical Devices, namely Ear Syringes (the Syringe, Nozzle(s) & Shield), that are subject to National and European Medical Device Regulations..

4. Intended use and indications

Only an attending physician, or more precisely a qualified user, may use the surgical instruments. The instructions for use are only intended to assist in the use of surgical instruments and are not intended to provide information on the surgical technique.

The qualified user is responsible for choosing the instrument for a certain use. It is a requirement that the user has received adequate training and has sufficient information and experience to use the instruments.

⚠ THIS INSTRUCTION FOR USE CANNOT REPLACE PROPER TRAINING

Target Audience: Persons to whom medical assistance is provided by a qualified user in the event of an illness, condition or injury requiring the use of a reusable surgical instrument.

Do not use the reusable surgical instruments for any other purpose than their intended use. Below is a list of the instruments with a specification of possible indications:

Product Group	Intended Use/Indication
Ear Syringes *(Syringe, Nozzle and Shield)*	Otology instruments are surgical instruments used in the performance of otology procedures (ear surgery). An ear syringe is a surgical instrument that is used for professional cleaning of the ear canal by means of lavage, for example when blocked by cerumen (ear wax). The treatment is carried out if there are complaints of pain, hearing loss, or a feeling of a blockage. Excess earwax will be diluted and removed during the treatment with water / rinsing solution.

5. Contraindications

The circumstances/situations listed below may negatively affect the likelihood of a successful outcome (contraindications). This list is not exhaustive;

- In case of perforation (possibly in the past) of the eardrum (rupture)
- If the patient has previously had surgery on the ear or eardrum
- In case of ear discharge caused by an (middle) ear infection
- If the patient has experienced difficulties in the past as a result of the same treatment
- In the case of an existing or recently infected ear canal
- Allergy or sensitivity to the materials of the instrument

6. Possible side effects

The risk of possible side effects can be minimised by following the directions in this instruction for use. In most cases, possible complications are not directly related to the use of the instruments, but rather attributed to incorrect choices, insufficient user training or to the patient's condition.

Side effects and complications can occur with all surgical procedures. We list some of the most common among the various reactions that may occur. This list is not exhaustive;

- Pain in the treatment area
- Dizziness after treatment
- Itching
- Early or late infection, both deep and/or superficial
- Metal hypersensitivity reactions in patients
- Damage to the ear canal or eardrum

7. Materials used

The durability of surgical instruments depends largely on the material the instrument is made of. Surgical instruments are made of stainless steel in accordance with ISO 7153-1:2016 and EN 10088-3:2014 and/or Ti-6AI-4V alloy in accordance with ISO 5832-3:2016/ASTM F136-13.

8. Precautions for First Use

The reusable instruments are supplied NON-STERILE. Before the first use, non-sterile instruments should be cleaned, disinfected and sterilised after removal of the protective transport packaging. Effective cleaning and disinfection is a prerequisite for efficient sterilisation. Information on processing (handling) reusable non-sterile surgical instruments can be found under point 10 of these instructions for Use (Cleaning, Disinfection, Maintenance and Sterilisation).

9. General Warnings

The manufacturer is not responsible for any complications resulting from an incorrect diagnosis, incorrect product selection or improper use of the medical device.

The attending medical specialist, as well as all other persons involved in the use of the reusable non-sterile instruments, are responsible within their own field of activity to have sufficient product knowledge, based on the current state of technology. This facilitates correct use of the reusable non-sterile instruments and prevents safety risks for patients, users or third parties.

It is the responsibility of the attending medical specialist to consider the patient's clinical and medical condition and to be well informed about possible complications that may occur.

Additional sources of information may apply to the use of certain reusable non-sterile instruments. This may include product catalogues, videos, technical specifications, instructions from medical product advisors, working groups, seminars, specialised courses, publications, etc.

The indications for use include standard instructions which may deviate in specific situations. This is done at the estimate of (sufficiently) trained medical personnel. The responsibility for proper treatment of the patient and the presence of adequate training rests with the attending medical specialist.

The attending medical specialist must discuss the expectations associated with the use of the instrument with the patient. Specific attention should be paid to the postoperative period and the need for periodic medical follow-up care. The patient should be instructed on proper post-operative hygiene procedures and should be instructed to report immediately to the treating medical specialist any unusual changes. The attending medical specialist should consider the possibility of clinical failure and discuss the necessary measures with the patient to achieve a cure.

After contact with or use in patients with Creutzfeldt-Jakob disease (CJD) (or its variants), we decline any responsibility. Please also note that the unused instruments in the instrument trays may also be contaminated. Reuse of these instruments, even in accordance with the RKI guidelines, rests solely on the user's own responsibility.

10. Processing of re-sterilizable Surgical Instruments
(Preparation, Cleaning, Disinfection, Maintenance and Sterilization)

Important: We recommend that you perform the cleaning / maintenance instructions below after each use as drying in can damage the ear syringe and make the cleaning process more difficult. In addition, consistent maintenance will significantly extend the life of the instrument and contribute to the correct functioning of the instrument.

NEN-EN-ISO 17664:2018 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2017,IDT)	
Activity	**Paragraph IFU**
Direct treatment at the location of use / pre-cleaning:	§ 10.1
Preparations prior to cleaning and disinfection	§ 10.2
Manual cleaning and disinfection	§ 10.3
Mechanical cleaning and disinfection	§ 10.4
(Sterilisation) - packaging	§ 10.5
Sterilisation	§ 10.6
Maintenance – lubrication	§ 10.7
Reassembly	§ 10.8
Storage of sterile medical devices	§ 10.9
Pre-use inspection	§ 10.10
Maintenance of Instruments	§ 10.11
(Internal) Displacement after processing	§ 10.12

10.1 Direct treatment at the location of use/pre-cleaning
Immediately after a procedure, coarse debris should be removed from surgical instruments using distilled or deionised water and a cloth intended for that purpose. This prevents blood and other fluids from attaching to the instruments.

10.2 Preparations prior to cleaning and disinfection
The surgical instruments covered by this document do not require any specific preparation or disassembly prior to cleaning and disinfection.

10.3 Manual cleaning and disinfection
Step 1. Disassemble
Open the ear syringe and disassemble the parts (the syringe, nozzle and shield). Clean and disinfect each of the parts individually.

Step 1. Maintain humidity
Instruments should be placed directly in an instrument tray or instrument container after use. Cover the instruments with a cloth moistened with distilled or demineralised water. Preservatives (foams) specifically suitable for this purpose are also acquirable.[1]

Step 2. Cleaning instruments
For cleaning and disinfecting, choose a cleaning and disinfectant [2]suitable for use with surgical instruments, as well as follow their instructions for use. At all times, the cleaning and disinfection solution needs to be renewed frequently. If a solution is used for too long, this may result in:
- Risk of corrosion due to contamination
- Risk of corrosion due to increasing concentration (as a result of evaporation)
- Reduced disinfection efficiency due to contamination

Hinged instruments should be placed open in the cleaning and disinfection solution (to minimise overlapping surfaces). When cleaning, use a soft hand brush to remove dirt from all surfaces of the instrument. Brush the instrument while it is immersed in the solution. Use a soft rager to clean instruments with an accessible opening.

Do not use steel wool, wire brushes, scalpel blades, or highly abrasive cleaners in the cleaning and disinfection process to remove debris from surgical instruments. These damage the passive layer of the instruments, which makes an instrument more likely to show signs of corrosion.

Step 3. Rinse
Rinse the instruments thoroughly after cleaning. Rinsing should be done with distilled water to prevent discoloration and deposits on the instruments.

Step 4. Ultrasonic cleaning (optional)
Ultrasonic cleaning is seen as a good support during the cleaning process but should definitely 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 instruments and "degassing" of the cleaner.

Step 5. Rinse (if Step 4 is carried out)
After ultrasonic cleaning, rinse the instruments thoroughly. You should also use distilled or demineralised water for this final rinse. The use of tap water, especially during this final rinse, can cause discoloration and deposits on the instruments.

Step 6. Drying
The instruments should be thoroughly dried after the final rinse. You can use lint-free disposable cloths for this. If available, you can use a drying gun with compressed air. Compressed air can be used to dry very carefully and efficiently. When drying hinged instruments, pay extra attention to the hinge points. Due to dehydration (in the air) the concentration of chlorides increases, increasing the risk of put corrosion. This can occur in particular with hinged parts which are usually difficult to dry. Good drying will reduce the risk of discoloration and deposition.

Step 8. Inspection instruments
Within this step, the instruments must be visually inspected. It should be ensured that the instruments are clean, but also that they function correctly.
- Defective or malfunctioning instruments should be withdrawn from use at all times and, if possible, be offered for repair.
- If instruments are visually not (completely) clean, they should undergo further cleaning. Depending on the nature of the contamination, continue the process on step 1 or 6.

Step 9. Maintenance/Lubrication of hinged instruments
Lubricating surgical instruments (which require this) is an important step in making the instruments suitable for reuse. It is very important that a lubricant is chosen that is suitable for the sterilisation method you are carrying out (the lubricant must be permeable and heat resistant) . The lubricant must be applied to the instrument before it is sterilised. The lubricant should be applied to the moving (hinged) parts of the instruments. These can therefore move freely and are better protected against deposits and wear. Correct lubrication is an essential step in ensuring the long life of an instrument.

10.4 Mechanical cleaning and disinfection
In addition to manual cleaning and disinfection of surgical instruments, the use of a disinfecting washing machine (Washer/Disinfector) can also be chosen. This form of cleaning is generally preferred over manual cleaning. Due to the automatic process and reduced influence of the human factor, the process will be carried out in a reproducible manner (B9100: 2015 nl).

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 DIN-EN-ISO-15883-1).
- Preferably use a proven thermal disinfection program (A0 value ≥ 3000). (In the case of chemical disinfection, there is a risk of residues of disinfectant on the instruments.*)
- The program used contains sufficient rinse cycles and is suitable for cleaning surgical instruments.
- The disinfectant washing machine should be periodically maintained and tested;
- De desinfecterende wasmachine dient periodiek te worden onderhouden en getest.

* *When making use of chemical disinfection, a disinfectant with proven effectiveness (FDA approval and/or CE marking) should be used and the product should be suitable for use in instruments (see chapter 12. "Material resistance") .* [3]

Correct loading of the machine is also a prerequisite for effective machine treatment. You should take the following into account;
- Open the ear syringe and disassemble the parts (the syringe, nozzle and shield). The parts must be placed separately on the sterilisation tray.
- Sterilisation trays must not be overloaded so that the instruments can be rinsed properly;
- Hinged instruments must be placed open in the disinfecting washing machine;
- Large instruments should be placed on the strainer tray in such a way that their rinse shadow does not impede the cleaning of other instruments;
- Instruments with hollow spaces should also be completely rinsed inside. For this purpose, special inserts adapted to the instruments must be used;
- The instruments must be deposited and stored in such a way that damage is excluded, depending on their mechanical vulnerability. [4]

10.5 (Sterilisation) - Packaging
After the surgical instruments have been cleaned and disinfected, they are ready for sterilisation. The instruments must be packed in laminate bags and/or sterilisation containers which meet the following requirements:
- In accordance with DIN-EN-868-5:2019/EN-ISO-11607-1:2019
- Suitable for steam sterilisation (resistant to temperatures of ≥ 137 °C (279 °F)
- Adequate protection of the instruments or sterilisation packaging against mechanical damage
- Regular maintenance according to the manufacturer's specifications (in case of sterilisation containers)

[1] I.e.: Neodisher® PreStop
[2] I.e.:Neodisher® Septo Plus
[3] I.e.: Eks® Hi Tech Oil
[4] Source: Instrumentenreiniging in de Praktijk, 2012

Labelling
The packaging must also offer the possibility to state certain information, including;
- Sterilisation date
- Packer/processor
- Best before date
- Content

10.6 Sterilisation

Sterilisation is a process that kills or inactivates all microorganisms on or in an object. Something is qualified as 'sterile' if; the probability of the presence of living organisms per sterilised unit is less than one in one million. When sterilising, the instructions from the steriliser's user manual should be observed at all times (each autoclave shall bear a CE marking).

According to current insights, sterilisation with an autoclaaf (steam steriliser) is preferred. The use of a hot air oven is strongly discouraged because they are significantly less reliable than autoclaves. In addition, the long exposure to the high temperature can cause discoloration on the instruments.

When sterilising the instruments, use the sterilisation method below (the instruments are not suitable for other methods).

Steam sterilisation
- Sterilisation with fractionated pre-vacuum or gravity steam sterilisation* (with adequate drying of the instrument)
- Steam steriliser according to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN ISO/ANSI AAMI ISO 17665 (valid commissioning and product specific performance assessment)
- Maximum sterilisation temperature 134 °C (273 °F); plus tolerance according to DIN EN ISO/ANSI AAMI ISO 17665
- Sterilisation time (exposure time and sterilisation temperature)
    - Min. 3 minutes at 134 °C (273 °F)

* *The less effective gravity method should only be used if Sterilization with fractionated pre-vacuum is not available.*

Flash sterilisation or sterilisation of unpacked instruments is not permitted in any way. In addition, do not use; hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation or plasma sterilisation.

To proof suitability of the instruments for effective steam sterilization, a test was carried out by an independent test laboratory. They have proven the suitability of the instruments in accordance with the test specifications ISO 13402: 1995.

⚠ PLEASE NOTE: STERILISATION IS NOT A SUBSTITUTE FOR CLEANING

10.7 Maintenance - lubrication

After the process of cleaning / disinfection / sterilisation, apply a few drops of new lubricant to the silicone O-rings or cylinder of the ear syringe. Proper lubrication is essential for the maintenance and functioning of the ear syringe.

We recommend the use of a synthetic, biodegradable lubricant specifically intended for use on medical instruments. The advantage of this compared to "traditional" oils and fats is the absence of toxic substances (not harmful to humans), it is not broken down by contact with water, and it offers optimal lubrication without affecting the materials (such as the silicone O- rings).

Important: For the correct functioning of the ear syringe, it is essential that this step is carried out. Proper lubrication prevents friction and allows the pestle 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 pestle during treatment. This can endanger the patient.

10.8 Reassembly

After the process of cleaning / disinfection / sterilization & maintenance of the ear syringe and its individual parts, the instrument must be reassembled. Place the plunger straight 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. The ear syringe is now ready for reuse.

10.9 Storage of sterile medical devices

Sterilised medical devices lose their sterility when the packaging is no longer intact. This can be caused by incorrect storage conditions[5]. In order to ensure the sterility of the instruments up to the point of use, the instruments must be stored in a dust-free, dry environment and temperature fluctuations should be avoided. For details regarding storage duration, see: DIN EN 868 and Table 1 of DIN 58 953 – Part 9.10.8.

10.10 Pre-use Inspection

Before use, the instruments must be visually inspected by the qualified user. Check the instruments 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 instruments are clean and that they function correctly.
- Defective or malfunctioning instruments (worn, corroded, deformed, or otherwise damaged) should be withdrawn from circulation at all times and, if possible, be offered for repair.
- If instruments are visually not (completely) clean, they should undergo further cleaning.

10.11 Maintenance of Instruments

The maintenance of instruments involves the application of maintenance products (lubricants) after the instruments have been cleaned and disinfected. Lubricating surgical instruments (which require this) is an important step in making the instruments suitable for reuse. The lubricant should be applied to the moving (hinged) parts of the instruments. These can therefore move freely and are better protected against deposits and wear (thus preventing frictional corrosion).

It is very important to choose a lubricant that is suitable for the sterilisation method you are carrying out (the lubricant must be permeable and heat resistant). The lubricant should be applied to the instrument before it is sterilised.

10.12 (Internal) Displacement after processing

In order to prevent damage during movement (to the place of use) of the surgical instruments, they must be placed in appropriate holders or be secured against shifting using aids..

11. Storage not-sterile instruments (before use)

The reusable non-sterile instruments should be stored in a clean, dry environment. The environment must be protected against moisture, dust, extreme temperatures/ humidity and from pests.

Instruments must be stored in such a way that there is no risk of damaging each other. If necessary, use tip covers to protect sharp ends.

12. Material Resistance

When choosing the Cleaning and Disinfectant, it should be taken into account that they are free of the following components:
- Organic, mineral and oxidising acids
- Strong lye solutions. PH> 11 is not allowed (mildly alkaline cleaners are recommended)
- Organic solvents (alcohols, acetone)
- Petrol
- Halogenated hydrocarbons (chlorine, iodine)
- Ammonia

13. Reusability/Product life

The instruments 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. Instruments that are damaged and/or do not function properly should be separated from the other instruments. Please take into account the limitations of paragraph 8 regarding Creutzfeldt-Jacob disease (CJK).

We do not define the maximum number of times that an instrument 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, storage and transportation of the instruments. Thorough examination and function testing before the next use is the best way to detect and sort non-functioning instruments.

We would also like to point out that due to detergent residues, the biocompatibility (biological compatibility) of the instruments cannot be guaranteed. The observation/ perception of the user is leading in this. We do not accept any liability arising from non-compliance with these directives (guidelines).

14. Warranty

The reusable surgical instruments from Medipharchem Netherlands B.V. are free from defects in material and workmanship. All our surgical instruments are designed and manufactured to the highest quality standards. As a result, we give a five-year warranty on all our general surgical instruments. A prerequisite for this is that the instruments are maintained and cleaned in the prescribed correct manner and that the instruments are used by a qualified user for their intended purpose.

[5] Source: Richtlijn Steriliseren en Steriliteit R5340-1

15. Returns

Returns within this instruction for use refer to reusable instruments that are returned (used or not) to the manufacturer.

The reusable instruments may have been used in or on patients who may carry both recognised and unrecognised infections. In order to prevent infections from spreading, all reusable instruments must be properly cleaned, disinfected and sterilised after use on a patient.

Return shipments of used instruments are only allowed after a visible disinfection/sterilisation has been carried out (a packaging with sterilisation indicator, disinfection certificate, etc.). The associated hygiene and operating regulations must be complied with.

16. Manufacturer

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17. Complaint handling

Immediately notify Medipharchem Netherlands B.V. by phone or e-mail of complaints, defects or incidents related to the instrument. If possible, store the product concerned and return it to Medipharchem Netherlands B.V.

Complaints about quality defects to packaging, patient information or the product itself must be reported to the manufacturer: info@medipharchem.nl

Should an 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 manufacturer and to the competent authority in your country. Competent authority for the Netherlands: meldpunt@igj.nl

18. Liability

Medipharchem Netherlands B.V. is not liable for any problems caused by the user's failure to follow these instructions.

Medipharchem Netherlands B.V. has no control over the final use of the surgical instruments and therefore accepts no responsibility or liability for any damage caused by improper application or incorrect use, or by the user's lack of control of the functionality of the instrument.

Medipharchem Netherlands B.V. cannot be held responsible or held liable for instruments (or parts) that have been repaired and/or modified or where an attempt has been made to do so, except where the repairs or modifications have been carried out by Medipharchem Netherlands B.V.

Complications or other effects that may result from an incorrect indication or surgical technique, inappropriate choice of material or treatment, improper sterilisation, improperly cleaned or sterilised medical instruments, asepsis etc., are the responsibility of the user, for which Medipharchem Netherlands B.V. cannot be held liable.

In the case of non-compliance, the manufacturer accepts no liability.

19. Standards - References

- AKI - "Proper Maintenance of Instruments" Guide
- RKI - Recommendation: "Hygiene Requirements with regard to the Preparation of Medical Products"
- DIN EN 285 Large steam sterilisers
- DIN EN 13060 Small steam sterilisers
- DIN EN ISO 15883-1-3 Washer-Disinfectors
- DIN EN ISO/ANSI AAMI ISO 11607 and EN 868-2 until -10 Packaging materials
- DIN EN ISO 17664/ANSI AAMI ST81 Sterilisation - Manufacturer's Information
- DIN EN ISO 17665-1 Sterilisation process - Moist heat