

1. Product Information

Product(group):	Speculums <ul style="list-style-type: none"> • Vaginal Speculums • ENT Speculums
Basic UDI-DI:	896110285Speculums4D
Intended User:	To be used by qualified users in the medical field, e.g. doctors, specialists, nurses.
Intended Use:	Speculums are medical devices intended to be used to dilate body orifices.













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, these speculums should not be used.

If you have any questions regarding these instructions, you can contact us regarding the (re-) use of speculums. 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 instrument must be cleaned and disinfected. In case of re-use the instrument should be cleaned and disinfected. Depending on the usage sterilisation is optional (for interpretation by the qualified user).

Initial treatment at the point of use

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

Manual cleaning and disinfection

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 available.¹

Step 2. Cleaning devices

For cleaning and disinfecting, choose a cleaning and disinfectant² suitable for use with medical devices, and follow their instructions for use. When cleaning, use a soft hand brush to remove dirt from all surfaces of the instrument. 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. 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.

Step 6. Drying

The instruments 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 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. If instruments are visually not (completely) clean, they should undergo further cleaning.

Step 8. Maintenance/Lubrication

Lubricating the instrument is an important step in making the instruments suitable for reuse. The lubricant should be applied to the rotating and/or moving parts of the instruments.

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 instruments.
- Sterilisation trays must not be overloaded so that the instruments can be rinsed properly.

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.
- If instruments are visually not (completely) clean, they should undergo further cleaning.

¹ E.g.: Neodisher® PreStop

² E.g.: Neodisher® Septo Plus

Maintenance

For maintenance of the instrument a maintenance product (lubricant) should be applied after the instrument has been cleaned and disinfected.³ The lubricant should be applied to the rotating, moving or hinging parts of the instruments. These can therefore move freely and are better protected against deposits and wear (thus preventing frictional corrosion). Correct lubrication is an essential step in ensuring the long life of the instrument. The lubricant must be applied to the instrument before it is sterilised.

(Sterilisation) -Packaging

After the speculums have been cleaned and disinfected, they are ready for sterilisation. The instruments 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 $^{\circ}\text{F}$)).

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 medical 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 speculums the following sterilisation cycle has been validated (in accordance with the test specifications EN-ISO 13402):

Sterilisation method	Pre-vacuum
Sterilisation temperature	134 $^{\circ}\text{C}$ (273 $^{\circ}\text{F}$)
Sterilisation time	3 minutes



 **Sterilisation is not a substitute for cleaning and disinfecting**

5. Storage, Handling and Transport

The instruments should be stored / handled in a clean and dry environment. The instruments should be stored, handled and transported in a manner that protects them against moisture, dust, extreme temperatures & 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 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

Speculums 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 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 and storage of the instruments. Thorough examination and function testing before the next use is the best way to detect and sort non-functioning instruments.

8. Warranty

Speculums from Expert International are free from defects in material and workmanship. All our Basic Care Equipment are manufactured to the highest

quality standards. As a result, we give a five-year warranty on manufacturing and workmanship on all our Speculums. A prerequisite for this is that the medical devices are (re)processed in the prescribed correct manner and that the medical devices are used for its intended purpose by a qualified intended user.

9. Company details



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Hungary

10. Complaint handling

Immediately notify Medipharchem Nederland B.V. (importer) by telephone or e-mail of complaints, defects or incidents related to Speculums. If possible, keep the product in question and return it to Medipharchem Nederland B.V. Complaints about quality defects to the packaging, instructions for use or 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@igj.nl

³ E.g.: Eks® Hi Tech Oil

