



EN Instructions for use
Hysteroscopy sheaths

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1. About this document

1.1. Purpose









This document describes the correct handling and function of hysteroscopy sheaths, obturators and flexible electrodes, as well as recommended reprocessing methods.






Carefully read these instructions of use before using these hysteroscopy systems. Keep these instructions for use in a safe place for future reference.

1.2. Symbols used

This section explains each symbols used on the product packaging and in this instructions for use:

Symbols	Description
	Manufacturer
	German product
	Reference number
	Batch number
	Quantity
	Non sterile
	Follow the instructions for use
	Warning

 0297	Conformity to the essential requirements with notified body number of DQS Medizinprodukte GmbH, Frankfurt, Germany
	Keep dry
	Keep away from sunlight

2. Intended use

Hysteroscopy sheaths are used for endoscopic explorations in gynecology exclusively. The sheaths allow diagnosis and treatment procedures of the cervical canal and the uterine cavity.

Hysteroscopy sheaths must be used only in medical facilities by trained and skilled medical personnel. The sheaths must not be used if, according to a qualified physician, the general condition of the patient is not adequate or if the endoscopic methods are contraindicated.

The endoscopic methods are contraindicated if one or more below reported conditions is present:

- Acute inflammation of internal genitalia ;
- Strong uterine bleeding ;
- Existing pregnancy ;
- Surgical patients who present or who are identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments. Therefore, devices that have been in use or suspected of use on a patient with CJD after surgery must be disposed according to current national recommendations.



Improper use can lead to hazardous situations.

3. Safety instructions

At the delivery of the products, inspect the delivery for completeness and damage.

Use the hysteroscopy sheaths only as intended. (See "Intended use" on page 4).



Carefully read, observe and keep these instructions for use in a safe place for future reference.

4. Testing, handling and maintenance



The products are medical instruments and handling them requires great care. Carry out visual inspection and function check at delivery and prior to each use. Only use products which are in a perfect condition.

- Prior to each use, inspect visually the products for twisted, broken or loose parts, fissures or scratches as well as worn or cracked parts.
- Ensure that the product works as described in these instructions for use.
- Damaged or faulty products should not be used and should be removed immediately
- Damaged parts should be immediately replaced by original manufacturer parts.

5. Guideline conformity



The CE marking of the medical product complies with the guideline 93/42/EWG. It applies only when the products and/or packaging features this marking.

6. Available models



200-301-7-DEL	100-235
200-311-7-DEL	100-237
200-122-PUR	



An incorrect combination of products can lead to injury for patients and medical personnel as well as product damage.

7. Preparation for use

7.1. Visual inspection and function check



Carry out visual inspection and function check at delivery and prior to each use. Only use products which are in a perfect condition.

- Perform and follow the instructions in section 4.
- Ensure that there are no residual cleaning agents or disinfectants on the products.
- Inspect the locks for deterioration.
- For the operative sheath, inspect the sealing cap and the working channel for function, damage and contaminant. Inspect free passage of the working channel.

7.2. Provisioning



Products are delivered non-sterile as reusable products. Clean, disinfect and sterilize the products prior to initial use as well as each additional use of the products. See "Reprocessing" on page 6.

8. Use



For hysteroscopy sheath with working channel: if an instrument is inserted, do not move the lever on the stopcock because otherwise the instrument could be damaged or sheared off.

Prepare the products for reprocessing immediately after use to prevent surface drying of the contaminants.

9. Reprocessing

9.1. Warnings and precautions

Surgical patients who present or who are identified as at-risk for Creutzfeldt-Jakob disease (CJD) and related infections should be treated with single-use instruments.

Therefore, devices that have been in use or suspected of use on a patient with CJD after surgery must be disposed according to current national recommendations.

9.2. Cleaning and disinfection (in automatic machine)

All products must be separated (inner and outer operative sheath for example). The sealing caps must be removed.

Manual Pre-Cleaning:

Brush the products under **cold** water until all visible contamination is removed.

Machine cleaning: (tested and validated with Miele G 7836 CD)

Step	Process step	Reagents	Time (min)	T (°C)
1	Pre-cleaning	Tap water	3	Cold
2	Drain			
3	Cleaning	Tap water with 0,5% of Sekumatic FR at 45°C (Ecolab)	3	55
4	Drain			
5	Cleaning	Deionized water with: - 0,5% of Sekumatic FR at 45°C (Ecolab) - 0,35% of Sekumatic Oxivario at 50°C (Ecolab)	2	55
6	Drain			
7	Neutralization	Deionized water with 0,1% of Sekumatic FNZ (Ecolab)	1	Cold
8	Drain			
9	Rinsing	Deionized water	1	Cold

Disinfection:

Thermal disinfection shall be performed according to EN ISO 15883-1. This standard uses the term A0 as a measure for the killing of microorganisms in moist-heat processes (hot water).

A0	Time	Temperature
3000	95 seconds	95°C
600	30 seconds	93°C

9.3. Sterilization



Prior to each sterilization, products must be cleaned and disinfected according to methods in these instructions for use.

The product must be sterilize with fractional pre-vacuum procedure, in accordance with ISO 17665:

- Temperature : 132°C ;
- Time of exposure: 4 min ;
- Drying Time: minimum 10 min.



Products must be sterilized in suitable packaging to avoid any subsequent contamination. The initial packaging in which non-sterile products have been delivered are not suitable for sterilization.

9.4. Control and testing

The products have to be visually examined for cleanliness after every cleaning and disinfection. They have to be macroscopically clean from visual residual and soil.

- If residue, liquids, impurities are visible, repeat cleaning process.
- Ensure that the instruments are in perfect working order before each application.
- Plastic components should be checked before sterilization.
- Products must be replaced if plastic components are broken, cracked or worn.

9.5. Reprocessing restrictions

There are no limitations regarding the number of cleaning and sterilization cycles. The products durability and lifespan is influenced primarily through wear and tear during application.

10. Assembly and disassembly

10.1. Sheaths

Quick-Lock system:

To remove an obturator or an inner sheath with the Quick-Lock system:

- Press the button to unlock the Quick-Lock device.
- Remove the obturator or the inner sheath.

To insert an obturator or to an inner sheath with the Quick-Lock system:

- Insert the obturator or the inner sheath so that the arrows on each of the two products to be aligned.
- Press the button by continuing to slowly insert the obturator or the inner sheath until the Quick-Lock system engages.

Locking system:

To remove an obturator or an inner sheath with the locking system:

- Turn the lever counterclockwise.
- Remove the obturator or the inner sheath.

To insert an obturator or to an inner sheath with the lockig system:

- Fully insert the obturator or the inner sheath.
- Turn the lever clockwise.



Never force to insert an obturator or an inner sheath, they should slide easily. If they do not, check the sizes or alignments of the different products.

10.2. Stopcocks



To disassemble the lever of the stopcock from its base (1):

- Unscrewing the lever nut (2) ;
- Remove the lever (3).

To assemble the lever of the stopcock from its base (1):

- Insert the lever (3) in the base.
- Fix the lever by screwing the lever nut (2).

11. Storage

Unsterile devices must be stored safely, until the next use, in a clean environment, in a sterilization basket. The storage room has to be:

- Dust-free.
- Have a low microbiological contamination.
- Be dark.
- Free of temperature fluctuations.



Keep dry.



Keep away from sunlight.

12. Service and repairs

In spite of application in compliance with intended use, medical products are subject to variable wear and tear depending on the intensity of the application. Wear is technically inevitable.

- Do not repair. Service and repairs must be carried out by the manufacturer or by authorized personnel.
- Medical products have to be cleaned, disinfected and sterilized prior to sending for repair. Soiled or contaminated medical products should not be shipped.
- Ideally, send the products in the original packaging. If this is not possible, package the product to secure it for transport. Delmont Imaging is not liable for damage resulting from improper shipping.

13. Warranty

Products are guaranteed two years against defects in workmanship and material. In the event of defects under guarantee, the product will be repaired or replaced.

Repairs, attempted repairs, alterations or other tampering of this product carried out by unauthorized personnel renders the guarantee invalid.

14. Disposal

Observe country-specific regulations and laws for the disposal of medical products.



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