



EN Instructions for use
Bipolar resectoscope

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1. About this document

1.1. Purpose









This document describes the correct handling and function of bipolar resectoscope, 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
	Manufacturing date
	Quantity
	Non sterile
	Follow the instructions for use

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

2. Intended use

Bipolar resectoscopes are intended for the endoscopic diagnosis and treatment during gynecological intervention. Resectoscopy will be used for controlled tissue ablation.

Resectoscopes connected to proper HF-Cable, are used in combination with suitable HF-Electrodes to perform endoscopic procedures.

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

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

- Acute inflammation of internal genitalia ;
- Infection of the vagina ;
- Strong uterine bleeding ;
- Existing pregnancy ;
- Patient with pacemaker ;
- Presence of flammable or explosive substance ;
- 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.

Side effects and residual risks:

- When direct or low-frequency current enters the body, electrolysis occurs at the electrode/tissue interface. The chemical effects of electrolysis disappear at higher frequencies ;
- Direct or low frequency current can depolarize cell membranes and cause neuromuscular excitation ;
- Electrosection results in more collateral tissue damage compared to scalpel surgery, creating some histologic distortion of surgical margins;
- Thermal damage may cause carbonization at the excision margin, vessel thrombosis, and collagen denaturation. Therefore careful evaluation of the advantages and suitability of the intended application is recommended.

3. Safety instructions

At the delivery of the bipolar resectoscope(s), inspect the delivery for completeness and damage.

Use the bipolar resectoscopes only as intended. (See "Intended use" on page 4).

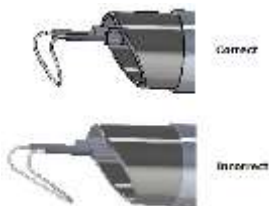


Carefully read, observe and keep these instructions for use in a safe place for future reference.

Warning and precautions:

- Electrodes in combination with standard resectoscopes must only be used with a recovery peak voltage of max. 2.0 kVp throughout both standard cutting and coagulation mode ;

- The electrode tip may remain hot enough to cause burns after current is deactivated ;
- Inadvertent activation or movement of the electrode outside the field of vision may result in injury to the patient ;
- Endogenous risk of burns caused by critical current density in the patient's tissue is existing. Probable causes: The patient has inadvertent contact with electrically conductive parts. In the event of direct contact between skin, HF cables and electrodes, capacitive currents may lead to burns ;
- Exogenous risk of burns caused by inflaming liquids or gases, as well as possible explosions is existing. Probable causes: inflammation of skin cleansers, disinfectants or anesthetic gases, etc. ;
- Only activate HF current, if the electrode is in your field of view and in contact with tissue otherwise excessive heating of the irrigation medium may result and may cause patient injury ;
- Do not bend, deform or tamper with the form of the electrode. It may damage the electrode and lead to hazards for both patient and user ;



- Ensure that the electrode size corresponds to the size of the inner sheath in use ;
- To minimize the associated health hazards, specially designed smoke evacuation systems should be used where available and surgical filtration masks donned for all surgical procedures.

4. Testing, handling and maintenance



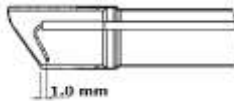
Bipolar resectoscopes are medical instruments and handling them requires great care. Carry out visual inspection and function check at

delivery and prior to each use. Only use products which are in a perfect condition.

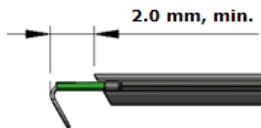
- Prior to each use, inspect visually the products for twisted, broken or loose parts, damaged insulation, fissures or scratches as well as worn or cracked parts.
- Ensure that the product works as described in these instructions for use.
- Damaged or faulty products should not be used and should be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

Electrode position:

In resting position, the electrode loop have to remain approximately 1.0 mm behind the distal end of the sheath.



The distance between non-insulated tip of the electrode and the tip of the endoscope has to be at least 2mm. Also the wire loop should be parallel to the sheath and optic.



Inadequate distance between HF conductive components and other conductive parts, may lead to unintentional damage of tissue and /or instruments.

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. Description



115-127-QL-PUR	100-127-QL-PUR
115-126-QL-PUR	100-126-QL-PUR
115-100-SL-PUR	100-100-SL/KS-PUR
115-123-QL-PUR	100-123-PUR

The HF cables supplied by Delmont Imaging are compatible with the resectoscopes and all our electrodes. The tip of the HF cable, generator side, must match the generator used.

Resectoscope can be used with all types of HF-Generators if it is ensured that maximum power outputs (max. 2.0 kVp) are not exceeded and the connection with suitable cables is ensured.



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 no parts are missing or loose
- Ensure that there are no residual cleaning agents or disinfectants on the products.

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 10.

8. Use

8.1. Recommended power setting

Excessive power setting can lead to significantly higher electrode wear. It is recommended to start with a low power setting gradually increasing until reaching the desired mode:

- Cutting mode: 120-180 watt ;
- Coagulation mode: 100 watt max.

8.2. Mode of application

According to the desired mode of action, the following solutions should be used:

- Monopolar application: e.g. Glycine, Purisole ;
- Bipolar application: 0,9% NaCl solution.

8.3. Electrode position

During application of high frequency to the HF Electrodes, a distance of at least 8mm is required from the HF application tip (loop wire, knife and roller) to the distal end of the endoscope or sheath



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.
- Country-specific regulations and laws for cleaning medical products have to be observed.

9.2. Cleaning and disinfection (in automatic machine)

All products must be separated (inner and outer resectoscope sheath for example). See the section "Assembly and disassembly" on page 12.

Manual pre-cleaning :

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

Rinsing with water jet pistol (static pressure above 4 bar) for a minimum time of 10 seconds. Use the water jet pistol to rinse holes, hinges, gaps and cavities.



Do not use metal brushes, sponges, abrasive cleanser, hard or sharp tools to remove contaminants in order to avoid products damages.

Do not bend or deform the electrode.

Machine cleaning: (tested with Niagara SI PCF – Medisafe)

Step	Process step	Reagents	Time (min)	T (°C)
1	Pre-cleaning with pulsed ultrasounds	Deionized water	3	25
2	Drain			
3	Cleaning with pulsed ultrasounds	Deionized water with 0,35% enzymatic detergent M20029 3E-Zyme Scope	20	40

Plus (Medisafe)					
4	Drain				
5	Intermediate rising	Deionized water	2	25	
6	Drain				
7	Rinsing	Deionized water	1	25	

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 resectoscopes 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.
- The insulation and HF connector must be intact.
- Plastic components should be checked before sterilization.
- The ceramic have to be checked if they are cracks or if it is broken.

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.

The products can be damaged if the manufacturer specifications are not observed.

10. Assembly and disassembly

10.1. Resectoscope

Assembling:

- Insert HF electrode through the small tube of the handle until the electrode clicks into place in the handle ;
- Insert the handle associated with the electrode into inner sheath and lock by pressing the Quick-lock system until the system locks ;
- Insert this set into resectoscope outer sheath and lock also by using a Quick-lock system ;
- Insert endoscope into the handle and lock by turning the lock lever in a clockwise direction.

Disassembling:

- Turn the locking mechanism counter clockwise to release the endoscope and then pull the endoscope off the handle ;
- Unlock the outer sheath by pressing the Quick-lock system and remove the outer sheath from the inner sheath ;

- Unlock the inner sheath by pressing the Quick-lock system and remove the inner sheath from the handle ;
- Unlock HF electrode by pressing the Quick-lock system and remove the electrode from the handle.

10.2. Stopcock



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, until the next use, in a clean and dry environment.
The storage time of unsterile units is not limited. 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

This product is 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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