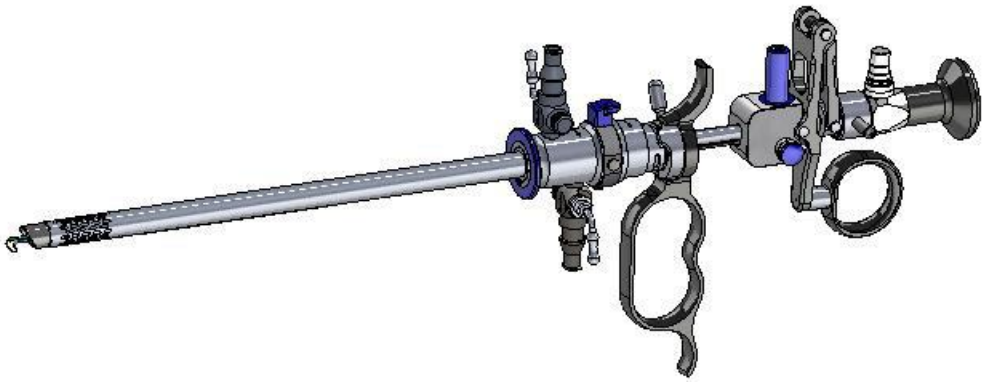
INSTRUCTION FOR USE

Precisely yours,

INVIDIA®
MEDICAL
GERMANY

Instruments for Resectoscopy



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CE

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1 Device Description

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

Carefully read these instructions before using INVIDIA MEDICAL Instruments for Resectoscopy. Keep them in a safe place for future reference.

1.1 Intended use – Sheaths and Guides

These products are intended for the endoscopic diagnosis and treatment during urological and gynecological intervention. Resectoscopy will be used for controlled tissue ablation.

1.2 Intended use – Working Elements

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

1.2.1 Intended User

The products must be used only in medical facilities by trained and skilled medical personnel. The products 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.

1.3 Contraindication

Do not use the devices if one or more below reported conditions is present:

- Acute inflammation of the abdominal area
- Infection of the vagina
- Existing pregnancy
- Patient with pacemaker
- Presence of flammable or explosive substance
- The device has been already used to treat patients with suspected or verified BSE, CJK / vCJK diseases.

Surgical patients 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

1.4 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

1.5 Warnings 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. 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. Probable causes: inflammation of skin cleansers, disinfectants or anaesthetic 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 or the cutting wire
- 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

2 Available Models and Combination Products

2.1 Monopolar HF-electrodes

Resectoscope are to be used in combination with HF-electrodes for resectoscopy.

The corresponding sheaths and electrodes are color coded according to size as follows:

- 19Fr white
- 24Fr yellow
- 27Fr brown/black
- 11Fr green
- 13Fr red

2.2 Bipolar/saline Electrodes

Bipolar/saline Electrodes are color coded with a double color code at the distal end

- 13Fr blue
- 17Fr green
- 19Fr white/blue
- 24Fr yellow/blue
- 27Fr brown/blue

2.3 Cables

HF cables supplied by INVIDIA MEDICAL are compatible with all our working elements and electrodes. The type of HF generator in use determines which size of plug the cable should have at the generator end.

2.4 Generator

Electrical safety tests were conducted in combination with the HF Surgical Generator ME MB2 by KLS Martin. Comparable HF-Generators can be used in combination with INVIDIA MEDICAL´s products if it is ensured that maximum power outputs (max. 2.0 kVp) are not exceeded and the connection with suitable cables is ensured

Please refer to section "Attached Document" for further information

An incorrect combination of products can lead to injury for patients, users or third parts as well as product damage.

3 Reprocessing Instructions

Products are delivered in a Non-Sterile State and must be cleaned, disinfected and sterilized before the first and any other subsequent use

3.1 Warning and Precautions

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

- For patients with Creutzfeld-Jakob-Disease, CJK-on-spec or its possible variants, Bovine Spongiform Encephalopathy or Transmissible Spongiform Encephalopathy country-specific regulations and laws concerning cleaning of instruments have to be observed
- Do not use metal brushes, sponges, abrasive cleanser, hard or sharp tools to clean electrodes
- Do not bend or deform the electrode or the cutting wire

3.1.1 Limitation of Reprocessing

INVIDIA MEDICAL ´s devices are made out of different materials. These were chosen regarding their ability to withstand to several cleaning, disinfection and sterilization cycles and thus, the multiple high temperature application. There are no concerns regarding material resistance or any known sensitivity to process parameters during reprocessing (heat, cleaning agents etc.) which may affect the safety of our devices. Nevertheless, the ability of INVIDIA MEDICAL devices to withstand several reprocessing cycles has been validated up to 20 times.

3.2 Cleaning - Automatic

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.

Cleaning: (i.e. Niagara SI PCF - Medisafe):

Step	Process Step	Reagents	Time (min)	T (°C)
1	Pre-cleaning with pulsed activation of ultrasonic cleaning	Deionized water	3	25
2	Drain			
3	Cleaning with pulsed activation of ultrasonic cleaning	Deionized water, 0.35% enzymatic detergent M20029 3E-Zyme Scope Plus (Medisafe)	20	40
4	Drain			
5	Intermediate rinsing	Deionized water	2	25
6	Drain			
7	Rinsing	Deionized water	1	25

Disinfection

Thermal disinfection has been validated using the following parameters:

Time	Temperature
95 sec	95 °C

3.3 Sterilization

Sterilisation of the products with fractional pre-vacuum procedure has been validated in accordance with ISO 17665.

Time of exposure (min)	Temperature (°C)	Drying Time (min)
4	132 ± 1	10

Packaging:

The products are delivered non-sterile in sealed plastic or in a protective box/foam packaging. Transport packaging is not suitable for sterilization. Devices have to be packed into suitable sterilization packaging systems (e.g. STERICLIN pouch used during sterilization validation) acc. to ISO 11607 and/or AAMI / ANSI ST77:2006 in order to be sterilized.

3.4 Control and Testing

The resectoscope 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 sterilisation.
- The ceramic have to be checked if they are cracks or if it is broken.

3.4.1 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:

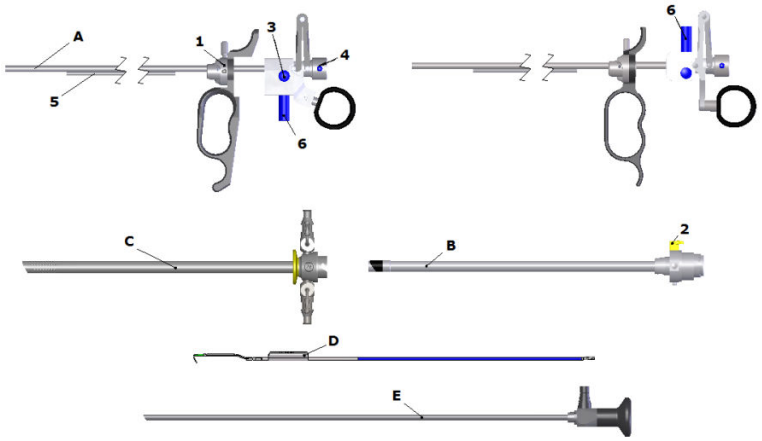
- Cutting Mode: 120-180 Watt
- Coagulation Mode: Max. 100 Watt

3.4.2 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

4 Assembling – Disassembling Instructions



4.1 Assembling

UTERIS XS

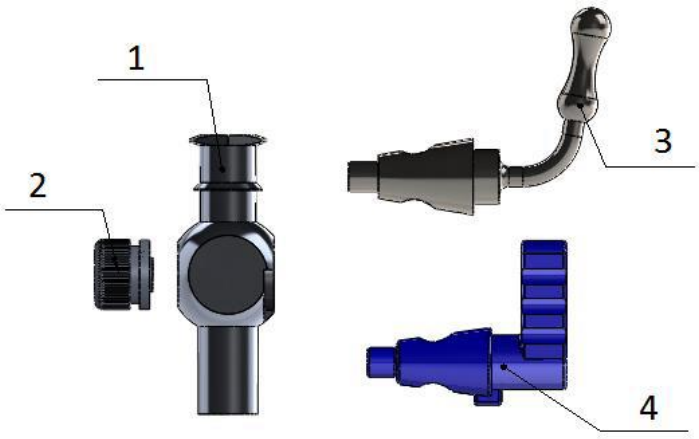
• Insert HF electrode (D) through the small tube (5) of the working element (A) until the electrode clicks into place in the working element • Insert working element (A) into inner sheath (B) and lock by turning locking lever (1) • Insert assembled inner sheath/working element (A+B) into outer sheath (C) and lock by using push button (2) • Insert endoscope (E) into working element (A) and lock by turning locking lever (4)	• Insert the endoscope (A) into the working element (B), and lock by turning the locking lever (1). • Insert the HF electrode (C) over the endoscope until the electrode clicks into place in the working section (2). • Insert the working element (B) into the sleeve (D) until the smart locl mechanism clicks (3).

4.2 Disassembling

UTERUS XS

• Turn the locking mechanism (4), release the endoscope (E) and pull it out of the working element (A) • Unlock outer sheath by using push-button (2) and remove outer sheath from inner sheath (B) • Turn locking mechanism to unlock inner sheath (1) and remove from working element (A) • Unlock HF electrode (D) by using push-button (3) and pull it out of the working element (A)	• Rotate the locking mechanism (1), release the endoscope (A) and pull it out of the working element (B) • Unlock the sleeve (D) using the button (3) and remove it from the working part (B). • Unlock the HF electrode (C) using the button (2) and remove it from the working part (B).

4.3 Sheaths with Stopcock



- Disassemble the stopcock from the housing (1) by un-screwing the thumbscrew (2) from the stop-cockplug (3-> stainless steel, 4 -> plastic)

5 Visual and Functional Inspection-Check

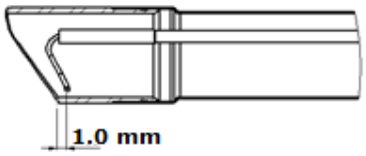
New medical products have to be inspected thoroughly visually and functionally after delivery and prior to each use

- Prior to subsequent use, products should be visually examined for bent, broken or loose parts, damaged insulation, fissures, scratches as well as worn out or cracked parts

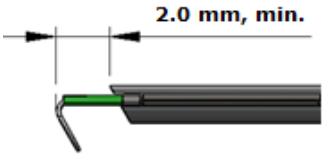
- Check that function is as described in the instructions
- Damaged or faulty products should not be used and should be taken out of circulation immediately
- Damaged parts should be immediately replaced by original manufacturer parts

5.1 Electrode Position

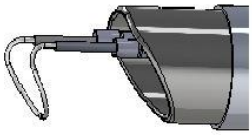
In resting position, the electrode loop have to remain approximately 1.0 mm behind the distal end of the sheath

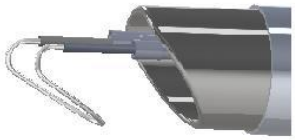


The distance between non-insulated tip of the electrode and the tip of the endoscope has to be at least 2mm. Also the wire loop should be parallel to the sheath and optic.



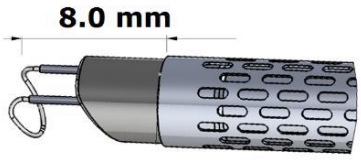
Never re-bend or tamper with the shape of the loop wire. *It may damage the electrode and lead to hazards for both patient and user*





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

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



6 Storage

The Resectoscope must be stored until subsequent use in a suitable sterilization container for steam sterilization according to the standards


Keep away from sunlight


Keep dry


Read carefully the reprocessing instructions

The storage room has to be dust-free, of low microbiological contamination, dark and free of temperature fluctuations.

7 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.

8 Warranty

This product is guaranteed against defects in workmanship and material. In the event of defects under guarantee, the product will be repaired, replaced or the charges refunded at the manufacturer's discretion.

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

9 Used Symbols

Symbol	Description		
	Symbol for “Manufacturer”	Legal Manufacturer: **INVIDIA Medical GmbH & Co.KG** Carl-Benz-Str. 28 D-78576 Emmingen-Liptingen Germany	Tel.: +49.7465.929830.0 Fax: +49.7465.929830.10 Email: info@invidia-medical.de www.invidia.medical.de
	German Product Description		
	Symbol for “Catalog Number”		
	Symbol for “Quantity”		
	Symbol for “Batch Code”		
	Symbol for “Year of Manufactue”		
	Symbol for “Consult the Instruction for Use”		
	Conformity to the essential requirements with notified body number of DQS Medizinprodukte GmbH, Frankfurt, Germany		
	Symbol for “Non-Sterile ”		
	Symbol for "Caution, consult accompanying documents”		
	Symbol for “Keep dry”		
	Symbol for “Keep away from sunlight”		
	Symbol for “Operating Instructions”		

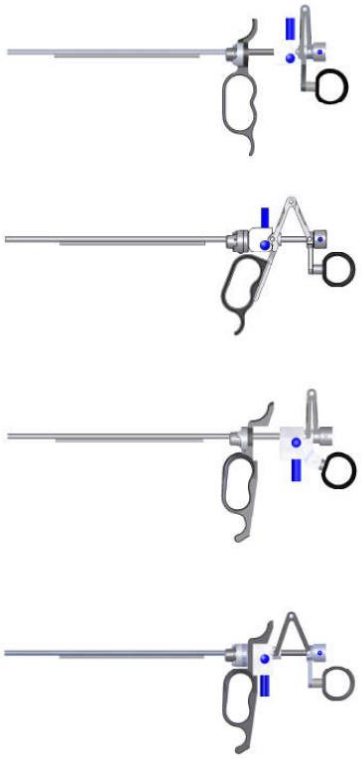
10 Relevant Note

In these IFUs have been reported info concerning to Class I devices. However, Class I devices are not under Notified Body responsibility. The Class I devices have been reported for descriptive information only.

11 Attached Document

Electrodes	
	
Sheath	
	

Guide

Working Element
 
Obturator
 

Cable* * HF-Anschlusskabel Martin; HF-Anschlusskabel Erbe; HF-Anschlusskabel Valleylap/Bovie	
	

11.1 Combination Product SL-SR Saline/Bipolar

Electrodes	Sheath and Obturator	Working Element	Cable
77-405-13 to 77-455-13 77-405-17 to 77-460-17 77-405-19 to 77-455-19 77-405-24 to 77-465-24	77-413-00 to 77-413-12 77-417-00 to 77-418-18 77-195-00 to 77-195-22 77-319-00 to 77-319-01 77-419-00 to 77-420-22 77-446-02 to 77-494-02 77-270-00 to 77-276-02 77-240-00 t0 77-246-24 77-424-00 to 77-425-26 77-444-02 to 77-446-02 77-245-00 to 77-245-24 77-324-00 to 77-325-01	77-400-13, 77-400-17 / 77-401-17 77-400-24 77-401-24 77-400-19 77-401-19 77-200-19 77-210-19	67-596-45, 67-591-45, 67-530-30

11.2 Combination Product 11 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
77-211-04 77-211-06 77-211-12	77-211-00; 77-211-01 77-211-00	---	---

11.3 Combination Product 13 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
77-213-04 77-213-06 77-213-12 77-213-08	77-213-00; 77-213-01 77-213-00	77-200-12	---

11.4 Combination Product 17.5 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
---	77-417-00	77-400-17 77-401-17	---

11.5 Combination Product 19 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
77-410-19	77-319-00 77-419-00 77-419-19 77-419-22	77-200-15; 77-200-19; 77-400-19 77-210-19; 77-401-19	---

11.6 Combination Product 27 Fr and Obturator

Electrodes	Sheath and Obturator	Working Element	Cable
---	77-275-00 77-275-27 77-275-28 77-327-00 77-270-00 77-270-27 77-270-28	77-200-24; 77-400-24 77-210-24; 77-401-24	---

11.7 Combination Product Gubbini

Electrodes	Sheath and Obturator	Working Element	Cable
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11.8 Combination Product 24 Fr

Electrodes	Sheath and Obturator	Working Element	Cable
---	77-245-00 77-425-00 77-245-24 77-425-24 77-245-26 77-425-26 77-240-00; 77-324-00 77-424-00 77-240-00; 77-240-24; 77-424-24 77-240-00; 77-240-26; 77-424-26	77-200-24; 77-400-24 77-210-24; 77-401-24	---

11.9 Combination Product Laser-guiding Working elements

Electrodes	Sheath and Obturator	Working Element	Cable
---	77-245-00; 77-425-00 77-245-24; 77-425-24 77-245-26; 77-425-26 77-240-00; 77-324-00 77-424-00 77-240-00; 77-240-24; 77-424-24 77-240-00; 77-240-26; 77-424-26	77-200-80; 77-200-82 77-220-00	---