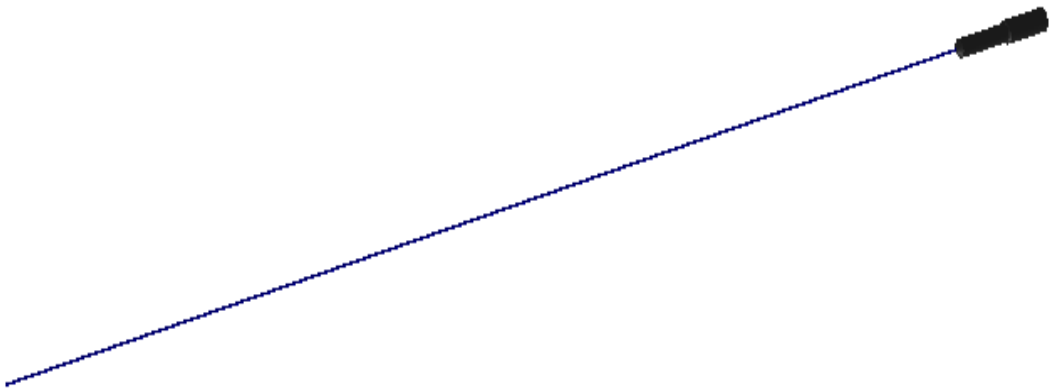




Instructions for Use

Flexible HF-Monopolar Electrodes



CE 0483



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Germany



IFU Flexible HF-Monopolar Electrodes			AMNOTEC  INTERNATIONAL MEDICAL
Issue Date:	04.07.2018	Revision:	

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REF	74-250-03 - 74-250-10	74-253-03 - 74-253-10
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	74-252-05, 74-252-07, 74-252-09, 74-252-10	74-255-05, 74-255-07, 74-255-09, 74-255-10

1. Device Description

HF-Flexible Electrodes are connected to suitable HF-Cable to perform Endoscopic procedures.



Carefully read these instructions before using Amnotec HF-Monopolar Flexible Electrode. Keep them in a safe place for future reference.

1.1. Intended use

These products are intended for ablation, cutting, vaporization and coagulation of tissue in the following surgical fields:

- Urology – Resectoscopy
- Gynecology – Hysteroscopy

1.1.1. 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.

1.2. Contraindications

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

1.3. 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

1.4. Warnings and Precautions

- The electrodes 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.
- Ensure that the electrode size corresponds to the size of the inner sheath in used

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- 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



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.

2.1. 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 Amnotec'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

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

Amnotec'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 Amnotec devices to withstand several reprocessing cycles has been validated up to 20 times.



Due to different surgical procedures and use of Amnotec Electrodes in terms of time-effort, we recommend replacing the electrodes after every use even if a deep inspection has been performed following this IFU.


3.2. Cleaning - Automatic

Manual Pre-Cleaning:

- Rinse electrodes for 5 min under cold water
- Brush electrodes until no debris is detectable with the naked-eye
- Rinse electrodes under cold water

Cleaning (i.e.RDA Miele G7735):

Step	Process Step	Reagents	Time (min)	T (°C)
1	Pre-cleaning	Tap water	2	
2	Drain			
3	Cleaning	Tap water with 0,5% concentration of cleaning agent such as neodisher MediClean (Dr. Weigert, Hamburg)	5	55
4	Drain			
5	Neutralisation	Deionized water	3	
6	Drain			
7	Rinsing	Deionized water	2	
8	Drain			

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3.3. Disinfection

Thermal disinfection has been validated using the following parameters:

Time	Temperature
95 sec	95 °C



Do not immerse electrodes in chemical disinfectant. Disinfectant residues can cause adverse effects in function

3.4. Sterilization

Product Sterilization with fractional pre-vacuum procedure, in accordance with ISO 17665 has been validated using the following parameters:

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.

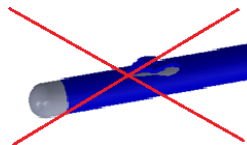


As HF electrodes are made out of thin metallic components sterilization wrap made out of paper should not be used as the electrodes could perforate the paper seal.

3.5. Control and Testing

The electrodes 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 electrode is faultless prior to each application
- The insulation and HF connector must be intact
- Plastic components should be checked before sterilisation. Electrode must be replaced if plastic components are brittle, cracked or worn



4. 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. Storage

The electrodes 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

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

6. 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.














7. 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.

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8. Used Symbols

Symbol	Description		
	Symbol for "Manufacturer"	Legal Manufacturer: Amnotec International Medical GmbH Take-off, Gewerbepark 9 78579 Neuhausen ob Eck Germany	Tel.: +49 (0) 74 67 94 93 900 Email: info@amnotec.de Website: www.amnotec.de
	German Product Description		
	Symbol for "Catalog Number"		
	Symbol for "Quantity"		
	Symbol for "Batch Code"		
	Symbol for "Year of Manufacture"		
	Symbol for "Consult the Instruction for Use"		
	Conformity to the essential requirements with notified body number of mdc medical device certification GmbH, Stuttgart, 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"		

9. 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.

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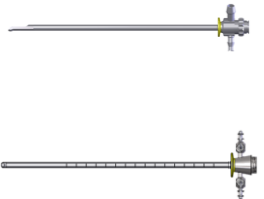





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10. Attached Document

Sheath	Obturator	Working Unit	Bridge and Adaptors	Flexible Electrodes, Baskets	Cable*
					

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

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10.1. Combination Product

Sheaths	Obturator	Accessories, Adapters	Flexible Electrodes and Basket	*Cable
<i>Sheaths:</i>		<i>Accessories:</i>	<i>Baskets:</i>	74-390-03
74-001-15	74-002-15	74-900-00	74-270-00	74-390-05
74-001-16	74-002-16	74-900-01	74-270-01	74-391-03
74-001-17	74-002-17	74-900-03	74-270-05	74-391-05
74-001-19	74-002-19	74-900-04	74-270-07	74-392-03
74-001-21	74-002-21	74-901-00	74-271-05	74-392-05
74-001-23	74-002-23		74-271-07	
74-001-25	74-002-25		74-272-05	
74-004-00	74-401-23		74-272-07	
74-004-01	74-402-23	<i>Adapters:</i>	74-273-03	
74-004-02	74-802-08			
74-004-15	74-802-09	74-006-00	<i>Flexible Electrodes:</i>	
74-004-16	74-802-10	74-101-00		
74-004-17	74-802-11	74-101-01		
74-005-01	74-802-13	74-101-02		
74-005-02			74-250-03	
74-005-15			74-250-04	74-254-03
74-005-16			74-250-05	74-254-05
74-400-23			74-250-06	74-254-07
74-403-23			74-250-07	74-255-05
74-801-08			74-250-08	74-255-07
74-801-10			74-250-09	74-255-09
74-801-11			74-250-10	74-255-10
74-801-13			74-251-03	
74-805-13			74-251-05	
74-806-13			74-251-07	
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