



## Instructions for Use

### Urethrotomy Instruments



CE 0483



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**Sheaths:**

74-510-21  
74-514-21  
74-515-21  
74-516-21  
74-500-15  
74-502-15  
74-871-13  
74-875-13  
74-871-11  
74-875-11

**Knives:**

74-517-00  
74-517-01  
74-517-02  
74-517-03  
74-517-04  
74-504-00  
74-504-02  
74-504-04  
74-880-13 to 74-883-13  
74-880-11 to 74-883-11

**Obturators:**

74-512-21  
74-511-21  
74-513-21  
74-501-15  
74-872-13  
74-872-11

## 1. Device Description

Amnotec GmbH has a range of urethrotomy instruments for use during urology procedures. The urethrotomy instruments include sheaths, obturators, knives and guides.



*Carefully read these instructions before using Amnotec Urethrotomy Instruments. Keep them in a safe place for future reference.*

### 1.1. Intended Use – Sheaths

The sheaths are endoscopic components. They are element shaped as a thin metal tube through which other elements are introduced and assembled to create the complete operative endoscopic unit.

### 1.2. Intended Use – Knives

The knives are medical device used for cutting and dissection of body tissue during surgical intervention.

### 1.3. Intended Use – Obturators

The obturators endoscopic components. They are devices with a distally rounded head or end that are placed into the sheaths of a rigid endoscope in order to fill out the sheath's lumen (open end), thereby assisting their insertion into the body and protecting against adverse damage to the patient.

### 1.4. Intended Use – Guides

The guides are endoscopic components. They are elements used to assist the entry of the endoscopic devices into an appropriate rigid endoscope.

#### 1.4.1. Intended User

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

### 1.5. Contraindication

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

- Urinary tract infection
- Coagulation disorder



*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*

## 2. Available Models and Combination Products



*Please refer to 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

- 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

##### 3.1.1. Limitation of Reprocessing

- There are no limitations regarding the number of cleaning and sterilization cycles
- Durability and lifespan of these instruments is influenced primarily through wear and tear during application

#### 3.2. Cleaning - Automatic

##### Manual Pre-Cleaning:

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

##### Cleaning: (i.e. G 7836 CD (Miele))

Step	Process Step	Reagents	Time (min)	T (°C)
1	Pre-cleaning	Tap water	3	Cold
2	Drain			
3	Cleaning	Tap water , Dosing: 0.5% Sekumatic FR (Ecolab) at 45°C	3	55
4	Drain			
5	Cleaning	Tap water, - Dosing: 0.5% Sekumatic FR (Ecolab) at 45°C - Dosing: 0.35% Sekumatic Oxivario (Ecolab) at 50°C	2	55
6	Drain			
7	Neutralization	Deionized water, 0.1% 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 sec	95 °C
600	30 sec	93 °C

#### 3.3. Sterilization

Sterilisation of the product with fractional pre-vacuum procedure, in accordance with ISO 17665

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

**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 in accordance with ISO 11607 and/or AAMI/ANSI ST77:2006.

### 3.4. Control and Testing

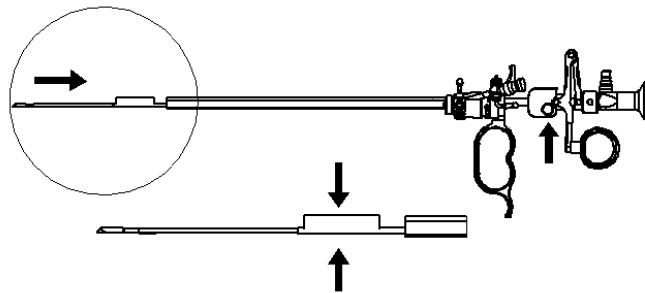
Urethrotomy Instruments have to be visually examined for cleanliness after every cleaning and disinfection. They have to be macroscopically clean from visual residual and soil.

- If residue, liquids, impurities are visible, repeat cleaning process
- Ensure that instruments are faultless prior to each application
- Plastic components should be checked before sterilization
- Instruments must be replaced if plastic components are brittle, cracked or worn out

## 4. Assembling – Disassembling Instructions

### 4.1. Knives

Touch the knife just with a cloth or similar. The knives can break easily if they get lateral force. Put the knife into the guide-tube until it snaps into the locking position. To proof if the knife is locked in, pull carefully on the guide tube (see next figure). Don't touch the knife!

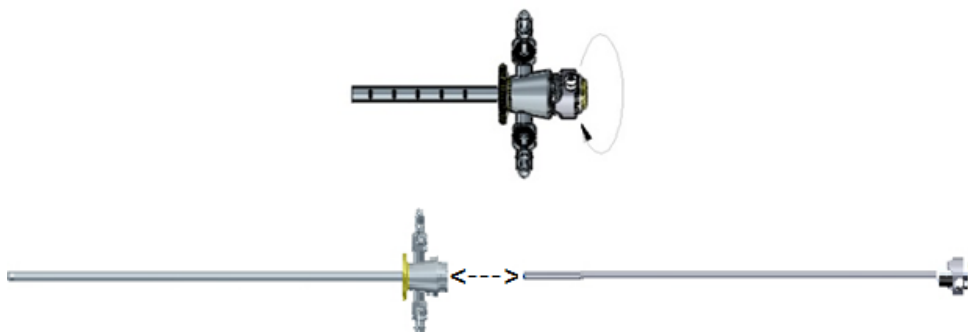


To unlock the knife, push the button in the side of the guide and pull it carefully out of the guide-tube.

### 4.2. Obturator

To remove an obturator from the sheath with the Quick-Lock-Device:

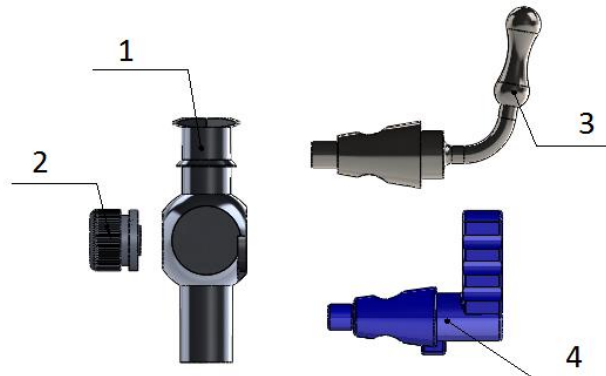
- Press the button to release the quick-lock device
- Insert the obturator, lining-up the arrow markings on the sheath and the obturator
- Lock in gently by pushing until the locking device clicks in



To remove the obturator from the sheath with the locking-device:

- Turn the lever anti-clockwise
- Insert the obturator, lining-up the arrow markings on the sheath and the obturator
- Lock in by turning the lever clockwise.

## 4.3. Sheaths with Stopcock



- Disassemble the stopcock from the housing (1) by un-screwing the thumbscrew (2) from the stopcockplug (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

## 6. Storage

The urethrotomy instruments 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: <b>Amnotec GmbH</b> Take-off, Gewerbepark 9 78579 Neuhausen ob Eck Germany
	German Product Description	
	Symbol for "Catalog Number"	
Qty	Symbol for "Quantity"	
	Symbol for "Batch Code"	
	Symbol for "Consult the Instruction for Use"	
 0483	Conformity to the essential requirements	
	Symbol for "Non-Sterile "	
	Symbol for "Caution, consult accompanying documents"	
	Symbol for "Keep dry"	
	Symbol for "Keep away from sunlight"	

# Instructions for Use Urethrotomy Instruments

## 10. Attached Document

### 10.1. Combination Product

Sheaths	Obturators	Knives	Guides
74-510-21 74-514-21 74-515-21 74-516-21 74-500-15 74-502-15 74-871-13 74-875-13 74-871-11 74-875-11	74-512-21 74-511-21 74-513-21 74-501-15 74-872-13 74-872-11	74-517-00 74-517-01 74-517-02 74-517-03 74-517-04 74-504-00 74-504-02 74-504-04 74-880-13 to 74-883-13 74-880-11 to 74-883-11	



# Instructions for Use Urethrotomy Instruments

## 10.2. Combination Chart

Sheaths	Obturator	Knives	Guides
