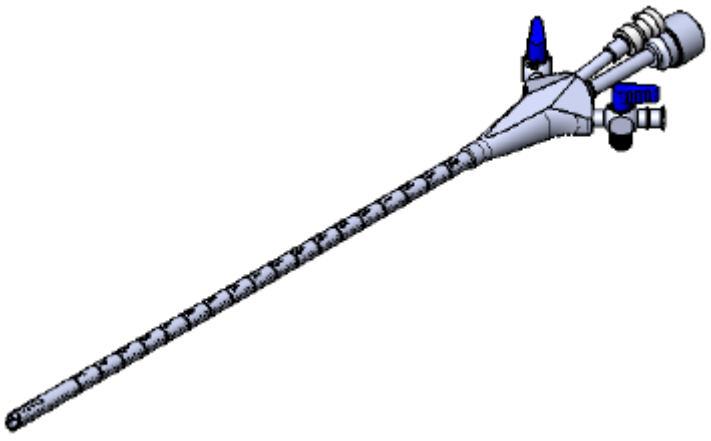
Instructions for Use

Hysteroscopy System



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1. Device Description

STEMA Medizintechnik GmbH has a wide range of hysteroscopy instruments for use during gynecology procedures. The hysteroscopy system include hysteroscopy sheaths, obturators and adaptors.

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

1.1. Intended Use - Sheaths

Continuous flow hysteroscopy sheaths permit visual examination and operational procedures, endoscopically, in the cervical canal and the uterine cavity.

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. Contraindication

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

- Acute inflammation of the inner genitals
- Strong uterine bleeding gravidity
- 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

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.

3. Reprocessing Instructions

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

STEMA 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 STEMA 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.

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 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.

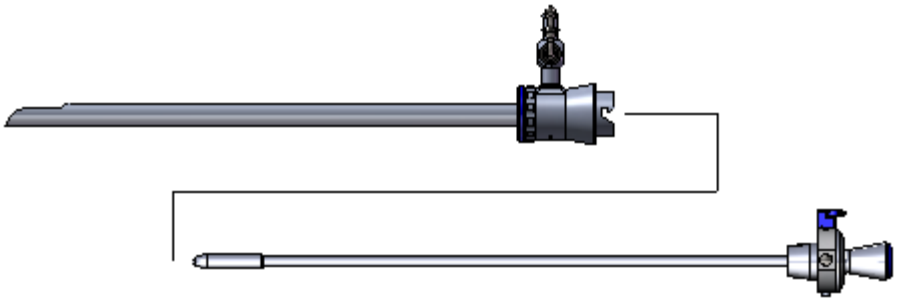
3.4. Control and Testing

Hysteroscopy 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 sterilisation
- Instruments must be replaced if plastic components are brittle, cracked or worn out

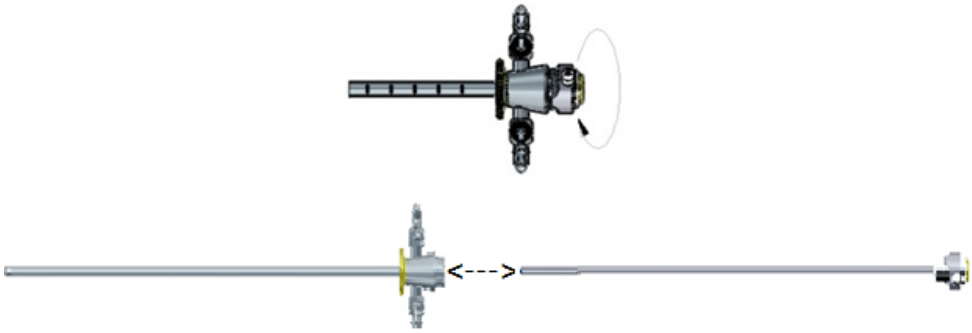
4. Assembling – Disassembling Instructions

4.1. Sheaths and Obturators



Hysteroscopy sheaths and corresponding obturators are color coded with the same color. 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



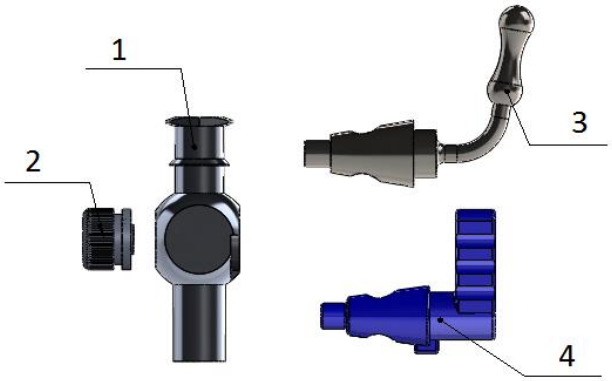
To remove the obturator from the sheath with the locking-device:

- 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.

Never use force to insert obturator, it should glide in easily, otherwise check for correct size or that it is correctly aligned.

- Adaptor can be attached using the same technique with the alignment arrows

4.2. 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

6. Storage

The hysteroscopy 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.

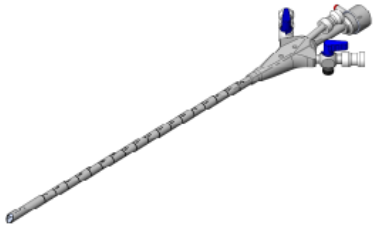
9. Used Symbols

Symbol	Description		
	Symbol for "Manufacturer"	Legal Manufacturer: **STEMA Medizintechnik GmbH** H.-E.- Busse-Str. 4 78333 Stockach Germany	Tel.:+49 (0) 7771-875351 Fax:+49 (0) 7771 875350 Email: info@stema-medizintechnik.de Website: www.stema-medizintechnik.de
	German Product Description		
	Symbol for "Catalog Number"		
	Symbol for "Quantity"		
	Symbol for "Batch Code"		
	Symbol for "Consult the Instruction for Use"		
CE 0483	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"		

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

Sheath	Obturators	Adaptors
  		

11.1. Combination Product

STEMA hysteroscopy instruments are to be combined following the color code:

Endoscope (mm)	**Color**
2,00	Red
2,90	White
4,00	Blue

Sheaths	**Obturators**	**Adaptors**
AN-001-000 to AN-001-002	AN-001-003	
AN-002-001 to AN-002-002	AN-002-003	
AN-003-001 to AN-003-002	AN-003-003	
AN-001-101 to AN-001-103	AN-001-104	
AN-002-101 to AN-002-103	AN-002-104	
AN-003-101 to AN-003-103	AN-003-104	
AN-002-201 to AN-002-205	AN-002-206	
AN-003-301 to aN-003-302	AN-003-303	
AN-005-301 to AN-005-303	AN-005-305	

12. Legend

FH → Fixes stopcock
XL → Extra Large (longer)
QL → Quick-Lock (locking system from STEMA)
TQL → Telescope Quick-Lock
TR → therapeutic (it's just a Name for special sheath)
S → for a Storz-Endoscope
SU → with Exctraction
H → with Handle (also H-G)