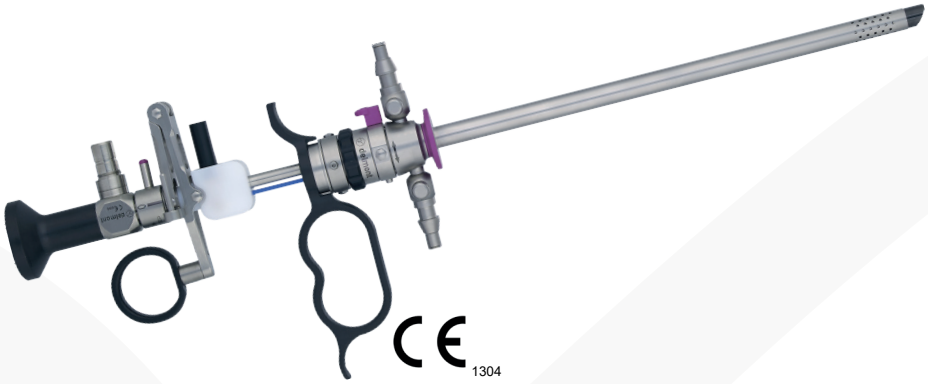
Data sheet
MaxiCare



The complete MaxiCare set contains:
- 1 HD hysteroscope
- 1 outer sheath
- 1 inner sheath
- 1 working element
- 5 HF electrodes
- 1 light cable

Passive set
Ref: D400 100 008
GTIN/UID ID code: 3701217802667

Active set
Ref: D400 100 004
GTIN/UID ID code: 3701217802650

General informations	
Conformity	Conform to MDD 93/42/CEE
Applicable standards	*See CE Conformity Declaration for more details*
Toxic/allergenic products	Latex free, DEHP free, Halogen free

Hysteroscope	
Regulation	
Description	HD 4 mm 12° hysteroscope
Intended use	Gynecological and urological endoscopy only
Photo	
Device class	IIa
Article reference	D300 100 002
GMDN code	36628
GTIN/UID ID code	3701217800182

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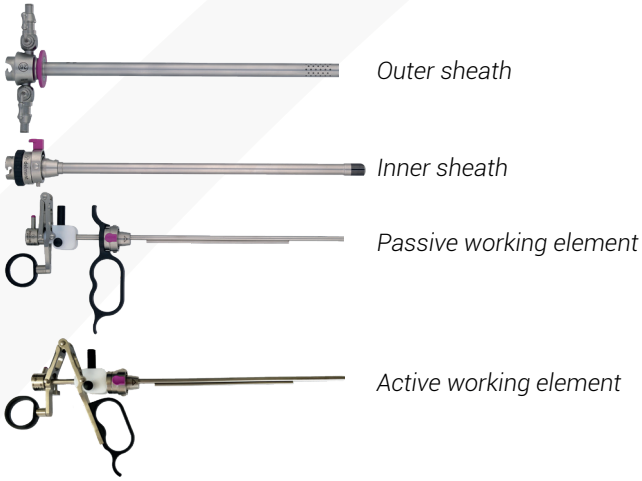
Technical data	
Resolution	HD
Hystroscope diameter	4 mm
Angulation (DOV)	12°
Type of technology	Lenses
Working length	300 mm
Autoclavable	Yes. *See instructions for use for further details*
Connection for light cable	ACMI type
Light cable adapter	Wolf, Storz, Olympus type
Resectoscopy system	
Regulation	
Description	Set comprised of working elements and associated sheaths
Intended use	Bipolar resectoscopy for gynecology and urology only
Photos	 *Outer sheath* *Inner sheath* *Passive working element* *Active working element*
Device class	IIb
Outer sheath	
Article reference	D300 130 004
GMDN code	37806
GTIN/UID ID code	3701217801318
Outer sheath's diameter	26Fr.
Working length	187 mm
Quick lock	Yes
Flow	Double
Autoclavable	Yes. *See instructions for use for further details*

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Inner sheath		
Article reference	D300 130 005	
GMDN code	37806	
GTIN/UID ID code	3701217801325	
Inner sheath's diameter	24Fr.	
Isolation	Black ceramic (4.5 mm)	
Rotatable sheath	Yes	
Separable internal and external sheaths	Yes	
Quick lock	Yes	
Autoclavable	Yes. *See instructions for use for further details*	
Working element		
Action	Passive	Active
Article reference	D300 130 006	D300 130 008
GMDN code	37805	
GTIN/UID ID code	3701217801332	3701217801356
Compatible with bipolar energies	Yes	
Compatible with monopolar energies	No	
Quick-lock between the two sheaths and the working element	Yes	
HF electrodes		
Regulation		
Description	HF electrodes for resection system	
Intended use	Gynecological and urological endoscopy only. Tissue removal, cutting, coagulation	
Photo	 *Cutting loop, 30°* *Cutting loop, straight* *Electrode rollerball* *Electrode knife* *Vaporisation electrode rollerball with tip*	
Device class	IIb	

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Single use electrodes					
Name	Cutting loop, 30°	Cutting loop, straight	Electrode rollerball	Electrode knife	Vaporisation electrode - rollerball with tip
Article reference	D300 140 078	D300 140 081	D300 140 080	D300 140 079	D300 140 082
GMDN code	61872				
GTIN/UID ID code	3701217802940	3701217802971	3701217802964	3701217802957	3701217802988
Packaging	10 units / box				
Autoclavable	None. Already sterile and single use				
Sterilisation method	ETO				
Reusable electrodes					
Name	Cutting loop, 30°	Cutting loop, straight	Electrode rollerball	Electrode knife	Vaporisation electrode - rollerball with tip
Article reference	D300 140 004	D300 140 007	D300 140 006	D300 140 005	D300 140 008
GMDN code	61873				
GTIN/UID ID code	3701217802179	3701217802209	3701217802193	3701217802186	3701217802216
Autoclavable	Yes. *See instructions for use for further details*				
Technical data					
Colour code	Purple				
Compatibility	26Fr. resectoscope				
Generator output power	max. 2 kVp				
Recommended power cutting mode	120-180 W				
Recommended power coagulation mode	max. 100 W				
Bipolar solution to be used	0.9% NaCl				
Light cable					
Regulation					
Description	Light cable				
Intended use	Endoscopy				
Photo					
Device class	I				

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Article reference	D200 150 500
GMDN code	35507
GTIN/UID ID code	3701217800090
Technical data	
Diameter	3.5 mm
Length	2.3 m
Colour	Grey
Autoclavable	Yes. *See instructions for use for further details*
End caps supplied	Storz

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Reprocessing

See Instructions for Use for more details.

Automated Cleaning and Desinfection

Pre-Cleaning	❶ Disassemble the device as much as possible. Immerse the device in cold water for at least 5 minutes. ❷ Brush the device under cold water until all visible residues have been removed. The inner channels, wires and holes should be rinsed with a water jet gun for at least 10 seconds in pulsed mode. ❸ Remove the device from the bath and rinse it with cold tap water.
Automated cleaning	❶ Place the device in a basket on the insert module and start the cleaning process. Machine used : Niagara SI PCF – Medisafe ❷ Pre-cleaning with pulsed activation of ultrasonic cleaning for 3 min, 25°C. ❸ Discharging. ❹ Cleaning with pulsed activation of ultrasonic cleaning for 20 min. at 40°C with a 0.35% enzymatic solution. Solution used : M20029 3E-Zyme Scope Plus, Medisafe. ❺ Discharging. ❻ Rinse with deionized water for 2min., 25°C. Discharging. ❼ Rinse with deionized water for 1min., 25°C.
Desinfection	❶ Automated thermal disinfection 95s. at 95°C. In accordance with ISO 15883 and taking into account national requirements for the A0 value.
Drying	Dry the outside of the device by carrying out a drying cycle of the cleaning/disinfection machine. If necessary, manual drying may additionally be carried out using a lint free cloth. Dry all cavities of the instruments by blowing with sterile compressed air.

Sterilisation

Fractionated Vacuum	Temperature	Time	Drying
3 phases with a pressure of at least 60 millibars	134°C	At least 4 minutes	At least 10 minutes
In accordance with ISO 13060, ISO 17665 and in consideration of the respective national requirements.			

Environnement

Condition	Temperature	Humidity	Pressure
Transport (non-sterile)	-10°C to +40°C	10 to 90%	800 to 1060 hPa
Storage (non-sterile)	-10°C to +40°C	10 to 90%	800 to 1060 hPa
Operating	+10°C to + 40 °C	30 to 75%	800 to 1060 hPa

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