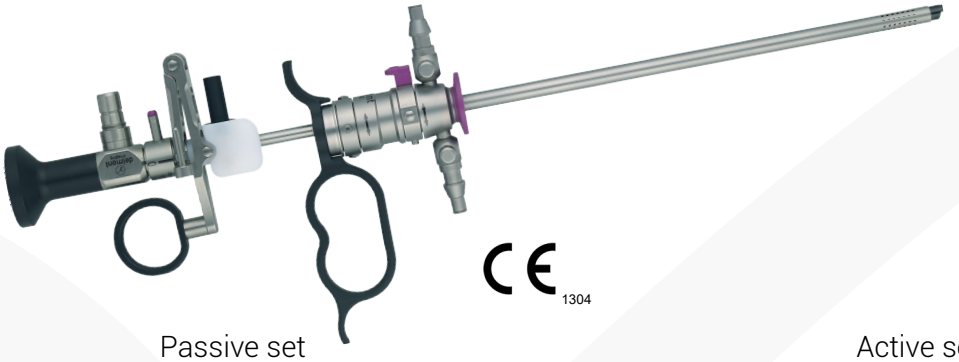
Data sheet
ReseCare

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



Passive set
Ref : D400 100 011
GTIN/UID ID code : 3701217802674

Active set
Ref : D400 100 013
GTIN/UID ID code : 3701217804111

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 2.9 mm 12° hysteroscope
Intended use	Gynecological endoscopy only
Photo	
Device class	IIa
Article reference	D300 100 004
GMDN code	36628
GTIN/UID ID code	3701217802599

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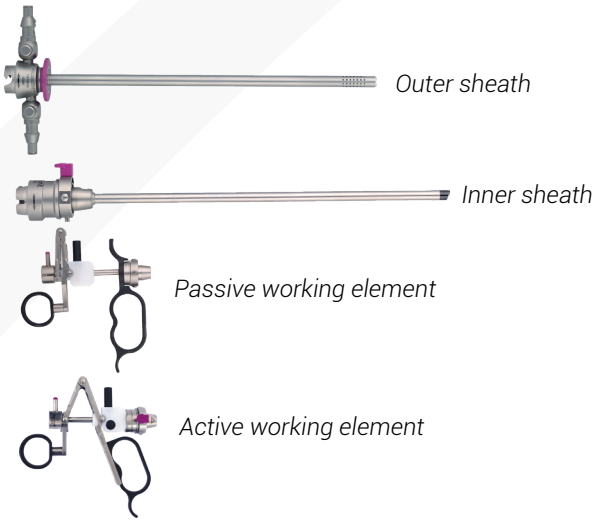
Technical data	
Resolution	HD
Hystroscope diameter	2.9 mm
Angulation (DOV)	12°
Type of technology	Lenses
Working length	300 mm
Autoclavable	Yes. *See instructions for use for further details*
Connection for light cable	ACMI type
Light cable adapter	Wolf, Storz, Olympus type
Resectoscopy system	
Regulation	
Description	Set comprised of working elements and associated sheaths
Intended use	Bipolar or monopolar resectoscopy
Photos	
Device class	IIb
Outer sheath	
Article reference	D300 130 000
GMDN code	37806
GTIN/UID ID code	3701217801271
Outer sheath's diameter	18.5Fr.
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 130 001			
GMDN code	37806			
GTIN/UID ID code	3701217801288			
Inner sheath's diameter	17.5Fr.			
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 130 002		D300 130 009	
GMDN code	37805			
GTIN/UID ID code	3701217801295		3701217801363	
Compatible with bipolar energies	Yes			
Compatible with monopolar energies	Yes			
Quick-lock between the two sheaths and the working element	Yes			
HF electrodes				
Regulation				
Description	HF electrodes for resection system			
Intended use	Gynecological endoscopy only. Tissue removal, cutting, coagulation			
Photo	 *Cutting loop, 30°* *Cutting loop, straight* *Electrode rollerball* *Electrode knife*			
Device class	IIb			
Single-use electrodes				
Name	Cutting loop, 30°	Cutting loop, straight	Electrode knife	Electrode rollerball
Article reference	D300 140 067	D300 140 068	D300 140 069	D300 140 070
GMDN code	61872			
GTIN/UID ID code	3701217802766	3701217802773	3701217802780	3701217802797
Packaging	10 units / box			

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Autoclavable	None. Already sterile and single use			
Sterilisation method	ETO			
Reusable electrodes				
Name	Cutting loop, 30°	Cutting loop, straight	Electrode knife	Electrode rollerball
Article reference	D300 140 000	D300 140 001	D300 140 002	D300 140 003
GMDN code	61873			
GTIN/UID ID code	3701217802131	3701217802148	3701217802155	3701217802162
Autoclavable	Yes. *See instructions for use for further details*			
Technical data				
Colour code	Purple			
Compatibility	18.5Fr. resectoscope			
Generator output power	max. 2 kVp			
Recommended power cutting mode	120-180 W			
Recommended power coagulation mode	max. 100 W			
Monopolar solution to be used	Glycine or Purisole for example			
Bipolar solution to be used	0.9% NaCl			
Light cable				
Regulation				
Description	Light cable			
Intended use	Endoscopy			
Photo				
Device class	I			
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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