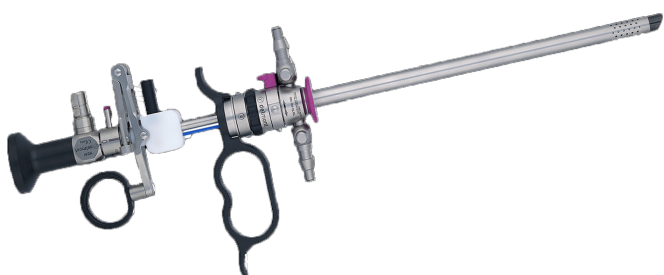


Data sheet MaxiCare



Passive set

Ref: D400 100 008

GTIN code: 3701217802667

The complete MaxiCare set contains:

- 1 HD hysteroscope
- 1 outer sheath
- 1 inner sheath
- 1 working element
- 4 HF electrodes
- 1 light cable

Active set

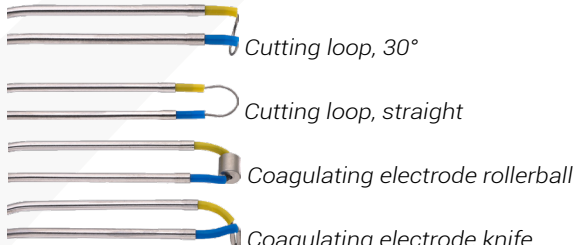
Ref: D400 100 004

GTIN code: 3701217802650

Hysteroscope	
Regulation	
Description	HD 4 mm 12° hysteroscope
Intended use	Gynecological and urological endoscopy only
Photo	
CE marking	Yes (CE 1304)
Device class	Ila
Article reference	D300 100 002
GMDN code	36628
GTIN code	3701217800182
Complies with European directive	93/42/EEC
Complies with international norms	EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 17665-1:2006, EN 1041:2008, EN ISO 10993-10:2013, EN ISO 17665-1:2006, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 10993-18:2009, EN ISO 17664:2004, ISO 8600-4:2014, ISO 8600-5:2005, ISO 8600-1:2015, ISO 8600-6:2005, ISO 8600-3:1997/AMD 1:2003, ISO 8600-7:2012
Toxic/allergenic products	Latex free, DEHP free, Halogen free

Technical data	
Resolution	HD
Hystroscope diameter	4 mm
Angulation	12°
Type of technology	Lenses
Usable length	300 mm
Cleaning and disinfection	Disinfection of the endoscope according to the manufacturer's instructions, rinsing and drying. <i>See instructions for use for further details</i>
Autoclavable	Yes
Connection for light cable	ACMI type
Light cable adapter	Wolf, Storz, Olympus type
Environment	
Transport and storage temperature	-10°C / +40°C
Transport and storage humidity	10 to 90%
Resectoscopy system	
Regulation	
Description	Resectoscopes and associated sheaths
Intended use	Bipolar resectoscopy for gynecology and urology only
Photos	 Outer sheath Inner sheath Passive working element
CE marking	Yes (CE 1304)
Device class	IIb
Complies with European directive	93/42/EEC

Complies with international norms	EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN 60601-1:2006, EN 1041:2008, EN ISO 10993-10:2013, IEC 60601-2-18:2009, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 17664:2004, EN 60601-2-2:2009, ISO 7153-1:2016, EN ISO 10993-18:2009, EN ISO 17665-1:2006, EN 60601-1-6:2010, EN ISO 10993-5:2009, ISO 7153-1:2016
Toxic/allergenic products	Latex free, DEHP free, Halogen free
Outer sheath	
Article reference	D300 130 004
GMDN code	37806
GTIN code	3701217801318
Outer sheath's diameter	26Fr.
Usable length	187 mm
Quick lock	Yes
Flow	Double
Cleaning and disinfection	Separate the internal and external sheaths beforehand. Pre-cleaning then cleaning and thermal disinfection in the machine according to the manufacturer's instructions of the solutions and machines used. <i>See instructions for use for further details</i>
Autoclavable	Yes. <i>See instructions for use for further details</i>
Inner sheath	
Article reference	D300 130 005
GMDN code	37806
GTIN code	3701217801325
Inner sheath's diameter	24Fr.
Isolation	Black ceramic (4.5 mm)
Rotatable sheath	Yes
Separable internal and external sheaths	Yes
Cleaning and disinfection	Separate the internal and external sheaths beforehand. Pre-cleaning then cleaning and thermal disinfection in the machine according to the manufacturer's instructions of the solutions and machines used. <i>See instructions for use for further details</i>
Autoclavable	Yes. <i>See instructions for use for further details</i>

Working element				
Action	Passive		Active	
Article reference	D300 130 006		D300 130 008	
GMDN code	37805			
GTIN code	3701217801332		3701217801356	
Compatible with bipolar energies	Yes			
Compatible with monopolar energies	No			
Quick-lock between the two sheathes and the working element	Yes			
HF electrodes				
Regulation				
Description	Reusable HF electrodes for resection system			
Intended use	Gynecological and urological endoscopy only. Tissue removal, cutting, coagulation			
Photo				
CE marking	Yes (CE 1304)			
Device class	IIb			
GMDN code	42553			
Complies with European directive	93/42/EEC			
Complies with international norms	EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN 60601-1:2006, EN 1041:2008, EN ISO 10993-10:2013, IEC 60601-2-18:2009, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 17664:2004, EN 60601-2-2:2009, ISO 7153-1:2016, EN ISO 10993-18:2009, EN ISO 17665-1:2006, EN 60601-1-6:2010			
Toxic/allergenic products	Latex free, DEHP free, Halogen free			
Technical data				
Name	Cutting loop, 30°	Cutting loop, straight	Coagulating electrode rollerball	Coagulating electrode knife
Article reference	D300 140 004	D300 140 007	D300 140 006	D300 140 005

GTIN code	3701217802179	3701217802209	3701217802193	3701217802186
Color code	Yellow and blue			
Compatibility	26Fr. resector			
Reusable electrode	Yes			
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			
Cleaning and disinfection	Pre-cleaning then cleaning and thermal disinfection in the machine according to the manufacturer's instructions of the solutions and machines used. <i>See instructions for use for further details</i>			
Autoclavable	Yes. <i>See instructions for use for further details</i>			
Light cable				
Regulation				
Description	Light cable			
Intended use	Endoscopy			
Photo				
CE marking	Yes			
Device class	I			
Article reference	D200 150 500			
GTIN code	3701217800090			
Complies with European directive	93/42/EEC			
Complies with international norms	IEC 60601-1:2005, IEC 60601-2-18:2009, DIN EN ISO 10993-1:2010-04, DIN EN ISO 10993-5:2009-10, DIN EN ISO 10993-12:2009-08, EN ISO 17664:2004			

Technical data	
Diameter	3.5 mm
Length	2.3 m
Color	Grey
Cleaning and disinfection	Pre-cleaning then cleaning and disinfection in the machine according to the manufacturer's instructions of the solutions and machines used, manual cleaning and disinfection possible but not recommended. <i>See instructions for use for further details</i>
Autoclavable	Yes. <i>See instructions for use for further details</i>
End caps supplied	Storz