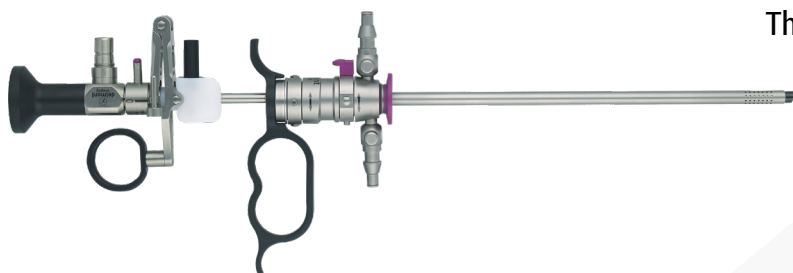


Data sheet

ReseCare



Passive set

Ref: D400 100 011

GTIN code: 3701217802674

The complete ReseCare set contains:

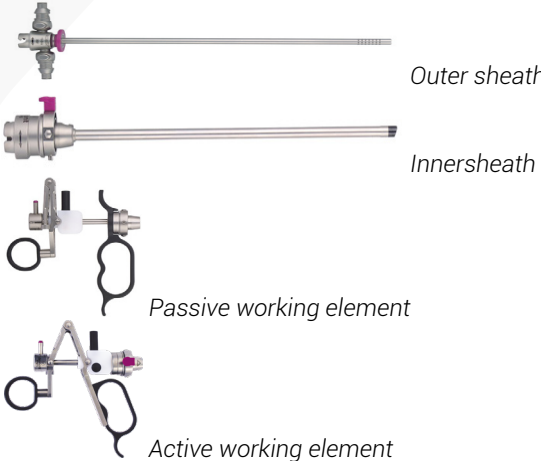
- 1 HD hysteroscope
- 1 outer sheath
- 1 inner sheath
- 1 working element
- 4 HF electrodes
- 1 light cable

Active set

Ref : D400 100 013

GTIN code: 3701217802674

Hysteroscope	
Regulation	
Description	HD 2.9 mm 12° hysteroscope
Intended use	Gynecological endoscopy only
Photo	
CE marking	Yes (CE 1304)
Device class	Ila
Article reference	D300 100 004
GMDN code	36628
GTIN code	3701217802599
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	2.9 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 or monopolar resectoscopy
Photos	 Outer sheath Innersheath Passive working element Active 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 130 000
GMDN code	37806
GTIN code	3701217801271
Outer sheath's diameter	18.5Fr.
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 130 001
GMDN code	37806
GTIN code	3701217801288
Inner sheath's diameter	17.5Fr.
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. See instructions for use for further details	
Working element		
Action	Passive	Active
Article reference	D300 130 002	D300 130 009
GMDN code	37805	
GTIN code	3701217801295	3701217801363
Compatible with bipolar energies	Yes	
Compatible with monopolar energies	Yes	
Quick-lock between the two sheathes and the working element	Yes	
HF electrodes		
Regulation		
Description	Reusable HF electrodes for resection system	
Intended use	Gynecological endoscopy only. Tissue removal, cutting, coagulation	
Photo	 Cutting loop, 30° Cutting loop, straight Coagulating electrode rollerball Coagulating electrode knife	
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 140 000	D300 140 001	D300 140 003	D300 140 002
GTIN code	3701217802131	3701217802148	3701217802162	3701217802155
Color code	Green			
Compatibility	18.5Fr. resector			
Reusable electrode	Oui			
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			
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. See <i>instructions for use</i> for further details			
Autoclavable	Yes. See <i>instructions for use</i> for further details			
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