

Data sheet EasyCare



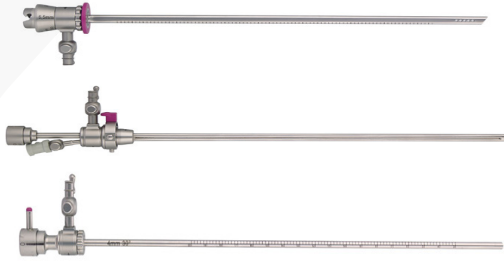
The complete EasyCare set contains:

- 1 HD hysteroscope
- 1 outer graduated operating sheath
- 1 inner graduated operating sheath
- 1 graduated diagnostic sheath
- 4 instruments
- 1 light cable

Ref: D400 100 000

GTIN code: 3701217802612

Hysteroscope	
Regulation	
Description	HD 2.9 mm 30° hysteroscope
Intended use	Gynecological endoscopy only
Photo	
CE marking	Yes (CE 1304)
Device class	Ila
Article reference	D300 100 000
GMDN code	36628
GTIN code	3701217800168
Complies with European directive	93/42/CEE
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 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	30°
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%
Hysteroscopy system	
Regulation	
Description	Diagnostic and interventional hysteroscopic sheaths
Intended use	Hysteroscopy
Photos	 Outer operating sheath Inner operating sheath Diagnostic sheath
CE marking	Yes (CE 1304)
Device class	Ila
GMDN code	37086
Complies with European directive	93/42/CEE

Complies with international norms	EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN 1041:2008, EN ISO 10993-10:2013, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 17664:2004, ISO 7153-1:2016, EN ISO 10993-18:2009, EN ISO 17665-1:2006, EN ISO 10993-5:2009
Toxic/allergenic products	Latex free, DEHP free, Halogen free
Outer graduated operating sheath	
Article reference	D300 110 000
GTIN code	3701217800618
Outer sheath's diameter	5.5 mm
Usable length	216 mm
Rotatable suction stopcock	Yes
Quick lock	Yes
Graduation	Yes
Atraumatic outer sheath	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>
Inner graduated operating sheath	
Article reference	D300 110 001
GTIN code	3701217800625
Inner sheath's diameter	4.9 mm
Usable length	230 mm
Operative canal's diameter	7Fr.
Rotatable irrigation stopcock	Yes
Insertion canal's length of the operative canal	Short
Graduation	Yes
Atraumatic inner 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>
Graduated diagnostic sheath	
Article reference	D300 110 002
GTIN code	3701217800632
Diagnostic sheath's diameter	4 mm
Usable length	270 mm
Rotatable irrigation stopcock	Yes
Graduation	Yes
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>
Instruments	
Regulation	
Description	Reusable surgical instruments: scissors and forceps
Intended use	Endoscopic surgery
Photos	 Graduated scissors Graduated biopsy forceps Graduated forceps (alligator) Graduated IUD grasping forceps
CE marking	Yes
Device class	I
Complies with European directive	93/42/CEE
Complies with international norms	DIN EN ISO 15223-1, DIN EN 1041
Toxic/allergenic products	Latex free, DEHP free, Halogen free

Technical data				
Name	Graduated scissors	Graduated biopsy forceps	Graduated for- ceps (alligator)	Graduated IUD grasping forceps
Article reference	D300 120 000	D300 120 002	D300 120 001	D300 120 003
GTIN code	3701217801196	3701217801219	3701217801202	3701217801226
Flexibility	Semi-rigid			
Diameter	7Fr.			
Usable length	340 mm			
Mobile jaws	1	2		
Luer-Lock	Yes			
Graduation	Yes			
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/CEE			
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

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