

Data sheet EasyCare



Instruments with flushing port set
Ref: D400 100 017
GTIN/UID ID Code: 3701217802896

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

Instruments without flushing port set
Ref: D400 100 000
GTIN/UID ID Code: 3701217802612

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 30° hysteroscope
Intended use	Gynecological endoscopy only
Photo	
Device class	Ila
Article reference	D300 100 000
GMDN code	36628
GTIN/UID ID code	3701217800168
Technical data	
Resolution	HD
Hystroscope diameter	2.9 mm
Angulation (DOV)	30°

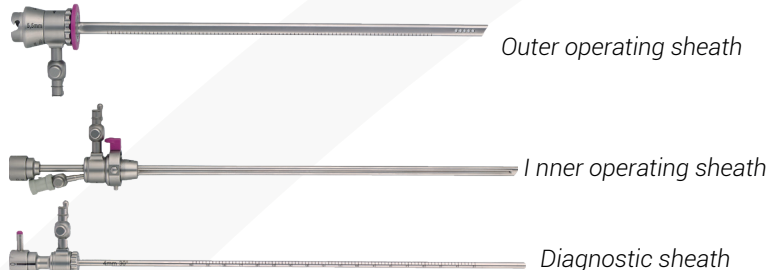
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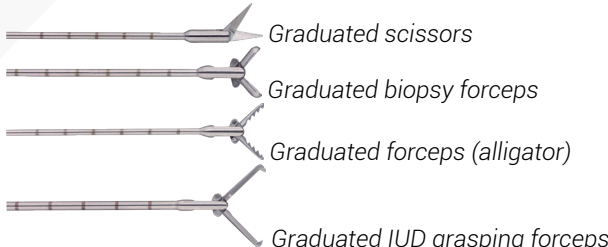
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SAS au capital de 237 200 euros - RCS Marseille 817 710 411 - N° de TVA Intracommunautaire : FR 81 817 710 411

Type of technology	Lenses
Working length	300 mm
Autoclavable	Yes. <i>See instructions for use for further details</i>
Connection for light cable	ACMI type
Light cable adapter	Wolf, Storz, Olympus type
Hysteroscopy system	
Regulation	
Description	Diagnostic and interventional hysteroscopic sheaths
Intended use	Hysteroscopy
Photos	 Outer operating sheath Inner operating sheath Diagnostic sheath
Device class	Ila
GMDN code	37086
Outer graduated operating sheath	
Article reference	D300 110 000
GTIN/UID ID code	3701217800618
Outer sheath's diameter	5.5 mm
Working length	216 mm
Rotatable suction stopcock	Yes
Quick lock	Yes
Graduation	Yes
Atraumatic outer sheath	Yes
Autoclavable	Yes. <i>See instructions for use for further details</i>
Inner graduated operating sheath	
Article reference	D300 110 001
GTIN/UID ID code	3701217800625
Inner sheath's diameter	4.9 mm
Working length	230 mm
Operative canal's diameter	7Fr.
Rotatable irrigation stopcock	Yes

Insertion canal's length of the operative canal	Long	
Graduation	Yes	
Atraumatic inner sheath	Yes	
Separable inner and outer sheaths	Yes	
Autoclavable	Yes. See instructions for use for further details	
Graduated diagnostic sheath		
Article reference	D300 110 002	
GTIN/UID ID code	3701217800632	
Diagnostic sheath's diameter	4 mm	
Working length	270 mm	
Rotatable irrigation stopcock	Yes	
Graduation	Yes	
Autoclavable	Yes. See instructions for use for further details	
Instruments		
Regulation		
Description	Reusable surgical instruments: scissors and forceps	
Intended use	Endoscopic surgery	
Photos		
Device class	I	
Graduated scissors		
Article reference	D300 120 008	D300 120 000
GTIN/UID ID code	3701217802858	3701217801196
Luer-Lock for flushing port	Yes	No
Flexibility	Semi-rigid	
Diameter	7Fr.	
Working length	340 mm	
Mobile jaws	1	
Graduation	Yes	
Rotation module	No	
Autoclavable	Yes. See instructions for use for further details	

Graduated biopsy forceps		
Article reference	D300 120 010	D300 120 002
GTIN/UID ID code	3701217802872	3701217801219
Luer-Lock for flushing port	Yes	No
Flexibility	Semi-rigid	
Diameter	7Fr.	
Working length	340 mm	
Mobile jaws	2	
Graduation	Yes	
Rotation module	No	
Autoclavable	Yes. See instructions for use for further details	
Graduated forceps (alligator)		
Article reference	D300 120 009	D300 120 001
GTIN/UID ID code	3701217802865	3701217801202
Luer-Lock for flushing port	Yes	No
Flexibility	Semi-rigid	
Diameter	7Fr.	
Working length	340 mm	
Mobile jaws	2	
Graduation	Yes	
Rotation module	No	
Autoclavable	Yes. See instructions for use for further details	
Graduated IUD grasping forceps		
Article reference	D300 120 011	D300 120 003
GTIN/UID ID code	3701217802889	3701217801226
Luer-Lock for flushing port	Yes	No
Flexibility	Semi-rigid	
Diameter	7Fr.	
Working length	340 mm	
Mobile jaws	2	
Graduation	Yes	
Rotation module	No	
Autoclavable	Yes. See instructions for use for further details	

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. <i>See instructions for use for further details</i>
End caps supplied	Storz

Reprocessing				
See Instructions for Use for more details.				
Automated Cleaning and Disinfection				
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 Immerse the device except the lectrodes and the scopes in an alkaline (0.5%) ultrasonic bath and treat with ultrasound for 15 minutes at 40°C. Solution used: Neodisher Mediclean forte, Dr. Weigert, Hambourg. ❹ 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 : Miele G 7736 CD, insertable module Miele E 327-06, module CMI Miele E 450 ❷ Prerinse for 1 min. with cold water. Discharging. ❸ Prerinse for 3 min. with cold water. Discharging. ❹ Wash for 5 min. at 55°C with a 0.5% alkaline. Solution used : Neodisher Mediclean forte; Dr. Weigert; Hamburg. ❺ Discharging. ❻ Neutralise for 3 min. with warm water (>40°C) and a neutralising agent. Solution used : Neodisher Z; Dr. Weigert. Discharging. ❼ Rinse 2 min. with warm water (>40°C).			
Disinfection	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