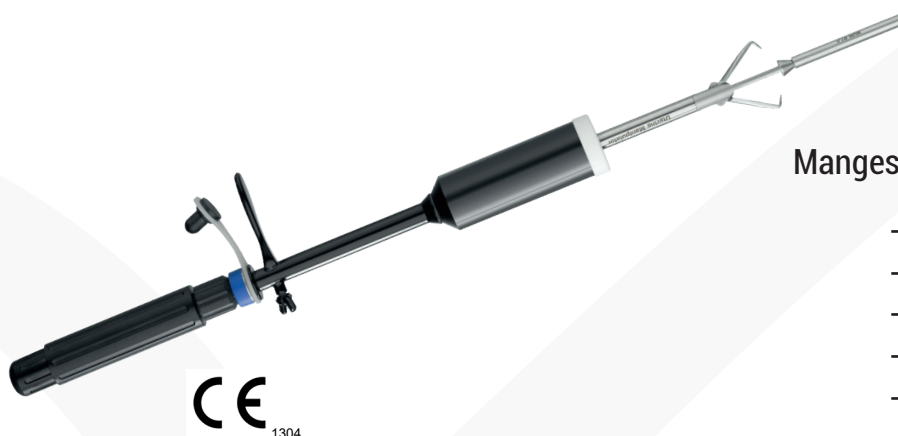


Data sheet

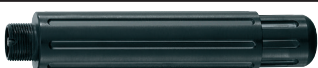
Mangeshikar



Mangeshikar device is composed of :

- 1 handle
- 1 outer sheath
- 1 inner sheath
- 1 insert with Pozzi forceps
- 1 sliding sheath
- 3 caps
- 7 intra-uterine inserts

General informations	
Description	Reusable uterine manipulator
Intended use	Use in coelioscopy for the uterus manipulation or/and ablation
GMDN code	15677
Device classe	Ila
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

Regulation	
Handle	
Description	Uterine manipulator Mangeshikar rotatable handle
Photo	
Article reference	D300 120 100
GTIN/UID ID code	3701217803602
Rotation	- Clockwise rotation : Pozzi forceps opening - Counter-clockwise rotation : Pozzi forceps closing
Length	110mm
Autoclavable	Yes. See instructions for use for further details
Outer sheath	
Description	Uterine manipulator Mangeshikar outer sheath with fixation screw
Photo	
Article reference	D300 120 101
GTIN/UID ID code	3701217803596
Outer sheath diameter	10mm
Length	290mm
Autoclavable	Yes. See instructions for use for further details
Inner sheath	
Description	Uterine manipulator Mangeshikar inner sheath with retaining pin
Photo	
Article reference	D300 120 102
GTIN/UID ID code	3701217803589
Autoclavable	Yes. See instructions for use for further details
Sliding sheath	
Description	Uterine manipulator Mangeshikar sliding sheath to use with cap
Photo	
Article reference	D300 120 103
GTIN/UID ID code	3701217803572
Sealing plug	Yes
Autoclavable	Yes. See instructions for use for further details

Pozzi forceps				
Description	Pozzi forceps for cervical holding, for uterine manipulator Mangeshikar			
Photo				
Article reference	D300 120 107			
Code GTIN/UID ID	3701217803534			
Forceps length	30mm			
Autoclavable	Yes. See instructions for use for further details			
Caps				
Description	Caps with white insulating ring			
Photo				
Article reference	D300 120 104	D300 120 105	D300 120 106	
Code GTIN/UID ID	3701217803565	3701217803558	3701217803541	
Diameter	35mm	40mm	45mm	
Length	100mm			
White insulating ring	oui			
Ring thickness	4mm			
Ring length	10mm			
Autoclavable	Yes. See instructions for use for further details			
Intra-uterine inserts				
Description	Intra-uterine inserts			
Photo				
Autoclavable	Yes. See instructions for use for further details			
List of products (1/2)				
Article reference	D300 120 108	D300 120 109	D300 120 110	D300 120 111
GTIN/UID ID code	3701217803527	3701217803510	3701217803503	3701217803497
Diameter	4mm	5mm	6mm	7mm
Length	40mm	50mm	60mm	70mm
List of products (2/2)				
Article reference	D300 120 112	D300 120 113	D300 120 114	
GTIN/UID ID code	3701217803138	3701217803121	3701217803091	
Diameter	8mm	8mm	8mm	
Length	80mm	120mm	150mm	

Reprocessing			
See Instruction 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 Immerse the device 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/131°F with a 0.5% alkaline or at 45°C/113°F with an enzymatic cleaning agent. Solution used : Neodisher FA; Dr. Weigert (alkaline) ou Endozime, Ruhof (enzymatic) ❺ Discharging. ❻ Neutralise for 3 min. with warm tap water (>40°C/104°F) and a neutralising agent. Discharging. Solution used : Neodisher Z; Dr. Weigert ❼ Rinse 2 min. with warm tap water (>40°C/104°F). Discharging.		
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	Drying
3 phases with a pressure of at least 60 millibars		134°C	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)	-20°C to +60°C	10 to 90%	800 to 1060 hPa
Storage (non-sterile)	-20°C to +60°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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