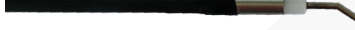


Data sheet

Bipolar flexible electrodes

Regulation			
Description	Flexible bipolar electrodes		
Intended use	Gynecologic hysteroscopy		
Photos	 <i>Bipolar electrode, button-type</i>  <i>Bipolar electrode, needle-type</i>  <i>Bipolar electrode, curved-needle type</i>		
Device class	IIb		
GMDN code	42553		
Conformity	Conform to MDD 93/42/EEC		
Applicable standards	See CE Conformity Declaration for more details		
Toxic/allergenic products	Latex free, DEHP free, Halogen free		
Technical data			
Name	Bipolar electrode, button-type	Bipolar electrode, needle-type	Bipolar electrode, curved needle-type
Article reference	D300 140 010	D300 140 011	D300 140 038
GTIN code	3701217802230	3701217802247	3701217802513
Working length	360 mm		
Diameter	5Fr.		
Flexibility	Flexible		
Compatibility	5 and 7Fr. operative canal		
Reusable electrode	Yes		
Generator output power	500 Vp		
Recommended power cutting and coagulation mode	max. 60 W		
Bipolar solution to be used	0.9% NaCl		
Autoclavable	Yes. See instructions for use for further details		

Reprocessing				
Manual pre-cleaning				
- Rinse electrodes for 5 min under cold water. - Brush electrodes until no debris is detectable with the naked-eye. - Rinse electrodes under cold water.				
Cleaning				
Step	Process step	Reagents	Time	Temperature
①	Pre-cleaning	Tap water	2min	
②	Drain			
③	Cleaning	Tap water Dosage : 0,5% concentration of cleaning agent such as neodisher MediClean (Dr.Weigert, Hamburg)	5min	55°C
④	Drain			
⑤	Neutralisation	Deionized water	3min	
⑥	Drain			
⑦	Rinsing	Deionized water	2min	
⑧	Drain			
Disinfection				
Thermal disinfection has been validated using the following parameters:				
Time		Temperature		
95sec		95°C		
Sterilisation				
Products sterilization with fractional pre-vacuum procedure, in accordance with ISO 17665 has been validated using the following parameters.				
Time of exposure		Temperature	Drying time	
4min		132 ±1 °C	10min	