

		mm, Ø 10 mm	Electrodes, unipolar for Minimally Invasive Surgery	MIS Hollow Shaft Instruments, not detachable, with LuerLock, Ø 5 mm, Ø 10 mm
Advice		Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function/wear of the device. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.		
Preparation at the Point of Use		Remove gross soiling by submerge the instrument into cold water (< 40°C) immediately after use. Don't use a fixating detergent or hot water (> 40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.		
Transportation		Safe storage and transportation in a closed container to the reprocessing area to avoid any damage and contamination to the environment.		
Preparation for Decontamination		The devices must be reprocessed in an opened or disassembled state.		The devices must be reprocessed in an opened or disassembled state.
Pre-Cleaning		Immerse the instrument into cold tap water for at least 5 minutes. Brush the instrument tip in a cold water bath with a soft bristle brush until all visible residues are removed.	Swivel the tip of the instrument (hook/spatula) for at least 1 minute in hydrogen peroxide. Immerse the instrument into cold tap water for at least 5 minutes. Brush the instrument under cold tap water until all visible residues are removed with a soft brush. Inner lumens, threads and holes are flushed each with a water jet pistol for minimum 10 seconds in the pulsed mode.	Immerse the instrument into cold tap water for at least 5 minutes. Brush the instrument tip in a cold water bath with a soft bristle brush until all visible residues are removed. The hollow shafts are flushed each through the LuerLock with a water jet pistol (static pressure at least 3,7 bar) for minimum 10 seconds with cold water in the pulsed mode. Last brush the hinges, threads and holes with a soft bristle brush and flush them again with a water jet pistol for minimum 10 seconds.
Automated cleaning		Put the instruments in an opened state with the jaw parts into the receptacles of the MIS-Rack and start the cycle according to the program no. 105 of the Miele G 7735 CD Washer - Disinfector:	Put the instruments on an instrument tray. Put the tray on an instrument rack in the washer/disinfector and start the cycle:	Put the instruments in an opened state with the jaw parts into the receptacles of the MIS-Rack and start the cycle:
	Step 1	1 minute pre-cleaning with cold tap water	1 minute pre-cleaning with cold water	3 minutes pre-cleaning with cold tap water
	Step 2	Draining		
	Step 3	3 minutes pre-cleaning with cold tap water	3 minutes pre-cleaning with cold water	3 minutes cleaning with tap water, dosing: 0,5% Sekumatic FR Cleaner (Ecolab) at 45°C, heat up to 55°C.
	Step 4	draining		
	Step 5	5 minutes cleaning with tap water at 55°C with 0,5% alkaline detergent (Neodisher FA, Dr. Weigert)	5 minutes cleaning at 55°C, 45°C with 0,5 % alkaline, enzymatic detergent (if enzymatic detergent is used the cleaning temperature is 45°C).	2 minutes cleaning with tap water, dosing: 0,5% Sekumatic FR Cleaner (Ecolab) at 45°C, dosing: 0,35% Sekumatic Oxivario (Ecolab) at 50°C, heat up to 55°C.
	Step 6	Draining		
	Step 7	3 minutes neutralisation with cold tap water	3 minutes neutralisation with warm water (> 40°C) and neutraliser	1 minute neutralisation with cold de-ionised water, 0,1% Sekumatic FNZ (Ecolab)
	Step 8	Draining		
	Step 9	2 minutes rinse with cold tap water	2 minutes rinse with warm water (> 40°C)	1 minute rinse with cold de-ionised water
	Step 10	Draining		
Disinfection		Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A ₀ -Value. (see ISO 15883)		
Drying		Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.		
Functional Testing and Maintenance		Visual inspection for cleanliness, assembling and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean.		
Packaging		Appropriate packaging for sterilization according to ISO 11607 and EN 868.		
Sterilization		Sterilization of instruments by applying a fractionated pre-vacuum process (according to DIN EN 13060/ISO 17665) under consideration of the respective country requirements. Parameters for the pre-vacuum cycle: 3 prevacuum phases with at least 60 millibar. Heat up to a minimum sterilization temperature of 132°C; maximum temperature: 137°C.		
		Minimum holding time: 3 Minutes		
		Drying time: minimum 10 min		
Storage		Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.		
Validation information of the cleaning process		The following devices, materials & machines have been used in this validation study:		
	Detergent:	Neodisher FA (alkaline); Dr. Weigert Hamburg	Neodisher FA; Dr. Weigert Hamburg (alkaline) Endozime, Fa. Ruhof (enzymatic)	Sekumatic FR (pH-value 12,1) Ecolab Sekumatic Oxivario (pH-value 7,8) Ecolab
	Neutraliser:		Neodisher Z; Dr. Weigert Hamburg	Sekumatic FNZ (pH-value 2,2) Ecolab
	Washer / Disinfector	Miele G 7735 CD	Miele G 7736 CD	Miele G 7836 CD
	Key Hole Surgery Rack:	E 450/1 (Miele)	E 327-06	E 450/1 (Miele)
	Steam Sterilizer	Selectomat HP (MMM)		Selectomat HP (MMM)
Documentation:	10109011407-27 (cleaning) 12708021009 (sterilization)	01707011901-2 (cleaning) 12708021009 (sterilization)	10109011407 (cleaning) 12708021009 (sterilization)	
Additional instructions		If the described chemistry and machines are not available, it is the duty of the user to validate his process. It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable of reaching the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.		