EC REP
S&T Medical GmbH
Bachstrasse 3
D-79798 Jestetten

S&T AG
Tobelraastr. 2
CH 8212 Neuhausen
/Switzerland

Cleaning Process of Microsurgical Instruments

Procedure:	**Manual Cleaning Process**
Products:	**Microsurgical Instruments manufactured by S&T AG, Tobelraastr. 2, CH-8212 Neuhausen / Rhf.**
Advice:	Due to the products' design and the materials used a defined limit for the maximum number of reprocessing cycles cannot be given. 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.

Reprocessing Instructions

Preparation at the Point of Use:	Remove gross soiling immediately after use. Don't use fixating detergents or hot water (>40°C) as this can cause 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 of the environment.
Preparation for Decontamination:	-
Manual Cleaning:	• Fully immerse all items in cold tap water for a minimum time of 5 min. • Brush all items separately with an appropriate brush. While brushing mobilize all movable parts of the items. • Treat all items in an ultrasonic bath for a minimum time of 10 min.* Store instruments in the appropriate instrument racks. • Rinse all items carefully with deionized water. While rinsing mobilize all movable parts of the items. *Refer to the recommendations of the manufacturer of the detergent
Disinfection:	Chemical disinfection: Prepare a solution of the disinfectant according to the instructions for use of the manufacturer of the disinfectant. Fully immerse all items in the solution (for the interaction time refer to the IFU of the manufacturer of the disinfectant). Only use disinfectants with proven effectiveness.
Drying:	Manual drying can be performed using lint free towels and/or sterile compressed air.
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Functional Testing, Maintenance:	Visual inspection for cleanliness 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:	Steam sterilization by applying a fractionated pre-vacuum process (according. ISO 13060 / ISO17665) under consideration of the respective national requirements. Minimum parameters for the pre-vacuum cycle: • 3 pre-vacuum phases • Sterilization temperature 132°C • Holding time 3 minutes • Drying time 20 minutes Exemplary sets of parameter values are: • 3 pre-vacuum phases • Sterilization temperature 132°C • Holding time 4 minutes • Drying time 20 minutes • 3 pre-vacuum phases • Sterilization temperature 134°C • Holding time 3 minutes • Drying time 20 minutes • 3 pre-vacuum phases • Sterilization temperature 134°C • Holding time 5 minutes • Drying time 20 minutes • 3 pre-vacuum phases

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	• Sterilization temperature 135°C • Holding time 3 minutes • Drying time 20 minutes • 3 pre-vacuum phases • Sterilization temperature 134°C • Holding time 18 minutes • Drying time 20 minutes
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.
Reprocessing validation study information	The following test devices, materials & machines have been used by SMP GmbH to validate the cleaning and sterilization processes: Detergent: Cidezyme (ASP) Ultrasonic bath: Elmasonic S 300 H, (Elma Hans Schmidbauer GmbH & Co. KG) Sterilizer: Selectomat HP 666-1HR, (Münchner Medizin Mechanik GmbH) Details: Cleaning: SMP Report No. 09013-2 Sterilization: SMP Report No. 09213 Drying: SMP Report 09313 Accreditation of SMP GmbH according to DIN EN ISO/IEC17025 and the Council Directives 93/42/EWG and 90/385/EWG documented in certificate number D-PL-17769-01-01
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 to achieve the required results. State of the art and often national law require that these processes and included resources are validated and maintained properly.	