Strategic Business Holdings, Inc.

...Quality Products, Superior Customer Service, & Support

IFU FOR CLEAN WAVE KERRISONS

Procedure:	**Automated Cleaning Process**
Products:	**Clean-Wave Instruments non- detachable, Article-Number: 240-xxx-xxxxx-CW** **Laminectomy Punches Kerrison / Laminectomy Rongeurs**
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.
Reprocessing Instructions:	
Preparation of 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 state.
Pre-Cleaning:	Immerse the instrument into cold tap water for at least 5 minutes. Brush the instruments under cold tap water until all visible residues are removed. Inner lumens, holes, slots and hinges are flushed with a water jet pistol for minimum 10 seconds in the pulsed mode (pressure at least 3,7 bar).
Automated Cleaning:	Put the instruments in an opened state on an instrument tray. Put the tray on an instrument rack in the washer disinfector and start the cycle (program Vario TD Miele): 1. 4 min. pre-cleaning with cold water 2. draining 3. 5 min. cleaning at 55°C with 0,5 % alkaline detergent 4. draining 5. 3 min. neutralisation with cold water 6. draining 7. 2 min. rinse with cold water 8. draining
Disfection Cleaning:	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-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 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. Joints and Shaft guides must be lubricated with medical instrument oil to avoid fretting corrosion. Distribute the lubricant uniformly in the joint by opening and closing the instrument several times. Use only instrument oils, which are approved for sterilization and taking into account the maximum sterilization temperature applied, on which have proven biocompatibility.
Packaging:	Appropriate packaging for sterilization according ISO 11607 and EN 868 Validation of Sterilization was realized with double Sterilization wrap (VP Stericlin).
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum process (according. ISO 13060 / ISO17665) under consideration of the respective country requirements. Parameters for the pre-vacuum cycle: 3 prevacuum phases with at least 60 milli bar Heat up to a minimum sterilization temperature of 132°-134°C; maximum temperature 137°C Minimum Holding time: 3 min (full cycle) 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.
Reprocessing validation study information:	The following testing test devices, materials & machines have been used in this validation study; Detergent: Neodisher FA; Dr. Weigert; Hamburg (Alkaline) Washer / Disinfector: Miele G 7735 CD MIC-Instrument Rack: E 450/1 Steam Sterilizer: Selectomat HP 666- 1HR (MMM) Sterilization wrap: VP Stericlin, double Details: Cleaning: project no.: 14309011011 Sterilization: project no.: 14309021011
Additional Instructions:	
	If the described chemistry and devices 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 reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

Important information

You receive a high-quality product by purchasing SBH Instruments. Its proper handling and use will be described in the following.

Please read this user manual thoroughly and keep it in a safe place in order to minimise risks and unnecessary burdens for the patients, the users and third parties.

Please read carefully the warning notices identified by this symbol. Improper use of the products can lead to serious injuries to the patients, the users or third parties.

For more information you may contact us at:
Strategic Business Holdings, Inc.
9620 Research Dr. Irvine, CA 92618 USA
Tel. 800-303-3050 Fax 949-600-8847
www.sbhsurgical.com info@sbhsurgical.com

CE