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| These instructions for reprocessing are to be used for all SpineShape instruments that are currently available. | |
| WARNINGS | The instruments are non-sterile when supplied and must be cleaned and sterilised before their first use |
| Limitations on reprocessing | Visible damage to the instruments, such as cracks, deformation, impact marks, areas of corrosion or other changes, is sign that the instruments must no longer be reprocessed/reused. |
| INSTRUCTIONS FOR REPROCESSING – Procedure: Cleaning and steam sterilisation | |
| Initial treatment at the place of use | - Remove coarse contaminants from the instruments immediately, and rinse if necessary |
| Preparation before cleaning | - Inspect visually for damage - Open fasteners on cutting instruments and pliers - Disassemble detachable instruments (attached ratchets must be separated) -> For information on disassembling/assembling the instruments, also see separate instructions <i>Illustration for instructions on reprocessing the instruments</i> |
| Manual pre-cleaning, in accordance with the manufacturer's validation | - Immerse the instrument in tap water ranging in temperature from 10°C to 25°C and clean with an appropriate non-metallic instrument cleaning brush for one (1) minute - Clean all lumens of instruments with a round instrument cleaning brush larger than the lumen for three (3) minutes - Clean the instruments thoroughly by hand until no visible dirt remains - Operate moving parts on instruments five (5) times - Rinse thoroughly with water for one (1) minute, and use a water pistol for flushing lumens for at least fifteen (15) seconds |
| Ultrasonic pre-cleaning | - Pre-clean the modular spinal contractor REF 20.002.00 as well as the universal handle REF 20.013.00 and REF 20.013.02 and T-handle REF 20.013.01 in an ultrasonic bath for five (5) minutes at a max. temperature of 40°C with a mild alkaline cleaner, e.g. Dr. Weigert neodisher MediClean forte 0.5% |
| Automated cleaning in the washer-disinfector, in accordance with the manufacturer's validation | <p>Preparation:</p> <ul style="list-style-type: none"> - Place instruments in a sieve; connect instruments with cannulas to the flush inlets of the washer-disinfector <p>Pre-wash:</p> <ul style="list-style-type: none"> - Pre-rinse for at least four (4) minutes with cold tap water ranging in temperature from 10°C to 25°C <p>Main wash:</p> <ul style="list-style-type: none"> - Min. five (5) minutes of cleaning with 55°C tap water with mild alkaline detergent, e.g. Dr. Weigert neodisher MediClean forte 0.5% <p>First round of rinsing/neutralising:</p> <ul style="list-style-type: none"> - Min. three (3) minutes of rinsing with cold de-ionised water ranging in temperature from 10°C to 25°C <p>Second round of rinsing/neutralising:</p> <ul style="list-style-type: none"> - Min. two (2) minutes of rinsing with cold de-ionised water ranging in temperature from 10°C to 25°C <p>Thermal disinfection / Final rinse</p> <ul style="list-style-type: none"> - Min. five (5) minutes at a minimum of 90°C with de-ionised water - Drying at max. 100°C - A0 value ≥3000 |

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| Maintenance, inspection and checking | <ul style="list-style-type: none"> - Check instruments for dirt deposits (clean again if necessary) - Check instruments for damage - Lubricate moving parts with a medical white oil and operate them multiple times -> For information on maintenance/care of the instruments, also see the separate instructions <i>Illustration for instructions on reprocessing the instruments</i> |
| Packaging, in accordance with the manufacturer's validation | Place the instruments in the instrument sieves and the sterilisation container in which they were delivered, and close the safety cover with the single-use filter (hydrophobic) for sterilisation container systems. Different, in-house packaging procedures must be validated. |
| Steam sterilisation, minimum in accordance with the manufacturer's validation | <ul style="list-style-type: none"> • Cycle type: <ul style="list-style-type: none"> ○ Fractionated pre-vacuum (3-fold) • Sterilisation temperature: <ul style="list-style-type: none"> ○ 132°C • Minimum holding time – full cycle: <ul style="list-style-type: none"> ○ Four (4) minutes |
| Additional information | <p>The specified validated reprocessing procedures have been conducted in accordance with the requirements of EN ISO 17664. Sterilisation and holding times are subject to national regulations and guidelines and thus cannot be generally defined. The operator is responsible for ensuring that the preparation and sterilisation actually conducted achieve the required results with the devices, materials and personnel used for preparation and sterilisation. This requires validation and routine monitoring of the process.</p> <p>When reprocessing surgical instruments, Swiss preparation units must comply with Swiss Ordinance 818.101.21 on the prevention of transmission of Creutzfeldt-Jakob disease (CJD) during surgical and medical interventions. This stipulates steam sterilisation under the following cycle parameters:</p> <ul style="list-style-type: none"> • Sterilisation temperature: <ul style="list-style-type: none"> ○ 134°C in saturated / pressurised steam • Holding time: <ul style="list-style-type: none"> ○ Eighteen (18) minutes <p>In Germany, the following KRINKO/BfArM recommendation applies to steam sterilisation with regard to CJD: Sterilisation temperature:</p> <ul style="list-style-type: none"> • Holding time: <ul style="list-style-type: none"> ○ Five (5) minutes <p>Other national regulations on infection prevention, e.g. CJD, must be taken into account.</p> |
| Storage | The SpineShape instruments shall be stored in the sterilisation container in which they were steam sterilised. Store the containers dry, at room temperature and protected from extreme temperature fluctuations and intense sunlight. Remove/supply the instruments when required for surgery |
| Contact the manufacturer | <p>SpineSave AG, Stationsstrasse 66, CH-8424 Embrach, Switzerland</p> <p>Tel: +41 44 866 72 92 info@spinesave.com</p> |