This document contains detailed instructions on the **cleaning, disinfection and sterilization** of WAL infiltration and irrigation/aspiration cannulae.
Cannulae that are supplied non-sterile **must** be thoroughly cleaned and sterilized before use.

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| **Warning notices:**<br><br>**CAUTION!** | The use of ultrasonic baths for the processing of WAL cannulae may affect the surface quality of the anodized hand pieces.<br>Instruments containing aluminum are damaged by high alkaline (pH > 10) cleaning agents and disinfectants. Only cleaning agents recommended for anodized aluminum should be used.<br>**Please consult the manufacturer of the instrument cleaning agent or disinfectant to determine its suitability for use with anodized aluminum instruments.**<br>Cleaning, disinfection and sterilization should only be carried out by trained staff in facilities specifically intended for this purpose.<br>**Note: When processing medical devices always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.** |
| **Limitations on reprocessing:** | Provided that the products are used as intended by the manufacturer, the end of their service life is deter-mined by normal wear and tear. **WAL cannulae have been successfully tested for a thirty-time (30) reprocessing using the validated manual reprocessing procedure including sterilization.** Further reprocessing beyond this number or other than the validated reprocessing procedures are in the user's responsibility.<br>**WARNING!** WAL cannulae of Ø 2.5 mm must be reprocessed by automated methods! |

| MANUAL REPROCESSING | |
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| ***Instructions:*** | |
| **Preparation and Transportation:** | Remove surface contamination using a disposable cloth or paper towel.<br>Take care that blood, debris or bodily fluids do not dry on the cannulae. We recommend reprocessing immediately after use. Do not use fixing agents or hot water (> 40°C, 104°F) since these will result in the coagulation and fixation of protein to the instruments' surfaces, affecting the success of subsequent cleaning procedures.<br>Special care must be taken during transportation to ensure that the distal end of the WAL cannula is not damaged. Transport in a closed container to avoid contamination to the environment. For best results and in order to prolong the life of the WAL cannulae reprocess immediately after use. |
| **Pre-cleaning:** | Immerse the cannulae in an enzymatic instrument cleaning solution (e. g. Enzol®, concentration as indicated by the manufacturer; diluted with cool to lukewarm deionized water).<br>Clean the inner cannula using a pipette brush (approx. 4mm Ø, approx. 20mm Ø for the hand piece); then flush the irrigation/aspiration cannula in the suction direction using deionized water, and clean the pipette brush with deionized water to remove visible contaminants.<br>Repeat this procedure until the surfaces and the hollow spaces to be cleaned are free of visible contaminants.<br>The instrument cleaning solution must be replaced at least once a day, and more often in the case of visible contamination. Discard the pipette brush after use. |
| **Cleaning:** | Fully immerse the cannulae in an enzymatic instrument cleaning solution (e. g. Enzol®, concentration as indicated by the manufacturer; diluted with cool to lukewarm deionized water, for 15 minutes).<br>Flush the irrigation/aspiration cannula with instrument cleaning solution in the suction direction for 1 minute.<br>Flush the irrigation/aspiration cannula with deionized water in the suction direction for 1 minute. |

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| **Disinfection:** | Fully immerse the harvest cannulae in an instrument disinfectant solution (e. g. in an undiluted Cidex OPA® solution for 5 minutes). There must not be air bubbles on the cannulae surface anymore. |
| **Rinsing:** | Completely rinse the cannulae in a rinsing bath of sterile deionized water (at least 8 liters) for at least 1 minute. Afterwards rinse all lumens thoroughly by hand again. The sterile deionized water must be replaced.<br>The rinsing procedure has to be repeated twice as described. The sterile deionized water must be replaced after each flushing procedure. |
| **Drying:** | Dry the cannulae internally and externally using sterile compressed air. |
| AUTOMATED REPROCESSING | |
| **Warning notices:** | We recommend the exclusive use of enzymatic cleaning agents for WAL cannulae.<br>The use of ultrasonic baths for reprocessing may have a slight effect the surface quality of the cannulae.<br>Cleaning, disinfection and sterilization should only be carried out by trained staff in facilities specifically intended for this purpose.<br>We recommend the use of a washer-disinfector machine for MIS instruments with a washing program for MIS instruments (e.g. MIS INSTRM NEUTRAL).<br>**Note: When processing medical devices always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.** |
| **Limitations on reprocessing:** | Repeated processing may affect the appearance of the WAL cannulae. The end of the product's service life is normally determined by wear and damage in use. |
| ***Instructions:*** | |
| | **The following steps must be performed using a validated washer-disinfector:** |
| **Pre-cleaning:** | Pre-rinse with cold water in the washer-disinfector for 15 minutes. |
| **Cleaning:** | The WAL cannulae are cleaned in 55°C (131°F) hot water diluted with a 0.5% solution of enzymatic cleaning agent (e. g. Enzol® or neodisher MediZym) for a minimum holding time of 10 minutes.<br>When using neodisher MediZym, then rinse with a 0.1% solution of acidic neutralizing agent (e.g. Neodisher Z) for 10 minutes at a water temperature of 20°C (68°F). |
| **Disinfection:** | Thermal disinfection with softened water at 93°C (199°F) for a minimum holding time of 10 minutes.<br>**Please observe national requirements concerning $A_0$ values (see ISO 15883).**<br>Final rinse with deionized water at 20°C (68°F) for at least 5 minutes. |
| **Drying:** | Dry at 60°C (140°F) for at least 15 minutes. |
| **Cleaning check:** | After cleaning, visually check all surfaces, holes and lumens for complete removal of soil and fluids. If **ANY** soil or fluid is still visible return the cannula for repeat processing. |
| **Maintenance:** | Apply a small quantity of surgical grade silicone spray lubricant to the attachment point of the WAL cannulae. |
| **Visual check:** | Visually check cannulae for damage and wear (firm seating of the suction tube in the hand-piece and intactness of distal end of the WAL cannula). Remove for replacement any worn out, fractured or damaged cannulae.<br>**Note:** *If a cannula shall be returned to Human Med AG or an authorized supplier it must be cleaned, disinfected and sterilized and be accompanied with the relevant documented evidence.* |
| **Packaging:** | The cannulae must be individually packed in sterile packaging in accordance with ISO 11607. The packaging units must be large enough to contain the cannula without stressing the seals. |
| **Sterilization:** | Steam sterilization using a fractionated vacuum process at 121°C (250°F) for at least 15 minutes, and at 134°C (273°F) at a minimum exposure time of 3 minutes has been validated. Prior to sterilization always check the batch process record for the respective sterilizer to ensure that the required parameters are being met. |

For further information please contact Human Med AG under +49 (0) 385 395700 or the supplier of the medical device.

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| **Storage:** | Store in a closed cupboard, protected from dust and humidity and extreme fluctuations in temperature.<br>The shelf life is determined by the product specifications of the sterile packaging used. |

The instructions outlined above have been validated by Human Med AG as being suitable for the preparation of WAL cannulae for reuse.

**Information about validation of reprocessing**

The following test instructions, materials and machines have been used for validation:

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| Cleaning agent (automated): | Neodisher MediZym, Dr. Weigert |
| Neutralizer (automated): | Neodisher Z, Dr. Weigert |
| Cleaning agent (manual): | Helizyme, BBraun |
| Disinfectant (manual): | Stabimed, BBraun |
| Washer-disinfector machine: | GETINGE, CM 305, Program “MIS INSTRM NEUTRAL” |

Please contact Human Med AG for additional information on the validations.

If the above described chemicals and machines are not available, it is the user’s responsibility to ensure validation of the reprocessing method used.

It is the reprocessor’s responsibility to ensure that the reprocessing actually performed with equipment, materials and personnel in the reprocessing facility achieves the desired result.

This requires validation and routine monitoring of the process. Likewise any deviation from the instructions provided must be properly evaluated by the reprocessor for effectiveness and potential adverse consequences.