



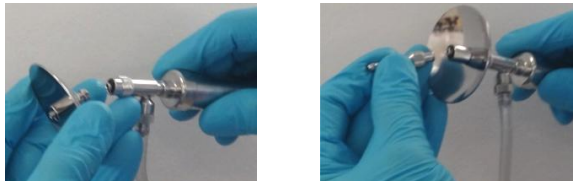


Instruction for use

- Important:**
- Syringes are supplied non-sterile and must be cleaned and sterilized prior to each use.
 - Please make sure that the syringes are only used by authorized persons.



- Notice:**
- To avoid stiffness, the O-ring has to be lubricated before the first use and after each disinfection and sterilization by means of instrument oil.

Procedure:	Automatic reprocessing
Instruction:	Due to the constructive design of our syringes, a clearly limit of expected reprocessing cycles cannot be determined. The service life of the syringes always depends on the appropriate utilization, its careful handling and maintenance.
<p>Assembling:</p>  <p>HSW Universal self-filling ear syringe</p>  <p>HSW Water syringe</p> <ol style="list-style-type: none"> 1. place O-ring on to the piston (see fig. 1) → O-ring must be lubricated thereafter 2. screw sleeve and piston together → hold piston rod with the O-ring slightly angulated to allow easier insertion (see fig. 2) 3. according to the application accessories needed like cannula, protecting disc, valve system should be fitted on the front part of the syringe (see fig. 3 & 4) → now the syringe is ready for use  <p>fig. 1: fit O-ring</p>  <p>fig. 2: insertion slightly angulated and screw them together</p>  <p>fig. 3 & 4: accessories according to the application the be fitted to the front part of the syringe</p>	
Instructions for reprocessing	
Preparations at the place of installation:	Remove obvious dirt particles from syringes immediately after utilization. It is not allowed to use fused agents or hot water (> 40°C) for cleaning as these agents lock residues and impede an effective purification process.
Transport:	Secure storage as well as secure transport in closed boxes is recommended in order to avoid any damage to the syringes as well as environmental contamination.
Manual pre-cleaning:	The syringes must be disassembled (see assembling) and cleaned by means of a soft multi-purpose brush and cold tap water until all obvious residues and defilements are removed. Drill holes and thread turns must be flushed for at least 10 seconds at a pressure of 3.8 bars by means of a water pistol.
Cleaning:	Disassembled or opened-up syringes must be put in a screen basin on the plug-in mode. Then start the cleaning process. <ol style="list-style-type: none"> 1. 4 minutes pre-washing by means of cold water - Draining 2. 5 minutes pre-washing at 55° C with 0,5% Neodisher Mediclaen, Dr. Weigert (Hamburg) - Draining 3. 3 minutes neutralization with warm tap water (> 40°C) - Draining 4. 2 minutes intermediate flushing by means of warm tap water (> 40°C) - Draining
Disinfection:	The automatic thermal disinfection must be carried out according to the national requirements regarding the A0-coefficient (see ISO 15883).
Drying:	Drying of the exterior parts of the syringes by means of the drying cycle of the cleaning / disinfection equipment. Additional manual drying is possible by means of a lint-free cloth. Hollow spaces of the syringes must be dried by means of sterile compressed air.
Functional test, maintenance:	The assembling and care of the syringes, as described above, must be carried out. If necessary, the reprocessing procedure must be re-run until the medical device is obviously clean.
Packaging:	Packaging of the syringes for sterilization must comply with standards according to ISO 11607 and EN 868.
Sterilization (autoclaving):	<p>Sterilization of the syringes by means of the fractionated pre - vacuum method (according to ISO 13060 / ISO 17665) in compliance with the individual national requirements.</p> <ul style="list-style-type: none"> - Fractionated pre - vacuum method (3-fold) - Sterilization temperature of 134°C - Minimum exposure time: 3 minutes (full cycle) - Drying time: at least 10 minutes
Storage:	Storage of sterilized syringes must be carried out in a dry, clean and dust-free environment at a moderate temperature of 5°C - 40°C.
Information on validation of processing:	<p>The following test instructions, materials and machines have been used for validation:</p> <p>Cleaning supplies: Neodisher Mediclean (alkaline); Dr. Weigert; Hamburg</p> <p>Cleaning / disinfection equipment: Miele G 7735 CD with plug-in module, vario-TD-program (without disinfection)</p>
Additional instructions:	According to the Ordinance on Installation, Operation and Use of the syringes (MPBetreibV in German), the operator is responsible for validating any reprocessing procedures, even if the above described chemicals and machines are not available.

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The referenced processes only have to be performed on the above mentioned HSW- products.