Procedure:	**Automatic reprocessing**
Products:	Human syringes
Instruction:	Due to the constructive design of medical devices, a clearly defined limit of expected reprocessing cycles can not be determined. The service life of a medical device depends on the appropriate utilization of the product and its careful handling and maintenance. Prior to reshipment of products for repair at the manufacturer's site, medical devices must be cleaned as well as sterilized according to the prescribed reprocessing requirements.
Instructions for reprocessing	
Preparations at the place of installation:	Remove obvious dirt particles from medical devices 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 medical device as well as environmental contamination.
Preparations for decontamination:	For further reprocessing, medical devices must be disassembled or opened up as far as possible. For details see separate instructions.
Manual pre-cleaning:	The medical device must be disassembled (see above) and cleaned by means of a soft multi-purpose brush and cold tap water until all obvious residues and defilements are removed. Lumen, 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 medical devices must be put in a screen basin on the plug-in mode. Then start the cleaning process. 1. 4 minutes pre-washing by means of cold water 2. Draining 3. 5 minutes pre-washing at 55° C with 0,5% Neodisher Mediclaen, Dr. Weigert (Hamburg) 4. Draining 5. 3 minutes neutralization with warm tap water (> 40°C) 6. Draining 7. 2 minutes intermediate flushing by means of warm tap water (> 40°C) 8. Draining
Disinfection:	The automatic thermal disinfection must be carried out according to the national requirements regarding the A_0-coefficient (see ISO 15883).
Drying:	Drying of the exterior parts of medical devices by means of the drying cycle of the cleaning / disinfection equipment. Additional manual drying is possible by means of a lint-free cloth. Hollow space of medical devices must be dried by means of sterile compressed air.
Functional test, maintenance:	Afterwards, a visual appraisal regarding purity is necessary. The assembling of medical devices, maintenance and functional tests must be carried out according to the instruction manual. If necessary, the reprocessing procedure must be re-run until the medical device is obviously clean.
Packaging:	Packaging of medical devices for sterilization must comply with standards according to ISO 11607 and EN 868.
Sterilization (autoclaving):	Sterilization of products by means of the fractionated pre - vacuum method (according to ISO 13060 / ISO 17665) in compliance with the individual national requirements. 1. Fractionated pre - vacuum method (3-fold) 2. Sterilization temperature of 134°C 3. Minimum exposure time: 3 minutes (full cycle) 4. Drying time: at least 10 minutes
Storage:	Storage of sterilized medical devices 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:	The following test instructions, materials and machines have been used for validation: Cleaning supplies: Neodisher Mediclean (alkaline); Dr. Weigert; Hamburg Cleaning / disinfection equipment: Miele G 7735 CD with plug-in module, vario-TD-program (without disinfection) For details see report Cleaning: 17607011411 - 1 Sterilization: 17607010811 - 1
Additional instructions:	According to the Ordinance on Installation, Operation and Use of Medical Devices (MPBetreibV in German), the operator is responsible for validating any reprocessing procedures, even if the above described chemicals and machines are not available. The operator must ensure that any reprocessing procedures – including resources, material and staff - are capable of achieving the required results. National legislation as well as the state of technology requires compliance with validated procedures.