

Processing instruction for reusable All glass syringes

Rev. 20170720

Manufacturer: Poulsen & Graf GmbH, Karl-Carstens-Straße 10, D - 97877 Wertheim, Telefon: +49 (0)9342 9229-0.

Products: All Glass Syringes with Glass tip Luer, Luer-Lock tip - Brass nickel-plates. The Glass Cylinder and Glass Piston are manufactured from **Borosilicate glass**
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Please note: All Glass Syringes will be delivered non sterile and should be cleaned, disinfected and sterilized before and after each use. (Cleaning and disinfection after removing packaging) (sterilization after packing)

Please note

That only suitable equipment and product-specific procedures should be used for cleaning / disinfection and sterilization

That the equipment used (RDG, sterilizer) should be serviced and checked regularly

That the life expectancy and frequency of use will not be exceeded and the required cleaning/disinfection and sterilization procedures will be adhered to for every cylinder

Please consider additionally the legal regulations in your country as well as the hygiene regulations of the doctor's surgery or of the hospital. This is especially important for the different standards concerning an effective prion activation, that could make the usage of cleaning chemicals with proven prion activation and an intensive sterilization, necessary (Note: only syringes without metal components can be used in alkaline treatments; all other syringes must not be used with alkaline solutions. Therefore, those syringes with metal components must not be used again after contact with the alkaline risk material)

For some syringes additional or different aspects of cleaning and use should be noted (see Table / Page 5 "Special references")

Limitations of reuse

Durability 2 years with use of sterilization, with an approximate number of 25 cycles/year.

Durability 5 years with use of cleaning/disinfection, but without sterilization, with an approximate number of 25 cycles/year.

Work area:

Remove surface contamination with a soft one-time-use cloth.

Essentials:

For cleaning and disinfection a manual cleaning procedure should be used. For mechanical processes the initial cleaning is very important as well as the correct positioning. Pretreatment is to be carried out in both cases.

CLEANING (pretreatment):

Directly after usage (within a maximum of 2 hours afterwards) coarse contamination has to be removed from the syringes:

1. Take the syringe apart including the cylinder and piston
2. Rinse out the syringe under running water both inside and outside, each time for 1 min (Temperature <35°C/95°F)
3. Use a single use syringe for rinsing out the syringe cylinders up to a volume of 3 ml (minimum volume: nominal volume of the syringe)
4. Remove all visible contamination manually by using a clean soft brush. (Diameter a bit bigger than inner diameter of the cylinder. This brush you should use just for this purpose) Do not use a metal brush or steel wool
5. Wash up again both inside and outside each time for 1 min under running water
6. Use a single use syringe for washing up the cylinder, up to a volume of 3 ml (minimum volume: nominal volume of the syringe)


Note:

¹When held horizontally, the cylinder works with heavily reduced efficiency. Furthermore, it is very likely that there will be detergent residues left in the cylinder.

²For cleaning syringes up to (and including) 3ml the mechanical process is generally prohibited.

³If cleaning or disinfection products are used is used, e.g. for safety reasons, please note that these need to be aldehyde-free and that their effectiveness is proven (e.g. VAH/DGHM- or FDA/EPA-admission/ clearance/ registration or CE-marking). Also, make sure that they are compatible with glass and metal instruments and also with the syringes. Note, Please be aware of the fact that the pretreatment with disinfectants is only for employee safety only and does not make the later disinfection process (after successful cleaning) obsolete.

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Manuel cleaning and disinfection

When choosing the cleaning and disinfection products, make sure that:

- these are generally suitable for the cleaning and disinfection of metal and plastic instruments,
- a disinfectant with proved efficiency is used (E.g. VAH/DGHM-approval or Ce-marking) and that these mediums are compatible with the cleaning product and the chemicals used are compatible with the syringes (see section "Material consistency")

If possible do not use combined cleaning/ disinfection mediums. Only in cases of low contamination (no visible contamination) can combined cleaning and disinfection mediums be used.

Concentrations, temperatures and application time as well as instructions for rinsing specified by the manufacturer of the cleaning and disinfectant products have to be strictly followed. Only use freshly made solutions, sterile or low-of-microbiological-contamination as well as low endotoxin-containing water (e.g. purified water/highly purified water). For drying only use a soft, clean and lint-free cloth and/or filtered air.

Procedure Cleaning

Equipment: cleaning chemicals, soft plastic brush, containers, sterile or low-germ water and appropriate protective clothes.

1. Place the disassembled syringes in a cleaning bath for the predetermined time, in such way that the syringes are covered sufficiently with water. Make sure that the syringes do not touch each other.
Support the cleaning process by brushing off the contamination on the outside and the inside of the syringe with a soft brush. For syringes up to a volume of 3 ml please rinse the cylinder at least five times at the beginning and at the end of the cleaning process, using a single-use syringe (minimum volume = nominal volume of the syringe)
2. Take the syringe out of the cleaning bath and rinse out the cylinders on the inside and outside for at least 1 minute, at least three times
For syringes up to a volume of 3 ml please rinse out the cylinders on the inside and outside at the beginning and at the end of the cleaning process, using a single-use syringe (minimum volume = nominal volume of the syringe)
3. Check the syringe (see "Control and function test")

Disinfection

4. Place the disassembled syringes in the disinfection bath for the predetermined time, in such way that the syringes are covered sufficiently with water. Make sure that the syringes do not touch each other.
For syringes up to a volume of 3 ml please rinse out the cylinder at least five times at the beginning and at the end of the cleaning process, using a single-use syringe (minimum volume = nominal volume of the syringe)
5. Take the syringe out of the disinfection bath and rinse out the cylinders on the inside and outside for at least 1 minute, at least three times
For syringes up to a volume of 3 ml please rinse out the cylinders on the inside and outside at the beginning and at the end of the cleaning process, using a single-use syringe (minimum volume = nominal volume of the syringe)
6. Dry the syringe by blowing off or through with filtered compressed air.
7. Pack up the syringe as soon as possible after taking out (see section "Packing" below)

Proof of the effectiveness of the manual cleaning and disinfection process for the syringes for the was provided by an independent, accredited testing laboratory Bode Chemie GmbH in Hamburg, by the usage of the cleaning material "Bododex forte" and the disinfectant "Korsalex plus". The laboratory worked according to the instructions given above.

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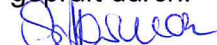
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Mechanical Cleaning / Disinfection (RDG (Cleansing and disinfection device))

When choosing the RDGs please make sure that:

- the effectiveness of the RDG is generally proven (e.g. DGHM-permission or CE-marking according to DIN EN ISO 15883)
- if possible a tested program for thermal disinfection is used (A_0 – Valued > 3000 or – for older devices – min. 5 min at 90°C/194°F). Note For chemical disinfection there is a risk of leftover chemical residuals on the syringes.
- the program used is suitable for syringes and that it has a sufficient number of washing cycles
- for rinsing, only sterile water or water that is low in germs (max. 10 germs/ml) and endotoxin (max. 0,25 units of endotoxin/ml) (e.g. purified water / highly purified water) is used
- the air used for drying is filtered (without oil, low in germs and particles)
- the cleaning device is regularly serviced and checked

When choosing a cleaning medium make sure that:

- it is generally suitable for the cleaning of instruments made of metal and plastic
- it is – if necessary – prion effective
- another suitable disinfectant is used additionally if no thermal disinfection is used, (e.g. VAH/DGHM-approval or CE-marking) and that this is compatible with the cleaning medium
- the chosen chemicals are compatible with the syringes

Concentrations, temperatures and application time as well as instructions for rinsing specified by the manufacturer of the cleaning and disinfectant products have to be strictly followed.

Note: Syringes with a volume up to 3 ml (inner diameter < 10 mm) are not suitable for mechanical cleaning.

Procedure:

1. Put the disassembled syringe into the cleaning device. Make sure that the syringes do not touch each other and put the cylinders onto a cleaning spike (with a significantly lower diameter) (Note: do not fix the cylinder horizontally))
Affix the syringes with a net onto the cleaning spike.
2. Start the program
3. Remove the syringe out of the cleaning device after the program has ended
4. Check and pack the syringe as quickly as possible after taking it out of the device (see sections "control and function test " and "packing")

Proof of the effectiveness of the mechanical cleaning and disinfection process for the syringes was provided by an independent, accredited testing laboratory Mechanical Devices GmbH which used the RDGs G 7836CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning chemical "Neodisher medizym" (Dr. Weigert GmbH & Co. KG., Hamburg). The laboratory worked according to the instructions given above.

Control and function Test:

After cleaning and disinfection, check all syringes for corrosion, damaged surfaces, splinters, contamination as well as discoloration and separate out any damaged syringes. Syringes which are still dirty should be cleaned and disinfected again.

Maintenance:

Oil or grease should not be used for maintenance.

Packing

Please pack the disassembled syringe into a single use sterilization packing after cleaning (simple or double packing) which meets the following preconditions:

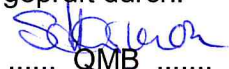
- DIN EN ISO 11607
- Suitable for steam sterilization (Temperature resistance up to min. 142°C/288°F, sufficient permeability of steam)
- sufficient protection of the syringes/ sterilization packaging from physical damage

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STERILIZATION

For sterilization only the following procedures are to be used; other procedures are not acceptable.

Do not attempt to sterilize syringes unless they are disassembled!

Steam sterilization

- fractional vacuum method 3,4 (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060/DIN EN 258
- Validated according to DIN EN ISO 17665 (valid IQ / OQ (commissioning) and product specific performance assessment (PQ))
- Maximum sterilization temperature 138 °C (280°F; with additional tolerance according to DIN EN ISO 17665)
- Sterilization time (exposition time at sterilization temperature) at least 3⁶ min. at 132°C (270°F)/134°C (273°F)

³ at least three vacuum steps.

⁴ The usage of the less effective gravitation method is only acceptable when the fractional vacuum method is not available; usually this method has a remarkably longer exposition time and has to be secured through an additional product and method specific validation. The user is responsible for this procedure.

⁵ The actual time necessary for drying depends directly on parameters that lie in the responsibility of the user. (Loading configuration and - density, condition of sterilizer...) and should therefore be determined by the user. Nevertheless drying times should not be less than 20 min.

⁶ or 18 min (prion activation)

Proof of the effectiveness of steam sterilization for the syringes was provided by an independent, accredited testing laboratory Mechanical Devices GmbH which used the HAST 6x6x6 (Zirbus technology GmbH, Bad Grund) steam sterilizer and the fractional vacuum method. For this, the typical conditions in a hospital and a doctor's practice were considered as well as the procedure described above.

The lightning sterilization method is generally not acceptable.

Moreover, do not use hot air sterilization, ray sterilization, formaldehyde, ethylenoxid sterilization or plasma sterilization.

Storage

After sterilization the syringes have to be stored in a sterilization packing to ensure that they are stored dry and dustless.

Material consistency

When choosing the cleaning and disinfection chemical, please make sure that the chemical does not contain the following ingredients:

- Organic, mineral and oxidizing acids (min. allowed pH-value 5,5)
- Syringes with Luer-Lock tip: Lyes (max allowed pH-value 8,5, neutral / enzymatic cleaner recommended) / Syringes without Luer-Lock tip: stronger lyes (max. allowed pH-value 11, neutral / enzymatic cleaner or slight alkali cleaner recommended)
- Oxidizing agent (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)

Do not clean the syringes with a metal brush or steel wool.


Note: Acidic-containing neutralization chemicals or rinsing agent must not be used.

All Syringes must never be exposed to temperatures over 142°C (288°F).

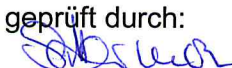
Reusability

The syringes can – when handled with appropriate care and if undamaged and unpolluted – be reused up to 25 times a year for a maximum of two years from first use; every further use or use of damaged and/or polluted syringes is the responsibility of the user.

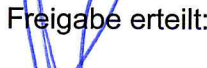
If the above recommendations are not followed, any liability and warranty is excluded.

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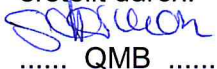
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Art.-NO.:	Description	Wash volume	Brush	Special / additional procedure				Packing	Sterilization	Max. allowed no. of cycle	In case of suspicion to Prionenrisik
				Processing	Manual cleaning/ disinfection	Mechanical cleaning / disinfection	Control / servicing				
	All Glass Syringe with glass tip (without metal) up to 3 ml	Nominal volume	Outer diameter of the brush a little bit bigger than the inner diameter of the cylinder	Standard procedure, flush out inside active with a single use syringe	Standard procedure, flush out inside active with a single use syringe	Not acceptable	Standard procedure	Standard procedure	Standard procedure	25	Alkaline preparation, intensive sterilization according to standards
	All Glass Syringe with Luer-Lock tip (with Metal) up to 3 ml	Nominal volume	Outer diameter of the brush a little bit bigger than the inner diameter of the cylinder	Standard procedure, flush out inside active with a single use syringe	Standard procedure, flush out inside active with a single use syringe	Not acceptable	Standard procedure, dispose product if it is damaged or corrosion	Standard procedure	Standard procedure	25	Dispose
	All Glass Syringe with glass tip (without metal) 5 ml to 100 ml	-	Outer diameter of the brush a little bit bigger than the inner diameter of the cylinder	Standard procedure	Standard procedure	Standard procedure, neutral and a little bit alkali	Standard-procedure	Standard procedure	Standard procedure	25	Alkaline preparation, intensive sterilization according to standards
	All Glass Syringe with Luer-Lock tip (with metal) 5 ml to 100 ml	-	Outer diameter of the brush a little bit bigger than the inner diameter of the cylinder	Standard procedure	Standard procedure	Standard procedure, neutral (alkali cleaning not acceptable)	Standard-procedure, dispose product if it is damaged or corrosion	Standard procedure	Standard procedure	25	Dispose

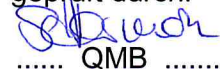
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