

## Instruction for use

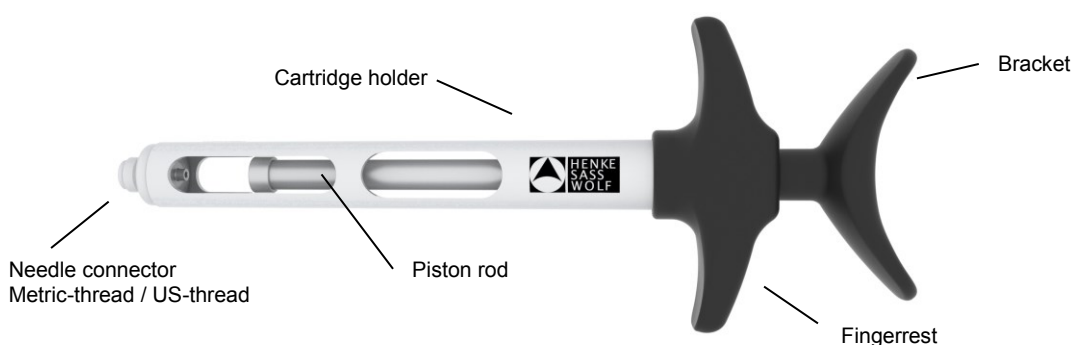
### HSW HENKE-DENT 3000 SA ERGO

**Intended use:** Dental self-aspirating cartridge syringe for infiltration- and block anaesthesia.

This self-aspirating syringe is used together with a sterile dental needle and a cartridge, prefilled with an anaesthetic, primarily for local anaesthesia (especially in dentistry).

#### Assembly of the HSW HENKE-DENT 3000 SA ERGO

The HSW HENKE-DENT 3000 SA ERGO is a non-detachable injection syringe.



#### Cleaning & Sterilisation

Prior to the initial use of the product and for each further use the product must be cleaned and sterilised:

<b>Preparations at the place of installation:</b>	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.
<b>Transport:</b>	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.
<b>Manual pre-cleaning:</b>	The medical device must be 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.
<b>Cleaning:</b>	Medical devices must be put in a screen basin on the plug-in mode. Then start the cleaning process. <ol style="list-style-type: none"> <li>1. 4 minutes pre-washing by means of cold water</li> <li>2. Draining</li> <li>3. 5 minutes pre-washing at 55° C with 0,5% Neodisher Mediclean, Dr. Weigert (Hamburg)</li> <li>4. Draining</li> <li>5. 3 minutes neutralization with warm tap water (&gt; 40°C)</li> <li>6. Draining</li> <li>7. 2 minutes intermediate flushing by means of warm tap water (&gt; 40°C)</li> <li>8. Draining</li> </ol>
<b>Disinfection:</b>	The automatic thermal disinfection must be carried out according to the national requirements regarding the A <sub>0</sub> -coefficient (see ISO 15883).
<b>Drying:</b>	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.
<b>Functional test, maintenance:</b>	Afterwards, a visual appraisal regarding purity is necessary. The 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.
<b>Packaging:</b>	Packaging of medical devices for sterilization must comply with standards according to ISO 11607 and EN 868.

<b>Sterilization (autoclaving):</b>	<p>Sterilization of products by means of the fractionated pre - vacuum method (according to ISO 13060 / ISO 17665) in compliance with the individual national requirements.</p> <ol style="list-style-type: none"> <li>1. Fractionated pre - vacuum method (3-fold)</li> <li>2. Sterilization temperature of 134°C</li> <li>3. Minimum exposure time: 3 minutes (full cycle)</li> <li>4. Drying time: at least 10 minutes</li> </ol>
<b>Storage:</b>	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.
<b>Information on validation of processing:</b>	<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> <p>For details see report</p> <p>Cleaning: 17607011411 - 1 Sterilization: 17607010811 - 1</p>
<b>Additional instructions:</b>	<p>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.</p> <p>The operator must ensure that any reprocessing procedures – including resources, material and staff - are capable of achieving the required results.</p> <p>National legislation as well as the state of technology requires compliance with validated procedures.</p>

## Application

### Infiltration anaesthesia:

In infiltration anaesthesia, the local anaesthetic is infiltrated into the tissue of the target area to be anaesthetised.

### Block anaesthesia:

In the lower jaw, mainly block anaesthesia is used. The local anaesthetic is inserted as near as possible to the nerve trunk and the entire supply area of these nerves is anaesthetised.

### General:

The HSW HENKE-DENT 3000 SA ERGO can be used for all standard cartridge glass ampoules 1.7 ml or 1.8 ml with hole plugs and solid plugs.

## Preparation of device

1. Introduce a sterile dental injection needle corresponding to the requirements into the head of the cartridge holder. Fix the injection needle by screwing it on the thread of the cartridge holder. Note that only needles with a metric thread fit on injection syringes with a metric front part. Injection needles with an inch thread can only be used with injection syringes with an inch.
2. Pull the plunger completely back.
3. Insert a suitable cartridge (1.7 ml or 1.8 ml) into the back of the cartridge holder and then push the cartridge completely laterally into the cartridge holder.  
Please fix the cartridge until point 4. is finished.  
(Inserting the cartridge in reverse would cause the front rubber membrane of the cartridge to be punctured inaccurately and not centrally - this would have a negative effect on the self-aspirating behaviour.)
4. When the cartridge has been correctly inserted into the syringe, gently and slowly push the cartridge with the piston rod completely forward onto the rear part of the needle without anaesthetic escaping from the needle.  
Please check that the dental needle pierces the rubber membrane straight and in the middle.
5. For checking if the needle is situated correctly on the cylinder cartridge, the flow of the anaesthetic should be tested by a slight forward motion of the plunger. If there is a flow of the anaesthetic, the syringe is ready for application.
6. Self-aspiration is carried out during injection whenever the thumb ring (resp. bracket etc.) is released. The bounce of the elastic cartridge membrane, which is shortly pressed against a small cylindrical height in the front end of the syringe, causes the necessary low-pressure in the cartridge which secures the aspiration. It is recommended to check the correctness of the needle position by occasional decrease of the thumb pressure (and thereby automatically caused aspiration).
7. After the application is completed, the cartridge can be removed by pulling the cartridge in the syringe backwards.  
Now the cartridge can be carefully removed from the cartridge holder via the open side.
8. Now the dental needle can be unscrewed from the syringe.

**Warning notices:**

1. To avoid needle stick, please pay attention to the national and internal specifications and safety instructions.
2. The aspiration function of the self-aspirating cartridge syringes depends on the elasticity of the respective rubber membranes and the character of the respective dental needles.



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