



MANUFACTURER



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Classification acc. MDR: Class I | Rule 5



**IMPORTANT PRODUCT INFORMATION -
PLEASE READ CAREFULLY BEFORE
EACH CLINICAL APPLICATION!**



Dear Customer!

With the purchase of this instrument, you have acquired a high-quality product. The proper handling and use are described below. In order to minimize hazards to patients and users, we ask that you carefully observe the instructions for use.

Our different models:

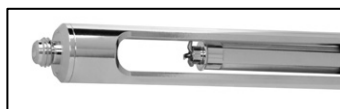
Bend-load-models (Type 1)

2650-00
2659-00 & 2659-50
2666-00



Models with aspiration hooks (Type 2)

2659-00 & 2659-50



Important:

**Our cartridge syringes are supplied clean but non-sterile.
It is therefore imperative that they are cleaned and sterilized before use on the patient.**

DESCRIPTION:

Cartridge syringes from deve med are used with a sterile dental needle and with a pre-filled anaesthetic cartridge barrel (both not included in delivery).

INTENDED USE / INDICATION:

Dental injection syringe for nerve block and infiltration anesthesia in dentistry

CONTRAINDICATION:

The products are contraindicated for all applications apart from the intended use and indication and must not be used:

- outside dentistry
- for direct application by the patient
- for intraligamental anaesthesia

The generally known contraindications for surgery must also be considered. Compromising anatomical structures around the planned measure must also be avoided. Improper use may lead to damage to tissues, premature wear, destruction of the instrument, and hazards for the patient, user, or third parties.

To preclude compromising adjacent structures such as blood vessels and nerve fibers, the user must have precise anatomical knowledge. A good view of the surgical site must be assured at all times.

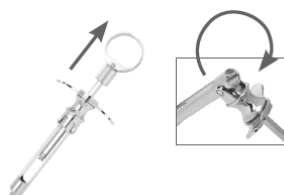


Warnings:

- The instruments may only be used by persons who are specially trained or instructed for this purpose.
- To avoid needle stick, please pay attention to the national and internal specifications and safety instructions.
- Syringes without aspiration possibility (2650-00 & 2666-00) must not be used for infiltration or nerve block anesthesia.
- As regards Type 2 (2659-00 & 2659-50): The aspiration hooks have to be in retracted position when inserting or removing the cartridge and the plunger must be pulled back as far as it will go. They may otherwise be bent. Syringes of type 2 are designated for the use of cartridges with hole plug. All other syringe models are designated for the use with cartridges with solid plug.

FUNCTION & HANDLING:

1. Pull the plunger completely back. Please note that towards the end a spring resistance has to be overcome. Please afterwards swing the cartridge holder out at a right angle.



2. Introduce the appropriate cartridge (1,8 ml) with the corresponding anesthetic into the cartridge holder. Make sure that during the introduction of the cartridge the cartridge head is directed forwards. Swing the cartridge holder back, whereupon the plunger has to be retracted against the spring resistance.
3. The plunger can be pushed forward several millimetres against the inserted cartridge; the plunger can be connected firmly with the plug of the cartridge.
Type 2 models: the front end of the plunger with the hooks are led into the gap of the hole plug. The connection is made by turning to the right of the knurled screw (=extension of the hooks). As soon as the hooks have been completely extended, the locking device to safeguard the connection is engaged and an aspiration is possible.
Push the plunger forwards with a light pressure to the solid plug and fix the aspiration help (arrow tip, corkscrew tip) into the solid plug of the cartridge.
4. After that, 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.
5. For checking if the needle is situated correctly on the cylinder cartridge, the flow of the anesthetic should be tested by a slight forward motion of the plunger. If there is a smooth flow of the anesthetic, the syringe is ready for application.
6. Please note that the injection must be done slowly. During aspiration the plunger respectively the necessary low-pressure for aspirating of liquid is effected by manual retraction of the plug in the cartridge. Please check the correct and tight fit of the aspiration help of the respective cartridge used before injection.
7. The withdrawal of the cartridge is effected in reverse order.

REPROCESSING - INSTRUCTIONS:

Due to the constructive design of the medical device, 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.

Procedure:	Automatic reprocessing
Preparations at the place of installation:	The syringe must be checked for any damage (coating, etc.) before each reprocessing. Damaged syringes must no longer be used. 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. Exception: Do not loosen/remove screws
Manual pre-cleaning:	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.
Cleaning:	medical devices must be put in a screen basin on the plug-in mode. Then start the cleaning process. 1. 4 min. pre-washing by means of cold water 2. Draining 3. 5 min. pre-washing with 0,5% Neodisher Mediclean, Dr. Weigert (Hamburg) 4. Draining 5. 6 min neutralization with 0,1% Neodisher Z, Dr. Weigert (Hamburg) (> 40°C) 6. Draining 7. 3 min flushing by means of DI-water (< 40°C) 8. 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 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 min (full cycle) 4. Drying time: at least 10 min
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 to +40°C.
Information on validation:	The following test instructions, materials and machines have been used for validation: Cleaning supplies: Neodisher Mediclean (alkalisch); Dr. Weigert; Hamburg Neutralization supplies: Neodisher Z; Dr. Weigert; Hamburg Cleaning / disinfection equipment: Miele G 7836 CD
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.

DISPOSAL:



Risk of Infection!

Cartridge syringes must be reprocessed before disposal. There are no special requirements for disposing of dental syringes. You must observe the laws and regulations applicable in the country of use.

REPAIRS & SERVICES

Do not carry out any repairs or changes to the product by yourself. Only authorized personnel of the manufacturer are responsible and provided for this. If you have any complaints, or information about our products, we ask you to contact us.

LIMITATIONS OF LIABILITY & GUARANTEE

The products are made of high-quality materials and are subjected to a quality control before delivery. Should errors nevertheless occur, please contact our service. However, we cannot guarantee that the products are suitable for the respective intervention. This is to determine by the user. We cannot accept liability for accidental or resulting damage.

Any type of product liability expires,

- in the event of damage due to improper storage, handling, cleaning and / or sterilization
- incorrect cleaning and sterilization
- failure to follow these instructions for use

REPORTING OF INCIDENTS

All serious incidents relating to the device must be notified to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

DEVEMED GMBH DOES NOT TAKE LIABILITY IF IT IS PROVIDED TO BE INFRINGEMENT OF THESE INSTRUCTIONS.

EXPLANATION OF SYMBOLS

	Manufacturer
	Manufacturing date
	Non sterile
	Attention
	Consider Instruction for Use
	CE-sign
	Batch
	Catalogue Number
	Medical Device

Revision: 26.05.2021