Instructions for Use
Suction Cannulas

MANUFACTURER

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Suction Cannulas: (Class IIa, Rule 6 / UMDNS: 10-212)

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

NON STERILE

CE 0483

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.

Attention

Please read the information in this instruction for use carefully. Improper handling and care as well as improper use can lead to premature abrasion or risks for patients and users. Please also note the imprints on the packaging.

INTENDED USE / INDICATION / MATERIALS

Intended Use/Indication

The intended use of these products is to aspirate saliva, water, blood, abrasion particles, bone chips and pieces of cement or impression material.

The surgical cannulas are intended for use in dentistry for diagnostic, conservative, endodontic and surgical treatments. They can therefore be used both invasively (e.g. saliva aspiration in diagnostics) and surgically invasively (e.g. suction of wound pockets).

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

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.

The products are not intended for use in direct contact with the central nervous system or for correcting defects in the heart or the central circulatory system.

Possible complications/side effects/risks

After contact with the instrument, hypersensitivity reactions can be triggered in a patient with material intolerance to stainless steel.

In case of such a reaction, the intervention must be stopped immediately and the necessary steps taken.

In the course of post market surveillance, further potential complications / side effects could be identified:

- wound infection
- carryover of bacteria

Warnings

- Use only for the intended use
- All specifications described in the accompanying documentation must be strictly observed.
- The instruments may only be used by persons who are specially trained or instructed for this purpose.
- Caution during handling and transport

Material

The suction cannulas are made of stainless steel according to DIN EN ISO 7153-1 and therefore biocompatible, corrosion-resistant and non-toxic in a biological environment.

Attention

The instruments may only be used by people who have been specially trained or instructed to do so.

INSTRUCTIONS FOR USE & SAFETY

The dental instruments must not be used as a lever.

When using dental instruments, users may be injured by sharp-edged tips or jamming of tissue.

The products must be checked for defects, cracks, notches or other damage before use. Damaged products must be sorted out.

NON STERILE

The products are delivered in a non-sterile state and must be completely cleaned, disinfected and sterilized by the user before the first and any further use.

COMBINATION PRODUCTS & ACCESSORIES

Our Suction Cannulas are produced with the following end pieces:

- Type A:Ø 6.00 (±0.10) mm conical
- Type B:Ø 6.00 (±0.10) mm cylindrical
- Type C:Ø 11.00 (-0.20) mm cylindrical
- Type D:Ø 16.00 (-0.20) mm cylindrical

Our Suction Cannulas are compatible with the following cannula connectors (KVST) (not from devemed).

KVST-#	Manufacturer	REF
1	Dentsply Sirona	# 5950084
2	Duerr Dental AG	# 7600?020-00 # 7600?020-55 # 7600?025-00 # 7600?025-50
3	Duerr Dental AG	# 7600?010-08 # 7600?010-04
4	Duerr Dental AG	# 7600?010-30 # 7600?010-07

Allocation of product ⇨ compatible cannula connector (KVST):

REF	Type	KVST #	REF	Type	KVST #
02-2421	C	4	02-2427-60	A	1, 2
02-2421-2	C	4	02-2428-15	A	1, 2
02-2421-3	D	3	02-2428-30	A	1, 2
02-2422	A	1, 2	02-2428-50	A	1, 2
02-2423	A	1, 2	02-2429-00	A	1, 2
02-2423-2	A	1, 2	02-2430-00	A	1, 2

02-2425	A	1, 2	02-2431	B	1, 2
02-2426-30	A	1, 2	02-2431 L	B	1, 2
02-2426-40	A	1, 2	02-2431-15	A	1, 2
02-2426-60	A	1, 2	02-2431-30	A	1, 2
02-2427-30	A	1, 2	02-2432-15	A	1, 2
02-2427-40	A	1, 2	02-2432-30	A	1, 2

Prior to use, make sure that the required instruments are available and compatible for combination with the appropriate hose systems and adapters.

REPROCESSING

Improper reprocessing of the instruments may cause inflammatory reactions and infections.

The products are in principle able to be reprocessed. The service life of the instruments is only negligibly affected by the number of reprocessing cycles performed provided the reprocessing is carried out according to the validated processes described here. The service life depends more on gentle and careful handling of the instruments in all phases of use, reprocessing, transport, and storage. The end of the service life is reached when any signs of wear and tear or defects that limit the functioning of the product are detected during the prescribed visual and functional inspection. The instruments in this case must be identified and excluded from further use and must be replaced by functioning instruments. The end of the useful life is also reached if clear identification of the instrument is no longer assured as a result of missing labeling. The products must no longer be reused:

- If there is damage on the surface (e.g., rust formation, cracks, sharp edges, or similar)
- If the inscription is no longer legible and the traceability is thus no longer assured
- After treatment of a patient infected with Creutzfeldt-Jakob disease
- If a secure connection between the suction cannula and the cannula adapter can no longer be made
- If the suction cannula no longer performs its function

In the cases indicated, the products must be disposed of.

PREPARATION & TRANSPORT

The products are delivered non-sterile. They must therefore be cleaned and sterilized before use on the patient.

Transport of the instruments in a closed container to the reprocessing department in order to avoid damage to the instruments and contamination of the environment.

CLEANING & DISINFECTION

Principles

For cleaning and disinfection, if possible, an automated procedure [WD (washer-disinfector)] should be used. A manual procedure – even using an ultrasound bath – should only be used according to country specific requirements (e.g. in Germany for critical B products automated procedure binding) and if an automated procedure is not available due to the significantly lower effectiveness and reproducibility.

Pretreatment must be carried out in both cases.

Pretreatment

Immediately after use (within maximum 2 h), large impurities must be removed from the products. If observation of this time is not possible in consequence of duration of application or of organizational reasons, it is the responsibility of the user to define and validate measures in order to avoid complete drying of contamination:

1. Disassemble the products as possible
2. Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).
3. Insert the disassembled products for the predefined soaking time in the pre-cleaning bath (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the pre-cleaning by completely brushing all internal and external surfaces (at the beginning of the soaking time). The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel.
4. Activate the ultrasound for an additional minimum soaking time (but not less than 5 min).
5. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Rinse all lumina of the products at least three times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).

When selecting the cleaning agent. ensure that,

- it is generally suitable for cleaning invasive medical devices made of metals and plastics
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- the cleaning agent is compatible with the products

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent or the cleaning/disinfecting agent as well as the specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

Automated Cleaning/Disinfecting [WD (Cleaning and Disinfection Device)])

When selecting the WD, ensure that,

- the WD generally has verified effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
- if possible, a tested program for thermal disinfection (A0 value ≥ 3000 or – for older devices – at least 5 min at 90 °C/194 °F) is used (in chemical disinfection danger of disinfecting agent residues on the products),
- the program used is suitable for the products and contains sufficient rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents),
- for rinsing only sterile (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used,
- air used for drying is filtered (oil-free, low-bacteria and low-particle) and
- the WD is regularly maintained, inspected, and calibrated.

When selecting the cleaning system, ensure that,

- it is generally suitable for cleaning medical instruments made of metals and plastics,
- providing no thermal disinfection is used – a suitable disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that it is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent and, if applicable, the disinfecting agent as well as specifications for rinsing must be adhered to.

Procedure:

1. Disassemble the products as much as possible
2. Place the disassembled products into the WD. Ensure that the products do not touch Enable active rinsing by connecting to the WD rinse port.
3. Start the program.
4. Disconnect the WD and remove the products after the program has completed.
5. Inspect and pack the products as soon as possible after removal.

The verification of products' general suitability for effective automated cleaning and disinfecting was provided by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher MediClean forte pre-cleaning and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg). Here, the procedure described above was taken into consideration.

FUNCTIONAL TESTING AND PACKAGING

The products must be checked for cleanliness and functionality after preparation and before sterilization. If necessary, the reprocessing process must be repeated until the product is optically clean. In the event of damage to the product (e.g. corrosion, cracks, etc.), the products may not be used further.

Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) in accordance with the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA-Clearance)
- suitable for steam sterilization (temperature stability up to at least 138 °C (280 °F) sufficient steam permeability)
- sufficient to protect the products or sterilization packaging from mechanical damage
- - undergo regular maintenance according to the manufacturer's specifications (sterilization containers)
- do not exceed a maximum weight of 10 kg per package/contents of the sterilization container

STERILIZATION

For sterilization, only the following sterilization methods may be used; other sterilization methods are not allowed.

Steam sterilization:

- fractionated vacuum procedure (with sufficient product drying)
- Steam sterilizer in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA-Clearance)
- validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

Country	Fractionated vacuum procedure
Germany	at least 5 min at 134 °C (273 °F)
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min
France	at least 5 min at 134 °C (273 °F) if required for prion inactivation sterilization time 18 min
other countries	at least 5 min at 132 °C (270 °F) / 134 °C (273 °F)

Verification of the general suitability of the products for effective steam sterilization was provided by an independent, governmentally accredited and respected (§ 15 (5) MPG) test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum procedure, as well as the instrument oil LAWTON MEDOIL. Here, the typical conditions in the clinic and medical practice and the procedure described above were taken into consideration.

Notice:

Further details and information on cleaning, disinfection and sterilization can be found in the document

AA_PG00-001-EN_20-08

which can be found by following this link

https://www.reicodent.de/en-US/downloads/

and is available for download.

STORAGE

There are no specific product storage requirements. However, we recommend storing the sterilized instruments in a dry, clean and dust-free environment. No indication of durability or functional restriction for the products after manufacture is given, if they are stored properly.

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.

HANDLING

The products must be handled and stored carefully. Damage or scratches can significantly affect the strength and fatigue resistance of the product. The products must not be overstressed by twisting or levering (with exception of root elevators), as this can damage or break instrument parts.

DISPOSAL

Risk of Infection!
The product or parts thereof may be contaminated after use. Clean and disinfect the product before disposal.

The disposal of the products, packaging material and accessories must be carried out in accordance with the applicable national regulations and laws.

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 aterilization
- 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
	Non sterile
	Attention
	Consider Instruction for Use
	CE-sign with ID number of Notified Body
LOT	Batch
REF	Catalogue Number
MD	Medical Device