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Instruction for use suction cannulae & suction elevator for ENT

Scope of validity:

034903FX, 034905FX, 034907FX, 034913FX, 034915FX, 034917FX, 035300FX, 035303FX, 035304FX, 035400FX, 035403FX, 035404FX, 035500FX, 035501FX, 035601FX, 434100FX, 434103FX, 049702FX, 049703FX, 049704FX, 049712FX, 049713FX, 049714FX, 049715FX, 049802FX, 049803FX, 049804FX, 110106FX, 110107FX, 110108FX, 110109FX, 110110FX, 110112FX, 110115FX, 110116FX, 110118FX, 110120FX, 110122FX, 110125FX, 111106FX, 111107FX, 111108FX, 111109FX, 111110FX, 111112FX, 111115FX, 165102FX, 165602FX, 165603FX, 166205FX, 166206FX, 166207FX, 166208FX, 166210FX, 166212FX, 166215FX, 166218FX, 166220FX, 166222FX, 166225FX, 166230FX, 168607FX, 166310FX, 166313FX, 166315FX, 166325FX, 166320FX, 167105FX, 167107FX, 167108FX, 167109FX, 168601FX, 168602FX, 168603FX, 168604FX, 168605FX, 168606FX, 168608FX, 168100FX, 168205FX, 168207FX, 168209FX, 168212FX, 168612FX, 169120FX, 169124FX, 169126FX, 250106FX, 250107FX, 250108FX, 250110FX, 250112FX, 250115FX, 250208FX, 250210FX, 305900FX **(*1)**, 532126FX, 532127FX, 532128FX, 541125FX, 541130FX, 049750FX**(*2)**, 049751FX**(*2)**, 049752FX**(*2)**, 049753FX**(*2)**, 111820FX**(*2)**, 111821FX**(*2)**, 111822FX**(*2)**, 111720FX**(*2)**, 111721FX**(*2)**, 111722FX**(*2)**,

1. USED SYMBOLS

	Manufacturer		Consult Instructions
	Caution		Article number
	Production batch, batch		Non steril
	CE- labeling and ID- number of the notified body DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt am Main For the abovementioned reusable suction cannulae & suction elevator (ENT) risk class IIa		

2. PURPOSE OF THIS INSTRUCTION

This document describes the correct handling and function of the product as well as the recommended treatment.

It must not be used for the performance or training of surgical operations. Therefore we assume that the relevant regulations, norms and recommendations (such as the RKI http://www.rki.de and the AKI http://www.a-k-i.de) are known and we therefore restrict ourselves by providing the user with such instructions and information that are interest for our products.

It is absolutely necessary that the requirements and specific information in these instructions shall be complied and taken into account. Otherwise the products for the clinical application can not be used.

3. INTENDED USE

The intended use of suction instruments is the aspiration of blood and other liquids from the surgery area in the course of a surgical or diagnostic operation in the ENT.

With Flushing Connector: Inducing (flushing) of physiological saline solution in the surgery area in the course of a surgical or diagnostic operation in the ENT. The group of the suction elevators (*1) and defined-edge suction tubes(*2) are determined for the increase or erection of impressed bone fragments and for the separation of tissues (e.g. periosteum).

4. INDICATIONS

Usage for ear/ nose/ throat (ent) examinations only.

5. CONTRAINDICATIONS

The instruments may be used exclusively for designated use in the ear/ nose/ throat (ent) area and only qualified medical experts who have been adequately trained in suction procedures and in the use of aspirators. Suction cannulae must not be used for suctioning explosive, easy flammable or corrosive liquids. Compliance with proper surgical procedures and techniques is the responsibility of the physician. Each physician must evaluate the appropriateness of the treatment based on his own knowledge and experience.

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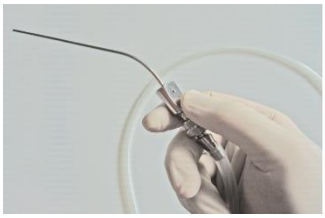
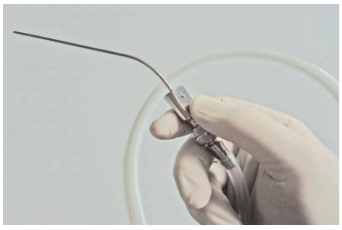
6. HANDLING

Connect the suction tube.



Suction: Cover the cut-off hole with your thumb in order to allow the built up vacuum at the instrument tip for effective suction.



No suction: release the cut-off hole to stop or lower the vacuum at the instrument tip.

Some suction cannulas have a LUER connection in addition to the suction tube. This standardized connection allows the connection to a suction adapter with LUER cone, see chapter 10 combination with other products.

7. SAFETY INSTRUCTION

The products must be used only by qualified medical experts and in medical facilities.

- Check the products for completeness and damage after their delivery
- Read the instructions and comply with the same
- Never leave the surgical suction pump unattended when it is switched on.
- Careful handling of the product and for proper use only, see chapter 3 Proper use

The state of the art and national legislation request the compliance of validated processes.

- The user is generally responsible for the validation of his process. Ensure that the treatment, material and staff are capable of achieving the required results.

Application:

- Do not use the product for levering, scraping or penetrating
- Do not bent the product if the label and product description do not identify the product as “bendable”
- Do not use the product with monopolar HF- instruments
- Do not use the product for inducing or suctioning of flammable gases or liquids
- Caution of using lasers. Glares, caused by reflection on the product, are possible
- Handle suction suction elevators and defined-edged suction tubes with great care – the suction end may be sharp, risk of injury
- Using the cut-off hole with the thumb only
- Never leave the product unattended when the suction pump is switched on
- Have a replacement product prepared

Infection hazard for patients and medical professionals. The products shall be delivered in non-sterile condition and are reusable.

- clean/ disinfect and sterilize the product before the first and each following use.
- bring the product to the decontamination area after its use (observe all applicable protective measures, to avoid contamination of the environment).
- We are not responsible for the use of the product, when it is used by patients with Creutzfeldt Jacob disease (CJD) or its variants.

Risk of injury due to defect product!
- check all functions before its use.
- use only a proper product.
- respect the valid local regulations during all manual cleaning and drying procedures.
- during storage, transport and preparation, ensure that the product is not subjected to mechanical loads.

Respect the following measures to avoid material damage:
- Do not expose the product to impacts

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- deposit the product carefully
- transport and store the product separately and safely: Use a filter basket or container

8. PREPARATION FOR USE

a. Function control

Hazard of injury due to defect instrument!
- perform a function control before the first and each following use (i.a. operability of the product)
- use only a proper product
- clean/disinfect and sterilize the product before the first and each following use
- ensure that no parts are missing or loose
- ensure that the instrument does not have residues of cleaning or disinfection means
- examine product on contaminations and damages of any type, such as dents, scratches, and sharp edges
- examine consistency (tube/pipe) with compressed air or cleaning stylet

b. Provision:

- clean/ disinfect and sterilize the product before the first and each following use
- Per patient one sterile set of tubes

9. INSTRUCTIONS FOR REPROCESSING ACCORDING TO DIN 17664

Due to the product design and used materials, no limit of maximum reprocessing cycles can be defined. The lifetime of a medical device is determined by their function and care handling.

Safety instructions:

Take special care when cleaning narrow lumina or bore! Our products are generally delivered in non-sterile form and must be prepared and sterilized before their first use, according to the following described procedures.

Restriction of reprocessing: Frequent reprocessing has a low impact on our instruments. The end of the product's lifetime is normally determined by wear and damage through use.

For return and repair, the defect products must go through the whole reprocessing process.

a. Preparation at the Point of Use:

Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.

Remove surface soiling with disposable cloth/ paper cloth.

b. Transportation:

Safe storage and transportation to the reprocessing area to avoid any damage.

c. Preparation for Decontamination:

The devices must be reprocessed in an open or disassembled state.

d. Cleaning:

Manual cleaning process:

1. Flush product under cold town water (< 40°C), until all visible contaminations are removed. Sticking contamination can be removed with a smooth brush or rather with the enclosed cleaning mandrel.
2. Insert product in an enzymatic cleaner (when ultrasound is used, sonication times of at least 3 minutes and frequencies of at least 35 kHz) have been tried and tested. In doing so, the instructions from the manufacturers of the cleaning agents must be followed.
3. Flush the product under regular town water to remove the cleaning agents.

Automated Cleaning:

1. 3 min pre-cleaning with pulsed activation of ultrasonic cleaning with 25°C warm deionized water
2. draining
3. 20 minutes cleaning with pulsed activation of ultrasonic cleaning at 40°C with 0.35% enzymatic cleaner M20029 3E-Zyme Scope Plus (Medisafe)
4. draining
5. 2 minutes intermediate rinsing with 25°C warm deionized water
6. 1 minute rinsing with 25°C warm water

Special instructions of cleansing machine manufacturer must be followed.

e. Disinfection:

Manual disinfection:

1. Immerse product in an enzymatic disinfection agent. In doing so, the instructions from the manufacturers of the disinfection agents must be followed.
2. Flushing of the product in deionized water.

Automated Cleaning:

Automated Thermal Disinfection in washer/ disinfector under consideration of national requirements in regards to A_0-Value.

f. Drying:

Manual drying:

Manual drying with a lint-free cloth. The product can be heated up to a max. temperature of 140° In order to avoid residual water in cavities, it is recommended that they are inflated by sterile compressed air.

Automated Drying:

Automatic drying through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

g. Functional Testing, Maintenance:

- Visual inspection for cleanliness.
- Assembling and functional testing according to instructions of use.
- If necessary perform reprocessing process again until the instruments are visibly clean.

h. Packaging:

Appropriate packaging for sterilization according ISO 11607 and EN 868.

i. Sterilisation:

- 3 pre-vacuum phases
- Sterilization temperature 132°C / 269.6°F
- Holding time: 1.5 minutes (half cycle)
- Drying time: 1 minute

j. Storage:

No special requirements for storage.

k. Reprocessing validation study information:

The following test instructions, materials & machines have been used in this validation study:

Used tap water must comply with the council directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

Detergent	0.35% enzymatic detergent (M20029 3E-Zyme Scope Plus (Medisafe)
washer/ disinfector	Niagara SI PCF (Medisafe)
Steam-sterilizer	Selectomat HP666-1HRED (MMM)
Validation report	Cleaning: 10109011407-7-1 ; Sterilization: 09715

10. COMBINATION WITH OTHER PRODUCTS

Suction pump: Suction pressure up to 0,95 bar.

For intended use of the suction pump, the instruction of the manufacturer must be followed.

Connection tube: Medical flexible tube (made of silicone) with 25 Charr / French diameter.

Suction adapter: Suction instruments with LUER connector:

Suction cannula by House (166205FX - 166230FX), Suction cannula malleable (166310FX - 166325X) and suction tube by Schuhknecht (169120FX – 169126FX)
can be combined with the suction adapters by House (165602FX, 165603FX) and the suction adapter by Wullstein (165102FX).
A suction tube by Zöllner (168100FX) can be combined with tips by Zöllner (168205FX, 168207FX, 168209FX, 168212FX).

11. ADDITIONAL INSTRUCTIONS

It is the duty of the user to ensure that the reprocessing process including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

12. SERVICE AND REPAIR

Only by the use of original parts, the original technical specifications and operational safety of the product are ensured. If a reparation is performed by a repair center that is not authorized by the FENTEX medical GmbH. all guarantee claims and rights with regards to the product shall be null and void. Reparations are only performed by the FENTEX medical GmbH, when this is economical in relation to the new price of the product.

- In case of return (such as for reparation or complaint), clean, disinfect and sterilize the product.

- The product may only be repaired by the FENTEX medical GmbH (return thereto the defect product)
- The product should ideally be returned in the original package (if this is not possible, pack the product safely for transport). The FENTEX medical GmbH is not liable for any damages caused by improper shipment.

13. DISPOSAL

- Comply with the country-specific rules and laws for the disposal of medical products
- Alternative: Return the product to the manufacturer. Please follow chapter 13. Service and Repair:
"In case of return (such as for reparation or complaint), clean, disinfect and sterilize the product."