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Instruction for use suction punch & suction forceps for ENT

Scope of validity:

234935FX, 234945FX, 235000FX, 235001FX, 235002FX, 235004FX, 235200FX, 235201FX, 235202FX, 235204FX, 235300FX, 235301FX, 236900FX, 236901FX, 236902FX, 237000FX, 237001FX, 237002FX, 238101FX, 238102FX, 238201FX, 238202FX, 238402FX, 238412FX

1. USED SYMBOLS

	Manufacturer		Consult Instructions
	Caution	REF	Article number
LOT	Production batch, batch	NON STERILE	Non steril
CE 0297	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 forceps and suction punch (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

These instruments are intended for cutting mucous membrane and soft tissue. They can be used alone or in conjunction with a roller pump (maximum 0.8 bar suction power) for suction or extraction by suction (connection to all common systems). Connection variants: Luer-lock or silicone tube.

4. INDICATIONS

Usage for ear/ nose/ throat (ent) examinations and treatment only and a period of less than 60 minutes.

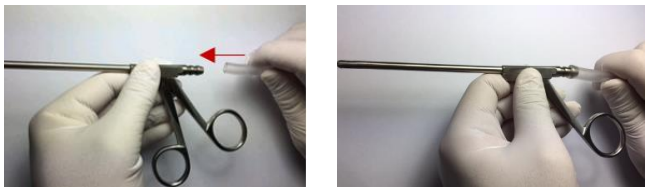
5. DESCRIPTION AND PRODUCT-SPECIFIC DETAILS

Application: ENT

Reprocessing: ☒ Yes ☐ No

Product is dismountable: ☐ Yes ☒ No

Combinable product: ☒ Yes ☐ No



Illust. 1-2: Connection of a suction instrument (exemplary)

6. CONTRAINDICATIONS

The instruments may only used according to their intended use in the area of sinuscopy (ENT) by suitable trained and qualified personnel.

7. SAFETY INSTRUCTIONS

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.
- Store the product only for proper use, 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.

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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

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 (e.g, 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

c. Servicing

- for instruments with moving parts, a small amount of physiologically harmless oil (paraffin oil DAB 8 or Ph.Eur. or USP XX) should be applied to the joints.

9. INSTRUCTIONS FOR REPROCESSING ACCORDING TO DIN 17664

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 fixating detergents or hot water (40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.

b. Transportation:

Safe storage and transportation in a closed container to the reprocessing area in order to avoid any damages or contamination.

c. Preparation for Decontamination:

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

d. Pre-Cleaning:

- Place instruments in cold tap water for 5 minutes
- Rinse for 10 seconds with a water pressure gun (3,8 bar static)
- Clean with a soft brush until all visible contaminations are removed
- Clean for 10 minutes in an ultrasonic bath (40°C, 0,5 % alkaline cleaner)
- Rinse for 10 seconds with a water pressure gun (3,8 bar static)

e. Cleaning:

Place the instruments in an open or disassembled state on a loading rack or sieve tray and start the cleaning process:

- 4 minutes pre-cleaning with cold tap water (5-15°C)
- draining
- 5 minutes cleaning at 55°C with 0,5% alcaline detergent
- draining
- 3 minutes neutralisation with warm tap water (> 40° C) and perhaps neutralizer
- draining
- 2 minutes rinse with warm tap water (> 40° C)
- draining

f. Desinfection:

Automated Thermal Disinfection in washer/ disinfector under consideration of national requirements in regards to A_0-Value (ISO 15883)

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g. 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.

h. 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..

i. Packaging:

Appropriate packaging for sterilization according ISO 11607 and EN 868.

j. Sterilisation:

Sterilization of instruments by applying a fractionated testing (according ISO 17665-1) under consideration of the respective country requirements.

We recommend a fractionated pre-vacuum procedure with 3 pre- vacuum phases:

- Heat up to a minimum sterilization temperature of 132°C
- Shortest holding time: 3 minutes
- Time to dry: at least 10 minutes

k. Storage:

No special requirements for storage.

l. 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	Alcaline detergent deconex 28 Alka One
Washer/ Disinfector	Miele G 7735 CD – Vario-TD program
Loading rack	Connected to MIC-loading rack E 450
Steam-sterilizer	Selectomat HP666-1HR
Validation report	Cleaning: 09808011406; sterilization: 09808022806

10. 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.

The instruments can be disposed to the usual disposal by suitable trained and qualified personnel.

11. 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.