Instructions For Use – ENT Suction Punch & Suction Forceps

PURPOSE OF THIS INSTRUCTION

This document describes the correct handling and function of the product as well as the surgical procedure(s) for which it is recommended. It should not be used for training in surgical operations. We assume that the relevant regulations, standards, and recommendations (such as www.a-k-i.org) are known and understood; therefore, we restrict the scope of this document to providing the user with instructions and information pertaining specifically to these products. It is necessary that the requirements and specifications contained herein are complied with and adhered to, otherwise the products cannot be effectively used for their clinical application.

INTENDED USE

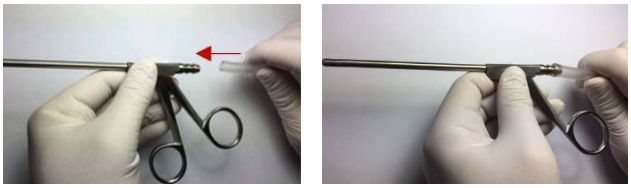
These instruments are intended for cutting mucous membrane and soft tissue. They can be used alone or in conjunction with a roller pump (maximum 0.8 bar suction power) for suction or extraction by suction through connection to all common systems. Connection variants: Luer-lock or silicone tube.

INDICATIONS

For use in ear/ nose/ throat (ENT) examinations and treatment only, and for a period of less than 60 minutes.

PRODUCT DETAILS

Application: ENT
Reprocessing: ☒ Yes ☐ No
Dismountable Product: ☐ Yes ☒ No
Combinable Product: ☒ Yes ☐ No



Connection of a suction instrument

CONTRAINDICATIONS

These instruments may only be used in accordance with their intended use in the area of sinuscopy (ENT) by suitably trained and qualified personnel.

SAFETY INSTRUCTIONS

- The products must be used only by qualified medical experts in medical facilities.
- Check the products for completeness and damage after delivery.
- Read and comply with these instructions.
- Never leave the surgical suction pump unattended when it is switched on.
- Use the product only for its intended use (above).
- Process validation is typically required to comply with applicable regulations and international standards. The user is generally responsible for the validation of their own processes. Ensure that the treatment, materials, and personnel can achieve the necessary results.

NON STERILE

Infection hazard for patients and medical professionals:
This product is delivered in non-sterile condition and is reusable.

- Use only a properly functioning product with no damaged or missing parts.
- Clean, disinfect, and sterilize the product before the first use and each following use.
- Bring the product to the decontamination area after use and 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 on patients with Creutzfeldt Jacob disease (CJD) or its variants.
- Respect the applicable regulations during all manual cleaning and drying procedures.
- Ensure the product is not subjected to heavy mechanical loads during storage, transport, or preparation.

PREPARATION FOR USE

A. Function Control

Risk of injury if the product is defective!

- Check all instrument functions prior to use to ensure the operability of the product.
- Use only if properly functioning and undamaged.
- Ensure that no parts are missing or loose.
- Ensure that the instrument does not have residue from cleaning or disinfection processes.
- Examine the product after contamination or damage of any type (including dents, scratches, and sharp edges).
- Examine the consistency of the tube/pipe with compressed air or a cleaning stylet.

B. Provision

- Clean, disinfect, and sterilize the product before the first use 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.

INSTRUCTIONS FOR REPROCESSING ACCORDING TO DIN 17664

Frequent reprocessing has a low impact on these instruments. The end of the product's lifetime is normally determined by wear and damage through use. For repair services, the defective products must first be reprocessed.

A. Preparation at the Point of Use

Remove gross soil and debris by submerging the instrument in cold or lukewarm water (<40°C / <104°F) immediately after use. Do not use fixating detergents or hot water (>40°C / >104°F) as this can cause the fixation of residue which may influence the result of reprocessing.

B. Transportation

Store safely and transport in a closed container to the reprocessing area to avoid damage or contamination.

C. Preparation for Decontamination

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

D. Pre-Cleaning

- Place the instruments in cold 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 contamination is removed.
- Clean for 10 minutes in an ultrasonic bath (40°C / 104°F, 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 water (5-15°C / 41-59°F).
- Draining
- 5 minutes cleaning at 55°C (131°F) with 0.5% alkaline detergent.
- Draining
- 3 minutes neutralization with warm water (>40°C / >104°F) and perhaps neutralizer.
- Draining
- 2 minutes rinse with warm water (>40°C / >104°F).
- Draining

F. Disinfection

Automated Thermal Disinfection in washer/disinfector with consideration for national requirements regarding A0- Value (ISO 15883).

G. Drying

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

H. Functional Testing and Maintenance

- Visual inspection for cleanliness.
- Assembly and functional testing according to these instructions.
- If necessary, perform reprocessing again until the instruments are visibly clean.

I. Packaging

Use appropriate packaging for sterilization according to ISO 11607 and EN 868.

J. Sterilization

Sterilize the instruments with fractionated testing (according to ISO 17665-1) under consideration of the applicable regulatory requirements.

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

- Heat up to a minimum sterilization temperature of 132°C (270°F).
- Shortest holding time: 3 minutes.
- Time to dry: At least 10 minutes.

K. Storage

No special requirements for storage, but it is recommended to store in a dry location between 1-35°C (34-95°F)

L. Reprocessing Validation Study Information

The following test instructions, materials, and machines were used in the validation study:

Detergent	Alkaline 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

ADDITIONAL INSTRUCTIONS
It is the responsibility of the user to ensure that their reprocessing procedure (including resources, materials, and personnel) can achieve the necessary results. International standards and often national law require these processes and associated resources to be validated and maintained properly. The instruments should be disposed of in accordance with applicable regulations by suitably trained and qualified personnel.
SERVICE AND REPAIR
The original technical specifications and operational safety of the product are ensured only through the use of original parts. If repairs are performed by a service provider that is not authorized by Sontec Instruments, all warranty claims and rights regarding the product shall be null and void. Repairs should only be performed by Sontec Instruments. • **If you return a used product (such as for repair or complaint), you must first clean, disinfect, and sterilize the product. The shipment must include a Certificate of Sterilization to verify contamination status. The forms and related instructions can be found online at https://sontecinstruments.com/repair/.** • The product may only be repaired by Sontec Instruments to avoid nullifying the warranty. • The product should ideally be returned in its original packaging. If this is not possible, please package the product safely for transport. Sontec Instruments is not liable for any damage caused during shipment as a result of improper packaging.

SYMBOLS USED ON LABELING		
Manufacturer	Consult Instructions for Use	
REF Reference Number	LOT Lot Number	QTY Quantity
Caution! See Warnings and Precautions.	NON STERILE Packaged Non-Sterile	Rx Only U.S. Federal law restricts this device to sale by or on the order of a physician.
Handling & storage in a dry location.	1°C 35°C Handling & storage between 1°C – 35°C.	