Instructions for use

Reusable Instruments

Manufacturer: **Strauss Surgical**
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Products:

- Flexible Grasping Forceps
- Flexible Biopsy Forceps
- Spoon Forceps
- Scissors
- Arthroscopic Instruments
- Stone Grasping Forceps
- Spinal-Endoscopy Forceps
- Spinal-Endoscopy Punches
- ENT-Punches
- Arthroscopic Punches
- Arthroscopic Probe
- Curette
- Suction Punches
- Laparoscopic-Needle holder

By acquiring this instrument, you will receive a high-quality product, the proper handling and use will be described below.
To minimize the risk to patients and users, please read the instructions carefully. The use, disinfection, cleaning, and sterilization ofthe instruments may only be carried out by trained specialists.

Symbolism

Note: additional help or other useful information

Indicates a possible danger for persons or tangible property

▪ Marking of Products in accordance with the guideline 93/42 EWG which are placed on the market

Symbol for „unsterile “

Symbol for „store in a dry place “.

Symbol for „Keep away from direct sun “.

Testing
The instruments must be checked for their proper functioning before each use.
Damage to the surfaces such as scratches, cracks, nicks, notches, etc., as well as bent parts, means that they may not be used.
The products must be repaired or be handed over to the clinical disposal. Do not use damaged products!

Application Area
Our instruments are standard instruments for invasive and surgically invasive treatments and procedures. The physician is responsible for the selection of the instrument for certain applications or the operative use. The doctor is also responsible for adequate training and adequate information from the accompanying staff and for sufficient experience in the handling of the instrument.

Handling
The instruments must not be overloaded by twisting or leaking, as this can lead to damage or breakage of the instrument parts

Risks

- Injury of nerves, vessels and tissues
- Bleedings
- Infections

Intricacies
In general, complications rarely occur. The frequency and severity of complications depend on the type of examination.

Combination with other products / instruments
The products of Strauss Surgical LLC may under no circumstances be combined with products, components and instruments from other manufacturers. Combinations with products from other manufacturers can adversely affect the results of the intervention and are not permitted since the components used may not be compatible with each other.
It is recommended to use only the instruments and accessories of Strauss Surgical LLC.

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Disposal

If the instruments can no longer be repaired and reprocessed, they should be handed over to the clinical disposal

Materials

The materials used are stainless steels according to DIN EN ISO 7153-1

Instructions for preparation

Procedure:	• **Cleaning** • **Disinfection** • **Sterilization with moist heat (DIN EN ISO 17665-1)**
Warnings: 	The instruments are supplied non-sterile and must be cleaned, disinfected, and sterilized before use. The instruments may only be prepared by those persons who have the necessary specialist knowledge and training and are able to assess the risks arising with the corresponding effects.
Restriction of reprocessing:	Frequent reprocessing has little effects on the instruments. The end of the product life is normally determined by wear and damage by use. The products should then be disposed of in accordance with the usual disposal procedures. Do not use damaged products!

Instructions	
Preparation at the place of use:	The instruments should be disinfected and cleaned as soon as possible after use. Remove surface contamination with a disposable cloth / paper towel. Do not use fixing agents or hot water (> 40 ° C) as this can lead to the fixing of residues and influence the cleaning results. Instruments must never be placed in a physiological saline solution because long contact will lead to pitting and rust. In the case of dry disposal, the instruments for avoiding incrustation and corrosions must be machined immediately. For this purpose, the instruments must be placed on machine-suitable instrument carriers. Please ensure that joint instruments such as scissors, needle holders, clamps, etc. are opened. In the disposal methods avoiding of long waiting times until processing is recommended, e.g., overnight or weekend, because of the risk of corrosion.
Preparation for decontamination:	If instruments can be disassembled, disassemble them before preparation.
Option 1	
Recommended method of cleaning: Manual	If possible, the instruments must be brushed under running water with a soft brush until all visible contamination has been removed. For cavities, bores and threads, pressurize (pressure at least 4 bar) for at least 10 seconds with a washing gun. If the brushing and / or rinsing does not lead to the desired result, the instruments must be placed in cold water for a minimum of 5 minutes. The instruments must then be placed in an ultrasonic bath for 10 minutes and sonicated in the cleaning liquid (0.5%). After removing the instruments, they must be flushed with the washing gun.
Ultrasonic Cleaning:	• Use an ultrasound device suitable for medical use • The ultrasonic cleaning bath should be heated to a temperature recommended by the manufacturers of the cleaning or disinfecting / disinfecting solutions before cleaning • As a rule, temperatures between 40 ° C and 50 ° C facilitate the cleaning effect • Place instruments in the screen basket • Insert instruments in the ultrasonic cleaning bath with approx. 40 kHz output power for 5 min • After ultrasonic cleaning, the instruments must be rinsed and dried with clean running water • The cleaning or cleaning / disinfecting solutions used must be determined according to the manufacturer's instructions • Avoid overdosing the cleaning or cleaning / disinfecting solutions • The cleaning or disinfecting solution which is used must be suitable for the cleaning of steel products The following points should also be considered:

	• The screen basket of the ultrasound device must be sufficiently large and deep to ensure a complete immersion of the instruments • Products must be completely covered by the cleaning solution • Use only those screens which do not impair the cleaning effect • Do not overload the screen basket • Avoidance of "sound shadow" • Fill all channels and cavities with a cleaning solution without air bubbles • Remove the instruments from the ultrasonic unit • Blow through all channels with air to remove fluid residues • The cleaning solution in the ultrasonic cleaning bath must be changed at least on a daily basis
Rinsing	• Use cleaned instruments in basins with clean tap water, use fresh tap water for each flushing operation. • Flush all channels fully and thoroughly with water • Thoroughly rinse the outer surfaces of the instruments with tap water • Remove instruments from the water • Blow all channels with air to remove rinsing water residues
Disinfection: Manual	• The disinfecting solution used must be suitable for disinfecting steel products • Place cleaned instruments in the tub with disinfectant solution • Fill all channels and cavities with a disinfectant solution without air bubbles • Cover the tub with its cover • Observe the concentration and exposure time of the disinfectant in accordance with the manufacturer's instructions • Remove instruments from fresh disinfectant solution with fresh disposable gloves
Option 2	
Recommended method for cleaning and disinfection Automatic	**Cleaning disinfecto : G 7836 CD (Miele)** Cleaning Program: **C xivario**

Step	Time (min)	Process step	Reagent	Temp. (°C)
1	3	Pre-Cleaning	Tap water	cold
2		Drain the water		
3	3	Cleaning	Tap water Dosage: 0.5% Sekumatic FR (Ecolab) at 45°C	55
4		Drain the water		
5	2	Cleaning	Tap water Dosage: 0.5% Sekumatic FR (Ecolab) at 45°C	55
6		Drain the water		
7	1	Neutralize	Deionized water Dosage: 0.1% Sekumatic FNZ (Ecolab)	cold
8		Drain the water		
9	1	Rinsing	Deionized water	cold

Disinfection: Automatic	Carry out the machine thermal disinfection according to the national requirements for the A0 value (see ISO 15883)
Neutralization/ Rinsing	• Insert disinfected instruments in the basin / tub with microbiologically sterile water, use fresh water for each instrument. • Thoroughly rinse the outer surfaces of the instruments, all channels and cavities with water to remove any disinfectant residues. • Remove the instrument from the water.
Drying and function test:	• Dry the exterior surfaces with lint-free cloth and with compressed air • Dry all channels and cavities completely with compressed air

	• Check the instruments for correct operation • Oil instrument with Sterilit JG 600
Maintenance, inspection: ⚠	Damaged instruments should be sorted out and be repaired. The instruments must be sterilized before shipment to the repair service.
Packaging:	The instruments should be packaged in a suitable container or sterilization package (EN 868, Part 1- 10) before sterilization. The sterilization packaging depends on the sterilization process, on transport and storage. The packaging has a considerable influence on the sterilization result. The packaging has to be chosen so that the instruments fit into the packaging. Use a sterilization indicator for packaging and note the sterilization and expiration date on the packaging.
Recommended method for sterilization:	*Recommended method:* — Steam sterilization with saturated steam with fractionated vacuum (DIN EN ISO 17665-1) *Recommended temperature:* — 134 °C *Recommended air pressure:* — 3 bar *Holding period:* — 3 - 5 min *Drying time:* — ≥ 10 min After sterilization, check sterilization packaging for damage, check sterilization indicators.
Storage: ☂ ☀	Sterilized instruments have to be stored in sterile packaging in a closed container, protected from dust, moisture and temperature fluctuations.

Additional information:	Further notes on the preparation of medical devices: • Internet: http://www.rki.de • Internet : http://www.a-k-i.org • Requirements for hygiene in the processing of medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Requirements for Hygiene in the Treatment of Medical Pro- Dukten " • For information, as the product is not re-sterilizable: DIN EN ISO 17664 Sterilization of medical devices. Information to be provided by the manufacturer for the treatment of re-sterilizablemedical devices (ISO 17664: 2004); German version EN ISO 17664: 2004
Contact to the manufacturer:	See manufacturer and service address

The instructions provided above have been validated by the medical device manufacturer as preparation for a medical device for its use. The preparator is responsible that the actual processing carried out by the treatment facilities with the equipment, materials and personnel achieves the desired results. Normally validation and routine monitoring of the process are required.

Information für validation and preparation:

Cleaning Agent Pre-cleaning:		Neodisher Mediclean (Dr. Weigert; Hamburg)
Application time:		10 min. with 45°C
Cleaning agent automatic cleaning	:	Neodisher Mediclean (Dr. Weigert; Hamburg)
Concentration:		0,5%
Cleaning disinfector:		Miele G 7735 CD
Software:		Ebro Software Winlog 2000 Version 1.21
Program:		Vario TD
Loading rack:		MIC Einschubwagen (Miele)

Warranty

The products are made of high-quality materials and are subjected to quality control before delivery. If errors occur, please contact our service However, we cannot guarantee whether the products are suitable for the intervention. The user must determine this himself

We cannot accept liability for accidental or consequential damages.

Strauss Surgical LLC assumes no liability whatsoever if it can be proved that this instruction manual has been violated.

Attention:

In the case of the use of the instruments in patients with Creutzfeldt-Jakob disease or an HIV infection, we reject any responsibility for reuse.