Instructions for use



Reusable surgical instruments

Hersteller: ROLAN Instruments GmbH
Ernst-Thälmann-Str. 50
15859 Storkow / Germany
Tel.: 0049 33678 449433
E-Mail: info@rolan-instruments.de

Item codes	Category
01-…	Diagnostic
02-…	Anaesthesia, Aspiration, Laryngoscopy
03-…	Scalpel handles, Scalpel blades, Operating knifes, General Surgery
04-…	Surgical scissors
05-…	Ophtalmology-and micro scissors
06-…	Dressing and tissue forceps
07-…	Haemostatic forceps
08-…	Towel clamps, Sponge holding foreceps
09-…	Retractors
10-…	Sounds, Spatula, Cotton Applicators
11-…	Trocars
12-…	Needle holder
13-…	Suture
14-…	Plaster
15-…	Bone Surgery
16-…	Amputation, Drills
18-…	Neurosurgery, Vascular Surgery
19-…	Ophthalmology
20-…	Otology
21-…	Rhinology
22-…	Mouth and Tongue
23-…	Tonsilectomy
24-…	Larynx
26-…	Tracheotomy
27-…	Thorax, Rib shears, Lung
28-…	Gall, Kidney
29-…	Intestines, Stomach
30-…	Urology
31-…	Rectum
32-…	Gynaecology
33-…	Obstetrics
34-…	Dermatology
35-…	Instrument cases, bowls, needle cases
36-…	Vascular clamps

Instructions for use

Reusable surgical instruments

38-….	Mammoplasty
50-…	Container, wire baskets
60-…	Various
70-…	Dental

Erläuterung der graphischen Symbole

 Indicates a potential risk

 Study instructions for use

Non-sterile

 CE marking according to directive 93/42 EEC

 Manufacturer

With the purchase of this instrument, you have acquired a high-quality product. The proper handling and use is described below. In order to avoid hazards to patients and users, we ask that you carefully observe the instructions for use. Only trained professionals may use, disinfect, clean and sterilize the instruments.

Tests
The instruments must be checked to make sure they work properly before every use.
Damage to the surface, such as scratches, cracks, nicks, dents, etc., as well as bent parts are indications that they may not be used. The products are then to be repaired or are to be disposed according to the hospital procedure. Do not use any damaged products!

Intended use
We manufacture our instruments as standard instruments for operative use in general surgery. The treating physician, however, is responsible for the selection of instruments for certain applications or for operative use. The physician is also responsible for the appropriate training and sufficient information for the OP personnel, and for having sufficient experience using the instruments.
The instruments are intended for an application period of < 60 mins.

Handling
The instruments may not be overstressed by twisting or levering, since this can lead to instrument parts becoming damaged or broken.

Risks
- Injury to nerves, vessels and tissue
- Bleeding
- Infections

Complications
In general, complications seldom occur. The frequency and severity of the complication depends on the type of examination.

Combination with other products / instruments
The products from ROLAN Instruments GmbH may not be combined with products, components and instruments from other manufacturers under any circumstances. Combinations with products from other manufacturers may

Instructions for use

Reusable surgical instruments

negatively affect the result of the operation and are not allowed, since the used components might not be compatible with one another. It is recommended to only use instruments and accessories from ROLAN Instruments GmbH.

Disposal
If the instruments should no longer be reparable and treatable, these are to be disposed according to hospital procedure.

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

Treatment instructions

Process:	• Cleaning • Disinfection • Sterilization with hot steam (DIN EN ISO 17665-1)

Warnings:	The instruments are delivered non-sterilized and must be cleaned, disinfected and sterilized before use. The instruments may only be treated by persons with the necessary specialized knowledge and training, and who can judge the potential risks with the corresponding effects.
	• The packaging cannot withstand the high temperature of autoclaving and must be discarded before sterilization.
	• The surgical instruments are intended for use by trained surgeons and staff thoroughly familiar with the surgical technique and use of these instruments.
	• Check each instruments for breaks, cracks or malfunction before EACH use. Do not use damaged instruments.
	• The instruments are intended for an application duration <60 mins.
	• Incorrect handling and care as well as misuse can lead to premature wear or can cause hazards to patients and users.
	• Remove protective caps (if any) prior to sterilization.
	• Do not apply mineral oil or silicone lubricants to instrument hinges because they introduce microorganisms, prevent penetration of the steam to the instrument's surface, and are difficult to remove.
	• Do not expose instruments, cassettes, trays or sterilization containers to temperatures higher than 141°C / 286°F. Exposure to higher temperatures is the responsibility of the user.
	• Do not use detergents or disinfectants containing the following substances:
	  • Strong alkalines (>pH9)
	  • Strong acids (<pH4)
	  • Phenols or iodophors
	  • Hydrogen peroxide (H2O2)
	  • Interhalogenic agents / halogenic hydrocarbons / iodiophors
	  • Strong oxidizing agents / peroxides
	  • Organic solvents
	• Water quality may influence the result of the cleaning and disinfection of the instruments. Therefore, use only deionised water, for example, purified water/highly-purified water (PW/HPW according to the pharmacopeias) for post-rinsing, as well as for other processing steps that require water. Corrosion of instruments may be caused by high contents of chloride or other minerals in tap water. If stains and corrosion occur and other reasons can be excluded, it may be necessary to test the quality of the tap water in your area. Most water quality problems can be avoided with the use of deionised water.
	• Never attempt to make repairs yourself. Any repairs made by the user may void the warranty.
	• Service and repairs should be referred to trained qualified persons only or return to ROLAN for replacement.
	• The use of an instrument for a task other than that for which it is intended, as well as improper, ineffective and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument’s warranty.
	• Consult National Infection Control / Prevention Protocols for specific guidance regarding processing of medical devices.
	• Discard devices that have reached their life expectancy.
	• Suction Unit (Suction Tubes): For correct use and maintenance of the available models

Instructions for use

Reusable surgical instruments

	in market, please refer to the individual manufacturer's instructions manual.
Limitation of re-processing	Frequent re-treating has little effect on the instruments. The end of the product lifetime is usually determined by wear and damage from use. They are then to be disposed of according to hospital procedure. Do not use any damaged products!

	Instructions for cleaning, disinfection and sterilization
Point of use:	Handle used and contaminated instruments with protective gloves that fulfill the requirements of Directive 89/686/EEC. Remove protective end caps before use. Remove surface contamination with a disposable cloth / paper towel. It is recommended to reprocess the instruments as soon as possible after they have been used. Directly after use, they can be disinfected by hand in order to reduce the risk of infection for the user. Here, the instruments are placed in a disinfection solution. Make sure that the instruments are fully immersed in the disinfection solution, and that no air bubbles are formed. Follow the instructions of the manufacturer of the disinfection solution.
Preparation for decontamin-ation	If instruments can be taken apart, do this before treating them or make sure that they are at least completely opened.
Pre-Cleaning: Ultrasonic	• Disassemble instruments if applicable (not required for hinged instruments) or open hinged instruments completely. Special attention should be paid to the cleaning of locks, teeth, hinges, ratchets, serrations and other areas. • Completely submerge instruments in the ENZOL® Enzymatic Detergent Solution. A minimum soak of one minute is recommended, for removal of dried-on matter, extend soak time. **Note:** There should be no contact between the instruments; do not overload the ultrasonic cleaning unit. • Use the processing time recommended by the manufacturer of the ultrasonic unit. • Remove instruments from the cleaning solution and post-rinse thoroughly at least 3 times for at least one-half minute each time with high quality water, e.g., PW/HPW (see warnings) • Inspect instruments for good cleaning result and repeat procedure if necessary. The best effects are achieved by cleaning and rinsing the instruments immediately after each application. • Instruments shall not touch each other during cleaning & disinfection process. • Follow recommendations of ultrasonic cleaning & disinfection machine's manufacturer
Cleaning: Manual	• Disassemble instruments if applicable (not required for hinged instruments) or open hinged instruments completely. Special attention should be paid to the cleaning of locks, teeth, hinges, ratchets, serrations and other areas. • Prepare ENZOL® Enzymatic Detergent upon manufacturers recommendations • Soak instruments immediately after use until all organic material is removed - A minimum soak of one minute is recommended, for removal of dried-on matter, extend soak time • Using brush, apply Detergent ENZOL® (Johnson & Johnson) solution to all surfaces ensuring that hinged instruments are cleaned in both open and closed positions. • Clean cannulations and holes using soft brush (no metal brush) ensuring that full depth of the feature is reached. • Thoroughly rinse instruments, aspirating water through all channels to remove detergent • Dry well • Inspect instruments for good cleaning result and repeat procedure if necessary. The best effects are achieved by cleaning and rinsing the instruments immediately after each application.
Disinfection: Manual	• **Disinfection Procedure:** o Completely submerge instruments in the CIDEX® OPA (Johnson & Johnson) disinfectant solution and soak for a minimum of 12 minutes at 20° C or higher to destroy all pathogenic microorganism o There should be no contact between the instruments. • **Rinsing Procedure** 1. Following removal from CIDEX® OPA (Johnson & Johnson) disinfectant solution thoroughly rinse the instruments by immersing it completely in a large volume

Instructions for use


Reusable surgical instruments

	(e.g. two gallons) of water. Use HP/HPW water. 2. Keep the device totally immersed for a minimum of one minute in duration 3. Manually flush all lumens with large volumes (not less than 100ml) of rinse water 4. Remove instrument and discard the rinse water. Always use fresh volumes of water for each rinse. 5. Do not reuse the water for rinsing for any other purpose. 6. Repeat the procedure two (2) additional times, for a total of THREE (3) rinses, with large volumes of fresh HP/HPW water to remove CIDEX® OPA solution residues. 7. Residues may cause side effects. Three (3) separate, large volume water immersions rinses are required.
Cleaning and Disinfection Automatic	Automated Cleaning & Disinfection Equipment: Thermal Disinfector Unit (Washer-Disinfector). Consider the following when using a thermal disinfector unit (washer – disinfector): • Efficiency of the thermal disinfector unit (washer –disinfector) e.g. EN ISO 15883-1, HTM-01 if required by local regulations and guidelines. • Thermal disinfection program that is approved and suitable for instruments *-recommended temperatures/times: 90°C / 194°F for 5 minutes* *-Alternatively a thermal disinfection process delivering an A0 value > 3000 may be used as required in some European countries*) as well as sufficient rinsing steps. • Thoroughly post-rinse, preferably with high quality water, e.g. PW/HPW **Procedure:** 1. Disassemble instruments if applicable (not required for hinged instruments) or open hinged instruments completely 2. Place the instruments in the thermal disinfector unit (washer – disinfector), assuring no contact between the instruments 3. Initiate the cycle 4. Remove the instruments from the thermal disinfector unit (washer-disinfector) after the end of cycle.
Drying	• Allow post-drying step in a clean place, or use filtered air for drying to prevent recontamination • If drying is achieved as part of a washer-disinfector cycle, do not exceed 110°C/230°F • Completely dry instruments before packing
Inspection, Maintenance & Function Test	• The instruments have to be inspected before each use. Visually examine the devices for obvious physical damage including: o Cracked, broken or otherwise distorted parts o Damage including cuts, punctures, nicks, abrasion, unusual lumps, significant discoloration o Tips for damages like corrosion or misalignment condition o Impurities, damage and wear o If Instruments cutting edges free of nicks • If instruments are still dirty, repeat cleaning and disinfection procedures • Reassemble disassembled instruments. Check for smooth movement of hinge so that not too much slack to it. Locking (ratchet) mechanism should be checked for action • Apply a small quantity of surgical grade lubrication oil (suitable for steam sterilization, with manufacturer's certification that the lubricant will not affect the sterilization efficiency of the oiled instruments and that the biocompatibility of the lubricant will be maintained during the sterilization cycle) to instrument hinges. • Do not use damaged instruments. Return damaged instruments to ROLAN for repair or discard them according to the hospitals regulations. The instruments **have to be** sterilized before being discarded or returned to ROLAN.
Packaging	Always use a protective outer packing for the packing / storage of cleaned instruments **Please note the following for the use of sterilization containers:** o According to ANSI AAMI (EN) ISO 11607 (EN 868-8)

Instructions for use



Reusable surgical instruments

	○ Compatible for the use of sterilization with moist heat (temperature resistance up to 141° C / 286°F ○ Sufficient protection of the instruments and the sterile packaging against physical damage ○ Maintenance of the sterilization containers has to be done according to the manufacturers specifications **Alternatively you may use standard sterilization packaging (e.g. paper / foil – single or double packaging):** ○ According to ANSI AAMI (EN) ISO 11607 (EN 868-2) ○ Compatible for the use of sterilization with moist heat (temperature resistance up to 141° C / 286°F ○ Sufficient protection of the instruments and the sterile packaging against physical damage
Sterilization	Only completely clean instruments can undergo the sterilization process. Follow the sterilizer manufacturer's instructions for operation and loading. **Recommended sterilization method:** Steam sterilization with damp heat with fractionated vacuum DIN EN ISO 17655-1 **Recommended temperature:** 132°C, max. 137°C (270°F, max 279°F) **Recommended pressure:** 2,1 bar **Exposure time:** ≥ 5 min Check sterile packaging for damages, also check indicators. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tube channels. Allow instrument to cool down to room temperature before use. **NOTE:** Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times. **CAUTION:** Autoclave temperatures should not exceed 137°C / 279°F; casing, cable insulation or other non-metallic parts may be damaged. **DO NOT STERILIZE WITH HOT AIR.**
Storage	Following a validated sterilization process, store instruments in a dry and dust-free place. Sterilization can only be maintained if the instruments remain packed or wrapped, impermeable to microorganisms.
Additional Information	Further information for the treatment of medical products: • Internet: www.rki.de • Internet: www.a-k-i.org • Hygienic requirements for treating medical products, recommendation of the commission for hospital hygiene and infection prevention at the Robert Koch Institue (RKI) and the Federal Institute for Medicine and Medical Products (BfArM) with regard to the "Hygienic requirements for treating medical products." • For information, since the product cannot be re-sterilized: EN ISO 17664 Sterilization of medical products. Information to be provided by the manufacturer of the treatment of re-sterilisable products (ISO 17664:2004)

The above listed instructions were validated as suitable by the medical product manufacturer for the reprocessing of medical products. The person who performs the treatment is responsible for making sure that the actual treatment carried out with the used equipment and material, achieves the desired results. For this, validation and routine monitoring of the method is required.

Guarantee

The products are made of high-quality materials and undergo a quality check before being delivered. If errors occur despite of this, please contact our service department.
We cannot make guarantees as to whether the products are suitable for the operation in question. That must be determined by the user himself.

Instructions for use



Reusable surgical instruments

We cannot accept liability for random or consequential damage. ROLAN Instruments GmbH accepts no liability if it can be proven that these instructions for use were violated.

Attention

In case the instruments are used on patients who have Creutzfeldt-Jakob disease or an HIV infection, we recommend that they are being discarded after use. We refuse to take any responsibility if they are being reused.

Manufacturer and Service Address:

ROLAN Instruments GmbH
Ernst-Thälmann-Str. 50
15859 Storkow
Germany
Tel.: 0049 33678 449433
E-Mail: info@rolan-instruments.de