Instruction for Use

for surgical and re-usable instruments

1. Manufacturer

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2. Field of application

All re-usable surgical instruments, which
- consist of stainless steel, pure titanium, titanium alloys, aluminum
- may contain simple joints or simple movable parts
- may be composed of several exchange- able parts (e.g., handles and various working parts)

Suitable for:
Scissors, needle holders, punches, scalpel, kin- vest, forceps, clamps, graspers, hooks, spread- ders, spatulas, specula, curettes, bone curettes, chisels and instruments.

- All kinds of the surgical and dental instruments, like, dental pliers, Dental forceps, scalers and elevators.

3. Basics

These instruction guide can 't replace the Training, carefulness and the user 's knowledge of technology. We therefore assume that the respectize legal rules, engineer standards and recommendations

Please read these instructions very carefully before you prepare and employ the product for the first time!

4. Purpose and indications

Instruments as standard instruments for surgical interventions in general surgery. Instruments may only be used by adequately qualified staff for the intended use in medical specialty.

The attending doctor or rather the user is responsible for the selection of instruments for certain utilization and accordingly to the surgical use, the adequate training and information and the sufficient experience for the handling with the instruments.

Duration of treatment: temporary (< 60 min. under normal conditions) according to the guide line of 93/42/ECC

5 **Maintenance.**

Maintenance and cure are usually performed before the test function. Maintenance and care mean a targeted application of the preventive into the surgical instruments in the joint, hingers or threads and sliding surface, at the scalpels, scissors, punches after a through cleaning and disinfection. Dis prevents friction of a metal and consequent friction corrosion. The surgical instruments are being movable state.
Requirements for the preservative for the surgical instruments Paraffin/ white oil based, complying with the applicable European pharmacopoeia or the United States pharmacopoeia, biocompatible, suitable for the steam sterilization.

A dismantled surgical device should be assembled prior to sterilization unless otherwise indicated.

6. Restrictions

Frequent reprocessing has little impacts on the lifetime, which is determined by abrasion, damage and misuse.

7. Warning notices

After receipt of the products, please check their identity, completeness, intactness and functionning before you prepare them.

It's necessary to inspect the instruments for breakage, cracks, deformation, damage, non-corrupted surface and functioning before every application. Thereby you particularly have to check parts such as cutting edges, tips, points, ratchets, snaps, locking devices as well as all movable parts.

Instruments that are fully worn, corroded, deformed, porous or otherwise destroyed have to be rejected.

The instruments are generally delivered non sterile! Before initial use and before all further use, the instruments must be prepared according to our care and cleaning instruction!

It's always necessary, especially for retractors and fixation clamps, to make a mechanical and optical check, whether the screws are screwed in and recessed

Particularly at handling, sterilizing, maintenance and packaging of fine surgical instruments (micro instruments), it has to be played attention to a carefully and gentle handling. It persists a danger of linking of the hooks ends into the netting of the wire baskets, as well as deforming and breaking of the tips ends. It's necessary to inspec the instruments for breakage, cracks, deformation, and damage before every application. Sort out damaged or defect instruments.

8. Combination with other products

if instruments are put together again after their disassembling, the separate parts must not be replaced by parts of other manufacturers, also if a part is exchangeable because of the product 's specific function (e.g., different work inputs)! We recommend ordering miscellaneous accessories, e.g., instrument oil as well at Surgicon

9. Materials

Only steel according to the DIN EN ISO 7153-1 for medical instruments is used.

10. Material durability

Cleaning supplies and disinfectants must 't contain the following components:
- organic, mineral and oxidising acids
- powerful leaches (> pH 12,5)
- halogenated hydrocarbons.
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11. Disposal and return consignments

Before being sent to Surgicon for repair or return shipment, the instruments must be prepared according to our care and cleaning instructions and packed safely.
The acceptance of repairs and returned shipments can only be performed with the proper forms for returning.
After a successful disinfection, defect or out-of- date instruments must be disposed professionally or returned to a recycling system.

12. Warranty

The responsibility for the instruments appropriate cleaning, disinfection and sterilization lies with the user.

National rules, inclusive restrictions on this, have to be respected to necessarily!
Surgicon excludes any warranty claims and assumes no liability for direct or consequential damages which result from use for purposes other than intended, inappropriate- the use, employment, or handling, inappropriate treatment and sterilization, inappropriate main- tenancy and reparations and disregard of this instruction sheet.
Repairs may only be made by companies or persons who are authorized by Surgicon. In case of disregard any warranty will be excluded.

13. General basics for hygiene and processing

Brand-new instruments and instruments of repair returns have to be processed before their first utilization just as used instruments. The transport protective package, protection caps, etc. are inapplicable for sterilization. Only approved agents (FDA, etc.) may be used.

Attention! Don 't uses alkaline cleaners >pH 7 for aluminum instruments.

- water quality according to DIN EN 285
- sterilizers according to DIN EN 285 or DIN EN 13060
- cleaning and disinfection machines according to DIN EN ISO 15883 part 1 & 2
- Only processes which are sufficiently device- and product specifically validated may be used for cleaning/disinfection/ sterilization.
- Manufacturer's instructions and recommend- dations have to be observed.
- Additionally you have to observe your country 's effective legal and hygienic rules, in particular for the different specific functions.

14. Transport

Storing and transport to the place of treatment has to occur in a safe and close box in order to avoid instrument damage and environmental pollution.

15. Preparation at the place of use and for the cleaning and disinfection

- Residues caused by the usage have to be removed immediately!
- Don't use metal brushes or steel wool!
- DO NOT put the instruments into common salt solution!
- Hinged and box-lock instruments must be loaded and cleaned in open postion.
- Take instruments apart as much as possible for cleaning.
- Machine cleaning and disinfection is only suitable for instruments with long or thin cannulations if the hot disinfection solution can actually flow through them.
- Appropriate handling and deposition!

16. Manual cleaning and disinfection

Only in case of non-availability and exceptional cases permitted. If so, additional product- and process-specific validation in responsibility of the user is necessary.

- Don 't use metal brushes or steel wool!
- Narrow lumina instruments and parts have to be cleaned very carefully!
- Appropriate handling and deposition!

17. Manual cleaning with ultrasonic cleaning

Please pay attention to the instructions referred to the manufacturer of the cleaning and disinfect- tion agents!

The used cleaning and disinfection agents must
be suitable for the cleaning of steel-, titanium and aluminum products.

- maximal temperature: 50°C
- frequency: 35 - 45 kHz
- time of cleaning: 4 - 5 minutes
- put in instruments with opened joint
- Instruments filled with lumina free of air bubbles and arranged according to the sound!
- Instruments must be covered completely with the cleaning liquid.
- After the ultrasonic cleaning, the instruments have to be flushed with clear running water first. Demineralised water is recommended in the last rinse cycle. Afterwards the instruments have to be dried.

18. Mechanical cleaning - thermal disinfection

- Always use preferentially mechanical cleaning/thermal disinfection!
- Put down openly all instruments which can be opened into a tray on the trolley and start the cleaning process.
- Put the MIC instruments fragmented on the MIC-trolley's inserts. Instruments that
  can't be inserted put openly into a tray on the MIC-trolley's.
- Pre-rinse with cold water!

Cleaning of stainless-steel instruments and instruments with a High-Tec surface:

- alkaline up to pH 12,5, cleaning time 10 minutes at 55°C

Thermo-disinfection
with consideration of the A0 value (time duration/ temperature) according to the classification of the products on the basis of the -guidelines

- Please also pay attention to the cleaning inst- ructions according to the manufacture's specific- tions of your cleaning detergents
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19. Control and attendance

- Instruments have to be cooled down on room temperature!
- For the functional tests reassemble the instruments!
- Maintain joints, worms (threaded) and sliding surface with oil spray after the cleaning and disinfection but before the function tests.
  Use other care products (paraffin/white oil basic and free of silicone) only if they're approved for/to steam pressure sterilization and checked biocompatibility.
- Sort out damaged instruments

20. Packaging

Packages to DIN EN 868 can be used. Chose the package so that the instruments fit in well. Use a sterilization indicator for the package and note the dates of sterilization and expiry.

21. Sterilization

- steam-sterilizer corresponding to DIN EN 13060 or DIN EN 285
- steam sterilization with fractionated vacuum according to DIN EN ISO 17665-1
- Other sterilization methods and the flash

sterilization method is not authorized.

- recommended temperature: 134° (max.138°)/273°F (max. 280°F)
- recommended pressure: 3 bar
- leave on time: > 5 minute

22. Storing

Dry, dustproof, without action of force from outside, without temperature variation and not within spitting distance to aggressive media, ex- pediment in trays, containers, cupboards.

23. Confirmation - notices

The user is responsible that the realized pro- cussing with used equipment, materials and personnel in the treatment institute achieves the desired results.

If the delivered instruments are split, there al- ways has to be an instruction at every range of
use/department.

25. Norm references

- DIN EN 285 large steam sterilizer
- DIN EN 13060 small steam sterilizer
- DIN EN ISO 15883-1-3 cleaners - disinfectors
- DIN EN 868 packing materials
- DIN EN ISO 17664 sterilisation- manufacturer`s information
- DIN EN ISO 17665-1 sterilization of health care products - moist heat - part 1

26. Labeling

item number

batch number


manufacturer


manufacturing date


expriry date


refer to instruction for use


Attention!

non-sterile product

latex-free


European CE

🔄 **MDR 2017/745 Compliance Addendum for Reusable Surgical Instruments – Instruction for Use (IFU)**

In accordance with Regulation (EU) 2017/745, this IFU has been updated to include the following mandatory elements for reusable surgical instruments:

1. **Device Classification**: This instrument is a reusable Class I medical device with reprocessing requirements, classified under Rule 5 (Class Ir) of Annex VIII.

2. **UDI Compliance**: Each device label includes a Unique Device Identifier (UDI) as per Article 27 and Annex VI of MDR.

3. **Validated Reprocessing Instructions**:
   - Cleaning and sterilization steps are validated in accordance with EN ISO 17664:2017.
   - A complete, validated process for cleaning, disinfection, drying, inspection, maintenance, packaging, and sterilization is included.
   - Compatible with washer-disinfectors (ISO 15883 series) and steam sterilization (ISO 17665-1).

4. **Maximum Number of Reuses**: The device may be reused up to the validated number of cycles provided in the labeling. The instrument must be inspected for wear or damage before each reuse.

5. **Warnings**:
   - Instruments not properly reprocessed may cause infection, device failure, or serious injury.
   - Do not exceed reuse limits. Improper use or reprocessing invalidates warranty and CE compliance.

6. **Inspection Prior to Use**: Inspect the device for mechanical integrity, corrosion, and cleanliness prior to each use.

7. **Traceability & Documentation**: Device batch/serial number must be recorded to ensure traceability as part of the user's quality management system.

8. **Symbol Compliance**: All symbols used in labeling and this IFU conform to ISO 15223-1:2021 and MDR Annex I, Section 23.

This section is in accordance with the GSPR (Annex I), Annex II (Technical Documentation), and Annex III (Post-Market Surveillance) of EU MDR 2017/745.

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