BERGER SURGICAL
MEDICAL PRODUCTS GMBH

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INSTRUCTIONS FOR USE (IFU-1.1)

Reusable Surgical Instruments

Part I: General Information

Part II: Information about the Processing

Part I: General Information

1. Scope of Application

All reusable surgical instruments that

- ✓ consist of only one piece,
- ✓ comprise simple joints or
- ✓ comprise simple movable parts,
- ✓ and, as the case may be, are put together using various changeable single parts (e.g. a handle piece and diverse assignments).

Exempt from this are products that

- are connected to an active appliance,
- are operated using electric power,
- consist exclusively of non-metal materials.

2. Fundamentals

These instructions for use cannot replace any training, carefulness, and the user's technical know how. Therefore we suppose the user to be familiar (see „Standards/References") with the respective legal regulations, standards, and recommendations (e.g. of the RKI[2] or the AKI[1]) and therefore only want to tell you the instructions and recommendations that have to be observed while using one of our products. Reasons for those instructions and the dangers arising if the user does not adhere to them are listed in the legal regulations and recommendations.

PLEASE READ THESE INSTRUCTIONS FOR USE VERY CAREFULLY BEFORE PREPARING AND USING THE PRODUCT FOR THE FIRST TIME!

3. Usage according to Purpose

The instruments may only be used according to their purpose in the medical specialized areas by qualified special personnel.

The physician treating the patient and the user respectively are responsible for selecting the instruments for certain applications and the use in the course of the surgery, the appropriate training and information of the users and seeing to it that the users are sufficiently experienced for handling the instruments.

4. Restrictions

The frequent preparing of the products has only few consequences for the product's life being determined by wear and tear, damage and misuse.

After having been applied on patients suffering from the Creuzfeldt-Jakob disease (CJK) or its variations we reject any responsibility for its reuse!

We recommend the instruments' destruction. The user assumes the full responsibility for the products' preparing and reuse, even if carried through according to the RKI[2]-guideline!

Instruments containing aluminium are damaged by the use of alkaline cleaning agents >pH 7!

5. Warning Hints

The instruments are always delivered in an UNSTERILE state!

Please inspect the products for their identity, completeness, sound condition and functionality, after they have been delivered and before you pass them on to the processing department.

Prior to being used the instruments have to be inspected for possible breakages, cracks, deformations, damage and functional efficiency. In particular you have to inspect such areas like e.g. cutting, sharpening, lockings, blocking, latching, and all movable parts. All parts that are worn, corroded, deformed, porous or damaged in another way have to be sorted out.

6. Marking – Label Symbols

REF	Article and order numbers respectively
LOT	Lot no.
NOT STERILE	Information for NOT sterile product
	Attention, observe the accompanying documents
	Observe the instructions for use
CE	European sign of approval
IFU-1.1	Respective instructions for use (e.g. no. IFU-1.1) Enclosed or available on www.berger-surgical.de

7. Combination with other Products

If instruments are put together again after having been disassembled single parts may not be replaced by parts of other producers!

If parts can be exchanged due to their use according to purpose (e.g. in the case of different assignments), no parts of different producers may be used!

We recommend to procure other accessories (e.g. maintenance products) as well with ***Berger Surgical***.

8. Materials

Steels according to DIN EN ISO 7153-1 for medical instruments. Plastics approved of for medical products and checked for bio compatibility.

9. Material Resistance

Cleaning and disinfection agents must not contain the following components:

- Organic, mineral and oxydizing acids,
- Stronger bases (> pH 11, in those cases mildly alkaline cleaning agents are recommended),
- Halogenated hydrocarbons, chlorine, iodine,
- Organic solvents (alcolhols, acetone,..),
- Ammonia.

The products are thermostable, but may not be exposed to temperatures above 141°C (286 °F)!

10. Disposal; Returns

The accepting of returns by Annahme von Retouren bei ***Berger Surgical*** only accepts returns, if they have been declared as being „hygienically harmless" (having been treated using disinfection processes) or having been marked as „not decontaminated" and packed safely.

After having been successfully disinfected defect and obsolete instruments have to be disposed of properly or taken into the recycling process.

11. Warranty

Safety hint: The responsibility for the appropriate cleaning, disinfection and sterilisation of instruments lies with the operator / product user. National regulations as well as restrictions concerning this particular field have to be observed under all circumstances.

Berger Surgical delivers only thoroughly inspected and immaculate products to their clients. All of our products are designed and produced in such a way that they meet the highest quality requirements.

Berger Surgical as the products' manufacturer excludes any warranty claims and assumes no liability for direct damage or consequential damage caused by:

- Usage of the product for a purpose other than the intended usage
- Inappropriate usage, application or handling of the respective product
- Inappropriate processing and sterilization
- Inappropriate maintenance and repairs
- Non-observation of these instructions for use

It has to be stressed that repairs may only be carried out by companies or persons being authorized by ***Berger Surgical*** to do so. This entails the ruling out of any warranty claims.

12. Producer - Service Contact

If you fail to understand the contents of these instructions for use this may have the following consequences:

- Death or severe injuries of the patient
- The user gets severely injured
- The equipment gets damaged

In the case of uncertainties or if you have any queries, we would like you to contact us before you (re)use or process the product again.

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13. Standards – References

- AKI[1]- Guideline „Instrumenten-Aufbereitung richtig gemacht" (Processing of Instruments done correctly)
- RKI[2]- Recommendation: „Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten" (Requirements for the Hygiene when Preparing medical Instruments).
- DIN EN 285 Steam-large-sterilizers
- DIN EN 13060 Steam-small-Sterilizers
- DIN EN ISO 15883-1-3 Disinfecting Applicances for Cleaning
- DIN EN 868/ ANSI AAMI ISO 11607 Packing Materials
- DIN EN ISO 17664 Sterilization – Information by the Producer
- DIN EN ISO 17665-1 Sterilizing process – wet heat

[1] AKI: Arbeitskreis Instrumenten-Aufbereitung (working group processing of instruments)
[2] RKI: Robert-Koch-Institut

Part II: Information about the Processing

14. General Basics for Hygiene and Processing

- Instruments just taken from the factory and instruments from repair returns have to be processed like used instruments before they are used for the first time. The transport protection packings, protective caps, etc. are not suited for being sterilized.
- Only approved means (RKI, DGHM/ VHA, FDA, etc.) may be used.
- Both alkaline and pH-neutral cleaning agents may be used.
- ATTENTION: FOR INSTRUMENTS CONTAINING ALUMINIUM DO NOT USE ALKALINE CLEANING AGENTS >PH 7!
- Water quality according to DIN EN 285 appendix B.
- Sterilizers according to DIN EN 285 or DIN EN 13060.
- Disinfecting appliances for the cleaning according to DIN EN ISO 15883 part 1 and 2.
- Use only sufficiently validated processes in terms of appliances and products for cleaning/disinfection/sterilization.
- Producer instructions and recommendations have to be adhered to.
- Additionally you have to observe the legal and hygiene regulations valid in your country. This applies in particular to the differing specifications regarding an effective deactivation of prions.

15. Preparation at the Place of Use and for Cleaning/Disinfecting Purposes

- Immediately remove any residues from the usage!
- Do not use any metal brushes or steel wool!
- Do NOT place it in saline solution (NaCl) !
- Never put down opened articular instruments, disassemble demountable instruments, specially pretreat instruments and spots with a narrow inner diameter!
- Appropriate handling and putting down of instruments!

16. Manual Cleaning and Disinfection

- Always prefer machine cleaning/ disinfection to the manual one!
- Only permitted in cases in which the machine is not available and in exceptional cases. In those cases, however, the user is responsible for a required additional product and process specific validation to be carried through.
- Do not use any metal brushes or steel wool!
- Clean instruments and spots with a narrow inner diameter with particular care!
- Appropriate handling and storage!

17. Ultrasonic Cleaning

- Maximum temperature: 50°C.
- Frequency: 35 – 45 kHz.
- Cleaning time: 4-5 minutes.
- Insert articular instruments in an opened state!
- Instruments with Lumina have to be filled without any air bubbles and aligned according to the sound!

18. Machine Cleaning – thermal Disinfection

- Machine cleaning/ Thermal disinfection has to be used preferably!
- Do never store instruments under voltage, store articular instruments only in an opened state, disassemble demountable instruments, position instruments with a narrow inner diameter in a special way and use special rinsing equipment respectively!
- Correct handling and storage!
- Temperature for disinfecting 95°C at most.
- A_0-value (time/temperature) according to the products' classification using the RKI-guideline!

19. Control and Maintenance

- Instruments must have cooled down to room temperature!
- Assemble the instruments for the functional check!
- Service joints, threads and sliding surfaces after they have been cleaned/disinfected but before they are inspected for their functionality and sterilized using BS oil spray (order no. 00-515-00). Use other service products (on paraffin/white oil base) only if they are approved of for the steam sterilization and inspected for their bio compatibility.
- Sort out damaged instruments, check instruments having been cleaned and disinfected (if need be, repeat the process) send them back to us enclosing a decontamination certificate.

20. Packing

- No special requirements.
- Packings according to DIN EN 868/ ANSI AAMI ISO 11607 may be used.

21. Sterilization

- Only steam sterilization may be used!
- Other sterilisation processes and the flash sterilisation process are not permitted for being used.
- Fractioned vacuum process (with sufficient drying of products of at least 15 minutes).
- Maximum sterilization temperature 138 °C (280 °F; plus tolerance according to DIN EN ISO 17665-1 respectively.
- Time for sterilization (exposing time at the sterilization temperature) at least 20 min (at 121 °C (250 °F) and 5 min at 132 °C (270 °F)/134 °C respectively.
- Steam sterilizer according to DIN EN 13060 and DIN EN 285 respectively.
- Validated according to DIN EN ISO 17665-1 (valid consignment sale and product specific assessment of performance).

CLEANLINESS CANNOT BE SUBSTITUTED BY STERILIZATION!

22. Validation reports of the manufacturer for reprocessing.

- - Final Report reprocessing validation by machine 2020-04-28 11759 and 11756
- - Final Report Sterilization Validation 2020-04-30 11760 and 11757

23. Storage

- Dry, protected from dust, without any external power application without more or less high temperature variations and definitely not next to aggressive media.
- Suitable for storage are trays, containers, cabinets.
- Otherwise no special or additional requirements.

24. Confirmation – Hint

The above instructions for the processing have been validated as „suitable" for the preparation of a medical product for being reused. The user (processor) assumes the responsibility that the processing including the equipment used, the materials, and the personnel working in the processing plant reach the desired results. To this end validation and routine monitoring of the process are normally requested.

The user (processor) should also analyse every deviation from the applications made available to him for their effectiveness and possible adverse consequences.

25. Life limitation

The service life of surgical instruments is only insignificantly affected by the number of reprocessing cycles performed, if they are performed according to the validated procedures described here. It rather depends on the gentle and careful handling of the instruments in all phases of use, preparation, transport and storage. The end of the service life is reached when the prescribed visual and functional inspection reveals signs of wear and tear or defects that limit the functionality of the product. In this case, the instruments must be labelled and excluded from further use and replaced by functioning instruments. Furthermore, the end of the utilisation cycle is reached when the clear identification of the instruments is no longer possible due to the missing identification marking.

26. Notification requirements

⚠ To comply with international regulatory requirements, we as a manufacturer are obliged to monitor our products even after delivery. This can only be done completely if our customers and users commit themselves to adhere to the following rules:

Product defects that have occurred during the proper use of our products should be reported directly to the manufacturer or to the specialist dealer who is responsible for them. Defects in which patients, users or third parties have been injured by the products (so-called reportable events) must be reported immediately to the manufacturer and, if necessary, to your competent authority. This notification of incidents must be made immediately after they occur so that important reporting deadlines can be met. The products in question must be sorted out, processed and sent to the manufacturer for investigation. Your specialist dealer will be pleased to assist you in this.

After receipt of your notification, we will inform you within a reasonable period of time about further necessary measures

27. Repair service

⚠**WARNING**

Risk of injury due to improper repair.

Repairs may only be carried out by the manufacturer or by persons authorised by the manufacturer.

⚠**WARNING**

Risk of infection from non-sterile instruments.

Prepare the instrument before returning it to the manufacturer. Instrument reprocessed and returned to the manufacturer in the original packaging.

/ See last page for manufacturer address.

28. Entsorgen

Valuable raw materials can be recovered through environmentally friendly disposal. Dispose of the product in an environmentally friendly manner in accordance with the applicable hospital guidelines after prior treatment.

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