

**Weber Instrumente GmbH & Co. KG**

User's manual

**Description**

Surgical instruments of Weber Instrumente are hand-operated tools. They are made of various materials, including steel, aluminum, titanium and plastic materials (silicone, PEEK, etc.), meeting the current standards. These materials must not be implanted. Instruments of Weber Instrumente do not contain latex!

**Possible side effects**

Improper maintenance, cleaning or handling render the instruments useless, cause corrosion, damage, deformation and / or fracture or injuries on patients and surgical staff.

The possible complications include:

- Neurological lesions, paralysis, pain, lesions of the soft tissue, the viscera or joints in the case of misuse or breakage of the instrument.
- Infections, if instruments are not properly cleaned and sterilized.
- Perforation of the dura mater with simultaneous cerebral-spinal fluid, leakage of the vessels, nerve damage or damage to adjacent organs if a damaged instrument slips or is incorrectly positioned.
- Damage caused by the accidental release of the shutter mechanism or feathers of certain instruments.
- Damage caused by the use of excessive force on tools for bending or cutting in situ.
- Cuts in the skin or the surgical gloves of personnel.
- Tissue lesions on patients or surgical personnel and / or longer duration of surgery, because the instrument must be disassembled during the surgical procedure.
- Cracks, breaks or accidental perforation of bones.

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Most instruments are made of non-implantable materials, because of the required mechanical properties. Fracture fragments of a broken instrument must not remain inside the patient, as this could lead to postoperative complications such as allergies, infections or complications of biological nature as result of the release of metallic compounds. This may make another surgery necessary.

## **Checks prior to use**

The life of an instrument depends on the frequency of use, and the careful use, proper cleaning and storage. The tools must be carefully maintained to keep them always in good condition.

The instruments should be examined for wear and damage prior to use.

The instruments must be visually examined and the working surfaces, joints, locking mechanisms and springs must be checked for proper function. In addition, verify that all welds are intact, all components of the instrument are available, all the holes and wells are cleaned and no cracks, deformations, wear, corrosion or other changes to the instrument are visibly. Instruments with joints and locking mechanisms must be eventually lubricated. A silicone lubricant is recommended.

Clamping springs, particularly those by latching devices should be carefully inspected. The latter may not show any signs of wear and tear, because damaged fittings can lead to detachment. The sharpness of the cutting edges of instruments made for the cutting of bones, such as milling cutters or reamers must be carefully examined.

Screwdriver must be carefully examined. It is extremely important that they are only used in accordance with their intended purpose, according to the manual of the surgical procedure. Certain surgical procedures require the use of instruments with a measuring function. These must be examined for wear and clearly visible surface marking.

Weber Instrumente and their representatives are always available for proper instrument inspection.

Weber Instrumente cannot be hold responsible if damaged, incomplete or worn tools or instruments are used or if instruments, which have not been repaired or sharpened by Weber Instrumente, are used.

## **Damaged tools must be replaced prior to surgery!**

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**Recommended pre-cleaning, cleaning and sterilization procedure for non-sterile surgical instruments**

Non-sterile instruments must be pre-cleaned, cleaned and sterilized before first use for safety reasons. In addition, reusable instruments must be pre-cleaned, cleaned and sterilized right after their use.

**Keep to the following working instructions:**

Weber Instrumente recommends the use of a standard cleaning detergent (such as Ecolab Sekumatic FR Cleaner 0.5%, 0.3% neutralizer Sekumatic FNP). Recommended sterilization procedure: steam sterilization!

- Autoclaving with saturated steam .
- Temperature: 134 ° C (278 ° F)
- Sterilization time: 18 minutes
- Drying Time: 10 minutes

Different sterilization methods are possible, but must be validated first. The autoclave must be validated by the hospital and reviewed regularly in order to ensure that the recommended sterilization temperature can be maintained throughout the sterilization period.

**Preoperative Precautions**

Users of products from Weber Instrumente may obtain a brochure of the surgical procedure, from the designated distributor or directly from Weber Instrumente at any time. If a brochure is used, which was published more than two years ago, it is recommended to order an updated version.

Instruments of Weber Instrumente are to be used only by trained physicians, who are familiar with the required surgical procedure. The surgeon must take care not to apply excessive pressure on the spine or the implants and to keep strictly to the surgical procedures provided by Weber. Too great forces, for example while changing the instruments position in situ, are to be avoided, as this may cause injury to the patient.

To avoid the risk of breakage of the implant, it is important not to deform, notch or scratch the implant, unless this is part of the surgical procedure.

Using the instruments close to vital organs, nerves or blood vessels should be done very cautiously.

The performing of surgical procedures on children requires very cautious use of the instruments.

The instruments can be reused after decontamination, cleaning and sterilization, otherwise no other instructions are given on the label.

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## **Storage**

Instruments of Weber Instrumente are non-sterile instruments delivered in containers or individual packages.

The containers and packages must be intact upon receipt.

The packaging material must be removed prior to sterilization

**The Instruments need to be stored in a clean and dry place with moderate temperature after use!**

**[www.weber-instrumente.com](http://www.weber-instrumente.com)**

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