# Information and direction for use

## 1. BASICS

It is imperative that all requirements and special information described in these instructions are met or taken into account. Otherwise, the products may not be used for clinical use. The specific instructions for use that may be attached to the products must also be observed.

If you are unsure or have any questions, please contact us before using the products.

These instructions for use cannot replace the training, care and state of the art at the user. We therefore assume that the relevant legal provisions, standards and recommendations (e.g. of the RKI or AKI) are known (see under "Standards / References") and therefore limit ourselves to the instructions and information to be followed by the user for each product which are important for our products. The reasons for these instructions and the dangers arising from non-compliance are listed in the legal provisions and recommendations.

All serious incidents that have occurred in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established.

READ ALL APPLICABLE INSTRUCTIONS FOR USE VERY CAREFULLY BEFORE USING A PRODUCT FOR THE FIRST TIME!

## 2. INFORMATION AND SYMBOLS ON LABELS


Batch number

Symbol for **"Follow the instructions for use"**


Symbol for **"content not sterile"**

Symbol for **"manufacturer"**

Attention! Failure to observe the warnings and precautionary measures can lead to death or serious injuries.

CE marking

## 3. DESCRIPTION AND PRODUCT SPECIFIC NOTES

Our products can be a single instrument or an instrument set. These are instruments that are intended for repeated use. The products are medical products within the meaning of national and international laws for products in human medicine.

## 4. INTENDED USE

Instruments and accessories are intended for multiple use. The instruments can be used individually for surgical use or as part of an operating room set. It must be ensured that the intended use of the instrument from best medical GmbH is observed.

**Cutting and separating instruments** are designed to cut and prepare different materials (tissue, skin, thread and suture / bandage material) in different areas of application by applying pressure between two cutting surfaces. Scalpels penetrate the skin and come into contact with blood. Therefore, these are classified as single-use items.

**Knives, dissector knives** are designed to press different materials on a cutting surface (Tissue, skin, thread and suture / bandage material) to be cut and prepared in various areas of application. Dissectors are used for the surgical removal of soft tissue or lymph nodes

**Saws** are designed for cutting or separating bones. The saw is a tool or machine tool used to separate or notch tissue or plaster casts.

**Bandage scissors** are instruments for cutting aids. An instrument for cutting bandages.

**Iris scissors** are scissors with pointed or blunt ends, straight or curved. Used for removing and cutting sutures and small cuts at the wound edge or for surgical interventions on the eye.

**Surgical scissors** are used as a tissue-cutting instrument, also for removing and cutting suture material.

**Holding, clamping and gripping instruments** are used to grip different materials, tissues or vessels in different areas of application, to hold them in place for a short time and to remove them. Depending on the area of application, the grasping instruments differ in shape and size.

**Forceps** are an instrument used to grasp and fixate tissue parts. Atraumatic designs prevent tissue from being crushed. Instrument for grasping smaller objects.

**Ligature clips** are clips that are used to ligate vessels and anatomical ducts or hollow organs in the form of a loop.

**Bronchial clamps and kidney clamps** are instruments for clamping blood vessels and anatomical ducts or hollow organs such as in the areas of the respiratory tract, bile ducts or the kidney envelope.

**Peritoneal clamps** are an instrument used to clamp the peritoneum.

**Organ clamps** are spring-loaded clamping forceps for clamping off vessel parts and anatomical ducts or hollow organs such as in the areas of the gastrointestinal tract.

**Hysterectomy clamp / vaginal clamp** is an instrument for clamping in the area of the uterus and adjacent structures such as parametrium and for pulling out the grasped part of the organ using hook pliers.

**Polyp clamp** is an instrument used to remove a polyp.

**Gallstone clamp** is an instrument used to clamp a gallstone.

**Tissue clamps** is an instrument for grasping tissue and for pulling out the grasped organ part using hook pliers.

**Cloth clamps** are used to fix drapes. The Backhaus drape clamp is a pointed, traumatic clamp that is used to fix drapes in the operating room.

**Bone holding forceps** are instruments for fixation and reduction of bones and bone fragments

**Needle holders** are instruments for performing a manual suture.

**Pliers** are used in a wide variety of operations. They support the grasping and grasping of tissues, skin or are used in connection with bandages.

**Clips** Vascular clips are used to clamp off arteries or tissue in order to control blood flow.

**Retaining and spreading instruments** are intended to hold tissue in place and thus to fix body entrances, surgical body openings and wounds and to ensure their access. Instrument with pointed and blunt hooks to keep the surgical field open. The wound area is made visible and accessible.

**Retractors** allow access to the surgical field and keep it open. They are used to hold off and expose tissue, muscles, organs or bones during the operation.

**Specula** is inserted into the vagina, for example, during gynecological examinations. Many specula then allow the two leaves to spread apart so that the vagina can be expanded. With a speculum, it is possible to take sterile swabs from the cervix or insert further instruments sterile into the uterus via the cervix.

**Dilators** (or bougie) is a medical device for widening (bougiening) existing body openings (e.g. urethra, anus, esophagus, vagina, cervix) or artificial accesses such as the puncture canal for the installation of a central venous catheter or a puncture trachotomy.

Tissue or bone surfaces are shaped, cleaned, smoothed or modeled using **abrasive instruments**. Another application is the taking of tissue samples.

**Exposed instruments** make access to the treatment area accessible by lifting bones, tissue, nerves and blood vessels.

**Force-exerting instruments** are intended to exert force on other instruments or directly on bones or tissue in order to increase the desired effect or to facilitate positioning.

**Gouge pliers** are used to cut through small, fine bones and to remove larger bones and bone splinters.

**Insertion or extraction instruments** contain material from organs or tissue that impair their function.

**Containers and storage** are intended to store or deposit instruments, objects or materials. The instruments and objects for sterilization are stored in the sterilization container in order to be freed from living microorganisms.

Other containers are used for storage or dispensers for instruments.

**Applicators** are an instrument used in endoscopy to hold and then attach a clip to a vessel.

**Medical hammers** are used to hammer in and out instruments such as chisels, implant inserters and other instruments with striking surfaces.

**Penetrating instruments / injection instruments** are intended to penetrate the skin, tissue, bones or blood vessels and to introduce materials or solutions into or out of the body.

**ENT cannulas** are used for rinsing or suctioning off tissue and / or liquids using rinsing fluid.

**Catheters** are small tubes or hoses with which hollow organs such as the urinary bladder, stomach, intestines, blood vessels, but also the ear and heart can be probed, emptied, filled or flushed.

**Examination instruments and diagnostic instruments** are intended to test the reflex, hearing and nervous feeling in patients.

Probes are instruments that are used to determine the length (compare), to palpate and track tissue ducts.

**Leading instruments** are intended to direct, guide and guide threads, wires, instruments or other objects in order to facilitate the attachment or positioning of these.

## 5. MATERIALS USED

Surgical instruments are made of stainless steels according to DIN EN ISO 7153-1 and EN 10088-3.

## 6. CONTRAINDICATIONS

1. Local infection due to poor soft tissue conditions in the area of osteotomy.
2. Increased fibrous tissue around the surgical site.
3. Early or late deep and / or surface infection.
4. Nerve damage is possible as a result of a surgical procedure.
5. Failure of the application due to insufficient healing phase before.

In most cases, any complications that may arise are not directly related to the use of an instrument, but rather are caused by the wrong selection of the patient, by inadequate training and by imprecise handling. Excessive forces can lead to unwanted injuries to the tissue or bones, or even break the instruments. Careful use of the instruments is therefore essential.
In order to rule out complications due to damage to the instruments, the material used must always be checked before use.
The instruments may only be used by trained personnel.

## 7. BASIC WARNINGS AND PRECAUTIONS

The products are delivered **UNSTERILE**! The packaged products are marked accordingly.

After receiving the products, check their identity, completeness, integrity and function.
Before any instruments are used, they must be examined for breaks, cracks, deformations, damage and functionality. Areas such as cutting edges, points, keys, locks, notches and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.
The attending physician and all other persons involved in the handling of the products are responsible for having appropriate product knowledge based on the latest technology standards within the scope of their area of activity. This enables the correct use of the products and prevents health or safety risks for patients, users or third parties.
The relevant product catalogs, videos, technical specifications, instructions from medical product consultants, working groups, seminars, specialist courses, publications, etc. serve as sources of information for the products. A corresponding product training - including the handling of the products - must be carried out prior to clinical use
The indications for use for the products represent a group of standard information that can be adapted to individual needs and situations that arise according to the skills, experience and diagnosis of a legally qualified medical user. The treating physician is responsible for the correct selection of the patient, the assessment of the indication and the selection of the instrument.
The attending physician should discuss in detail with the patient that the treatment results that can be expected with the use of the products. Particular attention should be paid to a post-operative consultation and the need for regular medical check-ups.
The products must be handled and stored carefully. Damage or scratches on the instrument can significantly impair the strength and fatigue resistance of a product.
The patient must be instructed in proper post-operative hygiene and should be instructed to inform the treating physician immediately of any unusual changes in the surgical area. The patient should be constantly monitored if a change in the operating area is noticed
After contact with or use on patients with Creutzfeldt-Jacob disease (CJD) or its variants, we decline any responsibility for the use! In this context, please note that you may have contaminated the unused instruments in the trays.

## 8. RETURNS

Any return of products may only be sent back to us after a clearly visible disinfection / sterilization (appropriate packaging with sterile indicators, decontamination certificate, etc.).

The relevant hygiene and industrial premises regulations must be observed.

## 9. PROCESSING, CLEANING, DISINFECTING THE INSTRUMENTS

### I. Basic warnings and precautionary measures

Instruments made of stainless steel must not be placed in physiological saline solution (NaCl solution), since prolonged contact leads to corrosion such as pitting and stress corrosion cracking.
WARNINGS Only cleaned and disinfected instruments may be sterilized.
**Reconditioning Limitations Frequent reprocessing has little impact on these instruments. The end of life is usually determined by wear and tear and damage from use.**
Please follow the instructions for use.
The products are delivered UNSTERILE! The packaged products are marked accordingly.
After receiving the products, check their identity, completeness, integrity and function.
Before any instruments are used, they must be examined for breaks, cracks, deformations, damage and functionality. Areas such as cutting edges, points, keys, locks, notches and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.
The attending physician and all other persons involved in the handling of the products are responsible for having appropriate product knowledge based on the latest technology standards within the framework of their area of activity. This enables the correct handling of the products and prevents health or safety risks for patients, users or third parties.
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The indications for use for the products represent a group of standard information that can be adapted to individual needs and situations that arise according to the skills, experience and diagnosis of a legally qualified medical user. The treating physician is responsible for the correct selection of the patient, the assessment of the indication and the selection of the instrument.
The attending physician should discuss in detail with the patient the expected outcome of the use of the products. Particular attention should be paid to a post-operative consultation and the need for regular medical check-ups.
The products must be handled and stored carefully. Damage to or scratches on the instrument can significantly impair the strength and fatigue resistance of a product.
The patient must be instructed in proper post-operative hygiene and should be instructed to inform the treating physician immediately of any unusual changes in the surgical area. The patient should be constantly monitored if a change in the operating area is noticed.
After contact with or use on patients with Creutzfeldt-Jacob disease (CJD) or its variants, we decline any responsibility for the use!
Please note in this connection that you may have contaminated the unused instruments in the trays.
Please also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements with regard to an effective prion inactivation.

### II. Instructions for reprocessing

1. Immediately after use, coarse soiling should be removed from the instruments with a damp disposable cloth / paper.
2. No fixing agents or warm water (> 40 ° C) may be used, as this leads to the fixation of residues and can affect the cleaning success.
3. The instruments must be sent to the reprocessing process immediately.
4. Preferred dry disposal.

Safe storage and safe transport to the preparation of the products in order to avoid damage and drying-on of soiling. The preparation should take place promptly (<4 hours)!

**Preparation for decontamination:**

Instruments with hinges must be opened for reprocessing. The instruments must be placed on machine-compatible instrument carriers in a manner suitable for washing. The instrument carriers (e.g. wire mesh trays) must be designed in such a way that the subsequent cleaning in the ultrasound or in the cleaning and disinfection device (WD) is not hindered by sound or rinsing shadows.

**Pre-cleaning:**

1. Rinse instruments under cold water (<40 ° C) until all visible dirt has been removed;
2. Stubborn dirt is to be removed with a soft brush or the enclosed cleaning mandrel. Until all visible dirt has been removed;
3. Cavities and lumens should be rinsed intensively (> 30 sec) with cold city water (<40 ° C) using a water pressure gun (or similar).

National guidelines must be observed.

**Automatic cleaning process (Miele G7835 CD):**

The cleaning and disinfection device (RDG) must meet the requirements of DIN EN ISO 15883-1.

1. Pre-rinse 1: 1 minute with deionized cold city water, without additives; (<40 ° C)
2. emptying;
3. Pre-rinse 2: 3 minutes with deionized cold city water, without additives; (<40 ° C)
4. emptying;
5. Cleaning: 5 minutes cleaning at 55 ° C ± 5 ° C with 0.5% alkaline cleaning agent (0.5% neodisher® MediClean forte)
6. emptying;
7. 3 minutes of neutralization (neodisher® Z) with cold city water <40 ° C
8. emptying;
9. Intermediate rinsing: 2 minutes with hot deionized water (> 71 ° C) (without any other additives).
10. Emptying

**Automatic disinfection (Miele G7835 CD):**

11. Automatic thermal disinfection in the washer-disinfector, taking into account the national requirements for the A0-3000 value; > 5 minutes at 92 ° C ± 2 ° C.).

**Drying:**

12. Automatic drying according to the automatic drying process of the washer-disinfector for 30 minutes at 60 ° C ± 5 ° C. Subsequent manual drying with a lint-free cloth and blowing out the lumen using sterile, oil-free compressed air.

## III. Cleaning / disinfection: manual

The cleaning agents and disinfectants used must be suitable for manual cleaning or disinfection of instruments and must be compatible with each other. The disinfectant must have a proven effectiveness. When choosing the disinfectant and method, the relevant lists and recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (DGHM) must be observed.

**Pre-cleaning:**

1. Rinse instruments under cold water (<40 ° C) until all visible dirt has been removed;
2. Stubborn dirt is to be removed with a soft brush or the enclosed cleaning mandrel. Until all visible dirt has been removed;
3. Cavities and lumens should be rinsed intensively (> 30 sec) with cold city water (<40 ° C) using a water pressure gun (or similar).

**Manual cleaning**

1. Completely clean the products with a soft brush and cleaner;
2. Thoroughly rinse out cavities and lumens, if present, with a water pressure gun (or similar) (> 30 sec);
3. Rinse the products under running tap water to remove the cleaning agent (> 15 sec).
   A high level of dirt in the ultrasonic tank impairs the cleaning effect and increases the risk of corrosion. The cleaning solution must be renewed regularly depending on the conditions of use. The criterion is visually recognizable contamination. In any case, frequent bath changes, at least once a day, are required.

**Manual / chemical disinfection:**

1 Immerse products in an RKI or VAH - listed disinfectant. The instructions of the disinfectant manufacturer must be followed;
2 All surfaces must be in contact with the disinfectant; moving parts are to be operated.
3 Rinse the products in deionized water.

**Optical control:**

Repeat the cleaning process if there are still visible impurities on the instrument;
Use solutions that are freshly prepared every day. In the case of heavy contamination, the working solution must be changed more and more. The national guidelines must be observed.

**Drying:**

Manual drying with a lint-free cloth. The product must never be heated above 140 ° C. In order to largely avoid water residues in cavities, it is recommended to blow them out with sterile compressed air.

**Maintenance, control and testing:**

After cleaning / disinfection, the instruments must be macroscopically clean, i.e. H. free of visible dirt and residues. The verification is done visually. All instruments with lumens (cannulas) must be checked for patency. Insufficiently cleaned instruments must be cleaned again and then sufficiently rinsed and dried. Instruments with moving parts must have cooled down and oiled with instrument care oil

before the function test. Instruments such as clamps and needle holders that have a notch may only be closed up to the first notch (risk of stress cracking). Defective instruments (hairline cracks, deformation or wear) must be replaced because they no longer fulfill their function or no longer fulfill their function with sufficient reliability. Corroded instruments must also be removed, since they can cause corrosion on intact instruments through the transfer of extraneous rust.

**Packaging:**
Sort the cleaned and disinfected instruments into the sterilization trays and pack them in sterilization packaging (single or double packaging) and / or sterilization containers that meet the following requirements:

- according to DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to -10
- suitable for steam sterilization (temperature resistance up to at least 138 ° C (279 ° F), sufficient steam permeability)
- Sufficient protection of the instruments and sterilization packaging from mechanical damage
- regularly maintained according to the manufacturer's specifications (sterilization container)

Sterilization accessories and sterilization packaging must be tailored to both the contents of the packaging and the sterilization process used.

## IV. Sterilization

Only the sterilization processes listed below are to be used for sterilization; other sterilization methods are not permitted.
Steam sterilization

- Fractional vacuum process / pre-vacuum process (3 pre-vacuum cycles) or gravitation process2 (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- validated according to DIN EN ISO / ANSI AAMI ISO 17665 (valid picking and product-specific performance assessment)
- maximum sterilization temperature 134 ° C (273 ° F; plus tolerance according to DIN EN ISO / ANSI AAMI ISO 17665) Sterilization time (exposure time at the sterilization temperature) at least 3 min3 at 134 ° C (273 ° F) / It is essential to have a SAL (Sterility Assurance Level) of 10-6. The less effective gravitational method may only be used if the fractional vacuum method / pre-vacuum method is not available or 18 min (prion inactivation)
- Drying for at least 10 minutes

The flash sterilization process is generally not permitted.
All instruments, sterilization trays and sterilization containers may only be exposed to temperatures no higher than 137 ° C (279 ° F)!

**Storage**:
Reconditioned sterile instruments must be stored in a suitable, reusable sterilization container, dry, dust-protected, germ-free, dark and in a cool room, free from vermin. In order to avoid the formation of condensation, larger temperature fluctuations should be avoided during storage. No chemicals should be stored with instruments. The walls, floors and ceilings of the storage room should be smooth, easy to clean and disinfect. Shelves must have a floor clearance of at least 30 cm. The permissible storage time on site depends on the type of sterile barrier system used and the storage conditions. The operator must determine the permissible storage period.

**Further information on reprocessing:**
A validated machine cleaning and disinfection process is always preferable to manual cleaning due to the higher level of safety in the process. Good cleaning also helps to maintain its value and is a prerequisite for successful sterilization. The following points must be observed for machine processing:

- For effective machine reprocessing, it is essential that the sieve trays are properly loaded. Sieve trays must not be overloaded.
- Rinsing shadows from large instruments must be avoided.
- Depending on their mechanical sensitivity, the instruments must be placed or stored in such a way that damage is impossible. The times and temperatures given in these instructions for reprocessing are minimum requirements that must not be fallen below. If, for procedural reasons, a downward deviation is required, this must be validated by the operator. In principle, it is possible to exceed the specified times and temperatures, but this leads to increased stress on the material, which can lead to premature aging of the instruments.

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## V. Material resistance

When choosing cleaning agents and disinfectants, please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids

- stronger alkalis (pH> 11 not permitted, mildly alkaline cleaners recommended)
- halogenated hydrocarbons, chlorine, iodine
- ammonia

Never clean all instruments, sterilization trays and sterilization containers with metal brushes or steel wool.
All instruments, sterilization trays and sterilization containers may only be exposed to temperatures not higher than 137 ° C (279 °F)!

## 10. CONTROL

After cleaning or cleaning / disinfection, check all instruments for corrosion, damaged surfaces, chipping and soiling and separate out damaged instruments (for numerical restrictions on re-use, see chapter "Reusability"). Instruments that are still soiled must be cleaned and disinfected again.

## 11. PACKAGING

Sort the cleaned and disinfected instruments into the sterilization trays and pack them in sterilization packaging (single or double packaging) and / or sterilization containers that meet the following requirements:

- according to DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to -10
- suitable for steam sterilization (temperature resistance up to at least 137 ° C (279 ° F), sufficient steam permeability)
- Sufficient protection of the implants or sterilization packaging from mechanical damage
- regularly maintained according to the manufacturer's specifications (sterilization container)

## 12. STORAGE

After sterilization, the instruments must be stored dry and dust-free in the sterilization packaging.

## 13. REUSABILITY

The instruments can - with due care and provided they are undamaged and fully functional - be reprocessed and reused. The service life is limited by damage and normal wear and tear; these products are to be sorted out after processing. Please note, however, the restriction from Section 9, last paragraph, regarding Creutzfeldt-Jacob disease (CJD).
best medical does not specify a maximum number of uses and reprocessing cycles for reusable instruments. The service life depends on many factors, including the type and duration of use, as well as handling, storage and transport of the instruments.
Careful checks and functional tests before the next use is the best way to identify and sort out an instrument that is no longer functional.
We would like to point out that the biological compatibility of the instruments can no longer be guaranteed due to the accumulation of detergent residues. This is the responsibility of the user to monitor.

Any liability is excluded in the event of disregard.

## 14. WARRANTY

Safety note: The operator / product user is responsible for the proper disinfection and sterilization of products. National regulations, including restrictions on this, must be observed.
best medical only delivers tested products to your customers. All of our products are designed and manufactured to meet the highest quality standards.
As the distributor of the products, best medical excludes any warranty claims and assumes no liability for direct or consequential damage caused by:

- improper use
- improper use, application or handling
- improper reprocessing and sterilization
- improper maintenance and repair
- Failure to observe the instructions for use

## 15. STANDARDS – REFERENCES

- DIN EN 285 large steam sterilizers
- DIN EN 13060 small steam sterilizers
- DIN EN ISO 15883-1-3 washer-disinfectors
- DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to -10 packaging materials
- DIN EN ISO 17664 / ANSI AAMI ST81 sterilization - Information from the manufacturer
- DIN EN ISO 17665-1 sterilization process - Moist heat

**best medical GmbH**
**Heudorfer Straße 32**
**78576 Liptingen**
**Germany**