1. GENERAL INFORMATION

It is absolutely essential that all conditions contained in these instructions are met and all special information taken into account. Otherwise, these products may not be clinically used. In addition, any instructions for use specific to the projects must be carefully followed. Should uncertainties, disagreements or questions arise, please contact us before (re)using or preparing the products. These Instructions For Use do not replace the training, care and best available technology for the user. Therefore, we assume that the statutory provisions, standards and recommendations (e.g. from RKI or AKI) are known (see Standards/References) and therefore, we restrict ourselves to the instructions and information for each product to be followed by the user, which are of importance for our products. The reasons for these instructions and risks that result from non-observance are listed in the statutory provisions and recommendations.

READ ALL APPLICABLE INSTRUCTIONS FOR USE VERY CAREFULLY BEFORE PREPARING OR USING A PRODUCT FOR THE FIRST TIME.

2. INFORMATION AND SYMBOLS ON LABELS

Article or Order number


Symbol of Manufacturer


Caution, observe the accompanying documentation!


Observe the Instructions for Use

Batch number


Community European

Information about NON-sterile product

3. DESCRIPTION AND PRODUCT SPECIFIC INSTRUCTIONS

The products are medical devices with regard to national and international laws for products in human medicine.

4. INTENDED USE

Exclusively adequately qualified personnel may only use the instruments in order to fulfill their defined functions. 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.

Distractors are intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of traumatic defects of the bones, where gradual bone distraction is required.

Scissors with and without carbide inserts Some Scissors can be used to sever tissue, organs, bones, bandaging materials and suture materials. Union Scissors can be used to cut bandage.

Wire Cutting Instruments wire cutting pliers are frequently used to cut bone wires. The maximum wire diameter to be cut can be determined on the basis of the features of the wire.

Punches punches are primarily used in neurosurgery and orthopedics for the preparation of cartilage and bones in the spine. However, the swages can also be used in other areas of medicine.

Bone rongeur and forceps are used to prepare parts of the cartilage and bone. They are also used to sever fine bones. They are primarily used in orthopedics.

Chisels, osteotomes and gouges are used to prepare bones.

Scalpels are used to sever tissue, vessels and organs. A sharp, even grinding of the blade is important for good cutting ability. The grinding is either hollow or flat.

Clamps are instruments used to grip, hold and clamp blood vessels, tissue, organs and medical supplies. They are classified as follows: Hard gripping clamps, Soft gripping clamps, Atraumatic clamps, Anatomical clamps, Surgical clamps.

Needle holders are used to grip and hold surgical suture needles during an operation. In medicine, sutures are only inserted using a needle holder. The right choice of needle holder is important. The appropriate needle holder can be determined using the list on the left hand side.

Forceps are used to hold and grip tissue, organs, medical supplies and materials. Forceps are divided into three main categories: Anatomical forceps, Atraumatic forceps, Surgical forceps.

Pliers are used to remove bone wires and rods. The beaks are designed with and without carbide inserts.

Handheld Trocars are used in minimally invasive surgery, a sharp or blunt trocar is used to create access to a body cavity, and this is kept open with a tube. Various different instruments can be inserted into the body cavity through this tube.

Wound spreaders are surgical instruments, which are used to keep an operating area open. Unlike tissue retractors, wound spreaders are self-holding instruments. This is mostly achieved using a rest lock.

Abdominal retractors are surgical instruments, which are used to keep an operating area open. Unlike tissue retractors, abdominal blades are self-holding instruments. This is mostly achieved using a rest lock.

Wound retractors are used to hold tissue, organs and bones and to spread the edges of wounds.

Rib retractors are used to spread the sternum during a heart condition.

Speculum is a medical examination instrument, which is primarily used in gynecology and ear, nose and throat medicine.

Plate cutting instrument may be used to divide a bone plate in the area of the connecting bridge between two screw holes. As a precaution when cutting a plate, the plate end to be cut should never be directed toward the patient or a third party to prevent the risk of injury from the plate segment spinning off. It is advisable to cover the plate segment to be cut with a towel or other material to prevent the segment from spinning off in the first place. The shortened bone plate segment should be de-burred after cutting (see matching de-burring instruments in the leaflet) to prevent injury to or irritation of the soft tissue.

Plate and Screw Holding Instruments The use of implant holding instruments for safe manipulation/positioning is particularly advisable in areas of poor accessibility or areas in which freedom of movement is limited.

Drill Guides centric and eccentric drill guides (in conjunction with compression plates) ensure a low-strain seat of the bone screw in the bone plate and thus, make maximum axial compression possible (for compression techniques).

5. MATERIALS USED

Surgical instruments are made of stainless steel according to ISO 7153-1 and EN 10088-3, and of Ti6Al4V alloy in accordance with ISO 5832-3/ASTM F136 and biocompatible, autoclavable, non-metallic materials on an individual basis.

6. POSSIBLE ADVERSE EFFECTS

In most cases, possible complications are not directly related to the use of the instruments, but are more likely attributed to the incorrect selection of the patient, inadequate training.

1. Increased fibrous tissue response around the osteotomy area.
2. Early or late infection, both deep and/or superficial.
3. Nerve damage may occur as a result of the surgical intervention.
4. Metal sensitivity reactions in patients have rarely been reported, and their significance awaits further clinical evaluation.

7. CONTRAINDICATIONS

The circumstances listed below may reduce the chances of a successful outcome.

1. Insufficient quantity or quality of bone, which would inhibit rigid fixation of the device.
2. Compromised vascularity.
3. Previous history of infections.
4. Ulcers in the area where the device is to be placed, or the use of radiation or chemotherapy.
5. Mental, physical or neurological conditions, which may impair the patient's ability to cooperate with the postoperative regimen.

8. GENERAL WARNINGS AND PRECUATIONS FOR USE

The products are supplied NON-STERILE. Sterile packaged products are labeled accordingly.
Check the identity, completeness, intactness and function upon receipt of the products before making them available for use.
Check instruments for breakage, cracks, deformations, damage and functional ability before each use. Particular attention should be paid to areas such as blades, tips, box locks, locks, ratchets and all moveable parts. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted.
The surgeon and all other persons involved in the use of the products are responsible in regards to their field of activity to have appropriate product knowledge based on the current technology standard. This ensures proper use of the product and prevents health or safety risks to patients, users or third parties.
Additional sources of information for the products may include applicable product catalogs, videos, technical specifications, instructions from medical product advisors, working committees, seminars, specialized courses, publications, etc. Appropriate product training, including proper handling, is required before clinical use.
The indications on the use of the products represent a group of standard instructions that can be adjusted to the particular needs and situations that may arise according to the ability, experience and diagnosis made by a legally qualified medical user. Responsibility for proper selection of patients, adequate training, rests with the surgeon.
The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient.
Particular attention should be given to a postoperative discussion and the necessity for periodic medical follow-up.
The correct selection of the product is extremely important. This can be determined by evaluating the patient's functional demands and anatomy. See also other general scientific documents with detailed indications regarding the selection of instruments.
Careful handling and storage of the products is required. The patient must be instructed on proper postoperative hygiene procedures and should be advised to report any unusual changes in the operated site to the surgeon.
The surgeon should evaluate the possibility of subsequent clinical failure and discuss the need for any measures deemed necessary to aid healing with the patient.
After contact with or use on patients with Creutzfeldt – Jakob disease (CJD) or its variants, we decline all responsibility. In this regard, take notice that the unused instruments in the trays could have also been contaminated.
Preparation and reuse even according to the RKI Guidelines rests solely on one's own responsibility.

9. RETURNS

All returns of products to us is only allowed after a visible disinfection/sterilization has been performed (respective packaging with sterilization indicator, decontamination certificate etc.)
The corresponding hygiene and company regulations are to be adhered to.

10. PREPARATION, CLEANING, DISINFECTION, MAINTENANCE, AND STERILIZATION OF INSTRUMENTS

10.1 General Principles

All instruments must be cleaned, disinfected and sterilized before each use. This also applies to initial use after delivery of instruments in particular, which are supplied non-sterile (cleaning and disinfection after removal of the

protective transportation packaging; sterilization after packaging). Sterile packaged products are labeled accordingly upon delivery. Effective cleaning and disinfection is an absolute requirement for an efficient sterilization.
Please pay particular attention that contaminated instruments are separated and not placed back into the instrument tray once used to prevent increased contamination of the filled instrument tray. Clean/disinfect reusable contaminated instruments, sort them again into the instrument tray and then sterilize the fully filled and previously cleaned/disinfected instrument tray.
With regard to your responsibility for the sterility of the instruments, please ensure, as a matter of principle that only adequate methods validated based on the device and product, are used for cleaning/disinfection and sterilization, that the devices used (RDG, sterilizer) are regularly maintained and checked, and that the validated parameters are observed during each cycle.
Please also follow the statutory provisions valid in your country and the hygiene regulations of the medical practice or hospital. This particularly applies to the various specifications with regard to effective prion inactivation.

10.2 Cleaning and Disinfection
Basic Principles
A mechanical method (RDG – cleaning and disinfection machines / disinfectors) should be used when possible to clean and disinfect instruments. A manual method – even when using a ultrasonic bath – should only used if a mechanical method is unavailable due to the much lower effectiveness and reproducibility of the manual method[1]
[1]The use of a manual cleaning and disinfection method must be verified by the user by means of an additional product and procedure specific validation.
Pre-treatment is required in both cases.

Pre-treatment
General contamination must be removed from the product directly after use (within a maximum of 2 hours).
To maximize cleaning and disinfection efficiency, products consisting of several components that can be disassembled should be disassembled according to the product specific Instructions for Use and the instructions in the section “Special Instructions” as the case may be (replaceable parts, accessories, adapters, interchangeable inserts, etc.)
Use running water or a disinfectant solution, the disinfectant should be aldehyde-free (otherwise fixation of blood contamination), exhibit proven effectiveness (e.g. VAH/DGHM or FDA approval or CE mark), be suitable for the disinfection of instruments and be compatible with the instruments (see chapter “Material Resistance”).
Only use a soft brush or a soft clean towel intended for this purpose to manually remove impurities, i.e. never use metal brushes or steel wool.
Please note that the disinfectant used for pre-treatment is intended for personal safety only and cannot replace the disinfection step to be performed after a successful cleaning.

Mechanical Cleaning/Disinfection (RDG)
In selecting the RDG, ensure that:

- The RDG exhibits proven effectiveness (e.g. DGHM or FDA approval or CE mark according to DIN EN ISO 15883).
- A proven program for thermal disinfection is used (minimum of 5 min at 134°C or A_0 value > 3000) if possible (for chemical disinfection, risk of disinfectant residues on the instruments).
- The program used for the instruments is suitable and contains adequate rinse cycles.
- That the water suitable for rinsing (e.g. Aqua purificata/Aqua purficita valde) is used, and furthermore that the air used for drying is filtered and therefore not decrease the hygiene status at this point.
- The RDG is regularly maintained and tested.

In selecting the detergent system used, ensure that

- It is generally suitable for cleaning the instruments.
- If no thermal disinfection is used, a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval or CE mark) and the disinfectant is compatible with the detergent is used and
- The chemicals used are compatible with the instruments (see chapter “Material Resistance”).

The detergent and disinfectant concentrations specified by the manufacturer must be strictly followed.

Procedure:

1. Disassemble the instruments to the maximum extent possible.
2. Place the disassembled instruments in the RDG. Make sure that the instruments do not touch one another.
3. If products with narrow lumens or cavities cannot be connected, they must be placed in the RDG to allow water and disinfectant to drain.
4. Start the program.
5. Take the instruments out of the RDG after program completion.
6. Check and package the instruments if possible immediately after removal from the RDG (see Chapters “Control”, “Maintenance” and “Packaging” and if necessary after an additional final drying process in a clean area).

Proof of basic suitability of the instruments for an effective mechanical cleaning and disinfection has been furnished by an independent accredited test laboratory using the “RDG G 7836 CD” (thermal disinfections, Miele & Cie. GmbH & Co., Gutersloh, Germany) and the detergent “Neodisher mediclean forte” (Dr. Weigert GmbH & Co. KG, Hamburg). The method described above was considered.

10.3 Lubrication
Before instruments are used and prior to each surgical procedure, instruments must be decontaminated, lubricated, and sterilized. Lubricate moving parts with a water-soluble lubricant in accordance with the manufacturer’s instructions.

11. INSPECTION AND TESTING PRIOR TO REUSE
Before each use, the instruments must be thoroughly inspected for damage such as fractures, cracks or deformation, as well as for functional reliability. Special attention must be paid to cutting edges, tips, joints, box locks, ratchets and all movable parts. If wear, corrosion, deformation, porosity or other damage is detected, the instrument must be immediately withdrawn from service. Due to their alloy stainless steel instruments typically develop a passive film in the form of a protective layer. However, this film does not protect them well against chemical attack by chloride ions and aggressive media and liquids! Therefore, in addition to the instrument manufacturer’s endeavors to select the right materials and process them carefully, the user must make an important contribution by ensuring proper instrument processing along with adequate and regular care.

12. PACKAGING
Sort the cleaned and disinfected instruments into the sterilization trays and package them in single use sterilization packaging (single and double packaging) and/or sterilization containers that meet the following requirements.

- In compliance with DIN EN 868/ANSI AAMI ISO 11607 and EN 868-2 until -10)
- Suitable for steam sterilization (temperature resistant up to min 137 °C (279 °F), sufficient vapor permeability)
- Sufficient protection of instruments or sterilization packaging from mechanical damage
- Regular maintenance according to manufacturer specifications (sterilization containers)

13. STERILIZATION
Only the sterilization methods listed below are to be used for sterilization, no other sterilization methods are permitted.

Steam Sterilization

- Fractionated vacuum procedure[1, 2] (with sufficient product drying[3])
- Steam sterilizer in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Steam sterilizer in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- Maximum sterilization temperature 134 °C (273 °F; plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

Country	Fractionated vacuum procedure	Gravity displacement
Germany	at least 5 min[4] at 134 °C (273 °F)	not recommended[2]
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]	not recommended[2]
France	at least 5 min at 134 °C (273 °F) if required for prion inactivation sterilization time 18 min	not recommended[2]
other countries	at least 5 min[4] at 132 °C (270 °F) / 134 °C (273 °F)	not recommended[2]

Verification of the general suitability of the products for effective steam sterilization was provided by an independent, governmentally *accredited and respected* (§ 15 (5) MPG) *test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum procedure, as well as the instrument oil LAWTON MEDOIL. Here, the typical conditions in the clinic and medical practice and the procedure described above were taken into consideration.*

The flash sterilization procedure is generally not permitted.

Do not use dry head sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

CAUTION: STERILIZATION IS NOT A SUBSTITUTE FOR CLEANLINESS.

14. STORAGE

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

15. MATERIAL RESISTANCE

When selecting the detergent and disinfectant, please ensure that they do not contain the following components

- Organic, mineral and oxidizing acids
- Strong lye solutions (pH > 11 not permitted, mildly alkaline cleaners recommended)
- Organic solvents (alcohols, acetone, etc.), benzines
- Halogenated hydrocarbons, chlorine, iodine
- Ammonia

Never clean instruments, sterilization trays or sterilization containers with metal brushed or steel wool.
Instruments, sterilization trays and sterilization containers should never be exposed to temperatures above 137 °C (279 °F).

Please be noted that special instructions and handling care needs to be accounted for all **Aluminum** instruments.

[1] at least three vacuum steps
[2] The use of the less effective gravity displacement is only permitted if the fractionated vacuum procedure is not available. It requires significantly longer sterilization times and must be validated by the user for each specific product, device, procedure and parameter.
[3] The actual required drying time depends directly on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer status) and must, therefore, be determined by the user. Nonetheless, drying time should not be under 20 min.
[4] or 18 min (prion inactivation, not relevant for the USA)

- **Do not** use alkaline cleaners > pH 7 for aluminum instruments!
- **Do not** clean aluminum instruments in an ultrasonic unit! Clean by hand or in some automated washers.
- Anodized aluminum **should not** be sterilized with stainless steel instruments, it may cause an adverse chemical reaction.

16. REUSABILITY

The instruments can, by the respective thoroughness and providing that they are not damaged and fully functional, be prepared again and reused. The life cycle is limited due to damage and normal wear; these products are to be separated after preparation from the others. Please consider the limits from Chapter 9, last paragraph regarding Creutzfeldt-Jacob disease (CJD). OrthoMed does not define the maximum number of usage or preparation cycles of reusable instruments. The life cycle is dependent upon many factors including the type and length of usage, as well as handling, storage and transport of the instruments. Thorough examination and function testing before the next use is the best possible way to detect non-functioning instruments and sort them out. We would like to point out that also through the accumulation of detergent residuals, the biological compatibility of the instruments can no longer given. This lies in the observation obligation of the user.

We assume no liability resulting from failure to observe these guidelines.

17. WARRANTY

Safety Instructions: Responsibility for proper cleaning, disinfection and sterilization of products is the sole responsibility of the operator / product user. National regulations including limitations must be carefully followed. OrthoMed supplies tested products free of defect to their customers. All our products are designed and manufactured to meet the highest quality demands.
OrthoMed as the manufacturer of the products excludes any warranty claims and assumes no liability for direct or consequential damage as a result of:

- Misuse
- Improper use, application or handling
- Improper preparation and sterilization
- Improper maintenance and repair
- Failure to observe the instructions for use

18. STANDARDS – REFERENCES

- AKI[1] – “Proper Maintenance of Instruments” Guide
- RKI[2] – Recommendation “Hygiene Requirements with regard to the Preparation of Medical Products”
- 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 until-10 Packaging materials
- DIN EN ISO 17664/ANSI AAMI ST81 Sterilization – Manufacturer’s Information
- DIN EN SIO 17665-1 Sterilization process – Moist heat

[1] AKI Working Group Instrument Preparation
[2] RKI Robert-Koch-Institute

REV.	SECTION	DESCRIPTION	DATE	AUTHORIZED BY
	All	Initial Release	6/16/2020	Mardi Trone
A	13	Update throughout this section to reflect current guideline for the US and elsewhere	7/2/2023	Mardi Trone