KK-01 10.2020 / Rev:04

INSTRUCTIONS FOR USE

English

Cranial Stabilization Systems

BAHADIR TIBBİ ALET CİHAZ VE İNŞAAT MAKİNA SANAYİ VE TİCARET ANONİM ŞİRKETİ

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References

ASTM F3395/F3395M-19
EN ISO 15883
EN ISO 17664: 2017

CE

EN Cranial Stabilization Systems

Explanation of Symbols

	Read instructions before use!	CE	CE marking according to Directive 93/42 EEC
	Warning!		Manufacturer
NON STERILE	Non-Sterile		Production Date: Located on the package.
	Store in a dry place	LOT	Lot/Batch Number: Located on both the product and the package.
	Protect from sunlight	REF	Catalog Number: Located on both the product and the package.
MR	MR Unsafe	Rx ONLY	Caution: Federal (US) Law restricts this Device to sale by or on the order of a licensed healthcare practitioner.

INTENDED PURPOSE AND INDICATIONS

The Cranial Stabilization System is indicated for use in open and percutaneous cranial craniotomies as well as spinal surgery to hold the patient's head and neck securely in a particular position when rigid fixation is desired. It can be used for cranial fixation of the patient in prone, supine, lateral, and sitting positions.

CONTRAINDICATIONS

There are no known contraindications however contraindicated for all other applications except their intended use! The conditions that can risk the success of the operation such as injuries or accompanying diseases should be evaluated by the user. Risks should be taken into account for anatomical structures in the planned area.

Intended Population

warning The Skull Clamps are not recommended for use on children under five (5) years of age and extreme caution should be exercised in pediatric cases because of the thin skull.

GENERAL SAFETY WARNINGS

- Read, the instructions for use before each use.
- Keep this instructions for use throughout the product use.

NON STERILE
- Products are **NON-STERILE!** It must be cleaned and sterilized before use according to the instructions below.

- Used only by people the requisite training, knowledge and experience.
- Do not use for other than intended use.
- Before each use, instruments should be checked / inspected. (See **Inspection & Check**)
- In cases with infectious disease risk, the legislation determined by the relevant authority institution must be followed.
- Before each use, check the intercompatibility of instruments that are used with another device.

TECHNICAL DESCRIPTION

Structure / Shape

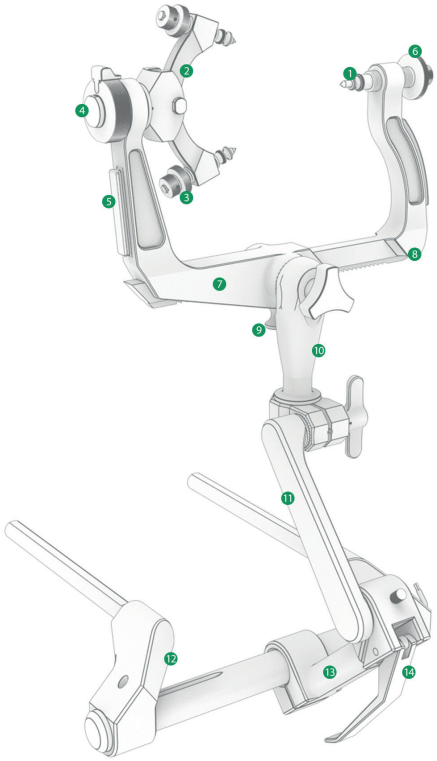
1- Skull Pins*
2- Rocker Arm
3- Spring-loaded Screws**
4- Index Knob
5- Side Rails
6- Torque Screw
7- Skull Clamp Base
8- Extension Arm
9- Release Knob
10- Swivel Adaptor
11- Transitional Arm
12- Base Unit (Rod System)***
13- Base Handle Assembly
14- Locking Lever

* For aluminum skull clamps, 2 different types of stainless steel pins are available as adult and pediatric (S540.06, S540.07). (see **Mounting of the Skull Pins**)

** The Spring-loaded Screws are provided optionally. Available in The Skull Clamp models with 3-point and single-point pressure (S540.30, S540.31).

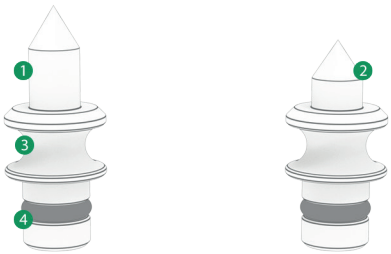
*** According to operation tables, 2 different types the bracket arms are available as rod and rail (S540.04, S540.18). (see **Mounting of the Base Unit**)

▸ **Materials:** Aluminum, stainless steel, polymer and silicone.



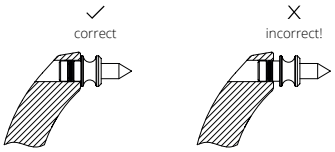
Usage / Application

Mounting of the Skull Pins



1- Skull Pin (for Adults) (S540.06)
2- Skull Pin (for Pediatrics) (S540.07)
2- Grooved Handle
3- O-Ring

- Use the grooved handle to safely hold the skull pins.
- Place the skull pins into the pin holder slots on the skull clamp. Ensure that the pins are firmly fitted and completely placed in the slot.

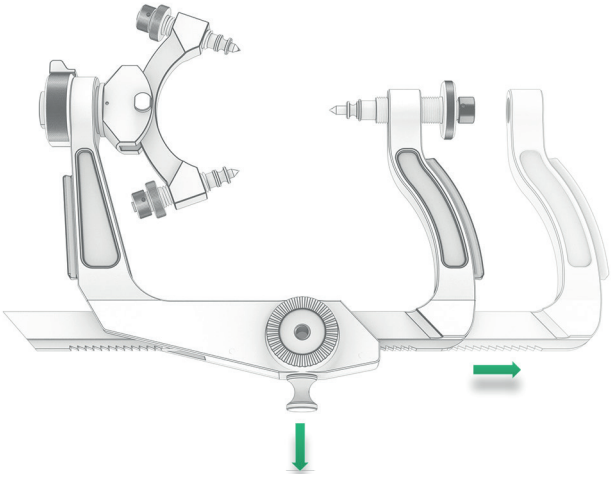


warning

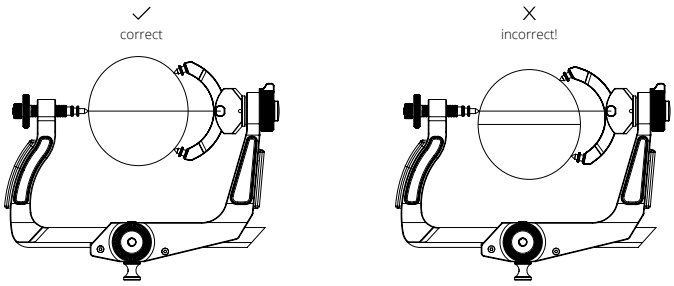
Do not place the skull pins on sensitive areas such as the frontal sinus, temporal fossa, blood vessels, or nerves!

MR

Stainless steel skull pins are **not safe** for MR!



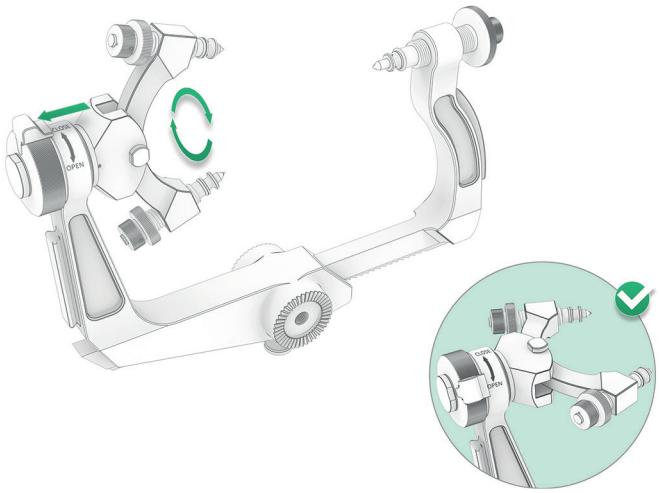
- To adjust the Extension Arm to the patient's skull, pull the Release Button at the bottom of the Clamp Base downwards and pull out the arm apart.
- Place the patient's head in the desired position in the Skull Clamp. The Skull Clamp should be applied along the centerline of the patient's head with pins entering the skull perpendicularly.
- Adjust the width to fixation the patient's head by pushing the Extension Arm to the Skull Clamp Base.



warning

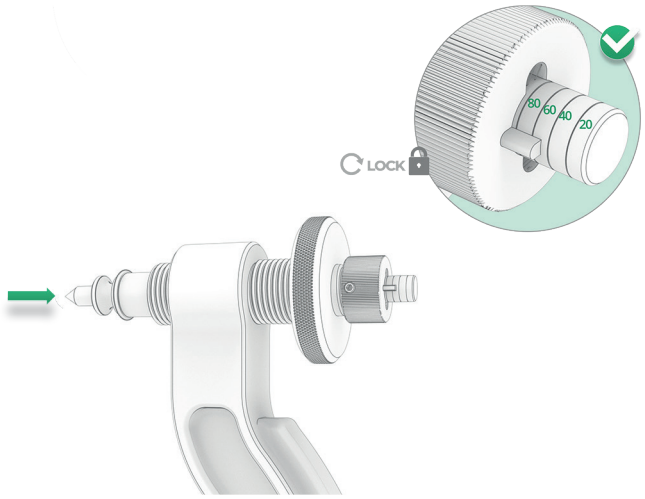
Failure to properly position the Skull Clamp on the patient's head and to fully tighten and secure all adjustable portions of this may cause skull pin slippages and serious patient injuries, such as scalp laceration, skull fracture, or even life-threatening.

Skull Clamp Patient Fixation



- Pull the button on the Index Knob outwards and move it to the "OPEN" indicator on the arm to release the Rocker Arm.
- Rotate the Rocker Arm to the desired position on the 360-degree axis.
- To lock, move the Index Knob back to the "CLOSE" indicator on the arm and ensure that the Rocker Arm is fixed.

▸ **Note:** Once the force is applied to the clamp and the patient is positioned for surgery, the Index Knob should be turned to the locked position.



warning

Before adjusting the clamping force, ensure that the patient's head is securely fixed and the pins are properly seated on the cranial area. Ensure that all adjustable parts are firmly tightened.

- Adjust the clamping force by turning the torque screw clockwise. The adjusted clamping force appears at the line indicator on the torque screw (20/40/60/80 lbs or 89/178/267/356 N).

▸ The Torque Screw provides the surgeon with a visual display of the clamping force applied. Each line indicates 20 lbs (89 N) increment of force.

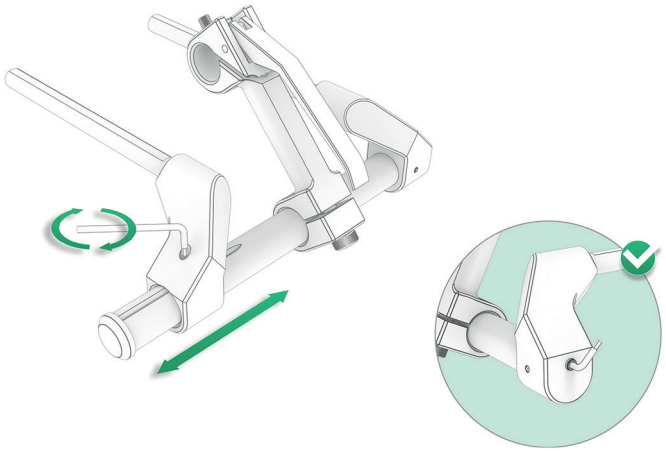
- Verify the total force applied to the patient by the line indicator. If necessary, readjust the clamping force.

  ▸ **Note:** To reach proper fixation for adults, it is recommended that a minimum of 60 lbs (267 N) of force be applied by the Skull Clamp. An additional clamping force reaching 80 lbs (356 N) is available if required.

warning

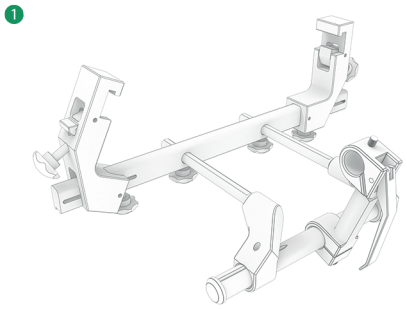
A clamping force of 40 lbs (178 N) is recommended for children and 60 lbs (356 N) for adults. The clamping force to be applied is the responsibility of the surgeon. Never exceed 80 lbs (356N) of force.

Mounting of the Base Unit



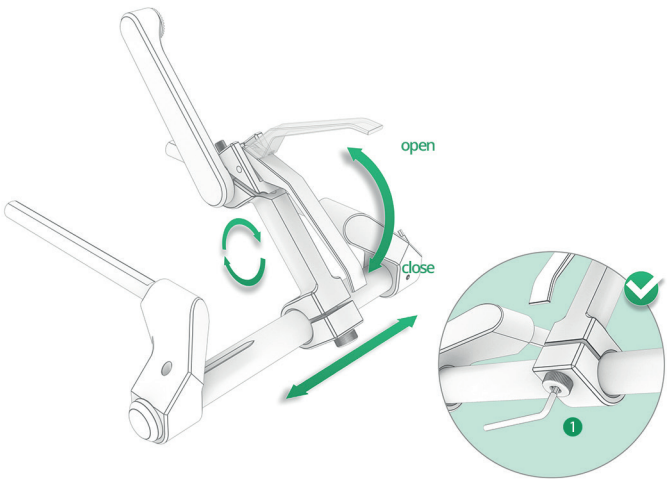
- Remove the Allen key from its slot on the right side of the Base Unit.
- To adjust the width, turn the hex screw located on the Movable Arm counter-clockwise by the Allen key until the bracket is loose.
- Slide the movable arm over the bar to adjust the arms width to the holes of the OR Table and ensure that the Base Unit is seated properly.

  ▸ **(1)** For operating tables that are not suitable for the rod system, prefer the side rail table adaptor (S540.09).



- Using the Allen key, lock the width by turning the hex screw clockwise. Return the Allen key to its slot.

Positioning of the Base Unit and Transitional Arm



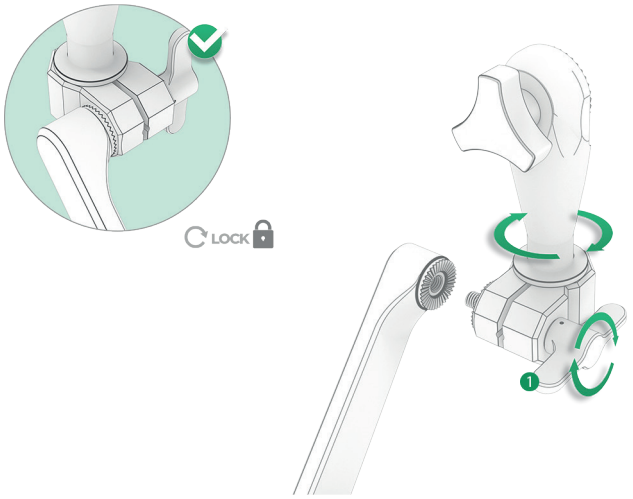
- Open the Locking Lever to release the Base Handle Assembly for positioning, and attach the Transitional Arm.

  ▸ **Note:** Do not close the Locking Lever without the Transitional Arm. The locking must be performed when all components are attached.

- Close the Locking Lever to lock the Base Handle Assembly and the Transitional Arm.

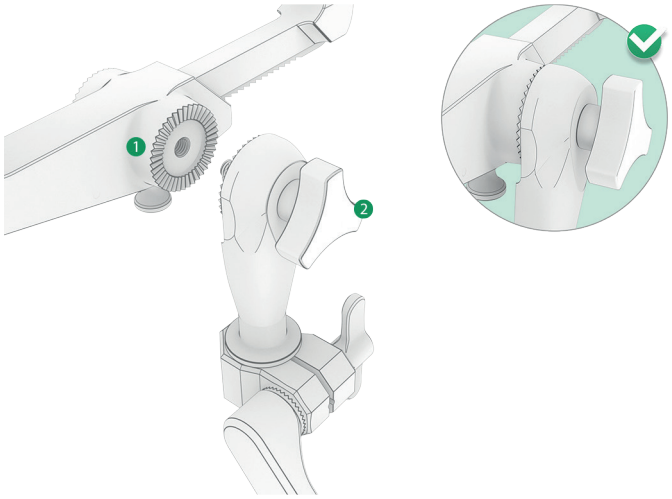
  ▸ **(1)** If necessary, the fastening tension can be adjusted. While the Locking Lever is fully opened, turn the hex screw located on the bottom counter-clockwise by the Allen key until the Tension Knob is loose. Adjust the fastening tension by turning the Tension Knob by hand. Check the tension by closing the lever to ensure that all components are fixed firmly.

Mounting of the Swivel Adaptor



- Place the Swivel Adapter into the Transitional arm and ensure the teeth are fully meshed and seated properly.
- Turn the lower locking screw **(1)** clockwise to tighten.

Mounting of the Skull Clamp



- Once the Transitional Arm and the Swivel Adaptor are in the desired position for mounting to the Skull Clamp, the Swivel Adaptor should be attached to the starburst connection **(1)** and ensure the teeth are fully meshed and seated properly.
- Turn the upper locking screw **(2)** clockwise to tighten.

⚠ WARNINGS REGARDING CLEANING, DISINFECTION AND STERILIZATION

- For the cleaning, disinfection and sterilization of products, national and international standards, directives and clinical hygiene instructions must be followed.
- Use cleaning and disinfectant agents according to the manufacturer's instructions.
- Apply cleaning processes (manual or mechanical) to newly purchased instruments before the first sterilization process.
- For patients with a diagnosis or suspicion of Creutzfeldt-Jakob disease (CJD) or variants, national regulations regarding disinfection and sterilization of products must be followed.
- Handle with validated methods and calibrated autoclaves and machines at all times.
- Use Personal Protective Equipment (PPE) when working with contaminated instruments. PPE: apron, mask, glasses, gloves, shoe covers etc.
- Prefer mechanical cleaning cleaning instead of manual cleaning as it gives more reliable results.
- Handle with care. Do not drop or apply excessive forces to the instruments during reprocessing.

Cleaning and Maintenance

⚠ warning **The use of metal brushes or clothes cause corrosion!**

⚠ warning **The use of chlorine solutions (saline solutions, bleaching agent, ringer solution) cause pitting corrosion or stress corrosion cracking!**

- Use cleaning and disinfection agents appropriate for aluminum, high-grade steel.
- Do not use hydrogen peroxide solutions (H_2O_2) on instruments with titanium and its alloys.
- Long-term processes with disinfectants based on alkylamine active ingredient in silicone elastomers (silicone-coated products) may cause hardening.
- Use cleaning agents with approved efficacy (VAH or FDA approval or CE mark)
- Cleaners with a disinfectant effect (manual cleaning) must be in accordance with EN 14885 or equivalent national guidelines.
- Use soft, lint-free fabrics, paper cloth, plastic, soft bristle brushes and water spray guns
- Do not use aldehyde based cleaning products due to its protein fixing properties.
- Cleaning solutions should be changed on daily basis. If the solution gets contamined visibly, it can be changed earlier.
- If powder products are used, the powder should be completely dissolved in water before use. Undissolved particles may cause changes in instrument surfaces and clog narrow tube instruments.
- Compressed air drying is more effective than drying with fabric or cloth.
- Ultrasonic cleaning is recommended to contribute to both manual and mechanical cleaning especiallyfor lumened and articulated instruments
- Suitable detergent should be selected for ultrasonic cleaning. (Non-foaming)
- Separate stainless-steel instruments from other metal instruments during ultrasonic cleaning to avoid electrolysis.
- Be sure that products are free of cleaning agent at the final rinse of ultrasonic cleaning step.

Water qualifications

Softened water* : Water hardening substances (calcium and magnesium cations) are reduced.

Demineralised water* : Mineral substances largely removed by reverse osmosis or cation & anion exchangers or electrode ionization or distillation.

For steam sterilization and the last rinsing of cleaning processing, limit values for feed water quality is specified in EN 285 and ISO 17665.

⚠ Non-conforming water properties cause:

- Scaling, lime deposits,
- Brown-red deposits, secondary rust,
- White-grey, colored appearance, thin scaling,
- Pitting,
- Spotting and scaling.

***** See www.ak-i.org, Publications, Red Brochure for water properties (softened water, demineralized water)

CLEANING, DISINFECTION AND STERILIZATION INSTRUCTIONS

Point of Use

- Remove excess biologic soil from the instruments with a disposable wipe.
- Rinse non-visible surfaces with demineralised water, with a disposable syringe.
- Place dry products in sealed waste containers.

Containment and Transportation

⚠ warning Wet disposal conditions increase the risk corrosion and microbial growth. The residues of cleaning agents interfere with the following processes.

- Transport the instruments to decontamination are in closed containers at dry state.
- Keeping the products at a dirty state more than 6 hours may cause corrosion and fail cleaning processes. Used instruments should be processed within 6 hours at dry disposal.
- Prevent slipping of the instruments by using special carrying tools during transportation.

Preparation for Cleaning / Precleaning

⚠ warning Do not exceed 25 °C for pre-cleaning temperature!

- Rinse the instruments to remove coarse contaminations.
- Disassemble the detachable instruments to preparing for cleaning.
- Ultrasonic washing is recommended before disinfection to increase the cleaning efficiency of heavily soiled or difficult to clean instruments such as lumened/tubular, micro and articulated instruments for mechanical support.
- If a pre-cleaning step is necessary before automatic cleaning/ disinfection, follow the 1st and 2nd process steps in the "**Manual Cleaning/Disinfection**" section of this document. Then send the instruments to the automatic washing-disinfection process by dry transfer.

Manual Cleaning / Disinfection

⚠ warning Do not exceed the maximum permitted cleaning temperature of 45 °C. Otherwise protein denaturation may ocur.

⚠ warning Use a non-protein fixing cleaning solution does not contain aldehyde, phenol and QUAT with a disinfection effect according to the manufacturer's instructions.

⚠ warning All scrubbing should be performed below the surface of the solution. Do not apply manuel cleaning to the cutting instruments or sharp pointed instruments to avoid physical demage to the operator !

	Process Step	Water Quality	Heat	Time
1	Cleaning/disinfecting[1]	Softened water*	Room Temp.	15 min
2	First Rinsing	Softened water*	Room Temp.	1 min
3	Disinfecting[1]	Softened water*	Room Temp.	15 min
4	Final Rinsing	Demineralized Water*	Room Temp.	1 min
5	Drying	-	Room Temp.	**

1. Pour a 25 ml dose cleaning/disinfectant solution in 5 liters of water (%0,5 dilution). Completely immerse instruments in the solution and gently shake them to remove trapped bubbles. Actuate instruments with hinges or moving parts to ensure contact of the solution with all surfaces. While soaking scrub surfaces using a suitable cleaning brush until all visible soil has been removed. Actuate moveable mechanisms. Particular attention should be given to hinged joints, box locks, instrument teeth, rough surfaces and areas with moving components or springs.

▸ **Note:** If the instrument is too large (such as skull clamp, table-mounted bars) to be immersed into the solution, a proper disinfectant cleaner should be sprayed out surface of the instrument.

2. Remove the instruments from the solution and rinse with softened water for a minimum of 1 minute. Actuate all moveable and hinged parts while rinsing. Allow excess water to drip of from the instrument prior to disinfectant solution.

3. Pour a 125 ml disinfectant solution dose in 5 liters of water (%2,5 dilution). Immerse fully in the disinfectant solution. Move the joints at least 5 times beneath the solution.

4. Rinse with running demineralized water for at least 10 seconds close and open the joints at least 5 times. We recommend using fully desalinated water (demineralized, drinking water quality at least) to avoid water spots.

5. Dry instruments with a clean, absorbent non-shedding lint free cloth or compressed air to remove moisture from lumens, holes, cannulas and difficult to access areas.

[1] Anios - Aniosyme DD1 Solution was used to verify cleaning.

▸ Check for cleanliness visually at the end the cleaning process especially the hinges, lumens, ratchets, teeth and etc. Repeat the cleaning process if necessary.

▸ Apply maintenance products (see **Maintenance & Care**)

▸ Control visually and functioning of the instruments according to the "**Inspection & Check**" part of this document.

Mechanical cleaning and thermal disinfecting

warning Use low alkaline cleaners (8.0-11.0 pH). Do not use high alkaline value (>11 pH) cleaning agents.

warning The washer disinfecfer must have either FDA approval or CE mark (validated according to EN ISO 15883)

▪ Place instruments in a washer/disinfector. Follow the washer / disinfector manufacturer's instructions for loading the instruments for maximum cleaning exposure; e.g. open all instruments, place concave instruments on their side or upside down, use baskets and trays designed for washers, place heavier instruments on the bottom of trays and baskets. If the washer/disinfector is equipped with special racks (e.g. for cannulated instruments) use them according to the manufacturer's instructions.

▪ Arrange the position of the instruments in the washer/disinfector to prevent mechanical damage through contact.

▪ Avoid overloading to make sure the surface of the instrument effectively gets in contact with cleaning solution.

▪ To prevent corrosion, unload the washer/disinfector immediately when the cleaning program ended.

▪ The following minimum wash cycle parameters are validated and recommended:

	Process Step	Water Quality	Heat	Time
1	Pre-wash	Softened water*	<25 °C	3 min
2	Cleaning	Demineralized Water*	40 – 55 °C	10 min
3	First rinse / Neutralization	Demineralized Water*	>10 °C	2 min
4	Intermediate rinse	Demineralized Water*	>10 °C	1 min
5	Thermal disinfection / Final rinse	Demineralized Water*	90 °C	5 min
6	Drying	-	-	**

▸ Check for cleanliness visually at the end the cleaning process especially the hinges, lumens, ratchets, teeth and etc. Repeat the cleaning process if necessary.

▸ Apply maintenance products (see **Maintenance & Care**)

▸ Control visually and functioning of the instruments according to the **"Inspection & Check"** part of this document.

***** See "Water qualifications" section of this document for water properties.

****** Dry time is dependent upon the load size placed into the washer/disinfector.

Maintenance & Care

warning Be sure to apply care product (lubricant) to metal sliding surfaces, moving parts, joints/box locks prior to **"Inspection & Check"**.

warning Raw materials used in care products must comply with pharmacopeias such as USP/NF, Ph. Eur, and national and international cosmetics regulations. **Do not use** silicone oil based products!

▪ Ensure that the instruments are cleaned effectively before maintenance. Visually and physically inspect the instruments for blood and protein soils. It is recommended to verify the cleaning with a chemical protein test, especially on surfaces that are difficult to clean or invisible such as ratchets, hinges, teeth, lumens.

Care products must be:

- ▸ Paraffin/white oil based,
- ▸ Biocompatible,
- ▸ Suitable for steam sterilization and vapor-permeable.

▪ Allow the products to cool down to room temperature.

▪ Assemble the diassembled parts. During the assembly for detachable rongeurs/punches make sure marked numbers are matched.

▪ Apply the care product directly to joints, hinges and friction surfaces by using a squirt oiler, an oil pen, or through targeted application of drops of oil.

▪ Actuate moving mechanisms a few times to distribute the care product evenly.

▪ Wipe the excessive care product with a lint-free cloth.

warning Failure to apply sufficient care products to moving parts causes friction related damage and corrosion!

Inspection & Check

Verify the following:

▪ Check the laser marking of the product. It must be easily readable visually or mechanically.

▪ There must not be any crack, fracture, wearing, burr, discoloration, spotting, rust or corrosion on the surface of the product.

▪ There must not be any loose, bent, broken, cracked, worn, or fractured components.

▪ There must not be any discoloration or deterioration in coating integrity on coated, painted and isolated coated products.

▪ Lumened/tubular instruments must be checked against blockages with a suitable cleaning brush. If a blockage is detected, reprocessing must be repeated.

▪ Cutting and puncturing instruments should not be dull.

▪ Moving parts must be able to move freely without getting stuck or rubbing.

▪ Products with spring-loaded components should regain their original form after use.

▪ Matching parts must be compatible with each other for the assembled products.

warning If any of the above controls are not confirmed, do not use the product, contact with Bahadır Medical Devices (manufacturer).
Damaged products must only be maintained by the manufacturer.

Sterilization Method

warning Do not steam sterilize the device. The heat may damage the internal parts, and coating if you autoclave the device. Sterilization is preferred for **only skull pins.** The entire unit may be ethylene oxide sterilized if required.

▪ The steam sterilizer must comply with the EN 285 standard and be verified according to the EN ISO 17665 standard.

- Ensure that the maximum permitted load according to the manufacturer's instructions is not exceeded.
- For steam sterilization, limit values for feed water quality as specified in EN 285 and ISO 17665.

Sterilization Method	Heat	Time
Prevacuum	134 °C[1,3]	5 min[2,3]

[1] Validated exposure time required to achieve a 10-6 sterility assurance level (SAL)

[2] Validated exposure temperature required to achieve a 10-6 sterility assurance level (SAL).

[3] Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.

Storage

- Storage and distribution of the product should be maintained by the designated staff according to the rules of the instutition which is used.
- Newly purchased products should be stored in a dust and moist-free environment.
- Surgical instruments should not be stored near to chemicals.
- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

Life Span

- As long as the instruments are regularly maintained, used according to their intended use, storage and maintenance conditions are followed, they can serve for 7 years depending on the average usage intensity.
- Products which can not pass from functional and visual inspection can not be used.

Disposal

- The disposal of a product that comes into contact with the human body and its packaging should be done in accordance with the national laws of the country where the product is used.

Technical Service

- Guarantee term: 1 years.
- The user is responsible for any adverse situation that may arise from the use of products whose warranty expires.

Manufacturer Contact Information

BAHADIR TIBBİ ALET CİHAZ VE İNŞAAT MAKİNA SANAYİ VE TİCARET ANONİM ŞİRKETİ

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