stryker

Stryker ENT Navigation System

Instructions for Use

Instrument Clamp
Electromagnetic Sphere
REF 8000-060-020

Instrument Clamp
Electromagnetic Universal
REF 8000-060-021

Rx Only

700000842818 | AD
2020-10-06

www.stryker.com

1. How to Use this Document

This document is the most comprehensive source of information for the safe and effective use of the product. Read this document carefully. Familiarization with the user documentation for the components of the Stryker ENT Navigation System prior to use is important. Pay special attention to safety information. Keep this document accessible to users.

When combined with other medical devices, the user manual of these devices is to be considered as well. Contact Stryker for training as needed. This document is a permanent part of the product.

The following signals may be used throughout this manual:

The signal word **WARNING** highlights a safety-related issue. Comply with this information to prevent patient and medical staff injury.

Supplements and/or clarifies information.

1.1. Contact Information

	Stryker Representative	
	+49 761 4512 0 (Germany)	+1 269 323 7700 (USA)
	www.stryker.com	

1.2. Symbol Definition

EN ISO 7010 Graphical Symbols – Safety Colors and Safety Signs – Registered Safety Signs:

Symbol/Number	Name: Definition
 W001	**General warning sign:** Signifies a general warning.
 M002	**Refer to instruction manual/booklet**: Signifies that the user instruction manual/booklet must be read.

EN ISO 15223-1 Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied - Part 1 General Requirements:

Symbol/Number	Name: Definition
 5.1.1	**Manufacturer:** Indicates the medical device manufacturer as defined in the European Union harmonization legislation.
 5.1.3	**Date of manufacture:** Indicates the date when the medical device was manufactured.
 5.1.5	**Batch code:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
 5.1.6	**Catalog number:** Indicates the manufacturer's catalog number so that the medical device can be identified.
 5.1.7	**Serial number:** Indicates the manufacturer's serial number so that the medical device can be identified.

Symbol/Number	Name: Definition
 5.2.7	**Non-Sterile:** Indicates a medical device that has not been subjected to a sterilization process.
 5.3.2	**Keep away from sunlight:** Indicates a medical device that needs protection from light sources.
 5.3.4	**Keep dry:** Indicates a medical device that needs to be protected from moisture.
 5.3.7	**Temperature limit:** Indicates the temperature limits to which the medical device can be safely exposed.
 5.4.3	**Consult Instructions For Use:** Indicates the need to consult the Instructions For Use.

IEC 60417 Graphical symbols for use on equipment:

Symbol/Number	Name: Definition
 5333	**Type BF applied part:** Identifies a type BF applied part complying with IEC 60601-1.

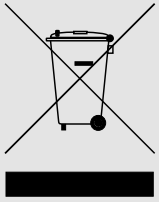
Product-Specific Symbols:

Symbol	Name: Definition
QTY	**Quantity:** Indicates the number of medical devices in the packaging.
MD	Indicates a medical device according to European Union harmonization legislation.
GTIN	Global Trade Item Number.

81 FR 38911 FDA Final rule for the use of symbols in labeling:

Symbol	Name: Definition
Rx Only	**Caution:** Federal law (USA) restricts this device to sale by, or on the order of a physician.

Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE):

Symbol	Name: Definition
	Indicates that the product must be collected separately and must not be disposed of as unsorted municipal waste.

2. Safety Information

WARNING

- The product is intended solely for use by medical professionals and may only be used by physicians who have the corresponding qualifications and have received the necessary training.
- The product is delivered in a non-sterile condition. Before first use, as well as before each following use, it must be reprocessed. Refer to *Section 6 'Reprocessing'*.
- Unauthorized modifications of the product are forbidden.
- Due to its composition, the product is not to be used together with other magnetically sensitive medical products, devices or instruments (e.g. MRI).
- Avoid subjecting the product to serious strains, such as heavy impacts. The product cannot be used if there are visible defects. After a heavy impact, the product must be checked for defects.
- Before using a medical product, assure yourself of its functional safety and proper condition via a visual inspection. Ensure there are no loose components or damage. Do not use the product if any defects are detected.

The user and/or patient should report any serious product-related incident to both the manufacturer and the national competent authority where the user and/or patient is established.

3. Product Information

WARNING

- The user manual is part of the product and must be accessible to personnel at all times. It must be handed over to subsequent owners or users.
- The product may only be used for its intended purpose and in accordance with the following user manual, as well as all current versions of the Stryker ENT Navigation System Instructions For Use.

3.1. Intended Use

The Instrument Clamp Electromagnetic Sphere and Instrument Clamp Electromagnetic Universal are accessories to the Electromagnetic Navigation Unit and are intended for navigating conventional surgical instruments.

3.2. Indications for Use

The Stryker ENT Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT- or MR-based model of the anatomy.

Example procedures include, but are not limited to the following ENT procedures:

- Transsphenoidal access procedures.
- Intranasal procedures.
- Sinus procedures, such as maxillary antrostomies, ethmoidectomies, sphenoidotomies/ sphenoid explorations, turbinate resections, and frontal sinusotomies.
- ENT-related anterior skull base procedures.

3.3. Contraindications

None known.

4. Product Overview

4.1. For Use With

WARNING

Use only Stryker-approved products, unless otherwise specified.

For primary related products, consult the following table:

Product	REF
Electromagnetic Navigation Unit	8000-010-003
Field Generator	8000-010-004
Scopis ENT Software	8000-020-001
Scopis ENT Software with TGS	8000-020-002

For a complete list of related products, consult the Stryker ENT Navigation System and Stryker ENT Navigation System with TGS instructions for use.

4.2. Product Description:

The Instrument Clamps Electromagnetic Sphere and Universal are used to localise surgical equipment in a dedicated working volume. The clamps are intended to navigate existing conventional instruments.

– The Instrument Clamp Electromagnetic Sphere (Figure 1) is optimised for tracking instruments with a cross-section between 2.0 mm and 4.6 mm in diameter (inclusive).
– The Instrument Clamp Electromagnetic Universal (Figure 2) is optimised for tracking instruments between 3.0 mm and 6.0 mm in diameter (inclusive).

	Height (mm)	Width (mm)	Length (mm)	Weight (g)
Sphere	25.0	13.2	18.7	25.0
Universal	27.1	13.1	19.4	25.0

Dimensions: Instrument Clamps Electromagnetic

– The Instrument Clamp Electromagnetic Sphere and Instrument Clamp Electromagnetic Universal are intended for a maximum of 10 uses.
– Cable length of clamps: 2 m +/- 0.05 m.

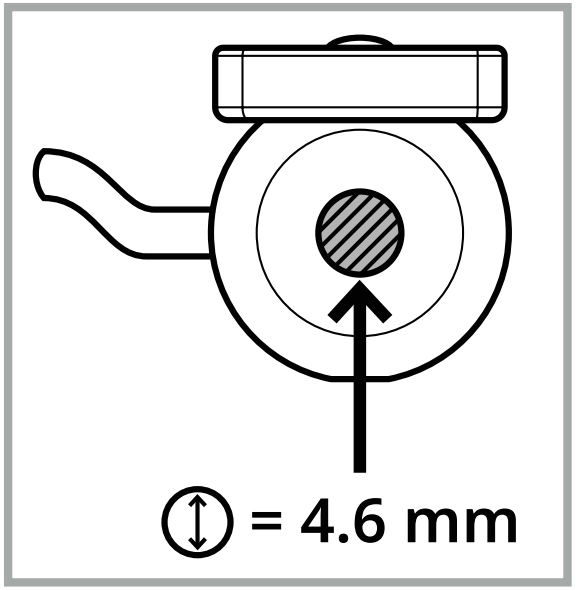


Figure 1 - Instrument Clamp Electromagnetic Sphere.

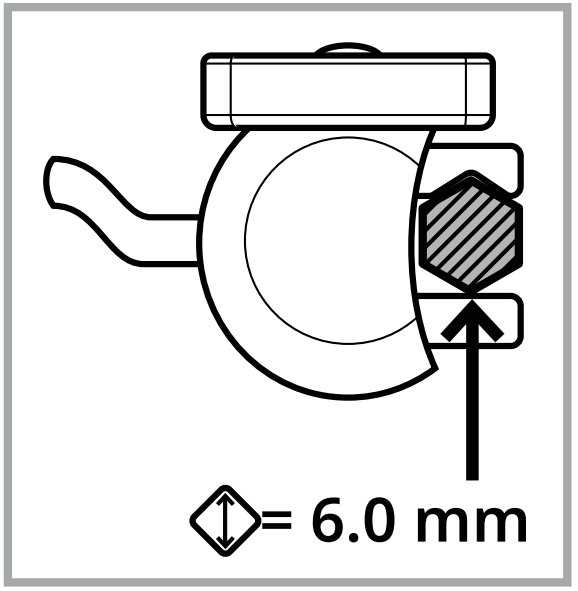


Figure 2 - Instrument Clamp Electromagnetic Universal.

5. Using Your Product

The Instrument Clamps Electromagnetic are a product of the Stryker ENT Navigation System and the Stryker ENT Navigation System with TGS. The System Instructions For Use provide essential steps and procedures of navigated surgery, and must be consulted —together with the instructions provided in this document—before any navigated surgery.

WARNING

Ensure an unused replacement copy is available for every electromagnetic instrument.

5.1. Suitability of Surgical Instruments

Numerous surgical instruments can be upgraded to navigated instruments if connected to the Instrument Clamps Electromagnetic. However, not all instruments are suited to navigation.

Refer to *Section 4.2 'Product Description'* for suitable instrument sizes for the respective clamps.

WARNING

- If the clamp cannot be attached to the surgical tool without causing damage, the tool is not suitable for use.
- Ensure that the instrument to be navigated is not restrained by the attached clamp. Should the attachment of either Instrument Clamp Electromagnetic restrict the functionality or moveability of the navigated instrument, do not navigate with the clamps.

5.2. Attaching the Product

- The figures in this section show the Instrument Clamp Electromagnetic Sphere. Attachment instructions are applicable to both clamps.
- Only use one clamp per navigated instrument.

WARNING

- Do not use any tools for tightening the fastening nut.
- During calibration, ensure the clamps are securely attached to the surgical tool. If the clamp moves, a new calibration will be required.
- The distance between tool tip and attached clamp must not exceed 150 mm. System accuracy will be impaired if this distance is exceeded.

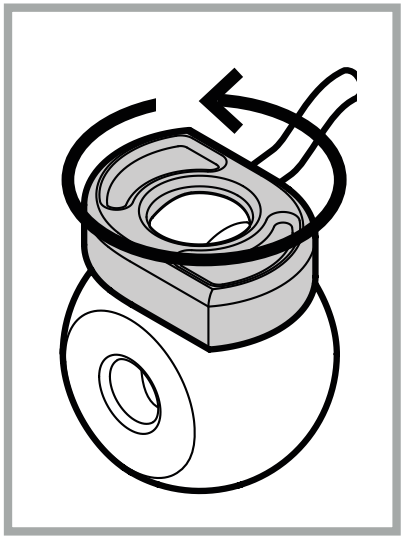


Figure 3 -
Step 1: Unscrew the clamp fastening nut (counterclockwise).

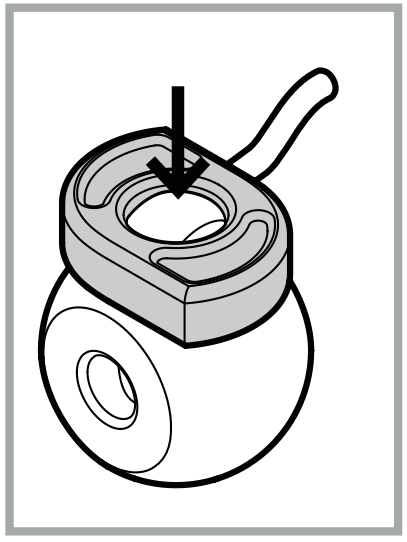


Figure 4 -
Step 2: Press and hold the fastening nut. An opening for the surgical tool is created.

Figure 5 -
Step 3: Slide the surgical tool to be navigated through the open clamp.

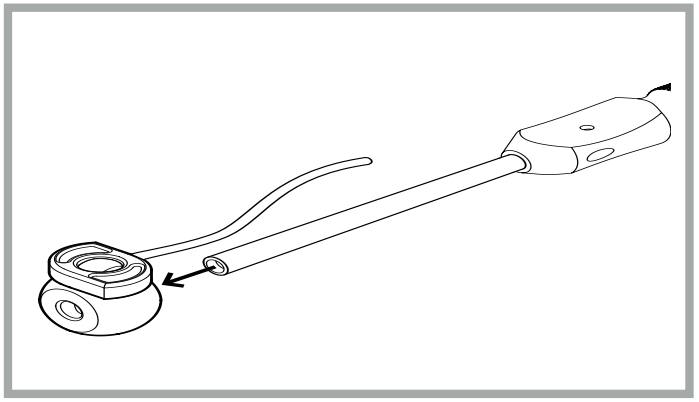
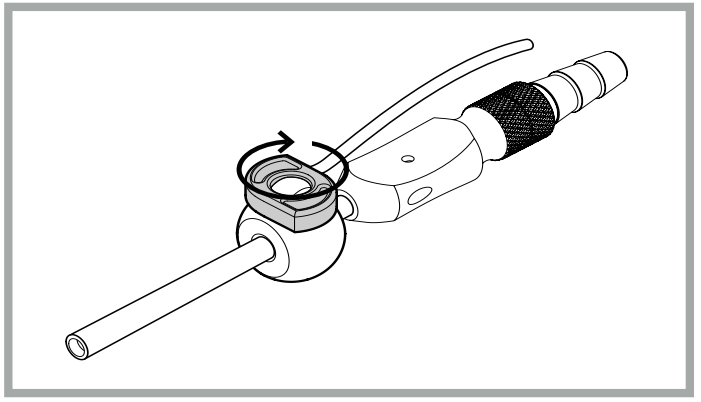


Figure 6 -
Step 4: Tighten the fastening nut clockwise until the clamp is securey connected to the navigated instrument.



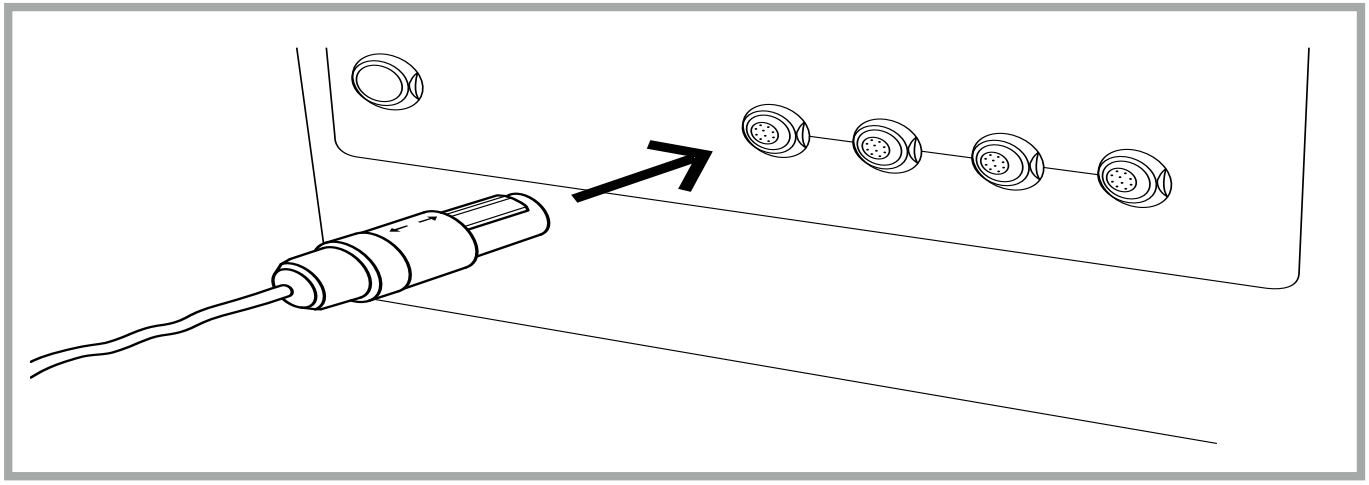


Figure 7 -
Step 5: Plug the clamp into the Electromagnetic Navigation Unit. Four ports are available at the front-right side of the unit for connecting instruments. The plug clicks in audibly.

WARNING

The clamp cable must be firmly attached to the instrument with medical tape to prevent clamp from being displaced by inadvertent pulling on the cable.

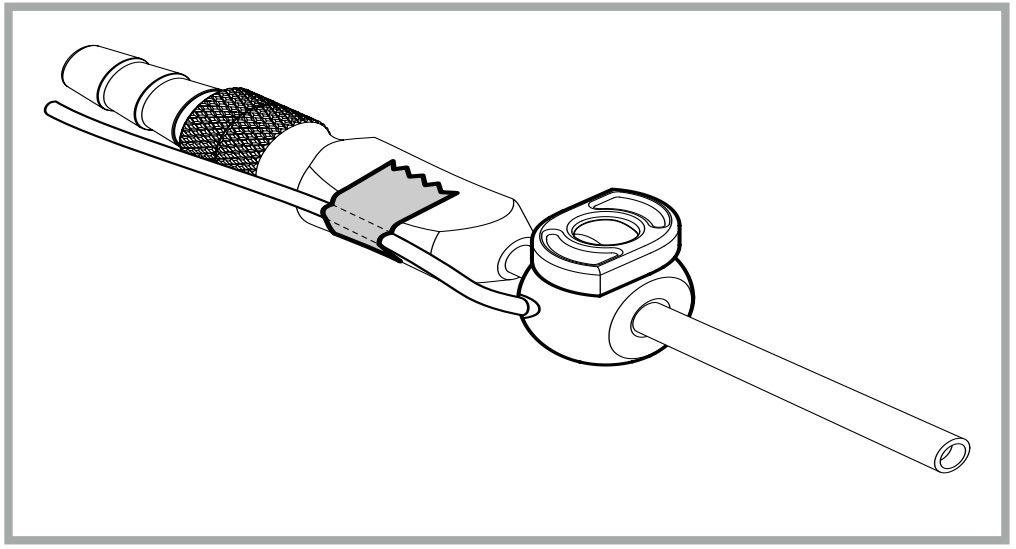


Figure 8 - Clamp cable attached with medical tape to navigated instrument.

5.3. Navigated Surgery Using the Product

For detailed instructions regarding navigated surgery using the Instrument Clamps Electromagnetic, refer to the following Instructions For Use:

- Stryker ENT Navigation System (TD8000010700).
- Stryker ENT Navigation System with TGS (TD8000010704).

Furthermore, pay careful attention to the following warnings:

WARNING

– Assess navigational accuracy repeatedly throughout a procedure when using the surgical navigation system. Reconfirm accuracy by positioning the navigated instrument tip on several suitable anatomical landmarks and comparing the actual tip location to that displayed by the system. Ensure these landmarks are sufficiently spaced apart, clearly identifiable, close to relevant anatomy and rigidly connected to the anatomy of interest.

6. Reprocessing

The following section will provide fundamental information for reprocessing of the Instrument Clamps Electromagnetic. Necessary steps for the reprocessing of medical products include preparation, cleaning, disinfection, sterilization, testing, maintenance, inspection and storage. In addition to this section, please consult the CDC Guidance Document Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

Also refer to professional organizations' clinical practice guidelines, and the clinical guidelines of the CDC, for the purpose of additional education (but not in lieu of validated reprocessing instructions).

Post-use, devices must be reprocessed within two hours, and must be reprocessed before they are returned to service.

Instruments used to treat patients whose diagnosis is unclear shall be regarded as potentially contaminated with CJD. Such instruments shall be quarantined until a non-prion diagnosis is identified.

All necessary reprocessing instructions for the Instrument Clamps Electromagnetic are found in this document.

WARNING

- The product is delivered non-sterile. Before first use, and before each following use, the product must be cleaned, disinfected, and sterilized according to a validated procedure.
- Use of the cleaning, disinfecting, and sterilization procedures mentioned in this manual does not by itself guarantee disinfection or sterility. This can only be achieved if the staff follows a recognized and validated reprocessing procedure.
- If the product is used on a patient who suffers from a disease whose pathogens cannot be eliminated with conventional, standardized procedures, the product must be disposed of or reprocessed following the requirements of the responsible public authority (e.g. WHO, RKI, CDC).
- When preparing and applying chemical solutions, the manufacturer's instructions regarding mixing ratios and dwell times must be followed closely. Using false mixing ratios or extended dwell times can lead to product damage.
- In regard to the composition of materials, ensure that the reprocessing is monomaterial. Instruments made out of titanium may change their surface color. Base metals may develop surface rust.
- Do not overload the washer-disinfector. Avoid unwashed areas. Ensure that the product is placed securely in the machine.
- Only use approved cleaning and disinfectant agents that comply with national requirements.
- Use only compatible agents. In order to guarantee material compatibility, ensure that the agents do not contain maintenance products.
- The product is a high-precision instrument. Avoid subjecting it to serious strains, such as heavy impacts. The product cannot be used if there are visible defects. After a heavy impact, the product must be checked for defects and calibrated anew.

– Inspect the product after cleaning for loose components or damage. Where possible, check for malfunction. Do not use if any of these conditions exist.

6.1. Reprocessing Cycles

Use the Reprocessing Cycles Tracking Chart to track the number of times the product has been reprocessed. Each instrument is labeled with a unique serial number on the plug. The Tracking Chart can be found in Section 10 of this document.

The use of the electromagnetic instruments is validated for **ten reprocessing cycles**. Each instrument contains a usage counter that blocks the instrument after running the tenth usage cycle in surgery. However, if an instrument is not applied with the navigation system during a procedure (i.e. if it is not plugged in), the usage counter is not updated. As such, the electronic counter displayed by the software may be below the actual number of completed reprocessing cycles.

The user is responsible for the handling of polluted and damaged instruments as well as for usage exceeding ten reprocessing cycles. If an instrument is used after ten reprocessing cycles, liability is excluded.

6.2. Preparation and Pre-cleaning

Required equipment:

- Automatic washer-disinfector compliant with DIN EN ISO 15883-1 with a validated procedure (e.g. Steris Vision Reliance Hospital Washer).
- Purified water.
- Low-lint absorbent wipes.
- Low-lint damp cloth
- Cleaning agent: neodisher MediClean forte (CFW), surfactant-based, 10.4-10.8 pH range.
  - 0.2% - 1.0% for machine cleaning
  - 0.5% - 2.0% for manual pre-cleaning.
- Medical grade compressed air.
- Thermometer.
- Syringe to inject solution into hard-to-reach areas.
- General cleaning and rinsing tools, including:
  - Soft brush
  - Bottle brush (rigid or flexible)
  - Brush with fine stiff bristles (for cable).

Brush recommendation for holes, slots or cavities:

Instrument Diameter	Recommended Nylon Brush
1.6 - 2.7 mm	Ø 2-3 mm, Brush head length ≥ 2.5 cm
2.7 - 4.0 mm	Ø 5 mm, Brush head length ≥ 2 cm
4.1 - 5.0 mm	Ø 6 mm, Brush head length ≥ 5 cm

Preparation for Reprocessing:

1. Detach the clamp(s) from the navigated instrument(s).
2. Wipe off clamp(s) immediately after use to remove coarse soiling.
3. Check the clamp(s) for damage and wear before and after each use. Pay attention to breaks, cracks, deformation, and corrosion. Check areas such as edges, notches, and all moveable components with extra care. Dispose of any damaged instruments.
4. Store the clamp(s) in a closed container during transport to the reprocessing site, in order to prevent damage and external contamination.

Pre-cleaning

1. Prepare the equipment and the devices:
   - Dilute the cleaning agent at 20-40°C. Stir the cleaning solution to homogenize it.
   - Open and loosen the screw nut.

2. Clean the devices for the duration recommended by the manufacturer of the cleaning agent — for at least 10 minutes:
   - Immerse the devices in the cleaning solution for 1 second to completely wet the devices.
   - Remove residues with a soft-bristle brush. Soak the brush in the cleaning solution every 30 seconds to ensure that all surfaces of the devices are completely wetted. Bend flexible parts and use the cleaning solution to flush all openings with a syringe every 3 minutes, at least 3 times.

3. Rinse the devices with running water for 1-3 minutes at 20-30°C. Operate articulated parts and bend flexible parts 3 times.
4. Inspect the devices for remaining soil or cleaning solution, especially in hard-to-reach areas. If residues remain, repeat cleaning or rinsing.

6.3. Machine Cleaning and Disinfection

Machine cleaning and disinfection is required for the Instrument Clamps Electromagnetic. A combined cleaning and disinfection process should take place in a fully automatic washer-disinfector. After manually pre-cleaning the clamp(s):

1. Load clamp(s) into the washer-disinfector

WARNING

To ensure that cleaning is effective, follow the user instructions of the washer-disinfector and consider the following:

- Do not overload the washer-disinfector.
- Place clamps such that they do not collide during cleaning.
- Place the clamps in the washer-disinfector baskets.
- Ensure that no device is obstructed by large objects (e.g. plates, cups).
- Ensure that the screw nut of each clamp is in an open position.

2. Add the cleaning agent as instructed by the manufacturer and add water.

3. Operate the washer-disinfector cycle, as follows:
   - Pre-cleaning with cold water (2 minutes).
   - Cleaning at 50 °C (10 minutes).
   - Rinsing with cold water (2 minutes).
   - Thermal disinfection with tap water at 90°C for 1 or 5 minutes, or in conformance with the national requirements according the A_0 value (without an additional agent).

– Drying at 110 °C for at least 15 minutes if the machine cycle includes a drying step.

4. Unload the washer-disinfector.

If the machine cycle does not include a drying step, dry the devices in an oven at 110 °C for at least 15 minutes.

Inspect cannulated, flexible and articulated parts for complete dryness. If required, use medical grade compressed air to further dry.

WARNING

– Only use washer-disinfectors that are suitable for the cleaning and disinfection of surgical instruments.
– Pay careful attention to the instructions for use from the detergent manufacturer.
– Inadequate rinsing or prolonged immersion in a cleaning or disinfection bath may lead to corrosion. Consult the instruction leaflet of the respective cleaning and disinfection products regarding dwell times.
– Do not use any disinfectants that contain phenols, chlorine components or peracetic acid without corrosion protection.
– Make sure that all product parts are dried. Take special care to ensure that areas inside the plug are dried.
– Do not use any drying aids (rinsing agents) for the last wash cycle. These could remain on the surface causing interactions that damage the instrument.

6.4. Visual Inspection and Functionality Testing

1. Ensure that the clamp(s) are free of contamination, and dry. Pay special attention to rough surfaces and hard-to-access areas. It may be necessary to use a magnifying glass. Check whether the product components are free from all apparent organic materials and cleaning residues, disinfected, and dried.

2. If the components are not visually clean, repeat the cleaning and disinfecting cycle until this is achieved. Otherwise effective sterilization cannot be guaranteed.

3. Check the clamp(s) for proper function and for damage and wear before and after each application. Pay special attention to breaks, cracks, deformations, distortions, and corrosions. Dispose of any damaged instruments.

6.5. Sterilization

Conduct sterilization using the validated steam sterilization process as indicated.

Sterilization Packaging

Always double-wrap the product in sterilization pouches that conform to DIN EN ISO 11607-1 standards (e.g. peel pouches). Do not pack more than one clamp per pouch. Validated accessories:

– Steriking flat rolls Type 43.
– Steriking flat rolls Type 44.

All relevant information regarding contents (i.e. sterilization method and date, expiry date, batch number and, if applicable, sterilization device number) needs to be clearly marked on the packaging.

- Ensure that the peel pouch packaging is not damaged (punctured) by the clamp(s).
- Ensure that the pouch-sealing device is validated.

WARNING

Ensure screw nut of clamp(s) is in an open position during sterilization.

6.5.1. Steam Sterilization

Steam sterilization with pre-vacuum with low pressure ventilation cycles is recommended, when in accordance with national requirements. The following processes (sterilizer compliant to AAMI ST79 and ISO 17665-1) are proven to be adequate:

Successful sterilization can only be performed reliably with a validated sterilization procedure.

Parameters	Pre-vacuum according to ANSI/AAMI ST79 (active, dynamic air removal with saturated steam)	
Sterilizer Type	Pre-vacuumed sterilizer	Pre-vacuumed sterilizer
Wrapping	Double wrap in sterile pouches	Double wrap in sterile pouches
Sterilization Temperature	132 °C (270 °F)	134 °C (273.2 °F)
Minimum Exposure Time	4 minutes	3 minutes
Drying	Min. 10 minutes	Min. 10 minutes
Number of Pre-Vacuum Phases	3	3
Validated sterilizer	Selectomat HP 666-1HR (MMM) (or other sterilizer compliant to AAMI ST79 and ISO 17665-1)	Selectomat HP 666-1HR (MMM) (or other sterilizer compliant to AAMI ST79 and ISO 17665-1)

In compliance with the recommendations from the WHO, RKI and others, the exposure time can be increased to 18 minutes and the temperature to 137°C for the pre-vacuum cycle. To avoid product damage, do not exceed these values. Since regular use of prolonged exposure time and increased temperature may affect product life, inspect the devices for visible damage and malfunction after sterilization.

6.6. Inspection, Storage and Handling of Sterile Packaging

After reprocessing, the sterilization packaging must be inspected for possible damage and remaining water. If the sterile packaging is compromised, the components need to be packaged and sterilized again.

Always store the dry, undamaged, sterile packaging in a dry, clean, dust free and temperature controlled environment. A maximum shelf life for sterilized devices before use should be defined by the hospital. Always check that the sterile packaging is intact before removal of products. Take account of the relevant aseptic prescriptions during removal.

7. Maintenance

Maintenance and repair may only be conducted by the manufacturer or authorized partners. All guarantees and warranties are lost if a user or unauthorized party conducts maintenance or repair services. The product components may only be sent back to the manufacturer in a cleaned, disinfected, and sterilized condition. Sharp or pointed components need to be sent back in a protected state.

8. Disposal

Risk of injury or infection can be avoided by safe disposal of the product components. Sharp and pointed components need to be collected and locked in a tight and break-proof container. They must be stored in such a way that they are protected from unauthorized use. Contaminated products are to be supplied to a hazardous waste site and handled in a way that contamination of third parties is excluded.

- After using the electromagnetic system, make sure that instruments that cannot be reprocessed again are disposed of.
- In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), the product should be collected separately for recycling.
- Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated before recycling.
- The plug used in this product contains the following substance: Lead, CAS No. 7439-92-1 (1907/2006 REACH). Handling Instructions: No specific precautions are required for handling items manufactured from alloys containing lead in the supplied condition.
- The silicone glue and cable used in this product contain the following substances: Decamethylcyclopentasiloxane, CAS No. 541-02-6 and Dodecamethylcyclohexasiloxane, CAS No. 540-97-6 (1907/2006 REACH).
- The product cable also contains Octamethylcyclotetrasiloxane (CAS No. 556-67-2)

9. Technical Specifications

Environmental Limitations	Operation	Storage and Transportation
Temperature	Between 10 °C and 30 °C	Between -10 °C and +50 °C
Relative humidity	30 % to 75 %	Keep Dry
Atmospheric air pressure	Between 80 kPa and 106 kPa	-

10. Reprocessing Cycles Tracking Chart

Cross off the corresponding number each time an Instrument Clamp Electromagnetic is reprocessed. Properly dispose of the product after it has been reprocessed 10 times.

Ser. No.	Number of times reprocessed										
	1	2	3	4	5	6	7	8	9	10	DISPOSE
	1	2	3	4	5	6	7	8	9	10	DISPOSE

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