Stryker ENT Navigation System

Instructions For Use

Endoscope Tracker Electromagnetic

REF 8000-060-001

R_x ONLY

EN

8000-060-700 Rev-AA 2018-04

Table of Contents

Important Information

Using this Manual

This manual is the most comprehensive source of information for the safe, effective, and compliant use and/or maintenance of the product. Read and understand this manual as well as the respective system user manual before using the product or any component compatible with the product. Contact Stryker for training as needed.

This manual is a permanent part of the product. Keep this manual for future reference.

The following signal words may be used throughout this manual:

WARNING - Highlights a safety-related issue. Always comply with this information to prevent patient and/or healthcare staff injury.

CAUTION - Highlights a product reliability issue. Always comply with this information to prevent product damage.

Note - Supplements and/or clarifies information.

Contact Information

Stryker Representative

1-269-323-7700, 1-800-253-3210

www.stryker.com

Intended Use

The Endoscope Tracker Electromagnetic is an accessory to the Electromagnetic Navigation Unit and is intended for navigating conventional surgical endoscopes.

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

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

Contraindications

There are not any known contraindications that directly refer to the product. The responsible physician is in charge of deciding if the general condition of the patient allows the intended application.

There are not any known side effects that directly refer to the product.

More information can be found in the current literature.

Safety Directives

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 the according to a validated procedure. Refer to the *Reprocessing* section.
- Unauthorized modifications of the product are forbidden for safety reasons.
- 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.

Definitions

Symbol	Definition
	Consult instructions for use
	Manufacturer
	Date of manufacturer
	Non-sterile
	Keep dry
	Keep away from sunlight
	Temperature limit
	Catalog number

Symbol	Definition
	Serial number
	Magnetic resonance unsafe

Using Your Product

General Functionality Testing

Before each use, check the product for:

- Deformations
- Correct installation and function
- Surface damage (cracks, dents)
- Other damage

Damaged products must not be used.

WARNING - Before using a medical product, assure yourself of its functional safety and proper condition via a visual inspection. Do not use the product If any defects are detected.

Instructions for Application

For instructions and procedures of navigated surgery, refer to the system instructions for use REF 8000-010-700 or REF 8000-010-704.

Reprocessing (Cleaning, Disinfection, Sterilization)

Necessary steps in the reprocessing of medical products include preparation, cleaning, disinfection, testing, maintenance, sterilization, inspection, and storage. Details on how to carry out these steps for the listed products will be provided below. Also consult the FDA Guidance Document *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. Also refer to the following for the purpose of additional education but not in lieu of validated reprocessing instructions: professional organizations' clinical practice guidelines or clinical guidelines of the CDC.

WARNING

- The product is delivered non-sterile. Before first use, as well as before each following use, the product must be cleaned, disinfected, and sterilized according to a validated 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.
- 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 mono-material. 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.
- Use of the cleaning, disinfecting, and sterilization procedures mentioned here does not by itself guarantee disinfection or sterility. This can only be achieved if the staff follows a recognized and validated reprocessing procedure.
- 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.

Reprocessing Cycles

Use the Tracking Chart for Reprocessing located in the References section of this manual or an equivalent method to track the number of each reprocessing cycle. Each instrument is labeled with a unique serial number on the plug.

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. The electronic counter displayed by the software may therefore 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.

Preparation for Reprocessing

1. Detach the instruments from the navigated product.
2. Wipe off instruments immediately after use to remove coarse soiling.

   WARNING - Do not use any fixing agents or hot water, as this could interfere with the success of the reprocessing procedure.

3. Rinse the instruments thoroughly with water (water temperature max. 45 °C).
4. Hard-to-access areas such as joints or cavities can be pre-cleaned with a cleaning pistol (static water pressure of at least 2 bar) or a syringe.
5. During transport to the reprocessing site, store the instruments in a closed container, in order to prevent damage to the instruments and contamination of the environment.
6. Check the instruments for damage and wear both before and after each application. Pay special attention to breaks, cracks, deformations, distortions, and corrosions. Check particularly important parts such as tips, notches, and all moveable components with extra care.

7. Dispose of any damaged instruments.

Cleaning

The cleaning can be performed manually or automatically, but automatic decontamination is preferred.

Manual Cleaning

For manual cleaning and disinfection, the following aids are required:

- Sterile disposables: lint-free cloth, swab, cotton swabs
- Soft cleaning brushes without metal (e.g. Medisafe MED100.25, bristle length 7 mm)
- Soft bottle brush without metal
- Syringe
- Cleaning pistol (at least 2 bar static water pressure, e.g. Stoeckert SELECTA, Cat. No. 1769534)
- Alkaline cleaner (e.g. neodisher MediClean forte, Dr. Weigert, Hamburg, Germany)
- Tap water
- Deionized water
- Optional: compressed air (filtered)

WARNING

- Make sure that the reprocessing cycle has been validated.
- Do not use any sharp objects such as metal brushes or other metal objects for manual cleaning.
- Inadequate rinsing or prolonged immersion in a cleaning or disinfection bath may lead to corrosion. Please consult the instruction leaflet of the respective cleaning and disinfection products regarding dwell times.
- Do not use ultrasonic baths for cleaning the EM instruments.

For manual cleaning, we recommend an alkaline cleaner, e.g. 0.5 – 3.0% neodisher MediClean forte (Dr. Weigert, Hamburg, Germany) in tap water.

1. Place the instruments in a cleaning solution (22-40 °C) for 5-10 minutes. Refer to the exposure times indicated by the manufacturer.
2. Remove remaining soil by cleaning inner channels and holes with an appropriate brush by brushing forward and backward at least 5 times from both sides. Ensure that the full depth and width is reached. Smaller diameters can be cleaned with a syringe filled with cleaning solution.
3. Wipe off the cable with a soft cloth soaked in tap water

WARNING

- Completely wet all instruments with the cleaning solution, keeping them free from air bubbles. Ensure that all cavities are accessible. If necessary, enable bubbles to escape by moving and tilting the instruments.
- Thorough cleansing is necessary to ensure successful disinfection.

4. Flush the instruments with a cleaning pistol (deionized water, 22-35 °C) for at least 20 seconds.
5. Rinse all inner and outer parts at least twice for 10 seconds each under running water (deionized water, 22-35 °C), in order to remove all residues. Use a syringe for channels with a small diameter.
6. Dry the product carefully using a lint-free cloth or swab. Hard-to-access areas can be dried using compressed air.
7. Verify that no visible staining remains on the product. Remove visible staining by repeating the cleaning process from the beginning.

WARNING - Make sure that all product parts are dried. Take special care to ensure that areas inside the plug are dry.

Automatic Cleaning

Cleaning of the instruments can be performed both manually and automatically. However, automatic cleaning is preferred. We recommend an alkaline cleaner, e.g. neodisher MediClean forte (Dr. Weigert, Hamburg, Germany).

Required tools:

- Automatic washer-disinfector with validated procedure
- Small part sieves for safe fixation in the device
- Alkaline cleaner (e.g. neodisher MediClean forte, Dr. Weigert, Hamburg, Germany)
- Cleaning pistol (at least 2 bar static water pressure, e.g. Stoeckert SELECTA, REF 1769534)
- Tap water
- Deionized water

WARNING

- Only use washer-disinfectors that are suitable for the cleaning and disinfection of surgical instruments.
- Refer to the maximum load of your washer-disinfector.
- It is essential to pay attention to the instructions for use from the detergent and disinfectant manufacturers.
- Inadequate rinsing or prolonged immersion in a cleaning or disinfection bath may lead to corrosion. Please 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.

1. For the removal of coarse dirt, place the instruments in cold water for 5-10 minutes and wipe off visible staining with a soft cloth soaked in cleaning solution.
2. Flush the instruments with a cleaning pistol (deionized water, 22-35 °C) for at least 20 seconds.
3. A combined cleaning and disinfection process should take place in a fully automatic washer-disinfector.
4. Use a small part sieve tray from the manufacturer of your washer-disinfector. All instruments must be safely fixed in the carriers.
5. Arrange the instruments in such a way that no areas are left unwashed and inner and outer surfaces are reached by the rinsing medium. The instruments must be connected to flushing connectors in the washer-disinfector.Do not overload the washer-disinfector.
6. Note the instructions from the manufacturer of your washer-disinfector for surgical instruments.

The following cleaning cycle was validated in a Miele G7836 CD (two level rack, injection rate 5 ml/l). Your automated cleaning program should adhere to or exceed the following recommendations:

- 1 minute pre-cleaning with tap water (16 °C)
- 5 minutes cleaning at 50 °C with 0.5% solution of neodisher MediClean forte (Dr. Weigert, Hamburg, Germany) in tap water
- 1 minute rinsing with deionized water (22-35 °C)

WARNING

- Make sure that all product parts are carefully dried. Take special care to areas inside the plug.
- 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.

Visual Inspection and Functionality Testing

1. Ensure that products about to be sterilized are sufficiently clean and dry. Pay special attention to rough surfaces and hard-to-access areas. It may be necessary to use a magnifying glass (9-fold magnification). 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 instruments for damage and wear both before and after each application. Pay special attention to breaks, cracks, deformations, distortions, and corrosions. Check particularly important parts such as tips, notches, and all moveable components with extra care.
4. Dispose of any damaged instruments.

WARNING - Make sure that the transparent sleeve is undamaged. If any contamination is detected under the sleeve the product must not be used.

Sterilization

Conduct sterilization using the validated steam sterilization process as indicated.

Packaging

Always double-wrap the product in sterilization pouches that conform to DIN EN ISO 11607-1:2006 standards (e.g. peel pouches). Do not pack more than one instrument 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.

Note - Ensure that the peel pouch packaging is not damaged (punctured) by the instrument.

Steam Sterilization

The steam sterilization procedure by means of a fractional pre-vacuum with low pressure ventilation cycles is recommended when in accordance with the relative national requirements. The following process (sterilizer compliant to AAMI ST79 and ISO 17665-1) is proven to be adequate:

Note - A successful sterilization can only be performed reliably if the sterilization procedure is validated.

Sterilization Temperature:	132 °C (270 °F)
Exposure Time:	4:00 minutes
Drying:	20-30 minutes from 100 mbar
Number of Pre-vacuum Pulses:	3
Validated Sterilizer:	Selectomat HP 666-1HR (MMM) Effective volume 4 STU Total load during validation: 30 kg of metal

Inspection and Storage

Visual Inspection

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.

Storage of the Sterile Packaging

Always store the dry, undamaged, sterile packaging in a dry, clean, and dust free environment.

Handling of the Sterile Packaging

Always check that the sterile packaging is intact before removal of products. Take account of the relevant aseptic prescriptions during removal.

References

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.

Note - After using the electromagnetic system, make sure that instruments that cannot be sterilized again are disposed of.

Maintenance and Repair

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.

Tracking Chart for Reprocessing

Each time an instrument is reprocessed, cross off the corresponding number.

Properly dispose of the instrument after the instrument has been reprocessed ten times.

Instrument Serial Number	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
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose
	1	2	3	4	5	6	7	8	9	10	Dispose

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: **the Stryker logo**. All other trademarks are trademarks of their respective owners or holders.

Stryker Leibinger GmbH & Co. KG
Bötzinger Straße 41
79111 Freiburg
Germany

Distributed By:
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001
USA

8000-060-700 Rev-AA 2018-04