

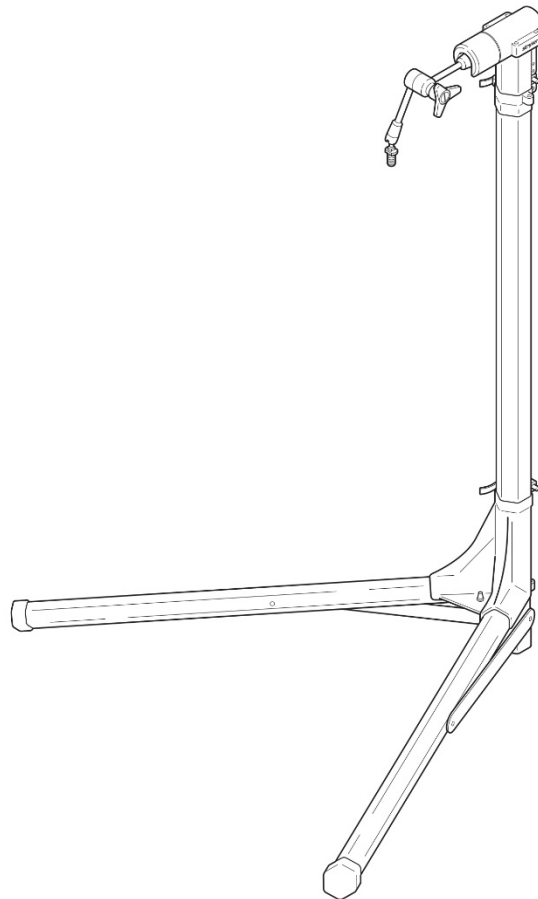


Stryker ENT Navigation System

Instructions For Use

Field Generator Stand

REF (8000-014-005)



R_x ONLY

Important Information

Using this Manual

These instructions are the most comprehensive source of information for the safe, effective, and compliant use of the product. Read and understand these instructions 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.

The following signal words may be used throughout this document:

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.

Contents

The Field Generator Stand consists of:

- 1 – Mounting Arm
- 1 – Stand
- 1 – Wrench

None of the components are made with rubber latex.

Intended Use

The Field Generator Stand is an accessory to the Stryker ENT Navigation System and intended for positioning the field generator during procedures requiring navigation.

WARNING - The product may only be used for its intended purpose and in accordance with the following instructions, 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.

CAUTION – Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The Stryker ENT Navigation System, for which the Field Generator Stand will be used, 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, 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 no known contraindications that directly refer to the product. The treating physician is responsible for deciding if the general condition of the patient allows the intended application.

For Use With

WARNING - The product may only be used in combination with the medical products listed here. All guaranties and warranties are lost if the product is combined with other products.

Compatible Product	REF
Electromagnetic Navigation Unit	8000-010-003
Field Generator	8000-010-004

Safety Directives

WARNING

- The product is intended solely for use by medical professionals.
- The Field Generator Stand may only be used if the safety instructions of the Stryker ENT Navigation System and other connected devices have been followed.
- The field generator of the Stryker ENT Navigation System can move and injure the patient if not properly secured.

CAUTION

- The legs of the Field Generator Stand must be fully deployed and locked in position to prevent the stand from tipping during use.
- Keep hands clear of the legs during deployment and folding to avoid pinch points.
- Unauthorized modifications of the product are forbidden for safety reasons.
- The Field Generator Stand is reusable and is delivered non-sterile. It is recommended to clean and disinfect the Field Generator Stand prior to each use. Reference the cleaning and disinfections sections of this IFU for instructions.

Using Your Product

Device Description

The Field Generator Stand is a reusable component intended to be used with the Stryker ENT Navigation System. The mounting arm provides fixation for the field generator of the navigation system allowing it to be positioned in proximity to the patient creating an optimal EM field.

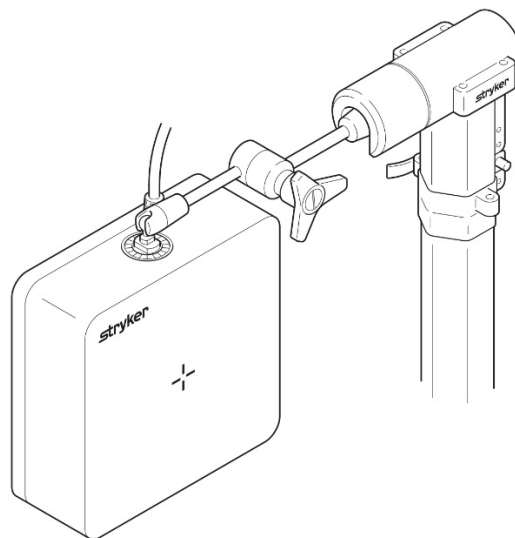


Figure 1: Field Generator Attached to Field Generator Stand

Assembly of the Field Generator Stand

CAUTION: The following instructions should be read and understood before assembling the Field Generator Stand.

1. Verify that all the components of the Field Generator Stand are available (stand and mounting arm). Inspect the components for damage prior to assembly. If damaged, contact Stryker.
2. Open the quick release lever on the yoke (Fig. 2). Slide the yoke down the upright tube to open the legs. The yoke must be slid all the way to the bottom of the upright tube to fully deploy the legs. Close the quick release lever to lock the legs in position.

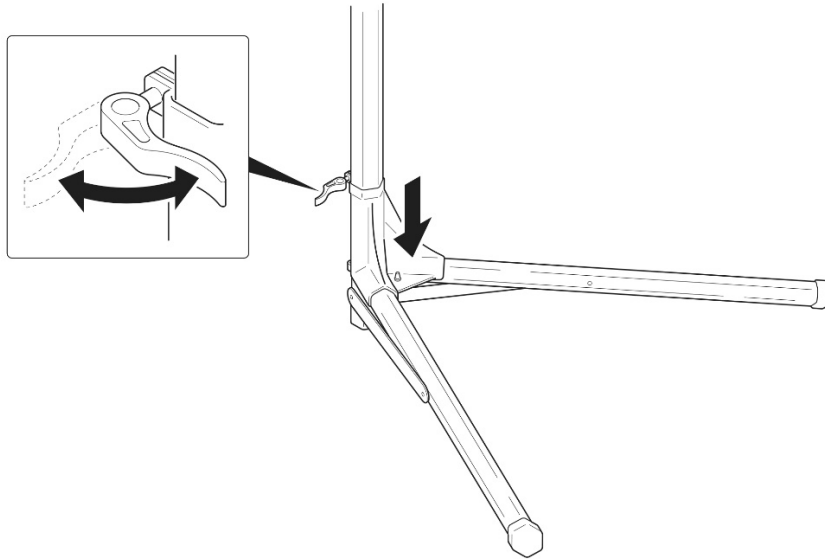


Figure 2: Field Generator Stand Quick Release Lever

3. Attach the mounting arm to the field generator by threading the post of the mounting arm into the threaded hole located on the field generator. The post should be fully inserted into the threaded hole and firmly tightened with the provided 8mm wrench (Fig. 3).

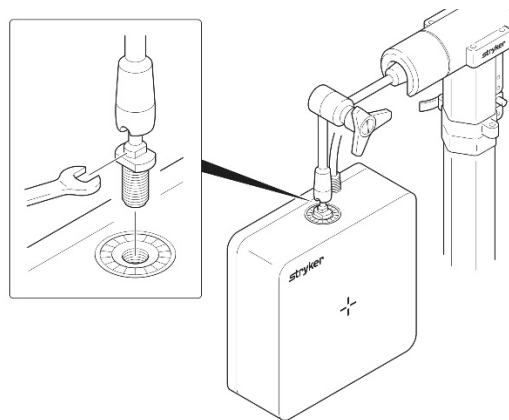


Figure 3: Field Generator Attachment to Mounting Arm

How Supplied

The Field Generator Stand is supplied non-sterile. It is recommended to clean and disinfect the Field Generator Stand prior to initial use and after every procedural use according to the cleaning and disinfection instructions provided.

Preparing for Navigation

1. Assure that the field generator is securely attached to the mounting arm and the legs of the stand are fully deployed and locked into position.
2. Place the Field Generator Stand adjacent to the procedure chair. Ensure the Field Generator Stand legs are placed on the floor and are not resting on the base of the procedure chair, on top of cables or cords.
3. While securely holding the field generator with one hand, loosen the knob on the mounting arm with the other hand to allow it to articulate. Maneuver the field generator to the desired position relative to the patient (Fig. 4). Securely tighten the knob on the mounting arm until it is entirely fixated. Confirm fixation by slowly removing support of the field generator and confirming it remains in position. If the field generator begins to move, regain support and tighten the knob on the mounting arm further until the mounting arm fixates the field generator position.

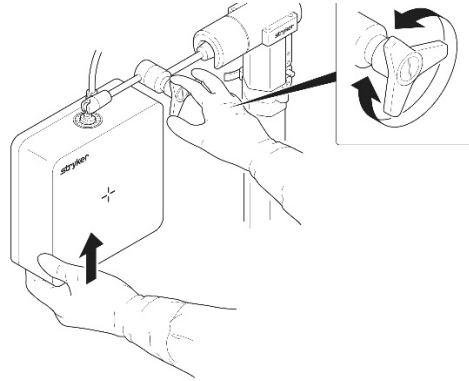


Figure 4. Positioning the Field Generator

4. If additional height is needed to accommodate patient positioning the stand height can be adjusted by opening the quick release lever on the collar, pulling the mounting arm to the desired height, and closing the quick release lever to lock the stand in position (Fig. 5).

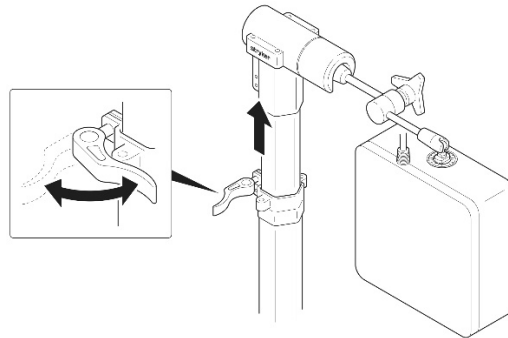


Figure 5: Stand Height Adjustment

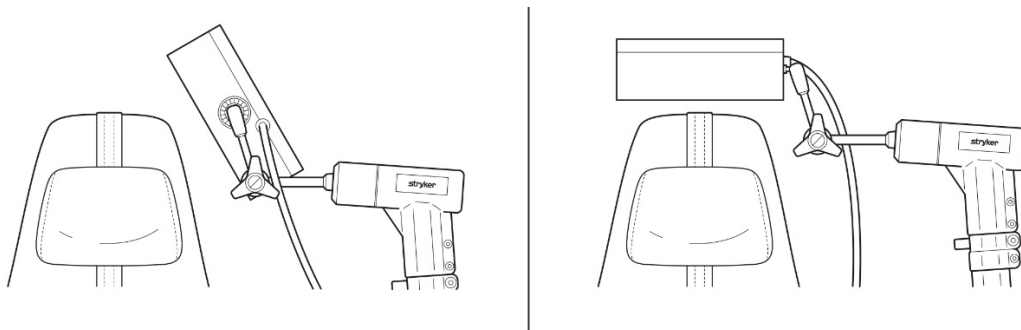


Fig 6. Examples of Field Generator Placement

WARNING – The field generator can move and injure the patient if not properly secured.

Note: For instructions related to the navigation system or navigated surgery, refer to the Stryker ENT Navigation System instructions for use.

Note: If the position of the field generator is not providing an optimal EM field it may be repositioned by following the instructions previously described.

5. After completing a procedure, clean and disinfect any surfaces that may have become contaminated per the cleaning and disinfection instructions provided. Contamination can occur if the field generator is repositioned during the procedure with contaminated gloves.

Note: Perform cleaning immediately after use, as it is more challenging to clean clinical soil when it is allowed to dry.

6. For storage, fold the legs by releasing the quick release lever, sliding the yoke up the upright tube and close the quick release lever. Lower the field generator to rest between the legs and tighten the knob of the mounting arm to secure it in place (Fig. 7).

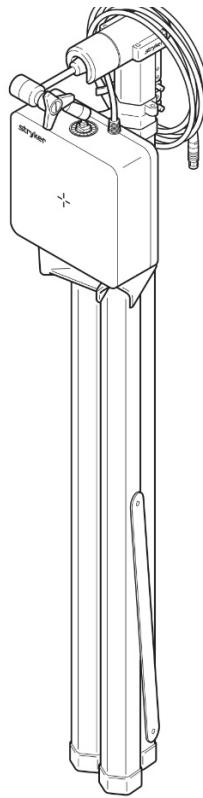


Fig 7. Field Generator Stand in Storage Position

Reprocessing (Cleaning & Disinfection)

Manual Cleaning and Disinfection

To clean and disinfect any external surfaces that may have become contaminated, use Stryker SideKick® Disinfecting Wipes (2060-000-001 6" x 10" or 2060-000-002 9" x 12"). Contamination can occur if the field generator is repositioned during the procedure with contaminated gloves.

Note: For safety information regarding the Stryker SideKick® Disinfecting Wipes, refer to the product label.

Cleaning:

- a. To clean, wipe the external surfaces with a fresh clean wipe for a minimum of 2 minutes. Discard dirty or dry wipes and use as many new wipes as needed. Repeat as necessary until the product is visually clean.
- b. Check all surfaces for remaining visible contamination and wipe again using a fresh wipe, if required.
- c. Allow the device to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning instructions if visible soil is present. Complete this step prior to disinfecting the device.

Disinfection:

- a. To disinfect, wipe the external surfaces with a fresh clean wipe until wet. Allow the external surface to remain wet for 2 minutes at room temperature.
- b. Allow the product to dry before returning it to service.

CAUTION

- Do not clean, disinfect, perform service or maintenance while the product is in use.
 - Do not immerse the mounting arm in liquid, as this could damage the device.
 - The mounting arm's central clamp must be tightened during cleaning/disinfection.
 - Do not sterilize the Field Generator Stand or subject the product to temperatures of more than 60°C, as this could damage the device.
 - Avoid contact between the mounting arm and physiological salt solutions (e.g. NaCl), as this could corrode the metal surface.
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Functionality Testing and Maintenance

1. After cleaning and disinfection, it is necessary to check that the surfaces are visually clean. Special attention should be paid to hard-to-reach areas and rough surfaces. If necessary, repeat the cleaning and disinfecting cycle until the components are visually clean.
2. All product components need to be checked for damage and wear. Special attention must be paid to breaks, cracks and deformations. Particularly important parts such as the mounting arm knob should be checked with extra care.
3. Damaged components must be disposed of.

Instructions for Application

For instructions and procedures of navigated surgery, refer to the Stryker ENT Navigation System instructions for use.

Symbols

 Consult Instructions for use (ISO 15223-1, 5.4.3)	 Serial Number (ISO 15223-1, 5.1.7)	 Catalogue Number (ISO 15223-1, 5.1.6)	 Caution (ISO 15223-1, 5.4.4)
 Manufacturer (ISO 15223-1, 5.1.1)	 Prescription Use Only	 Quantity	 Non-sterile (ISO 15223-1, 5.2.7)



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