



# Stryker ENT Navigation System

Instructions For Use

## TGS Universal Headrest with Mounting Arm

TGS Universal Headrest

**REF** (8000-010-007)

TGS Universal Headrest Mounting Arm

**REF** (8000-010-008)

TGS Universal Headrest Adapter A

**REF** (8000-010-009)

TGS Universal Headrest Adapter B

**REF** (8000-010-010)

TGS Universal Headrest Adapter C

**REF** (8000-010-011)



**R<sub>x</sub> 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:

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

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

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**Note** - Supplements and/or clarifies information.

## Contents

The TGS Universal Headrest with Mounting Arm consists of:

- 1 – TGS Universal Headrest
- 1 – TGS Universal Headrest Mounting Arm
- 1 – TGS Universal Headrest Adapter

Not made with natural rubber latex.

## Intended Use

The TGS Universal Headrest with Mounting Arm is an accessory to the Stryker ENT Navigation System and intended for positioning the field generator. It also provides a resting surface for the patient to place their head during procedures requiring navigation.

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**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.

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## Indications for Use

The Stryker ENT Navigation System, for which the TGS Universal Headrest with Mounting Arm 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 TGS Universal Headrest with Mounting Arm may only be used if the safety instructions of the Stryker ENT Navigation System and other connected devices have been followed.
- The headrest should only be mounted to procedure chair models that have matching adapter sizes.
- The field generator of the Stryker ENT Navigation System can move and injure the patient if not properly secured.

### CAUTION:

- The headrest must not be loaded with more than 30lbs otherwise damage may occur.
- Unauthorized modifications of the product are forbidden for safety reasons.
- The TGS Universal Headrest with Mounting Arm is reusable. It is delivered non-sterile and must be cleaned and disinfected prior to each use. Reference the cleaning and disinfections sections of this IFU for instructions.

## Using Your Product

### Device Description

The TGS Universal Headrest with Mounting Arm 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. The headrest also provides support for the patient's head while undergoing navigation guided procedures.



## Procedure Chair Compatibility

The TGS Universal Headrest has multiple adapter types that allow it to attach to various procedure chairs. Reference the chart below to determine which adapter is required.

Procedure Chair Headrest Post Dimensions (thickness x width)	Headrest Adapter Type	Additional Components
0.25in x 2.0in	Adapter A	Offset and Screws (4)
0.25in x 2.5in	Adapter B	Screws (4)
0.25in x 3.25in	Adapter C	Threaded Knob, Offset and Screws (4)

## Assembly of the TGS Universal Headrest with Mounting Arm

**CAUTION:** The following instructions should be read and understood before assembling the TGS Universal Headrest.

1. Verify that all the components of the TGS Universal Headrest with Mounting Arm are available (headrest, adaptor, mounting arm, and hardware). Inspect the components for damage prior to assembly. If damaged, contact Stryker.
2. Attach the supplied adapter and offset (if supplied) to the back of the headrest with the screws provided.
3. Remove the existing headrest from the procedure chair and verify that the supplied adapter matches the width and thickness of the headrest post of the existing procedure chair headrest.
4. Insert or attach the adapter of the TGS Universal Headrest to the procedure chair in the same manner the preexisting headrest was attached. Use the procedure chair locking mechanism (if available) to set the height of the TGS Universal Headrest or use the threaded knob provided with the adapter.



Examples of Headrest Adapter Inserted into Procedure Chair

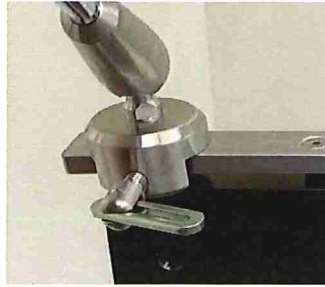
5. Attach the mounting arm to the field generator by threading the post of the mounting arm into the threaded hole located on the field generator. The post should be fully inserted into the threaded hole and firmly tightened.



Example of Mounting Arm Threaded into Field Generator

6. Secure the mounting arm rail clamp to the top rail of the headrest. The lever of the rail clamp should face away from the patient (cushion) to prevent accidental impact. Ensure the rail clamp is firmly tightened.

For storage, the field generator should be placed directly behind the headrest and the knob of the mounting arm tightened to secure it in place.



Example of Rail Clamp Attachment and Field Generator Storage Location

## How Supplied

The TGS Universal Headrest with Mounting Arm is supplied non-sterile. It must be cleaned and disinfected prior to initial use and after every procedural use according to the cleaning and disinfection instructions provided. Do not use a headrest if the cushion is torn or ripped, since the cleanliness and functionality of the device may be compromised.

## Preparing for Navigation

1. Assure that the field generator is securely attached to the mounting arm and the mounting arm rail clamp is securely fastened to the rail of the headrest. The field generator should be positioned directly behind the headrest prior to the patient being seated.
2. Once the patient is seated in the chair, adjust the headrest height so that the patient's head aligns in the middle of the headrest cushion.
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. 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.



Examples of Field Generator Placement

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

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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.

4. After completing a procedure, clean and disinfect the headrest and mounting arm per the instructions provided.  
Note: Perform cleaning immediately after use, as it is more challenging to clean clinical soil when it is allowed to dry.
5. For storage, place the field generator directly behind the headrest and tighten the knob of the mounting arm to secure it in place.

# Reprocessing (Cleaning & Disinfection)

## Manual Cleaning and Disinfection

To clean and disinfect the external surface of the TGS Universal Headrest and Mounting Arm use Stryker SideKick® Disinfecting Wipes (2060-000-001 6" x 10" or 2060-000-002 9" x 12").

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

### Cleaning:

- To clean, wipe the external mounting arm and headrest 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.
- Check all surfaces for remaining visible contamination and wipe again using a fresh wipe, if required.
- 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:

- 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.
- Allow the product to dry before returning it to service.

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### 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 TGS Universal Headrest with Mounting Arm 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

- After cleaning and disinfection, it is necessary to check that the TGS Universal Headrest with Mounting Arm is 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.
- 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 headrest cushion and the mounting arm knob should be checked with extra care.
- 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)	 Non-sterile (ISO 15223-1, 5.2.7)
				

Temperature Limit (ISO 15223-1, 5.3.7)	Manufacturer (ISO 15223-1, 5.1.1)	Prescription Use Only	Quantity	
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4707-001-rB Feb 2020