

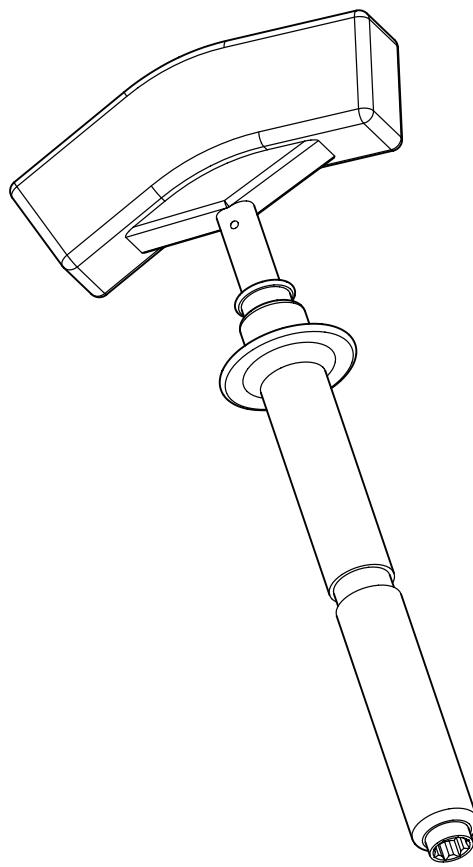
IMPORTANT INFORMATION: File in your records

stryker

Instructions For Use

Insertion Tool

REF 6007-015-000



CE conformity:
Essential Requirements of Medical
Device Directive 93/42/EEC

2016-10-14 TD6007015700 Rev. E

Important Information

WARNING - NOTE

Please read this manual and follow its instructions carefully. The words **WARNING** and **NOTE** carry special meanings and should be carefully reviewed.

WARNING: The personal safety of the patient and user may be involved. Disregarding this information could result in injury to the patient and/or user.

NOTE: This provides special information to make maintenance easier or important instructions clearer.



An exclamation point within a triangle displayed on the product is intended to alert the user to the presence of important operating and maintenance instructions in this manual.

User/Patient Safety



WARNINGS:

- Read and understand this information. Familiarization with the Stryker Navigation System prior to use is important. Only trained personnel are to use this system.
- Prior to each use, instruments should be operated and inspected for any loose components or damage. DO NOT use if these conditions exist. Contact your Stryker Navigation sales representative immediately in this case.
- Performing procedures with instruments other than those specified in these instructions or outside of their intended use compromises navigation accuracy.
- Clean and sterilize instruments before first and every use.

- DO NOT service instruments. Instruments do not contain parts that a user can service. Contact your Stryker Navigation sales representative in this case.
- Prior to surgery, this product should be checked with the Stryker Navigation System to ensure it is functioning properly.
- Use this manual with the Instructions For Use supplied with the Anchoring / Revision Pins for further User/Patient Safety Warnings and instructions related to the Pins.

Intended Use of the Navigation System

The Stryker Navigation System is intended as a planning and intraoperative guidance system to enable open or percutaneous computer aided surgery. The system is indicated for any medical condition in which the use of computer aided surgery may be appropriate, and where a reference to a rigid anatomical structure can be identified relative to the operative field.

Intended Use of the Insertion Tool

The Insertion Tool is a component of the Hip, Trauma, Knee and Spine Modules of the Stryker Navigation System.

The Insertion Tool is to be used with the Stryker System Platform, standard Stryker surgical instrumentation and the Stryker Navigation System Software Modules for Knee, Hip, Trauma and Spine surgery.

Function and Features

The Insertion Tool REF 6007-015-000 is used for bone insertion of Revision / Anchoring Pins and for fixation of any device which is locked with 5mm square head screws (e.g. the Stryker Hoffman coupling REF 6002-800-000).

Instructions

Instruction Steps for 5mm Square Head Screw Fixation

- 1 Mount to Screw**
 - Mount the screw to the Insertion Tool Interface.
See figure 1.
- 2 Apply**
 - Fixate screw.

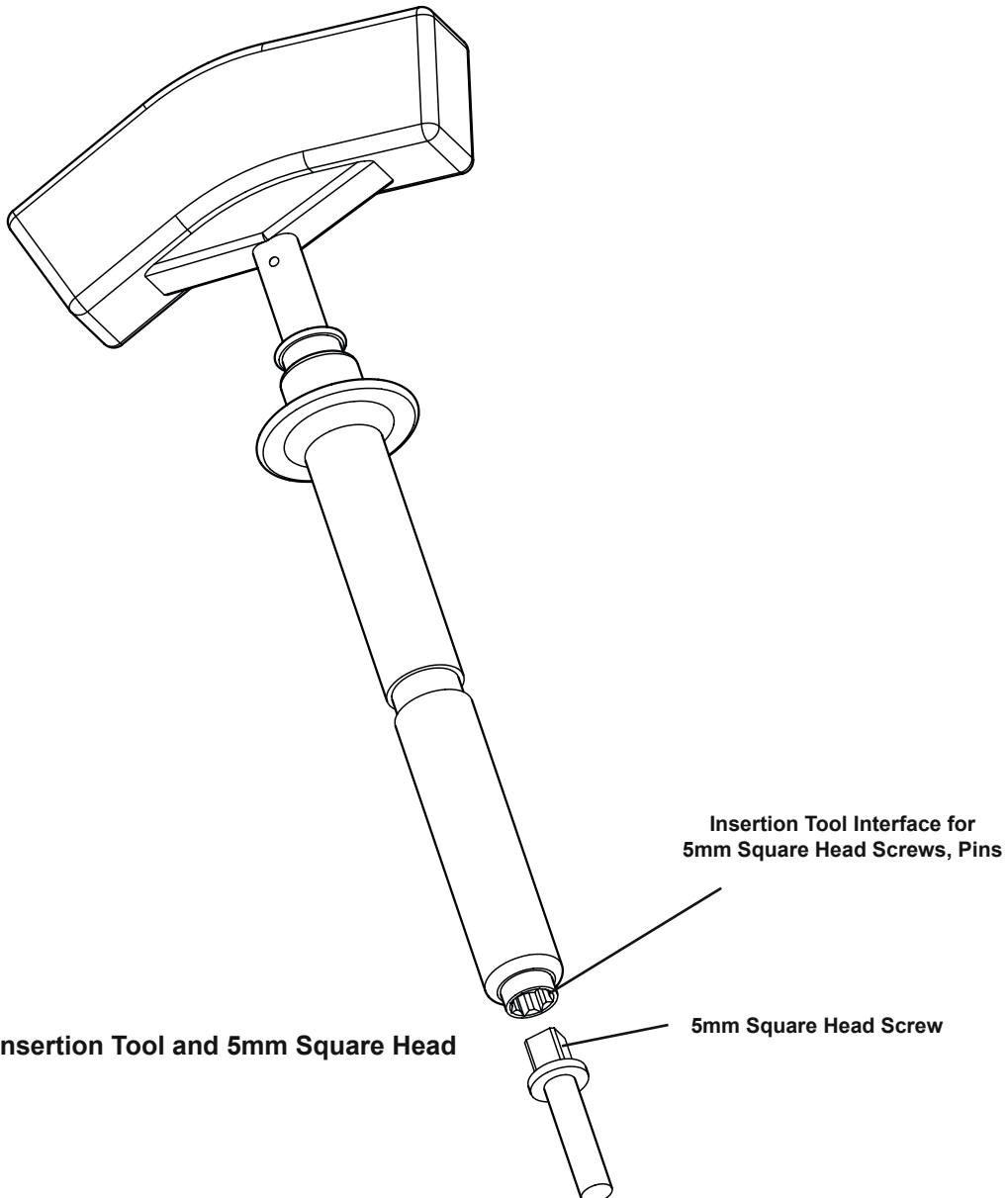


Figure 1: Insertion Tool and 5mm Square Head Screw

Instructions (cont'd)

Instruction Steps for Pin Fixation

1 Mount Insertion Tool to Pin

- Pull the holding mechanism back.
- Align the cross pin with the Insertion Tool Handle (fig. 2). Refer to the Instructions For Use supplied with the Pin.
- After proper alignment, mount the Pin to the Insertion Tool Interface. See figure 1.
- Release the holding mechanism to let it snap by a forward movement.

2 Insert Pin into Bone

- For Pin insertion, apply a gentle force while rotating.

3. Align with Sensor Array



WARNING:

During Pin fixation, take care that the Insertion Tool Handle is aligned with the sensor array to ensure visibility of the Tracker's LEDs for navigation.

4. Remove from Pin

- After Pin insertion and proper orientation, pull the holding mechanism back and remove the Insertion Tool.

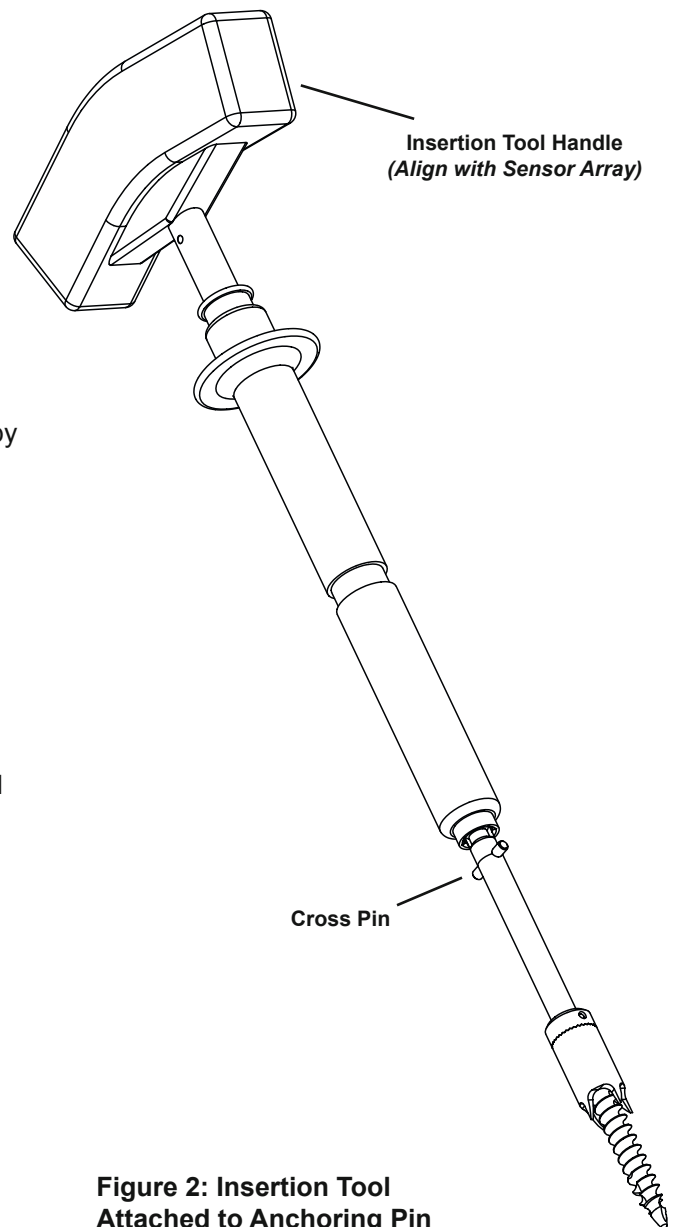


Figure 2: Insertion Tool Attached to Anchoring Pin

Cleaning Recommendations

We recommend machine cleaning method.

Refer to the *Cleaning and Sterilization Guide REF TD6000005750* for cleaning safety and caution notes, cleaning equipment and detailed cleaning instructions.

Refer to table 1.

| Instrument | Group |
|----------------|-------|
| Insertion Tool | III |

Table 1: Cleaning Groups

Instrument Preparation Instructions

1. Disconnect always the Insertion Tool from the Pin / 5mm square head screw.
2. Proceed to cleaning.

Inspection Recommendations

Inspect the Insertion Tool prior to sterilization. Refer to the *Cleaning and Sterilization Guide REF TD6000005750*.

Sterilization Recommendations

Follow the recommendations contained in this manual.

Hi Vac:

- Pre-vacuumed sterilizer
- 270-273°F (132-134°C)
- Wrapped or unwrapped
- 4-minute minimum exposure time
- 8-minute minimum dry time

270°F Gravity:

- Gravity displacement sterilizer
- 270-273°F (132-134°C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 35-minute minimum exposure time
- 8-minute minimum dry time

Sterilization Recommendations
Validation based on AAMI protocol

Storage and Handling

To ensure the longevity, performance and safety of this equipment, package in original packaging materials when storing or transporting.

Specifications*

| | |
|------------------|---|
| Model: | REF 6007-015-000 |
| Size: | 6.7 inch [170 mm] length (with Handle) 0.5 inch [12 mm] diameter |
| Material: | Stainless Steel Elastosil |
| Weight: | 0.3 lb. [155 g] |

*Specifications listed are approximate and may vary slightly from unit to unit.



Translated Equiv.: TD6007015713

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