

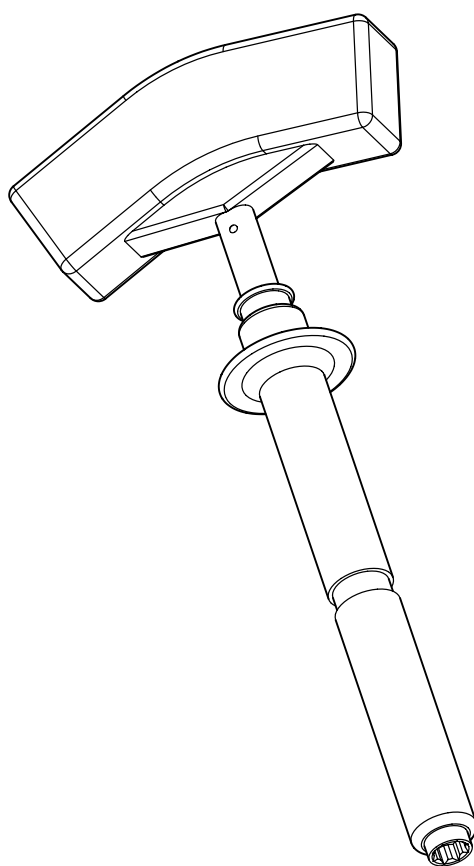


## Instructions for use

### Insertion Tool

REF 6007-015-000

Rx Only





The following conventions are used in this document:

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

The signal word **CAUTION** highlights a product reliability issue. Comply with this information to prevent product damage.

## ***User/Patient Safety***



### **WARNINGS**

- Read and understand this information. File it in your maintenance records. Familiarization with the Stryker Navigation System prior to use is important.
- 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 sales representative in this case.
- The healthcare provider performing any procedure is responsible for determining the appropriateness of using the product and for the specific technique for each patient. Stryker, as a manufacturer, does not recommend a specific surgical procedure.
- 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 sales representative in this case.
- 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.

#### **Note:**

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.

## ***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 Navigation System, standard Stryker surgical instrumentation and the Stryker Navigation System Software Modules for Knee, Hip, Trauma and Spine surgery.

## **Contraindications**

None known.

## ***User Group***

Healthcare professionals (surgeon/resident, nurse/professional caregiver) educated in computer-assisted surgery and thoroughly familiar with the instructions for use and with the operation of this product.

To request an additional in-service instruction, contact Stryker.

## ***Function and Features***

The Insertion Tool REF 6007-015-000 is used for inserting Anchoring/Revision Pins and for fixating any device which is locked with 4 mm or 5 mm square head screws.

### **1. Instruction Steps for Pin Fixation**

#### **1.1 Mount Insertion Tool to Pin**

- Pull the holding mechanism back.
- Align the Pin with the Insertion Tool. For proper Pin orientation, refer to the instructions for use supplied with the Pin.
- For Anchoring Pins only:  
Align the cross pin with the Insertion Tool handle. Refer to figure 1. For a detailed description, refer to the instructions for use supplied with the Anchoring Pin.
- After proper alignment, mount the Pin to the Insertion Tool interface. Refer to figure 1.
- Release the holding mechanism to let it snap by a forward movement. Ensure that the Pin is firmly secured in place.

#### **1.2 Insert Pin into Bone**

- For Pin insertion, apply a gentle downward force while rotating the Insertion Tool.

#### **1.3 Align with Camera Sensor Array**

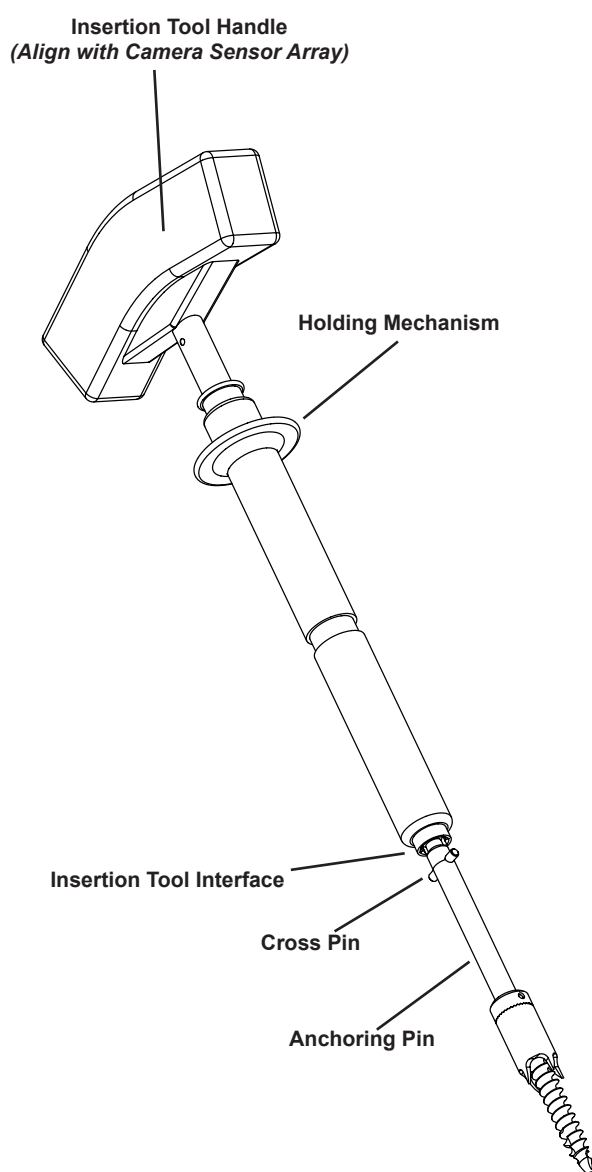
- After attaching the Tracker to the Pin, ensure that the Pin/Tracker interface allows proper alignment of the Tracker with the camera sensor array. For proper interface orientation,

refer to the instructions for use supplied with the Pin.

- For Anchoring Pins only:  
Ensure that the cross pin is in a parallel position to the long side of the Insertion Tool handle. At the end of Pin insertion, the long side of the handle must be oriented towards the camera sensor array.  
For proper interface orientation, refer to the instructions for use supplied with the Pin.

#### 1.4 Remove Insertion Tool from Pin

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



**Figure 1: Example of Insertion Tool attached to Anchoring Pin**

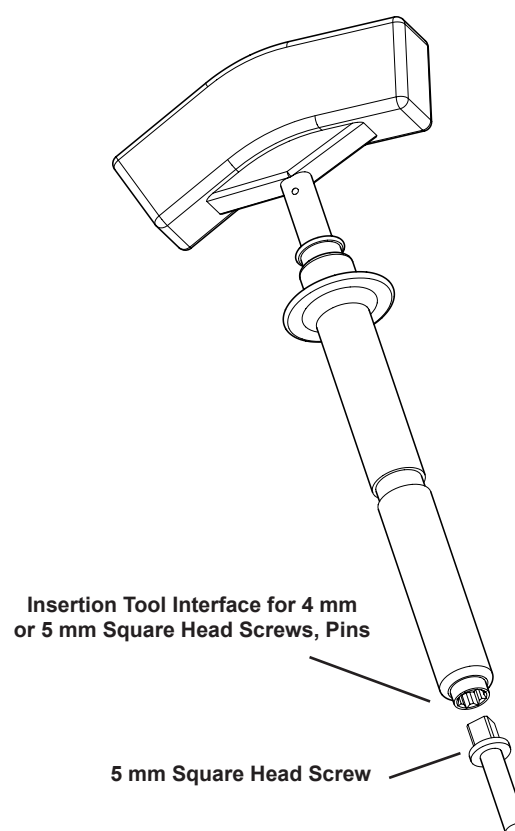
## 2. Instruction Steps for 4 mm or 5 mm Square Head Screw Fixation

### 2.1 Mount to Screw

- Mount the screw to the Insertion Tool interface. Refer to figure 2.

### 2.2 Apply

- Fixate the screw.



**Figure 2: Example of Insertion Tool and 5 mm Square Head Screw**

## Cleaning, Disinfection, and Sterilization Instructions

Disconnect the Insertion Tool from the Pin or square head screw. Start the cleaning process.

Refer to the Guide for Cleaning, Disinfection and Steam-Based Sterilization (GCDS, TD6000005750) for cleaning safety and caution notes, cleaning equipment and detailed cleaning, disinfection, sterilization, and inspection instructions.

Cleaning group (according to GCDS): IV

## Inspection Instructions

Inspect the Insertion Tool prior to sterilization.

Refer to the Guide for Cleaning, Disinfection and Steam-Based Sterilization (GCDS, TD6000005750) for cleaning safety and caution notes, cleaning equipment and detailed cleaning, disinfection, sterilization, and inspection instructions.

## Disposal

Products that have been in contact with material of human origin may be infectious. Dispose of with the necessary precautionary measures in accordance with local regulations. Ensure that infected products are decontaminated prior to recycling.

## For Use With



### WARNING

Use only Stryker-approved products unless otherwise specified.

For information related to compatible software applications, refer to the user manual of the software application.

For information related to compatible Pins, refer to the table below.

Anchoring Pin 20 mm / 4 mm	REF 6007-420-000
Anchoring Pin 25 mm / 4 mm	REF 6007-425-000
Anchoring Pin 30 mm / 4 mm	REF 6007-430-000
Anchoring Pin 35 mm / 4 mm	REF 6007-435-000
Anchoring Pin 40 mm / 4 mm	REF 6007-440-000
Anchoring Pin 45 mm / 4 mm	REF 6007-445-000
Anchoring Pin 50 mm / 4 mm	REF 6007-450-000
Anchoring Pin 55 mm / 4 mm	REF 6007-455-000
Anchoring Pin 60 mm / 4 mm	REF 6007-460-000
Anchoring Pin 30 mm / 5 mm	REF 6007-530-000
Anchoring Pin 40 mm / 5 mm	REF 6007-540-000
Anchoring Pin 50 mm / 5 mm	REF 6007-550-000
Pelvic Pin for Knee Navigation	REF 6007-551-000
Revision Pin for Spine Navigation 12 mm [0.47 in]	REF 6002-017-012
Revision Pin for Spine Navigation 18 mm [0.71 in]	REF 6002-017-018

## Technical Specifications\*

<b>Model:</b>	REF 6007-015-000
<b>Size:</b>	6.7 inch [170 mm] length (with handle) 0.5 inch [12 mm] diameter
<b>Material:</b>	Stainless Steel Elastosil
<b>Weight:</b>	0.3 lb. [134 g]

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

## Definitions of symbols



The following table defines the symbols used in this document, on the product and on the product label.

EN ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs



Symbol/ Number	Name: Definition
 W001	<b>General warning sign:</b> To signify a general warning.

EN ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements


Symbol/ Number	Name: Definition
 5.1.1	<b>Manufacturer:</b> Indicates the medical device manufacturer, as defined in the European Union harmonization legislation.
 5.1.3	<b>Date of manufacture:</b> Indicates the date when the medical device was manufactured.
 5.1.5	<b>Batch code:</b> Indicates the manufacturer's batch code so that the batch or lot can be identified.
 5.1.6	<b>Catalog number:</b> Indicates the manufacturer's catalog number so that the medical device can be identified.
 5.1.8	<b>Importer:</b> Indicates the entity importing the medical device into the locale.
 5.2.7	<b>Non-sterile:</b> Indicates a medical device that has not been subjected to a sterilization process.

Symbol/ Number	Name: Definition
 5.4.3	<b>Consult instructions for use:</b> Indicates the need for the use to consult the instructions for use.
 5.7.7	<b>Medical device:</b> Indicates a medical device according to European Union harmonization legislation.



#### Product-specific symbols

Symbol	Name: Definition
	<b>Quantity:</b> Indicates the number of products in the packaging.
	Global Trade Item Number

#### 21 CFR 801.109 FDA Final rule for the use of symbols in labeling

Symbol	Name: Definition
	<b>Caution:</b> Federal law (USA) restricts this device to sale by or on the order of a physician.

#### Regulatory marks and logos

Symbol	Name: Definition
	Indicates that a device is in conformity with the applicable requirements set out in applicable European Union harmonization legislation providing for its affixing.
	UK product marking that is used for goods being placed on the market in Great Britain.



# stryker

Translated Equiv.: TD6007015713

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