

IMPORTANT INFORMATION: Read carefully

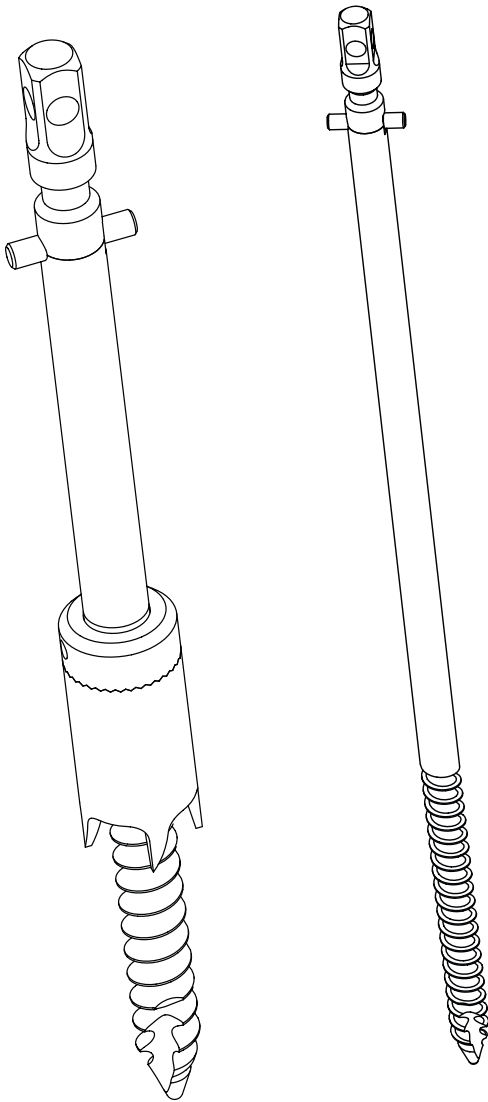
stryker[®]

Instructions For Use

Anchoring Pins

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



Single Use Only

CE 0197

Important Information

WARNING - NOTE

Please read this manual and follow its instructions carefully. The words **WARNING**, **CAUTION** 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, this product 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 this product other than those specified in these instructions or outside of its intended use compromises navigation accuracy.
- The Anchoring Pins and the Pelvic Pin (both called "Pin" hereafter) are single use. Sterilize the Pins prior to use.
- DO NOT service the Pins and instruments. The products do not contain parts that a user can service. Contact your Stryker Navigation sales representative in this case.
- Prior to surgery, this equipment should be checked with the Stryker Navigation System to ensure it is functioning properly.
- The Pins are **single use only**. Sterilize the Pins before use as directed and discard after surgery. Failure to comply will lead to product damage and malfunction. Do not reuse as this may increase the risk of fatigue failure and product damage due to worn parts or material. Reuse may increase the risk of cross-contamination of the product due to inappropriate reprocessing. Do not resterilize as this may compromise product performance.
- To avoid soft tissue injury during Pin insertion, select proper location for rigid fixation.
- If rigid fixation is not ensured, relocate the Pin or replace it with a thicker Pin.
- Avoid Pin attachment to osteoporotic bone with very low bone density. In this case fixation is not stable.
- Use 5 mm Anchoring Pins for fixation at cancellous bone structures.
- Use 4 mm Anchoring Pins for fixation at cortical bone structures.
- Use the Pelvic Pin only for the Knee Navigation System in order to determine the hip center by motion analysis with the pin-based method.
- Do not attach the Pelvic Pin to the pelvis for other applications than Knee Navigation. The Pelvic Pin does not ensure the rotational stability needed by other applications such as Hip Navigation or Trauma Navigation.
- For diaphyseal location, select bicortical fixation.
- Take care that Pin orientation enables proper alignment of the Tracker's LEDs with the sensor array.
- Repeat Landmark Tests or use Verification Checkpoints several times during application to ensure that the Tracker has not moved during surgery.
- Use this manual with the *Instructions For Use* supplied with the Tracker for further User/Patient Safety Warnings and instructions related to the tracking tool.
- Use this manual with the *Important Safety Information* and the Online manual of the applicable Stryker Navigation System Software Module for further User/Patient Safety Warnings.

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 Pins

The Anchoring Pins are components of the Hip, Trauma and Knee Modules of the Stryker Navigation System.

The Anchoring Pins are to be used with the Stryker System Platform, standard Stryker surgical instruments and the Stryker Navigation System Software Modules for Hip, Trauma and Knee Navigation.

The Pelvic Pins are components of the Knee Module of the Stryker Navigation System.

The Pelvic Pins are to be used with the Stryker System Platform, standard Stryker surgical instruments and the Stryker Navigation System Software Module for Knee Navigation.

Function and Features

The Pin is used to rigidly fixate a Tracker to a single bone. The Tracker is a Stryker Navigation smart instrument that is used to localize the patient's anatomy during surgery. The Pin is intended to be inserted into the bone undergoing treatment by using the Insertion Tool REF 6007-015-000.

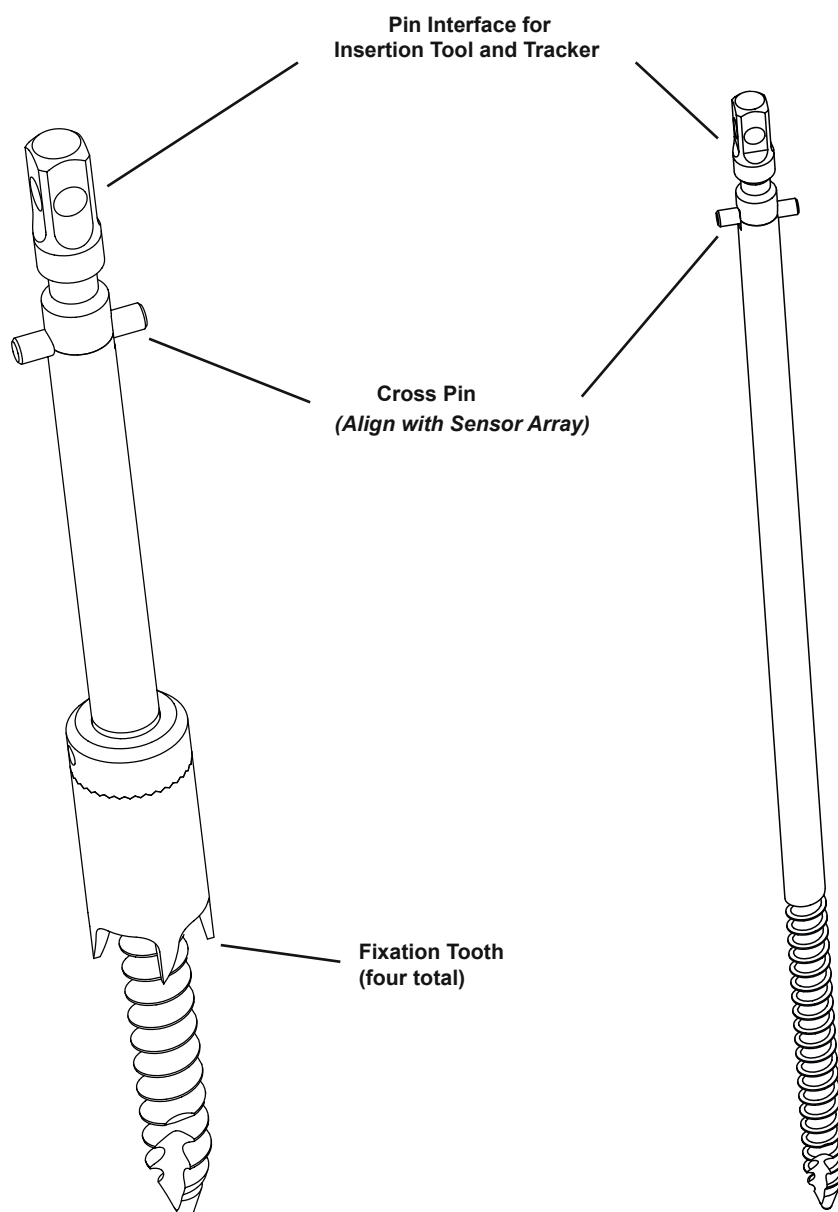


Figure 1: Toothed Anchoring Pin (left) and non-toothed Pelvic Pin for Knee Navigation (right)

Instructions

1 Sterilize

Sterilize the Pins prior to use as recommended.

2 Place in Surgical Area

Locate the bone undergoing treatment.

⚠ WARNING:

Always place the Pin in an area where no soft tissue loading occurs, such as from muscles and ligaments. Failure to comply may compromise initial registration and navigation accuracy.

3 Predrill Hole

Predrill a hole using a 3.2 mm drill.

NOTES:

- For cortical fixation, drill as deep as the length of the thread.
- For cancellous fixation, just opening the cortex with the drill bit is sufficient.

⚠ WARNING:

If the Anchoring Pin is used for bicortical fixation, select a thread of appropriate length.

4 Mount Insertion Tool to Pin

Mount the Insertion Tool onto the Pin Interface.

5 Drive Pin into Bone

Start to drive the Pin into the bone.

For Anchoring Pins only: When a certain insertion depth has been achieved, the fixation teeth will start penetrating the cortex of the bone. During cortex penetration a ratcheting noise is heard. Continue to drive the Anchoring Pin until a strong rotational resistance occurs. Depending on the quality of the bone, this typically occurs after one full rotation after the ratcheting noise.

Ensure that the Tracker / Pin Interface is aligned with the sensor array. For proper orientation, verify that the cross pin is aligned with the sensor array.

⚠ WARNINGS:

- During Pin insertion, make sure that no transverse forces (e.g. by oscillation) are applied to the Pin. Failure to comply may lead to Pin instability and damage.
- If excessive torque is applied, the Anchoring Pin may overdrill since the fixation teeth (*fig. 1*) can no longer penetrate into the bone.

⚠ WARNING:

Check that the Anchoring Pin is firmly fixed to the bone. To check fixation, try to rotate the Anchoring Pin and to move it back and forth. The Anchoring Pin is fixed to the bone if it can not move. Any change in the position of the Anchoring Pin during surgery will compromise navigation accuracy.

6 Mount, Optically Align and Lock Tracker on Pin

Pull the holding mechanism back to remove the Insertion Tool from the Pin Interface.

Insert the Tracker into the Pin Interface.

See *figure 2*.

Orient the Tracker. The Tracker's LEDs must be visible to the sensor array.

Lock the Tracker in position. The Tracker must not move during surgery.

⚠ WARNING:

Make sure that the Tracker is firmly attached to the Anchoring Pin and locked. If not secure in position, the Tracker may rotate during surgery, thus compromising the navigation accuracy. Check stability by rotating the Tracker. The Tracker must not move.

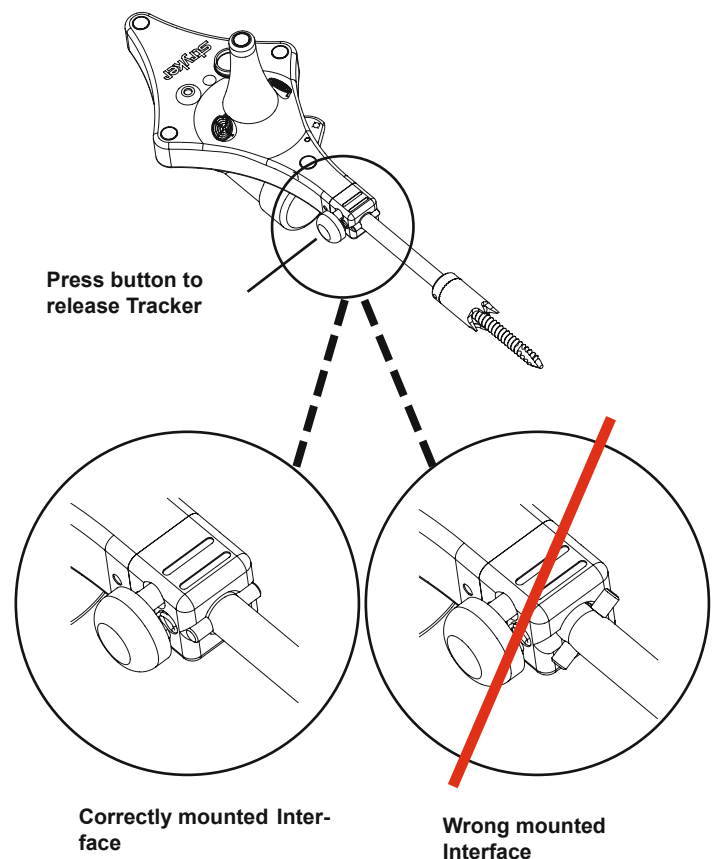


Figure 2: Tracker mounted on Anchoring Pin

Inspection Recommendations

Inspect the Pins prior to sterilization.

Refer to the *Cleaning and Sterilization Guide* REF 6000-005-750 for further information.

Cleaning Recommendations

For Cleaning of the Anchoring Pins, push the fixation sleeve towards the tip of the Pin. See *figure 3*.

Refer to the *Cleaning and Sterilization Guide* REF 6000-005-750 for further information.

Sterilization Recommendations



Single Use Only

The Pins are **single use only**. Sterilize the Pins before use as directed and discard after surgery.

Follow *preparation and operation instructions* contained in the *Cleaning and Sterilization Guide* REF 6000-005-750.

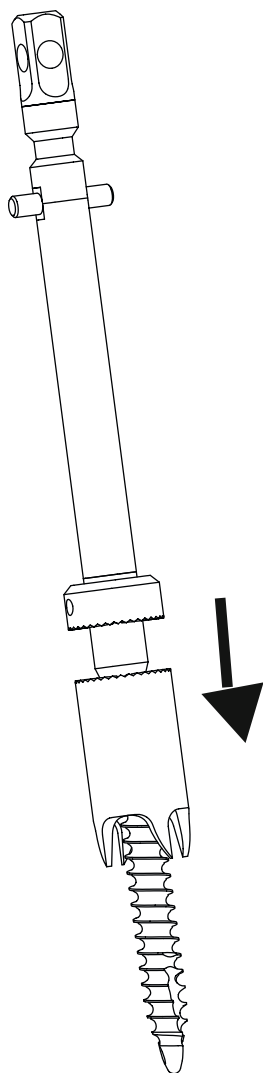


Figure 3: Anchoring Pin teeth sleeve properly positioned prior to cleaning

Troubleshooting Guidelines

PROBLEM	CAUSE	ACTION
The position of the instrument does not correlate with the instrument's location displayed on the system monitor.	Connections have become loose.	Verify system accuracy. For verification, perform Landmark Tests or use Verification Checkpoint. <i>Refer to the corresponding software manual.</i>
	Pin / Interface are bent or damaged.	Secure connections as required. In case of damage, replace.
	Pin has moved in the bone.	If Pin movement is detected, invalidate all images and acquire new images (for fluoroscopy based navigation system), or redigitize landmarks again (for imageless navigation system).

Specifications*

Model: 20 mm / 4 mm Anchoring Pin REF 6007-420-000
 25 mm / 4 mm Anchoring Pin REF 6007-425-000
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 Pelvic Pin for Knee Navigation REF 6007-551-000

Size: Anchoring Pins: 3.74 inch [95 mm] to 6.89 inch [175 mm] length, 0.39 inch [10 mm] diameter
 Pelvic Pin for Knee Navigation: 6.89 inch [175 mm] length, 0.39 inch [10 mm] diameter

Weight: Anchoring Pins: 0.56 oz. [16 g] to 0.77 oz. [22 g]
 Pelvic Pin for Knee Navigation: 0.71 lb. [20 g]

Material: Stainless steel

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



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