

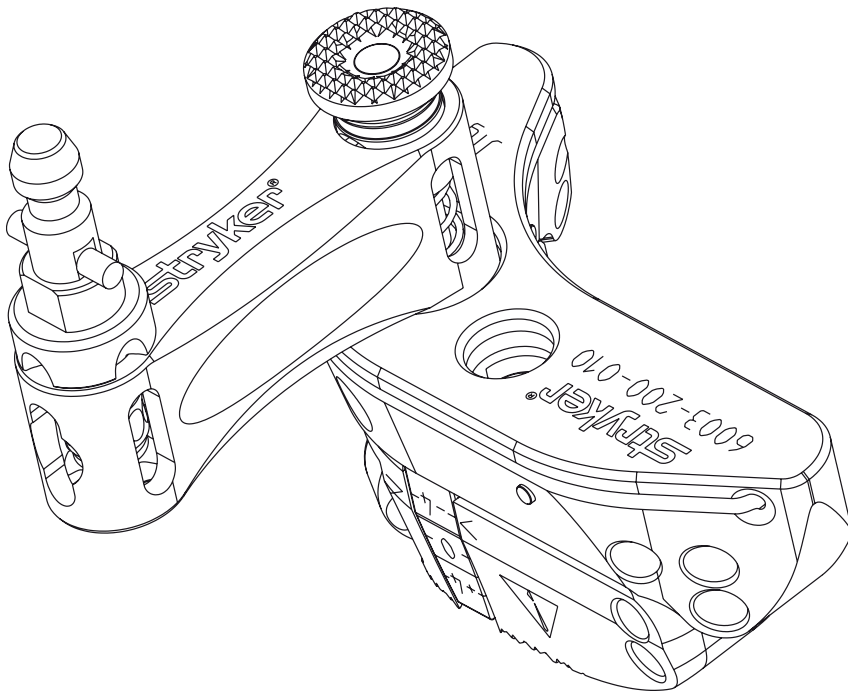


Instructions For Use

Navigated MIS Jig-A
REF 6003-200-010

Navigated MIS Jig-B
REF 6003-200-020

Tracker Adapter
REF 6003-200-030



Intended Use

The Navigated MIS Jig is intended as a dedicated cutting block system to support computer-assisted surgery. The instrument is intended for any medical condition in which the use of computer-assisted surgery may be appropriate and where a reference to rigid anatomical structures such as, but not limited to, the femur or tibia can be identified.

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.

NOTE:

In the following text the Navigated MIS Jig-A/Navigated MIS Jig-B is referred to as “cutting guide”.

NOTE:

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



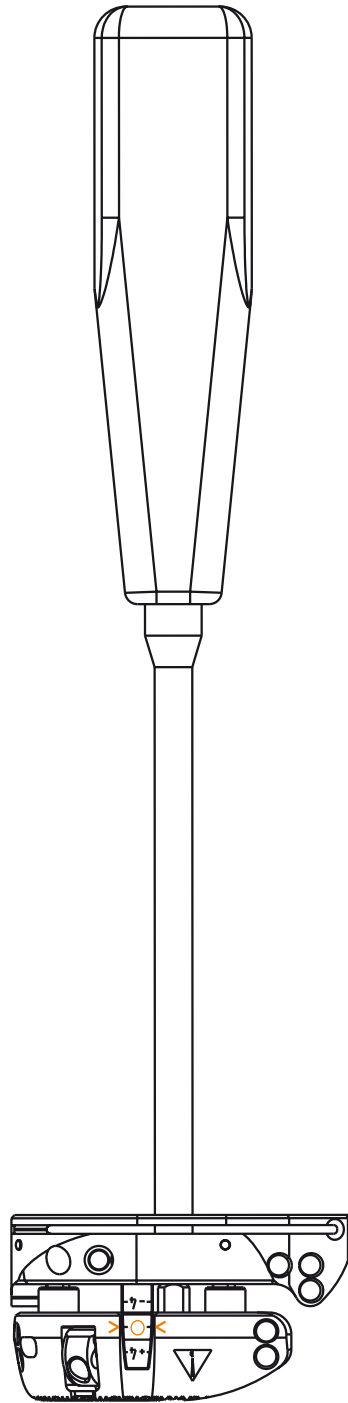
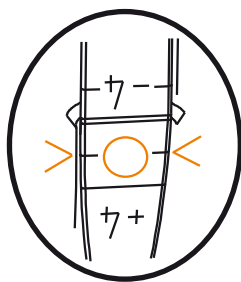
WARNING

- Read and understand this information. File it in your maintenance records. Familiarization with the Stryker navigation system prior to its use is important. Refer to the instructions for use supplied with the navigation system.
- Prior to each use, the Navigated MIS Jig should be checked for loose components and damage. Do not use if these conditions exist.
- Prior to surgery inspect the cutting guide slot for damage. For resection accuracy, replace the cutting guide if the slot is suspected of damage that has changed its geometry.
- Prior to surgery inspect the cutting guide slot for wear. For resection accuracy, replace cutting guide if the slot is suspected of wear that has changed its geometry (e.g. slot surface is uneven, broken off).
- Prior to surgery inspect the Navigated MIS Jig for slot flatness. For inspection, insert the saw blade into the slot of the cutting guide. The saw blade must be flush with the surface of the slot to ensure navigation accuracy. If the saw blade clamps or has significant play due to wear or damage, replace the cutting guide.
- Clean and sterilize the instruments before every use. *Refer to the Guide for Cleaning, Disinfection and Steam-Based Sterilization (TD6000005750).*
- 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 the Navigated MIS Jig other than those specified in these instructions or outside of their intended use will compromise navigation accuracy.
- Do not service this device. It contains no parts that the user can service. If service is required, contact your Stryker Navigation sales representative.
- Refer to the instructions for use supplied with the tracker for specific warnings related to the tracker.
- Prior to surgery verify that the Tracker Adapter is properly engaged on the cutting guide. The Tracker Adapter is properly assembled when the green marking is visible and no rotation is possible. Failure to comply may compromise navigation accuracy.
- Ensure that the tracker is locked onto the Tracker Adapter. Verify that the cross pin is engaged. Failure to comply may compromise navigation accuracy.
- If any play between the tracker/Tracker Adapter/cutting guide is suspected, contact your Stryker Navigation sales representative.
- When mounting the tracker choose the tracker orientation which ensures visibility of the tracker's LEDs to the camera. Rotate the tracker on the Tracker Adapter until the LEDs face the camera. Failure to comply may compromise the visibility of the tracker.
- For fixation use suitable pins. During insertion verify that the pins do not clamp or have a significant play. Failure to comply may compromise navigation accuracy.

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.

Instructions

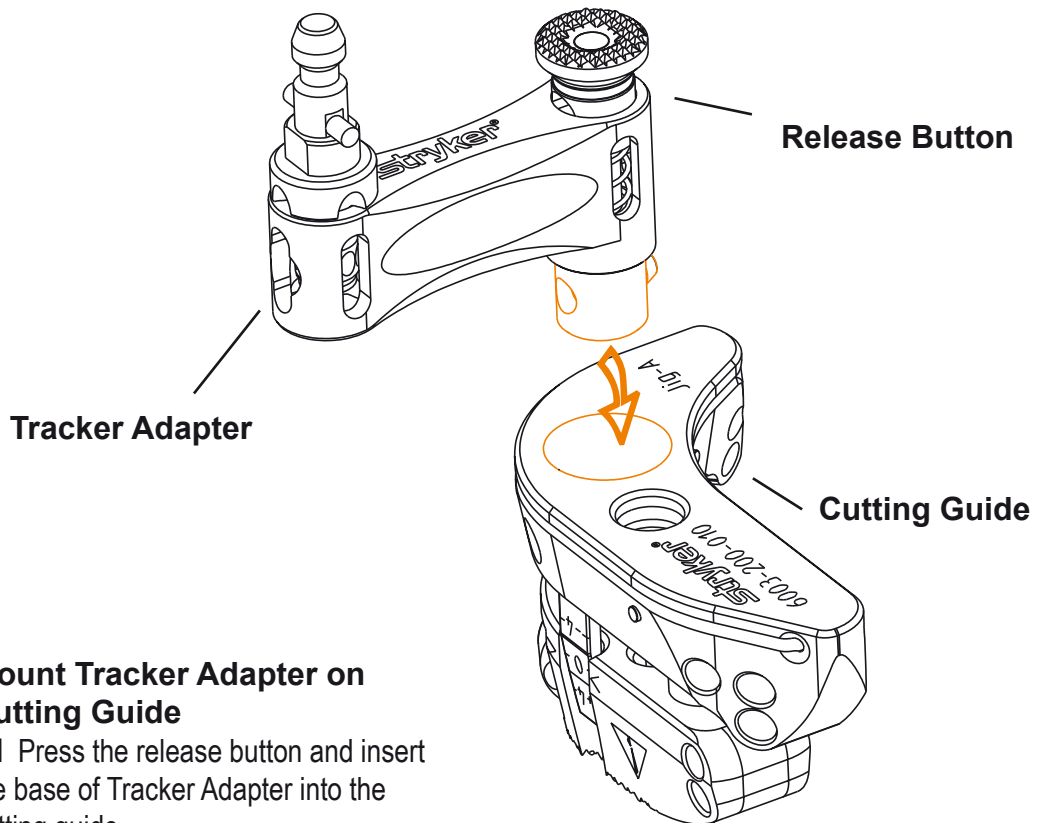


1 Adjust to Neutral Position

1.1 Insert the screwdriver into the screwdriver interface.

1.2 Rotate the screwdriver until the cutting guide is set to the 0 marking.

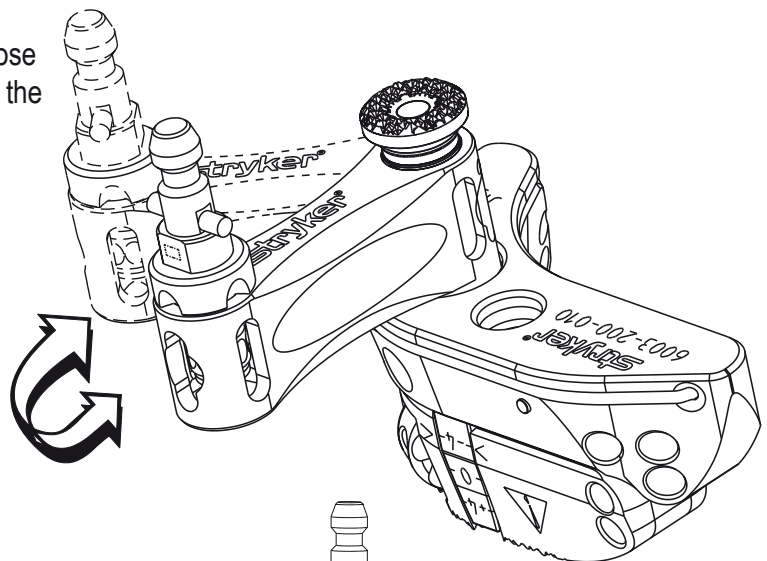
Instructions



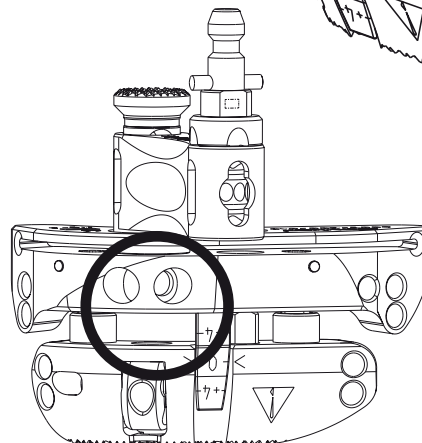
2 Mount Tracker Adapter on Cutting Guide

2.1 Press the release button and insert the base of Tracker Adapter into the cutting guide.

2.2 For tracker/camera alignment choose between the two adjustment angles of the Tracker Adapter on the cutting guide.

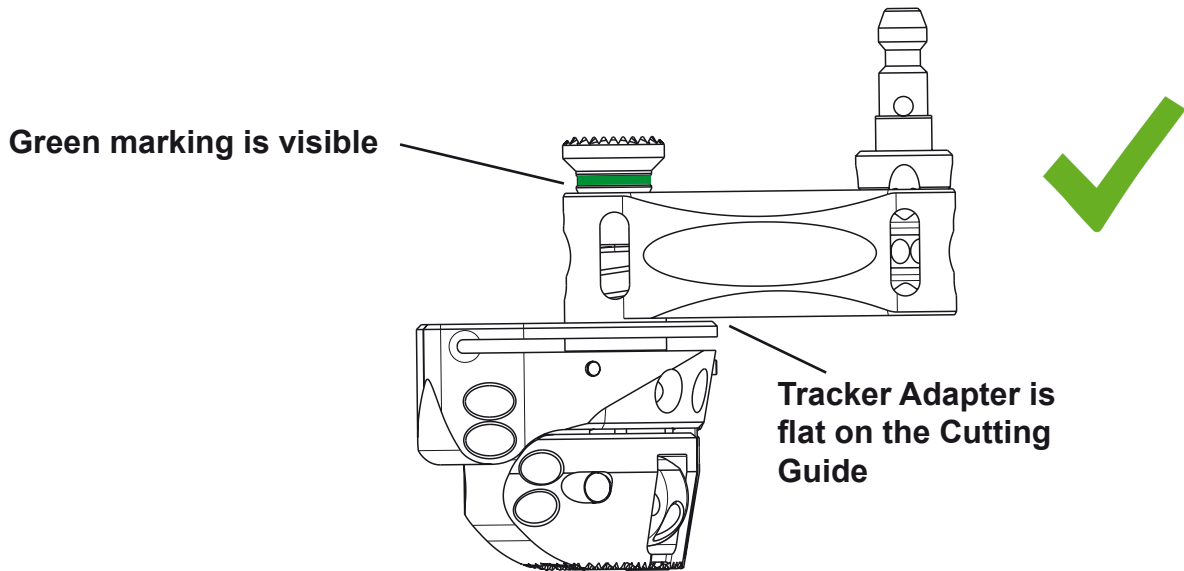


2.3. Release the release button and rotate the Tracker Adapter until the release button snaps in the required position. Verify that the Tracker Adapter is correctly engaged in the cutting guide.

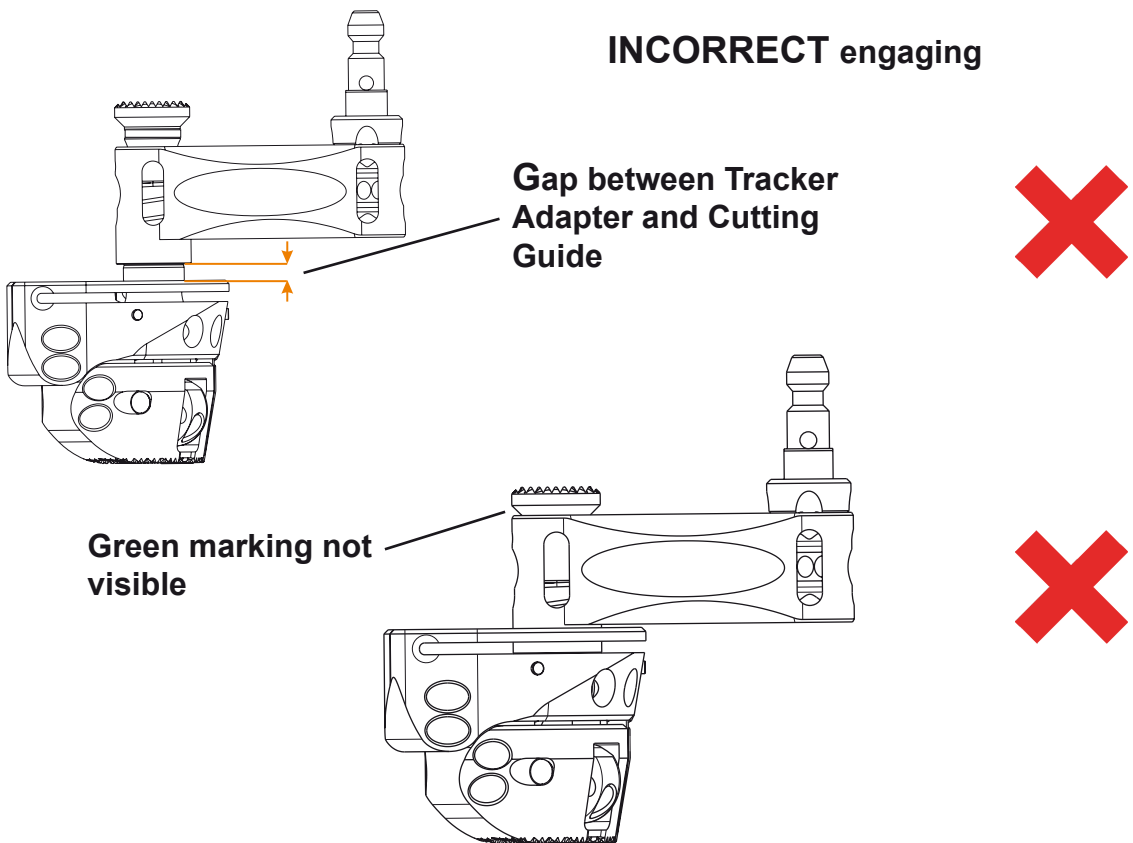


2.4 Double check that the Tracker Adapter is engaged and secure.

CORRECT engaging



INCORRECT engaging

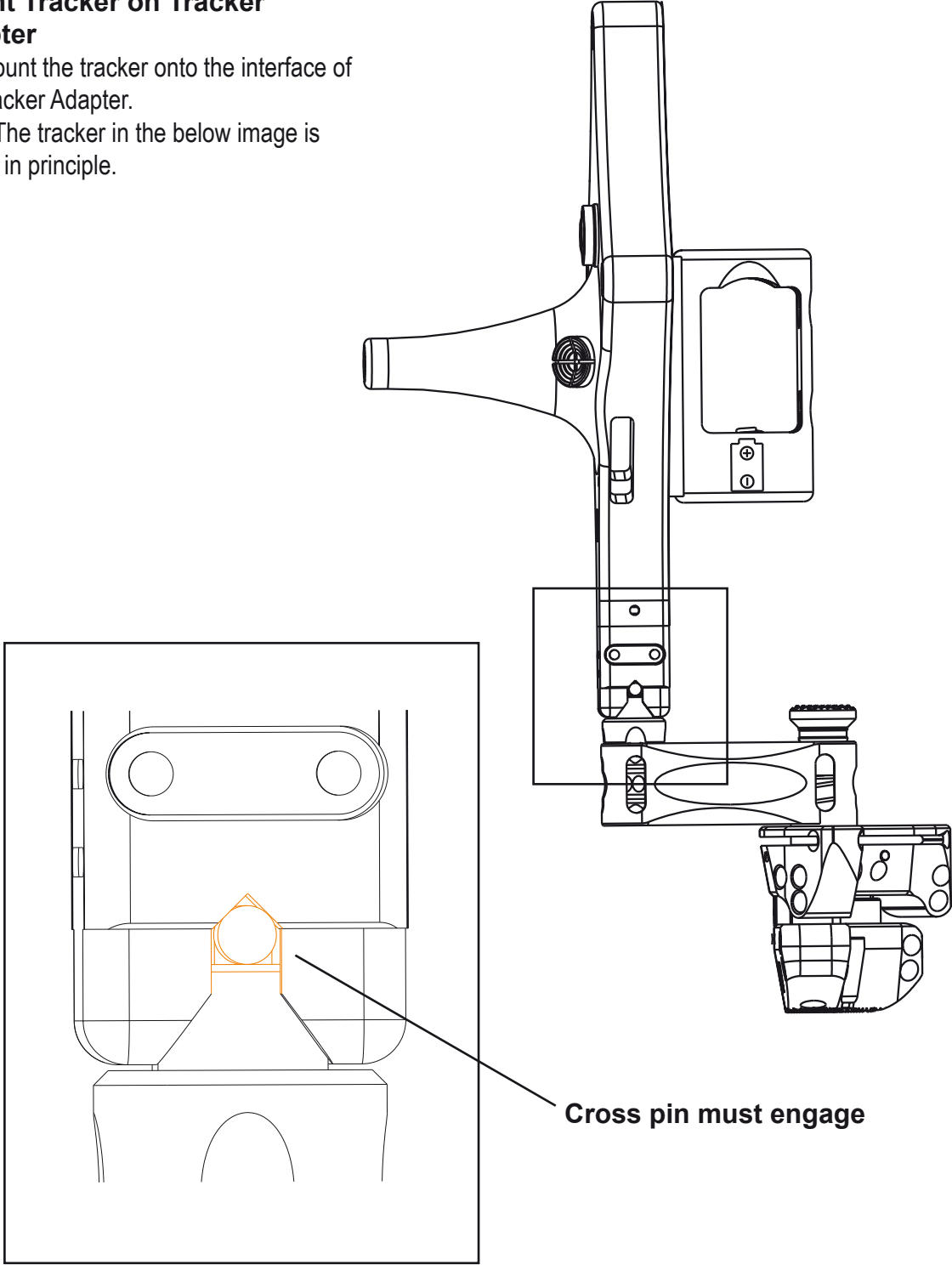


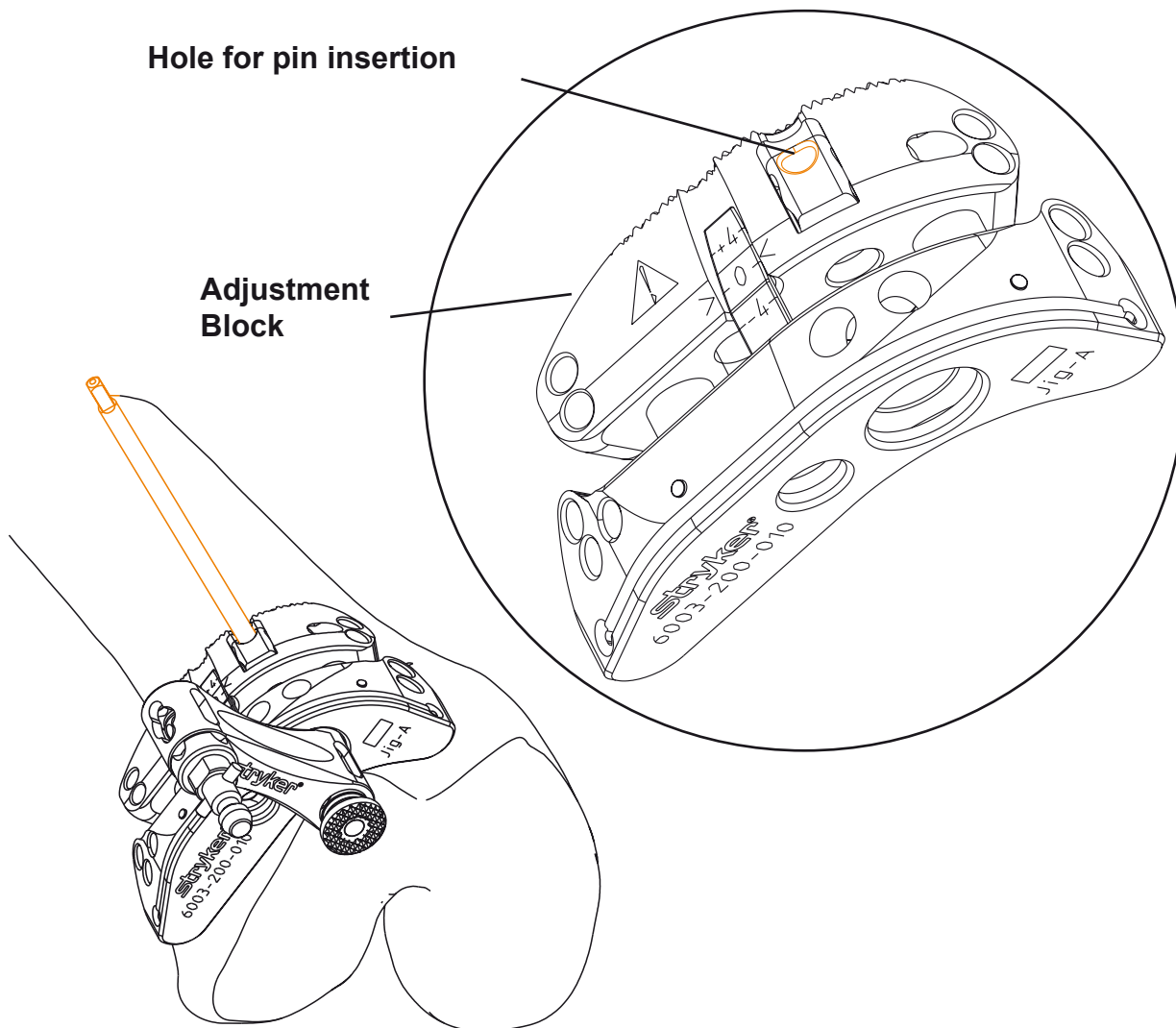
Instructions

3 Mount Tracker on Tracker Adapter

3.1 Mount the tracker onto the interface of the Tracker Adapter.

Note: The tracker in the below image is shown in principle.





4 Prealign and Prefixate Cutting Guide on Bone

4.1 Position the cutting guide on the bone with preadjusted varus/valgus, flexion/extension and resection level settings for preliminary fixation.

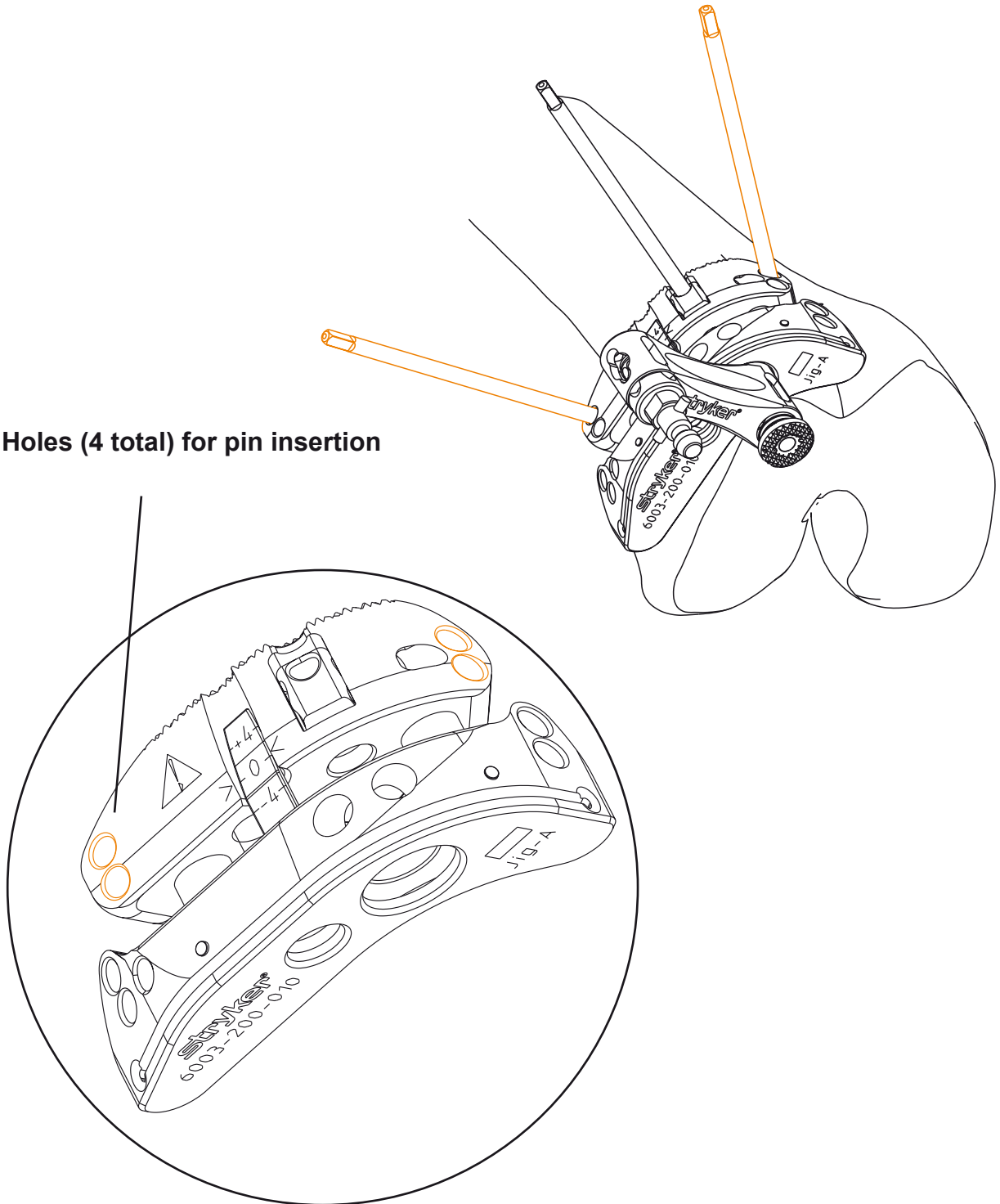
4.2 For preliminary fixation insert a pin into the swivel of the adjustment block as depicted in the detail above.

5 Varus/Valgus and Flexion/Extension Alignment

5.1 Align the cutting guide according to the varus/valgus and flexion/extension setting as displayed on the navigation screen.

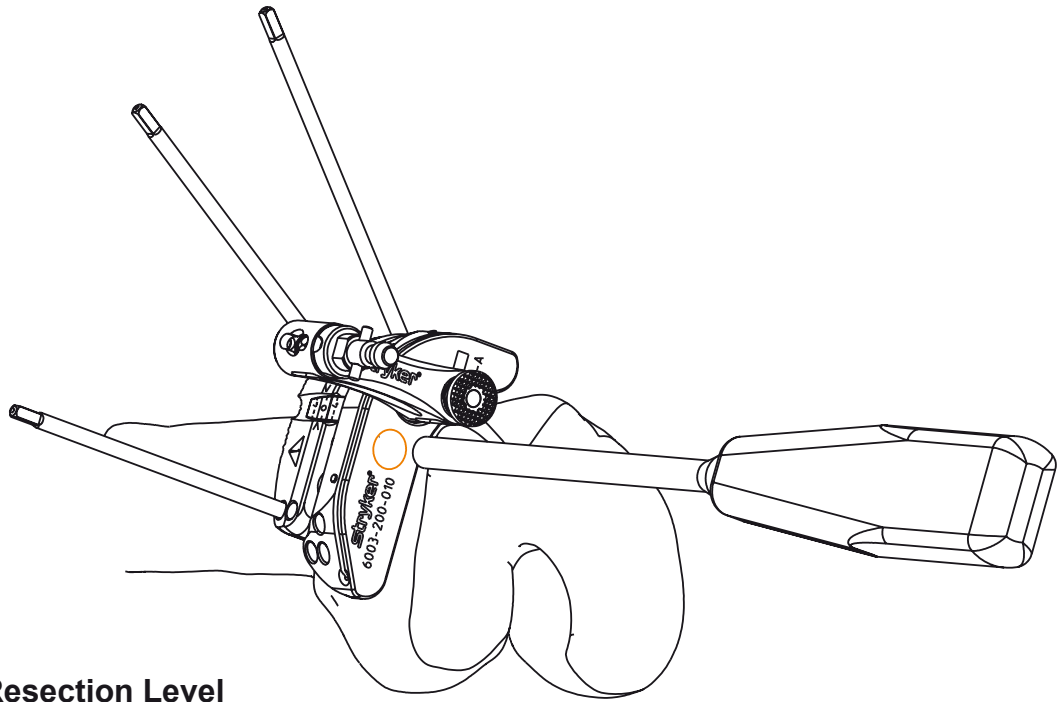
Instructions

Holes (4 total) for pin insertion



6 Fixate Adjustment Block

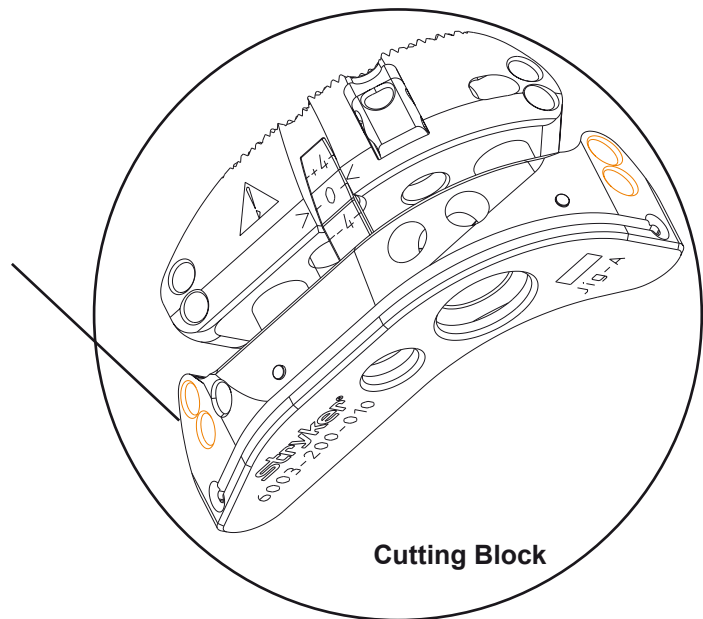
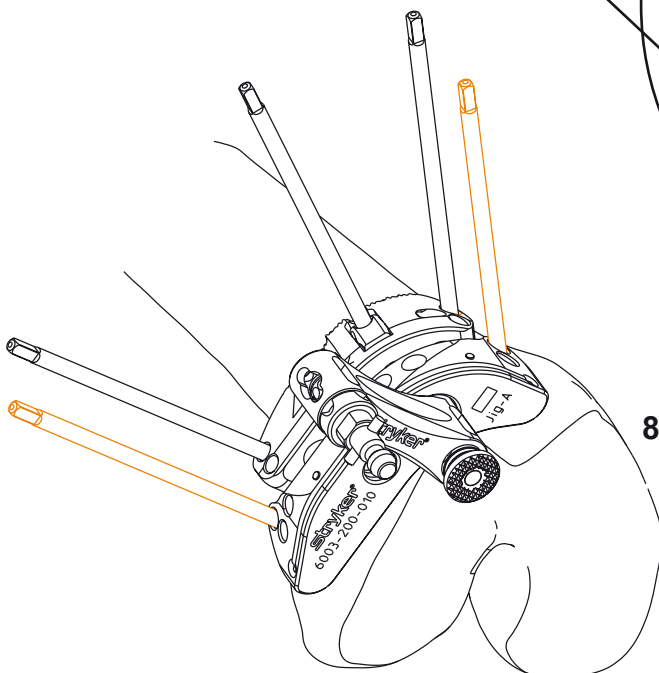
6.1 Insert two pins into the adjustment block for fixation as depicted in the detail above. Ensure that the adjustment block is stable and can not move relative to the bone.



7 Adjust Resection Level

7.1 Use the screwdriver as depicted above for resection level adjustment. The scale is not calibrated. Refer to the navigation screen for adjustment.

Holes (4 total) for pin insertion



Cutting Block

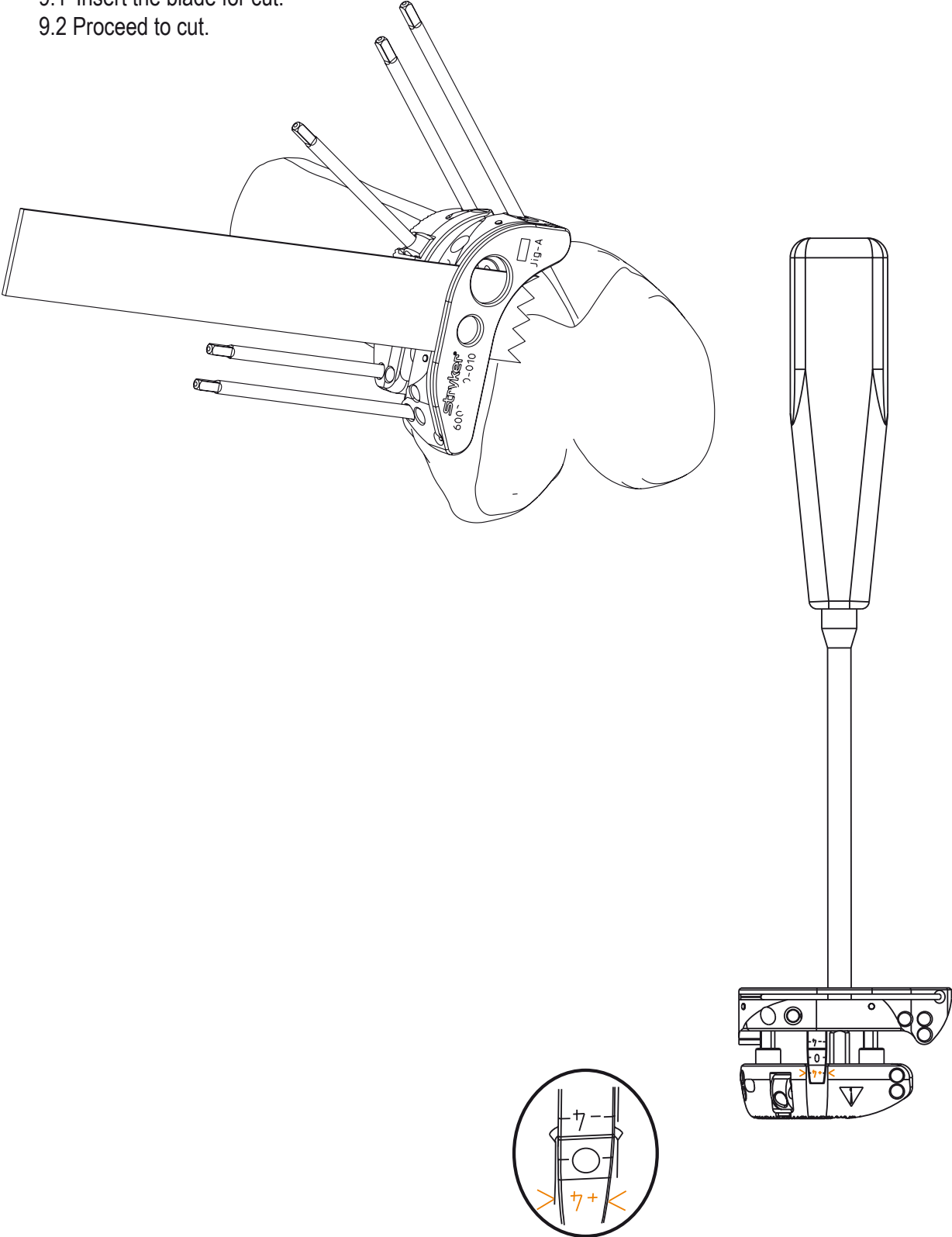
8 Final Fixation of Cutting Block

8.1 Insert two pins into the cutting block for fixation as depicted in the detail above.
 8.2 Remove the Tracker Adapter by pressing the release button.

Instructions

9 Bone Cut

- 9.1 Insert the blade for cut.
- 9.2 Proceed to cut.



Disassembly

Prior to cleaning and sterilization follow the instructions below for optimum cleaning and sterilization performance:

- 1 Remove tracker and Tracker Adapter.
- 2 Remove all pins.
- 3 Insert the screwdriver into the screwdriver interface.
- 4 Rotate the screwdriver until the cutting guide is set to the +4 marking.

Cleaning, Disinfection, Sterilization and Inspection Instructions

Cleaning group IV.

Refer to the Guide for Cleaning, Disinfection and Steam-Based Sterilization (TD6000005750) for cleaning safety and caution notes, cleaning equipment and detailed cleaning 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 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 product-specific compatibility, refer to the table below.

Product	For use with
Navigated MIS Jig-A REF 6003-200-010	Screwdriver REF 6003-100-100
	Universal Joint REF 6003-100-110
Navigated MIS Jig-B REF 6003-200-020	Screwdriver
Tracker Adapter REF 6003-200-030	Headless pins 3.175 mm (1/8 inch) diameter e.g. REF 6003-003-090, REF 7650-1038
	Saw blades 1.27 mm (0.05 inch) thickness e.g. REF 2108-189, REF 6625-127-105

Technical Specifications*

Model: Navigated MIS Jig-A REF 6003-200-010
 Navigated MIS Jig-B REF 6003-200-020
 Tracker Adapter REF 6003-200-030

Size: 40.5 x 43.1 x 11 mm (1.57 x 1.69 x 0.43 inch) Tracker Adapter
 54.5 x 25 x 31 mm (2.14 x 0.9 x 1.24 inch) Jig A/B

Weight: 130 g (4.58 oz) with Tracker Adapter assembled

Material: Stainless steel











	Operation	Storage and Transport
Temperature:		
Relative Humidity:		

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

Troubleshooting Guidelines

PROBLEM	CAUSE	ACTION
The Tracker can not rotate or be mounted onto interface and does not lock in position.	The interface is bent/damaged.	Return Tracker and Tracker Adapter to service.
The Tracker Adapter does not fit into cutting guide/jams.	The interface is bent/damaged.	Return Tracker Adapter and cutting guide to service.
The pin can not be inserted/jams.	The pin is bent, damaged or not properly sized.	Replace if damaged or not suitable.
The saw blade can not be inserted, has too much play, or jams. The saw blade can not be inserted, has too much play, or jams.	The blade is bent, damaged or not properly sized. slot is worn.	Replace if damaged or not suitable.
Resection level can not be set.	The cutting/adjustment block slides jam.	Replace. Return to service.

Definition of Symbols

Symbol	Name: Definition
	General warning sign: To signify a general warning.
	Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Date of manufacture: Indicates the date when the medical device was manufactured.
	Manufacturer: Indicates the medical device manufacturer as defined in the European Union harmonization legislation.
	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog number: Indicates the manufacturer's catalog number so that the medical device can be identified.
	Non-sterile: Indicates a medical device that has not been subjected to a sterilization process.
	Consult instructions for use: Indicates the need for the use to consult the instructions for use.
	Humidity limitation: Indicates the range of humidity to which the medical device can be safely exposed.
	Temperature limit: Indicates the temperature limits to which the medical device can be safely exposed.
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
CE	Indicates that a device is in conformity with the applicable requirements set out in applicable European Union harmonization legislation providing for its affixing.
MD	Medical device: Indicates a medical device according to European Union harmonization legislation.
GTIN	Global Trade Item Number.



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