



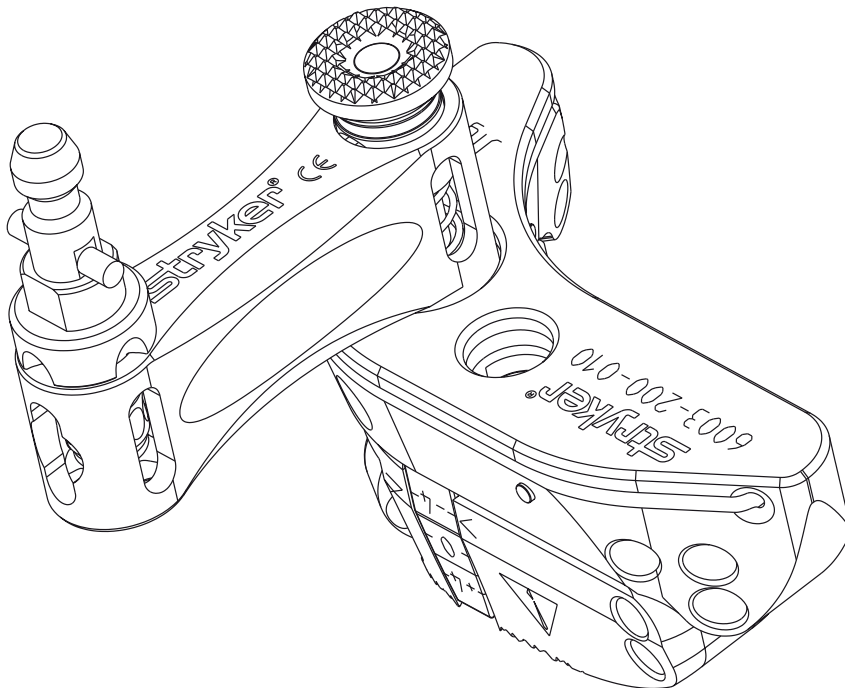
stryker

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



**US and Corresponding Foreign
Patents Pending**



**IMPORTANT INFORMATION FOR YOUR
NAVIGATION SYSTEM**

File in your maintenance records

TD6003200700 2018-01-11

Rev. D

Important Information

WARNING - CAUTION - NOTE

Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE carry special meanings and should be carefully observed.

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

CAUTION: These instructions point out special service procedures or precautions that must be followed to avoid damaging the instrument.

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



An exclamation mark 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.

Intended Use of the Navigated MIS Jig

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.

Function and Features

The Navigated MIS Jig consists of:

- Navigated MIS Jig-A
REF 6003-200-010
- Navigated MIS Jig-B
REF 6003-200-020
- Tracker Adapter REF 6003-200-030
- Screwdriver REF 6003-100-100

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. 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. If service is required, contact your Stryker Navigation sales representative immediately.*
- 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. Use saw blades with 0.05 in. (1.27 mm) thickness. The blade must be flush with the surface of the slot to ensure navigation accuracy. If the blade clamps or has significant play due to wear and/or damage, replace the Cutting Guide. Stryker Saw Blades REF 2108180000 are validated by Stryker as suitable.
- Inspect the Navigated MIS Jig before first and every use as recommended. Clean as instructed. Refer to the disassembling, cleaning and inspection instructions contained in this manual.
- 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 user/patient safety warnings related to the Tracker.
- To ensure the proper functioning of the Navigated MIS Jig, follow the assembling instructions explained in this manual carefully.

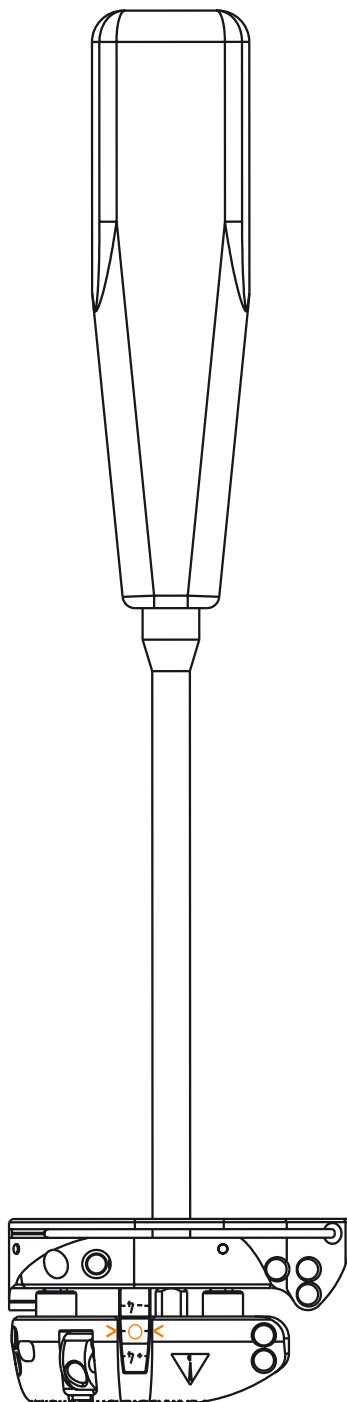
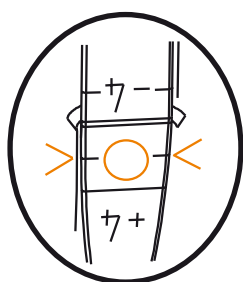
User/Patient Safety



WARNINGS:

- When assembling, choose the locking position of the Tracker Adapter on the Cutting Guide which ensures visibility of the Tracker's LEDs to the camera, also in case of overweight patients. Failure to comply may compromise the visibility of the Tracker.
- Prior to surgery verify that the Tracker Adapter is properly engaged on the Cutting Guide. The Adapter is properly assembled when the green marking is visible and no rotation is possible. Refer to the instructions contained in this manual for further information.
- Ensure that the Tracker is locked onto the Tracker Adapter. Verify that the cross pin is engaged. Failure to comply may compromise navigation accuracy. Refer to the instructions contained in this manual for further information.
- When mounting the Tracker choose the Tracker orientation which ensures visibility of the Tracker's LEDs to the camera. Rotate the Tracker on the Adapter until the LEDs face the camera. Failure to comply may compromise the visibility of the Tracker.
- Check the Tracker on the Adapter for rotability.
- For fixation use suitable pins. Failure to comply may compromise navigation accuracy. Use 1/8 in. (3.175 mm) headless pins. Permissible tolerance is 0.125 ± 0.001 in. (3.175 ± 0.0025 mm). During insertion verify that the pins do not clamp or have a significant play. Stryker Pins REF 7650-1038 are validated by Stryker as suitable. Prior to surgery verify pin suitability.
- It is part of the user's responsibility of due care to ascertain prior to use the safety and effectiveness of the combination of the Navigated MIS Jig with the saw blade/pins by means of the listed technical specifications.
- If the saw blade and/or the pins do not have the stated characteristics, they must not be used with the Navigated MIS Jig.
- In case of the slightest suspicion of incompatibility or risks, the user must not use the Navigated MIS Jig in combination with the third party products.
- If any play between the Tracker/Tracker Adapter/Cutting Guide is suspected, contact your Stryker Navigation sales representative immediately.

Instructions

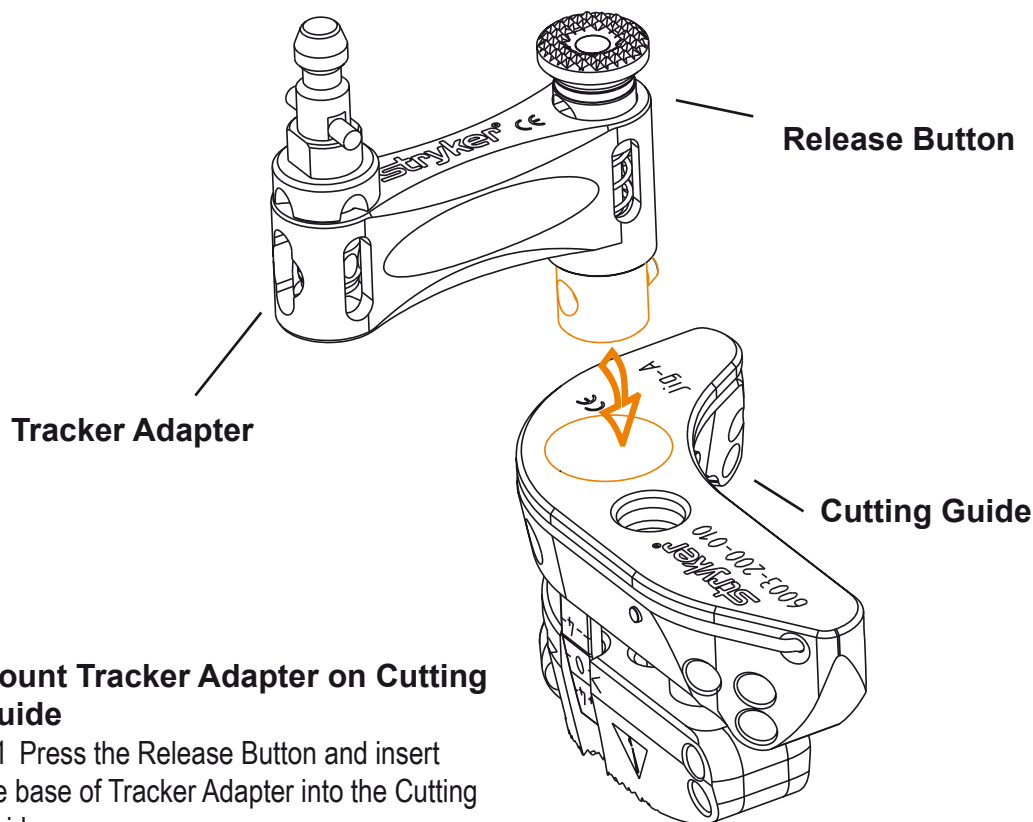


1 Adjust to Neutral Position

1.1 Insert the screwdriver into the screwdriver interface.

1.2 Rotate the screwdriver until the Cutting Guide is set to the 0 marking.

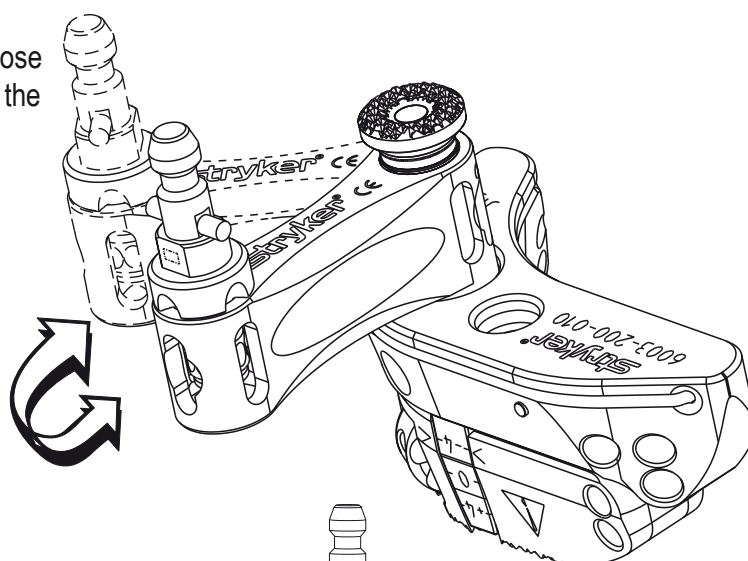
Instructions



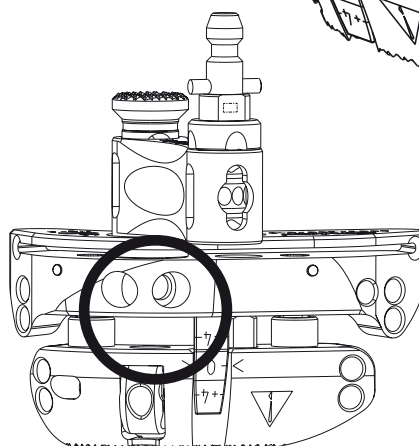
2 Mount Tracker Adapter on Cutting Guide

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 Adapter on the Cutting Guide.



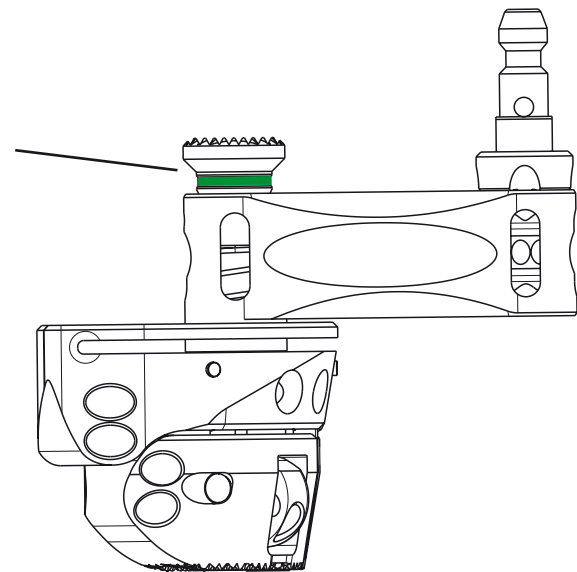
2.3. Release the Button and rotate the Adapter until the Button snaps in the required position. Verify that the Adapter is correctly engaged in the Cutting Guide.



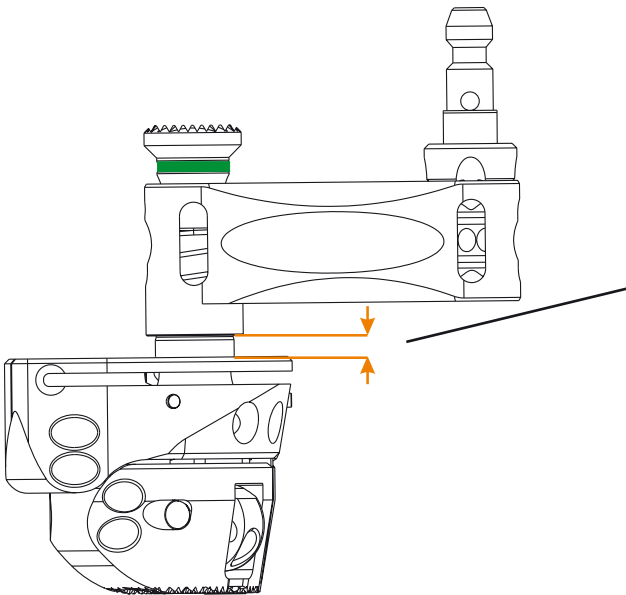


2.4 Double check that the Tracker Adapter is engaged and secure.

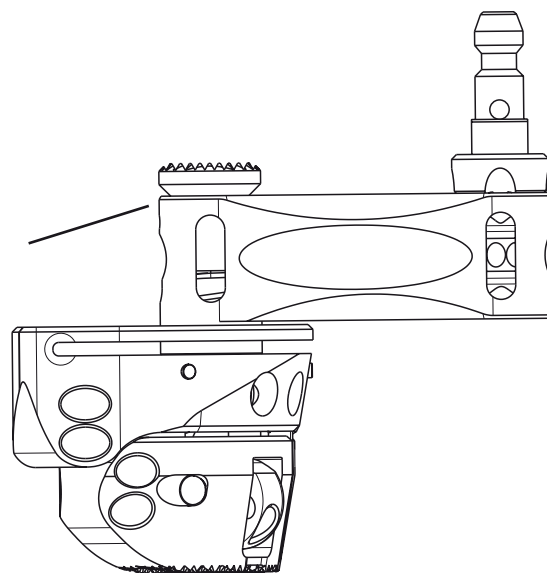
CORRECT engaging shows green marking



INCORRECT engaging shows gap between Adapter and Cutting Guide



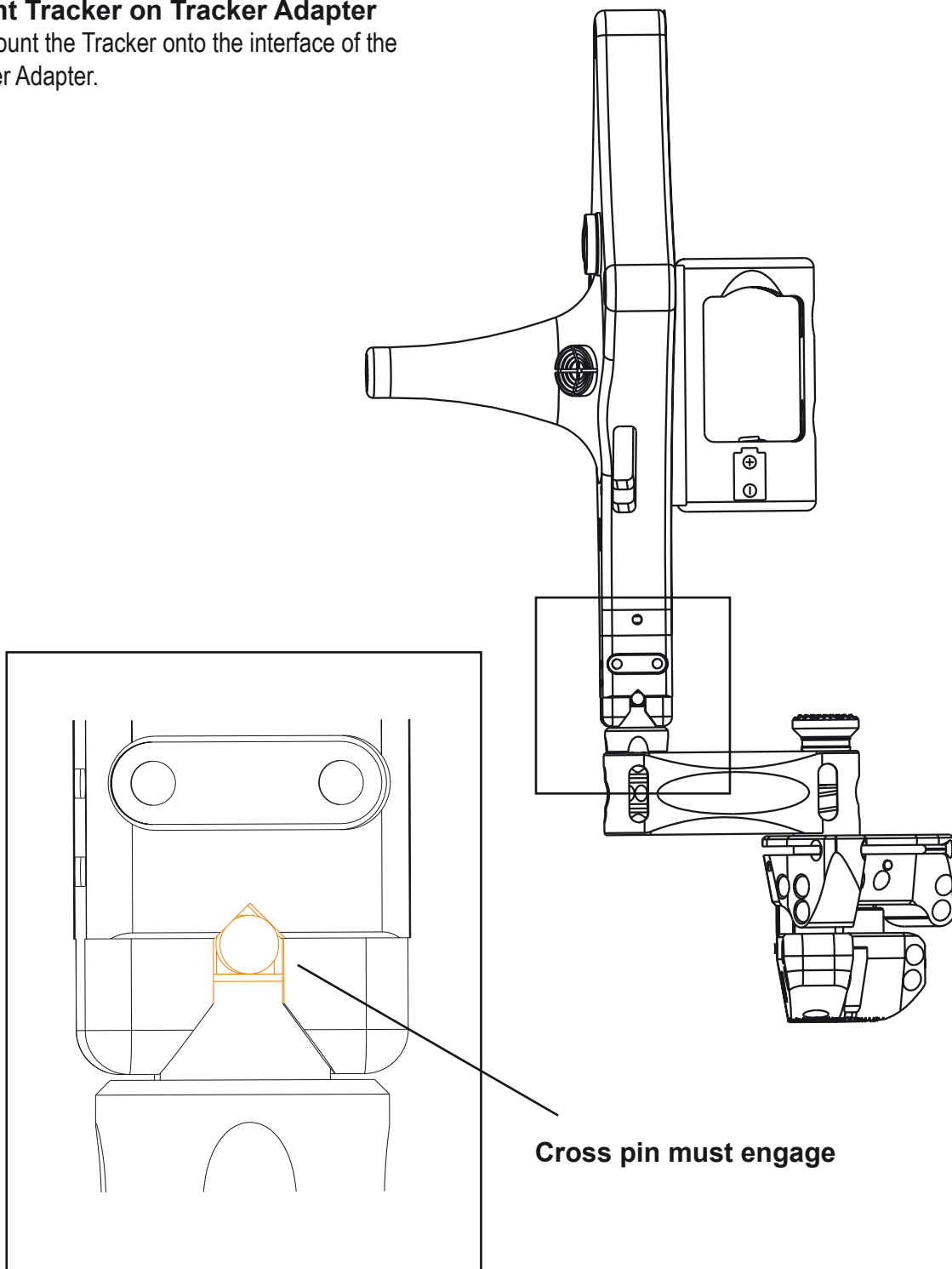
INCORRECT engaging hides green marking

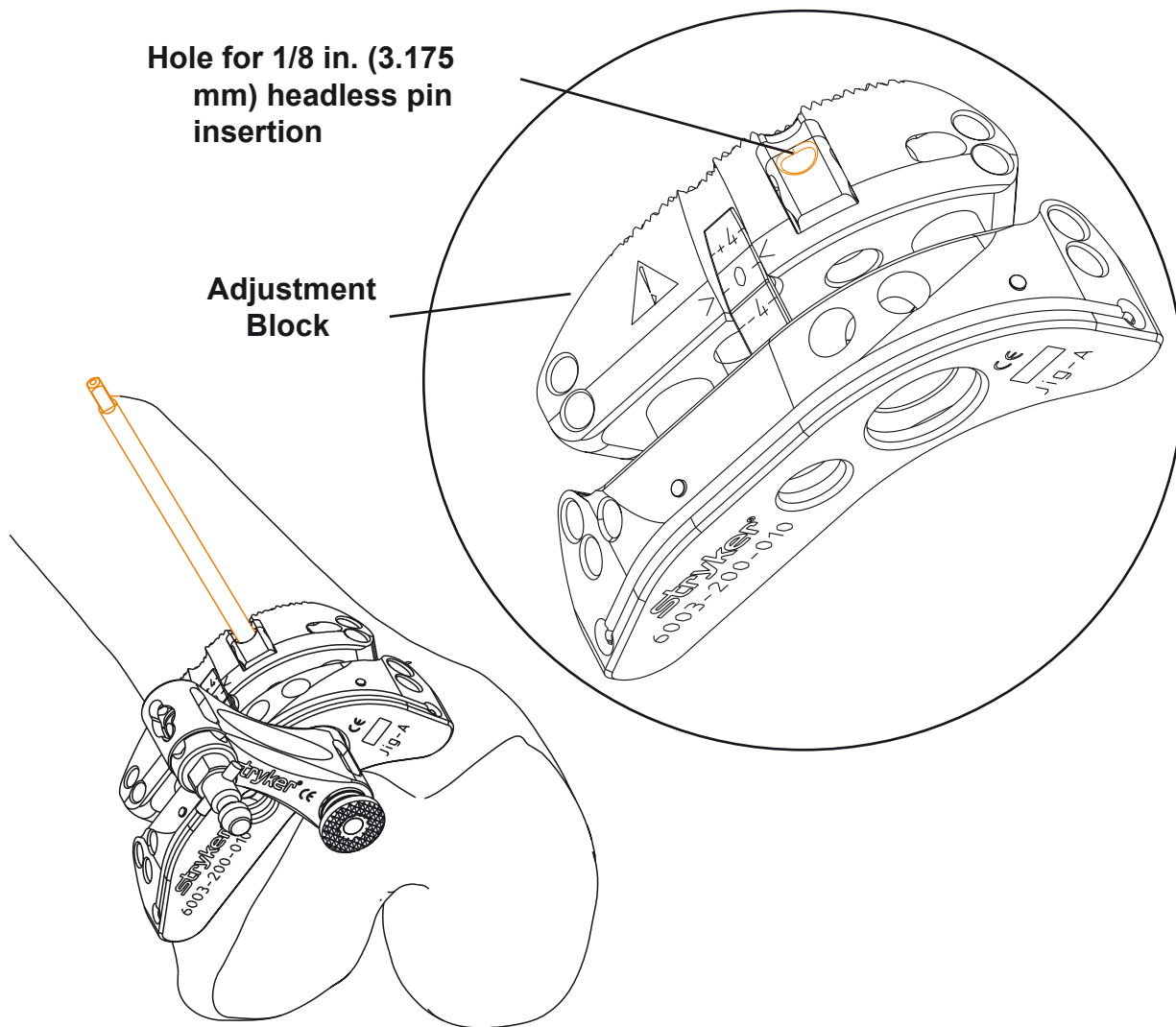




Instructions

- 3 Mount Tracker on Tracker Adapter**
 - 3.1 Mount the Tracker onto the interface of the Tracker Adapter.





Hole for 1/8 in. (3.175 mm) headless pin insertion

Adjustment Block

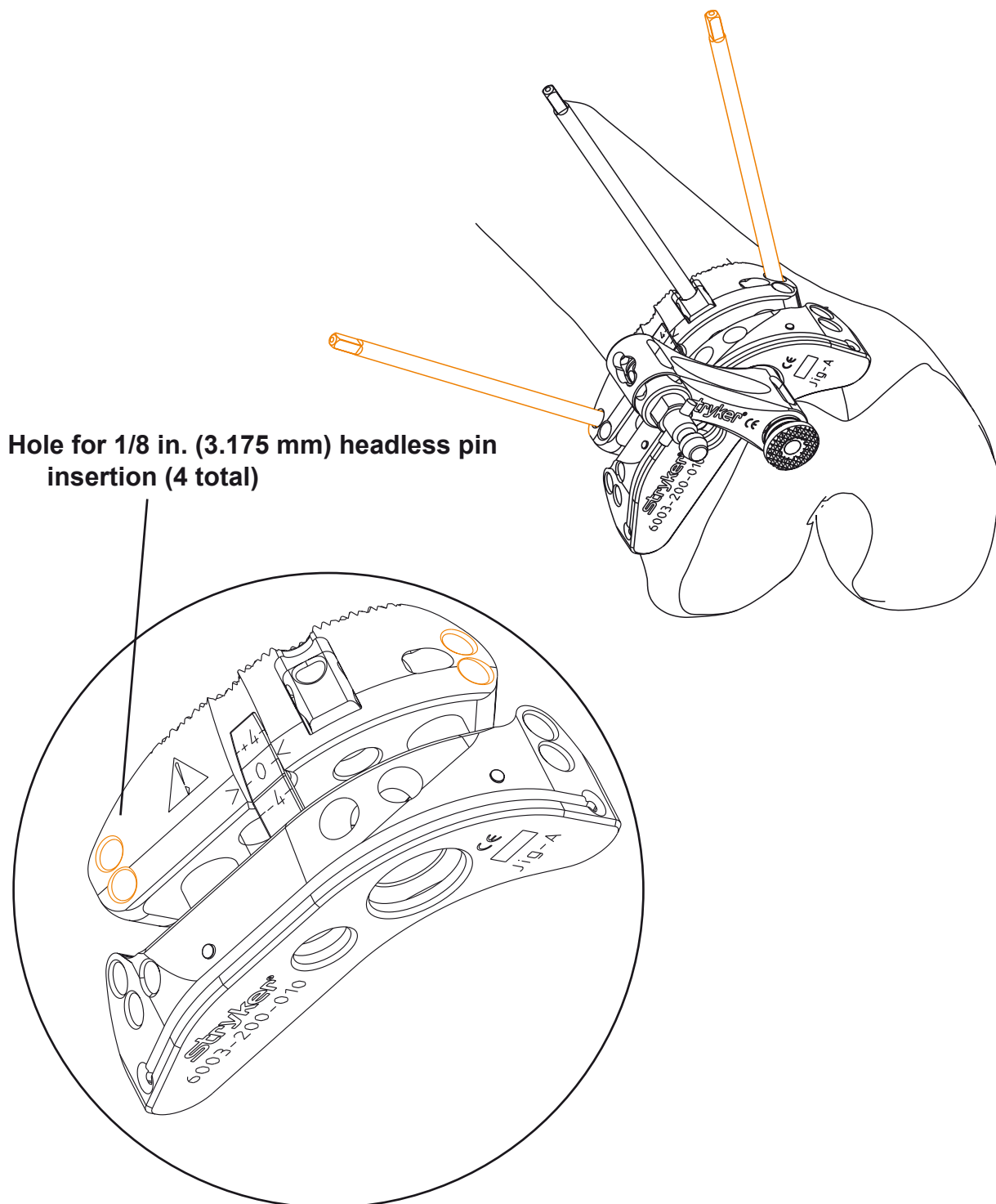
4 Prealign and Prefixate Cutting Guide on Bone

- 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 1/8 in. (3.175 mm) headless pin into the swivel of the adjustment block as depicted in the detail above.

5 Varus/Valgus and Flexion/Extension Alignment

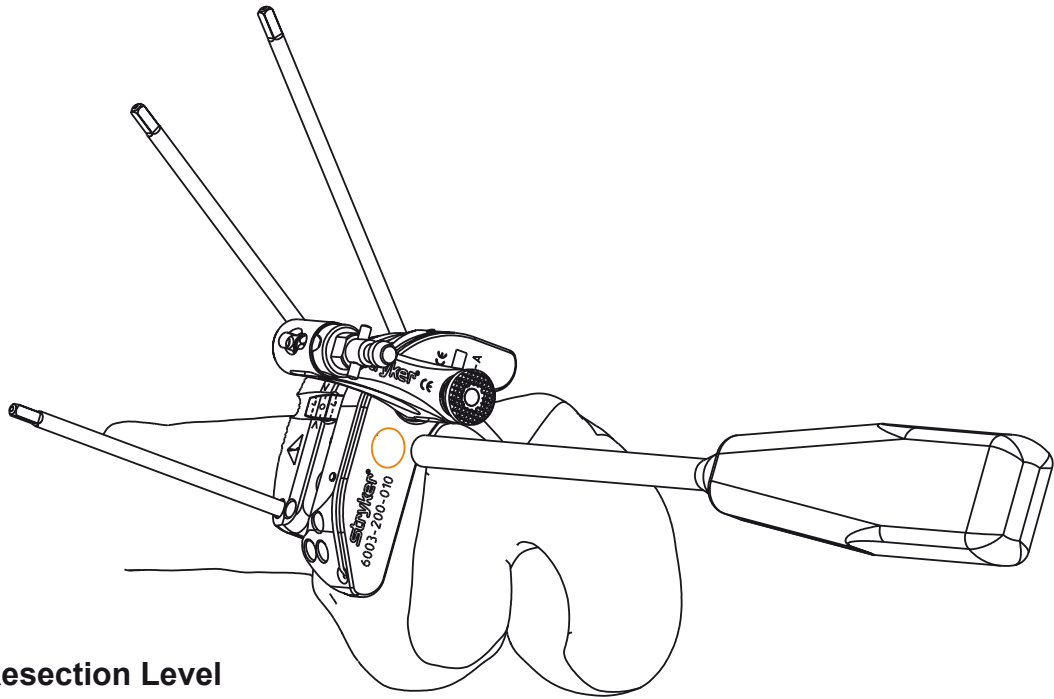
- 5.1 Align the Cutting Guide according to the varus/valgus and flexion/extension setting as displayed on the navigation screen.

Instructions



6 Fixate Adjustment Block

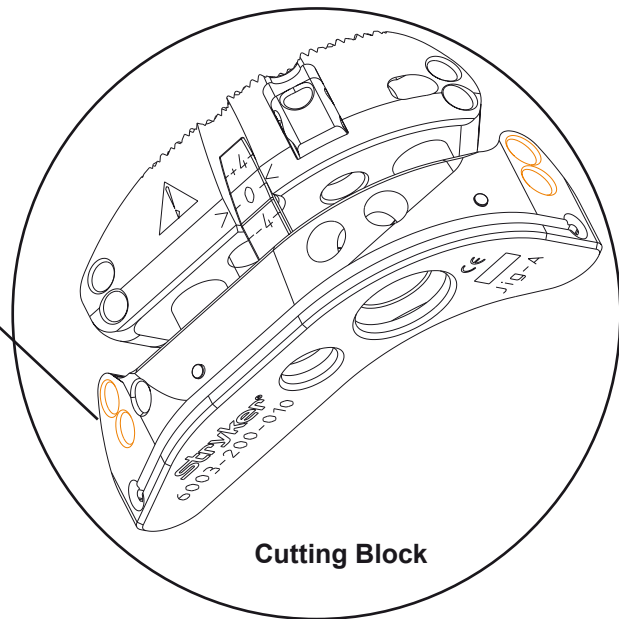
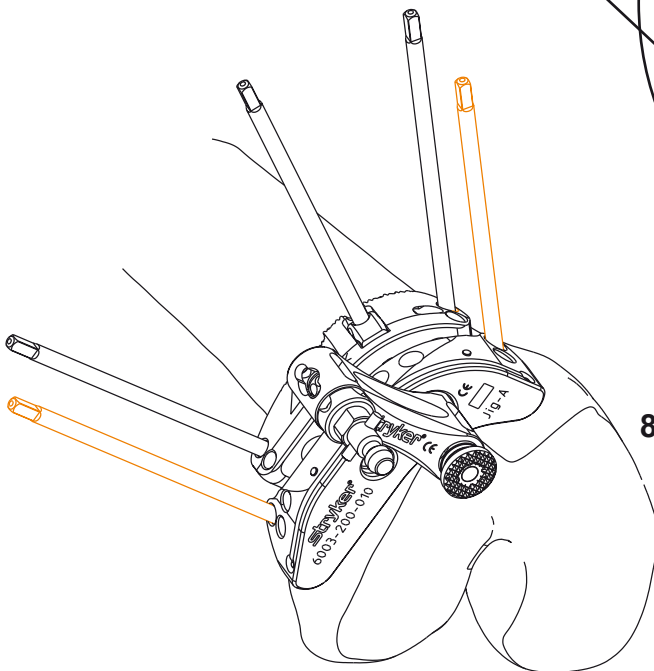
6.1 Insert two 1/8 in. (3.175 mm) headless pins into the adjustment block for fixation as depicted in the detail above. Ensure that the adjustment block is stable and can not move relative to the bone.



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.

Hole for 1/8 in. (3.175 mm) headless pin insertion (4 total)



Cutting Block

8 Final Fixation of Cutting Block

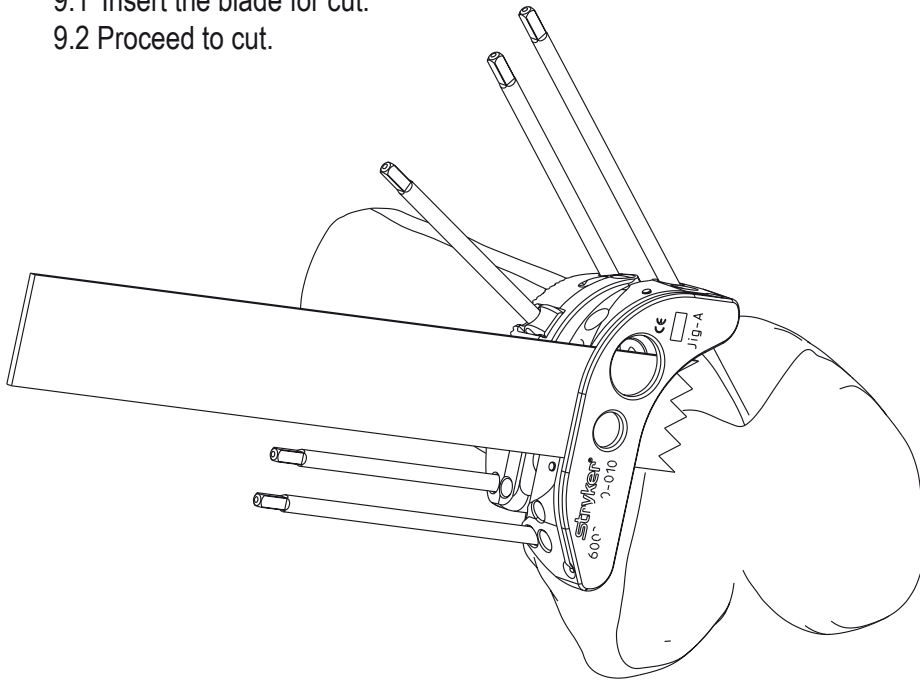
8.1 Insert two 1/8 in. (3.175 mm) headless pins into the cutting block forfixation as depicted in the detail above.

8.2 Remove the Tracker Adapter by pressing the Release Button.

Instructions

9 Bone Cut

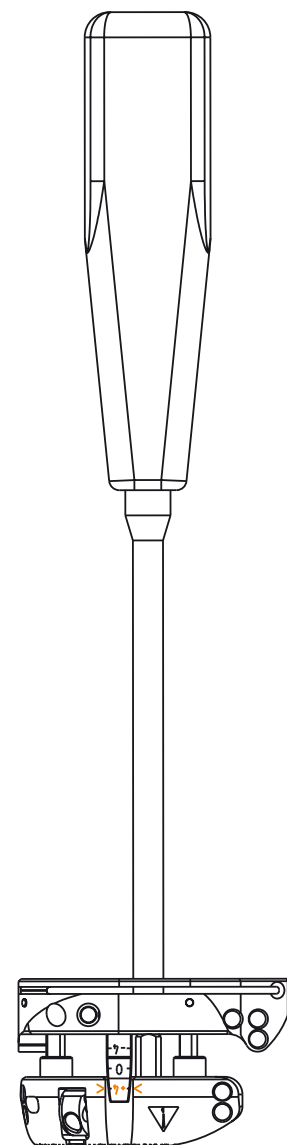
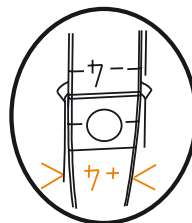
- 9.1 Insert the blade for cut.
- 9.2 Proceed to cut.



Disassembling Instructions for Cleaning

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 Recommendations

We recommend manual precleaning and machine cleaning method. The Navigated MIS Jig has cleaning group IV. Refer to the Cleaning and Sterilization Guide.

Inspection Recommendations

We recommend visual inspection after cleaning prior to sterilization. Refer to the Cleaning and Sterilization Guide.

Sterilization Recommendations

To obtain optimum performance and help prevent product damage, it is essential that the following sterilization procedure is followed for the Navigated MIS Jig. For the pins, refer to the Instructions For Use supplied with the pins.

Pre Vac - 3 Pre-vacuumed sterilizer cycles
- 270-273° F (132-134° C)
- Double wrapping or double packed in sterilization pouches
- 4 min minimum exposure
- 10 min minimum drying time

270° F Gravity - Gravity Displacement Sterilizer
- 270-273° F (132-134° C)
- Double wrapping or double packed in sterilization pouches
- 35 min minimum exposure
- 10 min minimum drying time

Flash Gravity - Gravity Displacement Sterilizer
- 270-273° F (132-134° C)
- Unwrapped
- 10 min preheating time
- 10 min minimum exposure
- 10 min minimum drying time

The Sterilization Recommendation's validation is based on ANSI/AAMI/ISO 11134 protocol. The respective individual laws, standards, directives and instructions of each country must be followed and have priority of the specified procedure (e.g. flash gravity). It remains to the user to consider this and to acquire the corresponding information.

Troubleshooting Guidelines

| <u>PROBLEM</u> | <u>CAUSE</u> | <u>ACTION</u> |
|--|---|--|
| 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 blade is bent, damaged or not properly sized. | Replace if damaged or not suitable. |
| | The slot is worn. | Replace. |
| Resection level can not be set. | The cutting/adjustment block slides jam. | Return to service. |

Handling and Storage

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



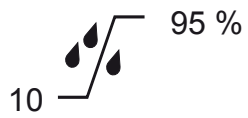

Specifications*

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 in.) Tracker Adapter
54.5 x 25 x 31 mm (2.14 x 0.9 x 1.24 in.) Jig A/B

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

Material: Stainless steel

| | Operation | Storage and Transport |
|-----------------------|--|---|
| Temperature: |  40° C |  75° C |
| Relative Humidity: |  95 % |  95 % |
| Atmospheric Pressure: | n.a. | n.a. |

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



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