Dedicated Mini Jig

Adjustment Component	**REF 6003-100-020**
Tracker Adapter	**REF 6003-100-090**
Mini Cutting Guide	**REF 6003-300-010**
Mini Fixation Plate	**REF 6003-300-021**
ASM Fixation Plate A	**REF 6003-300-031**
ASM Fixation Plate B	**REF 6003-300-041**

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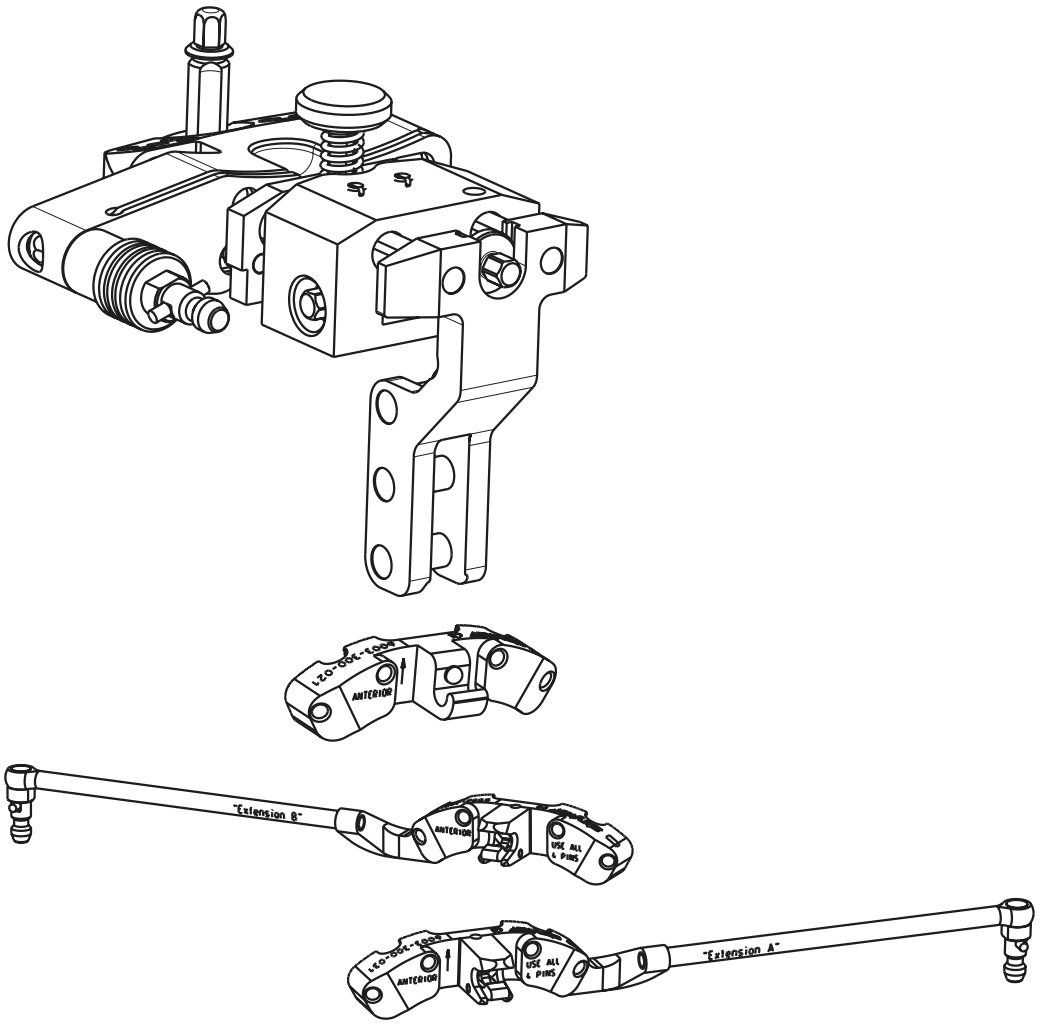
Instructions For Use



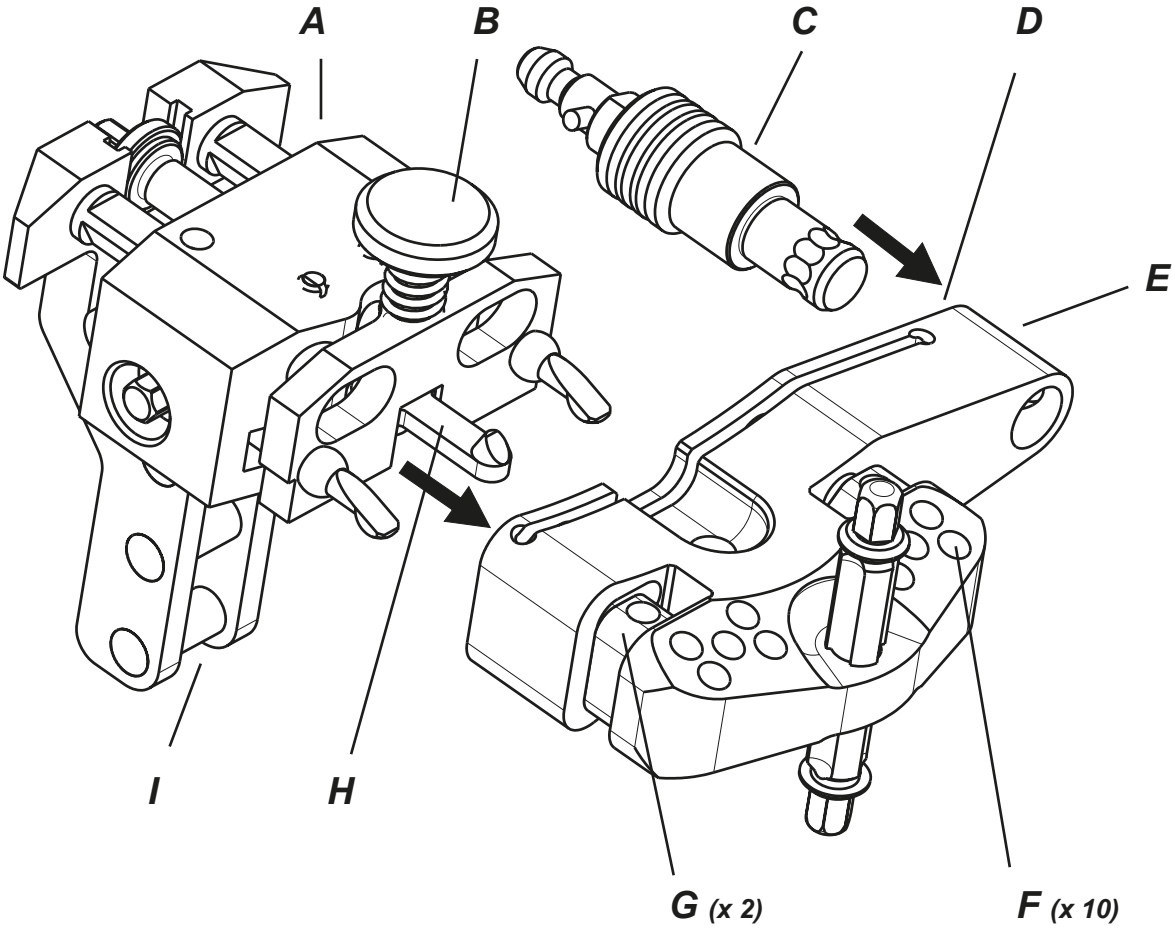


Figure 1

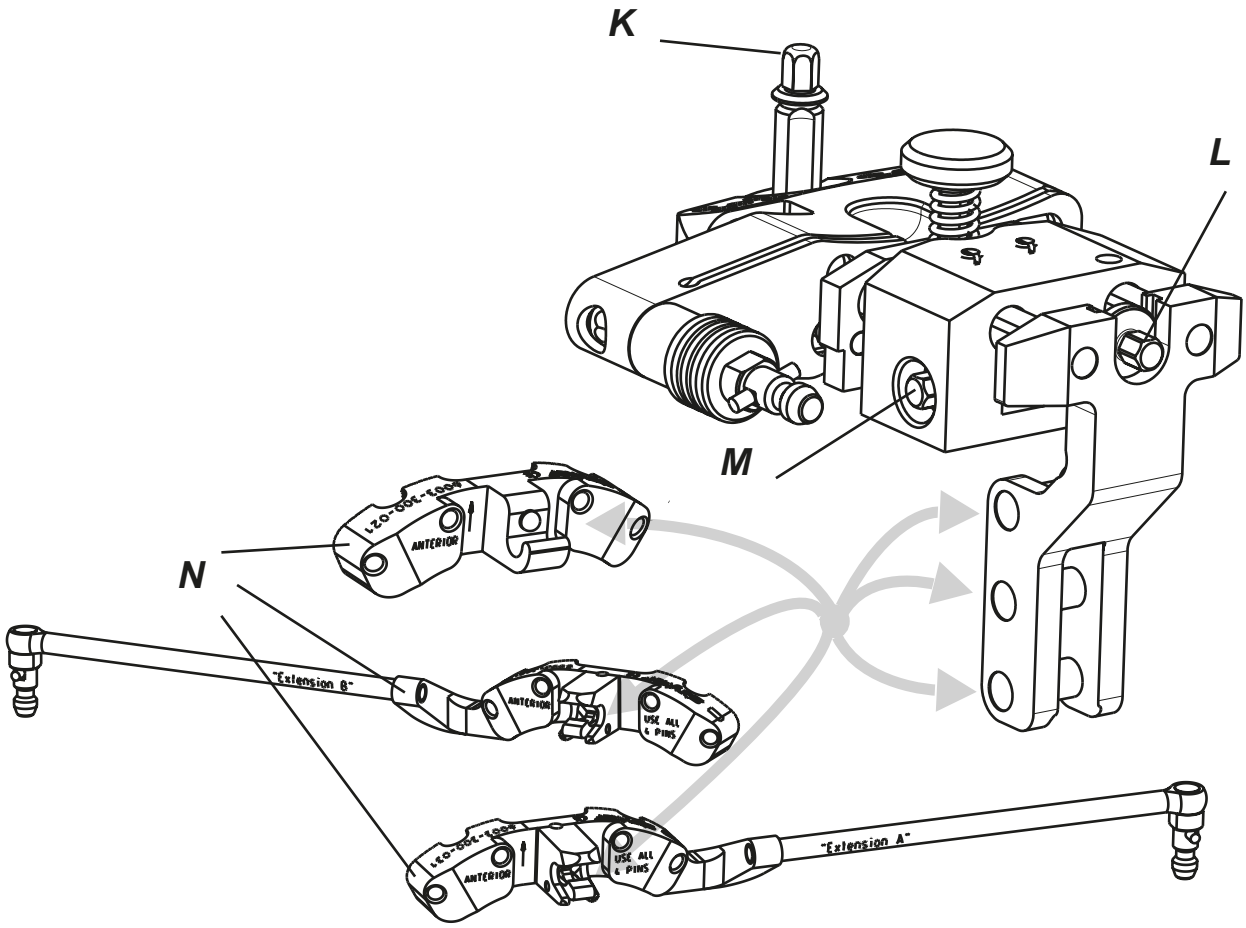


Figure 2

Intended Use

The Dedicated Mini Jig is intended as a dedicated cutting block system to support computer-assisted surgery. The instrument is indicated 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:

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 use is important. Refer to the instructions for use supplied with the navigation system.
- The instruments should only be used in accordance with the instructions for use contained in this manual.
- Prior to each use, the instruments should be operated and checked for any loose components or damage. Do not use if these conditions exist. Contact your Stryker Navigation sales representative in such case.
- The healthcare provider performing any procedure is responsible for determining the appropriateness of using the product and the specific technique for each patient. Stryker, as a manufacturer, does not recommend a specific surgical procedure.
- Check Mini Cutting Guide **(E)** for slot integrity before use. For inspection, insert the saw blade into the slot of the Mini Cutting Guide. 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 Mini Cutting Guide.
- Performing procedures with instruments other than those specified in these instructions or outside of their intended use compromises navigation accuracy.
- Do not use the Dedicated Mini Jig if the incision is minimal invasive.
- Clean and sterilize instruments before every use. *Refer to the Guide for Cleaning, Disinfection and Steam-Based Sterilization (TD6000005750).*
- Do not service the instruments. They do not contain any parts the user can service. If service is required, contact your Stryker Navigation sales representative.
- Inspect the Mini Cutting Guide **(E)** for damage. For resection accuracy, replace the Mini Cutting Guide if it is suspected that damage has changed its geometry.
- Ensure that the Tracker Adapter **(C)** is securely engaged on the Mini Cutting Guide **(E)**. Failure to comply will compromise navigation accuracy.
- Refer to the *Instructions For Use* supplied with the tracker for specific warnings related to the tracker.
- Regularly verify that the tracker is rigidly attached to the tracker interface of the Tracker Adapter and that the cross pin is engaged.

- For the application of pins, enough appropriate and healthy bone substance for the temporarily rigid fixation of the pins must exist. The surgeon needs to assess if the bone condition is appropriate for the use of pins.
- Pin holes alter the stress distribution and decrease the breaking strength of any bone and may cause a stress fracture.
- Ensure that the Dedicated Mini Jig is aligned in such way that the fixation pins are properly placed in the bone (e.g. not creating pin holes tangential to the corticalis).
- Place the pins in such a way that they do not collide with implants and/or instruments.
- Do not use the Dedicated Mini Jig if the bone quality is too poor to enable a stable fixation of the fixation plate **(N)**.
- For fixation use suitable pins. Failure to comply may compromise navigation accuracy. During insertion verify that the pins do not clamp or have significant play.
- 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 Dedicated Mini 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 Dedicated Mini Jig.

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.

Product Overview

The Dedicated Mini Jig is composed of:

- Mini Cutting Guide **(E)**
  REF 6003-300-010
- Adjustment Component **(A)**
  REF 6003-100-020
- Tracker Adapter **(C)**
  REF 6003-100-090

and one of the following plates **(N)**:

- Mini Fixation Plate
  REF 6003-300-021
- ASM Fixation Plate - Extension A
  REF 6003-300-031
- ASM Fixation Plate - Extension B
  REF 6003-300-041

Instructions

For all instructions, *refer to the Figures 1 and 2.*

1 Assembly and Preparation

*1.1. Mount Adjustment Component **(A)** to Mini Cutting Guide **(E)**.*

- The Adjustment Component **(A)** can be oriented in two different positions to the Mini Cutting Guide **(E)**. Orient the Adjustment Component such that the tracker can be mounted medially.
- Press the release button **(B)** and insert the Adjustment Component locking bracket **(H)** into the entry slot of the Mini Cutting Guide **(E)**. Take care that the Mini Cutting Guide locks in position.

*1.2. Mount tracker to Mini Cutting Guide **(E)**.*

- Insert the Tracker Adapter **(C)** into the Tracker Adapter interface **(D)**. The Tracker Adapter must engage and rotate in discrete steps.
- Mount the tracker onto the Tracker Adapter.

2 Preliminary Fixation

2.1. Position on bone

- Press the fixation plate **(N)** on the anterior regions of the femoral condyles or, respectively, on the anterior regions of the tibial compartments.
- Pin the fixation plate using all four pin holes.

- For OrthoMap Express Knee Navigation: attach the tracker to ASM Fixation Plate - Extension A/B interface. The tracker must be attached in a way that its LEDs are visible for the camera.
- Select one of the three possible bolts **(I)** of the Adjustment Component **(A)** and mount the adjustment component to the fixation plate **(N)** .
- If needed, rotate the tracker so that the tracker's LEDs are in line of sight of the camera.

3 Cut Alignment

3.1. To adjust the varus/valgus angle, rotate the adjustment screw **(M)**.
3.2. To adjust the resection level, rotate the adjustment screw **(L)**.
3.3. To adjust the flexion/extension angle rotate the adjustment screw **(K)**.

4 Cutting Guide Fixation

4.1. Insert a minimum of two pins into the Mini Cutting Guide pin holes **(F)** and fixate the Mini Cutting Guide **(E)**.
4.2. Insert a minimum of one pin into the cannulated swivel **(G)**. After insertion, align the pin perpendicular to the bone and fixate the Mini Cutting Guide **(E)**.

5 Resection

5.1. Gently remove the pins from the fixation plate **(N)**.
5.2. Press the release button **(B)** and gently remove the adjustment component **(A)** from the Mini Cutting Guide **(E)**.
5.3. Proceed to cutting.

Cleaning, Disinfection, Sterilization and Inspection Instructions

Cleaning Group IV

Refer to the Guide for Cleaning, Disinfection and Steam-Based Sterilization (TD6000005750) for cleaning and sterilization safety and caution notes, cleaning equipment and detailed cleaning, sterilization and inspection instructions, which are intended for instruments without electronics.

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.

*Technical Specifications**

Approx. Size and Weight:

Adjustment Component
70.25 mm [2.76 in.] Width,
37 mm [1.45 in.] Length,
55 mm [2.17 in.] Height,
165 g [5.82 oz.] Weight

Mini Fixation Plate
58 mm [2.28 in.] Width,
18 mm [0.69 in.] Length,
25 mm [0.97 in.] Height,
46 g [1.63 oz.] Weight

ASM Fixation Plate - Extension A/B
165 mm [6.49 in.] Width,
31 mm [1.21 in.] Length,
22 mm [0.85 in.] Height,
72 g [2.54 oz.] Weight

Mini Cutting Guide
71 mm [2.79 in.] Width,
35 mm [1.37 in.] Length,
42 mm [1.65 in.] Height,
120 g [4.23 oz.] Weight (without tracker)

Material: Stainless Steel

REF 6003-300-021, REF 6003-300-031, REF 6003-300-041:
These devices contain the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0
Current scientific evidence supports the position that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

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

For Use With

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.

WARNING

Use only Stryker-approved products unless otherwise specified.

Product	For use with	
Mini Cutting Guide REF 6003-300-010 Mini Fixation Plate REF 6003-300-021 ASM Fixation Plate Extension A REF 6003-300-031 ASM Fixation Plate Extension B REF 6003-300-041	Adjustment Component	REF 6003-100-020
	Tracker Adapter	REF 6003-100-090
	Screwdriver	REF 6003-100-100
	Universal Joint Screw-driver	REF 6003-100-110
	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

Troubleshooting Guidelines

If the tracker cannot be mounted onto the Mini Cutting Guide or does not lock in position, the tracker/Tracker Adapter/Mini Cutting Guide interface may be bent or damaged. Replace and return to service.

Definition of Symbols

Symbol	Name: Definition
	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.
	General warning sign: To signify a general warning.
	Manufacturer: Indicates the medical device manufacturer as defined in the European Union harmonization legislation.
	Date of manufacture: Indicates the date when the medical medical device was manufactured.
	Consult instructions for use: Indicates the need for the use to consult the instructions for use.
CE	Indicates that a device is in conformity with the applicable requirements set out in applicable European Union harmonization legislation providing for its affixing.
	Contains hazardous substances
GTIN	Global Trade Item Number.
MD	Indicates a medical device according to European Union harmonization legislation.

Translated Equivalent: TD6003300713

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U.S. Patents: www.stryker.com/patents

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REF 6003-100-090

CE

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