

# Dedicated Mini Jig

REF 6003-100-020

REF 6003-100-090

REF 6003-100-100

REF 6003-300-010

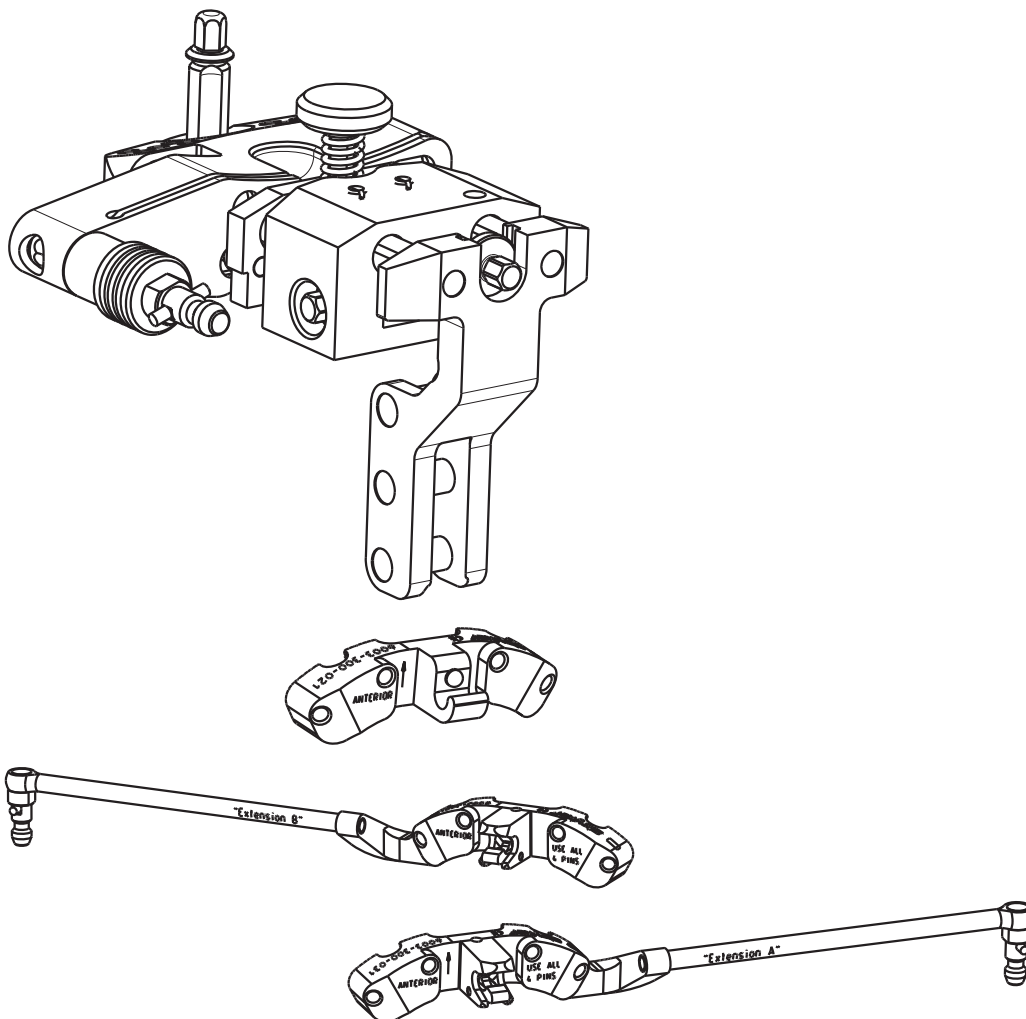
REF 6003-300-021

REF 6003-300-031

REF 6003-300-041

# stryker<sup>®</sup>

## Instructions For Use



CE

*Translated Equivalent: TD6003300713*



**Manufactured and Distributed by:**

Stryker Leibinger GmbH & Co. KG  
Bötzingen Straße 41  
79111 Freiburg, Germany  
t: +49 761 4512 0

**Distributed by:**

Stryker Navigation  
4100 East Milham Avenue  
Kalamazoo, MI 49001 USA  
t: +1 269 323 7700

**stryker**<sup>®</sup>

## 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. Only trained personnel are to use this system.
- The instruments should only be used in accordance with the instructions for use contained in this manual by authorized persons who have been fully trained in their safe and effective use. The failure to follow these instructions will void your warranty.
- 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 Navigation sales representative immediately in this case.
- The health care provider performing any procedure is responsible for determining the appropriateness of the instruments and the specific technique for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure.
- Check Mini Cutting Guide **(E)** for slot integrity before use. For inspection, insert the saw blade into the slot of the Cutting Guide. Use saw blades with 1.27 mm (0.05 in.) 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 Mini Cutting Guide. Stryker Saw Blades REF 2108180000 are validated by Stryker as suitable.
- 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 first and every use as instructed in this manual.
- DO NOT service instruments. Instruments 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.
- 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.
- To ensure the proper functioning of the Dedicated Mini Jig, follow the assembly instructions explained in this manual carefully.
- Ensure that the Tracker Adapter **(C)** is secure and 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 User/Patient Safety Warnings related to the tracking tool.
- To ensure the proper functioning of the Dedicated Mini Jig, use the appropriate fixation plate according to the knee procedure used.
- Select the best orientation of the Tracker Adapter to ensure tracker's visibility to the camera.
- Regularly verify that the tracker does not move with respect to the interface prior to surgery.
- Do not use navigation if the bone quality is too poor to enable a stable fixation of the Fixation Plate **(N)**.
- Fixate plate to bone as instructed in this manual.

## User/Patient Safety (cont.)



### WARNINGS:

- For fixation use suitable pins. Failure to comply may compromise navigation accuracy. Use 3.175 mm (1/8 in.) diameter headless pins. Permissible tolerance is  $3.175 \pm 0.0025$  mm ( $0.125 \pm 0.001$  in.). During insertion verify that the pins do not clamp or have significant play. Stryker Pins REF 7650-1038 and REF 6003-003-090 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 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.
- In case of the slightest suspicion of incompatibility or risks, the user must not use the Dedicated Mini Jig in combination with third party products like sawblades or pins.

### Intended Use of the Dedicated Mini Jig

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.

## Function and Features

The Dedicated Mini Jig is intended to be fixed onto the bone for computer-assisted alignment of the distal femoral and proximal tibial cut.

### The Dedicated Mini Jig consists of:

- Mini Cutting Guide  
REF 6003-300-010
- Mini Fixation Plate  
REF 6003-300-021
- Adjustment Component  
REF 6003-100-020
- Tracker Adapter  
REF 6003-100-090
- Universal Joint Screwdriver  
REF 6003-100-110

### For ASM Knee Navigation only:

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

## Cleaning, Sterilization, and Inspection instructions

Perform manual precleaning. We recommend the machine cleaning method.

Cleaning Group IV.

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

## Instructions

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

### 1 Assembly and Preparation

The Dedicated Mini Jig is modular and can be used for both femur and tibia cuts.

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

- Press the release button (B) and insert the Adjustment Component locking bracket (H) into the entry slot of the Mini Cutting Guide (E) as shown on the images below. Take care that the Mini Cutting Guide locks in position.
- The Adjustment Component (A) can be mounted from two directions to the Mini Cutting Guide (E). Select the direction where the tracker is mounted on the medial side of the knee.

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

- Insert the Tracker Adapter (C) into the Tracker Adapter interface (D). Adapter must engage and rotate in discrete steps.
- Mount the tracker to the 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 designed for conventional 3.175 mm diameter headless pins.
- For ASM Knee Navigation only, 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 applicable fixation plate (N) (refer to the images below).
- Align the tracker to the camera by rotating the adapter on the cutting guide.

### 3 Cut Alignment

#### 3.1. Adjust the varus/valgus angle

Rotate the adjustment screw (M).

#### 3.2. Adjust the resection level

Rotate the adjustment screw (L).

#### 3.3. Adjust the flexion/extension angle

Rotate the adjustment screw (K).

### 4 Cutting Guide Fixation

- 4.1. Insert a minimum of two 3.175 mm diameter headless pins into the Mini Cutting Guide pin holes (F) and fixate the Mini Cutting Guide (E).
- 4.2. Insert a minimum of one 3.175 mm diameter headless pin into the cannulated wheel (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 take care to remove the adjustment component (A) gently from the Mini Cutting Guide (E).
- 5.3. Proceed to cutting.

## Troubleshooting Guidelines

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

## 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

**Cleaning Group IV**

## Symbol Definition

Symbol	Definition
	Precautionary information
	Manufacturer
	Essential Requirements of Medical Device Directive 93/42/EEC.

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

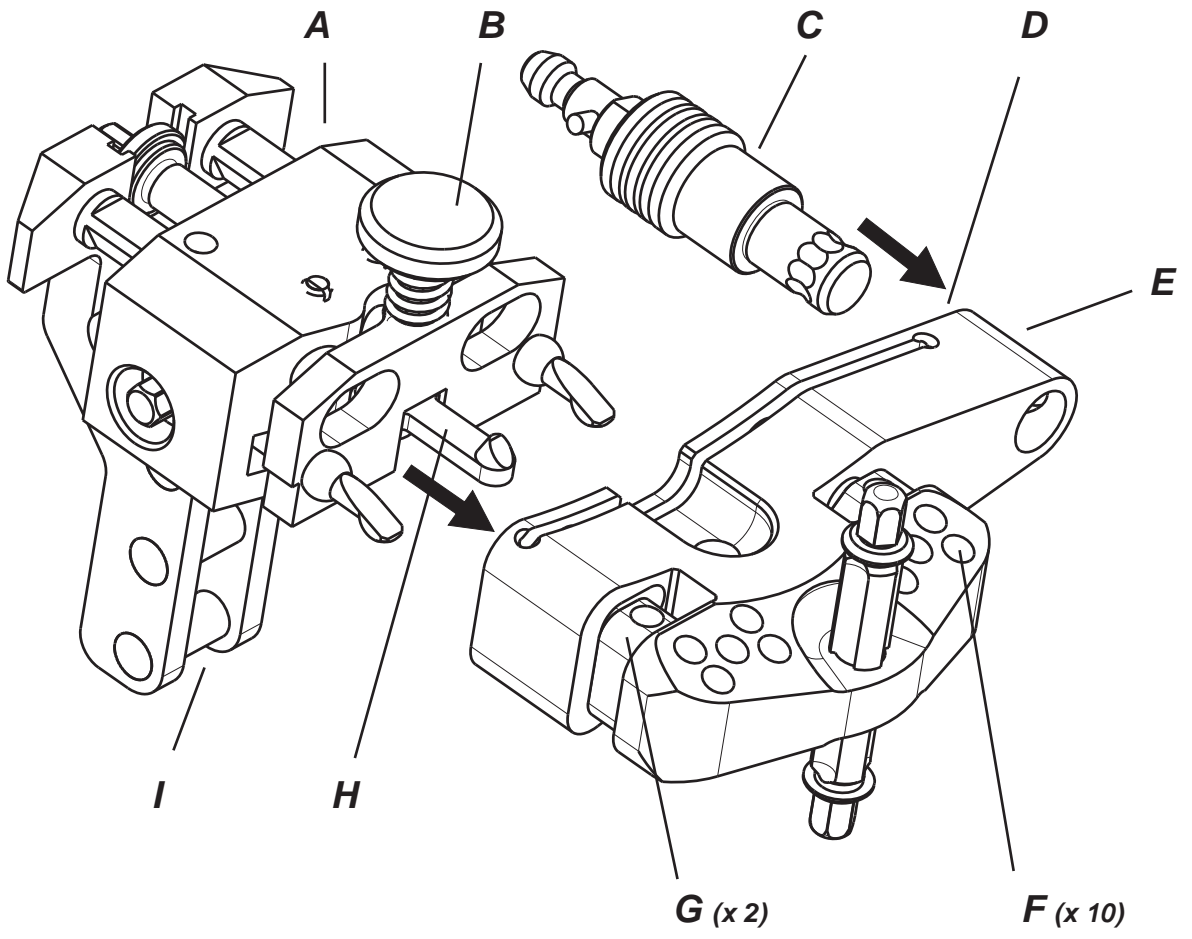


Figure 1

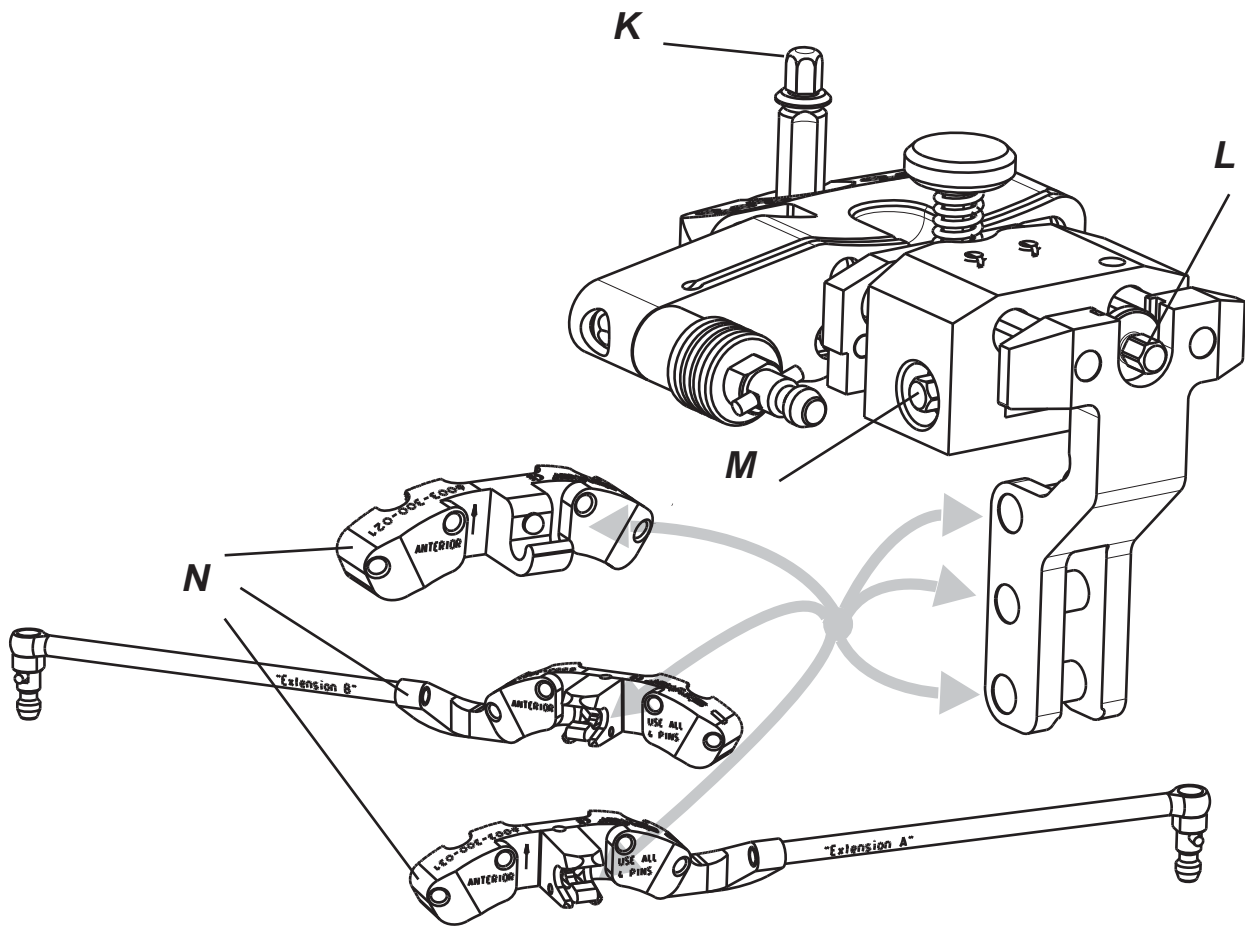


Figure 2