Axis Guide
REF 6007-300-000

Axis Guide, Small
REF 6007-310-000

stryker

Instructions for Use

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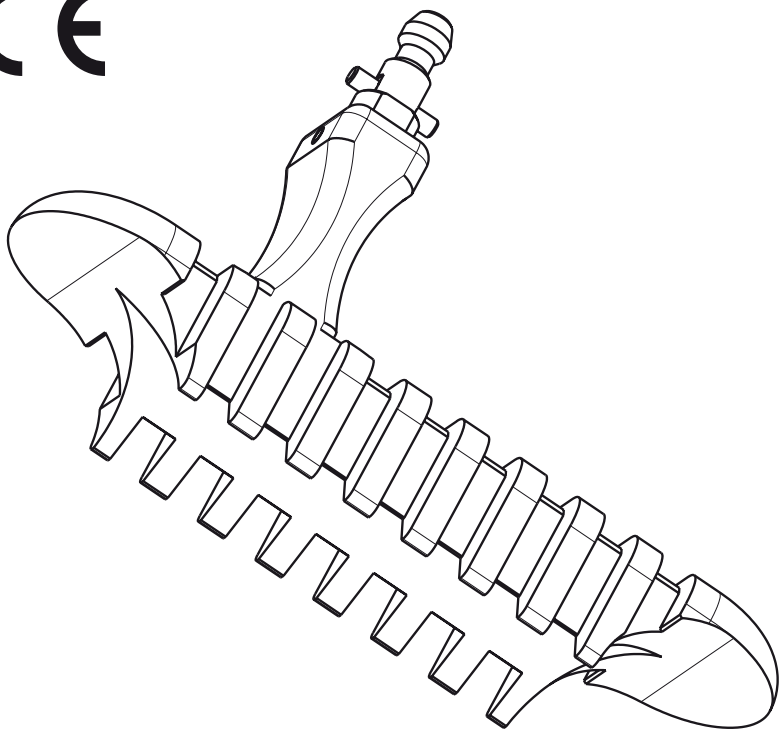

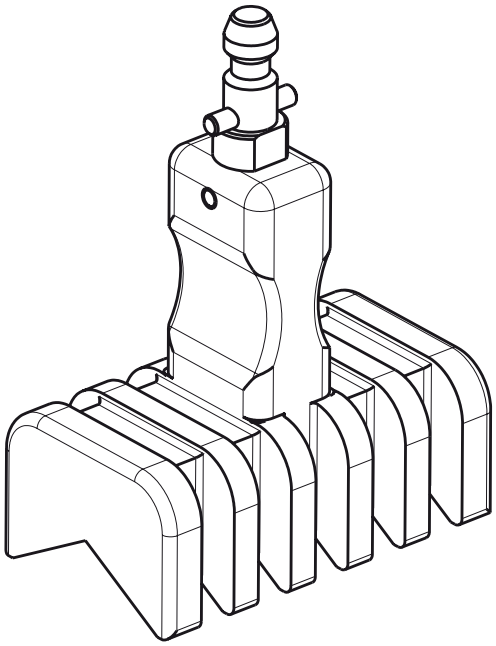

Intended Use of the Axis Guide / Axis Guide, Small

The Axis Guides are intended to be used with the Stryker Navigation Systems Hip Resurfacing Module, Hip Navigation Module to track the orientation of a conventional instrument axis.

The Axis Guides are intended to be used with the patient trackers used by the Hip Resurfacing and Hip Modules. (Femur Tracker, Pelvis Tracker, Knee Femur Tracker, Knee Tibia Tracker and Knee Universal Tracker are further referenced as Patient Tracker.)

The Axis Guide is intended to be used with any conventional instrument that has a round, rigid, linear shaft of at least 50 mm length and a diameter between 5 and 30 mm.

The Axis Guide, Small is intended to be used with any conventional instrument that has a round, rigid, linear shaft of at least 40mm length and a diameter between 15 and 60 mm.

Both Axis Guides may only be used with an instrument whose shaft is aligned with the transpolar orientation of the cup or reamer.

*Translated Equivalent: TD600731071*3

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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. Familiarization with the Stryker navigation system prior to use is important.
- Prior to each use, the Axis Guides should be inspected for loose components and damage. Do not use if these conditions exist. If service is required, contact your Stryker Navigation sales representative.
- Prior to surgery, the axis guides should be checked with the navigation system to ensure they are functioning properly.
- Clean and sterilize instruments before first and every use.
- Prior to and during the surgical procedure, regularly verify that the Patient Tracker is firmly attached to the Axis Guide / Axis Guide Small. If the tracker moves relative to the Axis Guide / Axis Guide Small, navigation is inaccurate.
- 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 instruments other than those specified in these instructions or outside of their intended use may compromise navigation accuracy.
- Do not service instruments. They contain no parts the user can service. If service is required, contact your Stryker Navigation sales representative.
- Prior to use, carefully verify that the axis guides and the instrument intended for navigation can be combined safely and without loss of functionality. For verification purposes, refer to the technical specifications in this document.
- In case of the slightest suspicion of incompatibility or risks, the applicant must not adapt/combine the product(s).
- If the product does not possess the stated properties, the instrument must not be used with the axis guides.
- Use the Axis Guide only with round instruments with a diameter between 5 and 30 mm.
  Use the Axis Guide, Small only with round instruments with a diameter between 15 and 60 mm.
  If the diameter is too small or too large, the instrument is not suitable for navigation.
- Use the axis guides only with an instrument having a shaft aligned with the transpolar orientation of the cup / reamer.
- During the entire application, ensure that the Axis Guide / Axis Guide, Small is aligned with the shaft of the instrument. Hold the Axis Guide / Axis Guide,

Small firmly against the shaft of the instrument. Misalignement leads to navigation inaccuracy.

- Use this manual and the instructions for use supplied with the Patient Tracker for further warning or caution notes.
- System accuracy decreases if surgical instruments not suitable for navigation (e.g., with flexible or soft shaft, bending parts) are used. Further, do not adapt your instrument if you are not sure that your instrument can be properly adapted for navigation.
- Use axis guides without damaging or limiting the functionality, safety, effectiveness, or intended use of the instrument. Do not use instruments which have deviating measures.
- Stryker Navigation tested only regulatorily cleared and approved instruments. Instruments that you adapt to the axis guides shall be regulatorily cleared and approved.

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.

Function and Features

The axis guides are used to firmly attach a Patient Tracker onto a generic instrument which meets the navigation requirements. The requirements are described in this manual. Refer to the chapter Intended Use of the Axis Guide / Axis Guide, Small.

The Patient Tracker is a Stryker navigation tool to enable navigation during surgery.

Instructions

1 Attach, Optically Align and Lock Patient Tracker onto Interface

1.1 Insert the Patient Tracker into Interface Pin (***A***). *See figure 1*.

1.2 Orient the Patient Tracker. The Patient Tracker's LEDs must be visible to the camera.

1.3 Lock the Patient Tracker. The Patient Tracker must not move during surgery.

WARNING

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

2 Mount Axis Guide / Axis Guide, Small onto Instrument

2.1 Align the Axis Guide / Axis Guide, Small Instrument Interface (***B***) (see *figure 1*) with the instrument shaft.

2.2 Hold the Axis Guide / Axis Guide, Small firmly against a straight part of the shaft.

WARNING

Make sure the Patient Tracker is aligned with the instrument shaft during navigation. Check the alignment. Failure to comply may compromise the navigation accuracy.

Cleaning, Disinfection, Sterilization and Inspection Instructions

Cleaning Group I.

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.

Troubleshooting Guidelines

The Patient Tracker cannot be mounted onto the Interface Pin and locked in position:
Replace and return for service as the interface between Patient Tracker and Axis Guide / Axis Guide, Small might be bent or damaged.

*Specifications***

Size: 54.7 mm [2.15 in.] height
24 mm [0.94 in.] width
40 mm [1.57 in.] length (Axis Guide, Small)
90 mm [3.54 in.] length (Axis Guide)

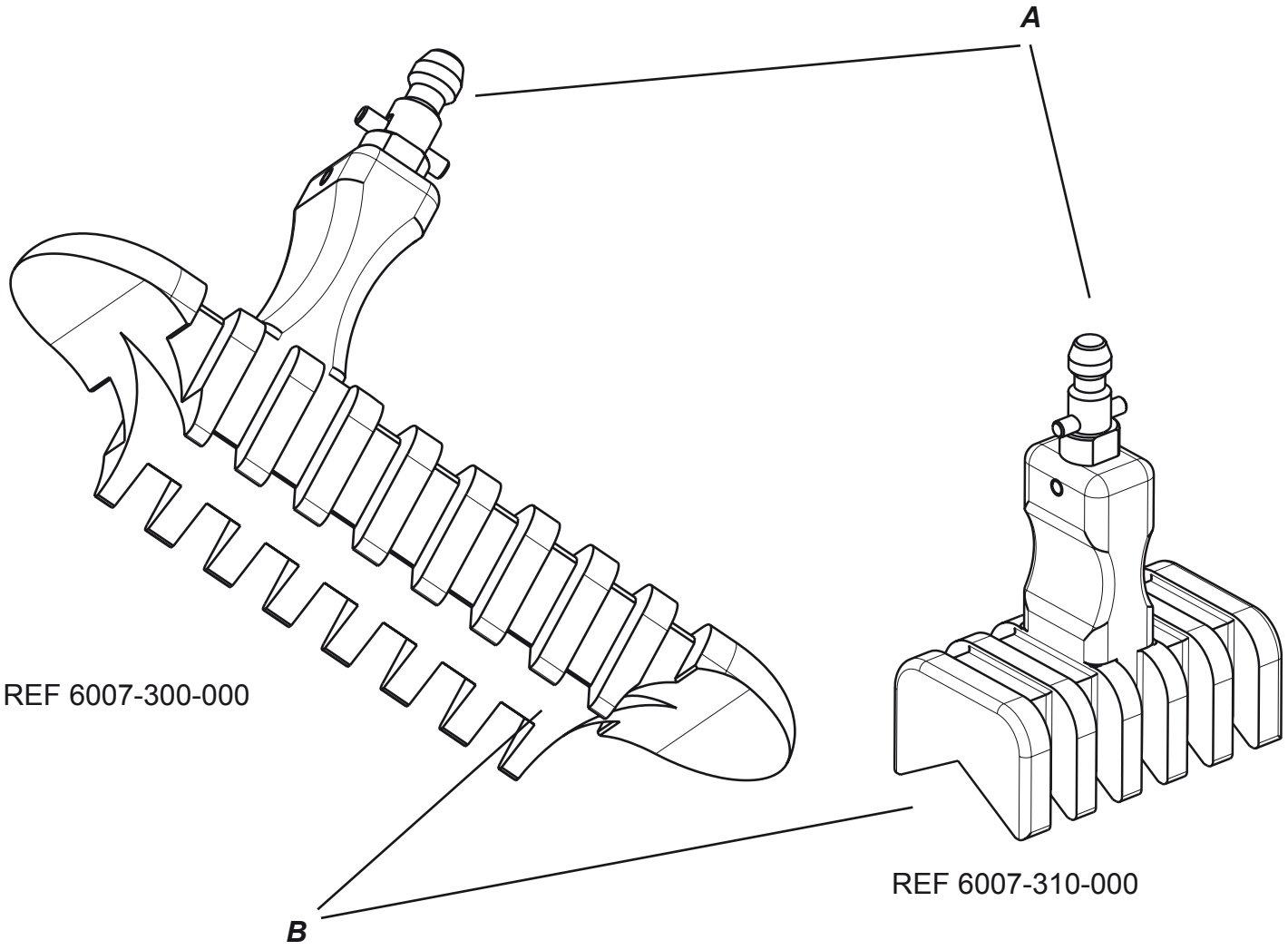
Weight without tracker:
120 g [4.23 oz.] (Axis Guide)
70 g [2.47 oz.] (Axis Guide, Small)

Material: Stainless steel

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

Symbol Definition

Symbol	Name: Definition
	**Safety alert symbol:** Alerts the user to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury or death.
	**Manufacturer:** Indicates the medical device manufacturer as defined in the European Union harmonization legislation.
	Indicates that a device is in conformity with the applicable requirements set out in applicable European Union harmonization legislation providing for its affixing.
	**Medical device:** Indicates a medical device according to European Union harmonization legislation.



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