

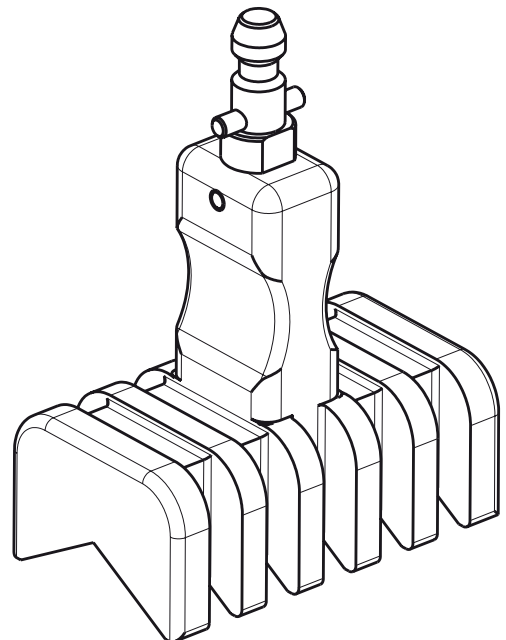
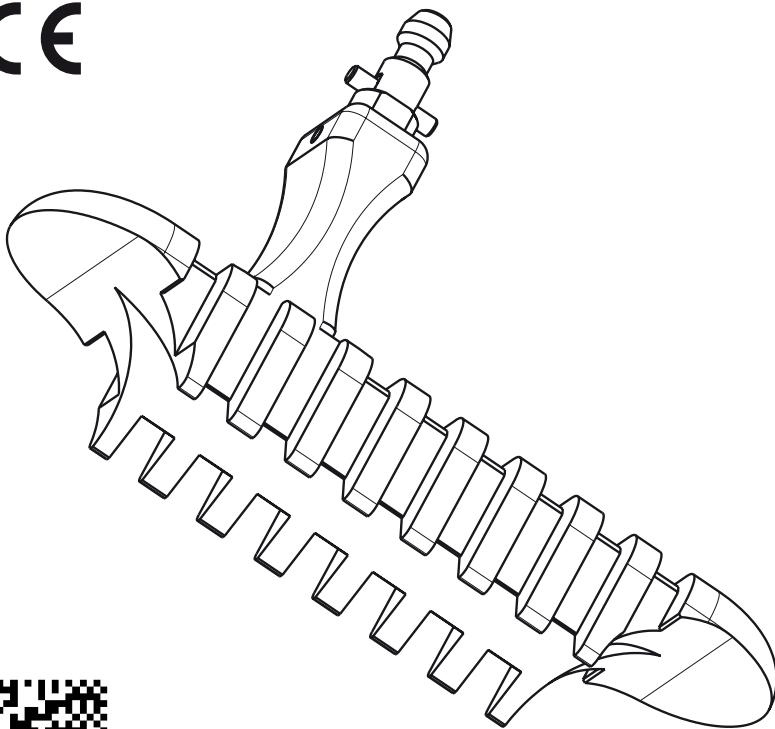
Axis Guide
REF 6007-300-000

Axis Guide, Small
REF 6007-310-000

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Instructions for Use

CE



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.

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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.
- 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 immediately.
- 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.
- 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 third party 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. Misalignment 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.

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.

Handling and Storage

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

Cleaning and Sterilization

Refer to the Guide for Cleaning and Steam-Based Sterilization (TD6000005750).

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

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.

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

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.

Symbol Definition

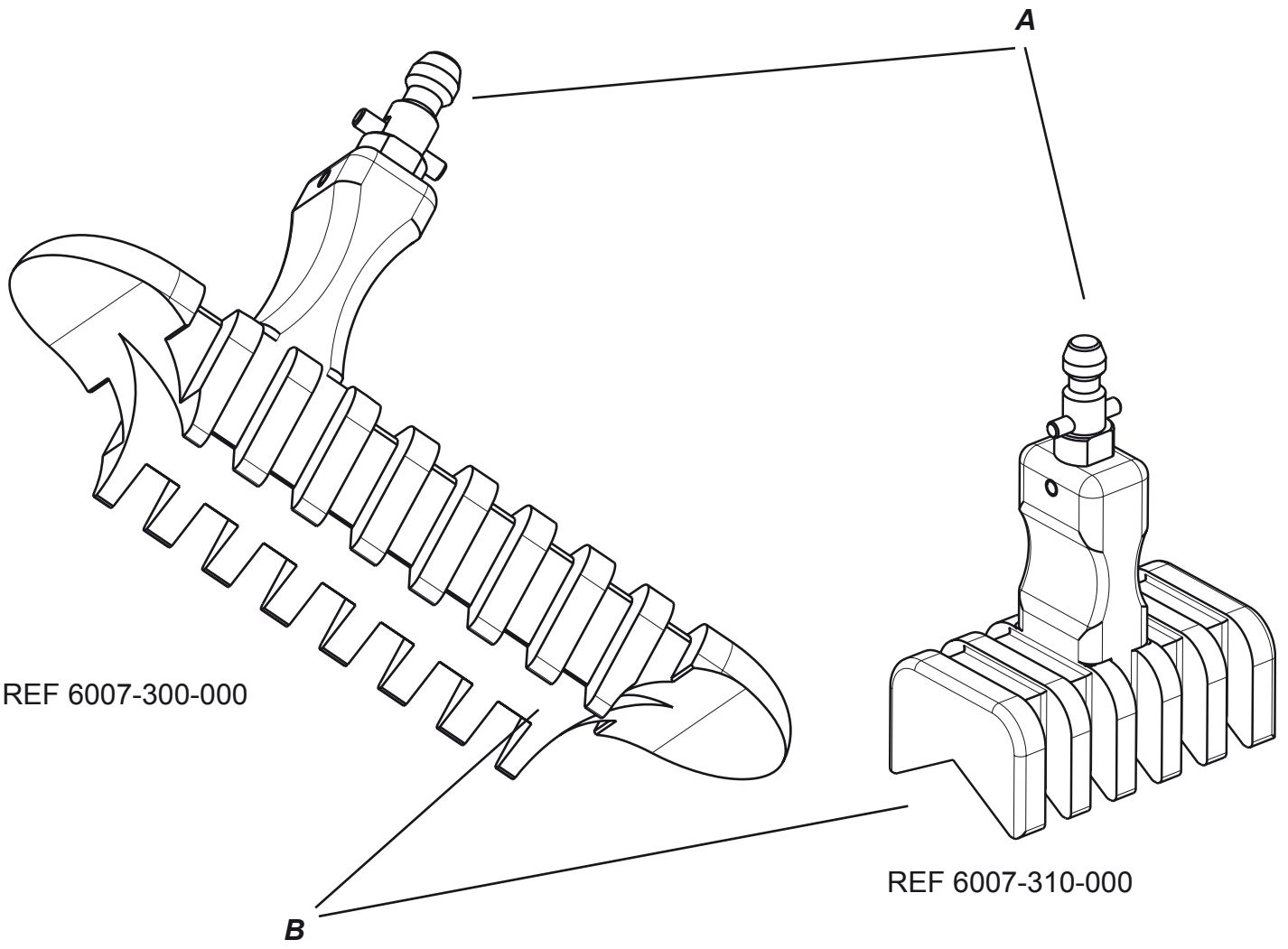


General warning sign

CE conformity: Essential Requirements of Medical Device Directive 93/42/EEC



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