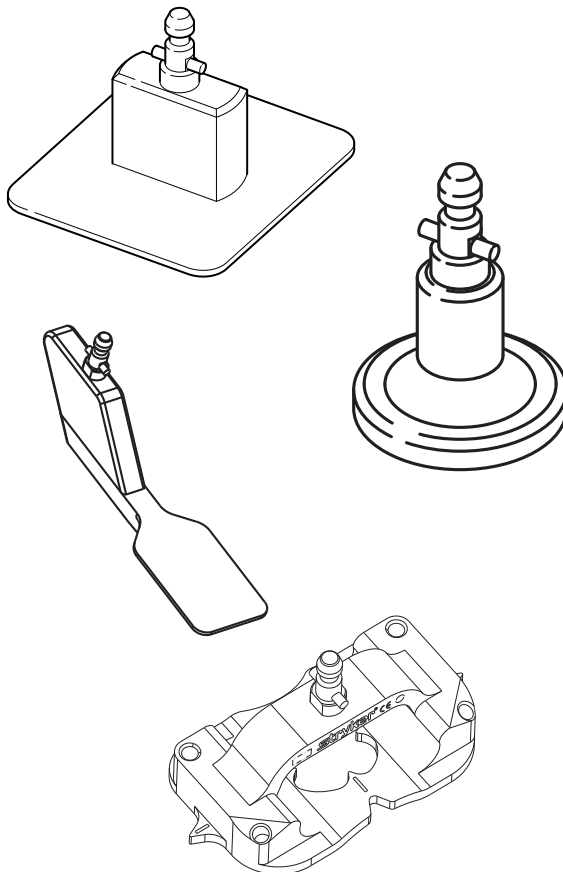


Plane Probes

stryker®

Instructions For Use

CE



Resection Plane Probe

- Slots 0.9 mm REF 6003-029-000
- Slots 1.0 mm REF 6003-050-000
- Slots 1.1 mm REF 6003-051-000
- Slots 1.2 mm REF 6003-052-000
- Slots 1.3 mm REF 6003-027-000
- Slots 1.4 mm REF 6003-054-000
- Slots 1.5 mm REF 6003-055-000

-Round REF 6003-028-000


Posterior Plane Probe

REF 6003-070-000

ASM Plane Probe

REF 6003-080-001

Translated Equivalent: TD6003027713

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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, damage or malfunction. Do not use if any of 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.
- Performing procedures with instruments other than those specified in these instructions or outside of their intended use compromises navigation accuracy.
- Clean and sterilize instruments before first and every use.
- Do not service instruments. Instruments do not contain parts that a user can service. Contact your Stryker Navigation sales representative in this case.
- For navigation, use only the Tibial/Pelvic Tracker REF 6003-005-000, the Femoral Tracker REF 6003-010-000 or the Universal Tracker REF 6000-005-000. Refer to the *Tibial/Pelvic Tracker and Femoral Tracker Instructions for Use* and the *Universal Tracker Instructions for Use* for specific User/Patient Safety Warnings related to the tracking tool.
- For navigation, never use cutting blocks whose slots are smaller than 0.9 mm or exceed 1.5 mm.
- During the procedure the Resection Plane Probe - Slots must not clamp or have a significant play. For this reason, select the appropriate probe from the kit according to the slot size of the cutting block (marked on the probe's plate prior to surgery).
- After selection, leave aside the probes which are not suitable for the prosthesis used.
- The ASM/Posterior Plane Probe is not intended to be used for the navigation of cutting blocks or AP sizers.
- Carefully align the ASM Plane Probe onto the distal femoral cut in order to avoid overlapping of the pin holes, which are created by the plane probe, and those, which are created by the AP sizer. Confusing the pin holes may lead to prosthesis misalignment.
- Ensure that the tracker mounted to the Plane Probe is firmly locked in position to prevent tracker movement during surgery. Failure to comply may compromise navigation accuracy.
- Ensure that the LEDs of the tracker attached to the Plane Probe are clearly visible to the camera and that the tracker is placed within the system's working space.
- Plane Probes must be flush with the flat surface of the measured plane to ensure navigation accuracy.

Intended Use of the Resection Plane Probes

The Resection Plane Probes - Slots and - Round are intended for cutting block navigation in both frontal and lateral views. The Resection Plane Probe - Slots is designed to be aligned with the slot of the femoral and tibial cutting blocks. The Resection Plane Probe - Round is intended to be aligned with the open plane of the cutting block.

The Resection Plane Probes - Slots and - Round are also intended to verify the femoral/tibial cut accuracy and correct the bone cut orientation required to seat and optimally align the prosthesis.

Moreover, the Resection Plane Probes - Slots and - Round ensure alignment of conventional AP sizers and Tibial Alignment Handle for rotation navigation in the axial view. After AP sizing and template positioning, the Resection Plane Probes - Slots and - Round enable rotation verification.

Intended Use of the Posterior Plane Probes

The Posterior Plane Probe is intended to record the posterior femoral cut and to verify rotation.

Intended Use of the ASM Plane Probe

The Articular Surface Mounted (ASM) Plane Probe is intended to be used in ASM Knee Navigation only to verify the femoral/tibial cut accuracy and orientation.

Cleaning, Sterilization, and Inspection instructions

Cleaning Group I.

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

Perform the following steps and refer to Figure 1.

1 General

- Mount the tracker to the Plane Probe while pressing the Release Button **(1)**.
- Ensure that the tracker is properly locked **(2)**.
- Press the Release Button to remove the tracker.

Note for Resection/Posterior Plane Probes:

If the femur is being tracked for treatment, mount the Pelvic/Tibial Tracker or the Universal Tracker to the Plane Probe. If the tibia is being treated, mount the Femoral Tracker or the Universal Tracker to the Plane Probe. The tracker can also be mounted in the 180° rotated position.

Note for ASM Plane Probes:

If the femur is being tracked for treatment, mount the Femoral Tracker to the Plane Probe. If the tibia is being treated, mount the Pelvic/Tibial Tracker to the Plane Probe.

2 Distal Femur/Proximal Tibia

- Place the cutting block in the surgical area and adjust its position as instructed in the manual supplied with the device.
- In case of a conventional cutting block, position the Resection Plane Probe - Slots or - Round on the cutting block or, alternatively, insert the probe into the slot of the cutting block for cutting block navigation. If a navigated cutting block is used, follow the respective instructions.
- Adjust the varus/valgus, proximal/distal and flexion/extension alignment of the cutting block as needed.
- Fixate the cutting block firmly in position to prevent cutting block movements during cutting.



WARNING:

Make sure that the cutting block is locked in position before proceeding to bone resection.

- Make the cut on the surface of the open cutting block or, alternatively, through the slot using an adequate sized saw blade.
- Align one of the Resection Plane Probes with the resected bone to verify cut accuracy.



WARNING:

In ASM Knee Navigation use the ASM Plane Probe REF 6003-080-001 only.

- If cut accuracy is not satisfactory and the Resection Plane Probe is used, reposition the cutting block to recut as needed.

3 Femoral Rotation Navigation

- If a conventional AP sizer is used, align the tracked Resection Plane Probe - Slots or - Round with the AP sizer to navigate femoral prosthesis rotation. If a navigated AP sizer is used, follow the respective instructions.
- Cut the bone as instructed.
- Place the Resection Plane Probe - Slots or - Round on the femur anterior cut to verify rotational alignment accuracy.

4 Posterior Femur Cut

- To record the posterior femur cut for gap monitoring or to verify the rotational alignment accuracy, use the Posterior Plane Probe.

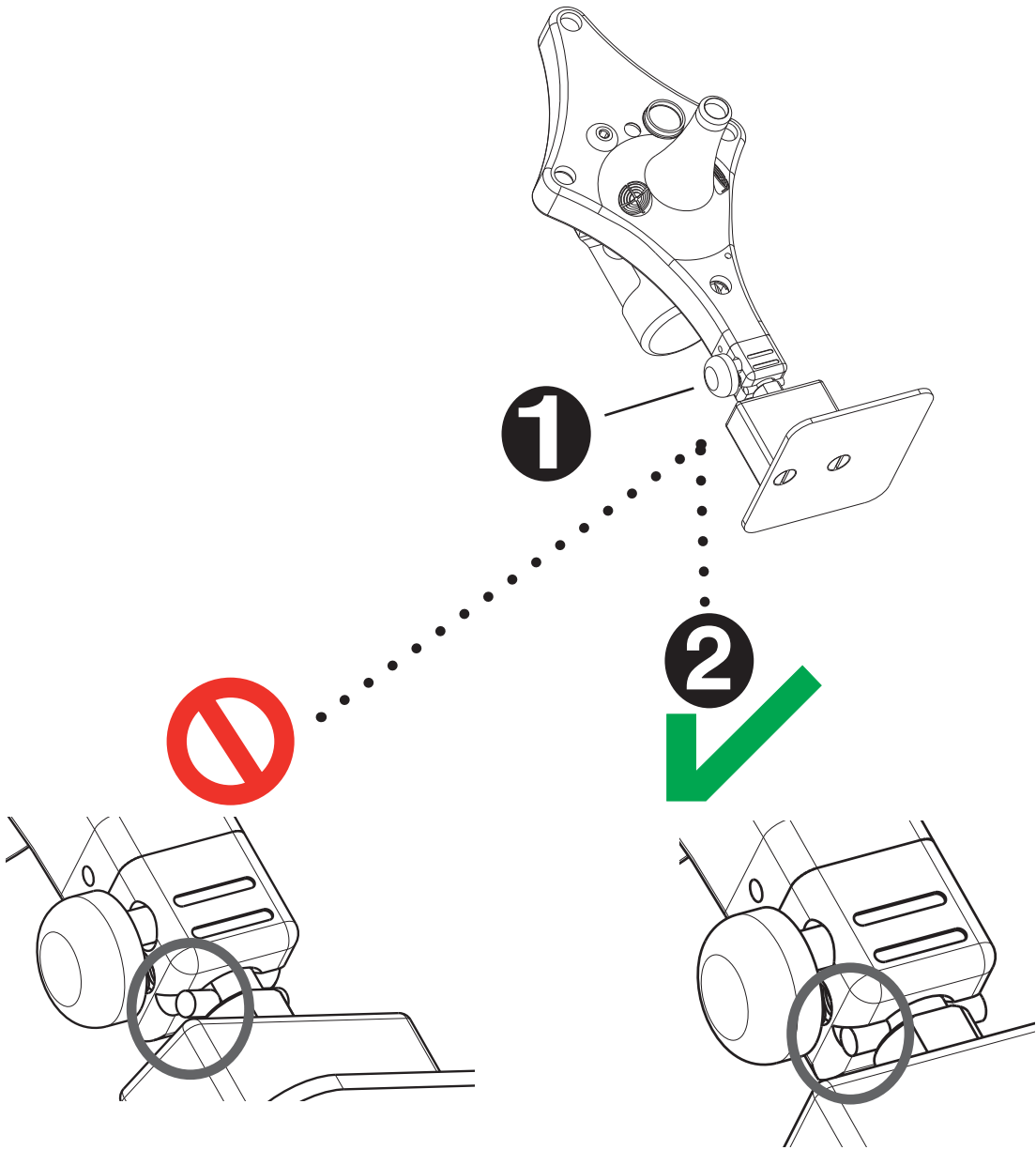


Figure 1

Troubleshooting Guidelines

Tracker cannot be mounted to probe and locked.

Tracker/probe interface is bent. Replace and return to service.

Resection Plane Probe - Slots not aligned with cutting block or does not fit into slot.

Cutting block is damaged or probe is bent/damaged. Replace and return to service.

Specifications*

Models are all in stainless steel:

REF 6003-028-000 Resection Plane Probe - Round

REF 6003-029-000 Resection Plane Probe - Slots 0.9 mm

REF 6003-050-000 Resection Plane Probe - Slots 1.0 mm

REF 6003-051-000 Resection Plane Probe - Slots 1.1 mm

REF 6003-052-000 Resection Plane Probe - Slots 1.2 mm

REF 6003-027-000 Resection Plane Probe - Slots 1.3 mm

REF 6003-054-000 Resection Plane Probe - Slots 1.4 mm

REF 6003-055-000 Resection Plane Probe - Slots 1.5 mm

REF 6003-070-000 Posterior Plane Probe

REF 6003-080-001 ASM Plane Probe

Approx. Size and Weight:

Resection Plane Probe - Slots: 40 mm [1.57 in.] Width, 45 mm [1.77 in.] Length, 58 g [0.12 lb.]

Blade Thickness:

1.01 mm [0.039 in.] (Slots 0.9 mm)

1.09 mm [0.042 in.] (Slots 1.0 mm)

1.19 mm [0.046 in.] (Slots 1.1 mm)

1.29 mm [0.050 in.] (Slots 1.2 mm)

1.37 mm [0.053 in.] (Slots 1.3 mm)

1.49 mm [0.058 in.] (Slots 1.4 mm)

1.59 mm [0.062 in.] (Slots 1.5 mm)

Resection Plane Probe - Round: 25 mm [0.98 in.] Diameter, 35 mm [1.37 in.] Length, 28 g [0.98 oz.]




Posterior Plane Probe: 41.1 mm [1.62 in.] Height, 25 mm [0.98 in.] Width, 105 mm [4.13 in.] Length, 80 g [2.82 oz.]

ASM Plane Probe: 35 mm [1.38 in.] Height, 36 mm [1.42 in.] Width, 66 mm [2.6 in.] Length, 93 g [3.28 oz.]

Cleaning Group: 1

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

Symbol Definition

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