

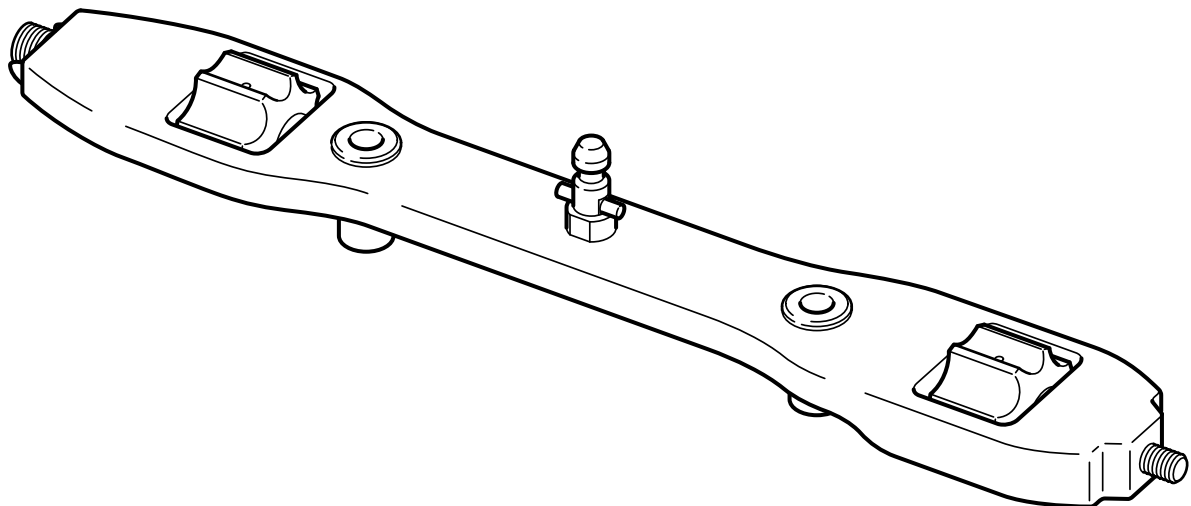
IMPORTANT INFORMATION: File in your records

**stryker**<sup>®</sup>

Instructions For Use

## Pivotal<sup>®</sup> Alignment Handle

REF 6003-175-000



CE

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



## Important Information

### WARNING - NOTE

Please read this manual and follow its instructions carefully. The words **WARNING** and **NOTE** carry special meanings and should be carefully reviewed.

**WARNING:** The personal safety of the patient and user may be involved. Disregarding this information could result in injury to the patient and/or user.

**NOTE:** This provides special information to make maintenance easier or important instructions clearer.



An exclamation point within a triangle displayed on the product is intended to alert the user to the presence of important operating and maintenance instructions in this manual.

## User/Patient Safety

### Regard these 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, 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.
- 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.
- Refer to the *Pelvic/Tibial Tracker and Femoral Tracker Instructions For Use* for specific User/Patient Safety Warnings related to the tracking tool.

## Intended Use of the Navigation System - Knee Module

The Stryker Navigation System is intended as a patient-specific intraoperative guidance system to enable software guided surgery for Total Knee Arthroplasty. The system enables accurate determination of the leg mechanical axis for component positioning and exact alignment of knee implants without requiring medical imaging modalities. Moreover, the Stryker Navigation System - Knee Module enables the reporting of preoperative, intraoperative and postoperative assessments of the patient's joint kinematic measurements.

## Intended Use of the Pivotal® Alignment Handle

The Pivotal® Alignment Handle is a component of the Stryker Navigation System - Knee Module. The Pivotal® Alignment Handle is to be used in conjunction with the Pelvic/Tibial (6003-5) and Femoral (6003-10) Tracker, standard Stryker Howmedica-Osteonics surgical instruments and Stryker Navigation System - Knee Module.

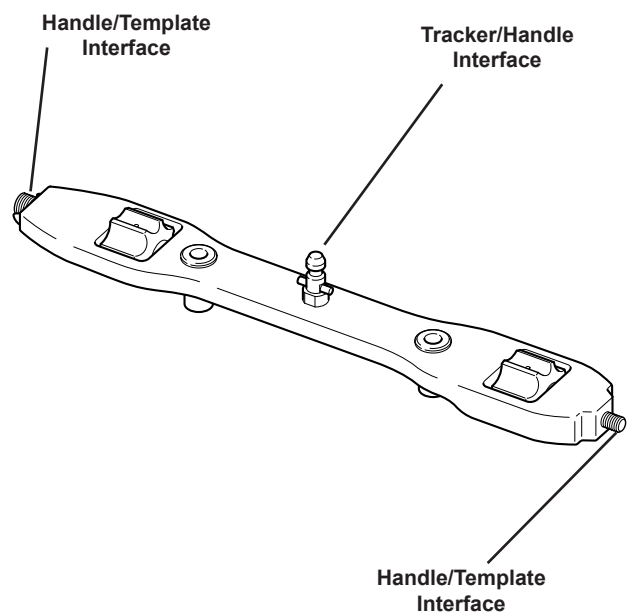


Figure 1: Pivotal® Alignment Handle

## Function and Features

The Pivotal® Alignment Handle is intended to be used in conjunction with Duracon®, Scorpio®, Kinemax® and Interax® prosthesis families for implantation of the tibial component.

The Pivotal® Alignment Handle is intended to be mounted to the Femoral Tracker REF 6003-10 and tibial template. The Knee Module software allows the user to navigate templates for optimal rotation accuracy required to seat and optimally align the prosthesis.

## Instructions

### 1 Clean and Sterilize

- Clean and sterilize the instruments before first and every use (*refer to cleaning and sterilization recommendations*).

### 2 Prepare Surgical Area

- Prepare the surgical area for placement of the Pivotal® Alignment Handle. The Pivotal® Alignment Handle is intended to be placed within the surgical area.

*Refer to the Stryker Knee Navigation System manual for more detailed instructions.*

### 3 Mount to Femoral Tracker

- Mount the sterilized tracker to the Alignment Handle (*see figures 1-2*).

#### Note:

The tracker can also be mounted in 180° rotated position.

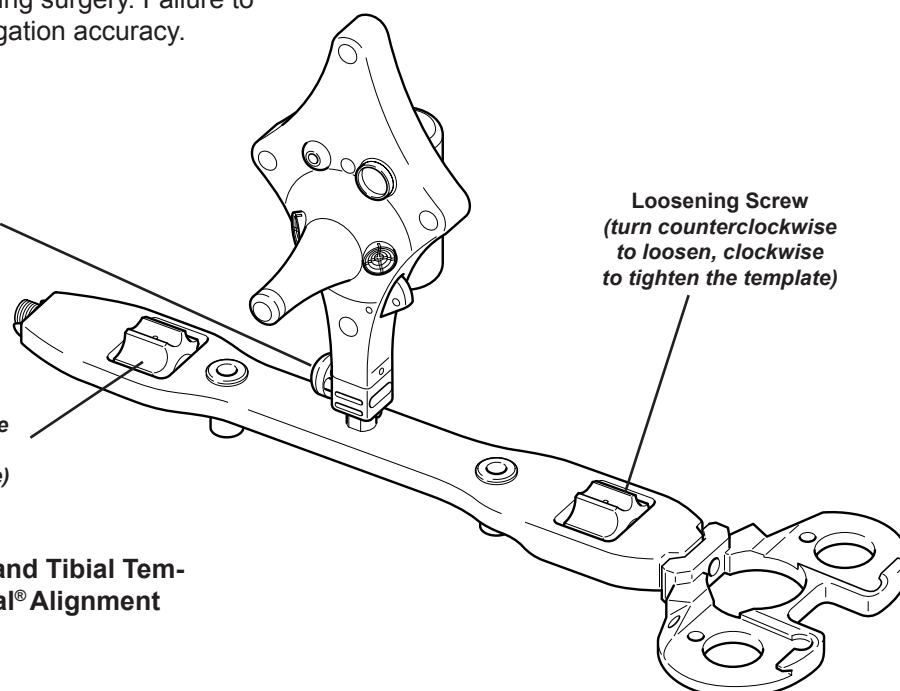


#### WARNING:

Ensure that the tracker mounted to the Pivotal® Alignment Handle is firmly locked in position to prevent tracker movement during surgery. Failure to comply may compromise navigation accuracy.

RELEASE Button  
(Press to release or lock the tracker in position)

Loosening Screw  
(turn counterclockwise to loosen, clockwise to tighten the template)



**Figure 2: Femoral Tracker and Tibial Template mounted to the Pivotal® Alignment Handle**

## Instructions (cont'd)

### 4 Mount the Tibial Template

- Correctly align the template with the Handle.



#### WARNING:

Mount the template with the top side directed to the Tracker/Alignment Handle Interface.

- Once properly aligned, attach the tibial template to the Pivotal® Alignment Handle.

*See figures 1-2.*



#### WARNING:

Ensure that the tibial template attached to the Pivotal® Alignment Handle is firmly tightened in position. Failure to comply may compromise navigation accuracy.

### 5 Tibia Rotation Navigation

- Using the Pivotal® Alignment Handle position the template on the resected tibial plateau as instructed in the manual supplied with the device.
- Use the Pivotal® Alignment Handle to orient the template as needed and assess optimal rotation.

#### Note:

The Tibia Rotation Navigation mode enables accurate internal/external rotation assessment in relationship to the tibial A/P axis. Valgus/varus and slope variations due to rotation adjustment are reported in axial view.

*Refer to the Stryker Knee Navigation System manual for more detailed instructions.*

## ***Instructions (cont'd)***

### **6 Tibia Rotation Verification**

- Once satisfactory template alignment is achieved, fixate the template to the bone as recommended.
- Complete tibial preparation.
- After impacting the punch, verify tibia rotation using the Pivotal® Alignment Handle.
- Once the template alignment is satisfactory, proceed to tibial component implantation.

## ***Cleaning recommendations***

1. Remove the tracker from the Pivotal® Alignment Handle.
2. Place the Handle into the cleaning machine.
3. Sterilize as recommended.

## ***Sterilization Recommendations***

### **Flash Autoclave:**

- Gravity displacement sterilizer
- 270-272°F (132-134°C)
- Unwrapped in an instrument tray
- 10-minute minimum exposure time

### **Hi Vac:**

- Pre-vacuumed sterilizer
- 270-272°F (132-134°C)
- Wrapped or unwrapped
- 4-minute minimum exposure time
- 8-minute minimum dry time

### **ETO:**

- 100% ETO
- 120-135°F (49-57°C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 2-hour 30-minute exposure time
- 8-hour minimum aeration time

### **250°F Gravity:**

- Gravity displacement sterilizer
- 250-254°F (121-123°C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 45-minute exposure time
- 8-minute minimum drying time

### **270°F Gravity:**

- Gravity displacement sterilizer
- 270-272°F (132-134°C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 35-minute minimum exposure time
- 8-minute minimum dry time

Sterilization Recommendations  
Validation based on AAMI protocol

## Troubleshooting Guidelines

<b>PROBLEM</b>	<b>CAUSE</b>	<b>ACTION</b>
The Femoral Tracker cannot be mounted to the Pivotal® Alignment Handle and locked in position. See figure 3.	The Tracker/Alignment Handle interface is bent or damaged.	Replace and return to service.

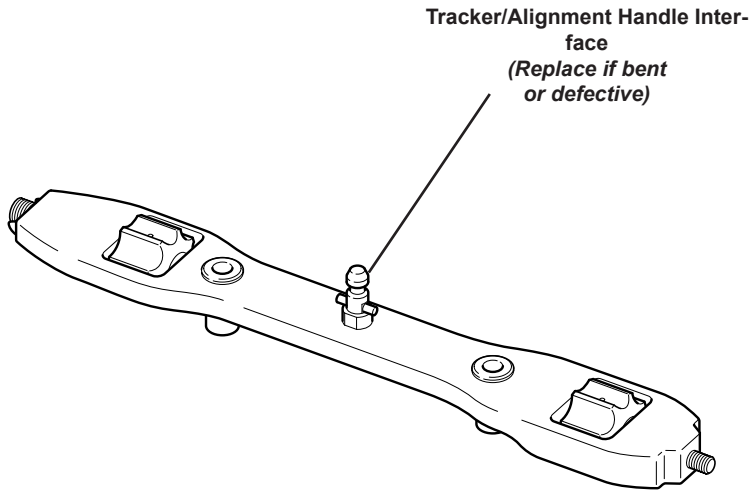


Figure 3: Tracker/Alignment Handle Interface

## ***Specifications\****

**Model:** REF 6003-175-000 Pivotal® Alignment Handle

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**Approx. Size:** 190 mm [7,48 in] Length

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**Approx. Weight:** 58 g [0.128 lb.]

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

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