OrthoMap® Precision Knee Navigation

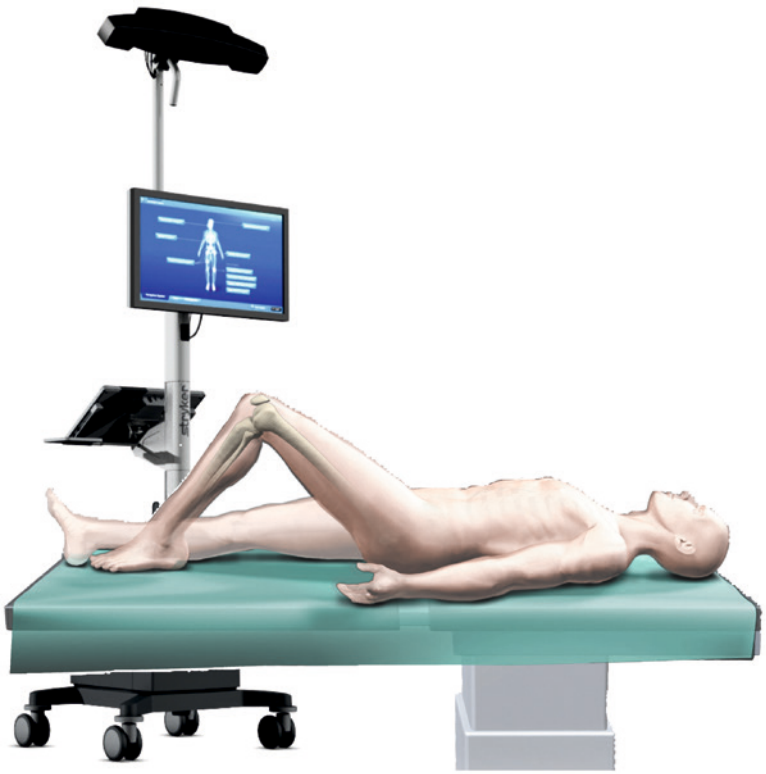
Version 5.0

REF 6003-655-000

stryker®

Safety Information

CE 0197



This booklet provides general instructions and safety information on the use of the Stryker Navigation System for navigated knee arthroplasty. Only operators who have received special training should use this system. Carefully read this manual with the online user instructions. Keep all user manuals where they are easily accessible for the Stryker Navigation System operators. If you have questions, contact your Stryker Navigation sales representative.

Indications for Use

The Stryker OrthoMap Precision Knee system, which is comprised of the OrthoMap Precision Knee 5.0 Software and a platform of the NAV3i platform family, is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery.
The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.
The system is indicated for conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

Contraindications

The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not. A pathological condition against the use of this system could be in some cases advanced osteoporosis or a dysplastic hip.

General

- The system must be used within the operating room and should be operated only by trained personnel such as orthopedic surgeons and clinic staff.
- It is the surgeon's responsibility to plan and perform surgery according to established medical standards. Stryker, as a manufacturer, DOES NOT recommend surgical procedures.
- Do not install any additional software on the system or modify Microsoft Windows settings. Any changes to the system might lead to altered software functionality (e.g. screen saver could appear unexpectedly during surgery). If necessary, call your Stryker Navigation System specialist.
- Do not manipulate patient data files at the operating system level. File manipulation might lead to inconsistencies and thus to an improper functioning of the software. If necessary, call your Stryker Navigation System specialist.
- Do not edit setup files. Do not manipulate system setting files. System operation may be changed causing improper functioning and patient injury. If necessary, call your Stryker Navigation System specialist.
- Do not reuse single use instruments. Multiple use can lead to product malfunction and/or tissue damage. *Refer to the Instructions for Use supplied with the devices.*
- In case the Navigation System is rendered useless, the operation can be continued using conventional instruments for knee surgery at any time.

User Settings

- Enable femoral and tibial verification point check. Check is recommended to detect movements of the tracker. Failure to comply compromises navigation accuracy.
- Use only integrated implant families as selected in the Implant Planning dialog.

Instrument Preparation

- Ensure that sterile replacement tools are available. If a tool becomes useless during operation or a pointer fails validation (*see paragraph "Tool Validation"*), the pointer/tool must be replaced for surgery. When no replacement tools are available, navigation is not possible.
- Ensure that all batteries are properly installed. In case of incorrect installation, the green status light will not illuminate and the instrument will not function. *Refer to the Instructions for Use supplied with the instruments.*
- Ensure that navigated instruments are visible to the system. If an instrument is not visible after initialization, the software displays this instrument status with a red icon. Align the instrument to the Navigation System Camera within the system´s working space (*see figure 1*), otherwise the navigation accuracy may be compromised.
- Ensure that enough sterile Instrument Batteries are available. If the battery power is low, the status light of the instrument illuminates continuously and the battery must be replaced. If no battery is available, the instrument can no longer be used for navigation.

Navigation System Camera Working Space

The optimal working space of the Navigation System Camera is depicted in figure 1. Failing to operate the instruments within the optimal working space will result in compromised system accuracy. Use the software´s Setup Mode to ensure optimal positioning of the Navigation System Camera. For detailed dimensions, also *refer to the Navigation System Camera´s Instructions for Use*.

System Accuracy

In the optimal working space, the system enables the determination of the leg´s mechanical axes as well as the cut and component alignment with a mean translational error of < 2 mm and a mean rotational error of < 1°.

Operating Room Setup

- Ensure all components of the system are available and operate properly. Prior to surgery, fully inspect all components for malfunction and altered geometry. Malfunctioning or loose components may cause the system to be inoperative.
- Handle the navigation components with care. Avoid dropping of instruments. Any deformity can lead to navigation inaccuracy. If damaged, suspected of being damaged, or unable to pass validation, return instruments for service.
- During surgery, disconnect the system from the hospital network or telephone line as these may cause the system to malfunction. *Refer to the instructions supplied with the Navigation System.*
- Ensure that the Navigation System Camera has been setup at the optimal distance and is oriented towards the surgical field. Ensure the patient is placed within the optimal working space. Inappropriate setup will decrease accuracy and cause the system to display inaccurate positional information.
- Do not change general position of the Navigation System Camera relative to the patient during surgery (e.g., do not move the Navigation System Camera to the opposite side of the patient). Failure to comply may lead to prosthesis misalignment.

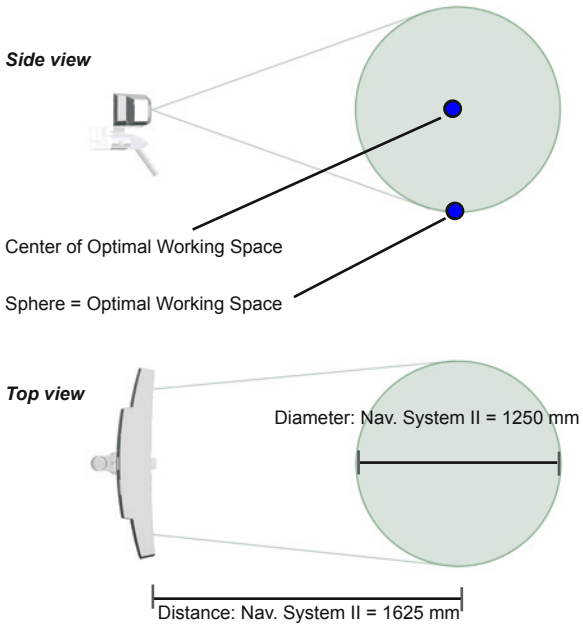


Figure 1: Navigation System Camera Working Space

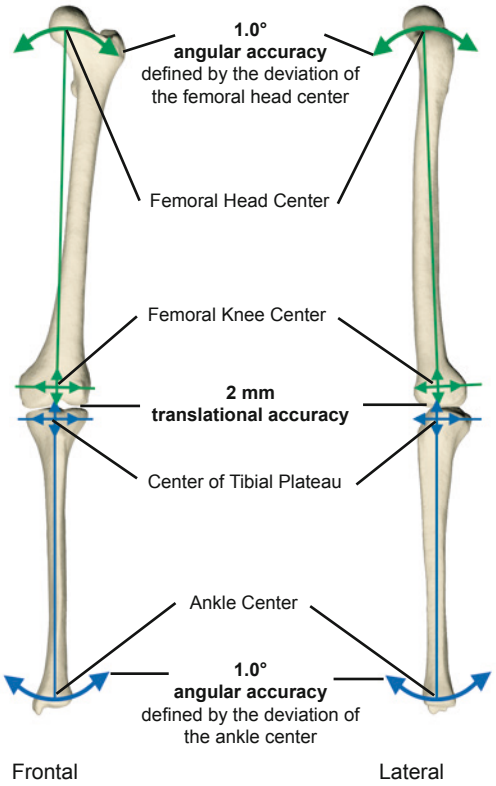


Figure 2: Mechanical Axes and Accuracy

Patient Preparation

- There are two Stryker anchoring systems possible for navigation: Anchoring Pins and OrthoLock. The OrthoLock can be used together with Navigation Pins or OrthoLock Ex-Pins. For detailed information refer to the respective *Instructions for Use* provided with the selected anchoring system.
- Select a safe and proper location for the pins of the selected anchoring system: distal femoral shaft for femoral pin and proximal tibial shaft for tibial pin. Avoid pin positions and pin orientations where any vulnerable neurovascular structures might be injured both at the entry and exit points. Avoid risk of pin collision with implant and/or instrument. For this purpose, select proper location for pin as instructed in the respective *Instructions for Use* provided with the anchoring device. If intrameduallary fixation of the jig is used, ensure that the pin is positioned medially or laterally of the femoral/tibial shaft centerline. Failure to comply could impede intramedullary rod insertion.
- Inspect bone quality for pin stability prior to insertion. If rigid fixation cannot be ensured, navigation accuracy is compromised. Avoid fixation to osteoporotic bone with very low bone density or otherwise damaged bones, e.g., if bone stock is compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the tracker. If bone quality is poor, do not use navigation for treatment.
- Avoid risk of soft tissue injury at the exit of the second cortex.
- During pin fixation, ensure proper alignment of the tracker to the Navigation System Camera. Otherwise, navigation cannot be used.
- During pin insertion, make sure that no transverse forces (i.e., by oscillation) or soft tissue loading (such as from muscles or ligaments) occur. If pin is instable, navigation accuracy is compromised. Refer to the *Instructions for Use* supplied with the pin.
- For correct fixation, refer to the *Instructions for Use* supplied with the respective pin. If bone is damaged, a new location for the pin is necessary.
- Carefully avoid pin/tracker collision with instrument or implant. Carefully avoid any stress on pin/tracker. Otherwise, registration will be inaccurate.
- Verify that both patient trackers in the surgical field are favorably positioned for instrument handling. Otherwise, handling and visibility of the instruments are compromised.
- For tracker stability, ensure proper engagement between pin interface and tracker. Refer to the *Instructions for Use* supplied with the appropriate anchoring device.

Tool Validation

- Verify tool functionality and any suspicion of damage by pointer validation. Navigation may be compromised if the tool is bent or damaged (i.e., after dropping or collision). Pointer validation is possible at any time during surgery. For activation, touch a tracker validation disk with the pointer's tip and follow the system instructions. Replace the tool if validation fails.

Patient Data Acquisition

- Carefully select the correct leg side. In case of swapped leg side, incorrect values are displayed on the navigation screen leading to prosthesis misalignment.
- Select the correct implant family in the patient dialog.

Patient Registration

- Digitize landmarks as prompted by the navigation software. All points digitized by the pointer must lie on the bone surface. Landmarks which are digitized in the air lead to faulty referencing. Prosthesis misalignment may occur. The software may calculate the wrong implant size based on incorrect referencing (optional functionality).
- To determine the hip center accurately, rotate the leg smoothly describing circles with changing radii. Avoid movements of pelvis, Navigation System Camera and operating room table during leg motion.
- Determination of the hip center may fail due to obesity and unavoidable pelvic movements. Operating time is extended or navigation is rendered useless in this case.
- Verify axes and all landmarks on the distal femur and proximal tibia on the Verify Registration screen. Points digitized outside the borders of the condyles and compartments must be deleted.

Verify Registration

Registration needs to be verified as it forms the basis for all cuts as well as for the optional calculation of prosthesis size and position.

Landmark / axis to be verified

- **Center of femoral head** can be verified indirectly by checking the computed femoral mechanical axis.
- **Center of the knee and distal condyles** can be checked visually with the aid of the pointer on the Verify Registration screen.
- **Mechanical axis of the femur** can be visually verified with the aid of the pointer on the Verify Registration screen by aligning the pointer's tip axis with the computed mechanical axis. If desired, an extramedullary rod can also be used to verify alignment.
- **Tibia center and compartments** can be visually verified with the aid of the pointer on the Verify Registration screen.
- **Mechanical axis of the tibia** can be visually verified with the aid of the pointer by aligning the pointer's tip axis with the computed mechanical axis. If desired, an extramedullary rod can also be used to verify alignment.
- **Epicondyles and AP axis** can be checked visually with the aid of the pointer on the Verify Registration screen.
- **Posterior condyles and anterior cortex** can be verified on the Verify Registration screen by analyzing the graphical values.

Operation

- Ensure the patient trackers do not move with respect to the patient. If the patient tracker moves, the navigation screen displays inaccurate positional information of the instruments. If movement is suspected, perform a landmark test or check verification points.
- Keep the same tracker orientation to the Navigation System Camera when re-attaching the tracker to the pin. Failure to comply leads to navigation inaccuracy and prosthesis misalignment.
- To resume communication with the system and to avoid extension of the operating time, reactivate tracker/pointer when battery is replaced or removed and re-inserted. *Refer to the Instructions for Use supplied with the devices.*
- Carefully avoid pin/tracker collision with instruments or implants.
- Carefully avoid any stress on pin/tracker. If tracker moves, prosthesis is misaligned. If collision occurs, perform a landmark test or check verification points. Replace pin if broken or bent.
- Prior to surgery, inspect the Resection Plane Probe for exact fitting within the slot of the cutting block. Avoid any noticeable play as the cut would be inaccurate and prosthesis misaligned. Select the properly sized Resection Plane Probe.
- Prior to surgery, hold the Resection Plane Probe flush against a flat surface. If the Resection Plane Probe is bent, cut is inaccurate and prosthesis is misaligned.
- Verify cut for alignment attaching a tracker to the Resection Plane Probe. Keep the Resection Plane Probe flush against the bone cut plane.
- Verify the calculated flexion axes on the Verify Registration dialog.
- Verify the calculated implant size on the Position Implant dialog with the corresponding trial or with the blade runner together with the cutting block for the anterior and posterior cut before cutting the bone.
- Enable the optional verification checkpoint for femur and tibia and keep it activated.
- Prevent excessive blood contact with the navigated instruments. Clean and sterilize all instruments immediately after use. The risk of contamination is high if cleaning and sterilization are delayed or inadequate. *Refer to the Cleaning and Steam-Based Sterilization Guide supplied with the devices.*
- Carefully check for notching at the anterior cortex of the distal femur. Notching may result from a strong femur curvature in the lateral plane. For this purpose, use conventional notching detection tools (e.g. blade runner) and enable the user setting for possible notching detection in the software.
- Apply equivalent force in flexion and extension for gap balancing. Otherwise knee is misbalanced. We recommend to use spacers, spacer blocks or any other mechanical distraction device. *Refer to the Instructions for Use supplied with the applied device.*
- Record each performed cut. Otherwise, virtual cutting planes may be misinterpreted as real cuts leading to prosthesis misalignment.

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