Patient Tracker, Green

REF 6007-005-000

Patient Tracker, Blue

REF 6007-010-000

Tibial/Pelvic Tracker

REF 6003-005-000

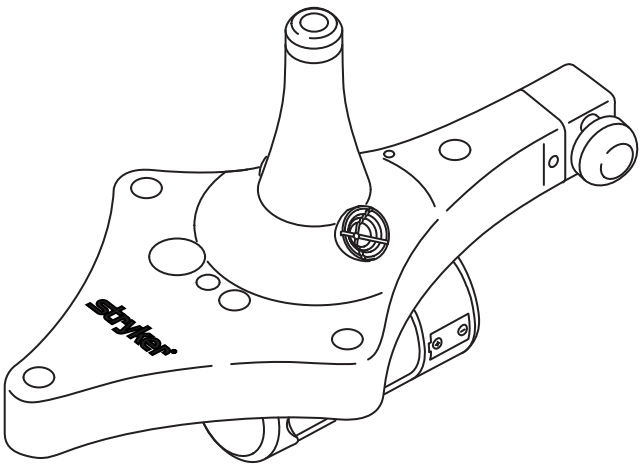
Femoral Tracker

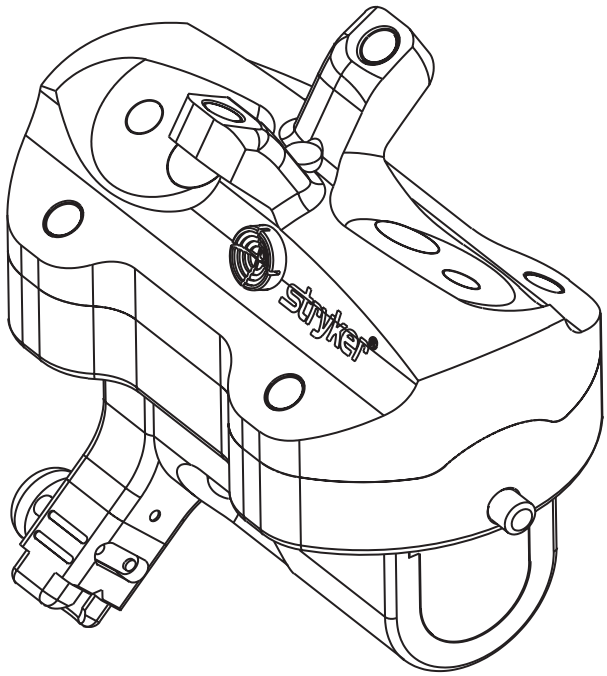
REF 6003-010-000

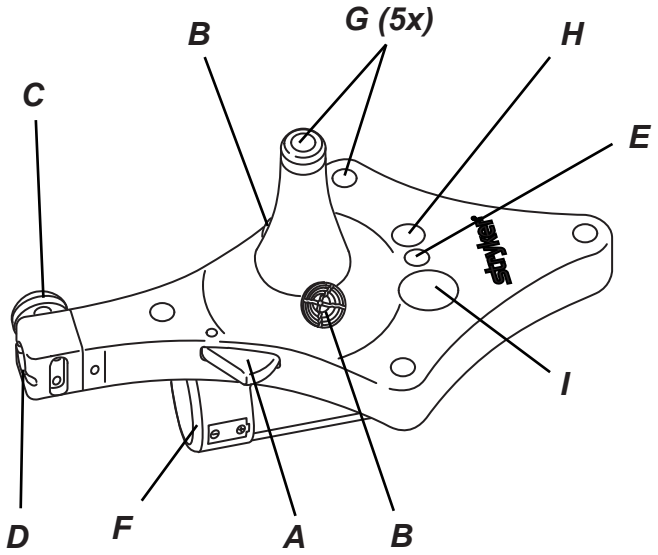
stryker®

Instructions for Use

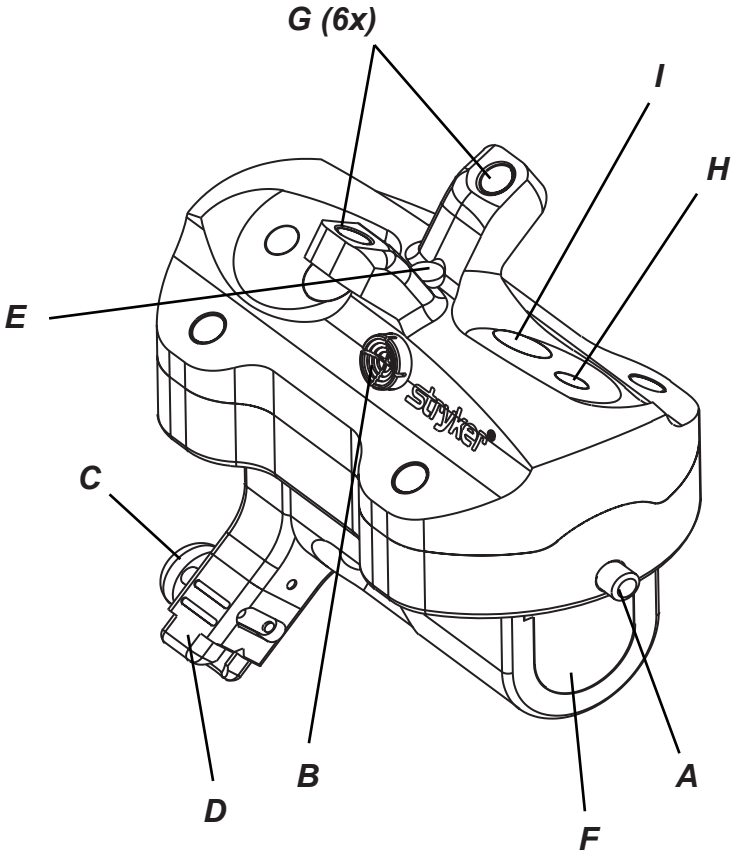
CE







REF 6003-005-000 / REF 6003-010-000



REF 6007-005-000 / REF 6007-010-000

Intended Use of the Navigated Instrument

The trackers are intended for patient tracking and for use with the Stryker® Navigation System. The trackers emit signals which are received by the camera. The system uses the signals to calculate the spatial relationship between the patient and the surgical instrument. The position of the instrument in relationship to the patient's anatomy is displayed on the monitor. Moreover, each patient tracker may be used to validate a pointer or navigated instrument.

The Patient Tracker, Blue
REF 6007-010-000 and the Patient Tracker, Green REF 6007-005-000 are intended to be used with the Stryker Navigation System - Hip Modules.

The Tibial / Pelvic Tracker
REF 6003-005-000 and the Femoral Tracker REF 6003-010-000 are intended to be used with the Stryker Navigation System - Knee Modules.

User/Patient Safety

WARNINGS:

- Read and understand this information, file it in your maintenance records. Familiarization with the Stryker® Navigation System prior to its use is important. *Refer to the instructions for use of the Navigation System.* Only trained personnel are to use this system.
- The instrument 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, the instruments should be operated with the Stryker Navigation System and inspected for any loose components, damage or malfunction. DO NOT use if any of these conditions exists. Contact your Stryker Navigation sales representative immediately in such case.
- The health care provider performing any procedure is responsible for determining the appropriateness of the instrument and 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 will compromise the navigation accuracy.
- Use only Stryker approved components and accessories, unless otherwise specified. Other accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system. DO NOT modify any component or accessory. Failure to comply may result in patient and/or health care staff injury.

- Ensure that the tracker snaps into position and is correctly assembled with the transverse bolt of the interface pin.
- Take special precautions regarding electromagnetic compatibility (EMC) when using this medical electronic equipment. Install and put the equipment into service according to the EMC information in the EMC Specifications Manual REF 6000-005-760. This medical equipment meets all requirements in the IEC 60601-1-2 standard and can be installed in a normal environment. The equipment must not be placed or installed close to strong electromagnetic sources which may influence the function of this equipment.
- Prior to surgery, the tracker should be checked with the navigation system to ensure they are functioning properly.
- Use Instrument Battery REF 6000-006-000 only. Load a new battery before first and every use as instructed in this manual.
- During surgery, always keep a sterile replacement Instrument Battery available.
- Remove the Instrument Battery as instructed in this manual before storing or sterilizing the navigated instrument.
- DO NOT sterilize Instrument Batteries; they are supplied sterile and must not be resterilized.
- Clean and sterilize the instrument before first and every use. *Refer to the Guide for Cleaning and Steam-Based Sterilization.*
- Ensure that you store and transport this device according to the instructions in this manual.
- Navigated instruments contain multiple infrared LEDs, a transmit LED and a receiver. All of the LEDs must be in view of the camera for the navigation system to function properly.
- If draping is required, use a thin, transparent draping material that is neither milky, striated, nor textured.
- This equipment is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.
- During surgery, if fluids such as saline solutions enter the battery holder, the electronics can fail and communication with the system will cease.
- During surgery, keep the LEDs clean and out of contact with liquids at all times.
- Excessive infrared radiation from external sources can influence localization of the instrument by the navigation system. *Refer to the Navigation System Camera Instructions for Use*.
- DO NOT service the instrument. It does not contain any parts the user can service. If service is required, contact your Stryker Navigation sales representative.
- Prior to and during the surgical procedure, regularly verify that the instrument is firmly attached to the anchoring device. If the tracker moves relative to the patient, the navigation is inaccurate.
- Use this manual with the instructions for use supplied with the anchoring device for further warning or caution notes and detailed anchoring instructions.
- Location and movement of the instrument as it relates to the patient tracking system is displayed on the navigation system monitor.
- After patient registration, any change in the position of the patient tracking system in relationship to the patient compromises navigation accuracy. Therefore, the patient must be re-registered.
- Upon any suspected movement of the trackers, perform a landmark check using verification points or movement checkpoints to ensure accuracy, depending on your software application. If the tracker is suspected of having moved, replacement of the tracker fixation and reacquisition of the registration points must be performed. Alternatively, the navigation must be abandoned and conventional techniques used.

CAUTIONS:

- DO NOT apply any physical impact to the navigated instrument, such as with a mallet or a similar tool. Any impact will cause product damage or operational failure due to battery movement.
- To avoid malfunction, DO NOT scratch or damage the LEDs in any way.
- Consult your local environmental protection agency regarding special disposal restrictions for lithium batteries.
- During resection or while hammering components in place, remove the trackers from their pins of the anchoring system used, as the registration can become compromised. Additionally, there is no need to track the bone while performing cuts.

*Specifications, General**

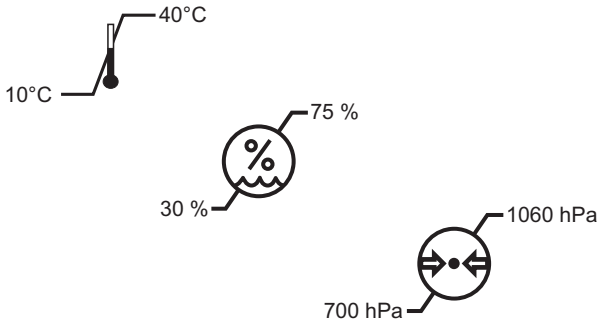
General specifications apply to all navigated instrument models.

Material:
Aluminum (housing); PPSU (battery housing); stainless steel (interface)

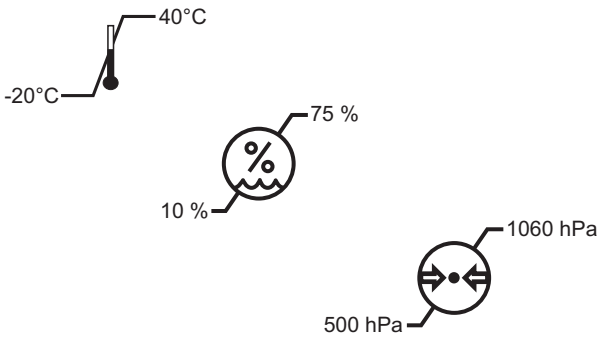
Power supply:
3 V ⎓ , internally powered (lithium battery CR 2)
Enclosure protection:
IPX0 Ordinary Equipment

Approvals:
CSA International cCSAus
EN / IEC 60601-1
EN / IEC 60601-1-2
ANSI/AAMI ES60601–1:2005
CAN/CSA-C22.2 No. 60601-1:08

Operation:



Storage and Transportation:



** Specifications listed are approximate and may vary slightly from unit to unit. Standards listed are valid unless a transition period may be applicable.*

*Specifications, by Model***

Model: **REF 6007-005-000**
Patient Tracker, Green
Size: 81.5 mm [3.21 in] height,
48.5 mm [1.91 in] width,
85.2 mm [3.35 in] length
Weight: 185 g [6.52 oz.]

Model: **REF 6007-010-000**
Patient Tracker, Blue
Size: 81.5 mm [3.21 in] height,
48.5 mm [1.91 in] width,
85.2 mm [3.35 in] length
Weight: 185 g [6.52 oz.]

Model: **REF 6003-005-000**
Tibial/Pelvic Tracker
Size: 71 mm [2.8 in] height,
55 mm [2.75 in] width,
113 mm [4.4 in] length
Weight: 78 g [2.56 oz.]

Model: **REF 6003-010-000**
Femoral Tracker
Size: 71 mm [2.8 in] height,
55 mm [2.75 in] width,
113 mm [4.4 in] length
Weight: 78 g [2.56 oz.]

*** Weight without instrument battery.*

Function and Features

Refer to figures on page 2.

Color Coding
- Blue identifies the Tibial/Pelvic Tracker and the Patient Tracker, Blue.
  Green identifies the Femoral Tracker and the Patient Tracker, Green.

SELECT Button *(A)*
- Press to initialize the instrument.
- After initialization, press to select software interface functions displayed on the navigation system monitor.

Validation Disks *(B)*
- Used as reference points, touch the disk cross-hairs with the instrument tip to validate the instrument.

Release Button *(C)* and Interface *(D*)
- These features allow the tracker to be secured to and detached from the navigated instrument.

Green Status Light *(E)*
- During instrument initialization, the light flashes rapidly.
- During normal operation, the light flashes every few seconds.
- The light illuminates continuously, if instrument power is low.

Battery Holder *(F)*

Infrared LEDs (Light Emitting Diodes) *(G)*, Transmit LED *(H)* and Receiver *(I)*
- Emit and receive infrared light signals that are used to provide a wireless communication link to the navigation system's camera.

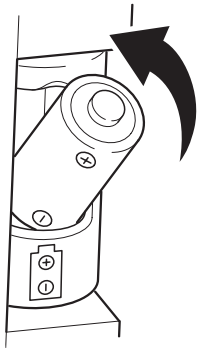
Instructions

1 Install Instrument Battery

WARNING:

Use only a new, sterile CR 2 lithium battery.

1.1 Remove Instrument Battery REF 6000-006-000 from the sterile package.
1.2 (Patient trackers only) Open the battery housing by sliding down the battery sleeve.
1.3 Press the negative end of the battery into the battery holder and against the spring.



1.4 (Patient trackers only) Close the battery holder by sliding the sleeve back in position.
1.5 Observe the green status light illuminate for three seconds to indicate that the device is functioning properly.
1.6 Gently press down on the positive end of the battery and pull it away from the battery holder to remove it.

NOTE:

After changing the battery during operation, press the SELECT button until the instrument is initialized again.

2 Initialize Instrument

NOTE:

Ensure the line of sight between the instrument and the camera is NOT blocked, and that the instrument's infrared LEDs, transmit LED and receiver directly face the camera.

2.1 Wait for the navigation system to prompt for the initialization before initializing the instrument.
2.2 Once in the system setup mode, and prompted by the software interface, press the SELECT button until the device is initialized.
2.3 Observe the green status light flash rapidly during initialization.
2.4 Once initialized, observe the green status light flash slowly and a system message appear on the monitor indicating instrument recognition.

3 Mount Instrument

3.1 Mount the required pin of the anchoring system used. *Refer to the instructions for use supplied with the respective devices for further details.*
3.2 Mount the trackers onto the pins of the anchoring system attached to the bone as instructed. For fixation, hold down the tracker's release button and use the tracker's interface for insertion.
3.3 Ensure that the tracker snaps into position and is correctly assembled with the transverse bolt of the interface pin. Double-check that the tracker/pin is firmly fixated. The tracker must not move during surgery. Failure to comply leads to navigation inaccuracy.
3.4 Ensure the tracker is aligned with the camera during anchoring and throughout the procedure (also during femoral preparation with luxated leg) and will not obstruct the surgical field.

NOTE:

- You may want to use the validation disk situated on the right or left side of the patient tracker to validate the pointer's tip.
- Place the pointer's tip into the center of the tracker's validation disk and press the SELECT button. *For further instructions, refer to the Instruction for Use supplied with the Pointer REF 6007-011-000 and to the user manual of the respective software.*
- To remove a tracker, press the release button and withdraw the tracker.

4 Tracker Use Under Sterile Conditions

4.1 If possible, exchange a tracker that is not sterile with a sterile tracker; otherwise, drape the tracker that is not sterile.

4.2 If draping is required, use a thin, transparent draping material that is neither milky, striated, nor textured.

NOTES:

- Suitable draping material that has been successfully tested, that is CE certified and available worldwide includes:
  Name: **Snap Kovers™ REF 01-3628**
  Size: 36 in [91.44 cm] width x 28 in [71.12 cm] length
  Manufacturer:
  Advance Medical Designs, Inc.
- For more information about draping material that is suitable for image guided surgery, contact your Stryker Navigation sales representative.

4.3 During draping, cover the tracker with only one layer of drape. To ensure the tracker will function properly, DO NOT allow folds or wrinkles on or near the tracker‘s infrared LEDs, transmit LED and receiver.

5 Using the Trackers to Validate Navigated Instruments

Required components:

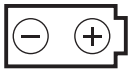
- Tracker mounted to the pin of the anchoring device used.
- Desired navigated instruments.

5.1 Initialize both the tracker and the instrument with the system. Press the SELECT button on each component.

5.2 Aim the instrument‘s LEDs at the camera and place the tip of the instrument into the center of the tracker‘s validation disks cross-hairs.

5.3 Press the navigated instrument's SELECT button. The system validates the instrument data.

Symbol definition

	Select
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limitation
	Battery + positive terminal, - negative terminal
	CSA International
	In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste. The product should be collected separately. Refer to your local distributor for return and/or collection systems available in your country.
	Essential Requirements of Medical Device Directive 93/42/EEC.
	This is the general warning sign. It is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm.
	Manufacturer
	Consult instructions for use
	Direct current
	Type BF Applied Part

Troubleshooting Guidelines

Tracker will not lock into place:

- Interface between tracker and pin of the anchoring system used is not properly aligned. Rotate tracker until it snaps into place on the pin of the anchoring system used.
- Release button is stuck or damaged. Return instrument for service.

Navigated instrument fails to power up when battery is installed:

- Battery is installed improperly. Reinstall battery.
- Battery power is low. Replace battery.
- Navigated instrument is damaged. Return navigated instrument for service.

Navigated instrument cannot be initialized:

- Battery is installed improperly. Reinstall battery.
- Battery power is low. Replace battery.
- Transmit LED or receiver are damaged. Return navigated instrument for service.
- SELECT button is stiff or defective. Return navigated instrument for service.

Tracker is unable to validate instrument:

- Instrument may have a bent tip. Return instrument for service.

Range of movement is limited:

- One or more of the LEDs are dirty or do not function properly. Clean surface of the LEDs. If cleaning does not improve the function, return the instrument for service.

Green status light illuminates continuously:

- Battery power is low. Replace battery.

Communication with the system fails after Navigation software is restarted:

- Remove and reinsert battery. Re-initialize instrument.

Sporadic electrical interference is experienced:

- Electrical noise is present. Turn off all electrical equipment not in use in the operating room. Relocate electrical equipment; increase spatial distance. Plug equipment into different operating room outlets.

Tracker cannot be mounted to anchoring device or instrument:

- Interface is damaged. Return for service.
- Positioning on anchoring device or instrument is not correct. Try to rotate tracker on interface until it snaps into position.

Line of sight between navigated instrument and camera is interrupted:

- Navigated instrument is not visible. Remove obstruction and system will resume communication.

Tracker is no longer visible on screen:

- Battery dislodged during surgical procedures. Reactivate tracker.

Cleaning and Inspection Instructions

Cleaning Group IV.

Refer to the Guide for Cleaning and Steam-Based Sterilization for cleaning safety and caution notes, cleaning equipment and detailed cleaning and inspection instructions intended for instruments with electronics.

Sterilization Instructions

Refer to the Guide for Cleaning and Steam-Based Sterilization for detailed sterilization instructions and caution notes.

Translated Equivalent: ***TD6003005713***

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