Instrument assembly

SmithNephew

CLEARLENS
Tracking Technology
Getting started

At the scrub table, prepare the CLEARLENS reusable metal instruments and unpack the CLEARLENS disposable tracking arrays.

The tibia and femur bone reference arrays, the CLEARLENS Pointer and Plane Tool are needed for a navigated surgical procedure. The Y-shaped array, marked with “F” is placed in a Two-pin Bone Fixator, which is then attached to the femur. The T-shaped array, marked with a “T” is mounted on to the tibia. During navigation these bone reference arrays define the position of the bones relative to the navigated instruments.
CLEARLENS Two Pin Bone Fixators

To prepare the CLEARLENS instruments, start with setting up the Two Pin Bone Fixators. The bone fixators will fix the CLEARLENS bone reference arrays to the femur and tibia for the navigated procedure.

If the bone fixators are in cleaning position (1), prepare them for clinical use by inserting the pin fixation screw into the wedge by hand (2). Carefully turn the screw until it securely engages the thread inside the wedge. Make sure not to cross thread the screw. Do not fully tighten the pin fixation screw (3, 4).
CLEARLENS femur and tibia tracking arrays

To assemble the CLEARLENS navigation arrays with the Two Pin Bone Fixators fix the bone reference arrays to the patient’s anatomy. Make sure the locking screw on the spring loaded ring interface of the Two Pin Bone Fixator is fully opened (1).

Snap the CLEARLENS tracking array into the interfaces of the reusable CLEARLENS bone fixators (2). Make sure the array has fully engaged (3).

Do not tighten the array locking screws for the reference arrays yet (4). Leaving the locking screws open at this point will allow you to adjust their orientation towards the navigation camera once the Two Pin Bone Fixators with the bone reference arrays are mounted onto the Schanz screws.
Schanz pins placement and array fixation

Insert the first Schanz pin into the bone (1). Make sure the bone fixator’s pin fixation screw is not closed. Slide the bone fixator with the reference array attached over the first pin (2). Insert the second Schanz pin through the bone fixator and drill it into the bone (3). Once the second pin is securely placed, close the pin locking screw using the 3.5mm hex screwdriver (4). Adjust the array orientation towards the camera (5) and close the array locking screw to its end stop using the screw driver (6).
CLEARLENS Pointer

The Pointer is used for registration of anatomical landmarks and measurements throughout the navigated procedure. The Pointer should be stored in its dedicated Pointer gauge. The gauge is used to protect the instrument during transport and sterilization. It is also used to verify that the Pointer tip is not bent (1).

If the Pointer tip does not sit in the center of the Pointer tip receptacle, it is likely that the Pointer tip was bent during the last navigated procedure or during the sterilization process. In that case Smith+Nephew strongly recommends to exchange the instrument.

Note. Smith+Nephew recommends to verify the Pointer at regular intervals, ideally before and after every procedure where the Pointer was or will be used.

To assemble the Pointer array with the CLEARLENS Pointer handle, remove the Pointer handle from its gauge (2).
Take the Pointer array out of the blister pack (3) to snap it into the array interface. Insert the disposable array into the Pointer handle interface with the lower marker lens first (4). Then, holding the lens in place inside the interface, press the Pointer array geometry down until it snaps into the interface (5, 6).

Verify visually that the array is fully seated to ensure the instrument is detected at the correct orientation and position by the navigation system. The array should sit flush with the Pointer handle interface (7).

Turn the Pointer over to visually verify that the array clip has fully engaged the Pointer handle (8).
CLEARLENS Plane Tool

The CLEARLENS Plane Tool is used to navigate the standard, implant specific cutting blocks to the desired resection level and orientation. Under live navigation, the Cutting Block Adapter plate (1) of the Plane Tool is inserted into the cutting block while fixing the resection block on to the bone. The verification plate (2) contained in the Plane Tool Kit is used to verify the bone resections.

The Pointer Gauge features a receptacle (3) that can be used to verify that the Cutting Block Adapter is not bent. In order to verify the Cutting Block Adapter, press its lever (4) and insert the foot plate of the Cutting Block Adapter (5) into the dedicated verification receptacle of the Pointer Gauge (3).

If the Cutting Block Adapter can be inserted easily into the gauge and if the foot plate sits flat inside the receptacle (6), the Cutting Block Adapter is safe to use for the navigated procedure.
Note: Smith+Nephew recommends to verify the Cutting Block Adapter foot plate at regular intervals, ideally before and after every procedure where the instrument was used.

If the Cutting Block Adapter foot plate is hard to insert into the verification receptacle or if it cannot be inserted at all, it is likely that the foot plate was bent during the last procedure or during the sterilization process. In that case Smith+Nephew strongly recommends to exchange the instrument.

To assemble the Plane Tool with the navigation array, take the Plane Tool array (7) from the array package and insert the tracking array’s lower marker lens into the Plane Tool interface first (8).

Once the marker lens is seated, press the array down into the interface (9) and verify it is fully seated, flush with the interface (10).

Turn the Plane Tool over to visually verify that the array clip has fully engaged the CLEARLENS Plane Tool interface (11).
CLEARLENS disassembly

The bone reference arrays and Schanz pins are single-use, disposable parts. They can be removed once final implant components are in place and the knee arthroplasty is completed.

To disassemble the bone reference arrays, fully open the pin fixation screws of the Two Pin Bone Fixators using the 3.5mm hex screw driver supplied with the instrument kit. Pull the Two Pin Bone Fixators off the Schanz pins. Now the Schanz pins can be removed from the femur and tibia.

At the scrub table, all CLEARLENS disposable parts can be disassembled from the reusable CLEARLENS metal Instruments.

To remove the “F” and “T” Bone Reference Arrays from the Two Pin Bone Fixators, use the 3.5mm hex screw driver to fully open the array locking screw on the ring interface to the end stop (1).

Lever the bone reference arrays out of the Two Pin Bone Fixator’s ring interface (2, 3).
To disassemble the CLEARLENS Pointer, simply pull the disposable array forward from the Pointer array interface (4), then remove and dispose of the array (5).

To disassemble the CLEARLENS Plane Tool, pull the disposable array forward from the Plane Tool interface (6), then remove and dispose of the array (7).

Note. CLEARLENS tracking arrays are single-use, non-sterilizable, non-autoclavable devices. Always dispose of all CLEARLENS tracking arrays after clinical use.