bolt®

spine navigation system

Instructions for Use

v5.3 US

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1. Operational Guidelines

1.1 Rx Only

⚠ CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

1.2 Device Description

The Bolt® Navigation System (the BNS) is comprised of the Bolt Navigation Unit (BNU) (a 7th Generation iPod Touch® mobile digital device with the Bolt navigation software loaded on it), and the Bolt single use case. The BNU is placed in a sterile drape prior to entry into the sterile field.

The BNS is intended to provide navigational guidance during spine surgery. The system uses pre- and perioperative imaging data, and input from the surgeon via the BNU touchscreen to construct the proper angular position of the instrumentation and implants relative to the surgeon selected entry point and communicates this information to the surgeon via the BNU screen attached to the instrument allowing the surgeon to look at both the surgical site and the navigation data at the same time, thus attenuating the risk of attention shift.

The BNS provides guidance data by displaying the angular orientation of a surgical instrument (such as a pedicle probe or awl) relative to a surgeon selected entry point on the patient and the angular position planned by the user. Angular orientation of the instruments is linked to the imaging data via the BNS.

The system is intended to be used for both image fusion and navigation for spine surgery applications where reference to relevant rigid structures can be identified relative to a perioperative image data of the anatomy and the patient's position relative to gravity.

1.3 Indications For Use

The Bolt Navigation System assists in the accurate placement of pedicle screws when used in conjunction with an intraoperative fluoroscope. It utilizes intraoperative fluoroscopic and preoperative MRI or CT axial images to provide surgical planning and navigational telemetry relative to gravity, based on a fixed entry point ascertained by the user and validated by intraoperative fluoroscopic imaging. It is not intended to track patient position. The System is indicated for open and minimally invasive pedicle screw placement using a posterior approach in the thoracolumbar and sacral spine (T9 to S1) where the patients' relevant rigid anatomical structures can be clearly identified on the imaging.

1.4 Contraindications

The BNS is contraindicated in patients for whom the placement of posterior spine fixation is contraindicated.

The BNS is not to be used on spinal segments including and below S2.

The BNS is not to be used on spinal segments including and above T8.

The BNS is not to be used for the placement of occipital hardware.

1.5 Warnings

⚠ Images on the BNU should not be used for the purpose of diagnosing a disease.

⚠ Do not use the BNS in the presence of strong magnetic fields such as an MRI.

⚠ Do not expose the BNS to direct radiation while imaging.

⚠ Do not use the BNS, the sterile drape, or the single-use case if they have been dropped or otherwise potentially contaminated.

⚠ Sterile technique must be used when opening the sterile drape and the single-use case.

⚠ The BNU must be placed in a sterile drape and the drape must be sealed prior to placing it in the single-use case.

⚠ The entry point and trajectory of the spinal fixation must be defined during planning.

⚠ The BNU should not be connected to a WiFi network during the surgical procedure.

⚠ The entry point must be reconfirmed with fluoroscopic images prior to use of the BNS.

⚠ The BNS does not contain any user serviceable parts.

⚠ Maintenance should not be performed on the BNS while in use.

⚠ Do not modify, change or update the BNS.

⚠ The BNS does not track and cannot identify patient movement. The patient must be in the same position as when the perioperative fluoroscopic imaging is acquired. If movement is suspected, new images should be acquired, and use of the system restarted from the beginning.

⚠ Ensure the BNU is parallel to the long axis of the patient and correctly oriented with respect to left and right.

⚠ The BNS should only be attached to a non-tapered mid-shaft of a surgical instrument (which may include, for example, a pedicle probe, awl or gearshift probe), well below the handle (i.e., the proximal portion) of the surgical instrument, to provide sufficient space for the user to grip the handle of the surgical instrument during use and allow for rotation. Do not attach the BNS to the proximal portion, or proximal end, of the surgical instrument.

⚠ The BNS should not be used for percutaneous advancement of a surgical instrument through the patient's body tissue to locate the instrument at the patient's pedicle entry point.

Additional topic-specific ⚠ Warnings are found throughout the remainder of this document.

1.6 Cautions

⚠ Maintain control of the BNU and single-use case during handling.

⚠ The BNU should be cleaned prior to the start of the procedure.

⚠ The BNU should be cleaned before returning it to storage.

⚠ Store the BNU according to the acceptable storage conditions outlined in Section 8.4.

⚠ Handle the BNS with care. The unit can be damaged if dropped, burned, punctured or crushed, or if it comes into contact with liquid. If you suspect damage do not use the device and contact the manufacturer or your representative.

⚠ Do not use the BNU if the glass is cracked.

⚠ The BNU should only be charged with the charging cable included with the device.

⚠ The BNS should be kept as dry as possible at all times.

Additional topic-specific ⚠ Cautions are found throughout the remainder of this document.

1.7 Other Guidelines

☑ The BNS can only be used according to the Indications for Use outlined in Section 1.3.

☑ Always verify compatibility of the single-use case and the surgical instrument prior to surgery.

☑ The BNU should not be connected to WiFi during the surgical procedure.

☑ When connecting the BNU to the Internet for software updates, as directed by the manufacturer, it should only be connected to a trusted WiFi network.

Additional topic-specific ☑ Guidelines are found throughout the remainder of this document.

1.8 Clinical and System Benefits

The benefits of the Bolt Navigation System include:

- The BNS provides a superior accuracy compared to fluoroscopic guided placement without the need for repetitive fluoroscopy during pedicle screw placement resulting in minimal radiation exposure to patient and surgeon.
- The BNS provides accuracy comparable to O-arm/CT image guided navigation without the cost and complexity of capital-intensive O-arm/CT image guided navigation systems while eliminating the need for peri-operative CT scans and reference frame attachment for registration purposes.
- The BNS provides trajectory guidance to the surgeon via the BNU screen attached to the surgical instrument, enabling simultaneous visualization of both the surgical site and the navigation data at the same time by the surgeon. Thus attenuating the risk of attention shift (experienced with fluoroscopic and O-arm/CT image guided navigation procedures) that has been linked with reduced accuracy.

1.9 System Performance

Accuracy of the Bolt Navigation System has been demonstrated via clinical phantom, cadaveric and human clinical studies.

Clinical Phantom Results:

Mean	Std Deviation	95% CI of Mean	95% CI of Individuals	99% CI of Mean	99% CI of Individuals
0.35°	0.20°	0.39°	0.69°	0.41°	0.82°

Cadaveric Study Results:

	Estimate	2-sided 95% CI LB	2-sided 95% CI UB	1-sided 95% CI UB
Parametric*	1.59°	1.31°	1.86°	1.81

* Overall mean accuracy error estimate and 2-sided 95% CI and 1-sided 95% CI based on t-student distribution.

Clinical Study Results (Head-to-head Vs. CT-based Navigation):

- 98.9% successful placement rate with the BNS (91 out of 92 Gertzbein-Robbins "A", 1 Gertzbein-Robbins "C".)
- 98.9% agreement between the BNS and CT-based navigation (95% Exact CI; 94.09% - 99.97%)
- Post-hoc probability of superiority of BNS relative to the historical accuracy rate of 91.5% for fluoroscopy assisted procedures is > 0.999.

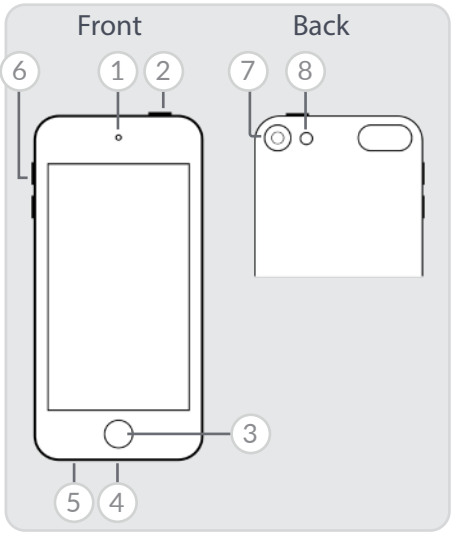
2. Understanding the System

2.1 Introduction

The BNS is comprised of the BNU (an iPod Touch® with the Bolt navigation software loaded on it) and the Bolt single use case. The BNU is intended to be placed in a sterile drape prior to entering the sterile field.

Pre-operatively the surgeon uses the BNU camera system to capture images for each level on which they plan to operate following the system prompts. The images are: 1) a perioperative lateral image taken utilizing a fluoroscope once the patient is positioned on the operating table; and 2) an axial image from the patient's pre-operative CT or MRI. The BNU is then placed in a sterile drape and enters the sterile field where it is placed in the single use case. The surgeon identifies and confirms the entry point utilizing the fluoroscope and plans the placement of the implants, and establishes the pilot hole. They then attach the BNS to a surgical instrument to prepare the site, and/or place the implant with guidance from the system. The program makes use of gyroscope-on-chip™ technology to provide accurate trajectory guidance based on the images.

2.2 Reusable Component

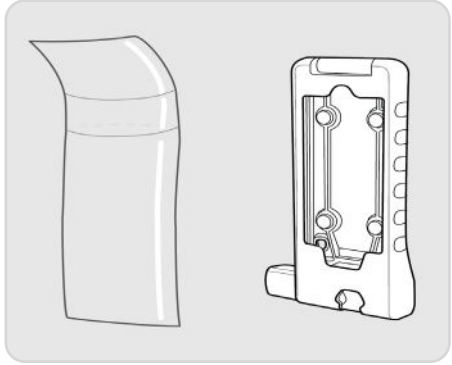


The BNU is reusable and comes with the BNS application installed. It contains the following sub-components:

1. Front camera
2. Sleep/Wake button
3. Home button
4. Lightning connector
5. Headphone jack
6. Volume buttons
7. Rear camera
8. Flash

⚠ The BNU is provided non-sterile. Do not attempt to sterilize.

2.3 Disposable Components



The BNS case is packaged sterile and single-use only. A sterile drape should be utilized.

⚠ Do not use if integrity of packing is violated or if expiration date has passed.

⚠ Do not reuse, reprocess, or re-sterilize single-use components. Reusing, reprocessing, or re-sterilizing may create risk of contamination of the device, cause patient infection, or cross-infection.

2.4 Exploded Assembly View

1. BNU with the Bolt navigation software installed

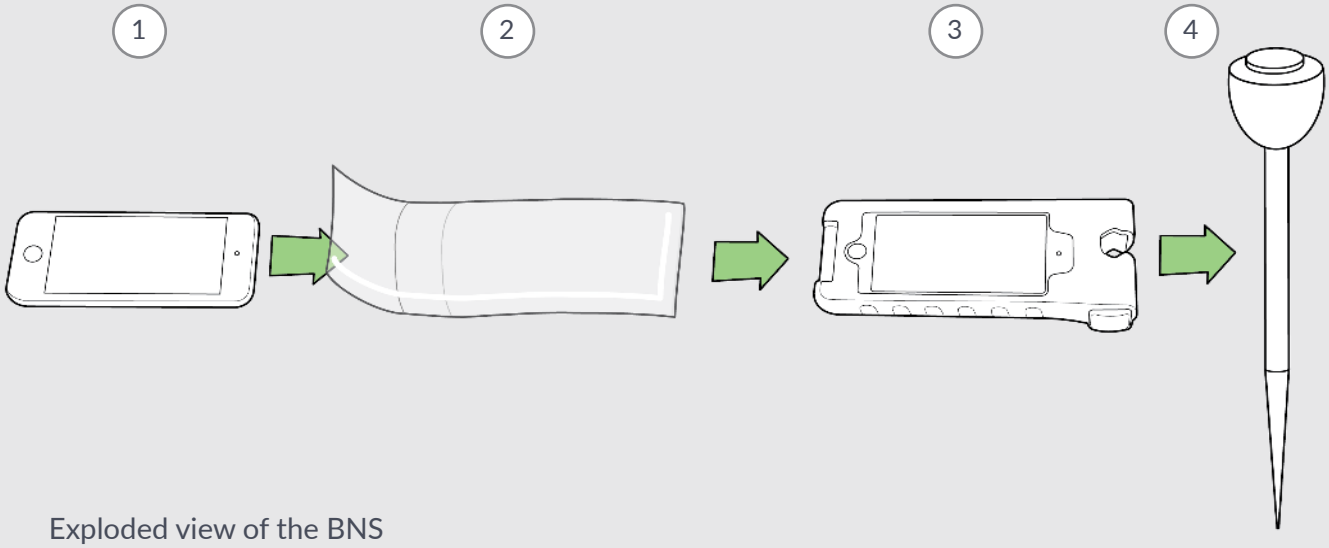
   ☑ Do not attempt to add additional applications or delete the BNS application. The BNU is locked and will not allow the user to add or delete applications.

2. Sterile drape (off-the-shelf)

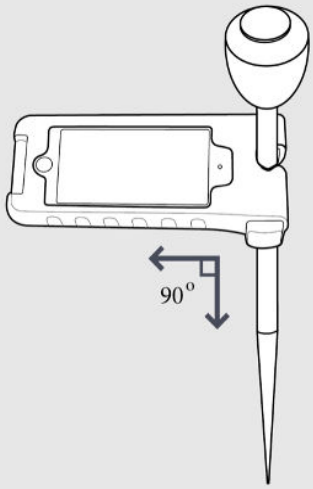
3. Single-use Bolt case, which holds the draped BNU

4. Surgical instrument (such as a pedicle probe, awl or driver) (by others)

   ☑ The BNS should only be used with instruments with a constant OD (no taper) of between 5 mm - 12 mm.



Exploded view of the BNS



Assembled view of the BNS

3. Getting Started

3.1 Gather & Prepare Supplies

1. Gather the BNS reusable and disposable components listed in Section 2.

   ⚠ The single-use case is stored in a sterile pouch within a shelf box. Within the sterile pouch, it is wrapped in a white plastic strap. Remove and dispose of this strap and all packaging before use.

2. Gather a surgical instrument (not included in the BNS packaging).

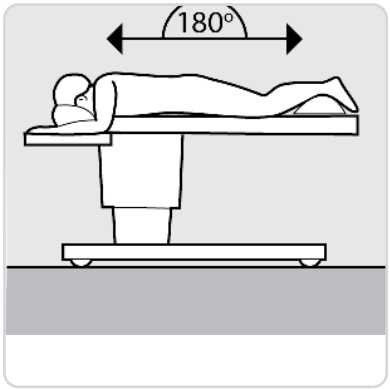
   ⚠ The single-use case must be attached to the instrument in a location where the instrument shaft is not tapered.

3. Ensure BNU battery is charged to 50% or greater. The battery percentage in the status bar can be turned on by: Settings > Battery > turn on Battery Percentage.

   ⚠ Do not use a BNU below 50% charge.

3.2 Prepare Patient & Images

Before interacting with the BNS, the following preparation steps must be taken to ensure accurate planning and placement:



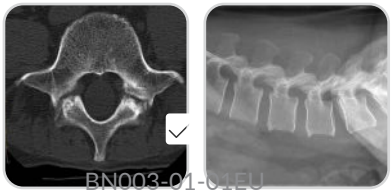
1. Prepare the table, patient, and C-arm.

   ⚠ The operating table and patient must be flat, i.e. not tilted, and horizontal prior to using the BNS. Confirmation of patient and table position can be achieved by following the steps outlined in Section 4.2 below.

   ⚠ The C-arm image projector must not be rotated after the initial image is acquired until the image is acquired by the BNS.

2. Prepare the axial and lateral patient images.

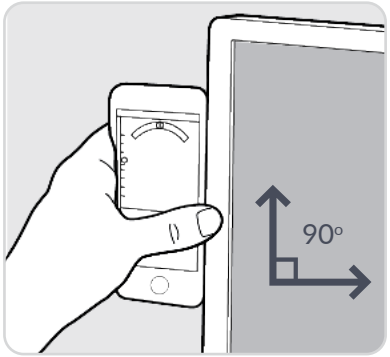
   - Once the patient is properly positioned, a true lateral image should be acquired with the C-arm.
   - Select an axial image from pre-operative imaging (CT or MRI) of the level(s) in which implants will be placed.



   ⚠ Only use lateral and axial images for navigation that are of acceptable quality.

   ⚠ New C-arm images must be acquired if the operating table or patient is repositioned after the lateral image is acquired. Procedure planning must utilize the images obtained from the immediate patient/table position.

   ⚠ Axial and lateral images must be displayed on a level (not rotated or tilted) monitor.

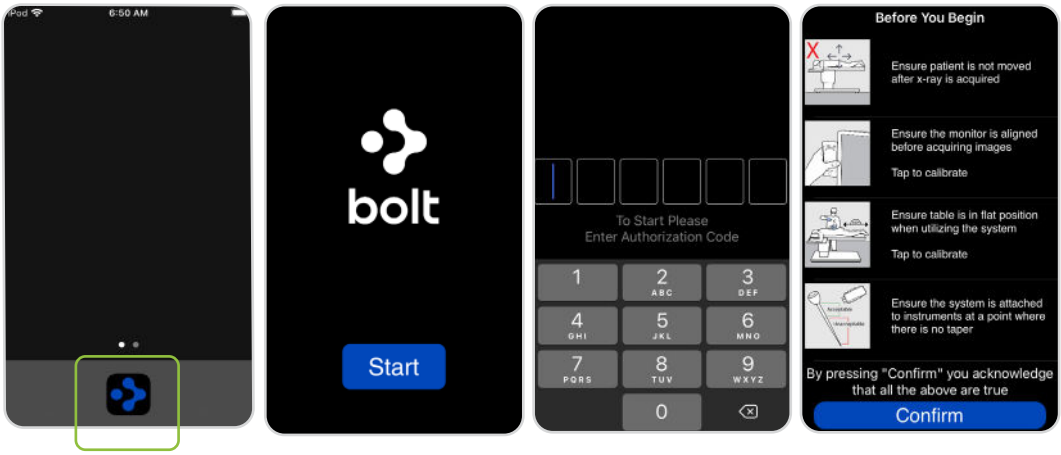


   ☑ Monitors should be positioned at eye level for the most efficient capture of patient images with the BNU.

4. Perform the Procedure

4.1 Log In

1. Tap the BNS icon to open the application.
2. Press Start.
3. Enter security password.
4. The ***Before You Begin*** page will appear.



⚠ The flatness calibration screen should be utilized to ensure that the patient is not tilted ("airplaned"). The BNU must be placed on the patients back such that it provides a true reading of the anatomy. If necessary, a flat surface can be placed on the patients back and the BNU placed upon it.

4.2 Complete Safety Checks

1. Read each line of the ***Before You Begin*** page.

   ⚠ Follow each ***Before You Begin*** instruction to ensure you are properly set up for the procedure. Failure to do so could result in pain, non-union, re-operation, CSF leak, nerve damage and / or other complications.

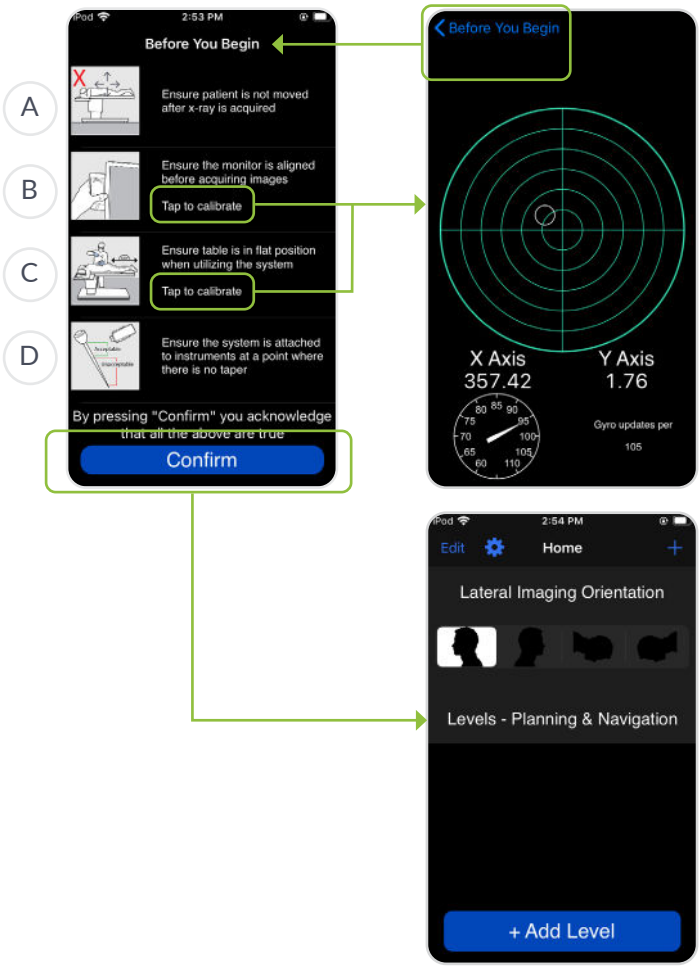
2. Line B requires user to use the BNU to ensure the monitor's proper (not rotated or tilted) alignment prior to use of the BNS. Touch ***Tap to calibrate*** and the calibration tool will appear.

3. Line C requires user to use the BNU to ensure that the patient is not tilted (airplaned) prior to use of the BNS. Touch ***Tap to calibrate*** and the calibration tool will appear.

4. Tap ***<Before You Begin*** in the upper left corner to return to the previous page.

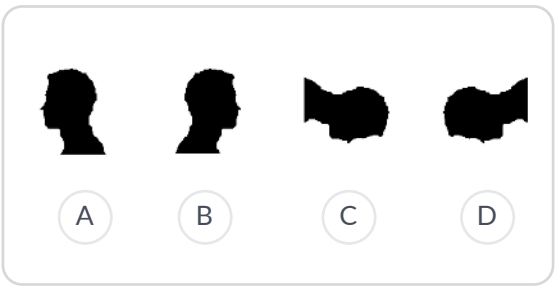
5. Once you have read and addressed each of the issues on the ***Before You Begin*** page, select ***Confirm***.

6. You will arrive on the ***Home*** screen.



4.3 Configure Orientation

1. On the ***Home*** screen, select or confirm the Lateral Imaging Orientation relative to the lateral image acquired by the in-room C-arm:



   A. Upright, dorsal right

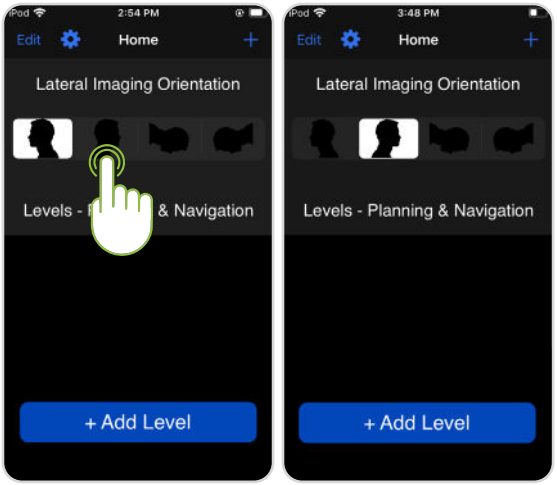
   B. Upright, dorsal left

   C. Prone, head right

   D. Prone, head left

2. To change the selection, tap the icon that corresponds to the correct lateral image orientation.

   The app will automatically save the new orientation once it is selected.



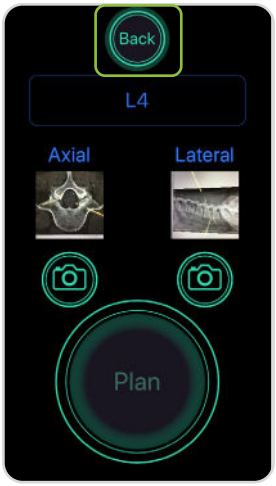
⚠ Confirm the lateral spine orientation matches the lateral image acquired by the in-room C-arm.

⚠ An incorrect selection will result in improper planning, which could lead to pain, non-union, re-operation, CSF leak, nerve damage and / or other complications.

4.4 Define Procedure Level

1. Tap ***+Add Level*** to add a new level.
2. Tap the ***Tap to Enter Level*** field.
3. Enter level to be operated on.
4. Press ***Done***.
5. The level entered will appear near the top of the screen.

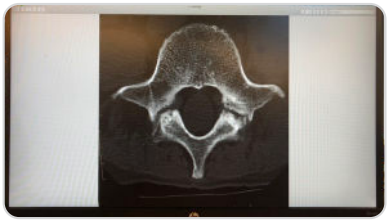
☑ Once images have been acquired for the first level, tap the ***Back*** button and repeat steps 4.4 through 4.6 for additional levels. There is no limit to the number of levels that can be added.

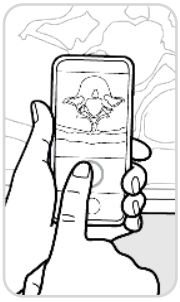


4.5 Acquire Axial Image

⚠ Axial and lateral images must be displayed on a level (not rotated or tilted) monitor. The upright calibration screen can be found via the 'Before You Begin' page or via Settings>Upright Calibration.

⚠ The image must include landmarks to aid in navigation and entry point identification.





⚠ Ensure that the BNU is centered on the image and avoid rotating or yawing the unit when acquiring images.

1. Display the axial image of the target level on the monitor.
2. Position the BNU in front of the image.

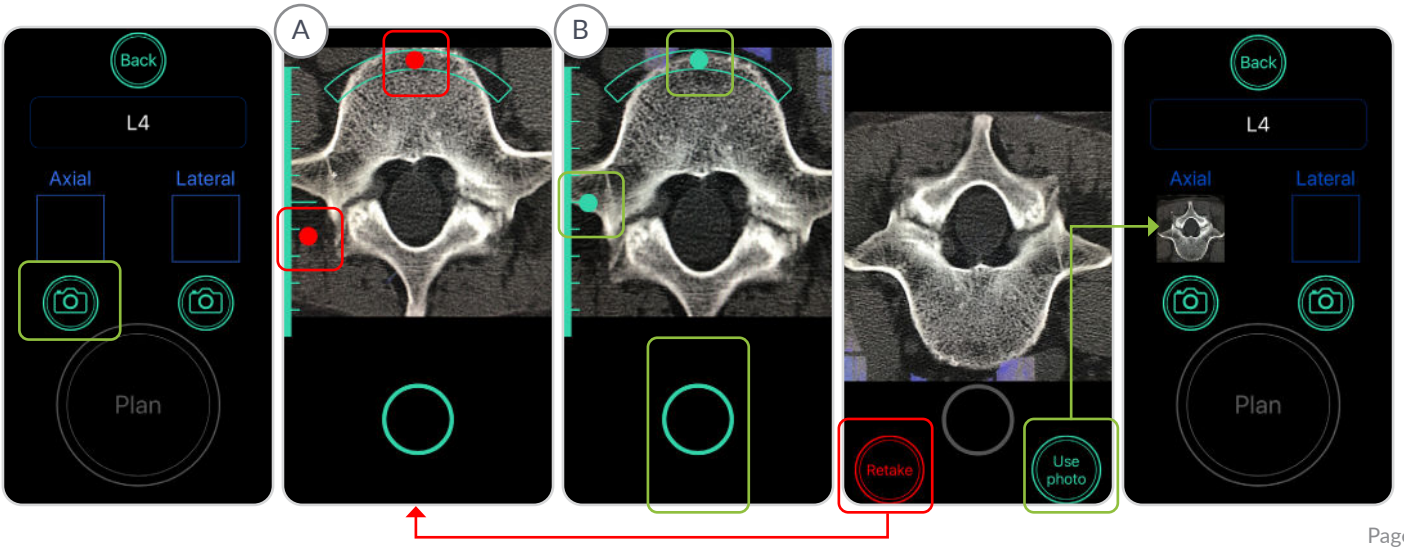
   ⚠ Ensure there are no obstructions between the camera and monitor. Ensure that the image is centered on the screen on the level to be operated on and is large enough to identify the relevant rigid anatomical landmarks and to effectively plan in section 4.9.

   ⚠ Hold the BNU steady when capturing image.
3. Tap the camera button under axial.
4. Use the horizontal and vertical "bubble" indicators to align the device to the image.
   - Screen shot A below shows the bubbles in **RED**, indicating the BNU is not aligned to the image.
   - Screen shot B below shows the bubbles in **GREEN**, indicating the BNU is aligned to the image.
5. Press the capture button to acquire the image.

   ☑ Image will not be acquired until the bubbles are green, indicating proper positioning of 1° or less.

   ☑ See Image Capture Alignment section 7.2 for details on proper positioning.

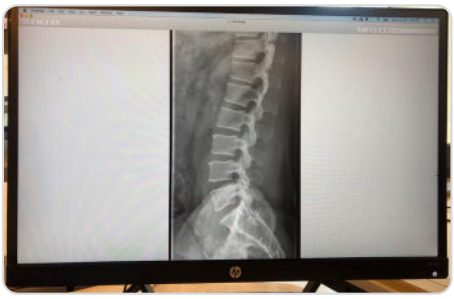
   ☑ The image will invert automatically.
6. Review image. ⚠ The image must include landmarks to aid in navigation and entry point identification. If the patient has severe atypical anatomy such that relevant anatomical structures cannot be identified, the BNS should not be used.
   - If acceptable, select ***Use photo***; the app will progress to the next step (acquire lateral image).
   - If unacceptable, select ***Retake***; the app will return to the image capture screen.

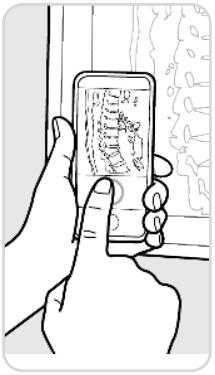


4.6 Acquire Lateral Image

⚠ Axial and lateral images must be displayed on a level (not rotated or tilted) monitor. The upright calibration screen can be found via the 'Before You Begin' page or via Settings>Upright Calibration.

⚠ The image must include landmarks to aid in navigation and entry point identification.





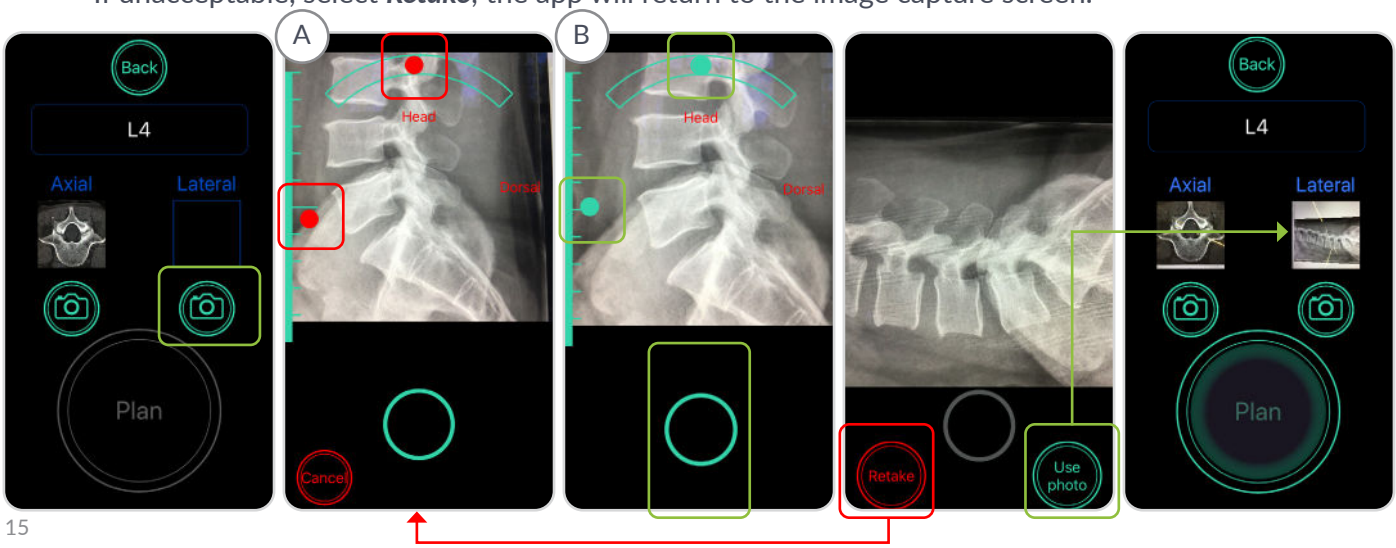
1. Ensure that the target image is displayed on the monitor.
2. Position the BNU in front of the image.

   ⚠ Ensure there are no obstructions between the camera and monitor. Ensure that the image is centered on the level to be operated on and is large enough to identify the relevant rigid anatomical landmarks and to effectively plan in section 4.9.

   ⚠ Hold the BNU steady when capturing image.
3. Tap the camera button under lateral.
4. Use the horizontal and vertical "bubble" indicators to align the device to the image.
   - Screen shot A below shows the bubbles in **RED**, indicating the BNU is not aligned to the image.
   - Screen shot B below shows the bubbles in **GREEN**, indicating the BNU is aligned to the image.
5. Press the capture button to acquire the image.

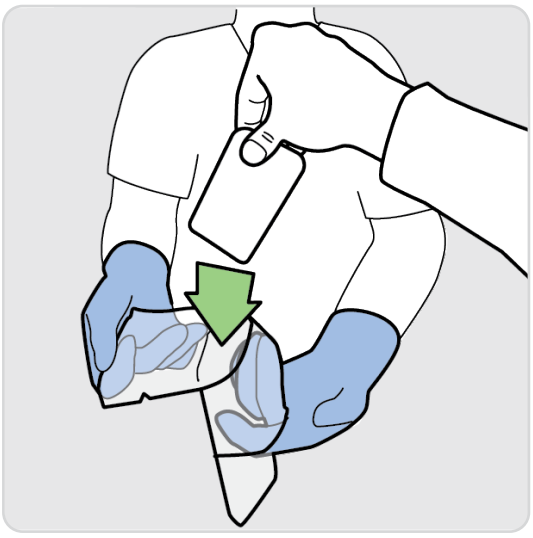
   ☑ Image will not be acquired until the bubbles are green, indicating proper positioning of 1° or less.

   ☑ The image will rotate automatically according to the settings established in section 4.3.
6. Review image. ⚠ The image must include landmarks to aid in navigation and entry point identification. If the patient has severe atypical anatomy such that relevant anatomical structures cannot be identified, the BNS should not be used.
   - If acceptable, select ***Use photo***; the ***Plan*** button will become active.
   - If unacceptable, select ***Retake***; the app will return to the image capture screen.



4.7 Drape the Device

⚠ Acquire all images prior to placing the BNU in the sterile drape.



Non-Sterile Team Member

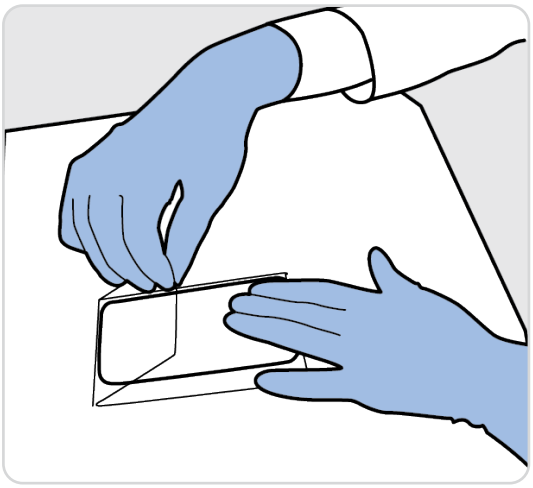
1. Open the sterile drape packaging and present the drape to a sterile team member.

Sterile Team Member

2. Remove the sterile drape from package using aseptic technique and hold it open.

Non-Sterile Team Member

3. Retrieve the BNU and place it top-down into the sterile drape with the front of the BNU facing the flap. The closure adhesive will be secured at the back of the BNU.



Sterile Team Member

4. Fold the sterile drape around the BNU and securely attached the closure adhesive.

   ☑ The closure adhesive must be secured at the back of the BNU.

   ☑ When securing the drape, ensure wrinkles are eliminated as much as possible from the front of the BNU and have not bunched up on the back .

[Step 5 Continued on next page]

4.7 Drape the Device

Sterile Team Member

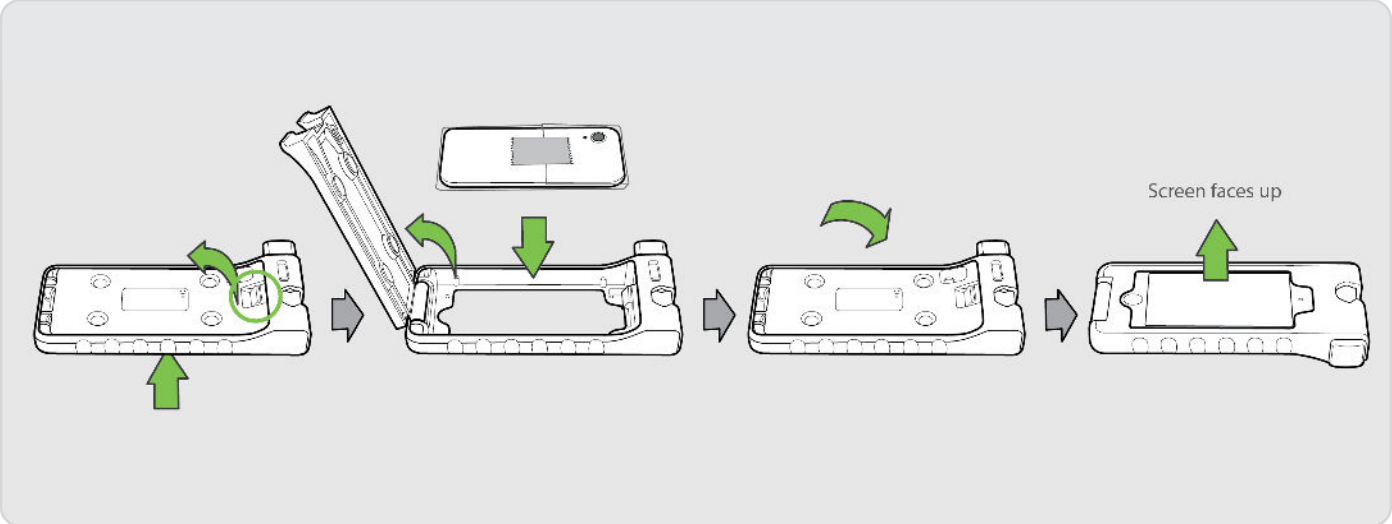
⚠ Ensure you are holding the BNS over a table before attempting to insert the draped BNU.

5. Press the release tab and push up from the bottom to open rear cover.
6. Insert draped device into the single-use case.

   ⚠ Ensure BNU is inserted with the screen facing down and the bottom of the BNU (look for the charging port) at the hinge of the interior of the single-use case.

   ⚠ Keep fingers clear while inserting the draped BNU into the single-use case.

   ⚠ Keep fingers clear while attaching the single-use case to the surgical instrument.
7. Close the rear cover until it snaps closed.
8. Turn the case over and check that the screen is facing up.



4.8 Establish and Confirm Entry Point with Fluoroscope

⚠ Utilize this step to confirm that the level marked is the intended operative level.

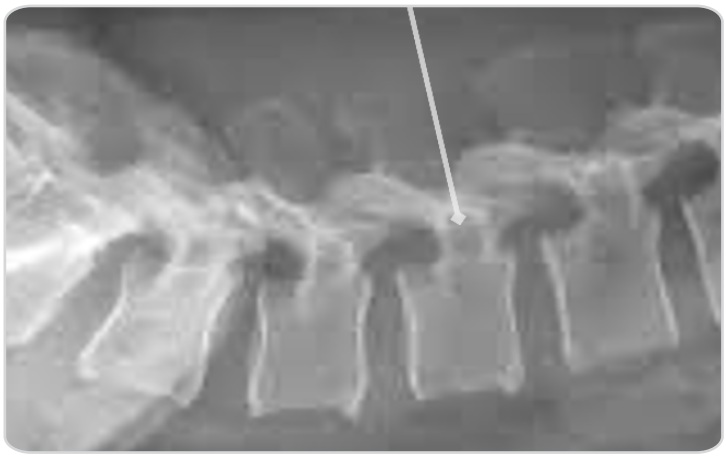
☑ Confirm entry point with a lateral fluoroscopic spine X-ray prior to planning the entry point on the BNU. Reacquire the image if it is not clear enough to confidently determine the appropriate entry point.

1. Establish entry point for the fixation device through the use of the fluoroscope and / or via direct visualization.

2. Decorticate the entry point where fixation is to be placed.

3. Place a radiopaque marker, such as a Penfield or Jamshidi needle, at the decorticated entry point.

4. Acquire lateral X-ray with the fluoroscope. This image will act as a reference during the planning phase with the BNU to assist in confirming correct navigation planning.



☑ Confirming the entry point just prior to trajectory planning is important as it assists in navigation planning and can alert the user if there has been unidentified patient movement since the original images were acquired with the BNU in step 4.6.

⚠ If the operating table has been repositioned since the images were acquired in 4.6, the table must be returned to the original position when the images were acquired.

⚠ If the patient has moved since acquiring the images in 4.6, the steps from 4.6 on must be repeated.

⚠ User must be able to identify all relevant rigid anatomical structures to identify the entry point and plan trajectory

⚠ For percutaneous procedures, AP and lateral X-rays must be used to determine entry point. If entry point cannot be clearly identified, the BNS should not be utilized.

4.9 Plan Trajectory

☑ Use the fluoroscopic image acquired in 4.8 as a reference during the planning process.

⚠ Utilize this step to confirm that the level marked is the intended operative level.

⚠ User must ensure that they are planning the correct side as indicated by the “L” (left) and “R” (right) indicators. Failure to do so will result in incorrect navigational guidance.

⚠ The BNS does not provide guidance on screw size. User should use existing tools to establish and confirm screw size including length and width. Anatomical conditions that require avoidance of critical structures identified on the original display should be assessed for planning appropriateness considering the possibly degraded image and lack of length / diameter screw planning.

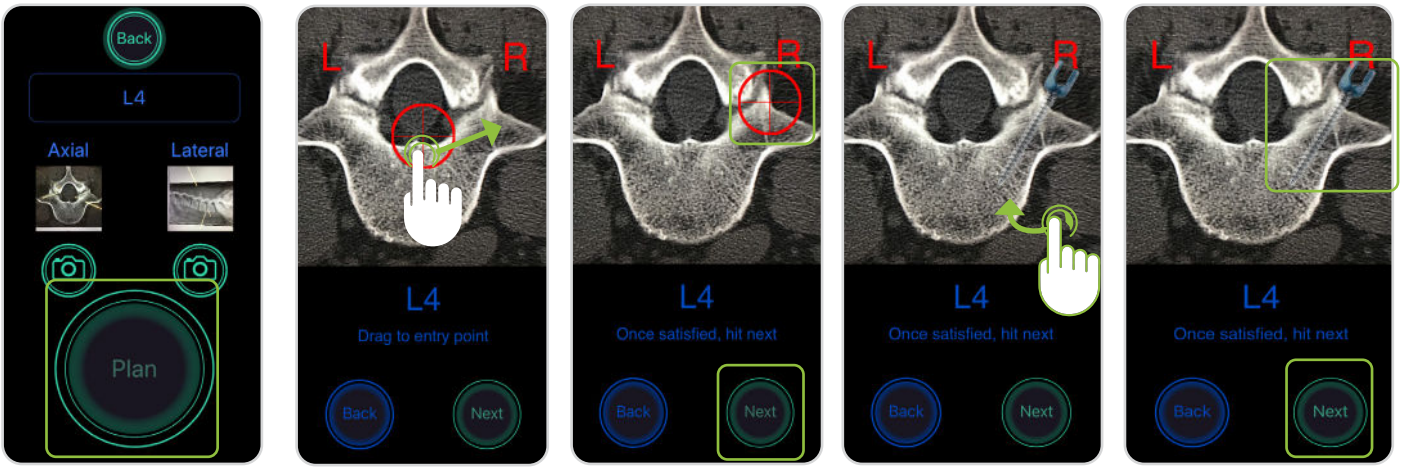
1. Tap ***Plan***.

   The app begins planning with the axial image.

2. On the axial image, position the cross hairs to the desired entry point as established by the surgeon on the first side, then tap ***Next***.

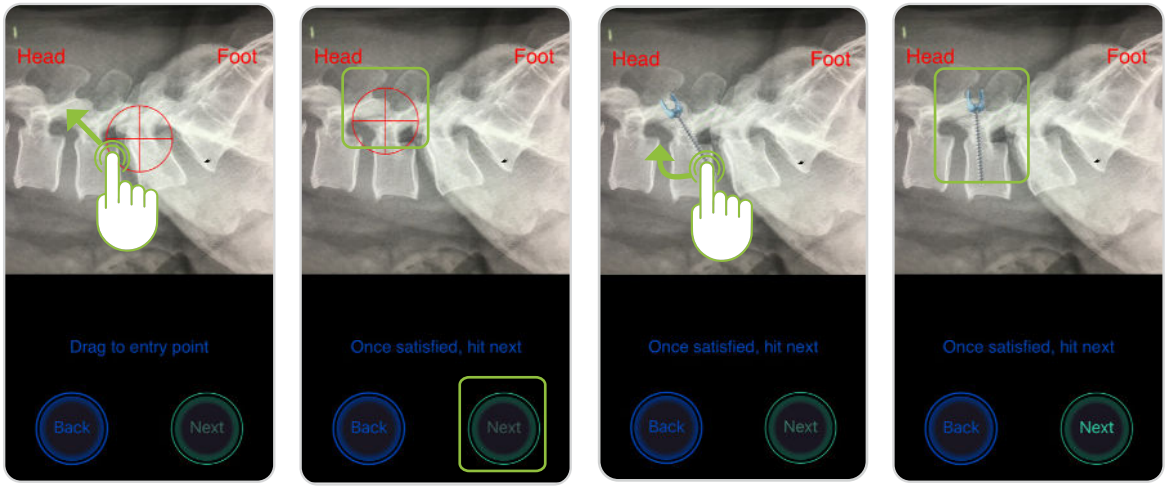
3. When the implant image appears, use your finger to rotate to the implant image to the desired trajectory, then tap ***Next***.

4. On the lateral image, position the cross hairs on the desired entry point on first side, then tap ***Next***.



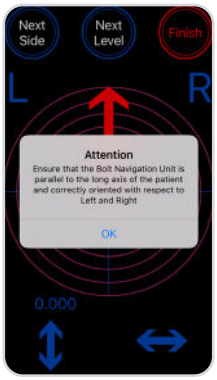
5. When implant image appears, use your finger to rotate to rotate the implant image to the desired trajectory.

6. Tap ***Next***.



4.10 Navigate to Establish Pilot Hole / Fixation Trajectory

1. An Alert Box with the following message will appear:



   "Ensure that the BNS is parallel to the long axis of the patient and correctly oriented with respect to left and right."

   ⚠ The user must ensure the BNS is parallel to the long axis of the patient and correctly oriented with respect to left and right. Failure to do so may result in incorrect navigational telemetry.

2. Adjust positioning if necessary to the Alert Box message and press ***OK*** when ready.

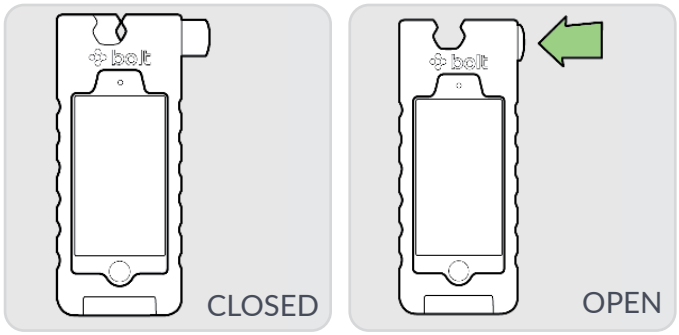
   ⚠ The BNS does not track and cannot identify patient movement. The patient must be in the same position as when the perioperative fluoroscopic imaging is acquired. If movement is suspected, new images should be acquired, and use of the system restarted from the beginning.

3. Depress the plunger to open the surgical instrument receptor.

   ☑ The single-use case has two positions, CLOSED and OPEN.

   ☑ The single-use case defaults to the CLOSED position using a spring-loaded plunger.

   ⚠ Do not fully depress then suddenly release the plunger.

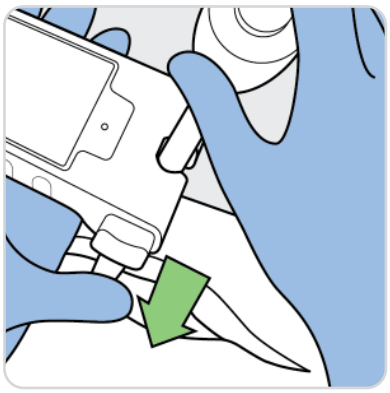


4. With the surgical instrument receptor in the OPEN position, situate the single-use case so that the surgical instrument shaft sits completely within the receptor opening.

5. Once in place, release the plunger to clamp the single-use case onto the surgical instrument shaft.

   ⚠ Ensure there is no interference between the clamping mechanism and the surgical instrument shaft.

   ⚠ The single-use case must be attached to the instrument in a location where the instrument shaft is not tapered.



☑ In the event that the user needs to re-acquire the image, the BNU can be removed from the case and handed off the field in its sterile drape. The BNU can then be removed, and image(s) reacquired per steps 4.5 and / or 4.6 above. The device can then be re-entered into the sterile field by being placed in a new drape per section 4.7 above and placed back in the Bolt Navigation Case.

4.10 Navigate to Establish Pilot Hole / Fixation Trajectory

⚠ The single-use case must be perpendicular to the surgical instrument.

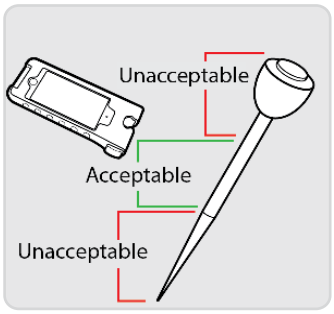
⚠ Positioning must allow for angular travel necessary to establish proper fixation positioning.

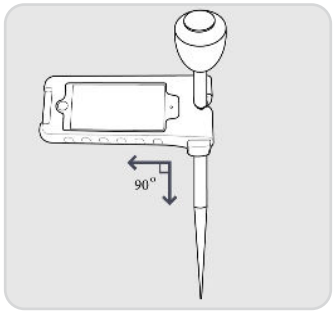
6. Place the distal tip of the surgical instrument at the established, decorticated entry point, then attach the BNS to the non-tapered mid-shaft of the instrument.

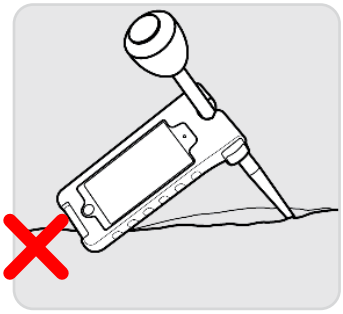
⚠ Misplacing the entry point of the surgical instrument may result in misplaced fixation resulting in pain, non-union, re-operation, CSF leak, nerve damage or other complications

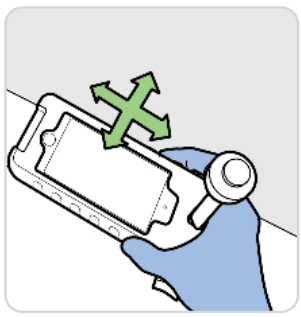
⚠ If entry point has been modified from that selected in the planning phase, Section 4.9, tap the “Next Side” button and re-plan according to the revised entry point.

7. Follow the high visibility arrow and direction finder to establish the planned position.









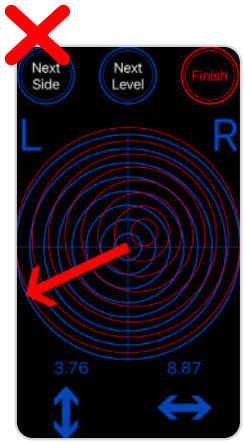
RED arrow indicates that the tool is greater than 3° from the planned trajectory.

YELLOW arrow indicates that the tool is between 1°and 3° from the planned trajectory. (Note that the arrow becomes progressively longer and more orange as it approaches 3°.

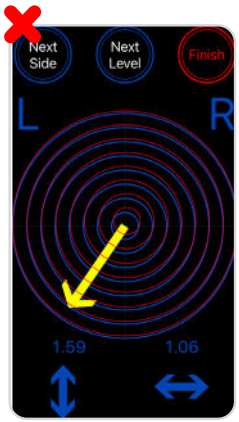
NO arrow indicates that the tool is less than 1° from the planned trajectory

BLUE and **RED** circles indicate the trajectory is not correctly aligned.

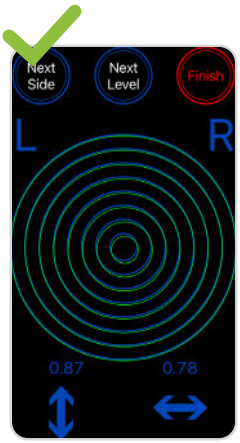
GREEN blinking circles indicate alignment is less than 1° of the planned trajectory.



>3°



>1° and <3°



<1°

⚠ Do not use the case to manipulate the tool.

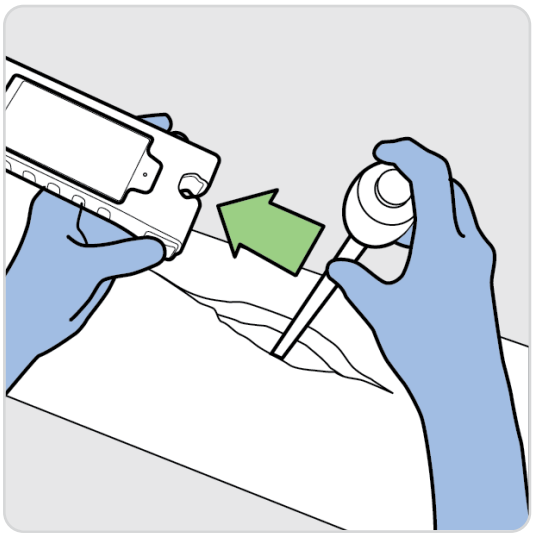
⚠ If the BNS is removed after trajectory is established and before pilot hole creation/fixation placement,ensure trajectory is not altered.

⚠ If entry point has been modified from that selected in the planning phase, Section 4.9, tap the “Next Side” button and re-plan according to the revised entry point.

☑ The arrow and bullseye navigation function of the BNU is intended to provide navigational guidance to the user on achieving the planned trajectory in three degrees of freedom from the entry point. This telemetry provides feedback on the direction to move the BNS / surgical instrument assembly to achieve the planned trajectory. When within 2° of the planned trajectory, the cross-hairs begin to flash. When within 1° of the planned trajectory, the circles turn green and the cross-hairs continue to flash. More exact trajectory still can be achieved by matching the circles completely. Position can be validated by confirming position based on the X and Y numerical feedback at the bottom of the bullseye trajectory screen.

4.11 Remove System & Complete Level

1. Once the correct angle for insertion has been established:
   - The BNU and single-case can remain in place on the instrument during pilot hole creation / fixation placement, or
   - The BNU and single-use case can be removed from the instrument.
2. Use the instrument to prepare the site for implant placement.
3. Complete implant placement utilizing the system in a similar fashion for taps and/or drivers as desired.



4.12 Repeat for Next Side & Next Level, as needed

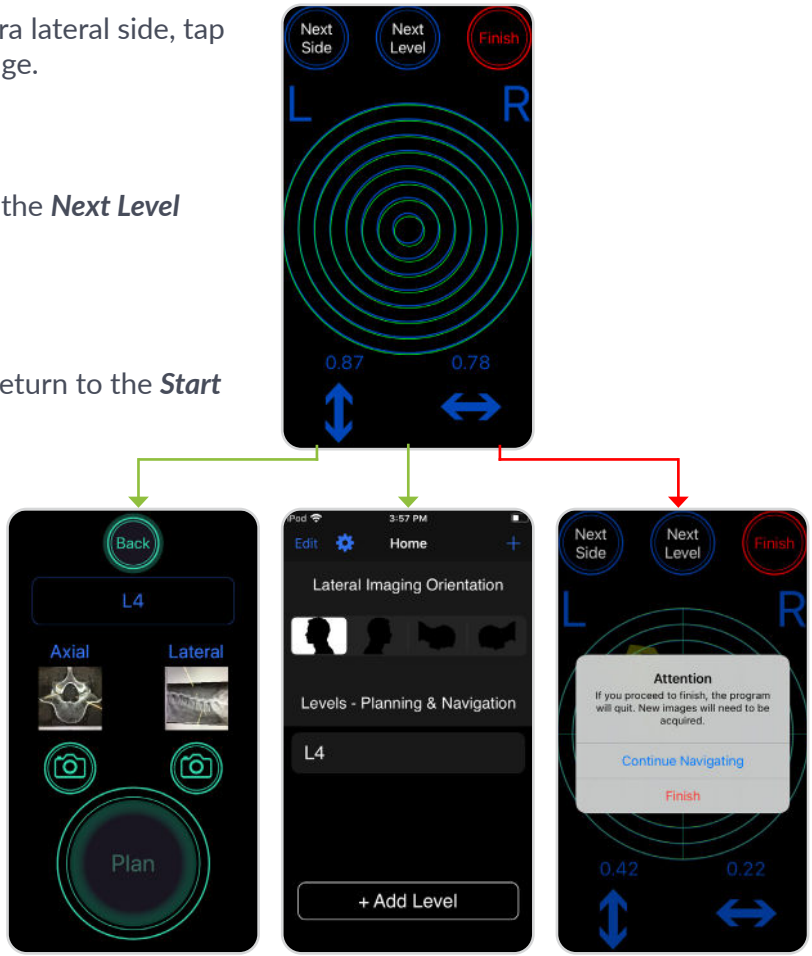
1. To complete fixation on the patient's contra lateral side, tap the ***Next Side*** button to return to axial image.

   Complete Sections 4.9 and 4.10.
2. To select the next level for operation, use the ***Next Level*** button to return to the ***Home*** screen.

   Repeat Section 4.8 onward.
3. To complete the procedure, tap ***Finish*** to return to the ***Start*** screen.

   A confirmatory alert will pop up to ensure that the desire is to finish the procedure and warn that if done, new images will need to be acquired.

   ⚠ Images will need to be re-acquired if ***Finish*** is tapped.



5. Complete Procedure

5.1 Complete Procedure Using Standard Clinical Practice

Complete the procedure according to standard clinical practice.

5.2 Procedure Data

Images are purged from the navigation system when Finish is selected. Screen shots of the planning screens are stored in the photos app.

⚠ New images will need to be acquired to continue using the BNS upon pressing ***Finish***.

5.3 Disassemble & Clean or Discard Bolt Components

Once the procedure is complete:

1. Remove the BNS from the sterile field.

   ⚠ Handle according to hospital procedures for managing potentially contaminated equipment.

2. Ensure you are holding the BNS over a table before attempting to remove the BNU.

3. Press tab and push up from the bottom to open rear cover.

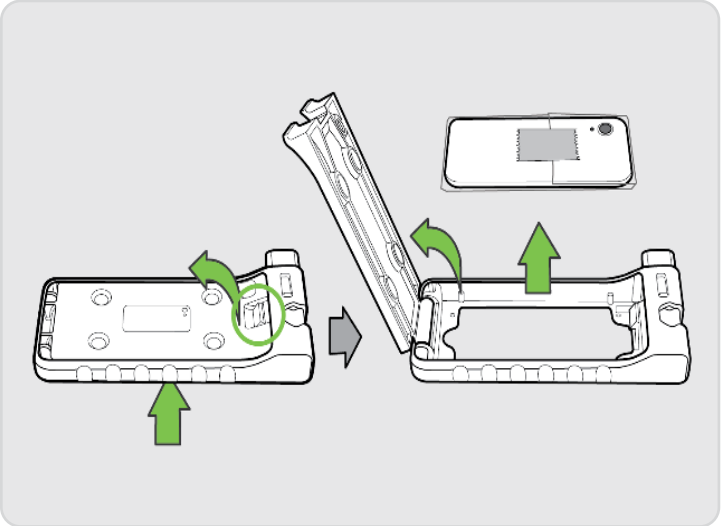
4. Remove the BNU from the case.

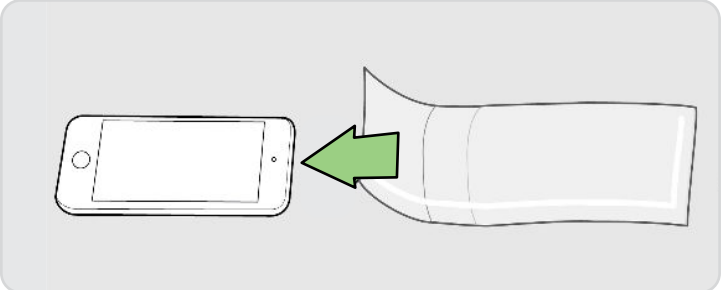
5. Open the drape and remove the BNU.

6. Discard the single-use case and the drape.

   ⚠ **DO NOT DISCARD the BNU.**

7. Clean and store the BNU according to approved procedures. See next section for details.





6. BNU Maintenance

6.1 Cleaning & Disposal

1. Once removed form the sterile field, clean the external surfaces of the BNU with either:
   - Isopropyl alcohol 70%
     - Wet a lint free wipe
     - Thoroughly wet all surfaces of the BNU, removing any visible particles
     - Allow the surfaces to remain wet for one (1) minute
     - Air dry

   or

   - Sani-Cloth® Prime Germicidal Disposable Wipes (or equivalent) - see manufactures instructions for additional details
     - Unfold a clean wipe
     - Thoroughly wet all surfaces of the BNU, removing any visible particles
     - Allow the surfaces to remain wet for one (1) minute
     - Air dry
2. Visually inspect if the external surfaces are clean. Repeat the above cleaning step if the user determines a surface is not visually clean
3. Dry the BNU using a dry cloth.
4. Place the clean BNU on the charger in the designated storage location.
5. Dispose of the single-use case, sterile drape, and all packaging.

⚠ The BNU must be cleaned thoroughly between uses.

⚠ The BNU should be cleaned prior to the start of the procedure and before returning it to storage.

⚠ Do not attempt to sterilize BNU.

⚠ Do not immerse the BNU in cleaning agents or any other liquid.

⚠ Ensure the BNU is dry before removing it from the procedure room.

6.2 Charging

When not in use, the BNU should be charging in the designated charging area outside of the OR. The BNU should be charged in the location it will be stored; storage locations will vary by facility and should align with the specifications found in Section 8.4.

To charge:

1. Ensure the BNU has been thoroughly cleaned according to the cleaning procedure in Section 6.1.
2. Connect the BNU USB 2.0 lightning power adapter directly into a power outlet outside of the operating room using the included charger cable and a compatible power adapter (sold separately).
   - The charger will be provided with the BNU. Only use the charger cord provided with the BNU.
3. Allow the BNU to charge to at least 50% battery before next use. The battery icon is in the upper-right hand corner and shows the battery level. ⚠ Do not use a BNU below 50% charge.

⚠ Do not charge in wet locations or where there is a risk that it could become wet. Do not connect the power adapter with wet hands. If you suspect there may be liquid in or on the charging cord do not use.

⚠ The BNU contains a Lithium ion battery. Please handle and dispose of properly; the BNU or its battery should never be thrown in the garbage.

⚠ Do not charge by or otherwise connect to a computer or any other device. The BNU should only be charged via wall socket.

⚠ Do not use the power adapter or charging cable if the cable becomes frayed or damaged, if either are exposed to liquid or excess moisture, or if the power adapter is dropped or damaged in any way .

USB power adapter specifications:

- Frequency: 50 or 60 Hz, single phase
- Line voltage: 100 to 240 V
- Output voltage: 5v/1A
- Output port: USB 2.0 lightning

6.3 Replacement & Disposal

⚠ **DO NOT DISPOSE OF THE BNU.**

The BNU should be returned to the manufacturer in a safe manner once it reaches the end of its life, or if any of its components malfunction.

Please contact the manufacturer for return instructions:

Circinus Medical Technology, LLC

dba Bolt Navigation

100-7 Domino Dr.

Concord, MA 01742

USA

www.boltnav.com

info@boltnav.com

Considerations prior to returning the unit:

- Always clean the BNU before shipping to ensure removal of any visible contaminants.
- The BNU contains a lithium ion battery. This should be taken into consideration when shipping the unit.

7. Reference Guide

7.1 Image Capture Sizing

When capturing the axial and lateral images from a monitor onto the BNU, ensure each image is displayed as large as reasonably possible on the monitor. This will ensure a clearer image transfer onto the BNU.

Ensure that images are of appropriate quality to identify the target skeletal anatomy with appropriate land marks.

7.2 Image Capture Alignment

If image capture is activated and then the phone is quickly swept up/down/left/right to the correct phone orientation, the bubble levels can not keep up with the image capture. The bubble levels will indicate the BNU was not within the image capture tolerance and the resulting image will appear incorrect, although it is not.

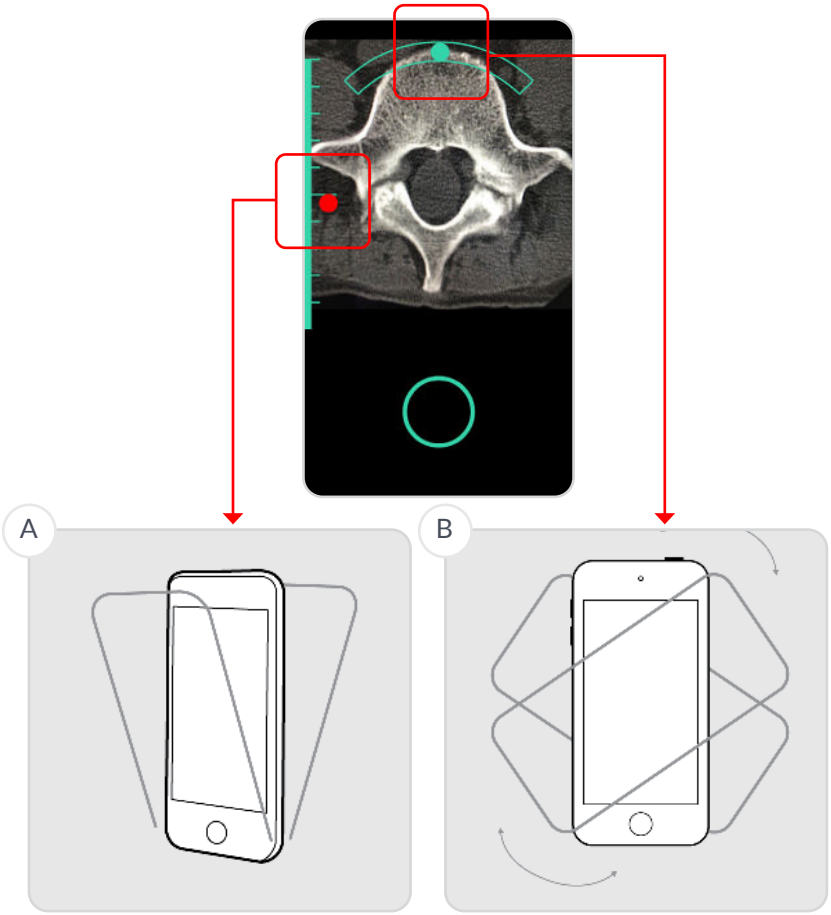
⚠ Do not rotate the phone quickly while capturing image.

The BNU will not capture the axial or lateral images until the alignment bubbles on the left and top of the screen are both centered on the mid line tick mark and the bubbles have turned green.

A. If the bubble on the left is red, slowly and slightly tip the top or bottom of the BNU until the bubble is centered and green.

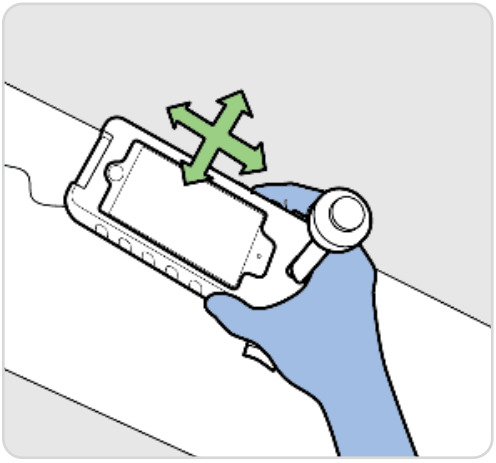
B. If the bubble on the top is red, slowly and slightly tip the left and right sides of the BNU until the bubble is centered and green.

If image capture button is tapped, blinks, but is not capturing the image, it is not properly positioned. Rotate as advised above until the bubble indicators are properly aligned and turn green

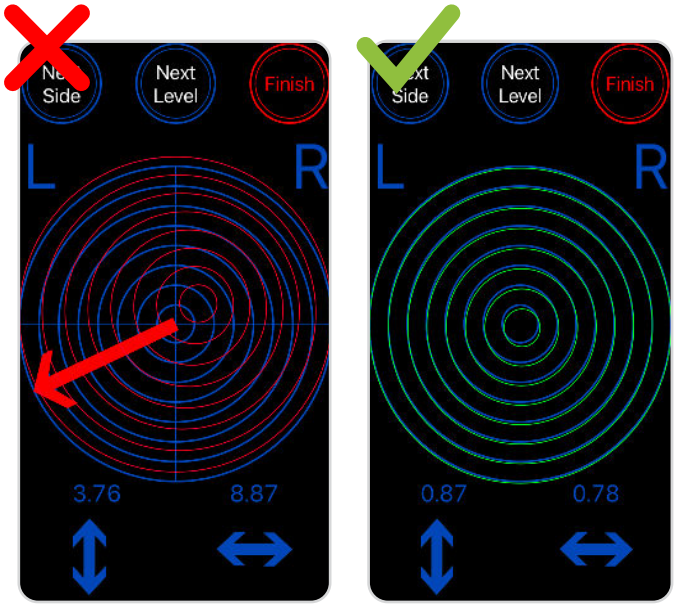


7.3 Fixation Angle Navigation

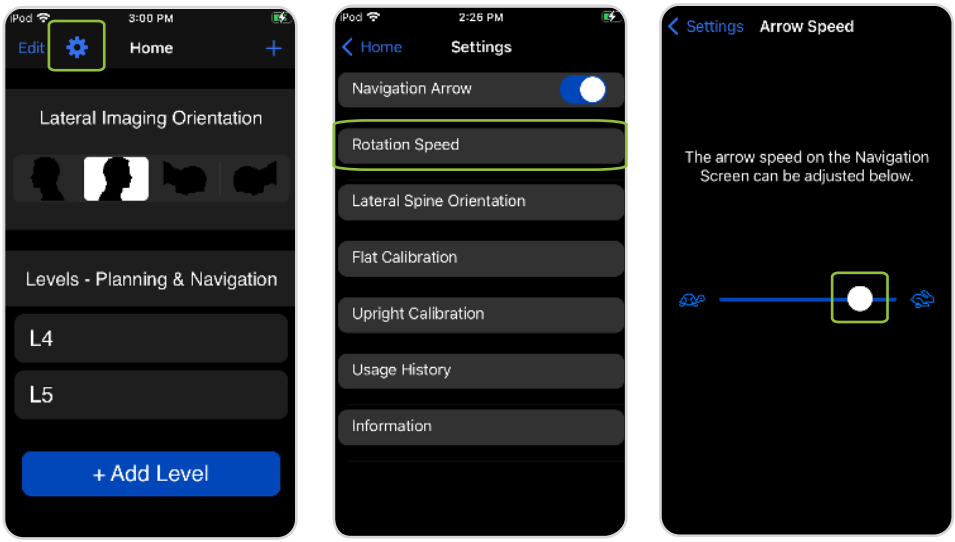
Place tip of surgical instrument on established entry point and move the BNS/surgical instrument assembly slowly forward/backward/left/right to align circles.



The optional high visibility arrow is recommended and comes in the on-position. This arrow directs the exact direction to move to achieve the planned trajectory.

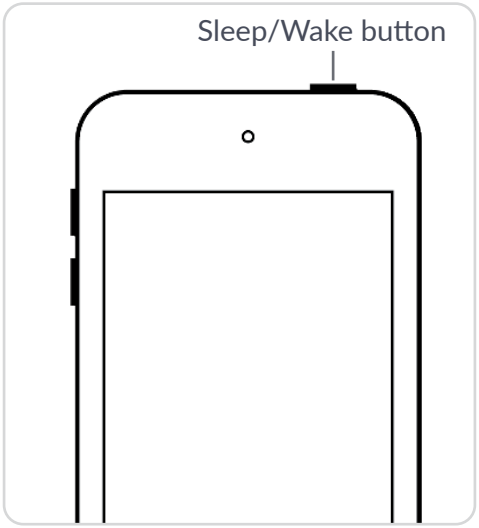


The speed at which the arrow travels can be adjusted in Settings > Rotation Speed.



7.4 Turning BNU On and Related Trouble Shooting

Wake the BNU



To wake BNU, do one of the following:

- Press the Sleep/Wake button, or
- Raise the BNU. You can turn off Raise to Wake in Settings > Display & Brightness.

Restart BNU

If your BNU isn't working, try restarting it by turning it OFF then ON.

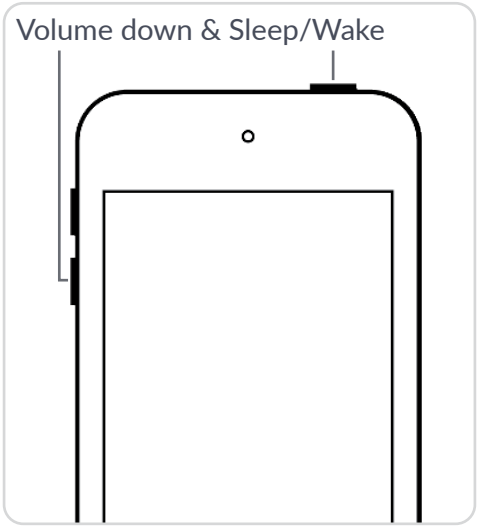
To turn off the BNU, do one of the following:

- Press and hold the Sleep/Wake button until the slider appears, then drag the slider, or
- Go to Settings > General > Shut Down, then drag the slider.

To turn the BNU back on, press and hold the Sleep/Wake button until the Apple logo appears.

If you can't turn the BNU OFF and ON, try forcing it to restart.

Force Restart of the BNU



If the BNU won't turn on or isn't responding, and you can't turn it OFF and ON, try forcing it to restart by completing the following two steps:

1. Press and hold the Sleep/Wake and the Volume down button at the same time.
2. When the Apple logo appears, release both buttons.

If the BNU still does not respond please contact the manufacturer per Section 6.3

7.5 Frequently Asked Questions

Q: Does it matter what orientation you hold the BNS in?
A: Yes, along the axis of the patient with the head at the top.

Q: What if the patient's spine segment demonstrates a rotational deformity?
A: That's OK, the system accounts for it.

Q: Why does the axial image flip?
A: Because right is left and left is right, following convention.

Q: What if the patient has scoliosis and one pedicle is more caudal than the other?
A: A true lateral image is necessary, thus multiple x-rays may be needed to ensure that the end plates of the vertebral body line up for each segment that will have pedicle screws.

Q: I like to use reverse Trendelenburg, is that OK?
A: Yes, as long as the lateral images captured by the BNS are in that orientation and the system is used while the patient is in that exact same position. The patient cannot be airplaned while capturing images or using the system.

Q: Can you change the table height?
A: Yes.

Q: What if the patient is not flat (not parallel to the table)?
A: Use the built-in calibration screen to ensure the patient is flat.

Q: How do you know which level is shown on the lateral x-ray?
A: You can place a marker, include anatomical landmarks, or zoom in so only the desired level is the only option.

Q: When checking the monitor, what angle is acceptable?
A: As close to zero degrees as possible. This can be checked using the built in calibration screen.

Q: Should you take the BNS off or leave it on when using the tap and/or driver?
A: It is user preference.

Q: Is patient data entered into the BNS from the EMR or hospital system?
A: No, it is not integrated with the EMR. The BNS allows the user to capture images of the axial slices of levels to be operated on from the patients diagnostic MRI or CT scans and lateral X-rays of the levels to be operated on once the patient is positioned on the table.

Q: What if the BNU gets lost?
A: The BNU is password protected and the company can wipe the system remotely.

Q: If your entry point is off will the system tell you?
A: No. You need to pick the entry point on the axial and lateral images. It is recommended that the user locate the entry point on the patient, then plan according to that location.

8. Specifications

8.1 Notice

Copyright

Patents

The Bolt Navigation System and its components are covered by U.S. and international patents including but not limited to U.S. patents: 11,123,840, 11,000,335, 11,737,828 and 11,832,886.

Trademark Acknowledgments

The name “Bolt” is a registered trademark of Circinus Medical Technology, LLC. Other product names may be trademarks of their respective owners.

Manufacturer:

Circinus Medical Technology, LLC

100-7 Domino Dr.

Concord, MA 01742

USA

Document Number BN003-01-01US

Parts covered by this IFU: BN 001-01-01 (Bolt Navigation Unit), BN 002-01-10 or BN 002-01-01 (Bolt Navigation Case) and illustrates use with 05-IP100 (off-the-shelf single use drape supplied by Advance Medical Design).

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

For complaints or technical support please call: +1.866.682.3422

For more information or to reorder, please visit: www.boltnav.com

8.2 Symbols

This section explains the symbols that appear on the device and packaging.

QTY	Quantity
LOT	Batch code
	Single use, do not reuse
	Do not re-sterilize
	Single sterile barrier system
℞ only	Restricted to sale by or on the order of a physician
	Manufacturer name and address
	Date of manufacture
STERILE EO	Sterilization method: Sterile drape sterilization method is EO
STERILE EO	Sterilization method: Single-Use Case sterilization method is EO
	Use by date
	Caution, see Instructions for Use
	Storage temperature range limits
	Storage humidity range limits
	Storage ambient pressure range limits
NON STERILE	Non sterile
eIFU Indicator	See on-line Instructions for Use, found at: www.boltnav.com
LATEX	No latex
	Do not use if package is damaged and consult instructions for use
MD	Medical Device
	BNU is locked.
	BNU battery level or charging status.
	BNU battery is charging.
UDI	Unique device identifier
	BNU connected to the Internet over Wifi.

REF	Catalogue number
EC REP	Authorized representative in the European community
CE 2460	European Union certificate of conformity
	Importer

8.3 Electrical

USB 2.0 Lightning to USB charger cable (1 m length)

Lithium Ion battery

1,043mAh battery capacity

Max charging speed of 5V/1.0A

8.4 Environmental

Operating, storage, and transportation conditions:

- The BNS shall operate in the following environmental conditions:
  - Temperatures between 15° C and 30° C, inclusive
  - Relative humidity between 10% and 90%, non-condensing
  - Pressures between 70 kPa and 101 kPa, inclusive
- The BNU shall operate after exposure to the following shipping and storage environmental conditions:
  - Temperatures between -25° C and 70° C, without relative humidity control
  - Relative humidity between 10% and 90%, non-condensing
  - Pressures between 70 kPa and 101 kPa, inclusive
- The Case shall operate after exposure to the following shipping and storage environmental conditions:
  - Temperatures between -29° C and 60° C, without relative humidity control
  - Relative humidity between 30% and 80%, non-condensing

Electromagnetic Conformance (EMC)

The Bolt Navigation System (BNS) is intended for use in hospital or hospital-like environments, typically in the Operating Room, by qualified healthcare professionals. The emissions characteristics of the BNU*, CISPR 11 Class A, make it suitable for use in hospitals settings. The BNU may not offer protection against radio-frequency communication equipment. The user may need to take mitigation measures such as relocating or re-orienting the BNU such that it is no closer than 30cm to the communications equipment.

Electro Magnetic Emissions	
Emission Test	**Compliance**
Radiated emission CISPR 11	Class B
Radiated emission CISPR 11	Class A (Tested to the higher Class B levels for compliance)

*The BNU is based on a 7th Generation iPod Touch®.

8.4 Environmental

Electromagnetic Immunity	
Immunity Test	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	8KV – Contact 15KV – Air
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2700MHz
Radiated RF IEC 61000-4-3	27V/m 385MHz
Radiated RF IEC 61000-4-3	28V/m 450MHz
Radiated RF IEC 61000-4-3	9V/m 710MHz, 745MHz, 780MHz
Radiated RF IEC 61000-4-3	28V/m 810MHz, 870MHz, 930MHz
Radiated RF IEC 61000-4-3	28V/m 1720MHz, 1845MHz, 1970MHz
Radiated RF IEC 61000-4-3	28V/m 2450MHz
Radiated RF IEC 61000-4-3	9V/m 5240MHz, 5500MHz, 5785MHz
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m 50 Hz and 60Hz

⚠ Use of the BNU in proximity to high intensity electromagnetic fields, such as from magnetic imaging, should be avoided.

⚠ The performance of the BNU should be monitored if used next to stacked equipment. The BNU should not be stacked with or placed on other equipment.

⚠ Use of the BNU with accessories, such as cables, other than those specified by Circinus Medical Technology could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

⚠ The BNU is intended for use in hospital environments. To maintain the performance and safety of the BNU the user should take care to follow all instructions and heed all warnings in these Instructions for Use, including the cautions outlined in the Electromagnetic Conformance section. Following the instructions will ensure proper performance throughout the life of the device, including device charging per section 6.2.

IEC Compliance

The BNS has been tested for compliance to the following international standards for Medical Electrical Equipment:

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

8.5 Reusable & Disposable Specifications

	BNU*	Case
Shelf Life:	NA	12-months
Expected Lifetime:	300 full charge cycles	NA
Sterilization Method:	Non-sterile	EO
Weight:	<1lb	<1lb
Dimensions (mm):	123.4 x 58.6 x 6.1	177.8 x 70.3 x 27.3
Material:	Aluminum and glass	ABS
Display Type:	• 4 in (100 mm) diagonal widescreen display with Multi-Touch IPS technology • 1136-by-640-pixel resolution at 326 ppi 800:1 contrast ratio (typical) 500 cd/m2 max brightness (typical) • Fingerprint-resistant oleophobic coating	NA
Processor Type:	• Apple A10 Fusion • 1.63 GHz 64-bit dual-core	NA
Battery Specs:	• Rechargeable • Lithium-Ion battery • Operating Time (100 - 0%): #hrs • Charge Time (0 - 100%): #hrs • 3-axis gyroscope	NA
Gyroscope/ Accelerometer	• 3-axis gyroscope • M10 motion coprocessor	NA

*The BNU is based on a 7th Generation iPod Touch®.

bolt®

spine navigation system

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