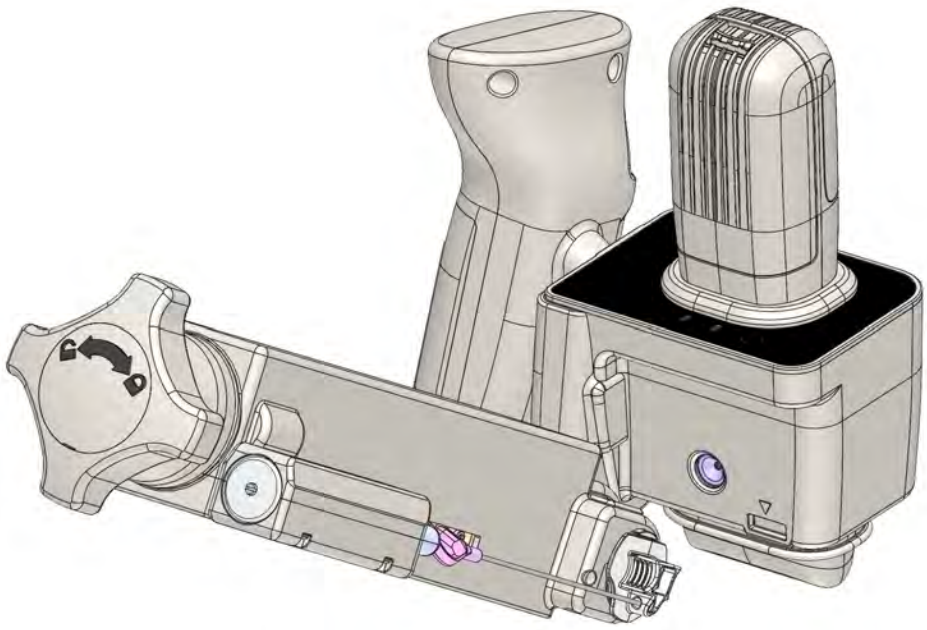
CERTA™ Access System Instructions for Use (IFU)



Important Safety Notice to Users of the OBVIUS Robotics CERTA Access System

This manual and the equipment it describes are for use only by qualified medical professionals with adequate training and experience in central venous access procedures and use of the CERTA Access System. It is intended as a guide for both the CERTA Access Device and components.

The safe, effective use of the CERTA Access System depends upon factors and variables controlled by medical professionals using the system. It is important that operating instructions and user warnings supplied with the CERTA Access System be read, understood, and followed.

Please contact OBVIUS Robotics if additional training resources are needed.

OBVIUS ROBOTICS, INC.
SEVEN PATTON AVE, #1403
ASHEVILLE, NC 28801
Obviusrobotics.com
Tel: +1-954-895-6883

P/N 23070001 Rev 2.2 2023-11

Rx only

CONTENTS

 **WARNING:** Be sure to read and understand all information, particularly caution and warning information, found in these IFUs before using these products. Failure to properly follow all instructions, including instructions supplied with accessory devices such as battery chargers, CERTA ultrasound probe and CERTA display and the applicable user manuals for the CERTA Access Device may lead to injury and result in improper functioning of the device.

1 GENERAL INFORMATION

1.1 CONTACT INFORMATION

For Customer Service and Reporting Complaints or Adverse Events

Use the following information for customer service, including ordering, reporting complaints or adverse events, and general information regarding OBVIUS Robotics or its products and services.

OBVIUS Robotics, Inc.
7 Patton Ave #1403
Asheville, NC 28801
E-Mail: customerservice@obviusrobotics.com

If you have questions regarding the use, cleaning, storing of the CERTA Access System, contact Obvius Robotics Customer Service.

For the Integrated Ultrasound Probe

Use the following contact information for safety and general information regarding the Integrated Ultrasound Probe.

HEALCERION Co., Ltd.
1403-ho, 12, Digital-ro 33-gil, Guro-gu, Seoul, 08377, Republic of Korea
Homepage: www.healcerion.com
Tel: +(82) 70-7582-6326 / E-mail: info@healcerion.com

Additional information for the Integrated Ultrasound Probe may be found in the HEALCERION SONON 500L Ultrasound Imaging System User Manual.

1.2 SYSTEM DESCRIPTION:

The CERTA Access System is intended to provide the medical practitioner with the capability to insert a guidewire accurately and reliably into a vessel.

The CERTA Access System includes the following reusable components:

- **CERTA Access Device:** A handheld, image-guided, electromechanical system that enables physicians to visualize a target vessel and automatically advance a needle to this target. The device has an integrated ultrasound probe for visualizing the target anatomy. A manually adjustable aiming arm on the device can be raised or lowered to position an aiming reticle at the center of the targeted vessel. A needle advance button is used to advance the needle and activate micro vibrations to reduce force of penetration. A separate needle retract button is used for retraction of the needle.

- **CERTA Ultrasound Battery:** A rechargeable battery that connects to the Ultrasound probe.

- **CERTA Battery Charger:** A charger for the CERTA Ultrasound Battery.

- **CERTA Charger Power Supply:** A power supply for powering the CERTA Battery Charger.

- **CERTA Tablet:** A portable tablet device that utilizes the image viewer software application from the CERTA Access Device integrated ultrasound probe through an ad hoc Wi-Fi network, providing visualization of the needle position with respect to the center of the targeted vessel.

- **CERTA Tablet Power Supply:** A power supply for powering and charging the CERTA Tablet.

- **CERTA Verification Tool:** A hand-held rigid tool that connects to the CERTA Access Device via a receptacle, enabling the physician to verify that the device is operating correctly before each use.

Caution: The CERTA Access Device, CERTA Tablet and CERTA Verification Tool are non-sterile devices and should not be sterilized between uses.

The disposable components for the CERTA Access System include:

- **CERTA Sterile Drape with integrated Needle Guide:** A custom fitted drape to create a sterile barrier for the CERTA Access Device. The drape comes supplied with an attached needle guide that magnetically connects to the CERTA Access Device. It also comes supplied with an ultrasound gel pad to adhere to the integrated ultrasound probe, and a gel pad window and elastic band for securing the gel pad to the CERTA Access Device during draping.

- **TearDrop Needle:** An 18-gauge, beveled tip needle with a magnetic coupler for attachment to the CERTA Access Device.

WARNING: The CERTA Sterile Drape, Integrated Needle Guide and TearDrop Needle single-use consumables are incompatible with re-sterilization. The risk of re-use is infection to the patient and compromised functionality of the CERTA Access System. After use, properly discard the single-use consumables as hazardous medical waste in accordance with local regulations.

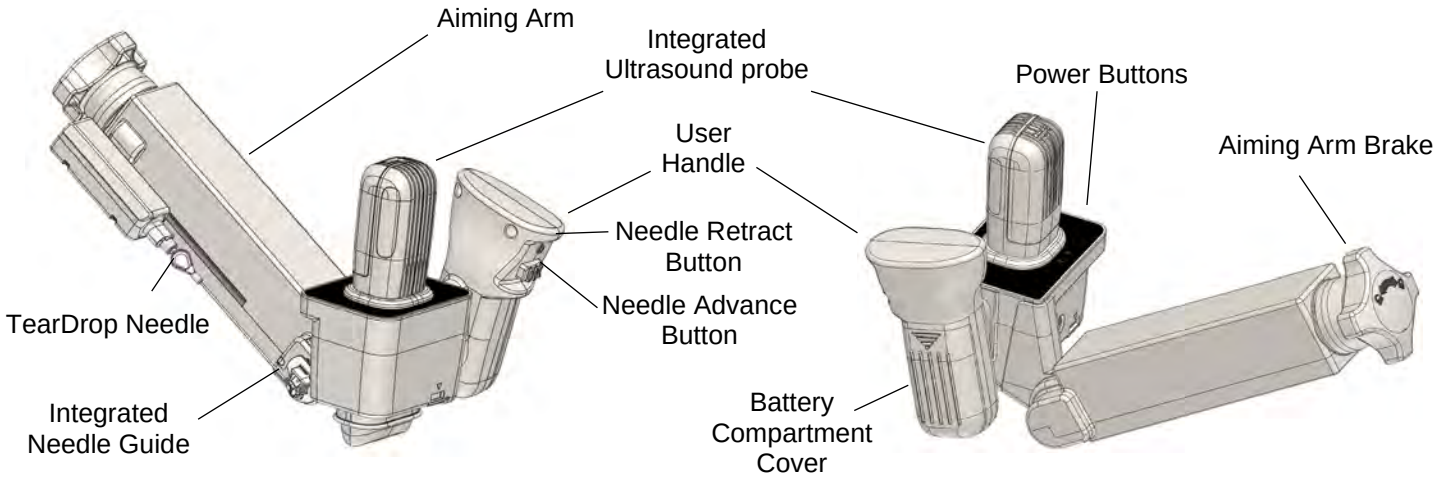


Fig. 1. Description of CERTA Access Device.

1.3 INDICATIONS FOR USE, WARNINGS AND PRECAUTIONS:

Environment: The CERTA Access System is intended for use in professional healthcare facility environments.

Indications for Use: The CERTA Access System is used to facilitate the placing of a needle at a targeted anatomical location for placement of a guidewire.

Contraindications:

- Vessel depth < 10mm
- Vessel depth > 50mm
- Vessel diameter < 9mm
- Overlying skin infection exists.

Warnings:

The CERTA Access System should only be used by qualified personnel familiar with vascular access procedures after they have completed the CERTA Access System training (which includes didactic and hands-on use with the CERTA Access System utilizing a vascular model).

The CERTA Access System may only be used with the Integrated Ultrasound Probe and CERTA Tablet, and is not compatible with any other ultrasound probe or tablet.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Do not attempt to substitute any other needle for the TearDrop Needle.

Do not attempt to manually advance the TearDrop needle while coupled with the CERTA Access Device.

The Aiming Arm Brake must be unlocked to align the target vessel and then relocked prior to advancing the TearDrop Needle.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS: (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE, AND (2) THIS DEVICE MUST ACCEPT ANY

INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRED OPERATION.

NOTE: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (For which CISPR class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

ELECTROSTATIC SENSITIVE DEVICE (ESD). OBSERVE PRECAUTIONS FOR HANDLING. UNINTENDED ELECTRO-STATIC DISCHARGE MAY CAUSE THE CERTA DEVICE TO POWER OFF OR RESET.

Precautions: The TearDrop Needle is compatible with guidewires with a maximum outer diameter (OD) of .035".

2 INSTRUCTIONS FOR USE

2.1 PRE-PROCEDURAL PREPARATION

1. Inspect the CERTA Access Device and CERTA Tablet for evidence of damage including the breakage of housing, loose parts, or tablet screen breakage. If damage is identified including breakage of the housing, loose parts, do not use.

2. Inspect the disposable components for packaging integrity and expiration dates. If the packaging appears to be damaged or the product expired, do not use.

WARNING: Patient injury may result if the package is opened or damaged prior to use, or if damaged components are used. Visually inspect the package and contents before each use. If there is any possibility that contamination may have occurred during set-up or use, remove the contaminated product and replace it with a new sterile product.

WARNING: The Sterile Drape, Integrated Needle Guide and TearDrop Needle single-use consumables are incompatible with re-sterilization. The risk of re-use is infection to the patient and compromised functionality of the CERTA Access System. After use, properly discard the single-use consumables as hazardous medical waste in accordance with local regulations.

3. Ensure the batteries are fully charged as indicated on the battery chargers and install in the CERTA Access Device User Handle and Integrated Ultrasound Probe respectively (Figure 2).

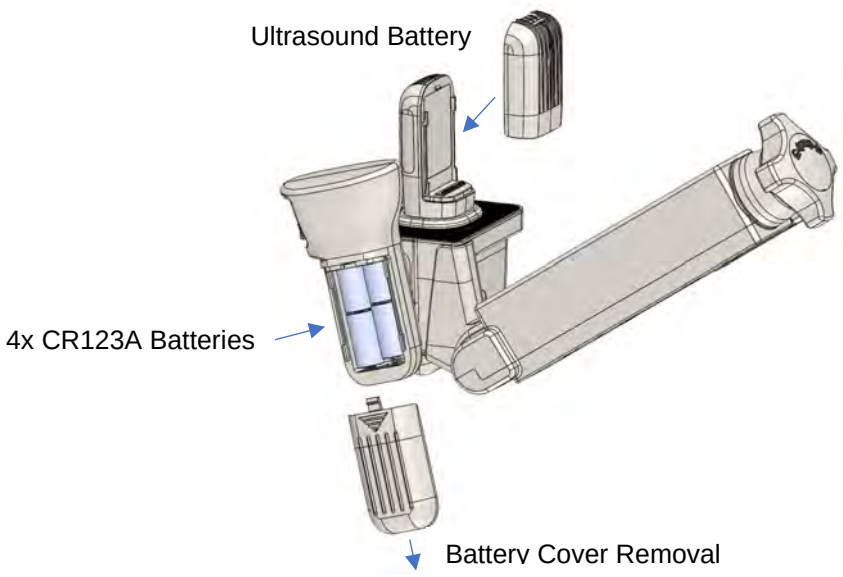


Figure 2. Battery Installation in CERTA Access Device.

Note: Uncharged batteries for the CERTA Device and Integrated Ultrasound Probe may inhibit the ability to complete the procedure.

4. Power on the CERTA Access Device, Integrated Ultrasound Probe and CERTA Tablet, allow it to perform a self-test and continue with the steps below. See Figure 3 for an explanation of the Battery and Status LED indicators which are located on the top of the CERTA Access Device.

Caution: Ensure the CERTA Tablet has been charged to at least 20% capacity before beginning a procedure. The loss of CERTA Tablet power during a case may delay the procedure.

Note: The power buttons for the CERTA Access Device, Integrated Ultrasound Probe and CERTA Tablet must all be turned on prior to use.

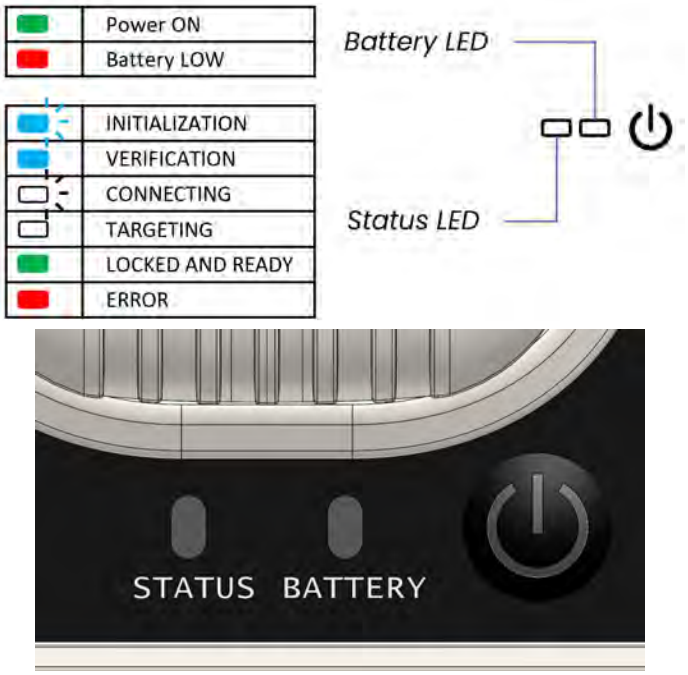


Figure 3: Battery and Status LED Indicators.

5. Complete wireless connections.
   - Open the Ultrasound Image Viewer Application on the CERTA Tablet. The application will automatically connect to the CERTA Access Device, and display a colored Aiming Reticle based on the state of the CERTA Access Device. See Figure 4 for an explanation of the Aiming Reticle colors.
   - Select the Quick Scan icon located in the upper right corner of the screen to start the Ultrasound image scan (Figure 5).

Figure 4. Explanation of Aiming Reticle Color Scheme.

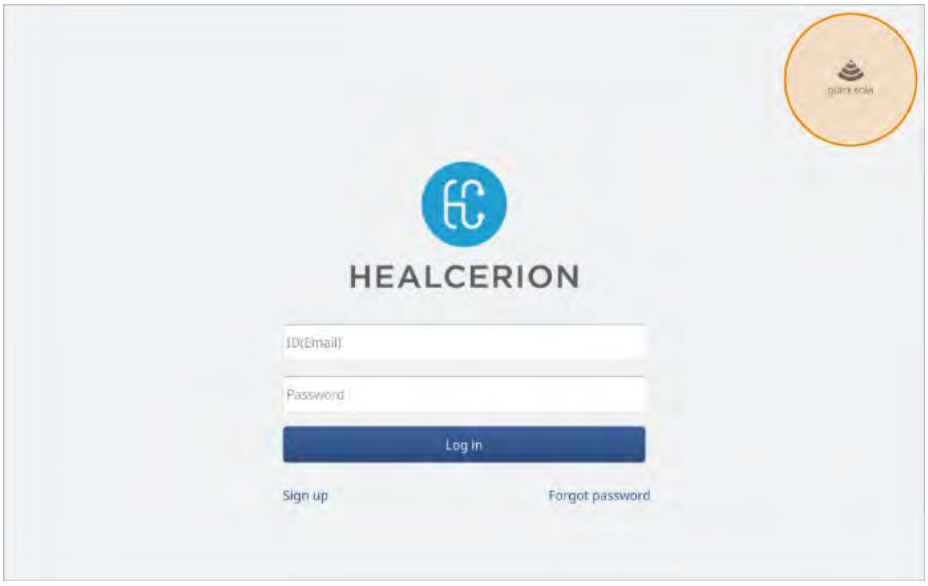


Figure 5. Quick Scan Icon location in Ultrasound Image Viewer Application.

Caution: Failure to complete the wireless connections will not allow the operator to properly use the CERTA Access System and may delay the procedure.

6. Complete Verification process using the CERTA Verification Tool.
   - Place the Aiming Arm of the CERTA Access Device on a flat surface.
   - Release the Aiming Arm Brake by rotating the locking knob to the left and adjust the angle of the Aiming Arm until it reaches its largest angle.

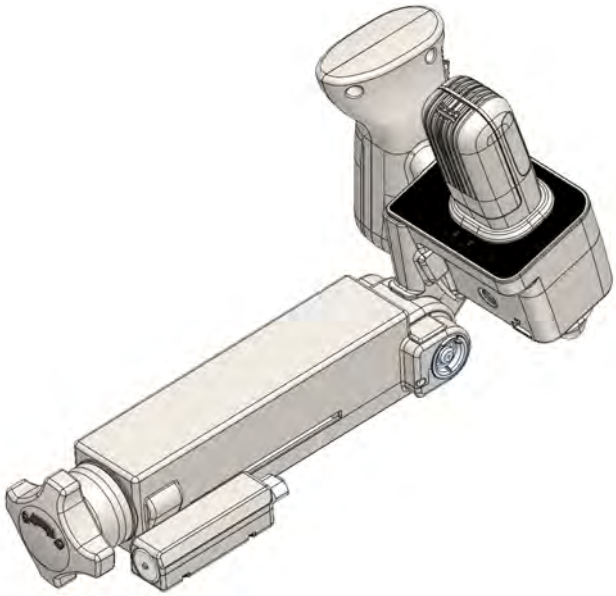


Figure 6. CERTA Access Device prior to inserting Verification Tool.

   - Attach the CERTA Verification Tool to the distal end of the CERTA Access Device, shown in blue in Fig. 7.

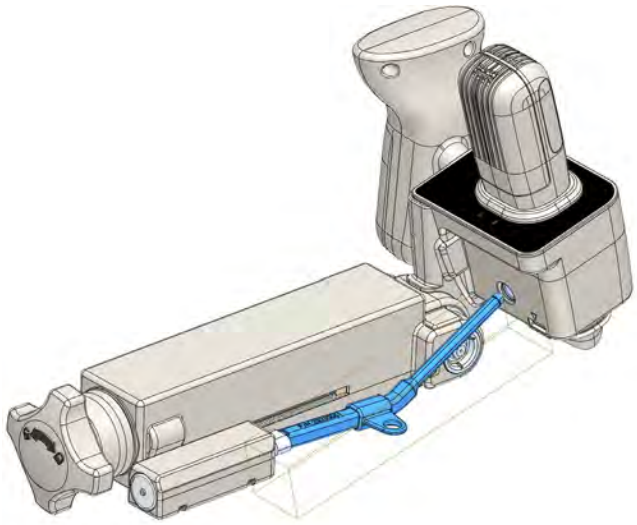


Figure 7. Verification Tool connected to CERTA Access Device.

- Adjust the Aiming Arm angle until the Verification Tool connects to the Verification Tool Receptacle (Figure 8).

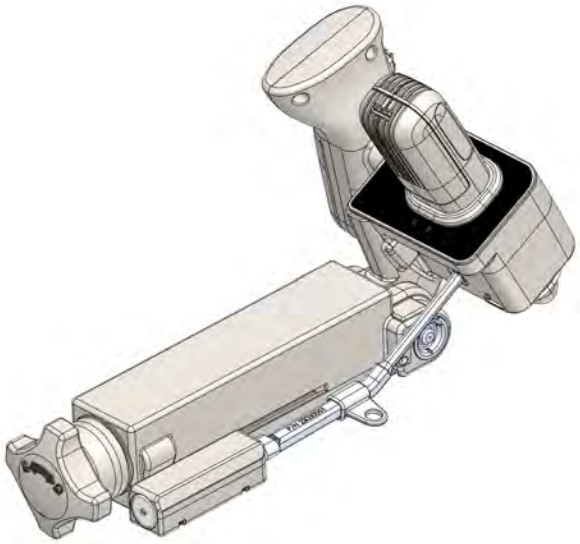


Figure 8. Verification Tool connected to the Verification Tool Receptacle.

- Engage the Aiming Arm Brake by rotating the locking knob to the right until the knob clicks. The Verification process has been successfully completed when the Status LED changes to a green or blinking white color.

Note: Failure to complete the Verification process will not allow the operator to use the CERTA Access System.

2.2 DRAPING THE CERTA ACCESS DEVICE

The CERTA Access Device should be draped with the CERTA Sterile Drape for every CERTA procedure.

Note: Be sure to follow proper sterile technique during draping.

1. From the stowage position, angle the CERTA Aiming Arm to the lowest elevation by releasing the Aiming Arm Brake Knob and manually adjusting downward (Figure 9). After reaching the lowest elevation, lock the Aiming Arm by rotating the knob to the right until the knob clicks.

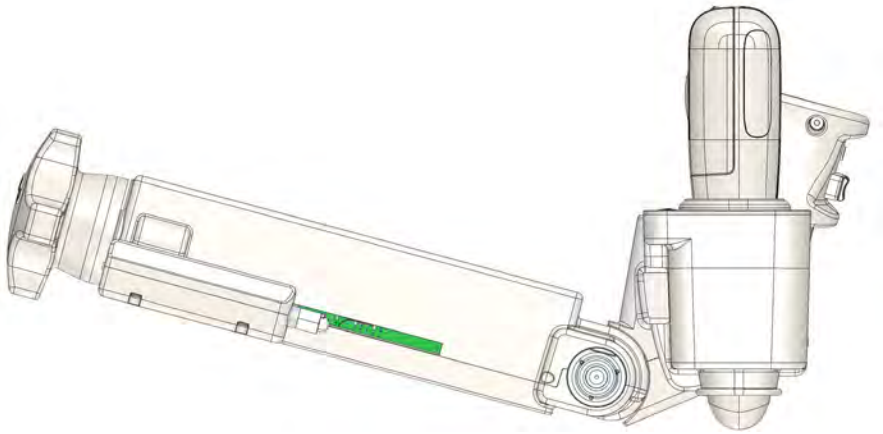


Figure 9. CERTA Access Device.

Caution: Do not attempt to adjust the Aiming Arm without releasing the brake or damage to the device could occur.

2. Separate the two packages of the Sterile Kit, and open the smaller, secondary package that contains the Gel Pad and Gel Pad Window, placing the contents on a non-sterile surface.

3. Attach Gel Pad to distal end of Ultrasound transducer (Figure 10).

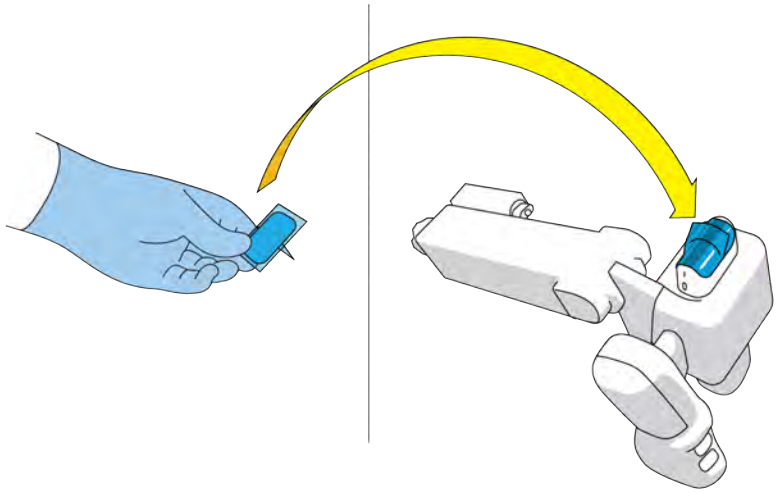


Figure 10. Gel Pad attached to Ultrasound Transducer.

4. Using both hands, remove adhesive-backed plastic film from Gel Pad exposing adhesive surface (Figure 11).

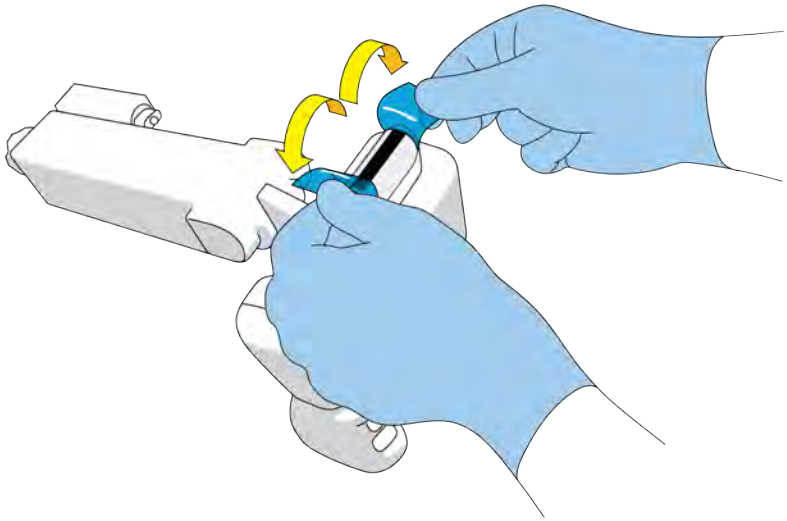


Figure 11. Remove adhesive-backed plastic film from Gel Pad.

5. Apply Ultrasound Gel Pad Window to Ultrasound Gel Pad, attaching securely via Ultrasound Gel Pad adhesive surface prior to draping (Figure 12).

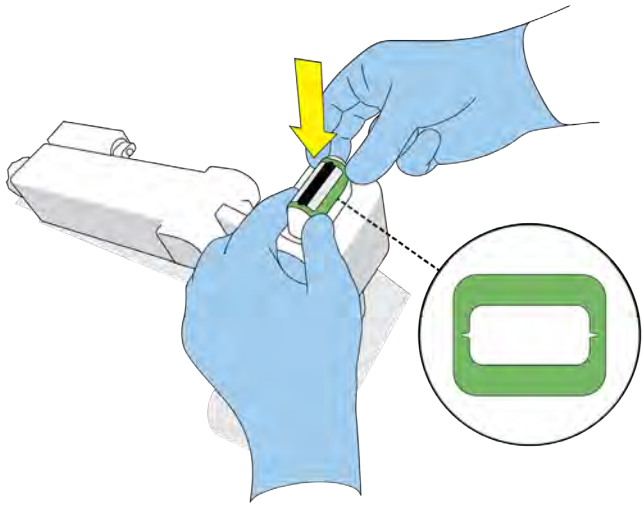


Figure 12. Apply Ultrasound Gel Pad Window to Ultrasound Gel Pad.

6. Open the larger, primary package, which contains the Sterile Drape, and place the contents of the package on a sterile table according to aseptic technique.

7. Place Sterile Drape on a sterile surface with the text NEEDLE facing to the left, and the text FRONT facing away from the user as shown in Figure 13.

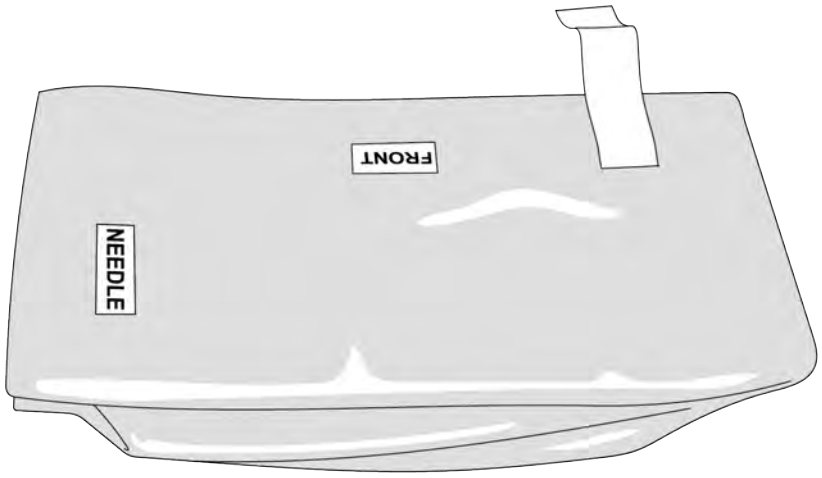


Figure 13. Proper Sterile Drape orientation after removing from sterile packaging.

8. Place both sterile hands inside the Sterile Drape with the text FRONT facing away from the user, and the text NEEDLE facing to the left. (Figure 14)

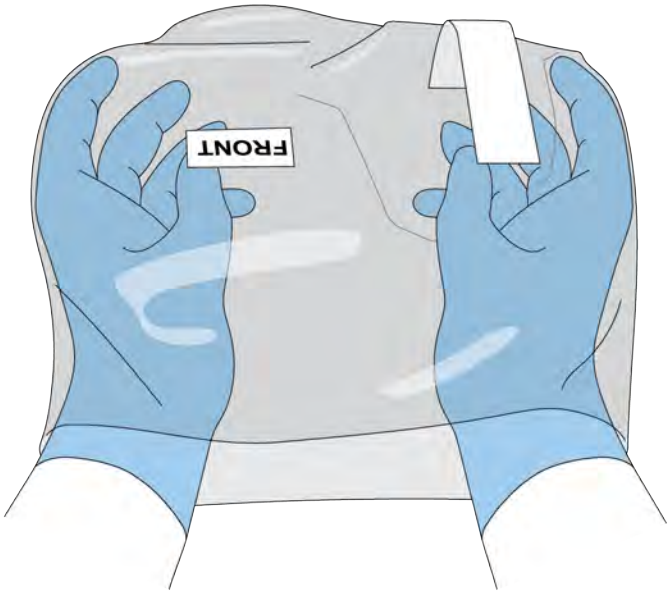


Figure 14. Proper drape orientation.

9. Hold the top end of the Integrated Ultrasound Probe with the left hand, and using the right hand, roll the drape toward the back of the CERTA Access Device (Figure 15) aligning the rectangular marking on the Sterile Drape with the head of the Integrated Ultrasound Probe.

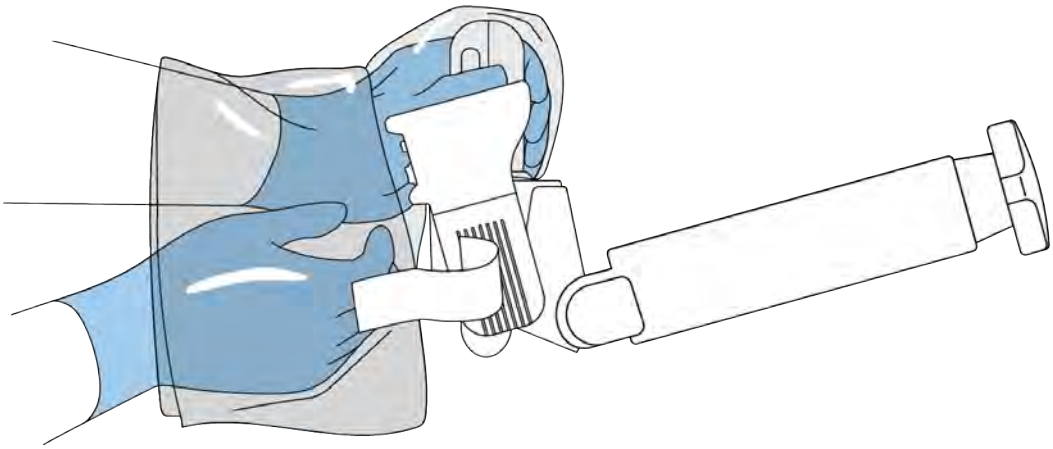


Figure 15. Hold Integrated Ultrasound Probe with left hand and roll drape toward back of CERTA Access Device.

Note: Ensure the Sterile Drape is pulled tight against the CERTA Access Device with excess drape material pulled to the back of the CERTA Access Device.

10. Connect magnetic Integrated Needle Guide to CERTA Access Device in the orientation shown in Figure 16.

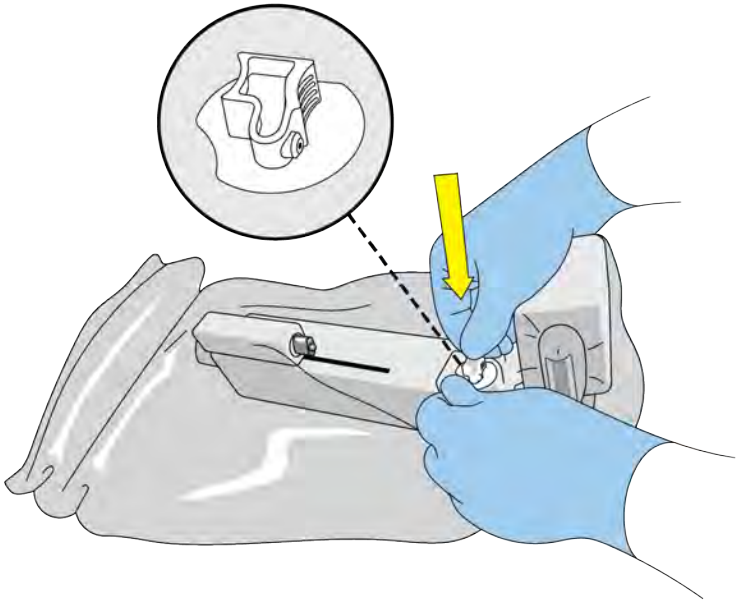


Figure 16. Integrated Needle Guide Attachment

⚠**WARNING:** Confirm the needle guide is magnetically attached to the CERTA Access Device, there is no Sterile Drape located underneath the needle guide, and it does not rotate when manipulated. Incorrect placement of the integrated needle guide can lead to serious injury.

11. Confirm the Sterile Drape marking is aligned with the head of the Ultrasound probe. Note that you can re-adjust the marking location on the Sterile Drape to align with the head of the Integrated Ultrasound Probe. Ensure there are no wrinkles or gaps between the Sterile Drape and the Gel Pad as this may interfere with imaging quality.

12. Place Elastic Band on distal end of Integrated Ultrasound Probe as shown to hold the head of the Integrated Ultrasound Probe tightly against the Sterile Drape (Figure 17).

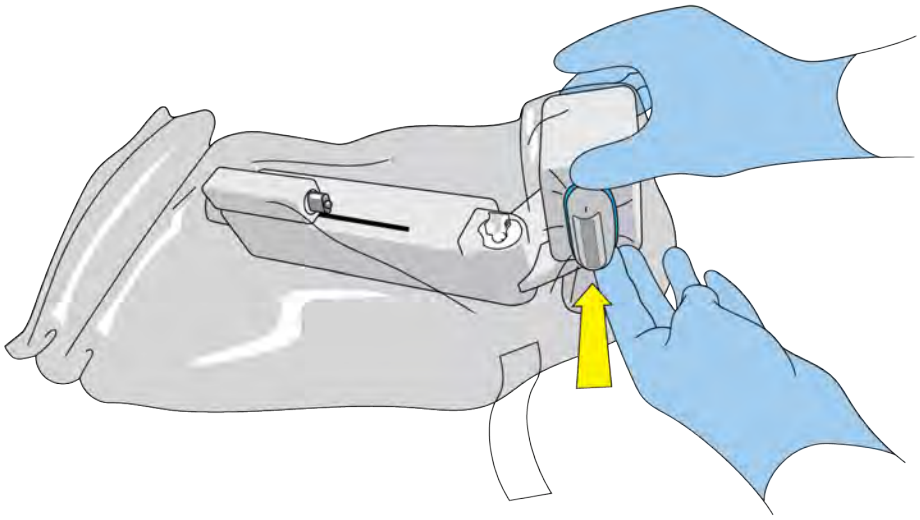


Figure 17. Rubber band placed on end of Ultrasound probe.

13. Disconnect Polytie from Sterile Drape and tightly wrap around rotary joint, removing any excess drape between Integrated Needle Guide and Integrated Ultrasound Probe (Figure 18).

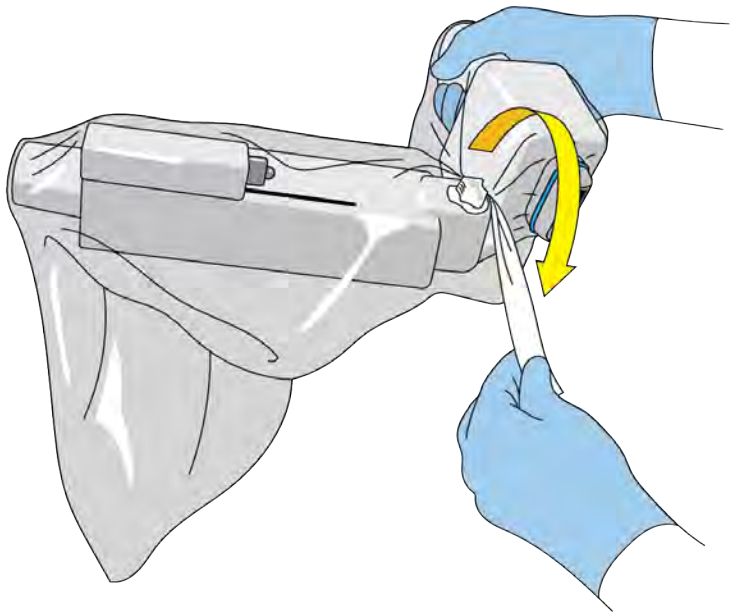


Figure 18. Wrap Polytie around rotary joint.

14. The draping procedure is now fully complete and the CERTA Access Device is ready for the needle assembly (Figure 19).

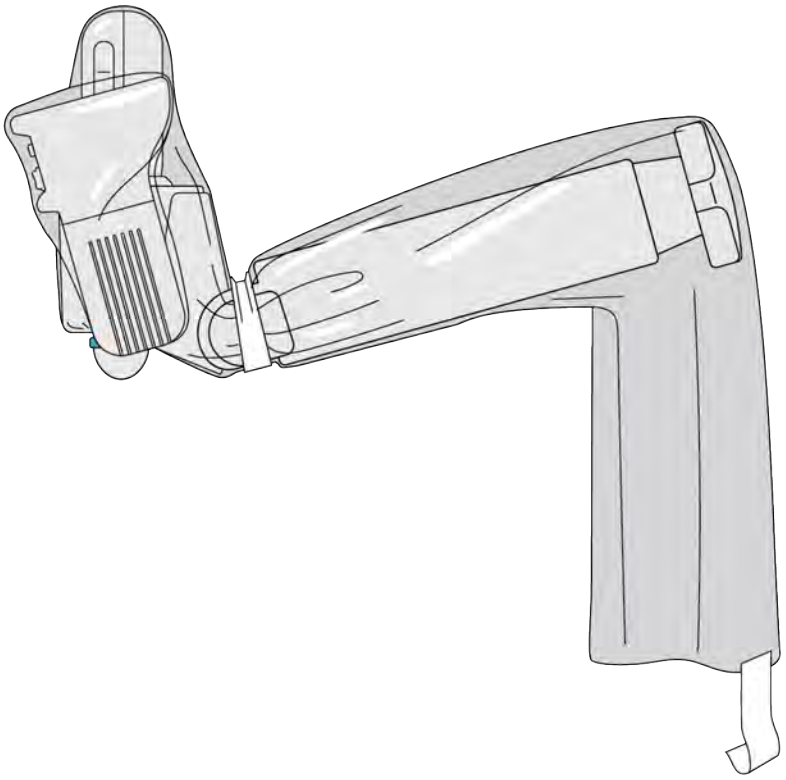


Figure 18. Complete draping procedure.

WARNING: Inspect the Sterile Drape and confirm that the Polytie is tightly wrapped around the rotary joint and the drape is fully enclosing the CERTA Access Device without any openings. A torn or damaged Sterile Drape may compromise sterility and lead to patient infection or introduce contaminants to the CERTA Access Device.

Note: The CERTA Sterile Drape, Integrated Needle Guide and TearDrop Needle are all single-use consumable supplies and are provided pre-sterilized via ethylene oxide (EtO) in accordance with the requirements of ISO 11135 and are intended for single patient use.

2.3 TearDrop NEEDLE ATTACHMENT

1. Remove the TearDrop Needle from the packaging according to aseptic technique.

2. Inspect the TearDrop Needle for evidence of damage. If observed, do not use.

3. Position the TearDrop Needle tip into the CERTA Integrated Needle Guide, and then, magnetically attach the proximal end of the TearDrop Needle to the flange of the draped CERTA Access Device (Figure 20). Rotate the TearDrop Needle as needed until it locks into position.

Note: Ensure the Sterile Drape has been placed prior to these steps.

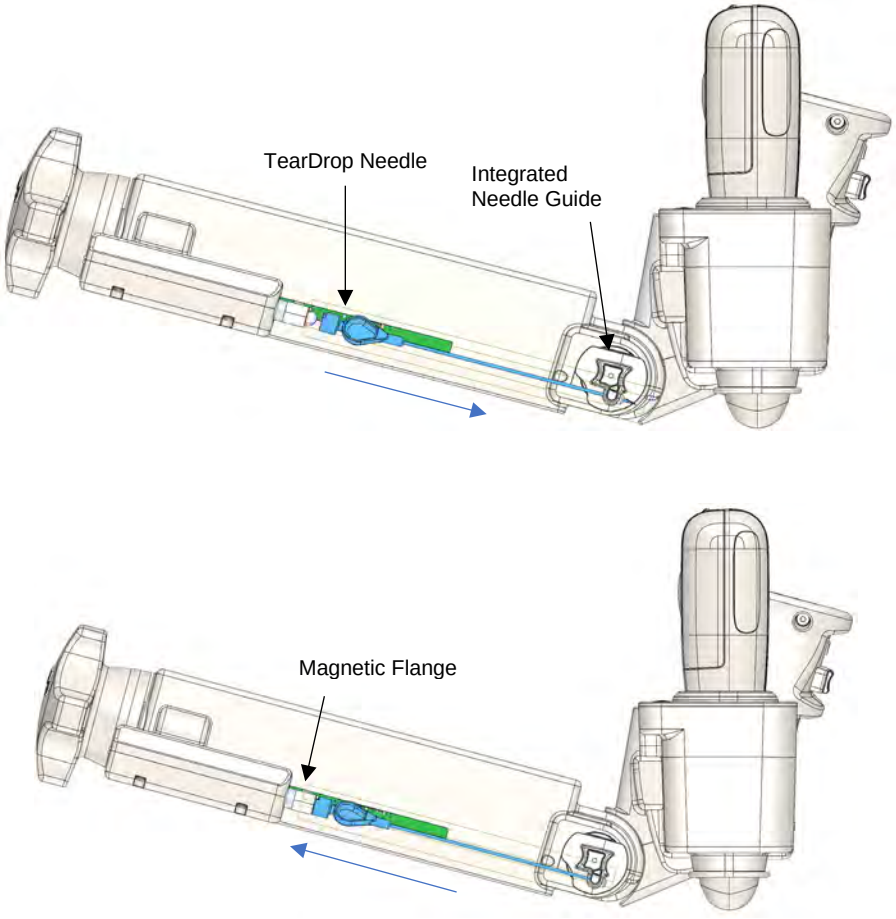


Fig. 20. Needle Assembly Attachment.

WARNING: Confirm the proximal magnetic connection is locked into position by attempting to rotate, and that the TearDrop Needle hub is oriented away from the CERTA Device, towards the operator. If not correctly locked, risk of bleeding is a potential complication.

WARNING: Confirm that the Polytie is tightly wrapped around the rotary joint and there is no excess drape material that may interfere with the needle advancement.

Note: If TearDrop Needle is oriented incorrectly this indicates the needle is incorrectly attached. Repeat Step 3. Confirm TearDrop Needle does not rotate once magnetically connected.

3 PROCEDURAL USE

3.1 POTENTIAL COMPLICATIONS

Air Embolism	Hematoma
Intimal Tear	Nerve Injury
Thrombosis	Extravasation
Vessel Wall Perforation	Phlebitis
Pseudo-aneurysm	Thromboembolism
Infection	Vessel Wall Dissection
Hemorrhage	Pneumothorax

3.2 PLANNING ANATOMICAL TARGET & NEEDLE/GUIDEWIRE PLACEMENT

1. Use conventional ultrasound technique for applying Ultrasound Gel, identifying the desired anatomical site, planning the targeted location, and administering local anesthetic as needed.

2. With the right hand, release the Aiming Arm lock by rotating the Aiming Arm Brake Knob to the left and adjust the CERTA Aiming Reticle to the desired needle access location (Figure 21).

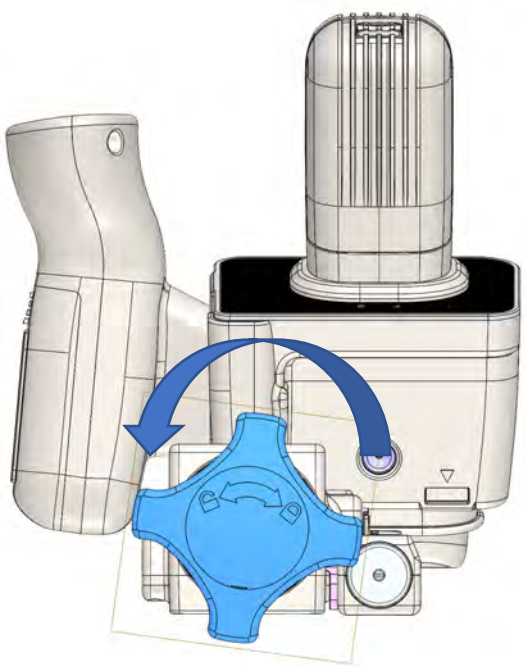


Figure 21. Unlocking the Aiming Arm Brake.

Caution: Do not attempt to adjust the Aiming Arm without releasing the brake or damage to the device could occur.

3. Lock the Aiming Arm by rotating the knob to the right until the knob clicks (Figure 22).

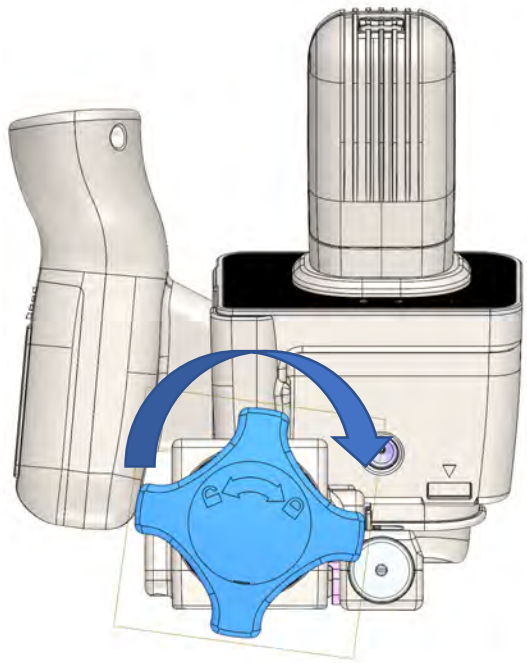


Figure 22. Locking the Aiming Arm Brake.

WARNING: If the Aiming Arm is not fully locked into position this could cause the needle alignment to change, potentially causing injury.

3. Use minor manipulation of the CERTA Access Device and ultrasound to secure centering of the of the CERTA Aiming Reticle with the target. The inner circle of the Aiming Reticle indicates the minimum allowable diameter of the target.

   WARNING: Ensure the target vessel has a diameter equal to, or larger than, the inner circle of the Aiming Reticle before proceeding. Targeting a contraindicated vessel may lead to patient injury.

   Note: If the CERTA Access Device senses excessive motion, the device will not allow the needle to be advanced.

4. To advance the TearDrop Needle, press and hold the Needle Advance Button. The vibration motor will activate, and the needle will simultaneously advance to the targeted location. (Figure 23)

   WARNING: Remove any obstacles, such as the patient drape, from the needle path before attempting to advance the TearDrop Needle as this may introduce non-pyrogenic materials into the patient and lead to infection.

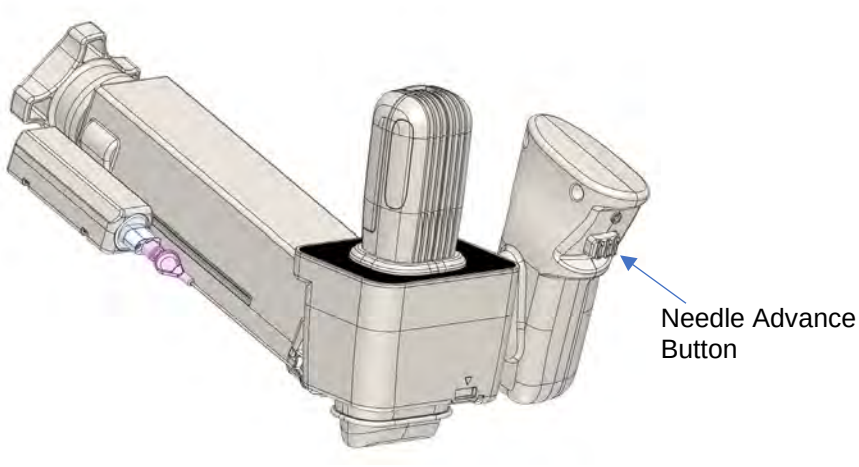


Figure 23. Needle Advance Button.

Note: Once the TearDrop Needle reaches the target position, both the vibration and needle advance motion will stop.

Caution: Hold the CERTA Access Device stationary while advancing the needle and during guidewire insertion. Failure to hold the device stationary may lead to patient injury.

Note: The CERTA Access Device may be stopped at any time while the needle is advancing or retracting. To do this requires removal of the clinician's finger from the Needle Advance or Retract Button. The device will automatically stop moving and vibrating at that time.

Caution: If at any time needle motion is paused during needle advancement, ensure needle is fully retracted before planning.

5. Confirm correct needle placement with blood filling the TearDrop Needle hub.

   Note: If target access is not achieved, move to Step 8 for retraction of TearDrop Needle and repeat steps 1-5.

6. While maintaining position of the CERTA Access Device with the operators left hand, using standard technique, the guidewire is advanced through the TearDrop Needle hub with the right hand.

   Note: The TearDrop Needle is compatible with guidewires up to .035" in diameter.

   WARNING:

- Do not advance the guidewire if the Status LED or Aiming Reticle is in the Error state.
- Stop guidewire advancement if excessive resistance is encountered.
- Do not withdraw guidewire when needle is advanced.

3.3 CERTA ACCESS DEVICE AND NEEDLE WITHDRAWAL

7. Optionally, press the Needle Retract Button on the CERTA Access Device to reposition the TearDrop Needle to the starting position (Figure 24).

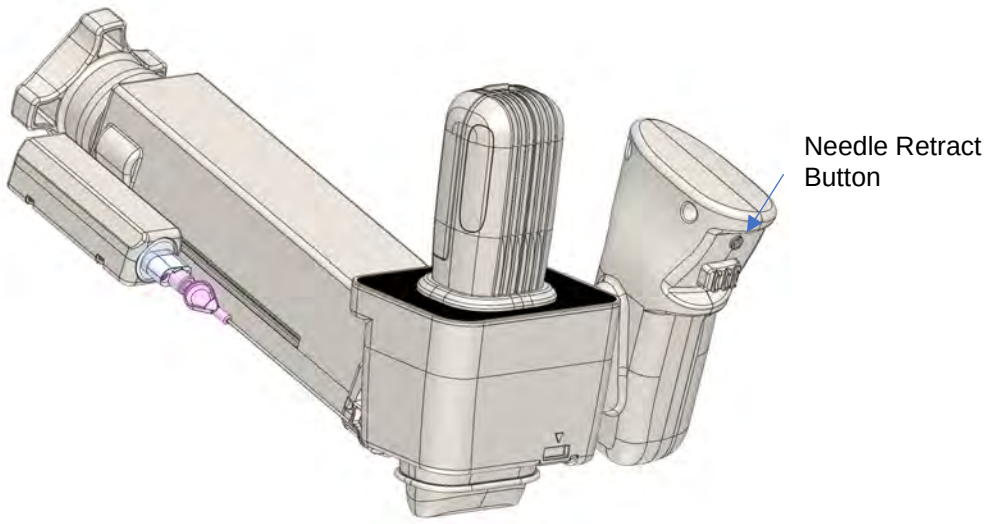


Figure 24. Needle Retract Button.

8. Using standard exchange technique, remove the CERTA Access Device and place on flat surface.

4 POST-PROCEDURE

4.1 REMOVAL OF TEARDROP NEEDLE AND STERILE DRAPE WITH INTEGRATED NEEDLE GUIDE

1. Detach the magnetic connection of the TearDrop Needle from the CERTA Access Device and remove needle and dispose of per guidelines.

   Caution: Use caution when removing the TearDrop needle as the sharp end of the needle may cause injury.

2. Detach the magnetic connection of the Integrated Needle Guide and remove Sterile Drape as a unit. The Sterile Drape may be removed by holding the Aiming Arm inside the drape with one hand, and carefully rolling the Sterile Drape with the other hand, toward the end with the Integrated Ultrasound Probe, until it has been fully removed from the CERTA Access Device. Dispose of per guidelines.

3. Power off the device by pressing the respective power buttons for the CERTA Access Device and the Integrated Ultrasound Probe.

4.2 CLEANING

1. Remove soil by thoroughly wiping with a Super Sani-Cloth® or equivalent EPA-registered intermediate level disinfectant cloth.

2. If soil is visible on the Super Sani-Cloth®, discard and use a clean Super Sani-Cloth®.
3. Continue wiping with fresh Super Sani-Cloth® until all areas are cleaned and no soil is visible.

4. While wiping, take care not to wipe over already cleaned areas.

5. Following the Super Sani-Cloth® IFU, allow treated surface to remain wet for two (2) minutes. Let air dry.

6. Inspect the device for cleanliness, function, and integrity.

7. If visible soil remains, re-clean the device.

8. Allow the device to dry under ambient conditions before placing in storage.

 Caution: Do not apply any liquid chemicals to clean the CERTA Access Device. Do not store the CERTA Access Device next to any liquid chemicals. Do not allow any liquid chemicals to spill onto the CERTA Access Device. If liquid chemicals are accidentally spilled onto the CERTA Access Device, do not use and contact customer support.

 Caution: Spraying disinfectant directly on or submerging the CERTA Access Device may damage components of the device.

 **WARNING:** If the device is unable to be cleaned, quarantine the device and contact Obvius Robotics.

 *Note:* The CERTA Access Device is shipped non-sterile and does not require sterilization for use when using the Sterile Drape. All disposable accessories including the Sterile Drape, Integrated Needle Guide and the TearDrop Needle are shipped in sterile packaging.

 *Note:* Cleaning procedures should begin as soon as possible following use to prevent soil from drying.

4.3 REMOVING THE BATTERIES AND CHARGING THE SYSTEM

CHARGING THE CERTA ACCESS DEVICE BATTERIES

1. The CERTA Access Device contains a set of four disposable CR123A batteries and one Removable Ultrasound Battery, which is rechargeable and must be removed prior to charging.
    a. Four disposable CR123A batteries are integrated in the handle of the CERTA Access Device.
    b. The Removable Ultrasound Battery is located integrated in the Integrated Ultrasound Probe.

2. To remove the Removable Ultrasound Battery, grasp the battery housing, depress the battery release lever, and slide the battery away from the Integrated Ultrasound Probe.

3. To remove the four disposable CR123A batteries in the User Handle, first push the Handle Battery Cover to lower the battery release clip and slide the cover away from the User Handle. Remove the four disposable CR123A batteries in the battery compartment.

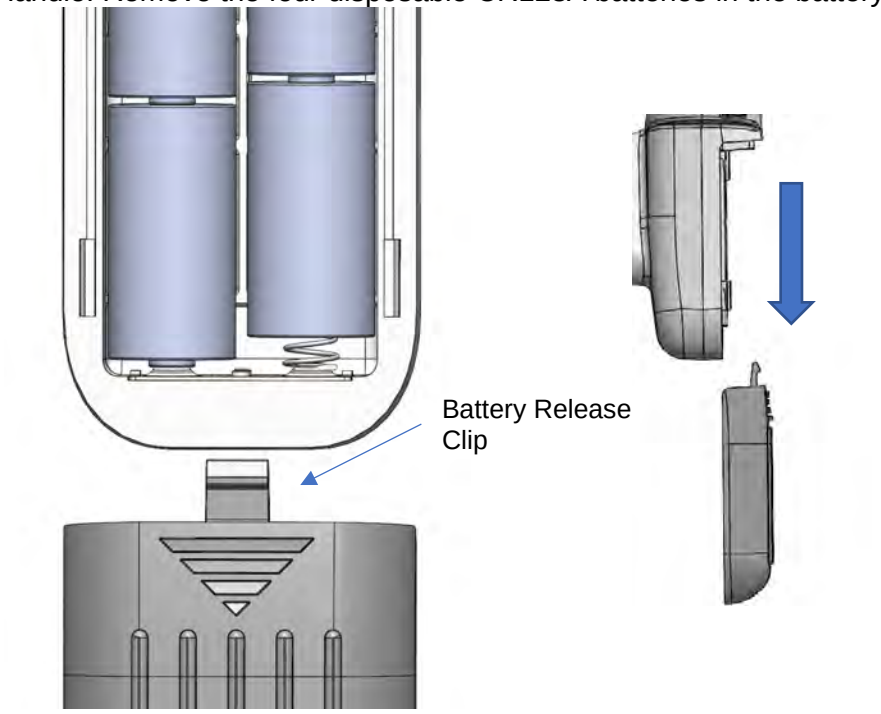


Fig. 25. Battery Release Clip.

4. To charge the Removable Ultrasound Battery, insert it into the Ultrasound Battery Charging Dock.

Note: Plug the Ultrasound Battery Charging Dock into an AC outlet.

5. Charging/LED Indication: The Ultrasound Battery Charging Dock emits a red color when the Removable Ultrasound Battery is not fully charged and charging, and a green color when charging has completed.

CERTA TABLET CHARGING

1. Plug the supplied charger into the CERTA Tablet and an AC outlet.

4.4 STORAGE BETWEEN USES

The CERTA Access System is shipped in a re-useable storage case intended for storage between procedures. The CERTA Access System may also be placed on a level surface such as a countertop for storage between uses.

Caution: Do not store the CERTA Access Device in areas where it is possible for the device to get wet.

5 TROUBLESHOOTING

5.1 WARNING MESSAGES

The CERTA Access System displays messages to the user on the CERTA Tablet to indicate a warning. The following section lists a summary of the warning messages, their causes, and solutions for addressing them.

Message:	Please recharge tablet for CERTA Application
Cause:	The CERTA Tablet does not have a sufficient battery capacity to complete the procedure.
Solution:	Plug the CERTA Tablet charger into the CERTA Tablet and an AC outlet until it is fully charged.

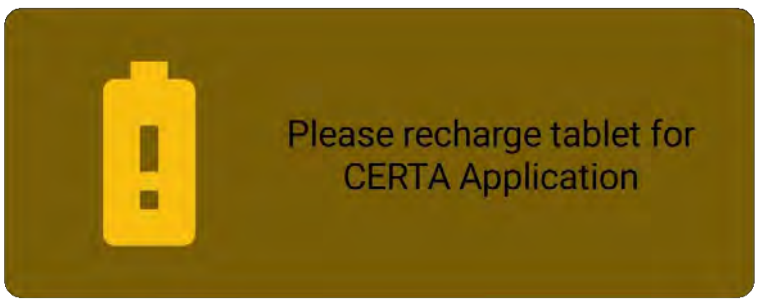


Fig. 26. Low Battery Warning Message.

Message: CAUTION: Target Depth out of Range. Prescribed for Target Depth of 10mm to 50mm

Cause: The Aiming Arm of the CERTA Access Device is aiming too high or too low and targeting a position outside of the prescribed range.

Solution: Release the Brake Knob and adjust the Aiming Arm to position the Aiming Reticle between 10mm and 50mm.

Fig. 27. Target Depth Warning Message.

Message: CAUTION: Unexpected Brake Motion. Please Unlock and Replan

Cause: The Aiming Arm has unexpectedly moved after locking the brake.

Solution: Release the Aiming Arm brake and plan the target needle position again.

Fig. 28. Brake Motion Warning Message

Message: CAUTION: Please Retract Needle to Start Position before Targeting

Cause:	The needle is not in the fully retracted position when planning the target.
Solution:	Retract the needle to the starting position by pressing and holding the Retract Button until the needle motion has stopped.

Fig. 29. Needle Position Warning Message.

5.2 CYBERSECURITY

In the event of a threat related to the cybersecurity of the equipment and software, immediately stop using the equipment or software and contact OBVIUS Robotics service personnel to take the necessary action.

WARNING: Do not attempt to download or install any application files not distributed by OBVIUS Robotics. This may expose the CERTA Access System to cybersecurity vulnerabilities.

6.0 TECHNICAL INFORMATION

ESSENTIAL PERFORMANCE

The CERTA Access System shall enable positioning of the TearDrop Needle no more than 4.5mm from the center of the CERTA Aiming Reticle displayed on the Ultrasound Image Viewer Application in the radial direction.

SPECIFICATION

Feature	Specification
Dimensions (L x W x H)	19.7 x 15.9 x 33cm

Weight	1.75 kg
Wireless Communication	Type: Soft AP, BLE x2 Frequency: 2.4 GHz BLE 4.2 & 5 GHz WLAN 802.11n40, ac40/80 Output power: BLE 8 dBm and X dBm, WLAN 21 dBm
IEC 60601-1	Type BF Applied Part Internally Powered Equipment

7.0 GUIDANCE AND MANUFACTURER'S DECLARATIONS

SEPARATION FROM OTHER RF WIRELESS COMMUNICATION EQUIPMENT

A user may degrade the essential performance of the CERTA Access Device by not maintaining the prescribed distance between RF wireless communication devices and the CERTA Access Device according to the output power of the RF wireless communication device as specified in the following table.

Frequency (MHz)	Band [MHz]	Service	Maximum power [W]	Distance [m]
385	380-390	TETRA 400	1.8	0.3
450	430-470	GMRS 460, FRS 460	2	0.3
710	704-787	LTE Band 13, 17	0.2	0.3
745				
780				
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	0.3
870				
930				
1720	1700-1990	GSM 1800, CDMA 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	2	0.3
1845				
1970				

2450	2400-2570	Bluetooth, WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	2	0.3
5240	5100-5800	WLAN 802.11a/n	0.2	0.3
5500				
5785				

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 20 cm (8 inches) to any part of the CERTA Access System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

8.0 EMC STANDARDS AND TEST REQUIREMENTS

Phenomenon	**Basic EMC standard or test method**	**Test requirement**
Radiated disturbance	EN 55011 CISPR11	Group 1, Class A
Electrostatic Discharge Immunity	EN 61000-4-2 IEC 61000-4-2	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3 IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	EN 61000-4-3 IEC 61000-4-3	28 V/m Table 9 in IEC 60601-1-2:2014
Power Frequency Magnetic Field Immunity	EN 61000-4-8 IEC 61000-4-8	30 A/m 50 Hz & 60 Hz

9.0 SYMBOLS GLOSSARY

Symbol	Symbol Title	Symbol Description	Standard Reference	Standard Title
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1 Reference #5.1.1 FDA Recognition #5-117	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 Reference #5.1.3	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Use By Date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Reference #5.1.4	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Sterilized by ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	IOS 15223-1 Reference 5.2.3	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 Reference #5.2.7	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Catalog #	Indicates the manufacturer's catalog # so that the medical device can be identified.	ISO 15223-1 Reference #5.18 FDA Recognition #5-117	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Serial Number	Indicates the manufacturer's serial number so that the specific device can be identified.	ISO 15223-1 Reference #5.1.7	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Unique Device Identifier	Indicates a carrier that contains unique device identified information.	ISO 15223-1 Reference #5.7.10	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Reference #5.1.5	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Non-Pyrogenic	Indicates a medical device that is non-pyrogenic	ISO 15223-1 Reference #5.6.3	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Consult instruction manual	Indicates the need for the user to consult the instruction manual	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	ISO 15223-1 Reference #5.4.3 FDA Recognition #5-117	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Keep away from sunlight	Indicates medical device that needs protection from light sources.	ISO 15223-1 Reference #5.3.2	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Keep Dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1 Reference #5.3.4 FDA Recognition #5-117	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements

	Do not use if package is damaged and consult instructions for use.	Indicates that a medical device that should not be used if the package has been damaged or opened	ISO 15223-1 Reference #5.2.8	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Product was not made with natural rubber latex	Indicates that the medical device or the packaging of a medical device was not made of natural rubber or dry natural rubber latex as a material of construction.	ISO 15223-1 Reference #5.4.5 + B2	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1 Reference #5.4.2	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Do Not Resterilize	Indicates a medical device the is not to be resterilized. * This symbol is only to be used when there is an accompanying Sterile symbols * This symbol is not to be used on reusable medical devices that are intended to be sterilized between uses.	ISO 15223-1 reference #5.2.6	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1 Reference #5.3.7 FDA Recognition #5-117	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements
	WEEE	Signifies waste from electrical and electronic equipment that should be collected separately from municipal waste	WEEE Directive 2012/19/EU	Waste Electrical and Electronic Equipment Directive
	Type BF applied part	Identifies a Type BF applied part complying with IEC 60601-1 Note: B = Body F = Floating	IEC 60417 Reference #5333 FDA Recognition #5-102	Graphical symbols for electrical equipment in medical practice
	FCC Compliance Mark	Complies with limits for Class B digital device established by FCC Rules, Part 15	Title 47 US Code of Federal Regulations Part 15.19	N/A
	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice
	Caution	Indicates that caution is necessary when operating the device close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1 Reference #5.4.4 FDA Recognition #5-117	Medical Devices – Symbols used with medical device labeling and information to be supplied – Part 1: General Requirements