AxoTrack Sterile Procedure Kit

Sterile Procedure Kit User Guide

- Syringe (not included)
- Needle assembly
- Alignment rest
- Needle clamp
- Front snap closure
- Top shield
- Magnet rail
- Release point for rear snap closure
- Needle hub
- R-bevel indicator
- Hub adapter
- Magnet
- Vertical rail
- Transducer (not included)
- Bottom shield
- Rear snap closure
- Transducer face
- Protective cap
- Needle guide
- Front snap closure
- Cannula
- Vertical rail
- Rear snap closure

Images 1-16 illustrate the components and assembly process.
Device description

The SonoSite AxoTrack Sterile Procedure Kit is for use only with an AxoTrack-equipped ultrasound transducer and imaging system. The SonoSite AxoTrack Sterile Procedure Kit consists of a top shield with needle clamp, bottom shield with needle guide and protective cap, needle assembly, sterile cable sleeve (not shown), and two (2) elastic bands (not shown) for securing the sterile cable sleeve to the shield. The top and bottom halves of the sterile shield are equipped to fit around a SonoSite AxoTrack-equipped ultrasound transducer. The magnet on the needle assembly provides axial position information to the electromagnetic tracking capabilities of the transducer. This axial position information is represented as a virtual needle overlay registered to the ultrasound image on the system display. The virtual needle information on the image provides the clinician with real-time needle tracking information. For intended use and clinical applications specific to your transducer and system, refer to the transducer and system labeling as appropriate.

Sizing guide

<table>
<thead>
<tr>
<th>SonoSite Catalog Number</th>
<th>Needle Gauge</th>
<th>Hub Color</th>
<th>Nominal Needle ID in (mm)</th>
<th>Guidewire Compatibility in (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P20810</td>
<td>18ga XTW</td>
<td>Pink</td>
<td>0.042&quot; (1.067mm)</td>
<td>Up to 0.038&quot; (0.97mm)</td>
</tr>
<tr>
<td>P21034</td>
<td>21ga TW</td>
<td>Green</td>
<td>0.020&quot; (0.508mm)</td>
<td>Up to 0.018&quot; (0.46mm)</td>
</tr>
</tbody>
</table>

Storage

The SonoSite AxoTrack Sterile Procedure Kit should be stored in a dry place between 10°C and 40°C (50°F - 104°F).

Package contents

- Top Shield with Needle Clamp
- Bottom Shield with Needle Guide and Protective Cap
- Needle Assembly with Magnet
- Sterile Cable Sleeve (80cm length)
- Elastic Bands (2)
- Blue Wrap

Recommended accessories

- 5-12 cc non-locking syringe
- Sterile acoustic gel
- Applicable procedure kit

Indications for use

The SonoSite AxoTrack Sterile Procedure Kit is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

Contraindications

No contraindications have been identified for use of this device for needle guidance. Do not use this device if there is a contraindication to guided needle access for a selected procedure. For contraindications specific to your SonoSite AxoTrack-equipped transducer and system, refer to the user guides for the transducer and system.
AxoTrack Sterile Procedure Kit

**Warnings**
- Procedures must be performed by trained medical personnel competent in ultrasound, safe techniques, and proper handling of potential complications. For instructions on the use of the transducer, refer to the user guides for the transducer and system.
- Practitioners must be aware of complications and contraindications associated with ultrasound needle guidance.
- Before using this kit, read all package insert warnings, precautions, and instructions. Failure to follow these instructions can result in serious complications.
- There is a magnet attached to the needle assembly. This magnet must be kept at least 15 cm (6 inches) away from an implanted or attached electrical medical device, such as a pacemaker or defibrillator. When using the SonoSite AxoTrack Sterile Procedure Kit on a patient with a pacemaker or defibrillator, the product should only be used on the contralateral side of the body.
- The SonoSite AxoTrack virtual needle display serves only to provide visual information for needle access. Traditional clinical markers of needle access (for example, blood flash in the syringe) should be used to confirm needle location.
- This product is designed only for use with the included SonoSite AxoTrack needle assembly with integral magnet. Do not attempt to use this product with a different needle.
- Do not reposition or reorient the transducer with the needle advanced into tissue. Doing so could result in serious patient injury. Withdraw the needle to the skin surface, then reposition and/or reorient the transducer.

**Cautions**
- Discard the blue wrap surrounding the tray upon opening the kit. The blue wrap is intended to cushion the tray and protect the integrity of the sterile pouch only. It is not qualified to provide a sterile barrier in a clinical environment. Using as a sterile barrier could result in patient infection.
- Examine the packaging and device before use. DO NOT use this kit if it has been previously opened or damaged, if the integrity of the packaging is violated, or if the expiration date has passed.
- Healthcare workers who use or may be exposed to needles are at increased risk of needle stick injury. Such injuries can lead to serious or fatal infections from blood-borne pathogens. Clinicians must adhere to state/federal OSHA standards for blood-borne pathogens when starting, discontinuing, or maintaining needle access to minimize the risks of exposure. Failure to do so may result in harm to the patient or user.
- Exposure to acetone and alcohol can result in a loss of visual clarity in the materials used in the SonoSite AxoTrack Sterile Procedure Kit. Do not clean or wipe the surface of the kit components with swabs, wipes, or sprays containing acetone or alcohol.
- Do not alter any of the items included in this kit during assembly or use.
- Do not alter the “Exp Date” (expiration date) printed on the label.

**To install the shield**

These instructions are intended to be used by an **operator in a sterile field** and a **non-sterile assistant** outside the sterile field.

1. **Non-sterile assistant:** Carefully peel open the pouch while avoiding contact with the blue wrap protecting the sterile tray and its contents.

2. **Sterile operator:** Remove the tray covered in the blue wrap, and discard the blue wrap. Place the tray on the sterile field or adjacent to the patient. Use care to maintain sterility of the tray.

3. **Non-sterile assistant:** Hold the transducer with the transducer face pointing up. Apply a small pea-sized bead of acoustic gel to the face of the transducer. The volume of gel should cover approximately one-half to two-thirds of the transducer face. See Figure 1.

4. **Sterile operator:** Hold the bottom shield to accept the transducer. Confirm proper positioning of the protective cap over the needle guide. This cap maintains needle guide sterility during the shield assembly on the transducer. See Figure 2.

5. **Non-sterile assistant:** Grasp the ultrasound transducer by the vertical rail, and lower the transducer into the bottom shield while guiding the protective cap through the needle guide receiver hole in the transducer. See Figure 2.

6. **Non-sterile assistant:** Remove the protective cap from the needle guide. Avoid contacting the bottom sterile shield or the gloved hand of the sterile operator. See Figure 2.

7. **Sterile operator:** Slide the top shield over the vertical rail on the transducer and align it with the bottom shield. See Figure 3.

8. **Sterile operator:** Snap the top and bottom sterile shield together. An audible “click” from the front and rear snap closures will confirm appropriate closure of the shield around the transducer. Visually verify proper shield closure. See Figure 4.

9. **Sterile operator:** Unfold the sterile cable sleeve.

10. **Non-sterile assistant:** Suspend the transducer/shield assembly by holding the transducer cable. Avoid contacting the transducer/shield assembly. See Figure 5.

11. **Sterile operator:** Slide the end of the sterile cable sleeve over the transducer/shield assembly. See Figure 6.

12. **Non-sterile assistant:** Holding the transducer by the cable, lower the transducer/shield assembly into the sterile cable sleeve. See Figure 6.
Sterile operator: Grasp the transducer/shield assembly once it is covered by the sterile cable sleeve, and advance the sterile cable sleeve over the cable and transducer/shield assembly until the transducer/shield assembly exits the other end of the sleeve. Avoid contacting the non-sterile transducer cable. See Figure 7.

Sterile operator: Wrap the sterile cable sleeve around the handle of the transducer/shield assembly, and secure it to the handle with an elastic band. Pull the sleeve and elastic band back until snug against the flange on the sterile shield. See Figure 8.

Preparing the transducer for injection
1. Attach the needle on a non-locking Luer-Slip syringe. See Figure 9.
2. Grasp the transducer/shield assembly by placing the handle/vertical rail junction in the webbing between the thumb and forefinger, and wrap the middle, fourth and fifth fingers around the handle. See Figure 10.
   a. Either the left or right hand can be used to hold the probe/shield assembly.
   b. The hand used to advance the needle through the needle guide corresponds to the virtual needle entry direction on the ultrasound image. If the needle is advanced with the left hand, the virtual needle should enter from the left side of the ultrasound image. If the needle is advanced with the right hand, the virtual needle should enter from the right side of the ultrasound image. Refer to the ultrasound system user guide for specific instructions relative to toggling the ultrasound image left to right.
3. Confirm the needle clamp is disengaged. The needle clamp should be in the forward/open position and the needle guide opening should be unobstructed. See Figures 11 and 21.
4. Place the needle assembly magnet against the proximal end of the magnet rail. Avoid contacting any surface with the needle tip.
5. Move the tip of the needle to the center of the notch in the alignment rest. The needle is now aligned with the needle guide lumen. Slide the needle smoothly into the needle guide while maintaining magnet contact with the magnet rail of the transducer/shield assembly. Avoid contacting any surface with the needle tip. See Figure 12.
6. Slowly slide the needle forward and backward in the needle guide, and observe the matching virtual needle movement on the sonogram. See Figure 13.
   a. Ensure the virtual needle image follows the needle motion throughout the extent of needle travel.
   b. Any dropout or jumping in the virtual needle image indicates improper needle tracking. If needle tracking is not functioning properly, do not use the product. Consult the transducer or ultrasound system user guide to confirm proper system settings and operation.
7. Retract the needle until its tip is just protruding from the base of sterile shield. Observe that the virtual needle tip is also just visible on the sonogram. See Figure 14.
   If needle tracking is not functioning properly, do not use the product. Consult the transducer or ultrasound system user guide to confirm proper system settings and operation.
8. Retract the needle tip into the needle guide, leaving a smooth bottom surface for patient scanning. Do not withdraw the needle from the needle guide.
9. Secure the needle position by engaging and holding gentle pressure on the needle clamp with your thumb. See Figures 11 and 15.
   The AxoTrack system is now ready for use. Continue holding gentle pressure on the needle clamp to maintain the retracted needle position during scanning. See Figure 16.

To position the needle
1. Apply sterile acoustic gel to the skin.
2. Stabilize the transducer/shield assembly on the skin with the forefinger placed on the skin surface. Using your thumb, continue holding gentle pressure on the needle clamp to maintain the retracted needle position during scanning. See Figure 17.
3. Image and identify target anatomy. Align the target line with the target structure, ensuring a clear path that avoids contact with intervening structures (for example, bone) during needle insertion.
   Note: The angle of the needle relative to the target structure will correspond to the angle of the transducer relative to the patient anatomy. It is important that the transducer be positioned and tilted appropriately to achieve the needle access angle typically used for the clinical procedure.

To advance the needle
1. Release the needle by rotating needle clamp forward with your thumb. See Figures 11 and 21.
   Note: The position of the needle bevel corresponds to the hub bevel indicator. See Figure 18.
Advance the needle. Observe needle progression along the target line and into the target. See Figure 19.

**WARNINGS:**
- Maintain the magnet in contact with the magnet rail at all times. Movement of the magnet away from the rail could cause needle tracking inaccuracy. Excessive movement of the magnet away from the rail will cause the virtual needle to disappear from the display. Refer to the transducer and system user guide for specific warnings that may be associated with movement of the magnet away from the rail. See Figure 20.
- Do not reposition or reorient the transducer with the needle advanced into tissue. Doing so could result in serious patient injury. Withdraw the needle to the skin surface, then reposition and/or reorient the transducer.

**Note:** If excessive resistance is encountered during needle advancement, check the components (such as if the needle clamp is in the closed position or if the needle is damaged or bent).

**To perform a procedure**

1. Once the target has been reached, move the needle clamp back to the closed position with your thumb. Maintain continuous, gentle pressure on the needle clamp to avoid undesired axial movement of the needle. See Figures 11 and 16.

**Note:** The needle clamp does not prevent needle rotation.

2. Verify needle location using standard clinical indicators (such as blood flash in syringe for vascular access).

3. If wire access is desired, remove the syringe from the needle hub by pinching the hub/syringe junction with the thumb and forefinger while maintaining stationary transducer/shield assembly position on the skin surface. See Figure 22.
   - Do not attempt to remove the syringe by twisting it in the hub. The needle clamp will not prevent needle rotation, and the syringe will not release from the hub.
   - Confirm proper orientation of bevel indicator following syringe removal.

4. If the angular orientation of the needle needs to be altered, move the needle clamp to the open position, and withdraw the needle to the skin surface before attempting to reposition the needle.

5. When removing the needle from the body over the wire, maintain the clamp in the closed position, and remove the transducer/shield assembly and needle as a unit.

**To remove the needle and sterile shield**

1. Disengage the needle clamp by moving the lever to the forward/open position. Remove the needle from the needle guide. See Figures 11 and 21.

2. Remove the elastic band and sterile cable sleeve.

3. Separate the sterile shield from the transducer.
   - Break the front snap closure. See Figure 23.
   - Squeeze the rear part of the handle to disengage the rear snap closures. See Figure 24.

4. Separate the top and bottom halves of the enclosure.

5. Handle the shield sections, needle, elastic band, and transducer cable sleeve as potential biohazard materials. Dispose of kit components in accordance with accepted medical practice and applicable local and national laws and regulations.

**Label definitions**

- **Use by**
- **Sterilized by irradiation**
- **Do not resterilize**
- **Consult User Guide**
- **Catalog number**
- **Manufacturer**
- **LOT**
- **RX only**
- **Magnet enclosed. Do not use within 6 in (15 cm) of implanted or attached electrical medical device**
- **Not made with natural rubber Latex**
- **Keep dry**
- **Single use only**
- **Non-pyrogenic**
- **Do not use if package is damaged or open**
- **Caution. Consult accompanying documents**
- **Store between 10° C and 40° C**

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AxoTrack Sterile Procedure Kit
Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

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Patents: US 8,900,151; US 8,152,724; US 8,147,408; US 6,690,159; US 7,244,234; AU 2004/289278; AU 2010/202877; CA 2544585; EP 2465440; EP 1686899

Part Number: P22470-02

Publication date: August 2016

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