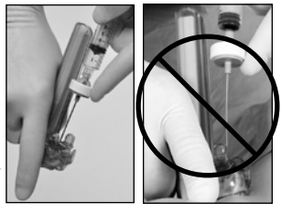
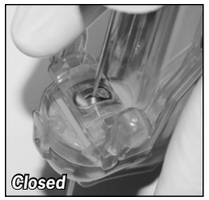
NEEDLE INSERTION

1. Confirm needle clamp is disengaged (i.e., forward/ open position).
2. Inspect the needle for any signs of bending or damage. Do not use product if needle damage is noted.
3. The position of the needle bevel corresponds to the hub bevel indicator.
4. While maintaining stable positioning of the probe/ shield assembly on the skin surface, insert the tip of the needle into the needle guide.
5. Confirm the appearance of the virtual needle on the ultrasound image.
6. During needle insertion, maintain the magnet in contact with the magnet rail.
   a. Movement of the magnet away from the rail could cause needle tracking inaccuracy.
   b. A warning will appear on the system display if the magnet is moved away from the rail. Extreme movement of the magnet from the rail will cause the virtual needle to disappear from the display.



7. **Do not reposition or reorient the probe 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 probe.
8. If excessive resistance is encountered during needle advancement, check the components (e.g., needle clamp in the open position, needle damaged or bent).



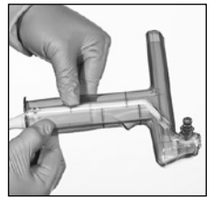
CLAMPING THE NEEDLE

1. Once the target has been reached, move the needle clamp back/closed with the thumb. Maintain continuous, gentle pressure on the needle clamp to avoid undesired axial movement of the needle. Note: The needle clamp does not prevent needle rotation.
2. Verify needle location using standard clinical indicators (e.g., blood flash in syringe for vascular access).
3. If wire access is desired, remove the syringe from the needle hub while maintaining stationary probe/ shield assembly position on the skin surface. Release the syringe from the hub by pinching the hub/syringe junction with the thumb and forefinger.
   a. 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.
   b. Confirm proper orientation of bevel indicator following syringe removal.

4. If needle repositioning is required, 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 probe/shield assembly and needle as a unit.

STERILE SHIELD AND NEEDLE REMOVAL

1. Disengage the needle clamp by moving the lever to the forward/open position. Remove the needle from the needle guide.
2. Remove the elastic band and sterile cable sleeve.
3. Separate the sterile shield from the probe by breaking the front snap closure, and squeezing the rear part of the handle to disengage the rear snap closures. Separate the top and bottom halves of the shield.



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

DEFINITIONS RELATED TO ALL LABELING

- Use By
- Sterilized using Radiation
- Do Not Re-sterilize
- Consult Instructions for Use
- Batch Code
- Restricted to Use By or On the Order of a Physician Only
- Magnet Enclosed. Do not use within 6in (15cm) of implanted or attached electrical medical device.
- Store between 10º and 40º C
- Single Use, Do Not Reuse
- Do Not Use if Package is Damaged or Open
- Caution. Consult Accompanying Documents
- Catalog Number
- This Product Does Not Contain Natural Rubber Latex
- Keep Dry
- Manufacturer

WARRANTY DISCLAIMER

This product is warranted by Soma Access Systems LLC ("Soma") to be free from defects in materials and workmanship from the date of delivery until, and including, the indicated expiration date when used for its intended purpose and in accordance with the product's labeling. Soma's obligation under this warranty is limited to the repair or replacement, at Soma's option, of the applicable components. This limited warranty shall only apply to defects that are reported to Soma within the applicable warranty period and which, upon examination by Soma, prove to be defective. This warranty does not cover and Soma shall not be liable for the following:

(1) defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering, or failure to seek and obtain repair or replacement in a timely manner;
(2) products which are not used in accordance with their labeling;
(3) products considered to be of a consumable nature; or
(4) accessories or parts not manufactured by Soma.

THIS WARRANTY IS SOMA'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. SOMA MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS.

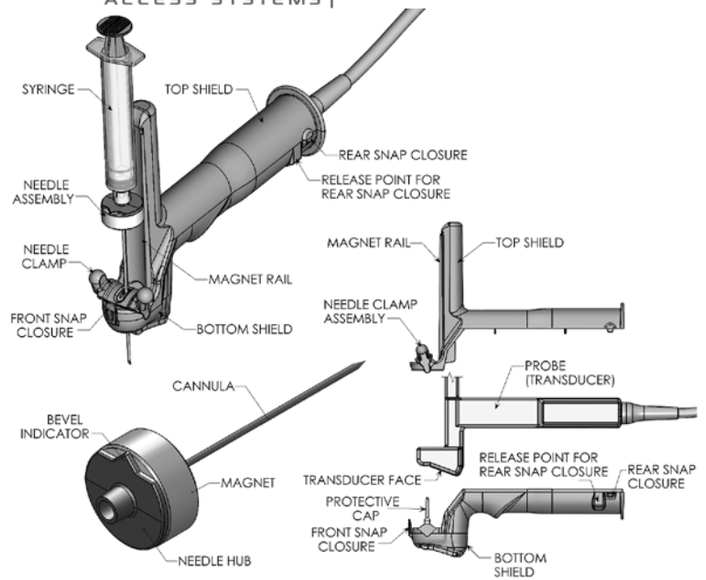
Protected by one or more of US Patents 6,690,159 B2. 7,244,234 B2. Other US and foreign patents pending.

Manufacturer

Soma Access Systems LLC
109 Laurens Road, Suite 4C
Greenville, SC 29607

864-240-7400
SomaAccessSystems.com

SOMA ACCESS SYSTEMS | AXOTRACK™ BY SOMA



Caution: Federal law restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in serious complications.

DEVICE DESCRIPTION

The Soma Access Systems AxoTrack™ I Sterile Procedure Kit is for use only with an AxoTrack™ I configured ultrasound probe and imaging system. The K1001 series AxoTrack™ I 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 probe cable sleeve to the shield. The top and bottom halves of the sterile shield are configured to fit around the AxoTrack™ I configured ultrasound probes. The integral ring magnet on the needle assembly provides axial position information to the electromagnetic tracking capabilities of the AxoTrack™ I configured probe. This axial position information is represented as a virtual needle overlay registered to the ultrasound image on the AxoTrack™ I configured 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 AxoTrack™ I configured probe and system, refer to the probe and system labeling as appropriate.

SIZING GUIDE

SOMA Catalog Number	Needle Gauge	Hub Color	Nominal Needle ID in(mm)	Guidewire Compatibility in(mm)
K1001-18XTW	18ga XTW	Pink	0.0420" (1.067mm)	Up to 0.035" (0.89mm)

STORAGE

The AxoTrack™ I 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 Integral Ring Magnet
- Sterile Cable Sleeve (80cm length)
- Elastic Bands (2)
- Instructions for Use

RECOMMENDED ACCESSORIES

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

INDICATIONS FOR USE

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

CONTRAINDICATIONS

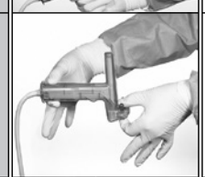
No contraindications have been identified for use of this device for needle guidance. Do not use this device if there is a contraindication to guided needle access for a selected procedure. For contraindications specific to your AxoTrack™ I configured probe and system, refer to the user's guide for the probe and system.

WARNINGS

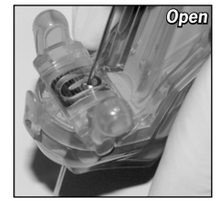
- Procedures must be performed by trained medical personnel competent in ultrasound, safe techniques, and proper handling of potential complications. For instructions on the use of the ultrasound probe, refer to the user's guide for the probe and system.
- Practitioners must be aware of complications 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 patient injury.
- There is a ring 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 AxoTrack™ I 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 AxoTrack™ I virtual needle display serves only to provide visual information for needle access. Traditional clinical markers of needle access (e.g., blood flash in the syringe) should be used to confirm needle location.
- This product is designed only for use with the included AxoTrack™ I needle assembly with integral ring magnet. Do not attempt to use this product with a different needle.
- Do not reposition or reorient the probe 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 probe.

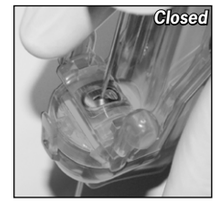
PRECAUTIONS

- Examine packaging and device before use. DO NOT use this kit if it has been previously opened, damaged, integrity of the packaging is violated, or if the expiration date has passed. Failure to do so may result in harm to the patient or user.
- 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 bloodborne pathogens. Clinicians must adhere to state/federal OSHA standards for bloodborne pathogens when starting, discontinuing or maintaining needle access to minimize the risks of exposure.
- Exposure to acetone and alcohol can result in a loss of visual clarity in the materials used in the AxoTrack™ I Sterile Procedure Kit. Do not clean or wipe the surface of the kit with swabs, wipes and sprays containing acetone or alcohol.
- Do not re-sterilize or reuse. This product is designed for single use only.
- Do not alter any of the items included in this kit during assembly, use, or removal.
- Do not alter the "Exp Date" (expiration date) printed on the label.

	NON-STERILE ASSISTANT		STERILE OPERATOR
A	Carefully peel open the pouch while avoiding contact with the sterile tray.		Remove the sterile tray from the pouch and place on the sterile field.
B	Hold the ultrasound probe with the transducer facing 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.		
C	Grasp the ultrasound probe by the vertical rail and position in bottom shield while guiding the needle guide and protective cap through the needle guide receiver hole in the probe.		Hold the bottom shield to accept the probe. **Confirm proper positioning of the protective cap over the needle guide.** This cap maintains needle guide sterility during shield assembly on the probe.
D	Remove the protective cap from the needle guide. Avoid contacting the bottom sterile shield or the gloved hand of the sterile operator.		
E			Slide the top shield over the vertical rail on the probe and align with the bottom shield.
F			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 probe. Visually verify proper shield closure.
G	Suspend the probe/shield assembly by holding the probe cable. Avoid contacting the probe/shield assembly. (1)		Unfold the sterile cable sleeve. (2)
H	Holding the probe by the cable, lower the probe/shield assembly into the sterile cable sleeve.		Slide the end of the sterile sleeve over the probe/shield assembly.
I			Grasp the probe/shield assembly once it is covered by the sterile cable sleeve. Advance the sterile cable sleeve over the cable and probe/shield assembly until the probe/shield assembly exits the other end of the sleeve. Avoid contacting the non-sterile probe cable.
J			Wrap the sterile cable sleeve around the handle of the probe/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.

DIRECTIONS FOR USE





VERIFY ACCURATE NEEDLE TRACKING

1. Attach the needle on a non-locking Luer-Slip syringe.
2. Confirm needle clamp is disengaged (i.e., forward/open position).
3. Insert the tip of the needle into the needle guide while maintaining the magnet in contact with the magnet rail of the probe/shield assembly.
4. Slowly move the needle in and out of the needle guide. Confirm virtual needle motion on the ultrasound screen mirrors actual needle motion.
   a. The virtual needle should be displayed through the extent of needle travel.
   b. Any dropout or jumping in the virtual needle image indicates improper needle tracking.
5. Verify proper needle tracking. The virtual needle should appear on the image as the needle begins to protrude from the end of the needle guide.
   a. **If needle tracking is not functioning properly, do not use the product.** Consult the user's guide for the probe and imaging system to confirm proper system settings and operation.
6. Remove the syringe with attached needle, and place in a secure location in the sterile field.

PROPER HAND GRIP AND PROBE ORIENTATION

1. Apply **sterile** acoustic gel to the skin.
2. Grasp the probe/shield assembly by placing the handle/rail junction in the webbing between the thumb and forefinger, and wrap the middle, fourth and fifth fingers around the handle.
   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 user's guide for the probe and imaging system for specific instructions relative to toggling the ultrasound image left to right.
3. Stabilize the probe/shield assembly on the skin with the thumb and forefinger placed on the skin surface.
4. Image and identify target anatomy. Align the target line with the target structure, ensuring a clear path that avoids contact with intervening structures (e.g., bone) during needle insertion. **Note that the angle of the needle relative to the target structure will correspond to the angle of the probe relative to the patient anatomy.** It is important that the probe be positioned and tilted appropriately to achieve the needle access angle typically used for the clinical procedure.