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 probe/shield assembly on the skin surface.
   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 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.
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 shield assembly position on the skin surface. The needle clamp will not prevent needle movement to avoid undesired axial movement of the needle.
   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 forward/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 SHEILD 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 snap closure, and squeezing the rear part of the hub bevel indicator.
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-stereilize
- Consult Instructions for Use
- 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 third anniversary date when used for its intended purpose and in accordance with the product's labeling. Soma's obligation under the warranty is limited to the repair or replacement, at Soma's option, of the applicable components. This limited warranty shall only apply to defects in materials and workmanship that become apparent to Soma prior to or during the warranty period. The warranty does not cover and Soma shall not be liable for the following:
- Defects, damages, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident, freight damage, tampering, or failure to heat and maintain replacement at a proper temperature;
- Products which are used in a manner contrary to the directions for use included in the product literature or which are converted or repurposed by the customer or third parties;
- Improper or improper installation, maintenance, or operation of the equipment;
- The use of any accessories, supplies, or other equipment or materials not manufactured or approved by Soma.
- Any product, accessory, or part which is not manufactured or approved by Soma.
- Any product, accessory, or part which has been altered or modified by a third party.
- Any product, accessory, or part which has been repaired, altered, or modified by a third party.
- The use of any product, accessory, or part which is not manufactured or approved by Soma.

THE MANUFACTURER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED. SOMA DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE MANUFACTURER IS NOT LIABLE FOR ANY INJURY TO PERSONS OR PROPERTY CAUSED BY ANY DEFECT IN THE PRODUCT OR IN ANY OTHER MATTER.

SIZING GUIDE
<table>
<thead>
<tr>
<th>SOMA Catalog Number</th>
<th>Needle Gauge</th>
<th>Hub Color</th>
<th>Nominal Needle ID (in.)</th>
<th>Guidewire Compatibility (in.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K1001-18XTW</td>
<td>18ga XTW</td>
<td>Pink</td>
<td>0.0420&quot; (0.1066mm)</td>
<td>Up to 0.035&quot; (0.899mm)</td>
</tr>
</tbody>
</table>

STORAGE
The AxoTrack™ Sterile Procedure Kit should be stored in a dry place between 10°C and 40°C (50°F - 104°F).
The AxoTrack™ Sterile Procedure Kit is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

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™ selected procedure, refer to the user’s guide for the probe and system.

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