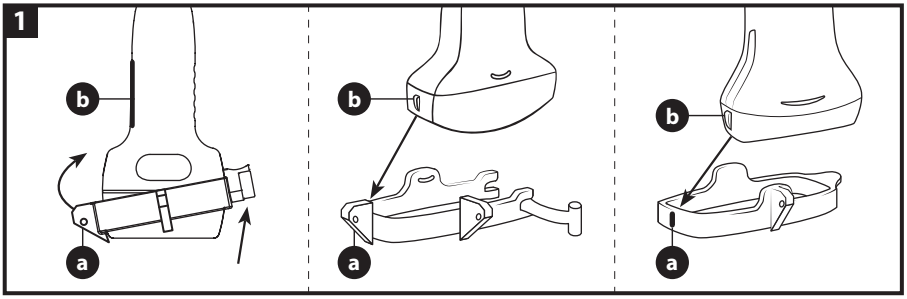
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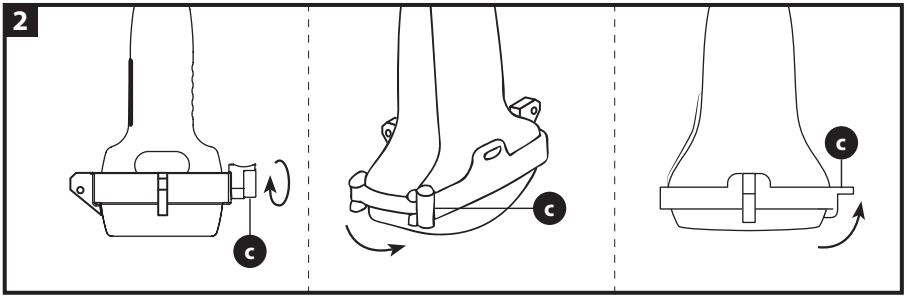
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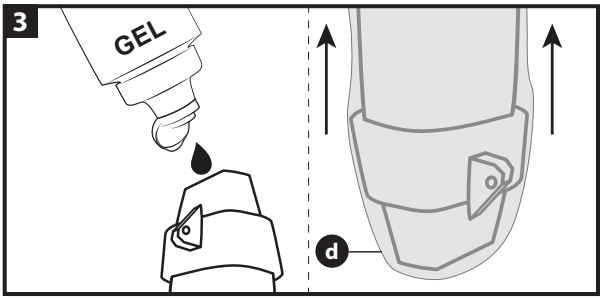
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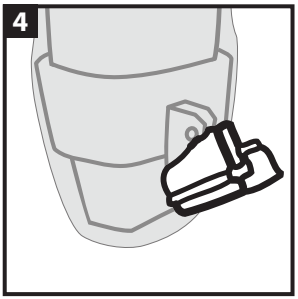
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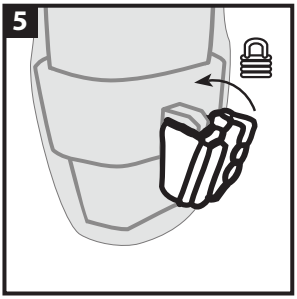
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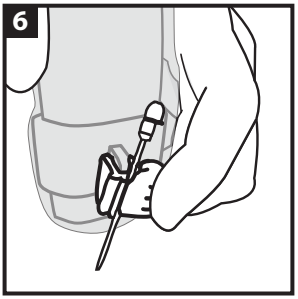
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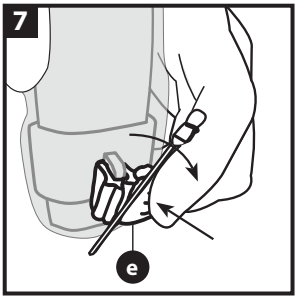
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Instructions For Use

for *ProV-Access*™ Sterile Disposable Needle Guide

ULTRASOUND ACCESSORIES

aspen surgical

INTENDED PURPOSE / INTENDED USE

This is a medical device used to provide precise needle placement to an intended target assisting healthcare professionals performing needle/instrument guided imaging procedures.

USE INSTRUCTIONS

Prepare probe per system's operational manual. Reusable bracket is provided non-sterile. Always verify needle follows guidelines prior to use.

⚠ If bracket/needle guide does not fit properly, do not use. Clean/sterilize bracket before use, following recommended instructions. Use appropriate needle length to reach target area.

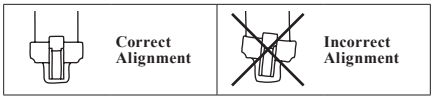
⚠ This needle guide is single-use only.
Do not reuse. Do not resterilize. Reuse, reprocessing or resterilization of the single use devices may create a risk of cross contamination, patient infection, and / or malfunction of the device.

After use, dispose of single-use components as infectious waste. Do not use if sterile package is damaged.

REUSABLE BRACKET

If using a bracket:

1. Attach bracket (styles vary) to the probe, aligning needle guide receiver / locator indicator on the bracket (a) with the scanning side of the probe (b).
2. Make sure bracket is securely attached to probe (c).



DISPOSABLE NEEDLE GUIDE

3. Place gel inside cover and/or on probe scanning surface. Place probe cover (d) over probe and bracket assembly. Secure cover with bands.
4. Slide needle guide onto needle guide receiver over probe cover as shown.
5. Rotate needle guide until secure.
6. Insert needle into guide.
7. For a quick release of the needle, press needle guide pad (e) and remove needle from guide.

CLEANING, DISINFECTING & STERILIZING REUSABLE BRACKETS

CLEANING

Reusable devices must be thoroughly cleaned before they are subjected to the sterilization process. Remember, you cannot achieve sterilization or high-level disinfection unless the assembly is cleaned first.

1. Rinse excess soil from device.
2. Prepare the enzymatic solution (like Enzol), following manufacturer instructions for proper dilution.
3. Fully immerse the device in the detergent and allow soaking for 10 minutes.
4. After the soak, brush device thoroughly using a soft bristle brush. Clean lumens and holes using an appropriate size brush. A syringe might be used to flush the hard-to-reach areas of the device.
5. Thoroughly rinse and dry the device. Always use R/O (reverse osmosis) or DI (de-ionized) water for rinsing the device, tap water may recontaminate the reprocessed device. Use a clean soft cloth to dry the device.
6. Thoroughly examine all surfaces to make certain that no visible bioburden remains. If any visible parts observed on the device, repeat cleaning and drying, until the ENTIRE device is clean.

RECOMMENDATIONS FOR HIGH LEVEL DISINFECTION/ STERILIZATION OF PLASTIC OR ANODIZED ALUMINUM REUSABLES

After cleaning by using the above recommendations, soak for a minimum of 5 minutes in a neutral pH Enzol Enzymatic detergent such as made by *Johnson & Johnson©*.
Sterilize with Cidex Activated Dialdehyde solution such as made by *Johnson & Johnson©*, or any equivalent validated sterilization method adopted by the sterilization department for like devices.

STEAM STERILIZATION OF STAINLESS STEEL REUSABLES

After cleaning by using the above recommendations, steam sterilize (sterilizer type - gravity) in an autoclave at minimum 132 degrees Celsius (270 degrees Fahrenheit) for a minimum of 15 minutes. Dry the device for a minimum of 25 minutes. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

WARNING

- Long narrow cannulations and blind holes require particular attention during cleaning.
- Do not reuse or reprocess devices labeled for single-use.
- After sterilization, appropriately package and store the device to ensure that sterility is not compromised prior to reuse.
- Always use a probe cover to minimized any contaminants.

INSPECTION AND FUNCTION TESTING

- Visually inspect for damage and wear. For hinged instruments, check for smooth movement of hinge without excessive "play."
- Locking mechanisms should be checked for action.

LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.

DISCLAIMER

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It is the user's responsibility to qualify any deviations from recommended method of processing, and properly evaluate for effectiveness and potential adverse consequences.

STERILE EO

Do not use if sterile package is damaged.

Do not re-use.

℞ ONLY

Not made with natural rubber latex

Do not resterilize

For translations of this instruction, go to aspensurgical.com/ifu

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