

Director XT™
RetroFit XT™
Protek™

Instructions For Use for General Purpose Needle Guide

Director XT™ | Director™ | RetroFit XT™ | RetroFit™
ULTRASOUND ACCESSORIES

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.

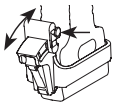
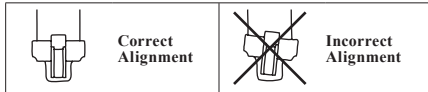
⚠ If bracket/needle guide does not fit properly, do not use. Clean/sterilize bracket before use, following recommended instructions. Use appropriate needle length to reach target area.

⚠ This needle guide is single-use only. **Do not reuse. Do not resterilize. Reuse, reprocessing or reesterilization 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.

SINGLE ANGLE/MULTI ANGLE BIOPSY BRACKET (Bracket is reusable)

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



Multi-Angle Bracket Changing Bracket Angle

Select bracket angle by pressing locator pad and moving to desired angle. Release pad to lock into position.

DISPOSABLE GENERAL PURPOSE 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. Place needle guide (e) onto mounting bracket over probe cover as shown with locking pad in elevated position.
5. Lock guide into position by pushing down locking pad and up on lock button (f) until completely closed.
6. For a quick release of the needle, press needle guide pad (g) and remove needle from guide.
7. After use, to remove needle guide, push up locking pad and down on lock button (f).

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 contaminate 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.

R_x ONLY



Not made with natural rubber latex



Do not resterilize

