

COOK® Bx CORE TISSUE BIOPSY DEVICE AND NEEDLE

Instruction for Use



T _ C B D _ R E V 1

COOK® Bx CORE TISSUE BIOPSY DEVICE AND NEEDLE

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION

- *Set components may vary*
- Bx Core Tissue Biopsy Device
- Periprostatic injection needle (for transrectal local anesthetic injection)
- Needles

INTENDED USE

The Cook Bx Device is a reusable system for histological core biopsies. It has a throw (advancement) of 25mm and is used in conjunction with a single use Cook Bx Needle. The Cook Bx Device is used to obtain tissue core biopsy of the prostate using only the Cook Bx Needle. These instructions for the Cook Bx Device are not meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.

CONTRAINDICATIONS

For use only for core biopsies of soft tissue as determined by a licensed physician. The device should be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of core needle biopsy. Physician judgment is required when considering biopsy on patients with a bleeding disorder, or receiving anti-coagulant medications.

WARNINGS

None known

PRECAUTIONS

- Not closing the lid may lead to malfunction of the device.
- Do not use device in presence of Magnetic Resonance Imaging (MRI).

INSTRUCTIONS FOR USING THE COOK® Bx DEVICE AND NEEDLE:

1. Inspect the product package for damage. If undamaged, open the package using proper aseptic technique.
2. Remove the needle from the pouch. Inspect the stylet for damage to the point, the cannula for damage to the cutting edge, and check for other imperfections that would prevent the proper operation of the needle assembly.
3. Open the lid of the biopsy device, load needle set into the biopsy device, close lid, and remove protective sheath.
4. Safety button must be set in the unlocked (right) position before cocking.
5. Cock the actuator handle twice to activate the device for firing (this automatically sets the safety.)
6. Release the safety by pushing the "Safety Release Button" located on the side of the device.
7. Firing the device can be achieved by pushing in on either the front trigger button or the rear trigger button. This action will trigger the spring mechanism, propelling the needle forward for a core biopsy sample.
8. The needle need not be removed from the biopsy device to retrieve the sample.
9. After removing the needle from the patient, reset safety button and cock the actuator handle once to expose the biopsy notch located at the distal end of the needle. This action exposes the

specimen for removal. Cocking the actuator handle a second time will activate the device for a second biopsy.

10. The disposable needle set is for Single Patient Use Only. Do not attempt to clean or resterilize the needle set. After use, this product may be a potential biohazard. Handle in a manner that will prevent accidental puncture. Dispose in accordance with applicable laws and regulations.

INSTRUCTIONS FOR CLEANING THE COOK® BIOPSY DEVICE:

1. The Cook Bx Device may be cleaned in a mild detergent and lukewarm water solution. Never place the device in bleach or alcohol, or in any bleach, or alcohol solution.
2. After washing completely, rinse the device in hot water.
3. A high level of disinfection can be achieved with CIDEK 7 or ProCide NS: follow the manufacturer's recommended procedure.
4. Thoroughly dry the device to ensure proper function.

AUTOClave STERILIZATION:

Sterilizing by normal autoclaving may be employed. The device should first be cleaned and placed in appropriate packaging materials capable of maintaining sterility. Although cycle conditions and times will vary, typical conditions for autoclaving are 270° F (132°C) for 15 to 25 minutes.

To ensure effectiveness, sterilization processes should be properly validated and monitored with the proper biological controls. Sterilization operations should proceed according to the sterilizer manufacturer's instructions.

NOTE: Do not sterilize by irradiation or gas plasma sterilization.

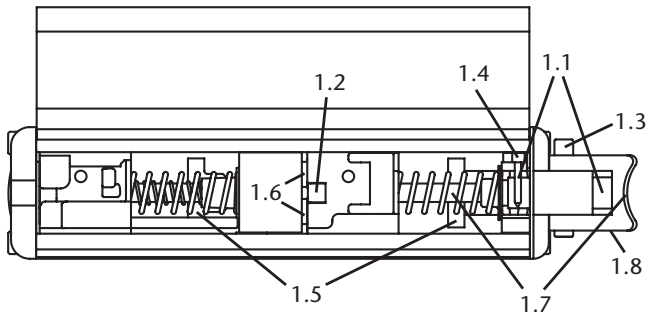


Figure 1

LUBRICATION INSTRUCTIONS:

Washing detergents may eventually remove the lubricant originally applied. Re-lubrication at the following points may be required: (Refer to figure 1)

- 1.1 Trigger Button (must move freely)
Recommended Lube: "B"
- 1.2 Top End of Actuator Pin
Recommended Lube: "B"

- 1.3 Safety Button (must move freely; lube both sides)
Recommended Lube: "B"
- 1.4 Lever Pivot
Recommended Lube: "B"
- 1.5 Top Edge of Ramps on Latch
Recommended Lube: "A"
- 1.6 Sides of Catch on Stylet Holder Block
Recommended Lube: "B"
- 1.7 Cam Surfaces
Recommended Lube: "A"
- 1.8 Link Pivots
Recommended Lube: "B"

Lubricant "A":

Permatex "Superlube" Synthetic Grease with Teflon

Lubricant "B":

Permatex "Superlube" Synthetic Oil with Teflon

Both Lubricants are U.S.D.A. approved for food grade applications and available locally in hardware and automotive stores. Use lubricants sparingly.

IMPORTANT: Lubrication on the sides of the carrier blocks will slow the action of the device.

DO NOT LUBRICATE.

Warranty Information:

Cook Urological Inc. warrants to the purchaser of this product that at the time of manufacture, the product was prepared and tested in accordance with Good Manufacturing Practices specified by the United States Food and Drug Administration and was true to label.

In the unlikely event of product failure due to defects in material or workmanship within a period of twelve (12) months from date of purchase, the product will be repaired, or at our option, replaced at no charge. The product must be returned clean, sterile, and properly packaged for shipment. This limited warranty does not apply to products damaged by accident, misuse, or to products altered or serviced by anyone other than Cook Urological, Inc.

Before returning a product for any reason, please call toll-free for assistance and instructions.

Because we have no control over the conditions under which this is used, diagnosis of the patient, anatomical or biological differences among patients, method of use or administration, and handling of the product after it leaves our possession, we do not warrant a good effect or against an ill effect following the product's use. The foregoing warranty is exclusive and in lieu of all other warranties whether written, oral, or implied. There are no warranties of merchantability or fitness for a particular purpose. No representative of the company may change any of the foregoing, and the buyer accepts the product subject to all terms hereof. We reserve the right to change or discontinue this product without notice.

Loaner Program:

If requested Cook Urological will provide a loaner device to the purchaser. Loaner devices that are not returned within (30) days after the return of the repaired device will be invoiced to the customer.

HOW SUPPLIED

Supplied non-sterile in peel-open packages. Reusable. Store in dark, dry cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred. Needles are sterile (ETO) if package is unopened or undamaged..



If symbol appears on product label, X = quantity per box



MANUFACTURER

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2014-08

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