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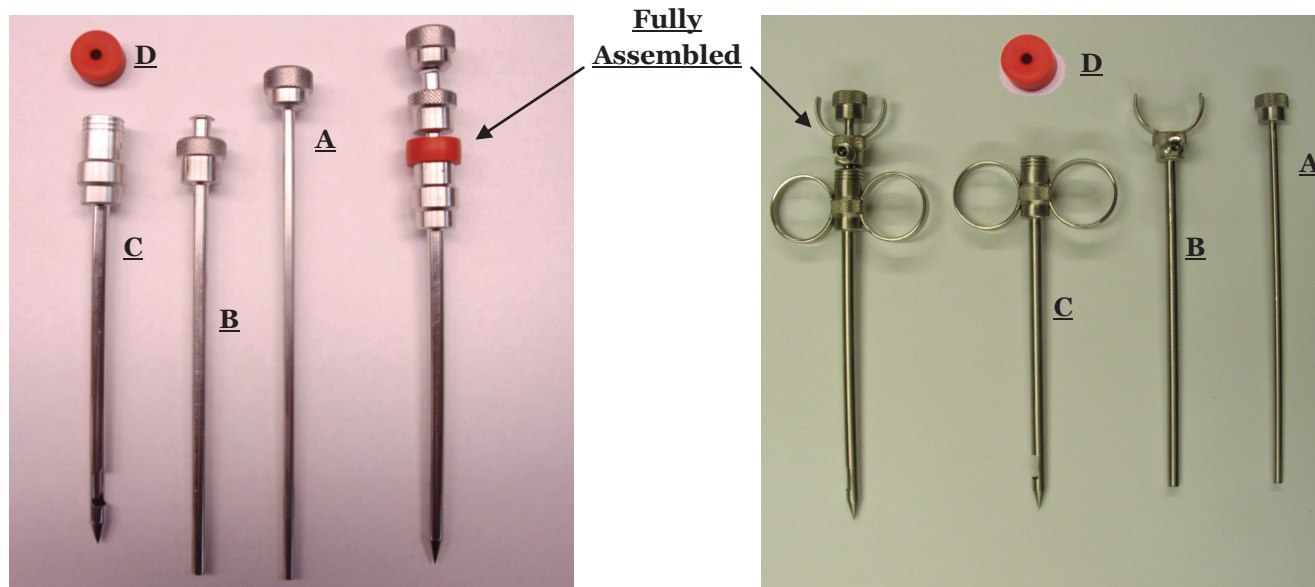
UNMATCHED SERVICE · UNLIMITED INSTRUMENTS

822 Montgomery Ave #205  
Narberth, PA 19072  
(800) 600-0428

# Biopsy Needles IFU

IFU-2014.11.18

These instruments are for minimal invasive surgery. They are shipped non-sterile and must be sterilized before use. Elmed, as manufacturer and seller of the product, accepts no liability for indirect damage or preparation, sterilization or maintenance. Instruments are only to be used as designated in their specialized medical fields by the respective trained and qualified personnel. They are not intended to be used on the central circulatory or central nervous system.



## MAINTENANCE AND CARE:

- Every instrument must be cleaned and sterilized before being used for the first time and after every subsequent use.
- Appropriate cleaning, inspection and maintenance help to ensure the serviceability of surgical instruments and prolong service life.
- Clean, inspect and test all instruments thoroughly, and sterilize before use.
- Cleaning and rinsing should be done promptly after every use. Otherwise tissue particles or dried secretions may adhere to it, which may make subsequent cleaning and sterilization difficult, if not impossible. Instruments must be entirely free of any foreign bodies.

## HANDLING, STORAGE AND STERILIZATION:

Extreme care must be exercised while using, transporting, cleaning, sterilizing, and storing. Damage to the function and safety of the instrument may occur if the instrument is handled roughly or improperly, or used for something other than its intended purpose.

## WARRANTY:

- These instruments are warranted against defects in material & workmanship for 1 year. Routine sharpening, reinsulating, and adjustments as well as repair of damaged instruments is available for a modest charge.
- Any servicing of these instruments performed by any source other than the manufacturer VOIDS this warranty.
- The manufacturer and seller of the product, accepts no liability for indirect damage or subsequent damages that result by improper usage, improper handling or through improper preparation, sterilization or maintenance.



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## DISASSEMBLING & CLEANING:

1. Take apart the biopsy needles so all the pieces are separate (A, B, C & D)
2. Check the condition of the sealing cap. Replace if broken or in hard, brittle condition

RE-ASSEMBLING: Reverse steps of disassembly.

STERILIZATION: The instruments can be sterilized fully assembled (recommended) or it can be sterilized disassembled and then reassembled in a sterile field in the operating room.

## Steam Autoclaving:

1. When using the wrap method, make certain that all complete instruments and all parts are individually wrapped or sealed in a sterile pack.

We recommend the following values/parameters, but also suggest following the manufacturer's sterilization unit instructions for steam sterilization

Cycle	Sterilizing Temp	Sterilizing Time	Drying Time
Prevacuum / Wrapped	270°F (132°C)	4 minutes	30 minutes
Gravity / Wrapped	250°F (121°C)	30 minutes	45 minutes
Gravity / Wrapped	270°F (132°C)	15 minutes	45 minutes

## 2. ETO Sterilization:

Instruments can be sterilized by ethylene oxide in any standard cycle. Pressure reading should not exceed 12 PSI. Temperature should not exceed 68.3°C (155°F).

It is recommended to follow the manufacturer's instructions for the ETO sterilization unit concerning humidity, vacuum, cycle time, gas concentration and temperature.

## 3. Sterrad Sterilization Process:

Uses low temperature plasma. Adhere to the sterilization instructions provided by the manufacturer (e.g. Johnson & Johnson)

## 4. Flash Autoclaving (fast heating/cooling cycle):

Flash autoclaving will reduce the useful life of the instrument, particularly when it is constructed of various materials, encompassing different expansion rates.

Caution: Continued use of this process will cause premature failure of instruments, especially the insulation.

## 5. Chemiclaving – Soaking: Not Recommended

This is destructive to the insulating and silicone materials and can cause rapid deterioration and failure.

**\*\*IMPORTANT:** Adhere to proper drying cycle to make sure that instruments are completely dry on the inside.

**Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!**