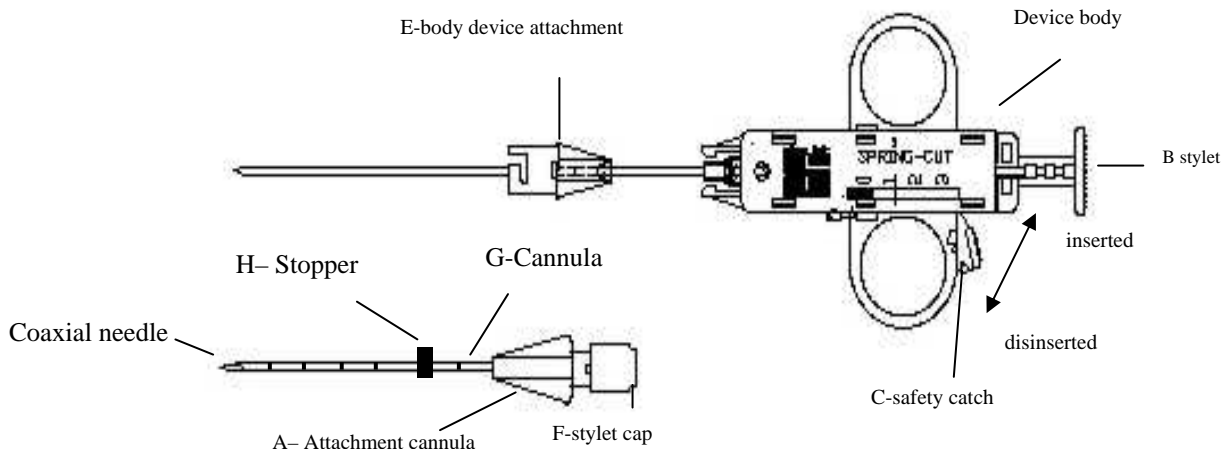


INSTRUCTIONS FOR USE OF THE SEMI-AUTOMATIC GUILLOTINE CUTTING SOFT TISSUE BIOPSY INSTRUMENT SPRING-CUT® TC/MR SET versions



- WARNING:**
- Store in a dry clean place away from heat sources
 - Before use ensure that the packaging is intact: if perforated, damaged or open discard the instrument
 - Check the expiry date and that the model corresponds
 - Peel open the package
 - Pay attention to not compromise the sterility of the instrument before use
 - In the event of a product defect or malfunction complete the yellow claim form to be found in the product carton and conserve the defective instrument

N.B.:

The use of this instrument is reserved to qualified medical personnel who are aware of its application.

The instrument is sterile (sterilized by ETO GAS) single use and should be discarded after use (Circ.Min:Sanità 403/9.5/1146-L. 10.81)

Sterylab declines any and all responsibility in the event of improper use or reutilisation.

D) COAXIAL NEEDLE USING

- Set the stopper (H) to the desired depth (1 marking = 1 centimeter)
- Penetrate using coaxial needle to reach the point to be biopsied
- Verify needle position by CT or MR (for MR-SET versions) scanning. Remove the stylet unscrewing the cap F and hook up loaded (point II) SPRING-CUT device using E and A hooks.
- Continue from point IV)

If you want to use SPRING –CUT without using coaxial needle remove the stylet unscrewing the cap F and hook up SPING-CUT and the cannula by using A and E hooks. Proceed from point II)

II) LOADING

- 1) Disinsert the safety catch (pushing on button “C”)
 - 2) pull back on the stylet “B” , until the desired bioptic excursion “D” *
 - 3)insert the safety catch (pulling on button “C”).
- | | | | |
|------------|--------|-----|--|
| position. | 1 = mm | 6 * | |
| position . | 2 = mm | 12 | |
| position | 3 = mm | 20 | (for this position pull fully and decisively back) |

In the event of pulling back beyond the desired point to correct the position disinsert the safety catch , advance the stylet “B” to release the spring ,and proceed again from point I),2)

***ATTENTION: SPRING-CUT is supplied already LOADED IN POSITION 1 (=mm 6). If the desired bioptic excursion is 6mm (position 1) control that the safety catch is inserted and proceeds from point II) PENETRATION**

III) PENETRATION

Grip the SPRING - CUT (index and middle fingers in the lateral rings, thumb on the stylet hub "B") and penetrate to reach the lesion pressing with all three fingers.

IV) BIOPTIC FIRING

Disinsert the safety catch "C" on the side ring using the thumb and advance the stylet "B" into the lesion activating the firing of the cannula

V) RECOVERY OF THE SAMPLE

Extract the instrument from the patient, load it completely (position 3), verify that the safety catch is disinserted (press button "C") uncover the stylet (button "B") being careful to not activate the firing mechanism or extract the instrument from the patient, rotate the hub "B" in an anticlockwise direction and remove completely the stylet from the instrument

N.B.: the device SPRING -CUT can be used to verify the quality of the cylinder with the instrument in situ and to perform multiple biopsies e.g. for prostate mapping ; in this case free the body device slightly rotating the body device attachment E and keeping the cannula attachment A firmly. Recover the sample from the stylet.

Load the device at desired position insert safety catch , hook up the device body to the cannula remained in situ into the patient and proceed from point III)