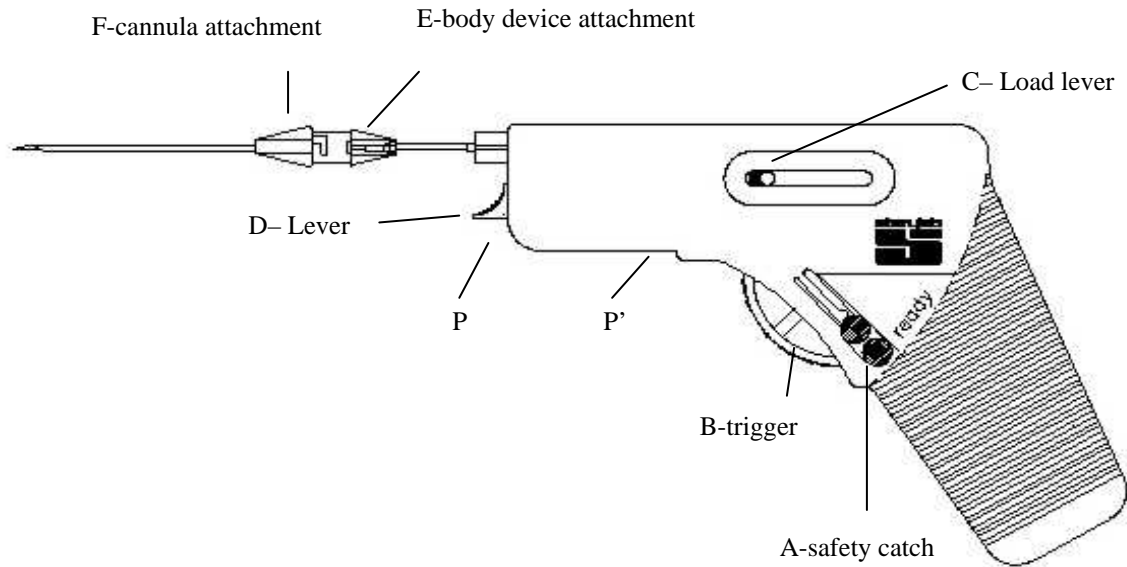


INSTRUCTIONS FOR USE OF THE GUILLOTINE CUTTING AUTOMATIC SOFT TISSUE BIOPSY INSTRUMENT COLT® DC version



- 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.

BIOPTIC PROCEDURE

- 1) Control that the lever “D” is in the position P and that the safety catch “A” is not in the “ready” position
- 2) Load using both hands by pulling back on the coloured wings until they click into position
- 3) Grip the instrument as you would a gun or if more comfortable by inverting the grip (laparoscopy, rectal ultrasound probe)
- 4) Penetrate to reach the lesion. For COLT DC + and ++ versions (with echonox cannula): verify the correct position of the needle by controlling with ultrasound
- 5) Make the instrument ready to use by moving the safety catch to the “ready” position with the thumb
- 6) Brace the wrist (to counteract kick-back), press the trigger until the first shot is heard (penetration of the stylet). After waiting a moment for the tissue to prolapse into the sample notch, press the trigger again to fire the cutting cannula.
Should a rapid succession biopsy be desired press down hard the first time on the trigger
- 7) Remove the instrument from the patient, uncover the sample notch by moving the level “D” into position P’

The device COLT can be used to perform multiple biopsies e.g. for prostate mapping ; in this case proceeds from point 1) to point 9) and then proceeds as follow:

- i) free body device slightly rotating the body device attachment E and keeping the cannula attachment F firmly.
- ii) Recover the sample.
- iii) Insert the safety catch, load the body device (as point 2)) and hook up it to the cannula remained in situ.
- iv) Penetrate to reach the lesion
- v) proceed from point 4)