

AUTO-CUT SEMI-AUTOMATIC GUILLOTINE TYPE BIOPSY NEEDLE

1. Auto-Cut is spring triggered semi-automatic biopsy needle used for the purpose of soft tissue biopsy.
2. Prepare patient for the procedure according to standard aseptic technique and ensure patient will remain in proper position throughout the procedure.
3. Open unit pack using sterile technique.
4. Remove plastic tip protector and examine needle body and tip in order to confirm its integrity.
5. In order to prepare **AUTO-CUT**[®] Semi-Automatic Guillotine Type Biopsy Needle for specimen harvest, pull back stylet plastic with one hand while holding main body of needle steady with the other. Automatic mechanism of needle is set when you hear a “click”.
6. To test proper functioning of mechanism, trigger the needle by pushing rear end of stylet.

⚠ Needle may hurl out due to the pressure created by the spring. Considering this risk, please direct needle tip towards ground during this test.

7. After completing test, pull back stylet plastic and re-load automatic mechanism.
8. Start the puncture from previously determined area. When you reach lesion or target tissue, push rear end of stylet to trigger the needle and harvest specimen.
9. Gently remove needle from patient and pull stylet plastic in order to re-load needle. Push gently from rear end of stylet and collect specimen from guillotine notch.
10. Dispose needle according to medical waste regulations.

AUTO-CUT SEMI-AUTOMATIC GUILLOTINE BIOPSY NEEDLE LIST OF MODELS:

| Reference Code | Product Description |
|----------------|---|
| ACT14 | Semi-Automatic Guillotine Biopsy Needle 14G |
| ACT14100 | Semi-Automatic Guillotine Biopsy Needle 14Gx100mm |
| ACT14150 | Semi-Automatic Guillotine Biopsy Needle 14Gx150mm |
| ACT14200 | Semi-Automatic Guillotine Biopsy Needle 14Gx200mm |
| ACT16 | Semi-Automatic Guillotine Biopsy Needle 16G |
| ACT16100 | Semi-Automatic Guillotine Biopsy Needle 16Gx100mm |
| ACT16150 | Semi-Automatic Guillotine Biopsy Needle 16Gx150mm |
| ACT16200 | Semi-Automatic Guillotine Biopsy Needle 16Gx200mm |
| ACT18 | Semi-Automatic Guillotine Biopsy Needle 18G |
| ACT18100 | Semi-Automatic Guillotine Biopsy Needle 18Gx100mm |
| ACT18150 | Semi-Automatic Guillotine Biopsy Needle 18Gx150mm |
| ACT18200 | Semi-Automatic Guillotine Biopsy Needle 18Gx200mm |
| AC14 | Semi-Automatic Guillotine Biopsy Needle 14G |
| AC14100 | Semi-Automatic Guillotine Biopsy Needle 14Gx100mm |
| AC14150 | Semi-Automatic Guillotine Biopsy Needle 14Gx150mm |
| AC14200 | Semi-Automatic Guillotine Biopsy Needle 14Gx200mm |
| AC16 | Semi-Automatic Guillotine Biopsy Needle 16G |
| AC16100 | Semi-Automatic Guillotine Biopsy Needle 16Gx100mm |
| AC16150 | Semi-Automatic Guillotine Biopsy Needle 16Gx150mm |
| AC16200 | Semi-Automatic Guillotine Biopsy Needle 16Gx200mm |
| AC18 | Semi-Automatic Guillotine Biopsy Needle 18G |
| AC18100 | Semi-Automatic Guillotine Biopsy Needle 18Gx100mm |
| AC18150 | Semi-Automatic Guillotine Biopsy Needle 18Gx150mm |
| AC18200 | Semi-Automatic Guillotine Biopsy Needle 18Gx200mm |

AUTO-CUT SEMI-AUTOMATIC GUILLOTINE TYPE BIOPSY NEEDLE

INDICATIONS:

Used for sample collection of soft tissue, when there is suspect of malignant growth
In soft tissues (liver, kidney, prostate, etc.) for the purpose of diagnosis before treatment.

CONTRAINDICATIONS:

Bleeding disorders
Coagulation disorders
Sclerotic lesions next to major arteries
Infected soft tissue surrounding a bone structure;
Biopsy of hemorrhagic lesions
Areas with densely vascularized

RISKS:

- Bleeding
- Pain
- Infection
- Pneumothorax following the lung biopsy.

SIDE EFFECTS:

Bruising
Tenderness
Blood in the semen or the blood after prostate biopsy.

⚠️ WARNINGS:

- All interventions related with the use of this medical device during and after its application should be conducted only by a doctor specialized in the subject.
- Do not use if package is torn or damaged. These are not sterile.
- Store in cool, dry and dust free environments.
- Needle cannula can be bent or broken upon applying excessive force during insertion.
- In case of a serious incident, it has to be reported to manufacturer and competent authorities.
- After use dispose device according to medical waste disposal regulations.
- Do not apply any techniques other than the approved procedure.
- Use this medical device only for the mentioned intended purpose.
- This medical device is for single use only. Reuse or re-sterilization of the original package after opening is dangerous and can cause cross contamination, infection and trauma.

Note: Measurement lines are marked at 1 cm. intervals, , first line is marked at 5 cm from the needle tip, two lines at 10 cm, 3 lines at 15 cm distances with a tolerance of +/- 1%.

SYMBOLS:



Sterilized using ethylene oxide



Keep dry



Do not re-use



Humidity limitation



Do not use if package is damaged



Batch code



Use-by date



Do not re-sterilize



INSTRUCTIONS FOR USE



AUTO-CUT SEMI-AUTOMATIC GUILLOTINE TYPE BIOPSY NEEDLE



Date of manufacture



Non-pyrogenic



Temperature limit



Keep away from sunlight



Consult (e IFU) instructions for use

www.egemen.com.tr

Information in this manual and information from other TMT Tıbbi Medikal Malzeme San. ve Tic. Aş. Sources indicates procedure only for guidelines. Use of the device should be based on the clinical training of the doctor

Manufacturer:

TMT TIBBİ MEDİKAL MALZ. SAN. TİC. AŞ.

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