

Opticore biopsy gun- Fully automatic

Device Description

Fully automatic biopsy gun is a sharp edged, hollow tubular metal device with handle designed to make the access and to collect the soft tissues.
The Fully automatic biopsy gun is available in the following configurations

Gage (G)	Length (cm)	Models
14, 16, 18 & 20	10, 16, 20 & 25	With coaxial needle Without coaxial needle

Intended Purpose & Duration

Used to obtain histological core samples from soft tissues and organs for a period of less than 60 minutes.

Indications For Use & Contraindications

One may undergo a biopsy if experiencing certain signs and symptoms or if health care provider has identified an area of concern, A biopsy can determine whether one have cancer or another condition.
No known contraindications.

Potential Complications

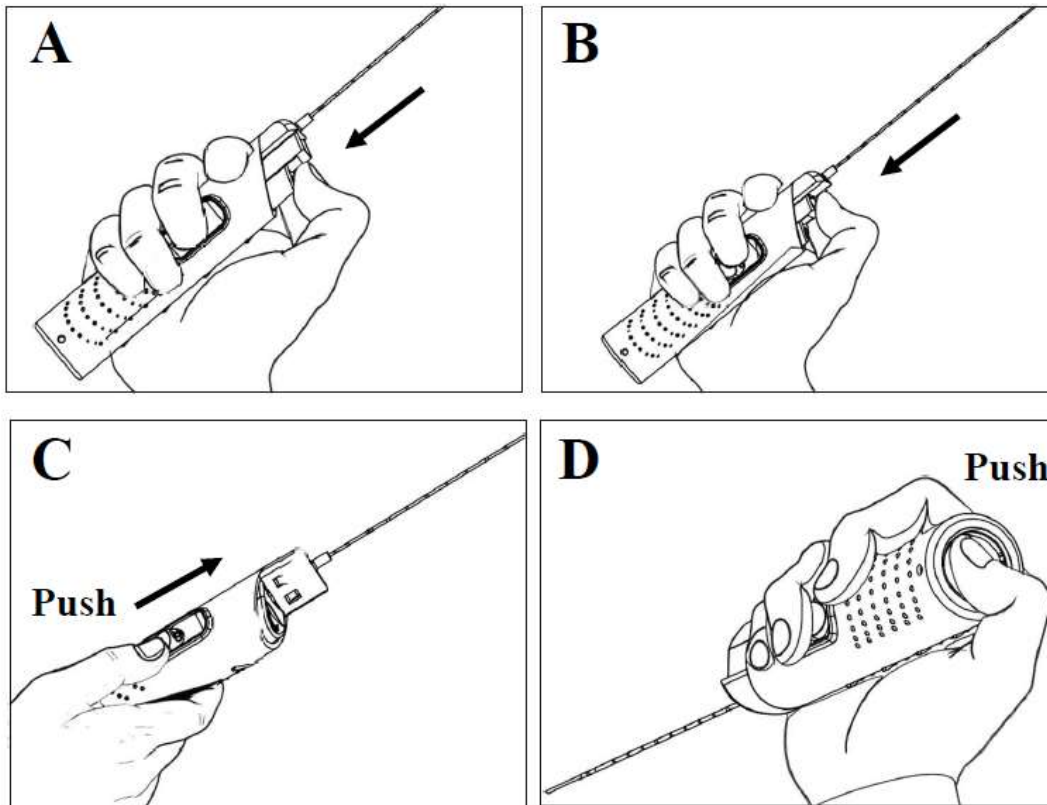
Potential complications include but not limited to Tissue perforation, Infection, Tissue trauma, Edema.

Warnings And Precautions

- Do not reuse the device. Reuse can cause severe infection. Intended use may fail on reuse. Do not use if package is opened or found defected. Do not use the product if there is suspect that the device is not sterile.
- Device is not intended for permanent use.
- The Biopsy Instrument should be used by a physician who is completely familiar with the indications, findings and possible side effects of core needle biopsy, in particular, those relating to the specific tissue being biopsied.
- The introduction of the needle into the body should be carried out under imaging guidance.
- Inspect the needle for bends and other possible damage. Please do not use the product if the device is found damaged.
- Before using this needle, test for proper function and alignment by sliding the cannula. if the parts do not move easily, the unit should be discarded. Do not apply unusual force to the assembly.
- Not intended for use in bone.
- On completion of the procedure, dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.

Instructions For Use

1. Identify the biopsy site preferably under US or CT.
2. Using the sterile technique, prepare the skin with anti-septic and drape.
3. If necessary, infiltrate the selected area with local anaesthetic.
4. Open the needle pouch and remove protective sheath from the needle.
5. Charge biopsy needle as shown in reference drawing.
6. Press The button 1 backward firmly as shown in image-A.
7. Press the button 2 Backward firmly as shown in image-B.
8. Introduce the needle to the patient and advance to the biopsy site.
9. Push or press any of firing buttons located in the rear end or middle part of the handle body to fire (Image-C: firing button located at middle of the handle. Image-D: Firing button located at rear end i.e. back side of the handle which have colour code.)
10. Draw the biopsy needle out form puncture site and press the Button 1 as shown in Image-A back to expose the specimen notch and remove the biopsy specimen at the tip of the needle for histological study.
11. Perform the same procedure to collect sufficient amount of sample required for histological study.



Intended population group

1. The patient population: Male and Female Population
2. Patient Age Group: Paediatric and Adult

Supply and Storage

The device is packed in package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not re sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



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