



Instructions for Use

BONEAID™

Soft Tissue Biopsy Needles

Description:

ALSPL's Soft Tissue Biopsy Needles are available in various configurations such as automatic gun, semi-automatic and manual needles. All needles have a needle and trocar for extraction of the tissue sample. All needles have a sharpened cannula for safe and painless percutaneous insertion and penetration. The needles have centimetre markings to know the depth of insertion. The hubs and handles are colour coded for easy size identification.

Indications for Use:

ALSPL's Soft Tissue Biopsy Needles are used for histological core sampling from soft tissue and organs.

Contraindications:

This device should be used only as indicated. Physician judgement is required when considering biopsy on patients with bleeding disorder, or receiving anti-coagulant medications.

Warnings and Precautions:

1. Rx Only. The device must be used by trained physicians only.
2. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in severe patient injury or death.
3. Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance.
4. Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
5. Aseptic techniques must be used wherever possible, especially during removal from packaging.

Instructions for Use:

1. Identify the biopsy site preferably under US or CT.
2. Using the sterile technique, prepare the skin with antiseptic and drape.
3. If necessary, infiltrate the selected area with local anaesthetic.
4. Open the biopsy needle and remove the protective sheath.

For Automatic Biopsy Gun

5. Rotate the handle at the proximal end to pull back the trocar.
6. Introduce the needle of the biopsy gun into the patient and advance towards the biopsy site
7. Press the button on the proximal end to obtain the sample.
8. Draw needle out.
9. Rotate the handle to expose the specimen notch and remove the biopsy specimen.

For Semi – Automatic and Manual Needles

10. Follow steps 1-4 as stated above
11. Pull back the trocar by pulling the handle
12. Introduce the needle of the biopsy gun into the patient and advance towards the biopsy site
13. Push back the handle (Manual) or press the button (Semi-automatic) to obtain the sample.
14. Draw needle out.
15. Push back the handle (Manual) or press the button (Semi-automatic) to expose the specimen notch and remove the biopsy specimen

Disposal:

16. The device can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal.





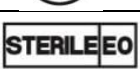







Potential Complications / Adverse Effects


Soft Tissue Biopsy Needles should not be used by physicians unfamiliar with the possible complications. Possible complication may include but not limited to excessive bleeding or drainage from the biopsy site, tumour seeding, redness, infection or swelling at the aspiration site, fever.

Warranty and Limitations

Soft Tissue Biopsy Needles are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit

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