



Instructions for Use

BONEAID™

Chiba Needle

Description:

Chiba Needle is a universal biopsy aspiration needle with depth marks, stopper and an echogenic marker placed on the distal tip. It has transparent Luer lock Connector. It is colour coded and available in different Gauges and Lengths.

Indications for Use:

BONEAID™ Chiba Needle is used for Cytological and amniotic liquid procedures, suction of cyst and alcohol & anaesthesia administration.

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.
6. Do not use under MRI

Instructions for Use:

1. Identify the biopsy site preferably under USG or CT.
2. Prepare the skin with antiseptic 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. Insert the biopsy needle and advance into the targeted area.
6. Remove the stylet.
7. Attach a syringe with a Luer taper to the hub of the biopsy needle with a firm, push, twist motion.
8. Raise the plunger and perform aspiration in different areas always keeping the plunger raised, moving the needle backwards, forwards and obliquely.
9. Remove the needle.
10. Transfer the collected specimen to a slide or suitable container.

Disposal:

11. 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













Chiba 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, Infection of the bone at the biopsy site, Tumour seeding, redness or swelling at the aspiration site, fever.


Warranty and Limitations

Chiba 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, tort, 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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