Indications For Use

Intended for the purpose of obtaining a core biopsy of bone.

Contraindications

For use only for obtaining a core biopsy of bone as determined by a licensed physician. Only a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of bone biopsy should use these needles. Physician judgement is required when considering biopsy on patients with bleeding disorder or receiving anti-coagulant medications.

Caution

For single patient use only. Do not attempt to clean or resterilize this product. After use, this product may be a potential biohazard. Handle in a manner that will prevent accidental puncture. Dispose of in accordance with applicable laws and regulations.

Note

These instructions are not intended to define or suggest any medical or surgical technique. The individual physician is responsible for the proper procedure and techniques to be employed with this device.

Recommended Technique

For Single Stick Biopsy

1. Using sterile technique, prepare the skin with antiseptic and drape.
2. After having determined the most suitable point of entry, the entire area between the skin and periosteum is anesthetized. The periosteum must be well anesthetized also. The fine anesthesia needle remains in position as a guide for a parallel puncture with the Osty-Core™ Bone Biopsy Needle. The position of the needle can be controlled using Fluoroscopic or “CT” guidance.
3. Hold the Osty-Core™ Bone Biopsy Needle with the proximal end in palm and the index finger against the shaft near the tip. This position stabilizes the needle and allows better control.
4. Introduce the Osty-Core™ Bone Biopsy Needle through the skin and bring it into contact with the area of biopsy interest.
5. The fine anesthesia needle can now be removed.
6. Using gentle, but firm pressure, advance the needle, rotating it in an alternating clockwise/counterclockwise motion through the cortex/area of interest. Once the cannula passes through the cortex, the stylet may be removed.
7. After reaching the lesion/area of interest, attach a syringe with luer taper to the hub of the Osty-Core™ Bone Biopsy Needle using a firm push/twist motion.
8. Apply suction by withdrawing the syring plunger. With vacuum applied, slowly rotate and remove the needle cannula with specimen.
9. Remove the syringe from the needle cannula.
10. Push the specimen out of the cannula using the obturator.