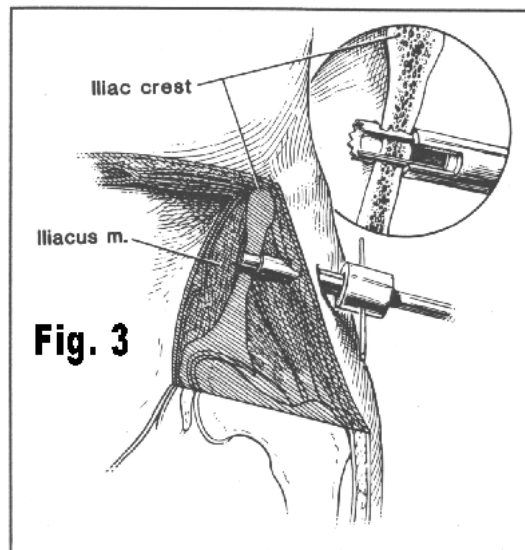




ROCHESTER BONE BIOPSY™ SET TR87400-000

The Rochester Bone Biopsy™ Trephine Set consists of instruments designed to obtain percutaneous trans-iliac 7.5 mm biopsy samples from the anterior ilium.



Unique kerf on cutting teeth allows for the instant removal of bone chips while avoiding compression of biopsy sample

Simple outpatient procedure

Multiple biopsies with specimens structurally intact

Hand ratchet and economical power surgical drill adapters available

Trephine has safety ring marks at 5 mm intervals that indicate depth and the Guide Sleeve prevents lateral movement caused by rotary action while preventing the Trephine from extending more than 3 mm

Page 1 of 3 - Additional information on page 2 photos on page 3

Medical Innovations International Inc.

Rochester MN USA • 1-507-289-0761

www.medicalinnovations.com



ROCHESTER BONE BIOPSY™ TREPHINE

SET ITEM #TR87400-000

INSTRUMENT OPERATION

Sterilization The instrument set can be properly cleaned and sterilized by autoclave or ethylene oxide.

Power Source The trephine may be driven with a sterilizable manual ratchet driver. As another option, a low speed surgical drill fitted with a 1/4" chuck can be used. An economical sterilizable cordless drill is available from Medical Innovations.

Attaching Trephine The drive end (largest) of the adaptor is inserted into the proximal end of the trephine and rotated approximately 1/2 turn until the lock mechanism "locks" into place (Fig. 2). The trephine may be separated from the drive adaptor by sliding the large release ring axially, away from the chuck and removing the adaptor.

Insertion Using the pointed obturator, the guide sleeve is inserted through the incision to the surface of the ilium (Fig. 1). The obturator is then removed and the trephine is inserted through the proximal end of the guide sleeve directing it to the biopsy site.

REFERENCES

Hodgson S.F., Johnson K.A. et. al.: Outpatient Percutaneous Biopsy of the Iliac Crest - Methods, Morbidity, and Patient Acceptance: Mayo Clinic Proceedings 61:28-33, 1986. Article available for download at www.medicalinnovations.com.

Mayo Medical Laboratories: Outpatient Percutaneous Biopsy of the Ilic Crest, 16 min. VHS Video available from Mayo Medical Laboratories, 1-800-533-1710 or 1-507-266-5700, order # T052

INSTRUMENT SPECIAL FEATURES

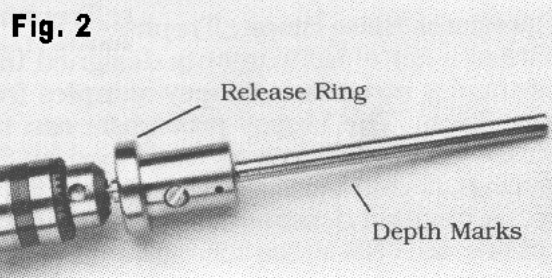
Tooth Design The cutting teeth on the trephine are specially designed by Dr. Robert Recker, Osteoporosis Research Center, Creighton University, of Omaha Nebraska. Without being traumatic to surrounding tissue, the unique kerf of the cutting teeth allows for the removal of bone chips while avoiding compression of the biopsy sample.

Depth Marks The trephine has 5 annular rings spaced at 5mm intervals that indicate the insertion depth of the cutting edge (Fig. 2).

Guide Sleeve When positioned properly, the guide sleeve isolates the biopsy site and prevents lateral movement caused by the rotary action of the cutting edge. The guide sleeve may be repositioned at an adjacent site for a second biopsy. The trephine cannot extend more than 3 cm beyond the guide sleeve, thus preventing excessive penetration (Fig. 3).

Resharpening The Rochester Bone Biopsy™ Trephine performs best when sharp. If your instrument becomes dull from use or damage, it can be reconditioned.

*note: when sending the Trephine for reconditioning send the entire kit to ensure the best possible reconditioning services.



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ROCHESTER BONE BIOPSY™ TREPHINE

SET ITEM #TR87400-000

Outpatient Percutaneous Biopsy of the Iliac Crest: Methods, Morbidity, and Patient Acceptance

Stephen F. Jodgson, MD; Kenneth A Johnson, MD; Joan M. Muhs, BSN; Edward G. Lufkin, MD; James T. McCarthy, MD

Background

“Clearly, the optimal use of bone histology is dependent on the development of biopsy techniques that are safe, simple to perform, and efficient.”

“Many physicians, however, consider bone biopsy excessively invasive and a potential source of morbidity and disability;”

“We herein describe a percutaneous method of obtaining transiliac bone samples with use of local anesthesia in an outpatient setting.”

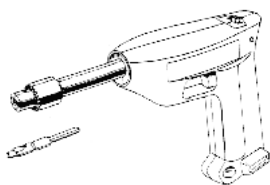
Clinical Experience

“The instruments used for the biopsy procedure are a pointed obturator, a guide sleeve, a trephine with a trephine with a threaded extension, a blunt extractor and a surgical rotary-drive source.”

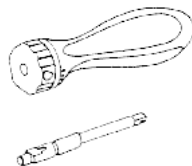
The Rochester Bone Biopsy™ Trephine instrument set was designed specifically for this procedure and used exclusively in this study. This instrument replaces the MAYO biopsy needle which is no longer available.

“The operative morbidity and patient acceptance of this biopsy procedure were assessed in 38 women with postmenopausal osteoporosis (mean age 66.1 years) each of whom underwent two separate biopsies.”

-Quoted from *Mayo Clinic Proceedings January 1986, Vol 61*, available for download at



TR87460-000



TR87470-000

Article Highlights

Results of studying a total of 124 patients

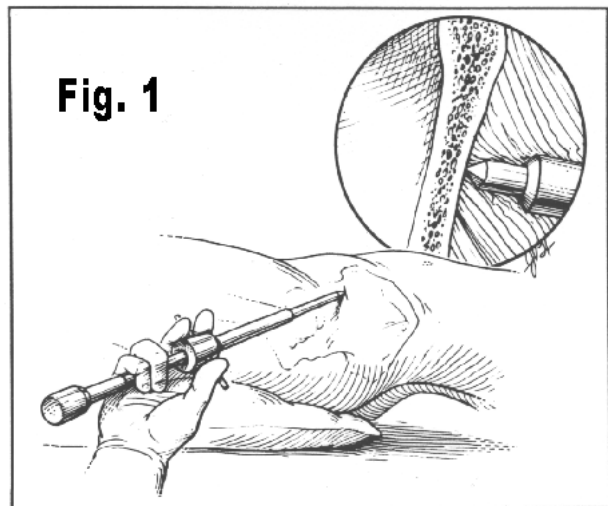
“No major infections were encountered.”

“In general, patients preferred to undergo biopsy in the less austere surroundings of the outpatient clinic, and no technical disadvantages were encountered in the setting. Furthermore, operating room costs were avoided.”

Conclusion “On the basis of these studies, we conclude that outpatient percutaneous iliac crest bone biopsy is safe, generally acceptable to patients as a standard clinical procedure, and efficient; moreover, it produces high-quality samples.”

“The use of this and similar biopsy procedures should lead to increased applications for bone histology in the diagnosis and management of metabolic bone diseases.”

Fig. 1



Order forms and other information is available for download at the website www.medicalinnovations.com.

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