

## INFORMATION INSERT



### Ranfac Snarecoil Bone Marrow Biopsy Needle

Sterile: Contents sterile unless package is opened, damaged or expired.

#### A. INDICATIONS FOR USE

The Ranfac Snarecoil Bone Marrow Biopsy Needle is intended for the purpose of harvesting bone marrow specimens.

#### B. CONTRAINDICATIONS

For use only for biopsies of bone/bone marrow as determined by a licensed physician. The device is intended to be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of bone biopsy. The procedure should be performed on patients that are suitable for such procedure only.

**WARNING:** This device must not be used for sternal procedures.

**CAUTION:** For single patient use only. The design of this device may not perform as intended by the manufacturer if it is re-used. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device.

After use, this product may be a potential biohazard. Handle in a manner, which will prevent accidental puncture. Dispose of in accordance with applicable laws and regulations. Carefully place the used needle in a sharps biohazard container after the procedure is completed.

**Note:** These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.

#### C. DIRECTIONS FOR USE

1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the contents from the pouch.
3. Following proper placing technique, locate the needle (1, 2) adjacent to the biopsy site.
4. Using gentle, but firm, pressure advance the needle (1, 2) by rotating it in an alternating clockwise - counterclockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance.
5. Unlock the stylet cap (2) by rotating it counterclockwise, and remove the stylet (2) from the cannula (1).
6. Use the needle vise (5) provided to cap the stylet (2) after use for safe disposal.
7. Very slowly and gently, advance the needle (1) using clockwise - counterclockwise motion until an adequate depth is achieved (2-3cm).
8. Insert the marked probe (3) without force to check sample length in needle lumen. Sample length is referenced by the marks in comparison to the needle hub. Remove the probe.
9. Deploy the gray lever by moving it from the "OPEN" to the "CLOSED" position.
10. Slowly withdraw the needle (1) from the patient.
11. Rotate the gray lever from the "CLOSED" to the "OPEN" position.
12. Place the probe guide (4) onto the distal tip of the cannula (1) as shown. Insert the probe (3) into the distal end of the probe guide (4). Advance the probe (3) into the needle (1) and collect the biopsy specimen as it emerges from the opening in the handle (proximal end).
13. Use the needle vise (5) provided to cap the needle (1) after use for safe disposal.

**CAUTION:** If any difficulty is encountered during the transfer of the sample, DO NOT force the sample. Remove the probe (3), activate the grey lever to the "CLOSED" position and return it to the "OPEN" position. Re-insert the probe (3) and transfer the specimen out the proximal end of the needle (1)

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

U.S. Pats. 5,522,398 and 5,634,473

Ranfac Corp.  
30 Doherty Ave.  
Avon, MA 02322-0635  
Tel: (800) 2-RANFAC  
(508) 588-4400  
Fax: (508) 584-8588  
Email: info@ranfac.com  
www.ranfac.com

1-800-2RANFAC (272-6322)

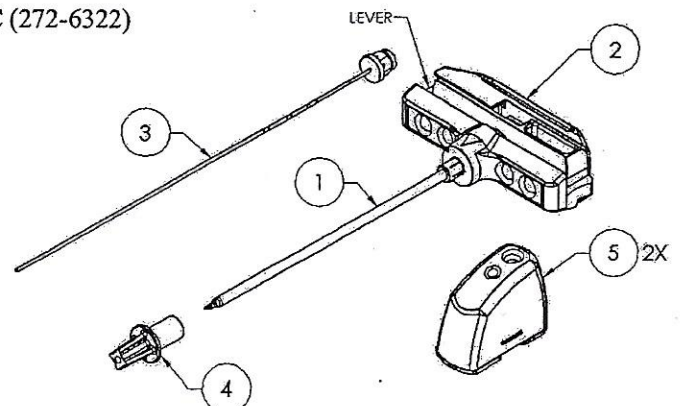


CMDR REP

EC REP

Dyna Medical Corporation  
843 Wellington Street  
London, Ontario N6A 3S6  
CANADA

Mermaid Medical A/S  
Frydensbergvej 25  
DK-3660 Stenløse  
DENMARK



P/N 09637-01M REV G