INFORMATION INSERT Ranfac Filter Assembly

A. INDICATIONS FOR USE

The Ranfac Filter Assembly is intended for use in filtering Bone Marrow aspirate and/or autologous blood prior to mixing with bone graft material.

B. CONTRAINDICATIONS

Use only for filtering Bone Marrow aspirate and/or autologous blood prior to mixing with bone graft material.

CAUTION: THIS DEVICE IS NOT INTENDED FOR INTRAVENOUS USE.

The device is intended to be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of filtering Bone Marrow aspirate and/or autologous blood.

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 the Ranfac Filter Assembly in a manner which will prevent accidental exposure or biohazard contamination. Dispose of in accordance with applicable laws and regulations. Carefully place the Ranfac Filter Assembly in a 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. Remove the cap from the Ranfac Filter Assembly and attach a syringe (A), filled with Bone Marrow aspirate and/or autologous blood to the now exposed luer lock connector. *NOTE:* Have at least 5cc of air in the back of the syringe from either the aspiration or by withdrawing the plunger. This will allow for all of the Bone Marrow aspirate and/or autologous blood to pass through the Ranfac Filter Assembly.
- 2. Attach an empty syringe (B), of a greater capacity than syringe (A) to the luer lock connection on the other end of the Ranfac Filter Assembly. NOTE: Ensure that the plunger on the empty syringe (B), is completely depressed prior to attaching to the Ranfac Filter Assembly.
- 3. Depress the plunger on syringe (A) to allow Bone Marrow aspirate and/or autologous blood to flow through the filter and into the empty syringe (B).
- 4. When syringe (A) is empty, or the desired amount of Bone Marrow aspirate and/or autologous blood has been filtered, remove syringe (B) from the Ranfac Filter Assembly for further processing.
- 5. Dispose of the Ranfac Filter Assembly with syringe (A) attached into a proper Biohazard container.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Product is not made with natural rubber latex.

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P/N 29171-04M Rev. 2





Sterilized Using Ethylene Oxide