



BONE MARROW ASPIRATION KIT
129433-5

The following languages are included in this packet:

English (en)

For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.



CE 0086*

Wright Medical Technology, Inc.
5677 Airline Rd.
Arlington, TN 38002
U.S.A.

EC REP

Wright Medical EMEA
Hoogoorddreef 5
1101 BA Amsterdam
The Netherlands

*The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.

Rx ONLY

June 2013
Printed in USA

Bone Marrow Aspiration (BMA) Kit

(129433-5)

GENERAL PRODUCT INFORMATION

The Bone Marrow Aspiration Kit consists of equipment needed for BMA aspiration.

The proper surgical technique is the responsibility of the medical professional. The following guidelines are furnished only as recommended techniques. Each surgeon must evaluate the appropriateness of the techniques based on his/her own medical training and expertise.

INDICATIONS

The Bone Marrow Aspiration Kit is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The syringe can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

WARNINGS

The following warnings apply:

- Each unit is intended for single patient use.
- Do not use the product if the package has been damaged.
- Unused product should be properly discarded.
- DO NOT RESTERILIZE THE BONE MARROW ASPIRATION KIT.

PRECAUTIONS

The Bone Marrow Aspiration Kit is sterile during the stated shelf life as long as the package is not opened and/or damaged. The product must be used before the expiration date. Unused or expired product should be properly discarded.

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

HANDLING AND USE

The Bone Marrow Aspiration Kit is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. The kits are for single patient use and should never be reused.

The following instructions are for guidance only. Location of aspiration site is at the surgeon's discretion:

1. Prepare Site

Prep and drape site as for iliac crest graft harvest. Palpate the anterior iliac crest.

Placement: 1cm posterior to the anterior superior iliac spine will avoid damage to the lateral femoral cutaneous nerve of the thigh.

2. Insert needle

Introduce the aspiration needle into the central position of the crest taking care to avoid penetrating the lateral overhang lip.

3. Prepare for aspiration

Remove the trocar and place the aspiration syringe onto needle.

4. Aspirate bone marrow

Begin aspiration of red marrow. If marrow does not aspirate easily, reposition needle slightly. If marrow still does not aspirate, redirect needle by removing syringe, replacing the trocar and following steps 1-4.

5. Redirect, continue aspiration

Redirect needle every 5cc during aspiration, to avoid aspirating peripheral blood.

STERILITY

All components of the Bone Marrow Aspiration Kit are supplied sterile.

This product is for single use only and should not be resterilized. Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

CAUTION: Federal law (U.S.A.) restricts this device to sale, distribution, and use by or on the order of a physician.