Marrow Cellution™
Bone Marrow Aspiration Needle

**Product Name:** Marrow Cellution Bone Marrow Aspiration Needle

**Manufacturer:** Ranfac Corp.

**Distributed:** Medtronic

**Sales Representative Name:**

**Phone:**

**Date:**

Marrow Cellution BMA System is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe in a measured and controlled manner over a large geography within the marrow space. The needle has a closed tip to prevent infiltration of peripheral blood during the aspiration procedure as well as a mechanical means for a measured and controlled movement of the aspiration cannula within the marrow space.

The Marrow Cellution system includes an 11 gauge introducer needle, an 11 gauge blunt stylet, and a 14 gauge aspiration cannula. The system may be used in the Iliac Crest, Pedicle, Calcaneous or Tibia.

**TECHNOLOGY OVERVIEW**

The Marrow Cellution Bone Marrow Aspiration System is a novel bone marrow access and retrieval device that incorporates features designed to minimize limitations of traditional trocar needles.

Traditional needles aspirate primarily through an open-ended cannula, which leads to excess blood collection that requires additional manipulation, i.e. centrifugation or chemical separation in a laboratory. By overcoming these limitations, Marrow Cellution improves stem and progenitor cell recovery and reduces peripheral blood infiltration. Marrow Cellution accesses aspirate flow collected exclusively laterally as the tip of the aspiration cannula is closed allowing marrow collection perpendicular to and around the channel created by the tip of the device thus avoiding excess peripheral blood infiltration. The device also incorporates technology to precisely reposition the retrieval cannula within the marrow space after each aspiration. These features achieve a clinicians’ desire for a single entry point as a single puncture with Marrow Cellution provides high quality bone marrow aspirate collected from numerous sites within the marrow geography.

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1 Data on file.
TECHNOLOGY APPLICATION

Instructions For Use

1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the needle from the pouch and inspect the tip of cannula and stylets for any damage or other imperfections that would prevent the proper operation of the needle.
3. Use suggested heparin flush procedure protocol on all components prior to use to prevent clotting.
4. Following proper placing technique, locate the needle adjacent to the aspiration site.
5. Determine the desired depth of insertion and set the Adjustable Guide to that distance.
6. Using gentle, but firm pressure, while holding the mated handles of the Access Needle and pointed stylet together, the user advances the Access Needle with either a clockwise/counterclockwise twisting motion or advancement can be by use of a bone mallet.
7. Entrance into the marrow cavity is generally detected by decreased resistance.
8. Once the Access Needle is secure in the bone, remove the pointed stylet. Attach a 10cc syringe (provided), apply negative pressure and draw 1cc of marrow.
9. Remove the syringe (use in step 12) and insert Blunt Stylet.
10. Advance the Access Needle into the marrow cavity until it reaches the desire depth. Advance the depth stop so that the tip is touching the patient.
11. Remove the blunt stylet and insert the Aspirator Cannula.
12. Attach syringe used in step 8 to the needle using the luer lock connection.
13. Apply negative pressure by quickly withdrawing the syringe plunger. Aspiration will begin. Release plunger after approximately 1cc of aspirate has been collected.
14. Rotate the introducer handle 360 degrees counterclockwise to retract the cannula tip approximately 1cm into a new marrow area.
15. Repeat previous two steps until aspiration is complete, remove the syringe from the needle, and remove the needle.

TECHNOLOGY PREPARATION

Education

Medtronic offers hospital staff a number of training opportunities on safe use of our products, including training on, where applicable, technologies, pathologies, and processes. Surgeon education and training events featuring the Ranfac Marrow Cellution Bone marrow aspiration needle are offered throughout the year at various locations. Please contact your local Medtronic sales representative for more information. Surgeons and hospital staff are also provided with other technology materials for review.

Sterilization

EtO Sterilization
CODING AND PAYMENT

Inpatient

Medicare Severity-Diagnosis Related Groups (MS-DRG)

Individual patient diagnosis(es) and the reporting of any surgical procedures performed will determine the appropriate MS-DRG.

Outpatient

CPT Code

For needle aspiration of bone marrow for the purpose of bone grafting, use 38220.

38220 – Bone marrow, aspiration only

A bone marrow aspiration (CPT code 38220) should not be reported separately with a spinal osteotomy, vertebral fracture repair, spinal arthrodesis, spinal fusion, laminectomy, spinal decompression, or vertebral corpectomy CPT code if the bone marrow aspiration is obtained from the surgical field. However, if the bone marrow aspiration is obtained from an anatomic site other than vertebrae on which the orthopedic/neurosurgical procedure is performed, it may be reported separately with an NCCI-associated modifier. – 2016 National Correct Coding Initiative Policy Manual for Medicare Services, Chapter IV.H.23. When the bone marrow is obtained prior to the arthrodesis, the placement of the bone marrow aspirate is included as part of the arthrodesis procedure and not reported separately.

Refer to individual payer policies and guidelines for specific guidelines/coverage criteria.

Payer Advocacy

Refer to payer policies and guidelines for specific coverage criteria.
CODING AND REIMBURSEMENT ASSISTANCE

SpineLine®

Spine Coding and Reimbursement Support
Provides coding, billing, and reimbursement assistance for spinal procedures performed using Medtronic products.

Phone: 877-690-5353
E-mail: (Physician) spinalcodingmd@medtronic.com
(Hospital) spinalcodinghospital@medtronic.com

The materials and information cited here are for informational purposes only and are provided to assist in obtaining coverage and reimbursement for health care services. However, there can be no guarantee or assurances that it will not become outdated, without the notice of Medtronic, Inc., or that government or other payers may not differ with the guidance contained herein. The responsibility for coding correctly lies with the health care provider ultimately, and we urge you to consult with your coding advisors and payers to resolve any billing questions that you may have. All products should be used according to their labeling.
SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

Indications
The Marrow Cellution Bone Marrow Aspiration Needle is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.

Contraindications
Use only for bone marrow or autologous blood aspiration 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 marrow aspiration. The procedure should be performed on patients that are suitable for such procedure only.

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.

ADDITIONAL INFORMATION

Is the product Implantable? No
How was the Product Cleared? 510(k) K150563
Does the product require additional instruments? No
Does the product need to be checked by Biomed? No
Does the product contain Mercury? No
Does the product contain Latex? No
### Product Details

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Description</th>
<th>Introducer</th>
<th>Components</th>
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</thead>
<tbody>
<tr>
<td>74279-01M</td>
<td><strong>MC-RAN-11C: Marrow Cellution</strong> Bone Marrow Aspiration System</td>
<td>11 Gauge, effective length: 3.5&quot;</td>
<td>11 Gauge Introducer Cannula &amp; Sharp Stylet</td>
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<td>11 Gauge Introducer Blunt Stylet</td>
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<td></td>
<td>14 Gauge Aspiration Cannula &amp; Blunt Stylet</td>
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<td>10 mL Syringe</td>
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<tr>
<td>74279-02M</td>
<td><strong>MC-RAN-11CSTS: Marrow Cellution</strong> Bone Marrow Aspiration System – Same as MC-RAN-11C but with longer introducer for obese patients</td>
<td>11 Gauge, effective length: 4.5&quot;</td>
<td>11 Gauge Introducer Cannula &amp; Sharp Stylet</td>
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