

ART BMC Processing Kit



SpineSmith®
93 Red River
Austin, TX 78701
Phone: 512-206-0770
Fax: 512-302-4920

- Sterile Instruments - Single Use Only



Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Rx Only

The Celling® Biosciences ART BMC Processing Kit is intended to be used in a clinical laboratory or intraoperatively at the point-of-care for the preparation of a cell concentrate from bone marrow. The kits are comprised of a collection of Class I devices.

Carefully read all instructions prior to using this product.

DESCRIPTION and INTENDED USE:

The ART BMC kit includes a 45cc or 60cc BMA processing device and the syringes necessary to interact with the concentrator to perform the concentration of bone marrow.

These kits are intended to be used in a clinical laboratory or intraoperatively at the point-of-care for the preparation of cell concentrate from bone marrow.

CONTRAINDICATIONS:

None.

STERILIZATION:

All kit components are supplied sterile and should not be reused. Kit components are sterilized either by ethylene oxide or gamma irradiation, as shown on their individual labels.

CAUTIONS:

- For single patient use only. Do not attempt to clean or re-sterilize any of the components in this kit.
- The kit should be stored and operated at ambient temperature.
- Handle in a manner to maintain sterility. Dispose in accordance with applicable laws and regulations.
- The individual practitioner is responsible for the proper procedure and techniques to be used with this device.
- The safety and effectiveness of this device for *in vivo* indications for use have not been established.
- Do not use the contents of the ART BMC Processing Kit if it is opened.

INSTRUCTIONS FOR USE:

1. Ensure centrifuge is placed level on a sturdy surface and within reach of power outlet. Turn on and verify centrifuge has two buckets, and two inserts if using an RC-4 centrifuge to contain the processing unit and counterbalance.

2. Set up a scale and tare. This will be used to verify the weight of the processing unit and counterbalance.
3. Break the kit seal and inspect the integrity of the sterile components. If undamaged, transfer components to the surgical field.
4. Remove the luer lock cap from Port A, and attach the clot filter.
5. Sterilely transfer the anti-coagulated bone marrow aspirate to the device by attaching the syringe to the clot filter. Up to 60cc can be added through Port A. Recap Port A.
6. Weigh the processing unit and prepare the counterbalance by filling with water to match the weights.
7. Ensure the thumb wheel is fully turned to the left, then place the units facing opposed to each other into the centrifuge buckets.
8. If using a RC-4 centrifuge, close the lid and set to 3000 rpm for 15 min. Otherwise, close the lid and set to 3200 rpm for 15 min.
9. Open the lid and transfer the device to a sturdy working surface. Be careful to not disturb the fractionation of the bone marrow concentrate.
10. Turn the thumb wheel to position the collection window 2 mm above the buffy coat, attach a syringe to Port B.
11. Draw the platelet-poor plasma (PPP) into the syringe. Then remove and reserve the PPP syringe.

12. Attach a 10cc syringe to Port B, reposition the collection window so that the upper white O-ring is even with the buffy coat and quickly pull. Additional volume may be obtained from the PPP syringe.

LIMITED WARRANTY:

SpineSmith products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact SpineSmith for current information.



SpineSmith Holdings LLC
93 Red River
Austin, TX 78701
Phone: 512-206-0770
Fax: 512-302-4920

For product information or questions pertaining to sales and service, please contact your local sales representative or SpineSmith customer service.

Catalog #0886-XXXX-LB3
Rev H per DCR# 0809

SpineSmith 2016