

ART-45 BMC Processing Kit



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- Sterile Instruments - Single Use Only



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

R_X Only

The Celling® Biosciences ART-45 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-45 kit includes a 45cc 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-45 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 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.

5. Sterilely transfer the anti-coagulated bone marrow aspirate to the device by attaching the syringe to Port A. Up to 45cc can be added depending on the unit.

Recap Port A.

6. Weigh the processing unit and prepare a counterbalance by filling another disposable with water or saline to match the weights.

7. Ensure the flow valve is in the vertical position and place the units into the centrifuge buckets.

8. Close the lid and centrifuge at 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 aspirate.

10. Turn the thumb wheel to position the collection window slightly above the buffy coat and remove the cap from Port B.

11. Attach a 30cc syringe to Port B and adjust the flow valve to the "Draw" position.

12. Draw the platelet-poor plasma (PPP) into the syringe. Then remove and recap the PPP syringe.

13. Attach a 10cc syringe to Port B, reposition the collection window to the needed position and draw the buffy coat. Recap Port B.

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.



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

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