



Preparation Guide



1. Gather Supplies

Prepare for BioCushion® implantation with sterile gloves, one sterile syringe, one sterile 18G or larger beveled needle, and one sterile 20–21G needle or cannula. **DO NOT USE** anything smaller than a 21G needle or cannula.



2. Inspect Packaging

Remove BioCushion® package from frozen or refrigerated storage. Inspect the package to ensure its integrity. **DO NOT USE** the product if the package integrity is compromised.

Note: Vial is aseptically packaged in two presterilized pouches.



3. Thaw Vial

Remove outer pouch and place the inner pouch with the vial onto a clean surface. Allow the product to thaw completely before use (approx. 30 minutes), if needed.

DO NOT RE-FREEZE the product.



4. Retrieve Vial

Retrieve the vial from the innermost pouch. Use aseptic technique to transfer the vial onto a clean surface or a sterile field.



5. Mix Contents

Shake the vial for 15–20 seconds and “wrist flick” the vial in the downward direction to ensure all product is on the bottom of the vial.



6. Withdraw Product

Immediately withdraw the product using a syringe with an 18G or larger beveled needle at a slow, steady pace.

Note: If the needle becomes clogged, expel clogged tissue. Repeat steps 5 and 6.



7. Replace Needle

After the product is in the syringe, replace the 18G beveled needle with a new 20–21G needle or cannula. Remove air bubbles from the syringe prior to implantation.

Important Note: Keep BioCushion® in the sealed package until ready for use. Once the package is opened, use within 4 hours. If not used within 4 hours, product must be discarded.



For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this allograft, please refer to the allograft specific instructions for use at <http://www.paragon28.com/ifus>

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