

Tactoset

Injectable Bone Substitute

Mixing Instructions

Step 1 | Unpacking

- Open packaging and transfer contents to the sterile field using sterile technique.
- Loosen stopper on each 1 mL syringe by pulling plunger rod back slightly to break seal.

Step 2 | Assembly

• Remove the cap from the prefilled mixing syringe containing the powder (do not discard).



Expel and discard 1 mL setting solution using a femalefemale Luer lock connector and a sterile 1 mL syringe, and replace with 1 mL BMA for a 4 mL mixing solution volume*



• Using a female-female Luer lock connector, attach the glass syringe containing the setting solution to the mixing syringe containing the powder.

Step 3 | Mixing

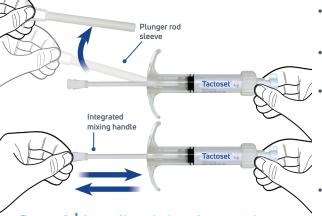
 Hold the syringes vertically with the glass syringe on top. Inject entire contents of setting solution into the mixing syringe containing the powder. Pull back powder syringe plunger rod to ensure contents are fully transferred.



 Remove the solution syringe and Luer lock connector (do not discard). **Recap** the mixing syringe.

Remove the plunger rod sleeve (do not discard) and use the integrated mixing handle to mix the solution and powder by pressing the handle in and out of the material from top to bottom, and rotating the handle if necessary.

Mix for 1 minute to ensure complete mixing.



Step 4 | Loading injection syringes

- Reattach the plunger rod sleeve over the integrated mixing handle. Remove tip cap and attach a Luer lock connector to the mixing syringe. **Expel residual air** from the mixing syringe until a small drop of Tactoset is ejected.
- Attach a 1 mL Luer lock syringe. Hold and pull back on the plunger rod of the 1 mL syringe to aid in transferring Tactoset material. Fill to 0.9 mL. Do not overfill.
- Fill and repeat as needed with remaining syringes.



Timing Notes

Start timer as soon as powder and setting solution make contact



Minute 0-1 | Mixing



• Mix powder and solution continuously for 1 minute

Minutes 1-7 | Fill syringes & wait

- Fill the provided 1 mL syringes to 0.9 mL
- Wait to inject until at least minute 7



Minutes 7-18 | Injection

- Inject Tactoset at desired timepoint after 7 minutes
- Continue checking material for paste-like consistency to ensure injectability, approximately 10 minutes (see IFU for more information)
- Inject at surgeon's desired consistency
- · Apply continuous pressure when injecting
- Inspect for extrusion and remove any excess material within 2 minutes following implantation

Ordering Information

Part Number	Description
1000040	11Ga delivery cannula set including: one drillable outer cannula with removable drillable stylet, one inner cannula for end delivery, one inner cannula for side delivery, one push rod
4000050	15Ga delivery cannula set including: one drillable outer cannula with removable drillable stylet, one push rod
6000041	Tactoset material set including: one prefilled mixing syringe containing Tactoset powder, one glass syringe containing Tactoset setting solution, four 1mL Luer lock syringes, one female-female Luer lock connector
6000151	Marrow Cellution Bone Marrow Aspiration Needle set including: one introducer needle with sharp stylet, one aspiration cannula, one 11Ga blunt stylet, one 10 mL syringe

Please note that both the Tactoset material set and one of the delivery cannula sets are needed for each procedure.

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^{*}If mixing with bone marrow aspirate, or for complete product information, please refer to the instructions for use on www.anikaifu.com