

TRAUMACEM™ V+ Augmentation System

Quick Step Guide
for OR Personnel



This description alone does not provide sufficient background for direct use of the product. Instruction in handling this product in accordance with the corresponding surgical technique and by a surgeon experienced in handling this product is essential.

TRAUMACEM™ V+ Augmentation System for TFNA System

Quick Step Reference Guide for Augmentation Preparation and Injection Into TFN-ADVANCED® Proximal Femoral Nailing System

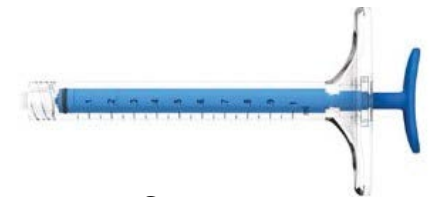
Instruments



07.702.040S
TRAUMACEM™ V+ Injectable Bone Cement



03.702.121S
TRAUMACEM™ V+ Injection Cannula, for TFNA System

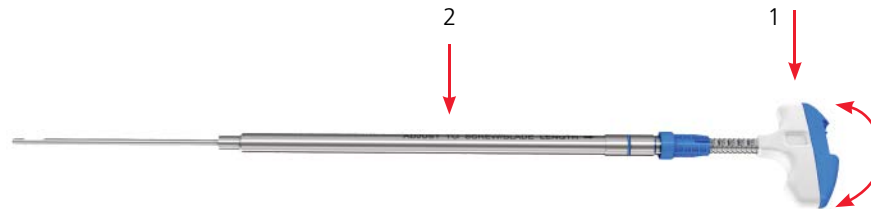


03.702.150S
TRAUMACEM™ V+ Syringe Kit,
4 x 1 mL, 2 x 2 mL

1. Adjust sleeve of side-opening cannula



Adjust the sleeve of the side-opening cannula to the selected head element length.



Length adjustments are made by turning the sleeve (2), while holding the handle of the side-opening cannula (1).

Ensure that the exact head element length is pre-set on the cannula before proceeding.

2. Check for possible cement leakage into joint



Attach syringe to the side-opening cannula and refill the side-opening cannula with approximately 4 mL of radiographic contrast agent.



Insert the side-opening cannula through the guide sleeve into the helical blade/screw until the stop.



No leakage into joint.

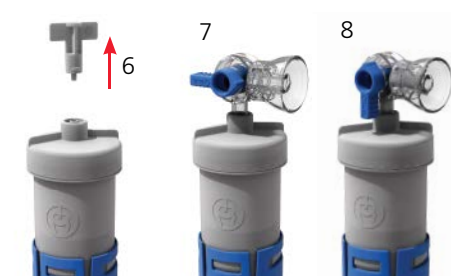


Leakage into joint, do not augment.

Inject radiographic contrast agent into the femoral head and monitor the flow under image intensification.

Warning: Do not augment if radiographic contrast agent leaks into the joint and proceed with distal locking. Radiographic contrast agent leakage into the joint indicates significant risk for intra-articular PMMA bone cement leakage and therefore augmentation is contraindicated.

3. Prepare cement



Hold the mixer upright and gently slap with the finger tip at the top of the mixing device.

While mixing, be sure to only handle the blue portion of the mixer.

Pull the handle until it is fully retracted (1).

Open the glass ampoule by breaking the bottle neck with the plastic cap (2). Remove and dispose of the mixing device sterilization lid (3).

Pour all monomer from the glass ampoule into the cement powder and close the mixing device tightly using the enclosed transferring lid.

Mix the cement by moving the blue handle back and forth from stop to stop approximately 20 times (4). Perform the first mixing strokes slowly with oscillating-rotating movements (5).

After mixing fully retract the handle (1).



Once the cement has been mixed remove the lid (1). Connect the stop-cock to the mixer (7). Ensure a tight fit.

Remove the air from the system. With the valve open, gently turn the handle of the cement mixer clockwise. The mixer piston will advance in the translucent cartridge and a steady flow of cement will move into the stop-cock. As soon as the cement is visible in the stopcock, close the valve (8).

Attach a 2 mL syringe to the one way stop-cock (9). Open the one way stop-cock. Gently turn the handle of the cement mixer clockwise to advance the piston (10). As soon as the syringe is filled, close the stop-cock again, by turning the "off" sign towards the mixer (11).

Disconnect the full syringe and attach the next syringe to be filled (12). Avoid spillage of cement into the funnel during the transfer process. Continue to fill all the 1 mL and 2 mL syringes in the same manner.



4. Insert side-opening cannula and inject cement



Insert the side-opening cannula through the guide sleeve into the helical blade/screw until the stop. Confirm length and verify under image intensification.

Slowly inject the cement using 1 mL syringes. Optimize the filling by rotating the handle to inject cement around the blade/screw. It is recommended that the surgeon maintain a minimum distance of 6 mm between the boundary of cement and the joint surface.

If noted under fluoroscopy that the cement is traveling towards the joint surface, move the cannula laterally by rotating the sleeve 1 clockwise turn.

Visualization of cement during injection must be guaranteed. Continuously monitor the cement flow under image intensification.

It is recommended to use 3 mL of cement for augmentation, but not to exceed 6 mL of cement.





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Synthes USA Products, LLC
1302 Wrights Lane East
West Chester, PA 19380

Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132

To order (USA): 800-523-0322
To order (Canada): 855-946-8999

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Please also refer to the package insert(s) or other labeling associated with the devices identified in this guide for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada.

Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.