

N-Force Blue Bone Substitute Material

Technique Guide



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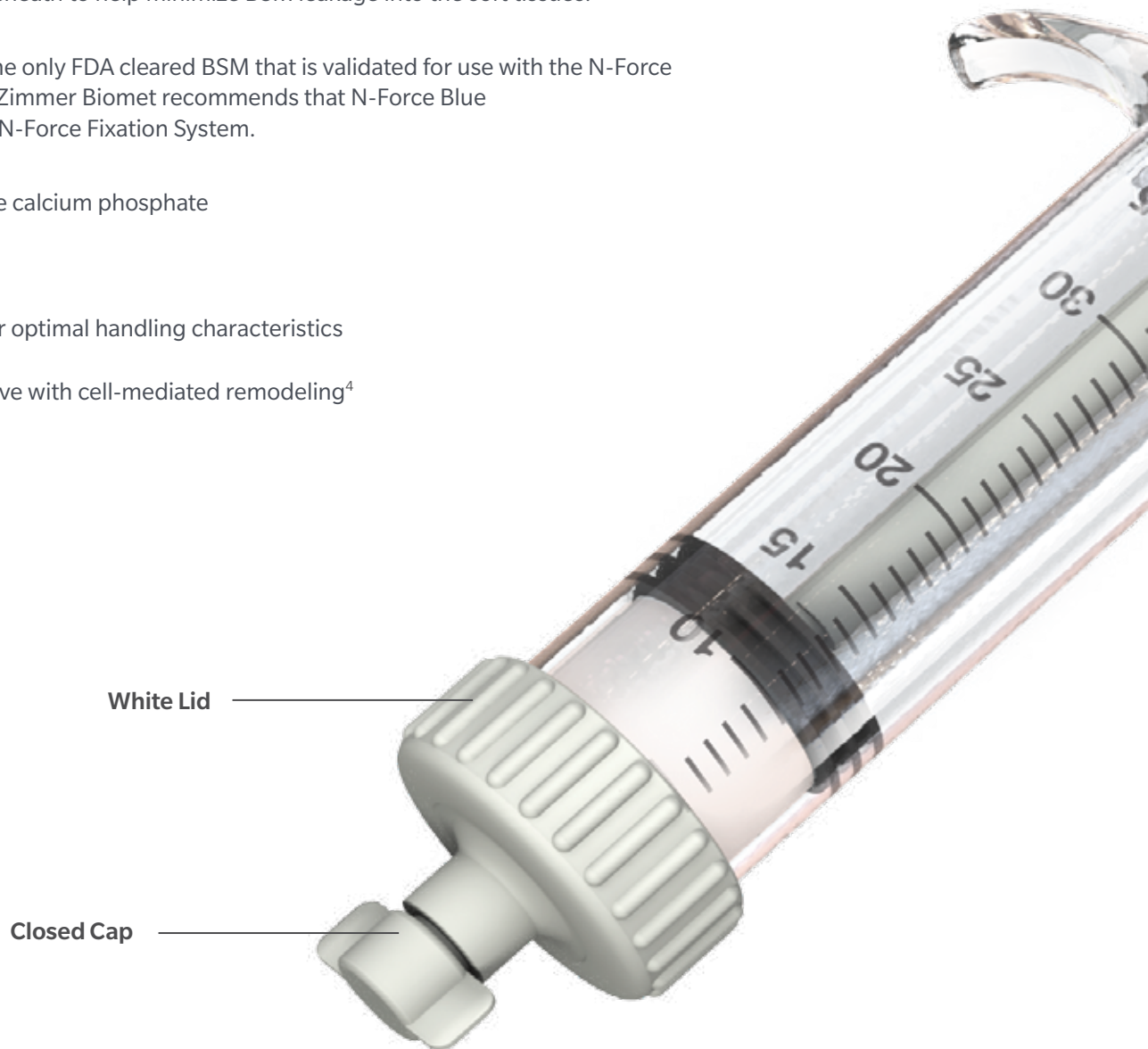
N-Force Blue Bone Substitute Material (BSM) is a biomimetic calcium phosphate with similar chemical and physical properties to natural cancellous bone.¹⁻³ It flows readily, then crystallizes and sets hard in an isothermic reaction at 37° C to form a macroporous scaffold in the bone. N-Force Blue BSM is replaced with new bone during the healing process.⁴

N-Force Blue BSM is used in conjunction with the N-Force Fixation System[®]

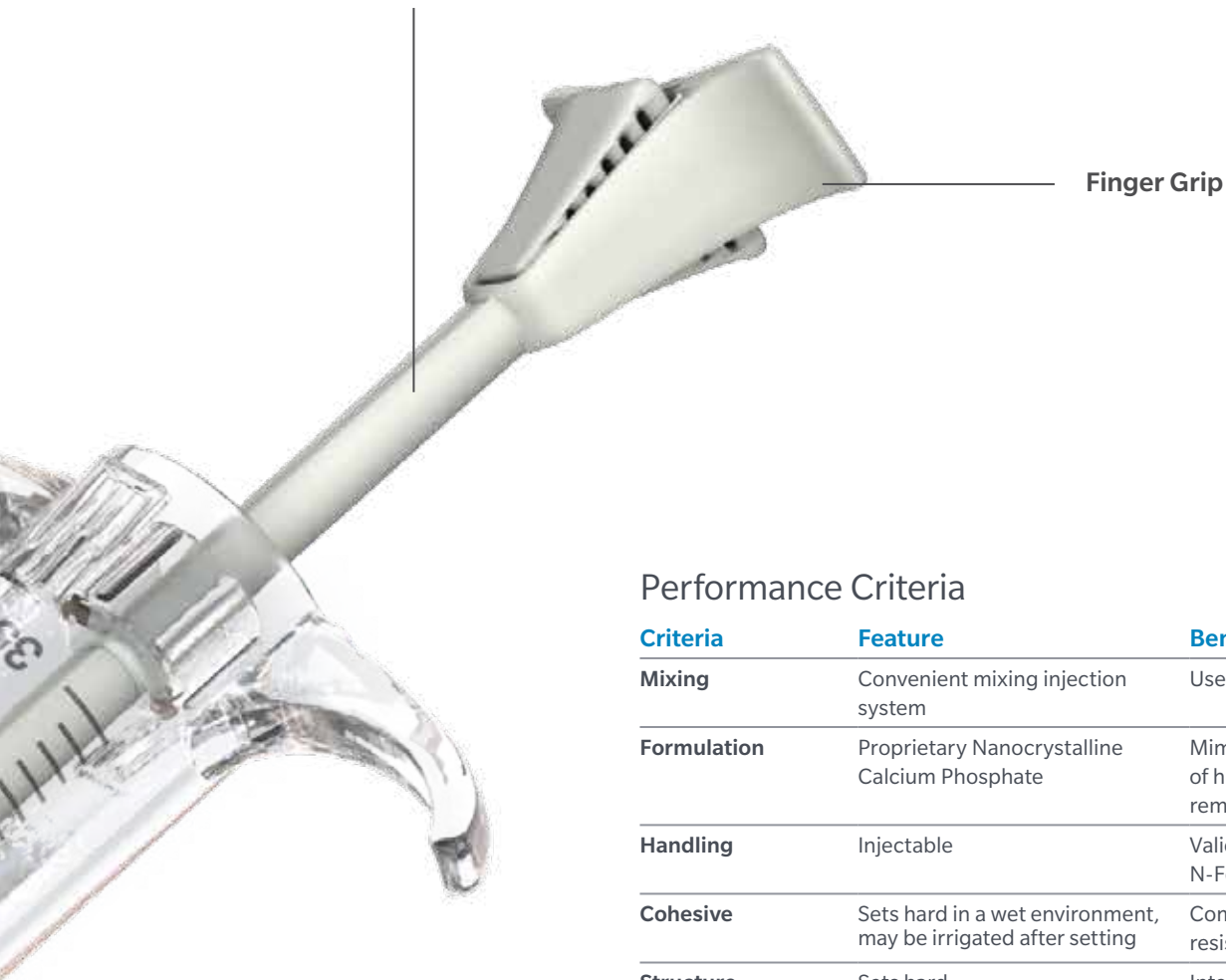
N-Force Blue BSM is injected directly into a N-Force fenestrated screw with the use of a sheath to help minimize BSM leakage into the soft tissues.

N-Force Blue is the only FDA cleared BSM that is validated for use with the N-Force Fixation System. Zimmer Biomet recommends that N-Force Blue be used with the N-Force Fixation System.

- Nanocrystalline calcium phosphate
- Isothermic
- Slow setting for optimal handling characteristics
- Osteoconductive with cell-mediated remodeling⁴



Combined Mixing Handle with Detachable Injection Handle



Finger Grip

Performance Criteria

Criteria	Feature	Benefit
Mixing	Convenient mixing injection system	User friendly
Formulation	Proprietary Nanocrystalline Calcium Phosphate	Mimics chemical structure of human bone to facilitate remodeling ¹⁻⁴
Handling	Injectable	Validated for use with N-Force Fixation
Cohesive	Sets hard in a wet environment, may be irrigated after setting	Complete defect fill ² /resists wash out
Structure	Sets hard	Interconnected Osteoconductive Scaffold
Working Time	15 Minutes	Intra-operative flexibility
Setting Time	Isothermally set in 10 minutes at 37° C	Sets hard after closure/no damaging heat release
Porosity	Interconnected/ 55% total porosity	Facilitates remodeling and bony ingrowth ^{1,4}
Pore Size	1-300 µm	Enables cellular infiltration and attachment ⁵
Drillability	Drillable during and after setting	Procedural flexibility
Comprehensive Strength	Average of 10 MPa	Comparable to cancellous bone/clinically proven to resist articular subsidence ¹⁻³
Cell Mediated Remodeling	Undergoes cell mediated remodeling	Mimics natural bone which also undergoes cell mediated remodeling
Sizes	10cc	Useful in tibial plateau and proximal femur applications

Step by Step Mixing/Injection Guide

Step 1

Carefully remove the Mixing/Injection Syringe from the tray and attach the Funnel. Hold it upright and load the unhydrated BSM powder into the Syringe using the attached Funnel. Gently tap the Syringe barrel to ensure that all the BSM powder has settled and all of the BSM powder is transferred from the container.



Step 2

Add a full 5cc of saline solution into the Mixing/Injection Syringe and BSM powder.



Step 3

Remove the Funnel and attach the White Lid with the Closed Cap.



Step 4

Remove the Detachable Injection Handle from the Mixing Handle and set aside temporarily to enable the Mixing Element. DO NOT DISCARD the Injection Handle.



Step 5

Mix the product back and forth while twisting the Mixing Element with long, consistent strokes for 1-2 minutes or until BSM reaches a smooth, paste consistency (approx. 30–60 cycles). If the BSM remains a doughy consistency, up to 0.5 cc of saline can be added. It is important to make sure the BSM is a smooth, creamy consistency.



Step 6

Once mixing is complete, remove the Closed Cap and attach the green Luer Connector with the Porous Plug.



Step by Step Mixing/Injection Guide

Step 7

Reattach the Injection Handle to enable the Plunger and plunge the BSM to remove the air from the Syringe. Pull back on the Plunger slightly to release pressure to prevent loss of BSM. Remove the green Luer Connector. Once again, remove the Detachable Injection Handle.



Step 8

Snap the Finger Grip off of the end of the Mixing Handle.



Step 9

Ensure the Screw Mechanism on the Mechanical Assist Device is backed out of the spindle at least halfway. Attach the Mechanical Assist Device to the Mixing Syringe by snapping it into place. Be certain that both sides are snapped firmly in place on the Syringe. Attach the N-Force Sheath Adapter to the Syringe.

Please reference the N-Force Fixation System Surgical Technique for proper screw installation instructions.



Step 10

Inject the BSM by turning the Screw Mechanism on the Mechanical Assist Device clockwise while maintaining tactile feel. Monitor the injection by fluoroscopy.*



*Extrusion of Bone Substitute Material Beyond the intended application site may irritate surrounding tissue. Remove any excess BSM before wound closure.

INDICATIONS

N-Force Blue Porous Bone Substitute is an injectable, self setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. N-Force Blue is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

CONTRAINDICATIONS

Do not use this product if one or more of the following conditions are present:

- Existing acute or chronic infections, especially at the site of the operation
- Nonviable bone
- Areas where surrounding bone is not viable or not capable of supporting and anchoring the implant
- Altered calcium metabolism
- Metabolic bone disease
- Immunologic abnormalities
- Systemic disorders which result in poor wound healing
- Inflammatory bone disease
- Acute traumatic injuries with open wounds close to the defect which are likely to become infected

Description	Part Number
N-Force Blue 10cc	IN050-1
N-Force Blue Large Mix System	IN050-2

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0354.1-US-en-REV0316



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