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N-Force Fixation System®

Surgical Technique

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Indication/Contraindications

INDICATIONS

The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System can also be used to deliver injectable bone substitute materials to a surgical site.

CONTRAINDICATIONS

Physical conditions that would preclude adequate implant support or retard healing such as impaired vascularity of the extremity or fracture site, insufficient bone quality or quantity, active or previous infection, obesity, inadequate fracture reduction or improper implant construct in relation to the fracture under treatment. Mental impairment or conditions that preclude cooperation with the rehabilitation regimen. The N-Force Fixation System is contraindicated in spinal fracture fixation. The N-Force Fixation System is contraindicated for use with Poly (methyl methacrylate) (PMMA).

Note

In United States:

N-Force Fixation System is cleared to deliver N-Force Blue® Bone Substitute Material (BSM) to a surgical site. N-Force Blue is the only FDA cleared BSM that is validated for use with the N-Force Fixation System. Zimmer Biomet recommends N-Force Blue BSM to be used with the N-Force Fixation System. Refer to the Package insert of the N-Force Blue Bone Substitute Material for more information.

4.0 mm Screw Surgical Technique

4.0 mm Screw Surgical Technique

The following surgical technique is explained using the example of a tibia plateau fracture.

Step 1: Preoperative Radiographic Fracture Assessment and Planning

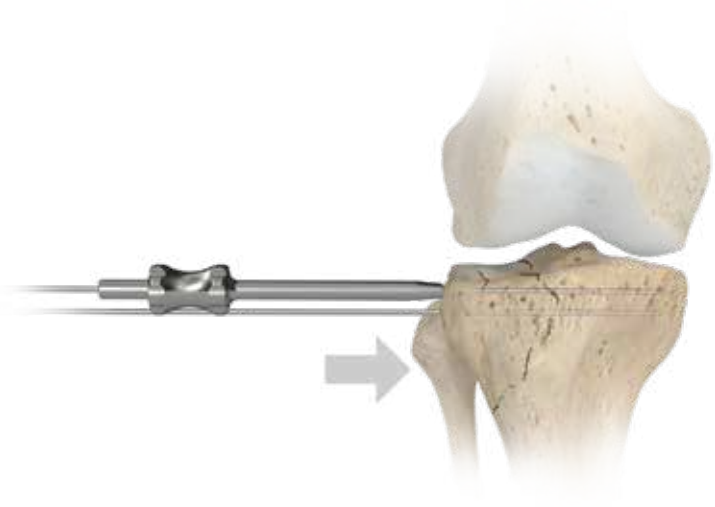
Assess the fracture pattern using radiographs and possibly a CT scan. Determine the appropriate type of fixation to repair the fracture and evaluate the need for Bone Substitute Material (BSM).

Step 2: Intraoperative Fracture Assessment and Reduction

Assess the fracture utilizing fluoroscopy and/or direct visualization. Reduce the fracture and elevate any central depression to reduce the articular fracture components. Provisionally stabilize the fracture as necessary with K-Wires and/or clamps.

Step 3: K-Wire Placement

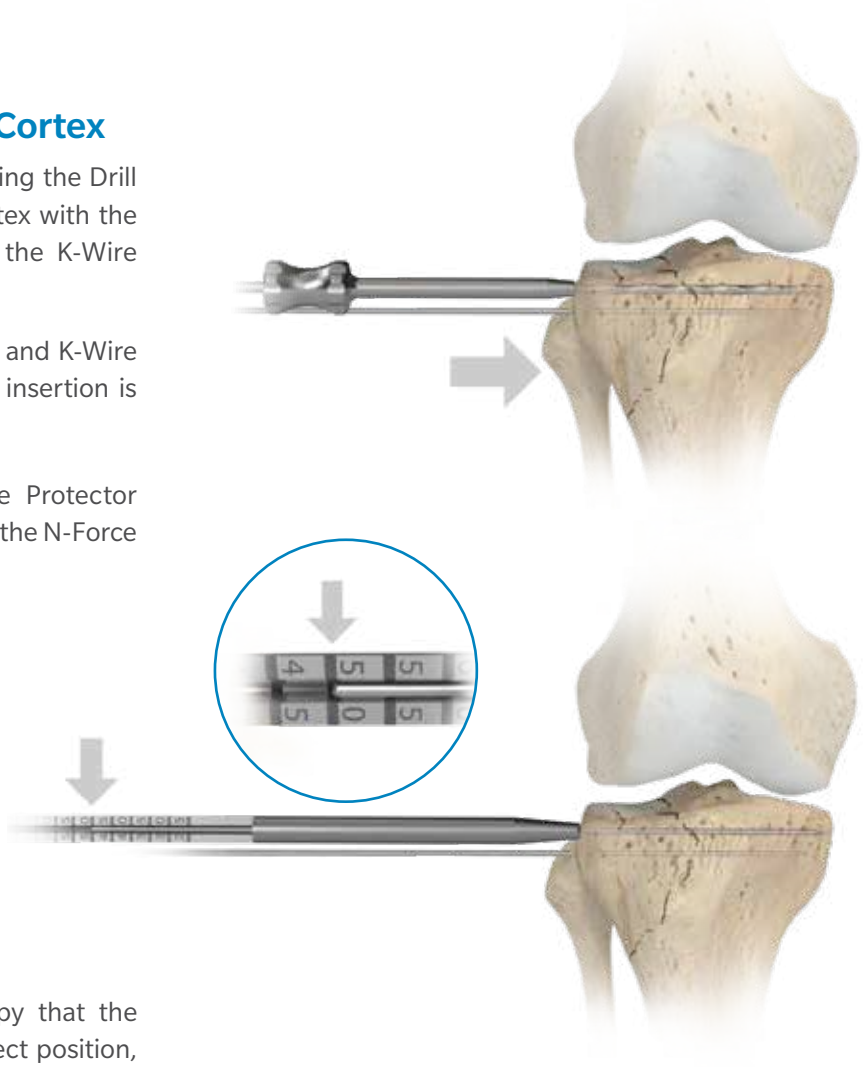
Insert the K-Wire Guide (IN018-3) into the Drill Guide (IN018-2). Using the combined Guides (IN018-3, IN018-2), place the 1.4 mm K-Wires (IN021-1) parallel to the joint line or in the surgeon's desired position for the N-Force Screw.



Step 4: Drilling of the Lateral Cortex

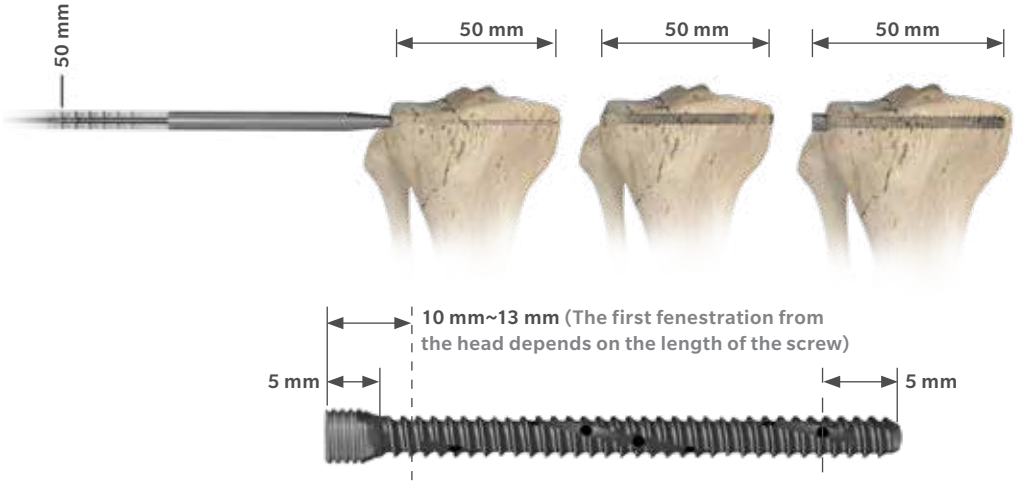
Remove the K-Wire Guide (IN018-3), leaving the Drill Guide (IN018-2) in place. Drill lateral cortex with the 2.7 mm Cannulated Drill (IN017-1) over the K-Wire (IN021-1), leaving the K-Wire in place.

- **TECHNIQUE TIP:** For fracture stability and K-Wire fixation, sequential drilling and Screw insertion is recommended.
- **TECHNIQUE VARIATION:** Use Tissue Protector (IN022-1) for percutaneous insertion of the N-Force Screw.



Step 5: Length Measurement

After confirming with C-arm Fluoroscopy that the 1.4 mm K-Wires (IN021-1) are in the correct position, remove the Drill Guide (IN018-2) and measure each K-Wire using the Depth Gauge (IN015-1). Use the measurement obtained to select the appropriate length N-Force Screw.



4.0 mm Screw Surgical Technique

The following surgical technique is explained using the example of a tibia plateau fracture.

Step 6: Assemble Sheath and Screw

Assemble the Sheath (IN048-FS) (the Sheath Adapter Assembly is made up of an outer Sheath and an inner Sheath Adapter) onto the selected N-Force Screw by turning the Sheath clockwise onto the threaded head of the N-Force Screw and advance the Sheath until it fully covers the head of the Screw.

TECHNIQUE VARIATION: A 4.0 mm Inset Washer (IN043-1) may be used and requires the use of the Inset Countersink (IN041-1). If an Inset Washer (IN043-1) is used, place Washer over the Screw before insertion.

Step 7: Attach the Cannulated Hex-Driver

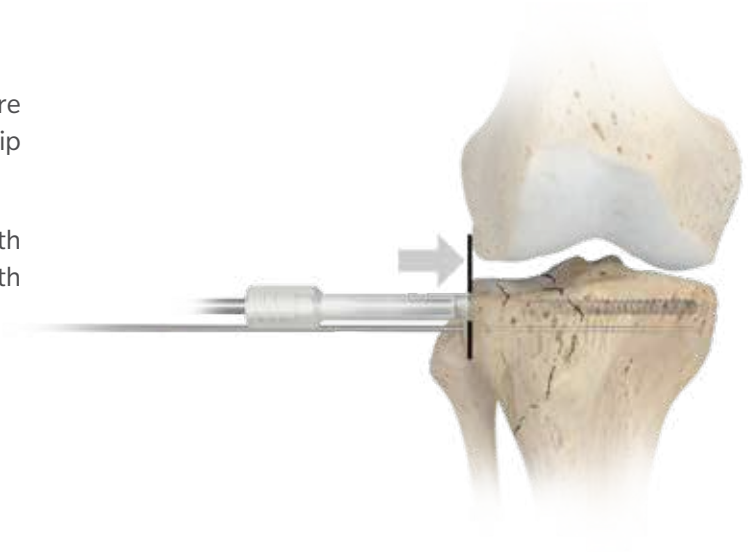
Assemble the Driver Handle (IN023-1) and the Cannulated Hex-Driver (IN008-1) using the AO Quick Connect. Insert the Driver Assembly into the Sheath (IN048-FS) and engage the Screw head with the Cannulated Hex-Driver (IN008-1).

TECHNIQUE VARIATION: For bi-cortical fixation and to limit BSM extrusion from the tip of the Screw into the soft tissue, an N-Force Fixation System Partially Cannulated Screw is recommended. To use this method, remove the K-Wire (IN021-1) and insert the correct size Partially Cannulated Screw. Drive into the predrilled hole using the Solid Hex-Driver (IN002-1) for insertion until the tip of the sheath (IN048-FS) is flush with the cortex. Skip to step 10.

Step 8: Insert N-Force Screw

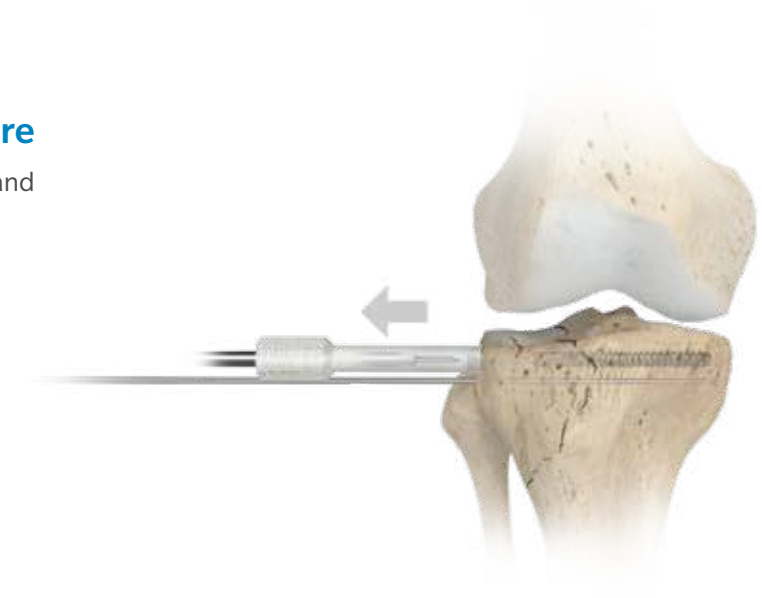
Place Screw/Sheath assembly over the K-Wire (IN021-1) and drive the N-Force Screw until the tip of the Sheath (IN048-FS) is flush with the cortex.

CAUTION: If Sheath (IN048-FS) is not flush with the cortex, BSM may leak around the bone/sheath interface.



Step 9: Remove Hex-Driver and K-Wire

Remove the Cannulated Hex-Driver (IN008-1) and K-Wire (IN021-1) from the Screw/Sheath assembly.



4.0 mm Screw Surgical Technique

The following surgical technique is explained using the example of a tibia plateau fracture.

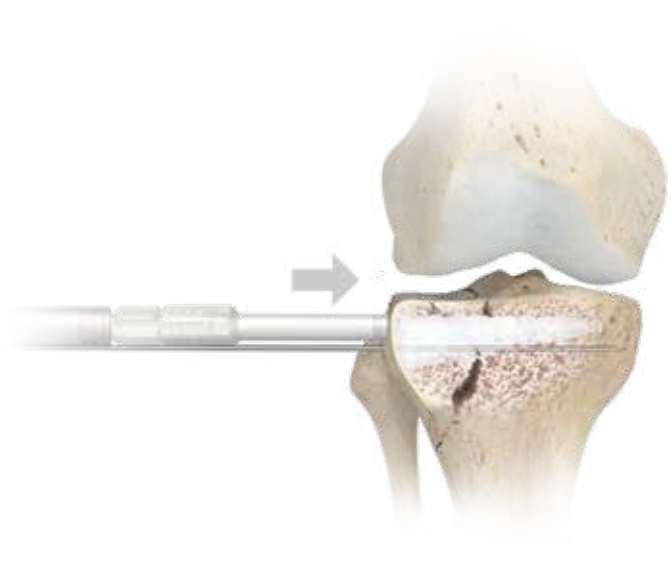
Step 10: Mix Bone Substitute Material and Attach BSM Delivery System

Insert the Sheath Adapter into the Sheath (IN048-FS) and turn clockwise to lock. Attach the BSM Delivery System to the Sheath Adapter. Inject the BSM. Use fluoroscopy to monitor the BSM as it fills the defect. Up to 5.0cc can be injected through each Screw to fill the void per surgeon's discretion. Remove the BSM Delivery System and the Sheath Adapter (IN048-FS) from the Sheath (IN048-FS).

Refer to the N-Force Blue BSM Technique Manual for mixing instructions.

- **TECHNIQUE TIP:** The amount of BSM may vary depending on the size of the defect and the anatomic area. N-Force Screws are intended for single injection. If further filling of the defect is required, insertion of additional N-Force Screws may be necessary.

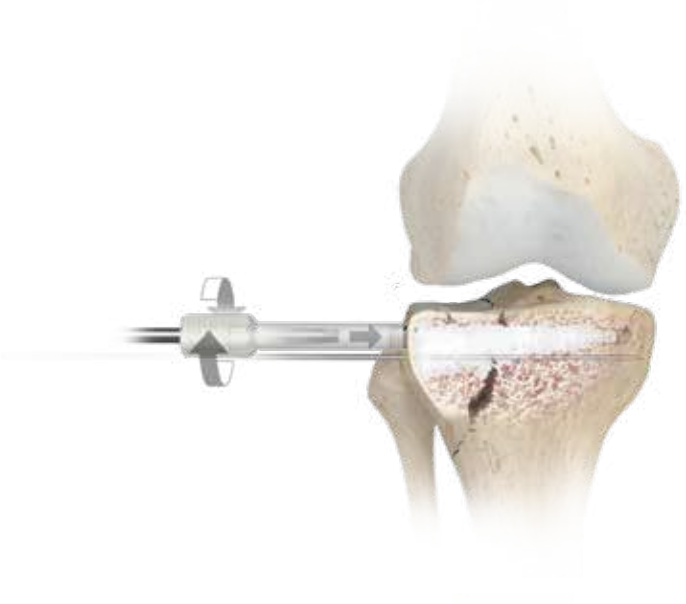
- **CAUTION:** Extrusion of BSM beyond the intended application site may irritate surrounding tissue. Remove any excess BSM before wound closure.



Step 11: Remove the Sheath

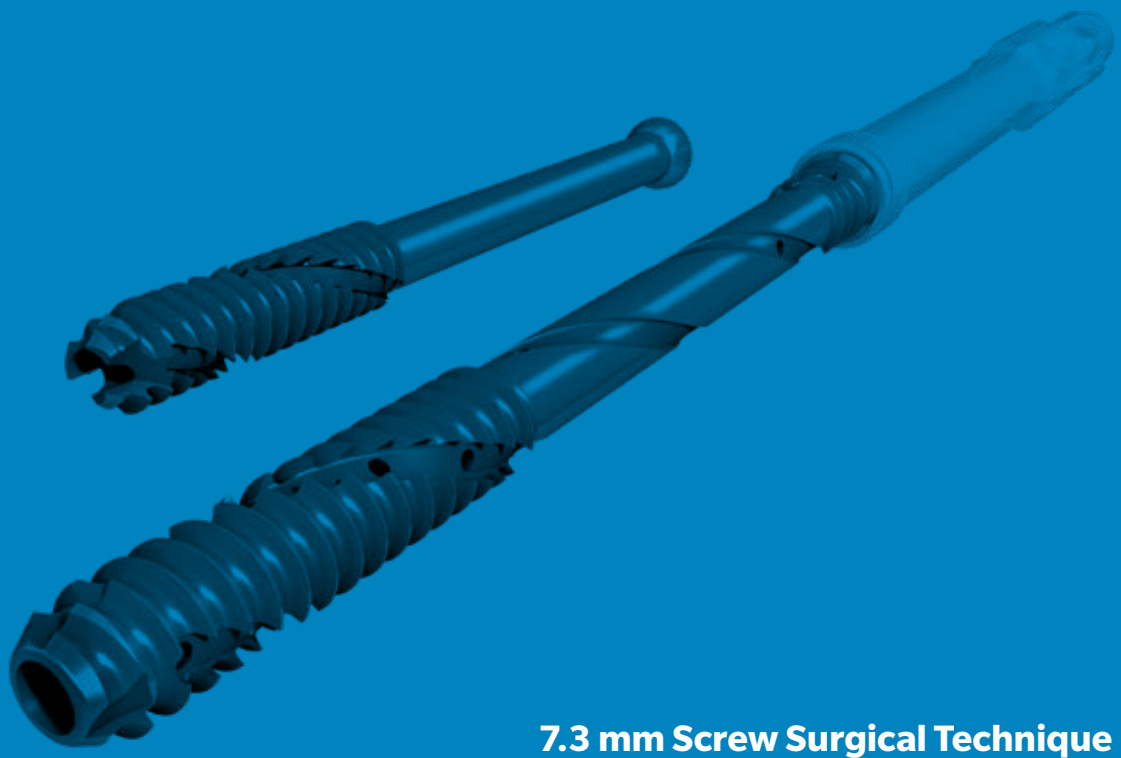
Insert the Solid Hex-Driver (IN002-1) into the Sheath (IN048-FS) and engage the head of the Screw. Turn the Sheath (IN048-FS) counterclockwise and disconnect from the Screw head. Slide the Sheath (IN048-FS) up the shaft of the Solid Hex-Driver (IN002-1).

CAUTION: Do NOT use the Cannulated Hex-Driver (IN008-1) to remove the sheath or to seat the Screw as it may fill with the BSM and possibly clog the instrument.



Step 12: Fully seat the N-Force Screw

With the Solid Hex-Driver (IN002-1) engaged into the head of the Screw, seat the Screw down to make flush with the cortex of the bone. Remove the Solid Hex-Driver (IN002-1) and Sheath (IN048-FS). Typically, 1–3 Screws are used to stabilize the fracture and inject the BSM.



7.3 mm Screw Surgical Technique

7.3 mm Screw Surgical Technique

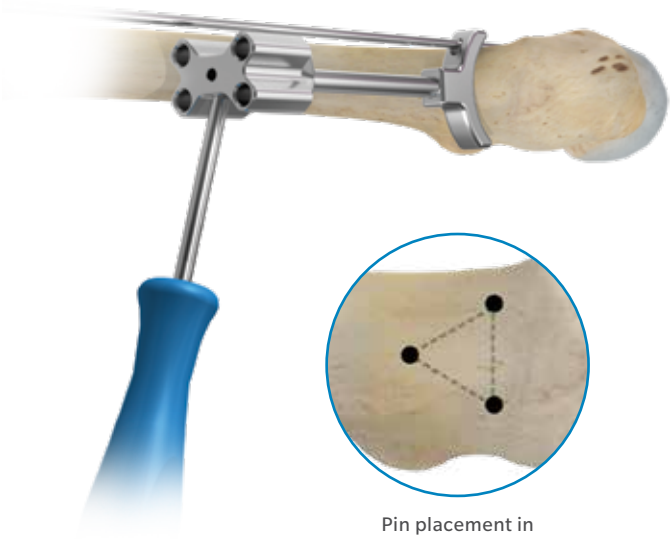
The following surgical technique is explained using the example of a femoral neck fracture.

Step 1: Reduce Fracture and Surgical Approach

Reduce the fracture and make an incision of approximately 6 cm.

Step 2: Position and Insert Guide Pin

Position the Multi-Hole Pin Guide (IN045-1) on the femur. The Multi-Hole Pin Guide (IN045-1) contains an anterior hole that may be used with a Guide Pin (IN034-1) to assess possible femoral neck anteversion/retroversion and allows for placement of pins in an inverted triangle.



Pin placement in an inverted triangle.

Step 3: Assemble Multi-Hole Pin Guide

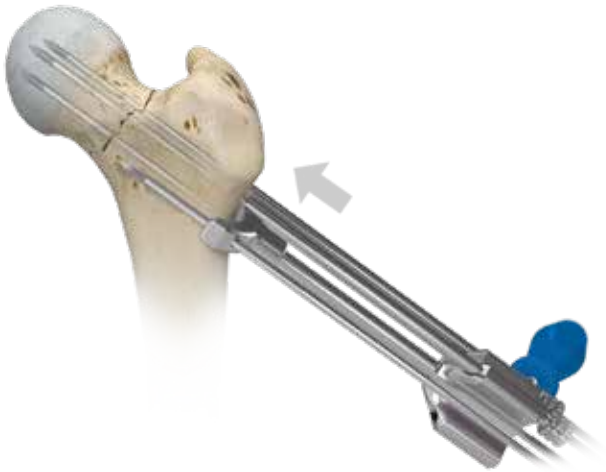
Use of Multi-Hole Pin Guide (IN045-1) gives adequate spacing between Screws for use of Washers. Insert both Pin Guides (IN030-3) in the proximal positions of the Multi-Hole Pin Guide (IN045-1).

TIP: If the Surgeon chooses to skip the Multi-Hole Pin Guide and use the individual Pin Guide/Drill Guide, the surgeon should carefully consider the placement of the screws and washers to avoid any overlapping of the washers and to limit any extrusion of the BSM at the cortical interface.

Step 4: Insert Guide Pins

Starting point of the inferior Guide Pin (IN034-1) should be proximal to the lesser trochanter. The inferior screw guide pin should be just above the calcar. This allows for more room to place the two superior screws in the neck. Insert the inferior Guide Pin. Insert additional Guide Pins (IN034-1) with tip of pins ending 5–10 mm from the subchondral bone, as needed. Remove the Multi-Hole Pin Guide (IN045-1).

CAUTION: Ensure that the Guide Pins do not penetrate the joint.

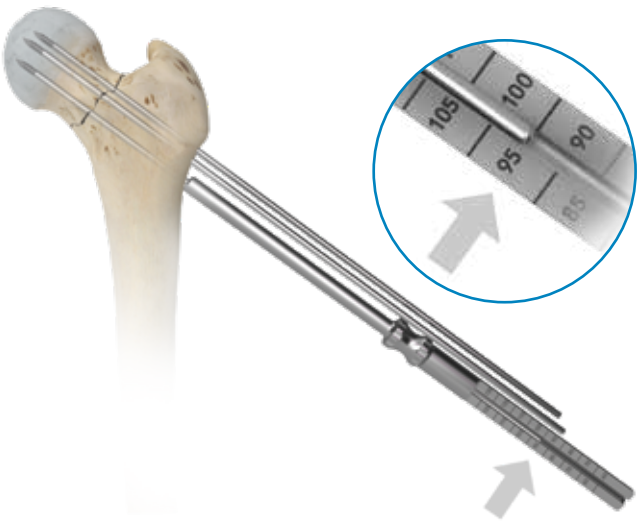


Step 5: Length Measurement

Slide the Drill Guide (IN030-2) over the Guide Pin (IN034-1). The Depth Gauge (IN033-1) must be used with Drill Guide (IN030-2). Use the Depth Gauge (IN033-1) to measure the length of the Screw needed. Measured length corresponds to the tip of Guide Pin (IN034-1).

TECHNIQUE TIP: Modification of the Screw length may be necessary based on the use and type of Washer, if used. See page 19.

TIP: The use of washers are encouraged for all femoral neck fractures.



7.3 mm Screw Surgical Technique

The following surgical technique is explained using the example of a femoral neck fracture.

Step 6: Drilling

Use the Drill Guide (IN030-2) and predrill the measured length with the 5.5 mm Drill (IN032-1). **C-arm fluoroscopy is recommended to help avoid over-drilling or advancement of the Guide Pin (IN034-1) into the joint.** Sequential drilling and Screw insertion is recommended for fracture stability.

- **TIP:** Predrilling is required. The fenestrated screws are self-tapping but not self-drilling. This is to limit the risk of penetrating through the femoral neck during screw insertion.
- **TECHNIQUE TIP:** If desired, a Hall-Jacobs adapter (IN036-1) can be used with the 5.5 mm Drill (IN032-1).

- **NOTE:** Use of Fenestrated and Non-Fenestrated Screws is based on the quality of bone and preference of the surgeon. Use of the Fenestrated Screw allows for injection of Bone Substitute Material (BSM) for augmented fixation.
- **NOTE:** The following technique is the suggested configuration. Use a Non-Fenestrated Screw with a Standard Washer for compression at the inferior position. Use two Fenestrated Screws in the superior-anterior and superior-posterior position with Inset Washers.

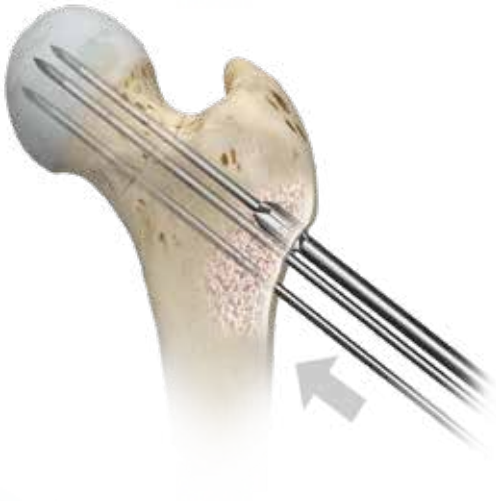
Step 7: Insert N-Force Non-Fenestrated Screw

Assemble the Driver Handle (IN035-1) and the Driver (IN031-1) using the Quick Connect and engage the head of the Screw. Place Screw and Standard Washer (IN039-1) over Guide Pin (IN034-1) and drive the N-Force Screw across the fracture, gaining compression of the fracture site.

TECHNIQUE TIP: Release traction on the leg prior to final compression with the Screws.

Step 8: Drilling and Countersink for N-Force Fenestrated Screw

A 7.3 Inset Washer (IN044-1) is recommended with use of the N-Force Fenestrated Screw. This requires the use of the Countersink (IN042-1). Use the Drill Guide (IN030-2) and predrill the measured length with the 5.5 mm Drill (IN032-1). C-arm fluoroscopy is recommended to help avoid over-drilling or advancement of the Guide Pin (IN034-1) into the joint. Remove the Drill Guide (IN030-2) and countersink the lateral cortex.



Step 9: Assemble Sheath and Fenestrated Screw

Assemble the Sheath (IN028-FS) (Sheath Adapter Assembly is made up of an outer Sheath and an inner Sheath Adapter) onto the selected N-Force Fenestrated Screw by turning the Sheath (IN028-FS) clockwise onto the threaded head of the N-Force Screw and advance the Sheath (IN028-FS) until it stops.

Step 10: Attach the Driver

Insert the Driver (IN031-1) into the Sheath (IN028-FS) and engage the Screw head. If a Washer is used, place the desired Washer over the Screw before insertion.

7.3 mm Screw Surgical Technique

The following surgical technique is explained using the example of a femoral neck fracture.

Step 11: Insert N-Force Fenestrated Screw

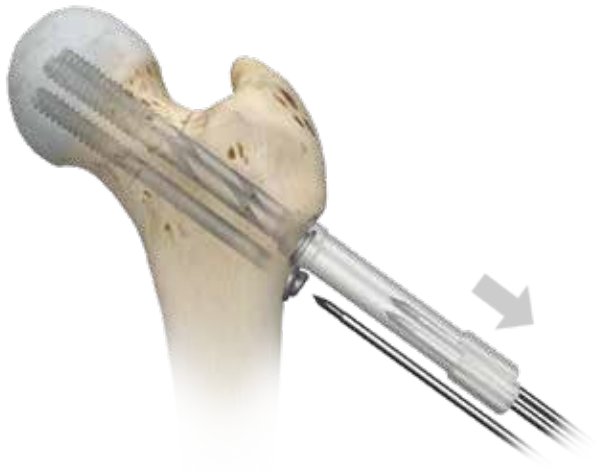
Place Screw/Sheath assembly over the Guide Pin (IN034-1) and drive the N-Force Screw until the Sheath (IN028-FS) and Washer are flush with cortex.

CAUTION: To prevent the Sheath from disengaging from the Screw, do not hold the Sheath when advancing the Screw.

Step 12: Remove Driver and Guide Pins

Remove the Driver (IN031-1) and Guide Pin (IN034-1) from the Screw/Sheath assembly.

CAUTION: Make sure the Sheaths (IN028-FS) are fully engaged on the head of Screw.



Step 13: Insert Sheath Adapter, Mix BSM, Attach BSM Delivery System

Insert the Sheath Adapter (IN028-FS) into the Sheath (IN028-FS) and turn clockwise to lock. Attach the BSM Delivery System to the Sheath Adapter (IN028-FS). Inject the BSM. Use fluoroscopy to monitor flow of BSM.

Refer to the N-Force Blue Bone Substitute Material Technique Manual for mixing instructions.

- **TECHNIQUE TIP:** Injection of 10cc of BSM is recommended in the anterior-superior Screw. Further injection of the posterior-superior screw is per the surgeon's discretion. The amount of BSM may vary depending on the anatomic area of the fracture and/or the existence and size of a bony defect. N-Force Screws are optimized for single injection. If further filling of a defect is required, insertion of additional N-Force Screws may be necessary.

- **CAUTION:** Extrusion of BSM beyond the intended application site may irritate surrounding tissue. Remove any excess BSM before wound closure.

If BSM is seen reaching the fracture sight under fluoroscopy, stop injecting.

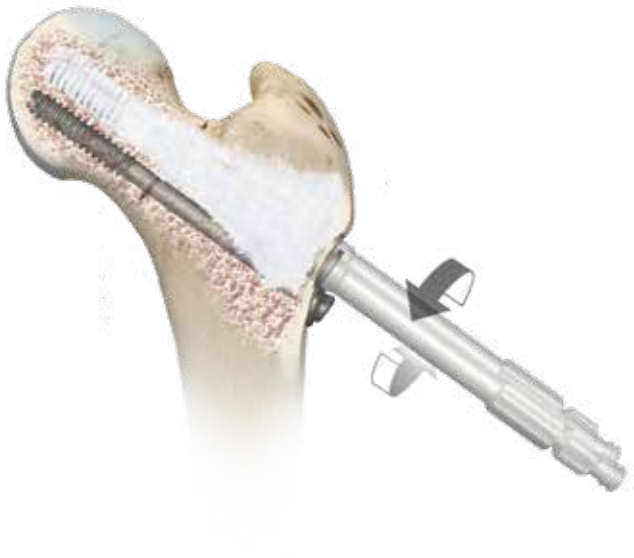
If a screw is riding the cortex, do not inject that screw or BSM may extrude out the fracture site. If a screw is not fully in the bone, do not inject the screw.

7.3 mm Screw Surgical Technique

The following surgical technique is explained using the example of a femoral neck fracture.

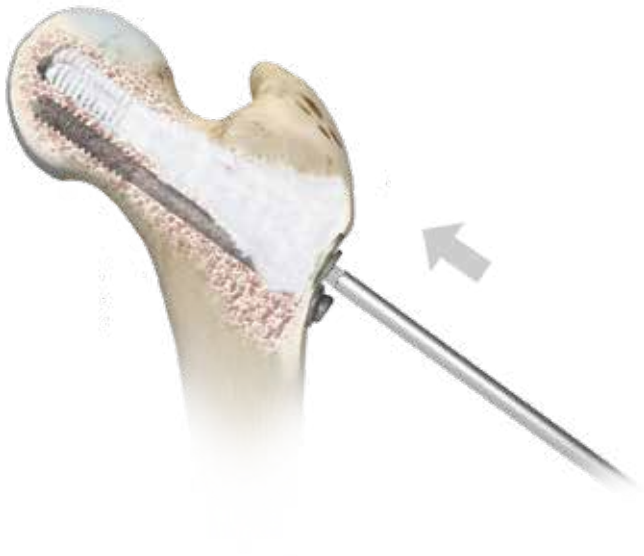
Step 14: Remove Sheath

Remove the Sheath Adapter (IN028-FS) from the Sheath (IN028-FS) by turning counterclockwise. Assemble the Driver (IN031-1) onto the Driver Handle (IN035-1). Insert the Driver (IN031-1) through the Sheath (IN028-FS) and engage the head of the Screw. Remove the Sheath (IN028-FS) from the head of the Screw by turning Sheath (IN028-FS) counterclockwise.



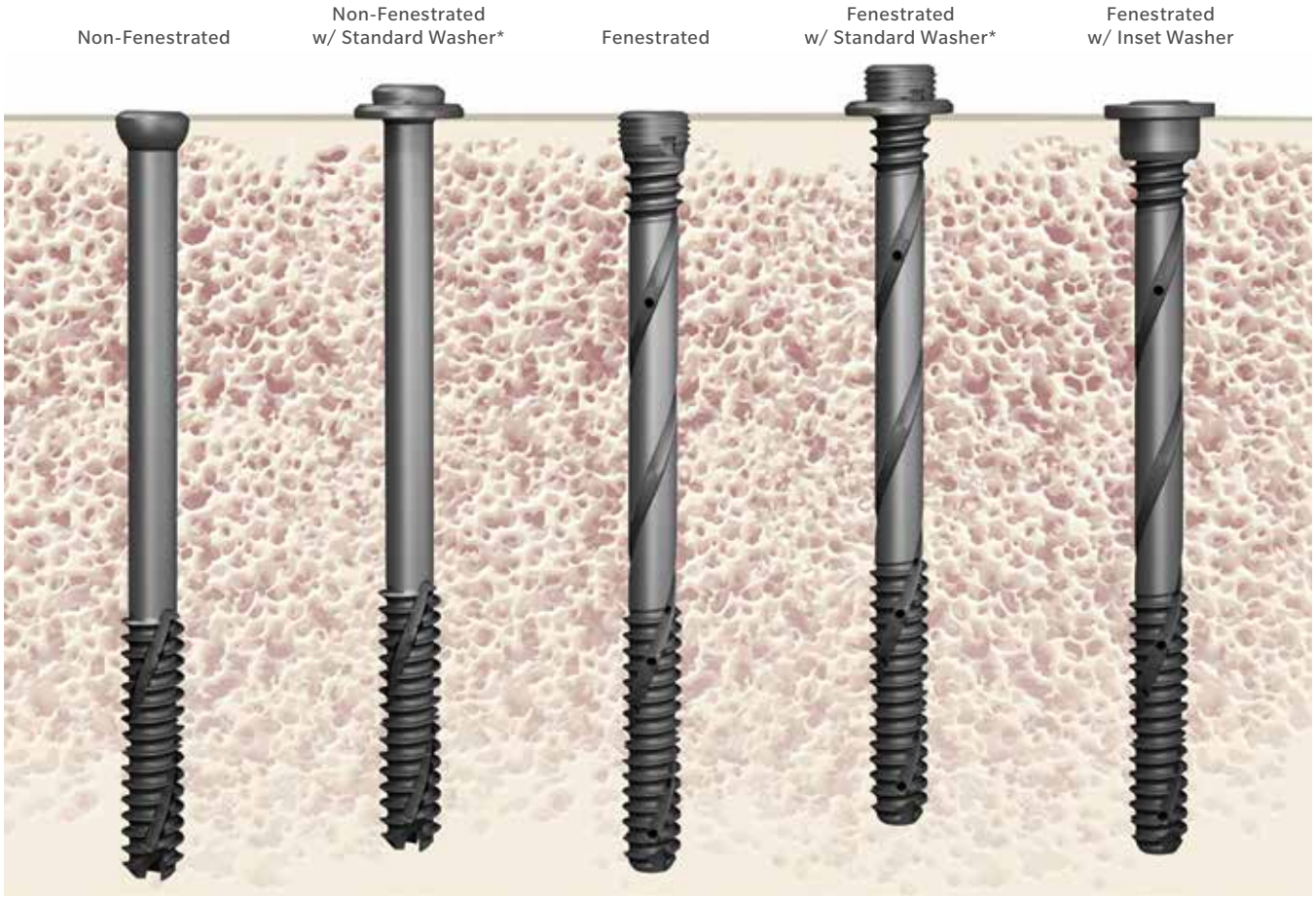
Step 15: Fully Seat the N-Force Fenestrated Screws

Seat the Screw down to make flush with the cortex or the Washer. Remove the Driver (IN031-1).



7.3 mm Screw/Washer Combinations

The illustration demonstrates the effect of the final Screw length based on the measured length from the Depth Gauge and the head prominence depending on the Screw/Washer combination. This provides the necessary Screw length adjustment if Washers are used.



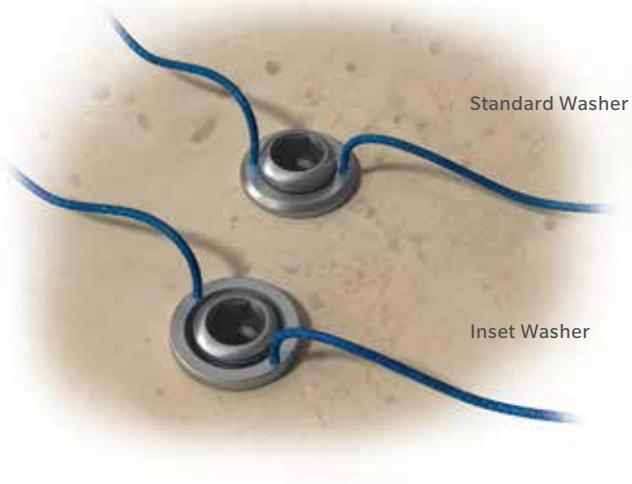
*It is recommended to add 5 mm screw length when using standard (flat) washer.

Use with Sutures

N-Force 4.0 mm Washers accommodate up to #2 Suture.

N-Force 7.3 mm Washers accommodate up to #5 Suture.

TECHNIQUE TIP: Add Suture prior to Screw/Washer insertion.



Implants/Sheaths

N-Force Fixation System 4.0 mm	Description	Recess	External Diameter	Shaft Diameter	Length
	**4.0 mm Fully Cannulated Screw**	**3.0 Hex**	4.0 mm	3.0 mm	25–75 mm
	**4.0 mm Partially Cannulated Screw**	**3.0 Hex**	4.0 mm	3.0 mm	25–75 mm
		Outer Diameter		**Inner Diameter**	
	**4.0 mm Inset Washer**	8.7 mm		4.8 mm	
	**4.0 mm Sheath**				
	**4.0 mm Sheath Adapter**				

N-Force Fixation System 7.3 mm	Description	Recess	External Diameter	Shaft Diameter	Length
	**7.3 mm Fenestrated Screw (32 mm thread length)**	**4.76 Hex**	7.3 mm	5.6-5.7 mm	60–130 mm
	**7.3 mm Non-Fenestrated Screw (32 mm thread length)**	**4.76 Hex**	7.3 mm	5.6-5.7 mm	60–130 mm
		Outer Diameter		**Inner Diameter**	
	**7.3 mm Standard Washer**	12.5 mm		7.5 mm	
	**7.3 mm Inset Washer**	12.7 mm		8.4 mm	
	**7.3 mm Sheath**				
	**7.3 mm Sheath Adapter**				

Instruments

N-Force Fixation System 4.0 mm	Description	Part Number
–	**4.0 mm Implant Set**	STIN40
–	**4.0 mm Instrument Set**	KTIN40
	**Solid Hex-Driver**	IN002-1
	Cannulated Hex-Driver	IN008-1
	**Depth Gauge**	IN015-1
	2.7 mm Cannulated Drill (Single Use Only)	IN017-1
	**Countersink**	IN041-1
	**Drill Guide**	IN018-2
	**K-wire Guide**	IN018-3
	1.4 mm K-wire (Single Use Only)	IN021-1
	**Tissue Protector**	IN022-1
	**Driver Handle**	IN023-1

* The N-Force Fixation System 4.0 mm - 1.4 mm K-wire (IN021-1) and 2.7 mm Cannulated Drill (IN017-1) are single-use only and can not be re-sterilized after use.

Instruments

N-Force Fixation System 7.3 mm	Description	Part Number
–	**7.3 mm Implant Set**	STIN73
–	**7.3 mm Instrument Set**	KTIN73
	**Driver Handle**	IN035-1
	**Hall-Jacobs Adapter**	IN036-1
	**Driver**	IN031-1
	**Tissue Protector**	IN030-1
	**Drill Guide**	IN030-2
	**Pin Guide**	IN030-3
	**Depth Gauge**	IN033-1
	Stylet	IN040-1
	**Inset Countersink**	IN042-1
	**Multi-Hole Pin Guide**	IN045-1
	3.2 mm Guide Pin (Single Use Only)	IN034-1
	**5.5 mm Drill**	IN032-1

* The N-Force Fixation System 7.3 mm - 3.2 mm Guide Pins (IN0341) are single-use only and CANNOT be resterilized after use.

Implants

N-Force 4.0 mm Partially Cannulated (PC) Screw & Sheath

Description	Size	Part Number
PC Screw & Sheath	4.0 mm x 25 mm	IN001-25-FS
	4.0 mm x 30 mm	IN001-30-FS
	4.0 mm x 35 mm	IN001-35-FS
	4.0 mm x 40 mm	IN001-40-FS
	4.0 mm x 45 mm	IN001-45-FS
	4.0 mm x 50 mm	IN001-50-FS
	4.0 mm x 55 mm	IN001-55-FS
	4.0 mm x 60 mm	IN001-60-FS
	4.0 mm x 65 mm	IN001-65-FS
	4.0 mm x 70 mm	IN001-70-FS
	4.0 mm x 75 mm	IN001-75-FS
Sheath & Adapter Assembly		IN048-FS

N-Force 4.0 mm Fully Cannulated (FC) Screw & Sheath

Description	Size	Part Number
FC Screw & Sheath	4.0 mm x 25 mm	IN006-25-FS
	4.0 mm x 30 mm	IN006-30-FS
	4.0 mm x 35 mm	IN006-35-FS
	4.0 mm x 40 mm	IN006-40-FS
	4.0 mm x 45 mm	IN006-45-FS
	4.0 mm x 50 mm	IN006-50-FS
	4.0 mm x 55 mm	IN006-55-FS
	4.0 mm x 60 mm	IN006-60-FS
	4.0 mm x 65 mm	IN006-65-FS
	4.0 mm x 70 mm	IN006-70-FS
	4.0 mm x 75 mm	IN006-75-FS
Sheath & Adapter Assembly		IN048-FS

N-Force 4.0 mm Washer

Description	Part Number
Inset Washer	IN043-1

Implants

7.3 mm Fenestrated Screw, Sheath, and Washer

Description	Size	Part Number
Fenestrated Screw & Sheath	7.3 mm x 60 mm	IN027-60-FS
	7.3 mm x 65 mm	IN027-65-FS
	7.3 mm x 70 mm	IN027-70-FS
	7.3 mm x 75 mm	IN027-75-FS
	7.3 mm x 80 mm	IN027-80-FS
	7.3 mm x 85 mm	IN027-85-FS
	7.3 mm x 90 mm	IN027-90-FS
	7.3 mm x 95 mm	IN027-95-FS
	7.3 mm x 100 mm	IN027-100-FS
	7.3 mm x 105 mm	IN027-105-FS
	7.3 mm x 110 mm	IN027-110-FS
	7.3 mm x 115 mm	IN027-115-FS
	7.3 mm x 120 mm	IN027-120-FS
	7.3 mm x 125 mm	IN027-125-FS
	7.3 mm x 130 mm	IN027-130-FS
Sheath & Adapter Assembly		IN028-FS

N-Force 7.3 mm Non-Fenestrated Screw & Washer

Description	Size	Part Number
Non-Fenestrated Screw & Sheath	7.3 mm x 60 mm	IN038-60-FS
	7.3 mm x 65 mm	IN038-65-FS
	7.3 mm x 70 mm	IN038-70-FS
	7.3 mm x 75 mm	IN038-75-FS
	7.3 mm x 80 mm	IN038-80-FS
	7.3 mm x 85 mm	IN038-85-FS
	7.3 mm x 90 mm	IN038-90-FS
	7.3 mm x 95 mm	IN038-95-FS
	7.3 mm x 100 mm	IN038-100-FS
	7.3 mm x 105 mm	IN038-105-FS
	7.3 mm x 110 mm	IN038-110-FS
	7.3 mm x 115 mm	IN038-115-FS
	7.3 mm x 120 mm	IN038-120-FS
	7.3 mm x 125 mm	IN038-125-FS
	7.3 mm x 130 mm	IN038-130-FS

Implants

N-Force 7.3 mm Washer	Description	Part Number
	**Inset Washer**	IN044-1
	**Standard Washer**	IN039-1

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

For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert, and visit www.zimmerbiomet.com or contact your local ZImmer Biomet representative.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with a health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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