

Biomet 4.0/5.0 mm Cannulated Screw System

Surgical Technique



BIOMET

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Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

4.0/5.0 mm Cannulated Screw System

Biomet 4.0/5.0 mm Cannulated Screw System

The Biomet 4.0/5.0 mm Cannulated Screw System is part of a series of systems developed by Biomet for cannulated screws ranging from 4.0 to 8.0 mm. Matching a combination of screw options with necessary instrumentation, the systems provide convenience and flexibility for the orthopaedic surgeon and the OR staff. Consistent with all Biomet Trauma implants, the screws offer TiMAX surface treatment benefits of increased fatigue strength compared to unanodized Ti and 316L stainless steel.¹ These systems are truly designed with the surgeon in mind.

4.0/5.0 mm Cannulated Screw System

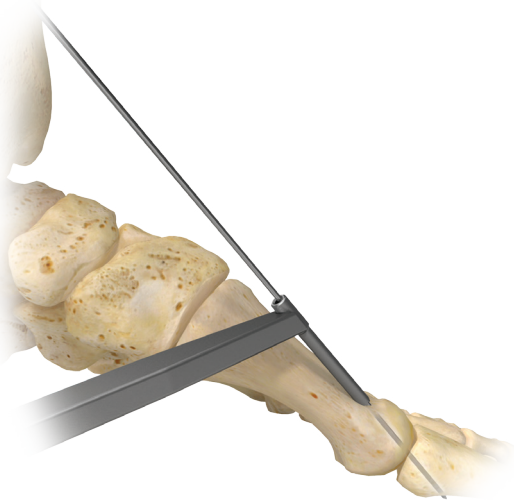


Figure 1

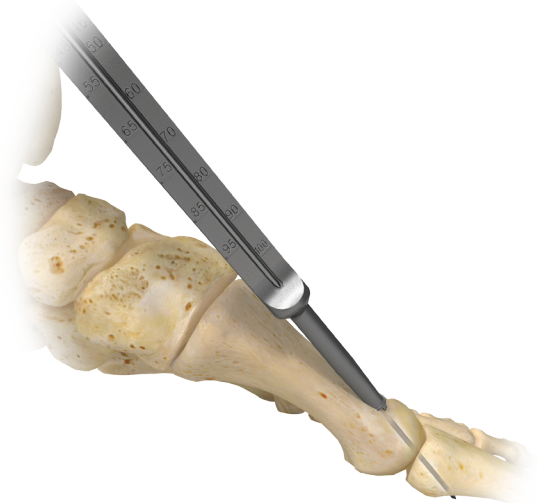


Figure 2

For illustrative purposes, the following surgical technique describes a 1st metatarsophalangeal joint arthrodesis using either a 4.0 mm or 5.0 mm cannulated screw.

Guide Wire Insertion

Position the guide wire end of the Drill Guide at the entry point and insert a Guide Wire to the appropriate depth and verify using fluroscopy (Figure 1). The drill end of the drill guide can be positioned over the entry point if the drill will be utilized through the drill guide.

SCREW	DRILL GUIDE	CAT. NO.	GUIDE WIRE
4.0 mm	1.25 / 2.4 mm	110008418	1.25 mm
5.0 mm	1.8 / 3.5 mm	110008423	1.8 mm

Countersinking and Measurement

Remove the drill guide and insert the 4.0 or 5.0 mm Depth Gauge with Countersink over the inserted guide wire (Figure 2).

SCREW	DEPTH GAUGE	CAT. NO.
4.0 mm	4.0 mm	110008461
5.0 mm	5.0 mm	110008463

Using the handle, rotate the depth gauge back and forth until sufficient countersinking has been achieved, and note the screw length measurement on the calibrated gauge.

Note: To prevent excessive bone removal, countersinking under power is not recommended.

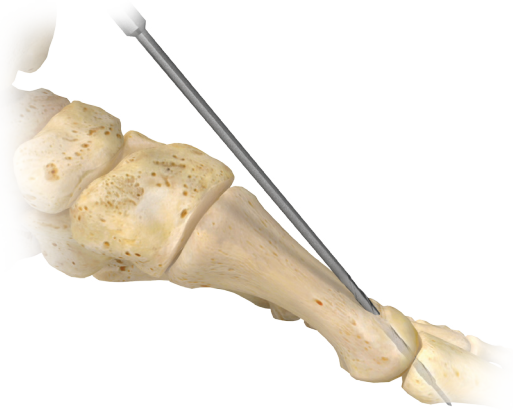


Figure 3

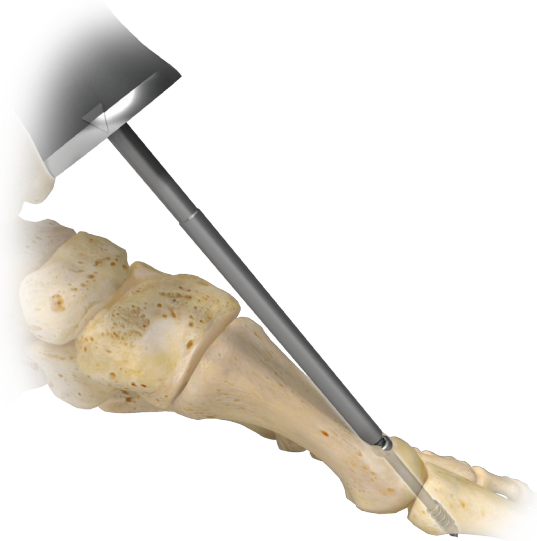


Figure 4

Pre-Drilling

Connect the 2.4 or 3.5 mm Cannulated Drill to an AO adapter and slide the drill over the guide wire. Drill to appropriate depth, and verify using fluoroscopy. Remove the drill, leaving the guide wire in place (Figure 3).

SCREW	CANNULATED DRILL	CAT. NO.
4.0 mm	2.4 mm	110008486
5.0 mm	3.5 mm	110008406

Screw Insertion

Advance the selected screw over the guide wire using a Cannulated Hexalobular Screwdriver attached to the Screwdriver handle (Cat. No. 110017408) until the head of the screw is completely seated in the bone (Figure 4). Verify final position via fluoroscopy.

SCREW	CANNULATED SCREWDRIVER	CAT. NO.
4.0 mm	BT15	110008451
5.0 mm	BT20	110008453

4.0/5.0 mm Cannulated Screw System

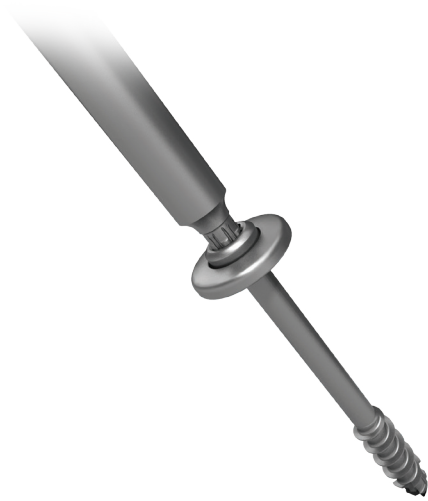


Figure 5

Screw Insertion (cont.)

A 4.0 mm Flat Washer (Cat. No. 110008347) or 5.0 mm Flat Washer (Cat. No. 110008349) may be used in conjunction with the same screw diameter size for osteoporotic bone or where the cortex is thin, increasing the surface area of the screw head (Figure 5).

Note: Washers should not be used if countersinking has already occurred.

Note: Screw removal or additional adjustment when not using a guide wire in the cannulation of the screw can be achieved by utilizing the BT15 (Cat. No. 110009963) or BT20 (Cat. No. 110009965) SOLID Hexalobular Screwdriver.

Screw Removal

Screw removal should always be started manually. Once started, screws may be removed either with power using the BT15 Solid Screwdriver Hexalobular Drive AO (Cat. No. 110009963) attached to the power adapter, or manually with the screwdriver shank attached to the screwdriver handle, or the T-Handle.

Caution: Under no circumstances should pliers or similar devices be used to grip the screw head as this will damage the screw and could lead to breakage.

If the cannulated screw becomes damaged or removal becomes difficult, the Easy Out (Cat. No. 110008496) should be used for screw extraction. The Easy Out must be used manually in conjunction with the T-Handle. The tip of the Easy Out is inserted through the head and down the center of the cannulated screw. The Easy Out is turned counter-clockwise while applying firm forward pressure. The Easy Out cuts into the cannula of the screw shaft to facilitate removal. The Easy Out Extractor may be used even if the head or shaft of the screw is not intact.

Implants

4.0 mm Partially-Threaded Cannulated Screws

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110007525	110009802	Cann Screw Part Thd 4.0 x 10 mm	2
110007527	110009803	Cann Screw Part Thd 4.0 x 12 mm	2
110007529	110009804	Cann Screw Part Thd 4.0 x 14 mm	2
110007531	110009805	Cann Screw Part Thd 4.0 x 16 mm	2
110007533	110009806	Cann Screw Part Thd 4.0 x 18 mm	2
110007535	110009807	Cann Screw Part Thd 4.0 x 20 mm	2
110007537	110009808	Cann Screw Part Thd 4.0 x 22 mm	2
110007539	110009809	Cann Screw Part Thd 4.0 x 24 mm	2
110007541	110009810	Cann Screw Part Thd 4.0 x 26 mm	2
110007543	110009811	Cann Screw Part Thd 4.0 x 28 mm	2
110007545	110009812	Cann Screw Part Thd 4.0 x 30 mm	3
110007547	110009813	Cann Screw Part Thd 4.0 x 32 mm	3
110007549	110009814	Cann Screw Part Thd 4.0 x 34 mm	3
110007551	110009815	Cann Screw Part Thd 4.0 x 36 mm	3
110007553	110009816	Cann Screw Part Thd 4.0 x 38 mm	3
110007555	110009817	Cann Screw Part Thd 4.0 x 40 mm	3
110007557	110009818	Cann Screw Part Thd 4.0 x 42 mm	3
110007559	110009819	Cann Screw Part Thd 4.0 x 44 mm	3
110007561	110009820	Cann Screw Part Thd 4.0 x 46 mm	3
110007563	110009821	Cann Screw Part Thd 4.0 x 48 mm	3
110007565	110009822	Cann Screw Part Thd 4.0 x 50 mm	3
110007567	110009823	Cann Screw Part Thd 4.0 x 55 mm	2
110007569	110009824	Cann Screw Part Thd 4.0 x 60 mm	2
110007571	110009825	Cann Screw Part Thd 4.0 x 65 mm	2
110007573	110009826	Cann Screw Part Thd 4.0 x 70 mm	2
-	110009827	Cann Screw Part Thd 4.0 x 75 mm	0
-	110009829	Cann Screw Part Thd 4.0 x 80 mm	0
-	110009831	Cann Screw Part Thd 4.0 x 85 mm	0
-	110009833	Cann Screw Part Thd 4.0 x 90 mm	0
-	110009835	Cann Screw Part Thd 4.0 x 95 mm	0
-	110009837	Cann Screw Part Thd 4.0 x 100 mm	0

Reference IFU 01-50-4048 for screw and washer product information.

4.0/5.0 mm Cannulated Screw System

Implants (cont.)

4.0 mm Fully-Threaded Cannulated Screws

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110007575	110009839	Cann Screw Full Thd 4.0 x 10 mm	2
110007577	110009840	Cann Screw Full Thd 4.0 x 12 mm	2
110007579	110009841	Cann Screw Full Thd 4.0 x 14 mm	2
110007581	110009842	Cann Screw Full Thd 4.0 x 16 mm	2
110007583	110009843	Cann Screw Full Thd 4.0 x 18 mm	2
110007585	110009844	Cann Screw Full Thd 4.0 x 20 mm	2
110007587	110009845	Cann Screw Full Thd 4.0 x 22 mm	2
110007589	110009846	Cann Screw Full Thd 4.0 x 24 mm	2
110007591	110009847	Cann Screw Full Thd 4.0 x 26 mm	2
110007593	110009848	Cann Screw Full Thd 4.0 x 28 mm	2
110007595	110009849	Cann Screw Full Thd 4.0 x 30 mm	2
110007597	110009850	Cann Screw Full Thd 4.0 x 32 mm	2
110007599	110009851	Cann Screw Full Thd 4.0 x 34 mm	2
110007601	110009852	Cann Screw Full Thd 4.0 x 36 mm	2
110007603	110009853	Cann Screw Full Thd 4.0 x 38 mm	2
110007605	110009854	Cann Screw Full Thd 4.0 x 40 mm	2
110007607	110009855	Cann Screw Full Thd 4.0 x 42 mm	2
110007609	110009856	Cann Screw Full Thd 4.0 x 44 mm	2
110007611	110009857	Cann Screw Full Thd 4.0 x 46 mm	2
110007613	110009858	Cann Screw Full Thd 4.0 x 48 mm	2
110007615	110009859	Cann Screw Full Thd 4.0 x 50 mm	2
110007617	110009860	Cann Screw Full Thd 4.0 x 55 mm	2
110007619	110009861	Cann Screw Full Thd 4.0 x 60 mm	2
110007621	110009862	Cann Screw Full Thd 4.0 x 65 mm	2
110007623	110009863	Cann Screw Full Thd 4.0 x 70 mm	2
-	110009864	Cann Screw Full Thd 4.0 x 75 mm	0
-	110009866	Cann Screw Full Thd 4.0 x 80 mm	0
-	110009868	Cann Screw Full Thd 4.0 x 85 mm	0
-	110009870	Cann Screw Full Thd 4.0 x 90 mm	0
-	110009872	Cann Screw Full Thd 4.0 x 95 mm	0
-	110009874	Cann Screw Full Thd 4.0 x 100 mm	0

Reference IFU 01-50-4048 for screw and washer product information.

5.0 mm Partially-Threaded Cannulated Screws

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110007636	110009881	Cann Screw Part Thd 5.0 x 30 mm	2
110007638	110009882	Cann Screw Part Thd 5.0 x 32 mm	2
110007640	110009883	Cann Screw Part Thd 5.0 x 34 mm	2
110007642	110009884	Cann Screw Part Thd 5.0 x 36 mm	2
110007644	110009885	Cann Screw Part Thd 5.0 x 38 mm	2
110007646	110009886	Cann Screw Part Thd 5.0 x 40 mm	2
110007648	110009887	Cann Screw Part Thd 5.0 x 42 mm	2
110007650	110009888	Cann Screw Part Thd 5.0 x 44 mm	2
110007652	110009889	Cann Screw Part Thd 5.0 x 46 mm	2
110007654	110009890	Cann Screw Part Thd 5.0 x 48 mm	2
110007656	110009891	Cann Screw Part Thd 5.0 x 50 mm	2
110007658	110009892	Cann Screw Part Thd 5.0 x 55 mm	2
110007660	110009893	Cann Screw Part Thd 5.0 x 60 mm	2
110007662	110009894	Cann Screw Part Thd 5.0 x 65 mm	2
110007664	110009895	Cann Screw Part Thd 5.0 x 70 mm	2
110007666	110009896	Cann Screw Part Thd 5.0 x 75 mm	2
110007668	110009897	Cann Screw Part Thd 5.0 x 80 mm	2
110007670	110009898	Cann Screw Part Thd 5.0 x 85 mm	2
110007672	110009899	Cann Screw Part Thd 5.0 x 90 mm	2
110007674	110009900	Cann Screw Part Thd 5.0 x 95 mm	2
110007676	110009901	Cann Screw Part Thd 5.0 x 100 mm	2

Reference IFU 01-50-4048 for screw and washer product information.

4.0/5.0 mm Cannulated Screw System

Implants (cont.)

5.0 mm Fully-Threaded Cannulated Screws

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110007688	110009907	Cann Screw Full Thd 5.0 x 30 mm	2
110007690	110009908	Cann Screw Full Thd 5.0 x 32 mm	2
110007692	110009909	Cann Screw Full Thd 5.0 x 34 mm	2
110007694	110009910	Cann Screw Full Thd 5.0 x 36 mm	2
110007696	110009911	Cann Screw Full Thd 5.0 x 38 mm	2
110007698	110009912	Cann Screw Full Thd 5.0 x 40 mm	2
110007700	110009913	Cann Screw Full Thd 5.0 x 42 mm	2
110007702	110009914	Cann Screw Full Thd 5.0 x 44 mm	2
110007704	110009915	Cann Screw Full Thd 5.0 x 46 mm	2
110007706	110009916	Cann Screw Full Thd 5.0 x 48 mm	2
110007708	110009917	Cann Screw Full Thd 5.0 x 50 mm	2
110007710	110009918	Cann Screw Full Thd 5.0 x 55 mm	2
110007712	110009919	Cann Screw Full Thd 5.0 x 60 mm	2
110007714	110009920	Cann Screw Full Thd 5.0 x 65 mm	2
110007716	110009921	Cann Screw Full Thd 5.0 x 70 mm	2
110007718	110009922	Cann Screw Full Thd 5.0 x 75 mm	2
110007720	110009923	Cann Screw Full Thd 5.0 x 80 mm	2
110007722	110009924	Cann Screw Full Thd 5.0 x 85 mm	2
110007724	110009925	Cann Screw Full Thd 5.0 x 90 mm	2
110007726	110009926	Cann Screw Full Thd 5.0 x 95 mm	2
110007728	110009927	Cann Screw Full Thd 5.0 x 100 mm	2

Washers

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110008347	110008489	Flat Washer 4.0 mm	3
110008349	110008362	Flat Washer 5.0 mm	3

Reference IFU 01-50-4048 for screw and washer product information.

Disposables

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110008393	-	1.25 x 150 mm K-Wire Trc (Pk/6)	1
110008391	-	1.25 x 150 mm K-Wire Thd (Pk/6)	1
-	110008486	2.4 mm Cann Drill w/ AO	2
-	14-450360	1.8 x 200 mm Pin Trc (Pk/5)	1
-	14-450385	1.8 x 200 mm Pin Thd (Pk/5)	1
-	110008406	3.5 mm Cann Drill w/ AO	2

Instruments

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110008418	-	1.25 / 2.4 mm Drill Guide	1
110008500	-	Guide Wire Pusher 1.1 mm	1
110008451	-	BT15 Cann Hexalobular Driver AO	2
110009963	-	BT15 Solid Hexalobular Driver AO	1
110008461	-	4.0 mm Depth Gauge w/ Countersink	1
110008423	-	1.8 / 3.5 mm Drill Guide	1
110008493	-	Guide Wire Pusher 1.8 mm	1
110008453	-	BT20 Cann Hexalobular Driver AO	2
110009965	-	BT20 Solid Hexalobular Driver AO	1
110008463	-	5.0 mm Depth Gauge w/ Countersink	1
13571	-	Screw Forceps	1
110008496	-	Easy Out Small Tip	1
110017408	-	Small Ratchet Handle AO	1

Case / Tray

NON-STERILE	STERILE NO.	DESCRIPTION	RECOMMENDED QUANTITY
110008471	-	Cannulated Screw Case 4.0 / 5.0 mm	1

Reference IFU 01-50-4202 for sterilization parameters of the Cannulated Screw instrument cases and contents.

INDICATIONS

Small Cannulated Screws (4.0 mm and smaller diameter) are intended for use in:

1. Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow.
2. Arthrodesis of the foot, wrist and elbow.
3. Small and long bone osteotomies.
4. Fracture fixation of small bones, small bone fragments and long bones.

Large Cannulated Screws (5 mm and larger in diameter) are intended for use in:

1. Fixation of fractures in long bones and long bone fragments.
2. Long bone osteotomies (femur, tibia, foot, ankle, olecranon).
3. Arthrodesis and fracture fixation of the foot and ankle, such as Jones fractures of the fifth metatarsal, and Calcaneal fractures.

Large Cannulated Screws (6.5 mm and larger in diameter) are intended for use in:

1. Slipped capital femoral epiphysis
2. Pediatric femoral neck fractures
3. Tibial plateau fractures
4. SI joint disruptions
5. Intercondylar femur fractures
6. Subtalar arthrodesis
7. Fixation of pelvis and iliosacral joint.

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Not for distribution in France.

CONTRAINDICATIONS

1. Infections.
2. Patient conditions including blood supply limitations, insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity where material sensitivity is suspected or unknown, testing is to be completed prior to implantation of the device.

References

1. Data on file at Biomet. Mechanical testing report # DVA-107504-DVER.

Mechanical testing is not necessarily indicative of clinical performance.

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