Biomet 3.0 mm Cannulated Screw System

Surgical Technique

BIOMET

One Surgeon. One Patient.

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.

3.0 mm Cannulated Screw System

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The Biomet 3.0 mm Cannulated Screw System is part of a series of systems developed by Biomet for cannulated screws ranging from 3.0 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 which has been shown to have increased fatigue strength compared to 316L electropolished stainless steel, type I anodized titanium, and machined titanium.[1] These systems are truly designed with the surgeon in mind.

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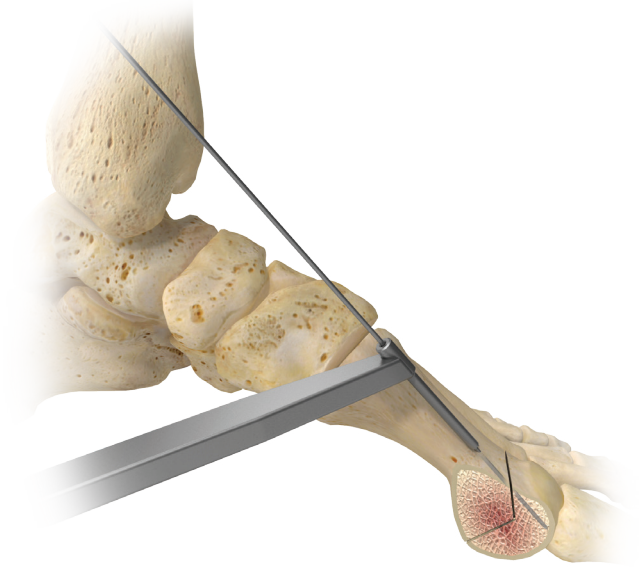

Figure 1

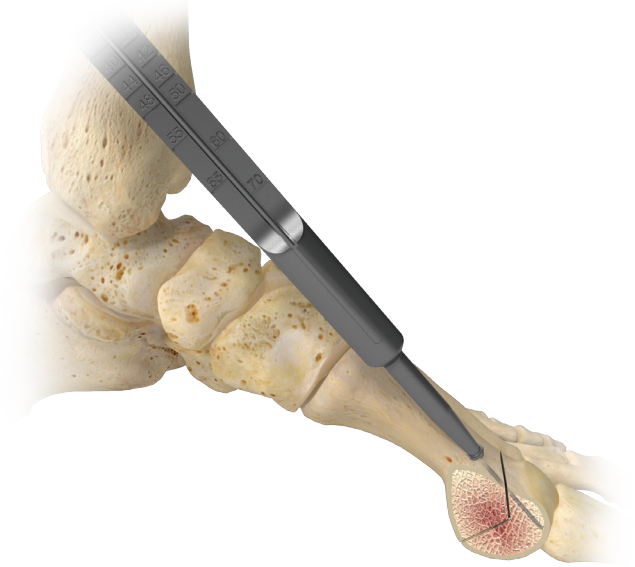

Figure 2

The following surgical technique describes the use of a 3.0 mm cannulated screw for a distal osteotomy of the first metatarsal.

Guide Wire Insertion

Position the 1.1 mm end of the 2.0 mm Drill Guide (Cat. No. 110008413) at the entry point and insert a 1.1 mm Guide Wire (Cat. No. 14-450350) by drilling to the desired depth (Figure 1), and verify with fluoroscopy.

Countersinking and Measurement

Insert the 3.0 mm Depth Gauge with Countersink (Cat. No. 110008459) over the inserted guide wire. Using the incorporated handle, rotate the depth gauge back and forth until sufficient countersinking has been achieved, and note the screw length measurement on the calibrated gauge (Figure 2).

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

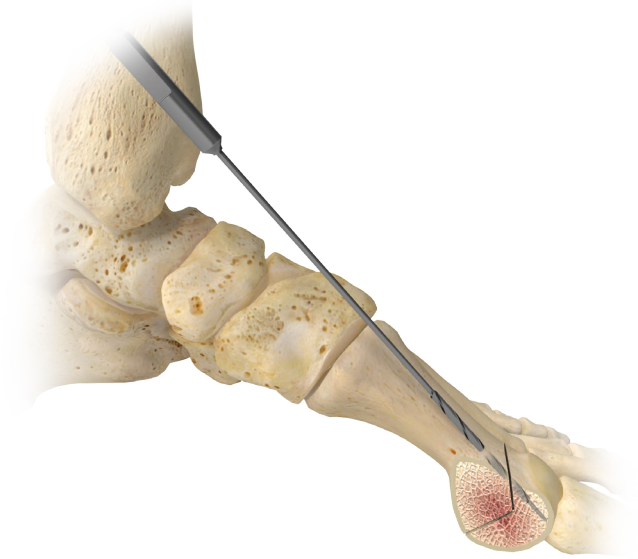

Figure 3

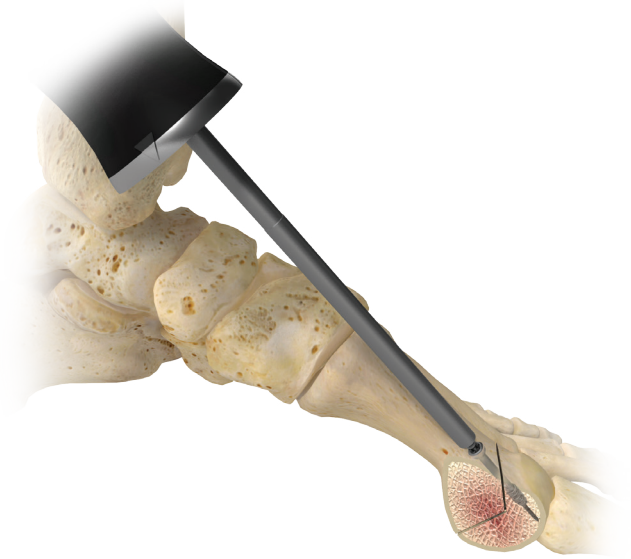

Figure 4

Pre-Drilling

Connect the 2.0 mm Cannulated Drill (Cat. No. 110008402) to an AO adapter and slide the drill over the guide wire. Drill to appropriate depth and remove drill, leaving the guide wire in place (Figure 3), and verify with fluoroscopy.

Screw Insertion

Advance the screw over the guide wire using the BT10 Cannulated Hexolobular Screwdriver (Cat. No. 110008449) attached to the Screwdriver handle (Cat. No. 110017406) until the head of the screw is completely seated in the bone (Figure 4), and then remove k-wire.

Figure 5

Screw Insertion (cont.)

A 3.0 mm Flat Washer (Cat. No. 110008345) may be used in conjunction with the screw 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 BT10 SOLID Hexolobular Screwdriver (Cat. No. 110009961).

In addition, a sterile 3 mm Screw Extractor (Cat. No. 110008497) is available for screw removal if a screw head is broken.

Equipment Maintenance

Special care should be exercised during the cleaning of cannulated instrumentation to ensure that all foreign material is removed from the inside of the instrument. Regular inspection and careful maintenance will increase the useful life of all instrumentation.

Caution

Guide wires should be replaced after each surgery. Use of scored or bent guide wires increases the risk of unwanted guide wire advancement or breakage during screw insertion.

During cannulated screw insertion the surgeon must periodically check for undesired advancement of the guide wire.

The text and schematic drawings included in this protocol are general instructions for the use of Biomet instrumentation only. Placement of screws and plates for the stabilization of specific fractures must be determined using the best judgment of the surgeon.

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Implants

3.0 mm Partially-Threaded Cannulated Screws

NON-STERILE	STERILE NO.	DESCRIPTION	QUANTITY
110007492	**110009774**	3.0 mm x 10 mm Partially-Threaded Cannulated Screw	2
110007494	**110009775**	3.0 mm x 12 mm Partially-Threaded Cannulated Screw	2
110007496	**110009776**	3.0 mm x 14 mm Partially-Threaded Cannulated Screw	2
110007498	**110009777**	3.0 mm x 16 mm Partially-Threaded Cannulated Screw	2
110007500	**110009778**	3.0 mm x 18 mm Partially-Threaded Cannulated Screw	2
110007502	**110009779**	3.0 mm x 20 mm Partially-Threaded Cannulated Screw	2
110007504	**110009780**	3.0 mm x 22 mm Partially-Threaded Cannulated Screw	2
110007506	**110009781**	3.0 mm x 24 mm Partially-Threaded Cannulated Screw	2
110007508	**110009782**	3.0 mm x 26 mm Partially-Threaded Cannulated Screw	2
110007510	**110009783**	3.0 mm x 28 mm Partially-Threaded Cannulated Screw	2
110007512	**110009784**	3.0 mm x 30 mm Partially-Threaded Cannulated Screw	2
110007514	**110009785**	3.0 mm x 32 mm Partially-Threaded Cannulated Screw	2
110007516	**110009786**	3.0 mm x 34 mm Partially-Threaded Cannulated Screw	2
110007518	**110009787**	3.0 mm x 36 mm Partially-Threaded Cannulated Screw	2
110007520	**110009788**	3.0 mm x 38 mm Partially-Threaded Cannulated Screw	2
110007522	**110009789**	3.0 mm x 40 mm Partially-Threaded Cannulated Screw	2
	110009790	3.0 mm x 45 mm Partially-Threaded Cannulated Screw	0
	110009792	3.0 mm x 50 mm Partially-Threaded Cannulated Screw	0
	110009794	3.0 mm x 55 mm Partially-Threaded Cannulated Screw	0
	110009796	3.0 mm x 60 mm Partially-Threaded Cannulated Screw	0
	110009798	3.0 mm x 65 mm Partially-Threaded Cannulated Screw	0
	110009800	3.0 mm x 70 mm Partially-Threaded Cannulated Screw	0

Washers

NON-STERILE	STERILE NO.	DESCRIPTION	QUANTITY
110008345	**110008488**	Flat Washer 3.0 mm	3

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

Disposables

NON-STERILE	STERILE NO.	DESCRIPTION	QUANTITY
14-450350	–	1.1 x 150 mm K-Wire Trc Tip (Pk/5)	1
14-450375	–	1.1 x 150 mm K-Wire Thd Tip (Pk/5)	1
	110008402	2.0 mm Cann Drill w/ AO	2

Instruments

NON-STERILE	STERILE NO.	DESCRIPTION	QUANTITY
110008413	–	1.1 / 2.0 mm Drill Guide	1
110008449	_	BT10 Cann Hexalobular Driver AO	2
110009961	–	BT10 Solid Hexalobular Driver AO	1
110008459	–	3.0 mm Depth Gauge w/ Countersink	1
110008500	–	Guide Wire Pusher 1.1 mm	1
13571	–	Screw Forceps	1
	110008497	Screw Extractor 3 mm	1
110017406	–	Mini Rachet Handle AO	1

Case/Tray

NON-STERILE	STERILE NO.	DESCRIPTION	QUANTITY
110008469	–	Cann Screw Case 3.0 mm	1

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

3.0 mm Cannulated Screw System

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.

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. Test #DVA-107504-DVER. Mechanical testing not necessarily indicative of clinical performance.

Check for country product clearances and reference product specific instructions for use. For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert, www.Biomet.com, or contact your local Biomet representative.

This technique was prepared in conjunction with a licensed health care professional. Biomet does not practice medicine and does not recommend any particular orthopedic implant or surgical technique for use on a specific patient. The surgeon is responsible for determining the appropriate device(s) and technique(s) for each individual patient.

Not for distribution in France.

CE Mark on the surgical technique is not valid unless there is a CE Mark on the product (description) label.

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