

Small Headed Screw System

1.5/2.0/2.5 mm

Surgical Technique

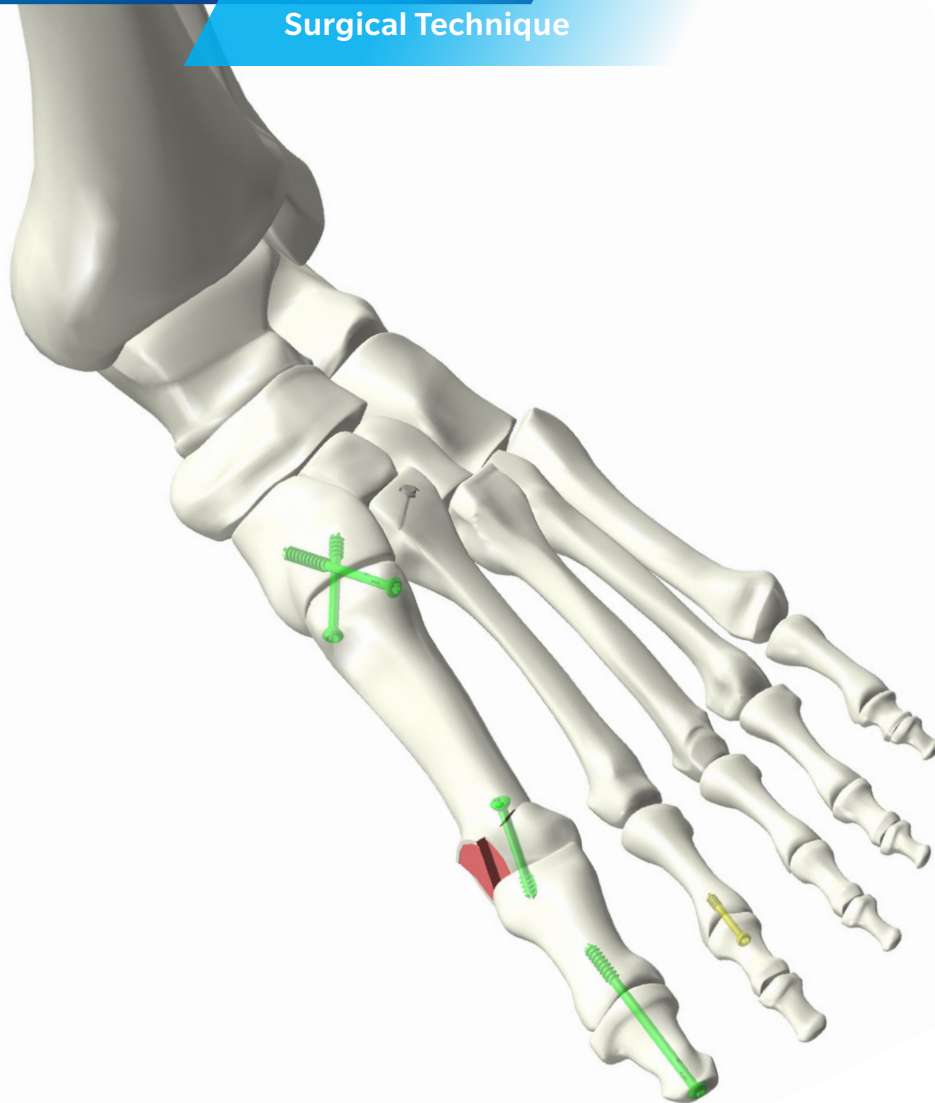


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Torx

Thread Length



Product Introduction

This comprehensive Headed Screw Set was designed to provide stable compression. The headed screw exhibits the following features:

- Low profile head to deliver compression
- Cannulation of 2.0 mm and 2.5 mm screws to allow for precise insertion using a guidewire
- Screws contain self-drilling and tapping features
- All inclusive instrument and implant set for three diameters of screws

Indications and Contraindications

These Headed Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

Contraindications

The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

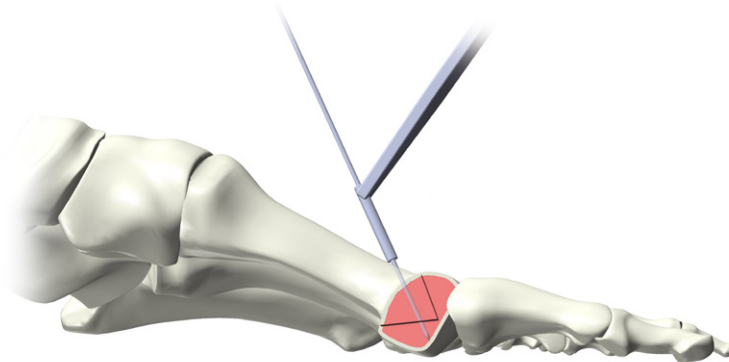


Figure 1a

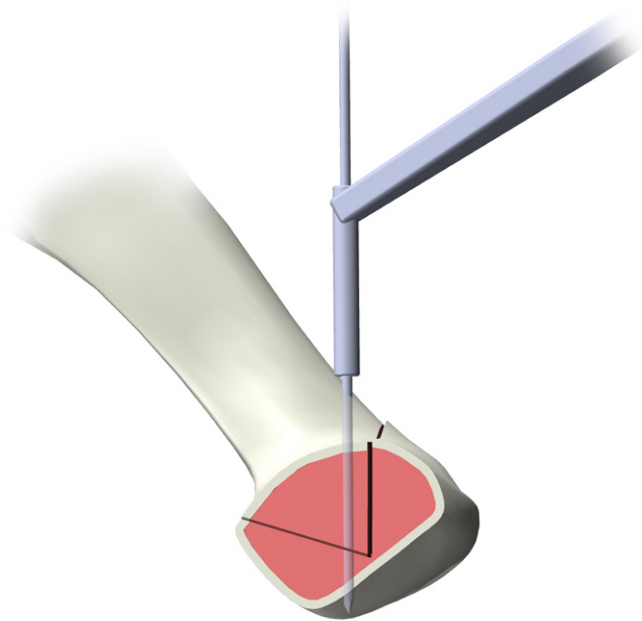


Figure 1b

Preparation

STEP 1 - Preparation & Insertion of Guidewire

Dissect a clean approach to the desired region of the bone where the compression screw will be inserted. Select the correct guidewire and tissue protector for the chosen screw diameter. (Table 1) Align the guidewire end of the tissue protector in the direction of screw insertion. Feed the guidewire through the tissue protector and advance it into the bone. Continue advancing the guidewire until it reaches the distal pole of the desired compression region.

Fluoroscopy should be continuously used to ensure correct guidewire position, alignment and depth. Do not remove guidewire. (Figures 1a and 1b)

Table 1 – Guidewire and Tissue Protector Sizing

Screw Diameter	Guidewire Diameter	Tissue Protector Size
Ø 1.5 mm†	Ø 0.9 mm*	–
Ø 2.0 mm	Ø 0.9 mm*	0.9 mm x 1.6 mm
Ø 2.5 mm	Ø 1.1mm*	1.1 mm x 2.0 mm

†Cannulated option not available for 1.5 mm screw, guidewire used during preparation and screw length determination steps only

* Contained in Guidewire Dispenser

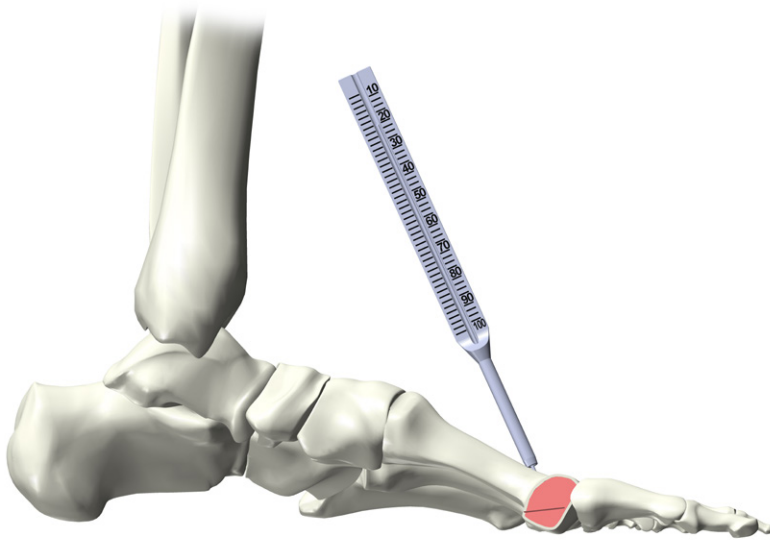


Figure 2a

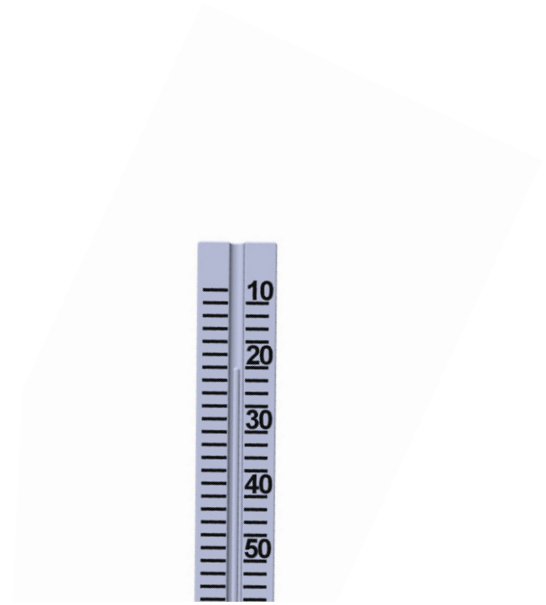


Figure 2b

Determine Screw Length

STEP 2 - Determine Screw Length

Use the 6" depth gauge for the chosen screw diameter. Feed the slimmer end of the depth gauge over the guidewire and place it flush against the bone.

Record the measurement at the distal end of the guidewire to determine the depth. This depth should be used to determine the length of the corresponding screw. (Figures 2a and 2b)

Do not remove guidewire, unless using the 1.5 mm solid screw.

- ⓘ **Note:** If using a non-cannulated 1.5 mm screw, remove the guidewire as it is used only as a pre-drill.
- ⓘ **Note:** Selection of a shorter length screw may be appropriate based on patient anatomy and compensation for compression of the fracture gap.

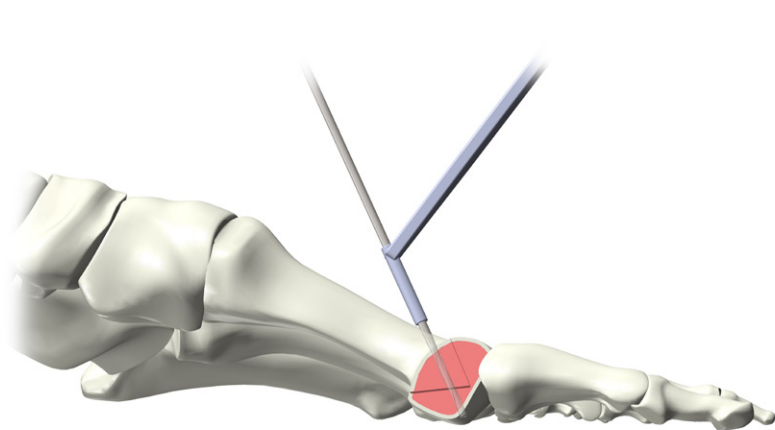


Figure 3a

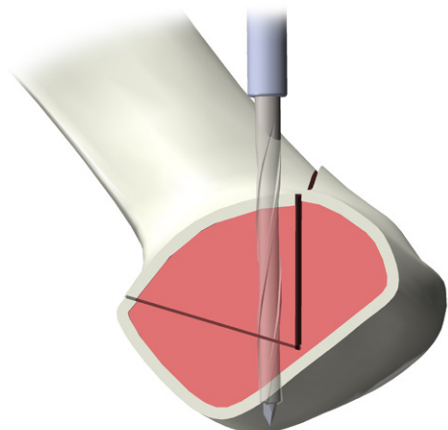


Figure 3b

Pre-Drilling (Optional)

STEP 3 - Pre-Drilling (Optional)

If applicable, select the correct drill size for the chosen screw diameter. (Table 2)

Slide the drill through the tissue protector and over the guidewire. Advance the drill tip through the bone to the distal pole of the desired compression region or flush with the tip of the inserted guidewire.

Fluoroscopy should be continuously used to ensure correct drill alignment and depth. Back the drill out of the bone once the desired depth has been reached. (Figures 3a and 3b)

Note: Drilling is optional due to the self-drilling flute feature of these screws. Drilling is beneficial for dense bone, as the axial force of self-drilling could distract the fragments of the compression site temporarily.

Table 2 – Guidewire and Drilling Sizing

Screw Diameter	Guidewire Diameter	Drill Diameter
Ø 1.5 mm†	–	–
Ø 2.0 mm	Ø 0.9 mm*	Ø 1.6 mm
Ø 2.5 mm†	Ø 1.1 mm*	Ø 2.0mm

† Cannulated option not available for 1.5 mm screw
* Contained in Guidewire Dispenser

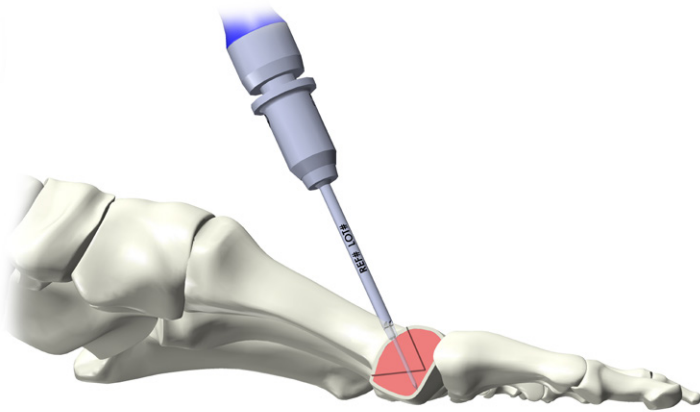


Figure 4a

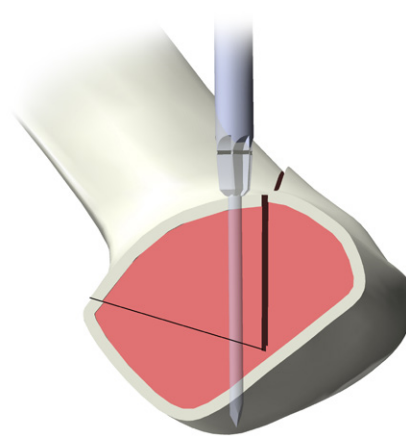


Figure 4b

Countersinking (Optional)

STEP 4 - Countersinking (Optional)

If applicable, select the correct countersink for the chosen screw diameter. (Table 3) Connect the countersink to the modular handle using the quick connection. Pass the countersink over the guidewire.

Advance the countersink tip into the bone by applying pressure and repeatedly rotating the countersink construct back and forth until the desired depth is attained. (Figures 4a and 4b)

Table 3 – Guidewire and Countersinking Sizing

Screw Diameter	Guidewire Diameter	Screw Countersink
Ø 1.5 mm†	–	–
Ø 2.0 mm	Ø 0.9 mm*	2.0 mm Screw Countersink
Ø 2.5 mm†	Ø 1.1 mm*	2.5 mm Screw Countersink

† Cannulated option not available for 1.5 mm screw

* Contained in Guide Wire Dispenser

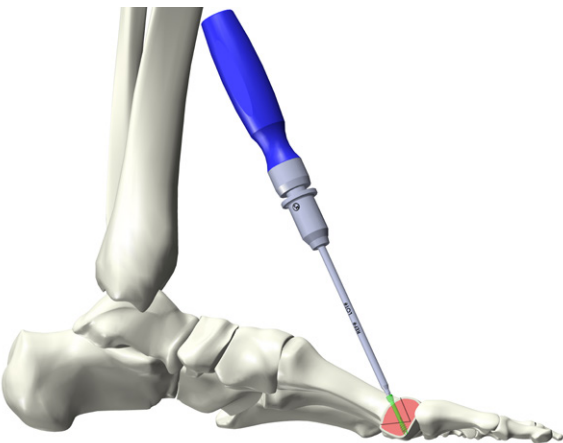


Figure 5a

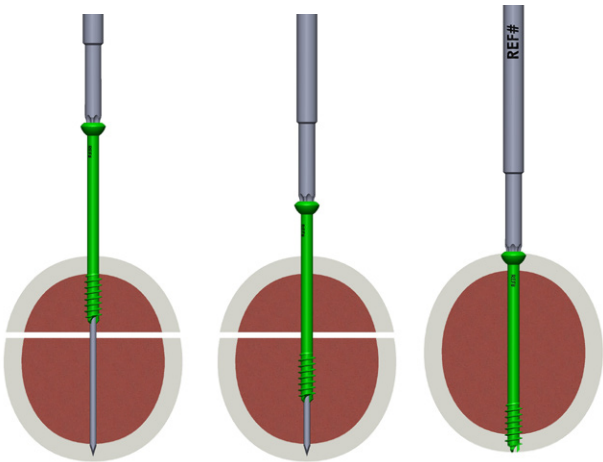


Figure 5b

Insert Screw and Apply Compression

STEP 5 – Insert Screw and Apply Compression

Select the correct driver size for the chosen screw diameter. (Table 4) Pass the screw over the guidewire. Using the driver, advance the screw into position. (Figure 5a) Compression is applied by continuously rotating the driver clockwise until all screw threads have passed into the distal fragment. Compression cannot be achieved if the screw threads bridge the fracture gap.

Fluoroscopy should be used continuously to ensure correct positioning of the screw. Use a two-finger approach when driving the screw in order to prevent over tightening or stripping. Advance the screw into the bone until the head of the screw sits just below the surface of the bone. (Figure 5b)

Remove the guidewire.

Table 4 – Guidewire and Driver Sizing

Screw Diameter	Guidewire Diameter	Driver Size
Ø 1.5 mm †	–	T4 Solid Torx Driver
Ø 2.0 mm	Ø 0.9 mm *	T6 Cannulated Torx Driver
Ø 2.5 mm	Ø 1.1 mm *	T8 Cannulated Torx Driver

† Cannulated option not available for 1.5 mm screw
* Contained in Guidewire Dispenser



Figure 6

Removal

The screw may be removed by using the drivers indicated in Table 4. Clear any tissue overgrowth from the screw head recess. Insert the driver and turn counterclockwise. If alignment is difficult, a guidewire (Table 4) may be inserted through the screw cannula to facilitate driver alignment.

Thread Length = 25% Total Length of Screw
or 4 mm Minimum Thread Length

Implants

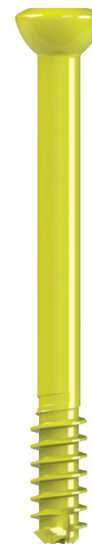
1.5 mm Headed Solid Screws

Part Number	Description	Quantity
9ZB15208	1.5 Headed Solid Short Screw x 8	2
9ZB15210	1.5 Headed Solid Short Screw x 10	2
9ZB15212	1.5 Headed Solid Short Screw x 12	2
9ZB15214	1.5 Headed Solid Short Screw x 14	2
9ZB15216	1.5 Headed Solid Short Screw x 16	2
9ZB15218	1.5 Headed Solid Short Screw x 18	2
9ZB15220	1.5 Headed Solid Short Screw x 20	2
9ZB15222	1.5 Headed Solid Short Screw x 22	2
9ZB15224	1.5 Headed Solid Short Screw x 24	2
9ZB15226	1.5 Headed Solid Short Screw x 26	2
9ZB15228	1.5 Headed Solid Short Screw x 28	2
9ZB15230	1.5 Headed Solid Short Screw x 30	2



2.0 mm Headed Cannulated Screws

Part Number	Description	Quantity
9ZB20210	2.0 Headed Cannulated Short Screw x 10	3
9ZB20212	2.0 Headed Cannulated Short Screw x 12	3
9ZB20214	2.0 Headed Cannulated Short Screw x 14	3
9ZB20216	2.0 Headed Cannulated Short Screw x 16	3
9ZB20218	2.0 Headed Cannulated Short Screw x 18	3
9ZB20220	2.0 Headed Cannulated Short Screw x 20	3
9ZB20222	2.0 Headed Cannulated Short Screw x 22	3
9ZB20224	2.0 Headed Cannulated Short Screw x 24	3
9ZB20226	2.0 Headed Cannulated Short Screw x 26	3
9ZB20228	2.0 Headed Cannulated Short Screw x 28	3
9ZB20230	2.0 Headed Cannulated Short Screw x 30	3
9ZB20235	2.0 Headed Cannulated Short Screw x 35	3
9ZB20240	2.0 Headed Cannulated Short Screw x 40	3



2.5 mm Headed Cannulated Screws

Part Number	Description	Quantity
9ZB25210	2.5 Headed Cannulated Short Screw x 10	3
9ZB25212	2.5 Headed Cannulated Short Screw x 12	3
9ZB25214	2.5 Headed Cannulated Short Screw x 14	3
9ZB25216	2.5 Headed Cannulated Short Screw x 16	3
9ZB25218	2.5 Headed Cannulated Short Screw x 18	3
9ZB25220	2.5 Headed Cannulated Short Screw x 20	3
9ZB25222	2.5 Headed Cannulated Short Screw x 22	3
9ZB25224	2.5 Headed Cannulated Short Screw x 24	3
9ZB25226	2.5 Headed Cannulated Short Screw x 26	3
9ZB25228	2.5 Headed Cannulated Short Screw x 28	3
9ZB25230	2.5 Headed Cannulated Short Screw x 30	3
9ZB25232	2.5 Headed Cannulated Short Screw x 32	3
9ZB25234	2.5 Headed Cannulated Short Screw x 34	3
9ZB25236	2.5 Headed Cannulated Short Screw x 36	3
9ZB25238	2.5 Headed Cannulated Short Screw x 38	3
9ZB25240	2.5 Headed Cannulated Short Screw x 40	3
9ZB25245	2.5 Headed Cannulated Short Screw x 45	3
9ZB25250	2.5 Headed Cannulated Short Screw x 50	3



Instruments

Product	Description	Part Number
	Ø 0.9 mm Guidewire (6")	T001000002
	Ø 1.1 mm Guidewire (6")	T001000003
	Ø 0.9 mm Guidewire Dispenser (6")	T001000051
	Ø 1.1 mm Guidewire Dispenser (6")	T001000052
	0.9 mm x 1.6 mm Tissue Protector	T001000024
	1.1 mm x 2.0 mm Tissue Protector	T001000025
	Depth Gauge 6"	T001000035
	Ø 1.6 mm Drill (6")	T001116096
	Ø 2.0 mm Drill (6")	T001120116
	2.0 mm Headed Screw Countersink	T009000038
	2.5 mm Headed Screw Countersink	T009000040
	T4 Solid Torx Driver	T001000009
	T6 Cannulated 0.9 mm Torx Driver	T001000010
	T8 Cannulated 1.1 mm Torx Driver	T001000011
	Mini Fixed AO Handle	TGC00008
	1.5 / 2.0 / 2.5 mm Headed Screw Set	T001000082

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Headed Screw Implants are manufactured from a Titanium alloy (ISO 5832-3).

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