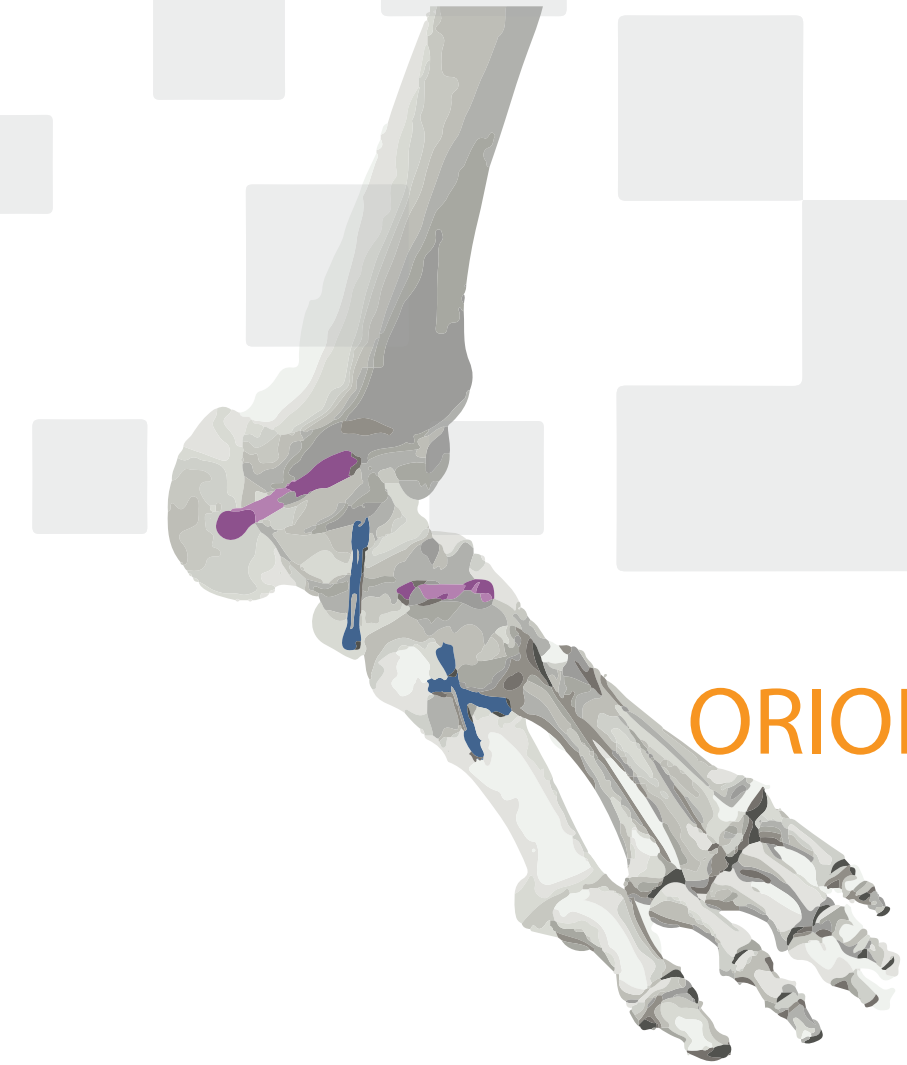
HNM
TOTAL RECON

SURGICAL TECHNIQUE

Headless Compession Screw

4.5 / 6.5



Titanium or Stainless Steel

Cannulated Headless Design

Multiple Thread Options

Torx Driver

Sterile and Non-Sterile Options

Simple Instrumentation

ORION Screw System

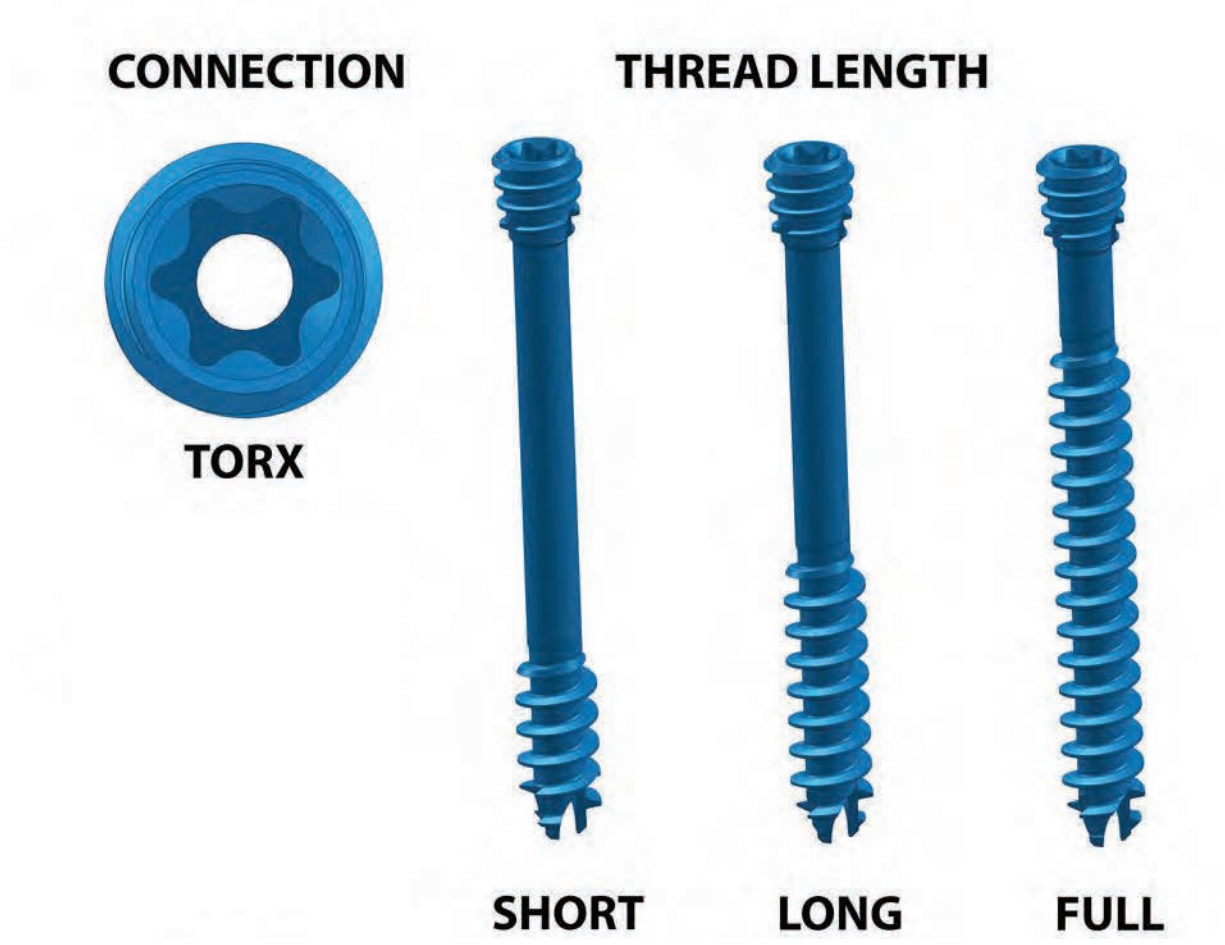
Table of Contents

HNM TOTAL RECON

Features and Benefits

The comprehensive HNM Total Recon Headless Compression Screw was designed to provide a superior level of stable compression. The compression Screw exhibits the following advantages:

- Multiple thread length options
- Tapered Head to deliver maximum compression
- Cannulation to allow for precise insertion using a guidewire
- Sterile and non-sterile packaging options
- Screws contain self-drilling and tapping features



Indications

The HNM Total Recon Trauma 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

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warnings and Potential Risks

The HNM Total Recon Implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the HNM Total Recon components should never be re-implanted under any circumstances.

The HNM Total Recon implants can become loose or break if subjected to inceased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery.
See the PRECAUTIONS section for additional warnings.

Precautions

The implantation of screw systems should be performed only by experienced surgeons with-speifics training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already should in contact with body flids or body tissues must not be resterilized. The HNM Total Recon Trauma Screw Sytem should never be used with dissimilar materials. Preoperative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of X-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected. Corect selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged. Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact the premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

IMPORTANT: The guidewires included in the HNM Total Recon Trauma Screw System are not intended as implants. The guidewires are only intended for use as instruments to facilitate screw insertion.

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. (Figure 1A and 1B)

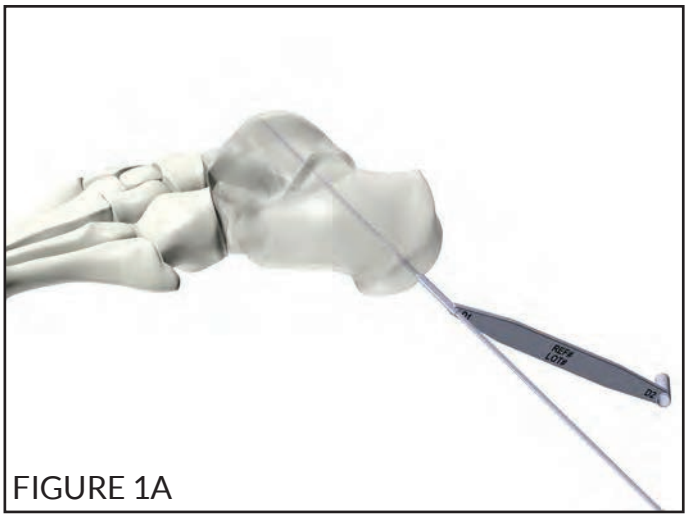


FIGURE 1A

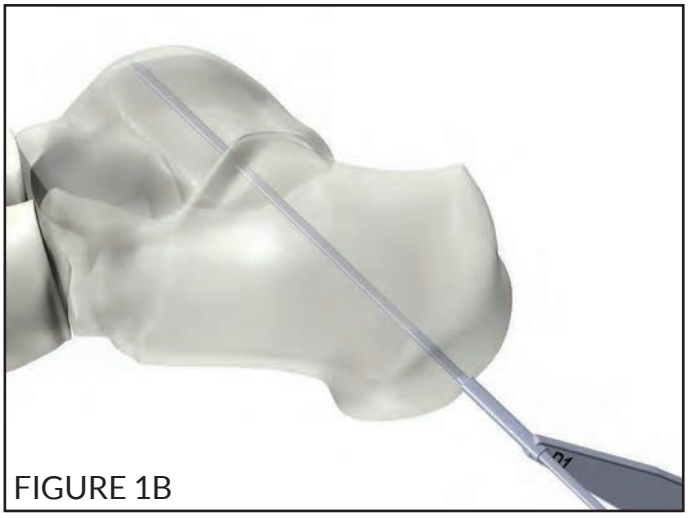


FIGURE 1B

TABLE 1 - GUIDEWIRE AND TISSUE PROTECTOR SIZING

Screw Diameter	Guidewire Diameter	Tissue Protector Size
Ø4.5mm	Ø1.6mm (6")*	1.6mm x 3.0mm
Ø6.5mm	Ø2.0mm (9")*	2.0mm x 4.5mm

* - Contained in Guidewire Dispenser

STEP 2 - Determine Screw Length

Select the correct depth gauge for the chosen screw diameter. (Table 2)

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.

Do not remove guidewire. (Figures 2A and 2B)

Note: Selection of a shorter length screw may be appropriate based on patient anatomy and compensation for compression of the fracture gap.

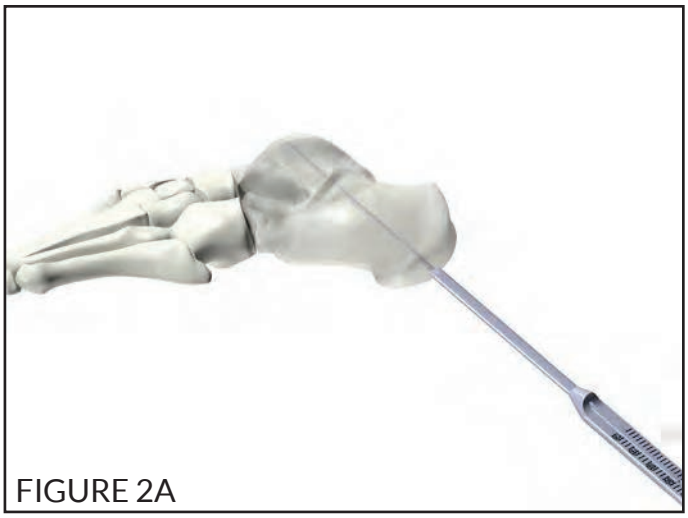


FIGURE 2A

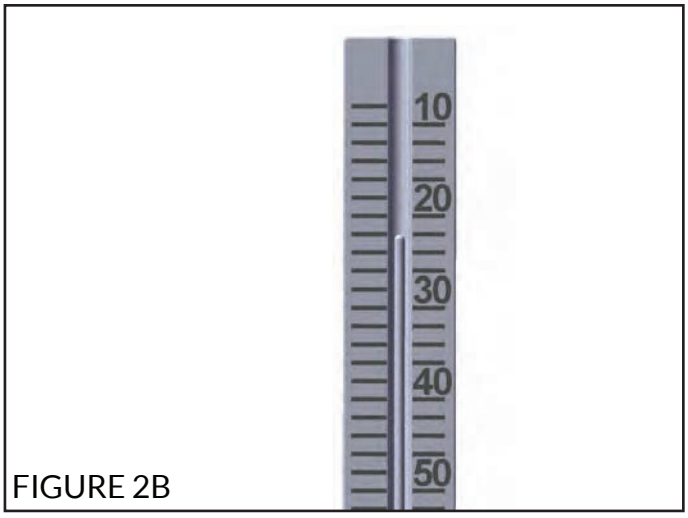


FIGURE 2B

TABLE 2 - GUIDEWIRE AND DEPTH GAUGE SIZING

Screw Diameter	Guidewire Diameter	Depth Gauge Size
Ø4.5mm	Ø1.6mm (6")*	6" Depth Gauge
Ø6.5mm	Ø2.0mm (9")*	9" Depth Gauge

* - Contained in Guidewire Dispenser

Pre-Drilling

STEP 3 - Pre-Drilling

Select the correct drill size for the chosen screw diameter. (Table 3)

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.

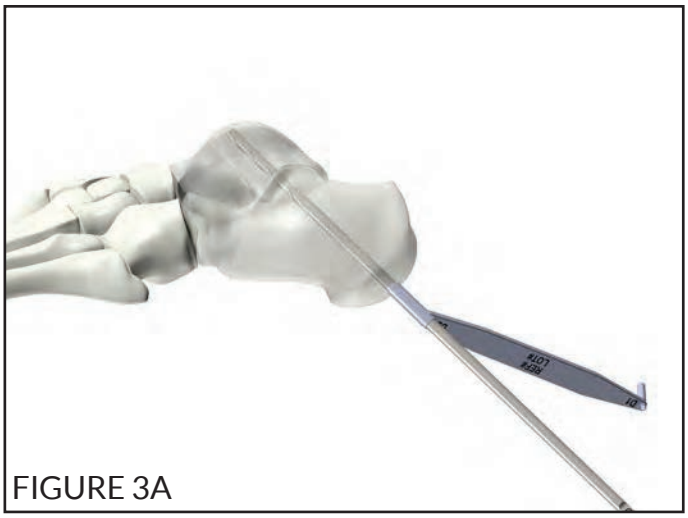


FIGURE 3A

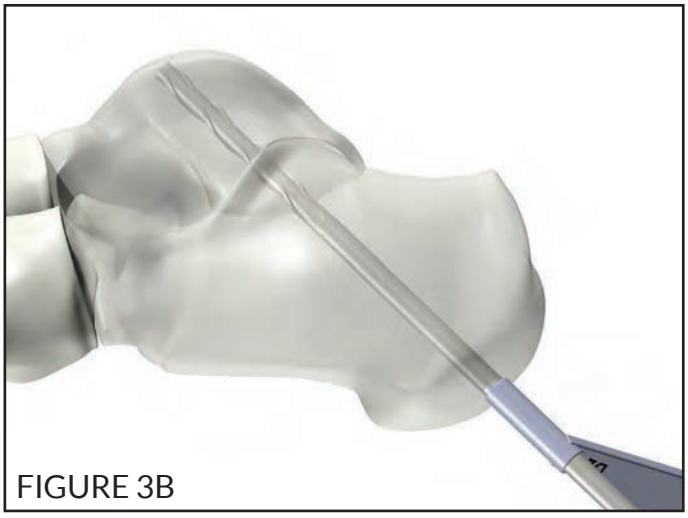


FIGURE 3B

TABLE 3 - GUIDEWIRE AND DRILL SIZING

Screw Diameter	Guidewire Diameter	Drill Diameter
Ø4.5mm	Ø1.6mm (6”)	Ø4.5(6”)
Ø6.5mm	Ø2.0mm (9”)	Ø6.5 (9”)

STEP 4 – Countersinking

Select the correct countersink for the chosen screw diameter. (Table 4)

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 black line is no longer visible.

The black line on the countersink represents the height of the screw head. (Figures 4A and 4B)

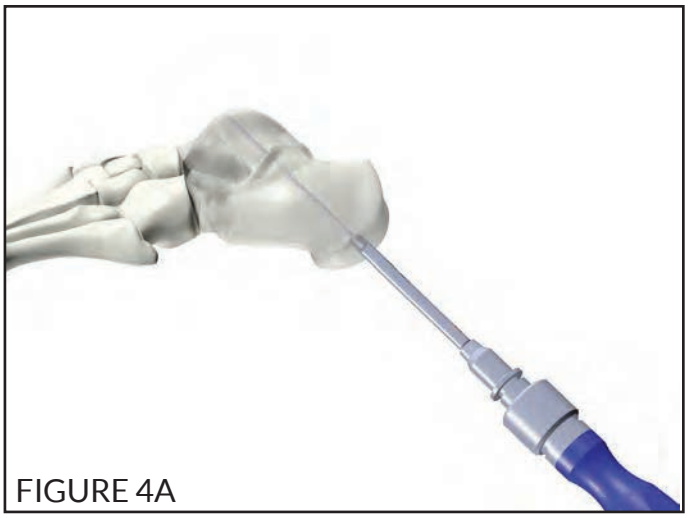


FIGURE 4A

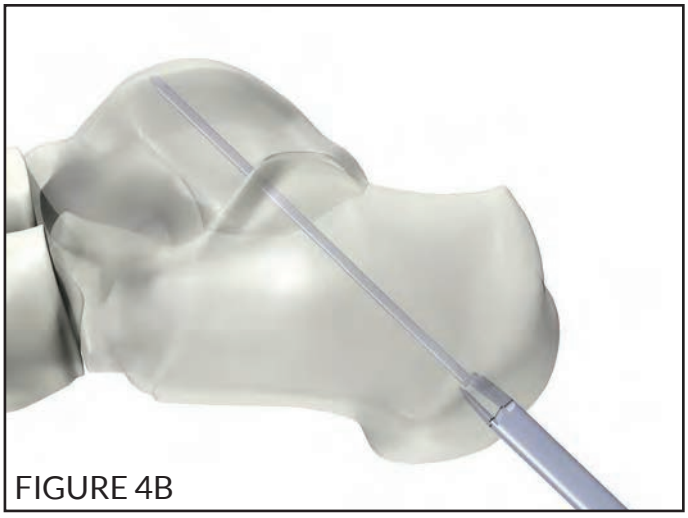


FIGURE 4B

TABLE 4 - GUIDEWIRE AND COUNTERSINK SIZING

Screw Diameter	Guidewire Diameter	Countersink
Ø4.5mm	Ø1.6mm (6”)	4.5 Screw Countersink
Ø6.5mm	Ø2.0mm (9”)	6.5 Screw Countersink

Insert Screw and Apply Compression

STEP 5 – Insert Screw and Apply Compression

Select the correct driver size for the chosen screw diameter. (Table 5)

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.

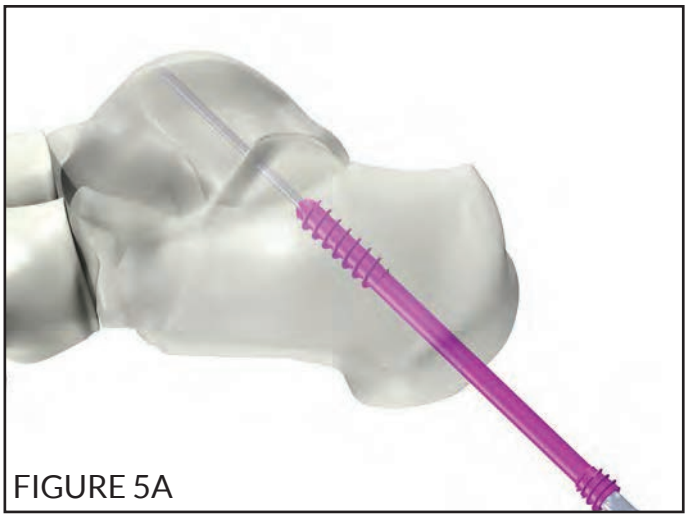


FIGURE 5A

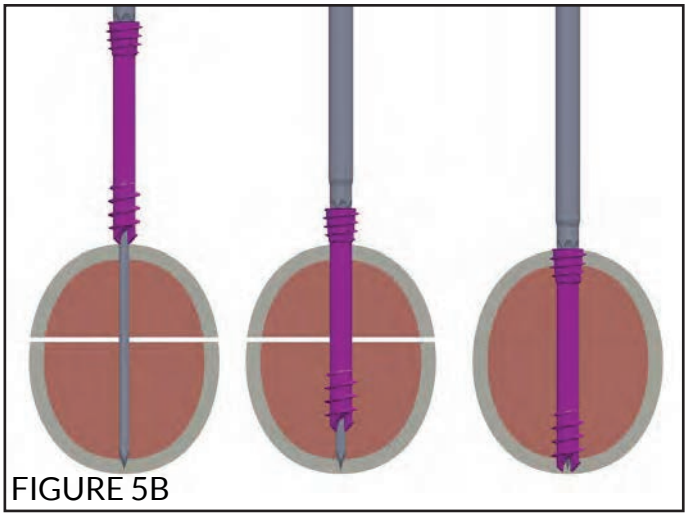


FIGURE 5B

TABLE 5 - GUIDEWIRE AND DRIVER SIZING

Screw Diameter	Guidewire Diameter	Driver Size
Ø4.5mm	Ø1.6mm (6”)	T15 Torx Driver
Ø6.5mm	Ø2.0mm (9”)	T25 Torx Driver

Removal

The screw may be removed by using drivers indicated in Table 5.

Clear any tissue overgrowth from the screw head recess. Insert the driver and turn counterclockwise .

If alignment is diffcult, a guidewire (Table 5) may be inserted through the screw cannula to facilitate driver alignment.

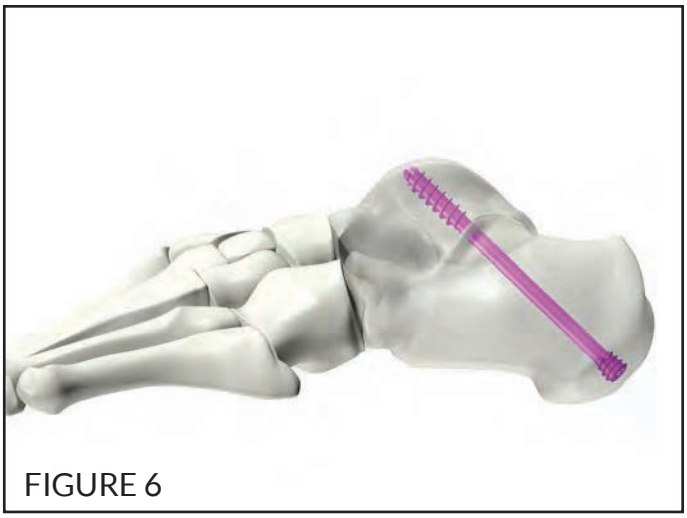
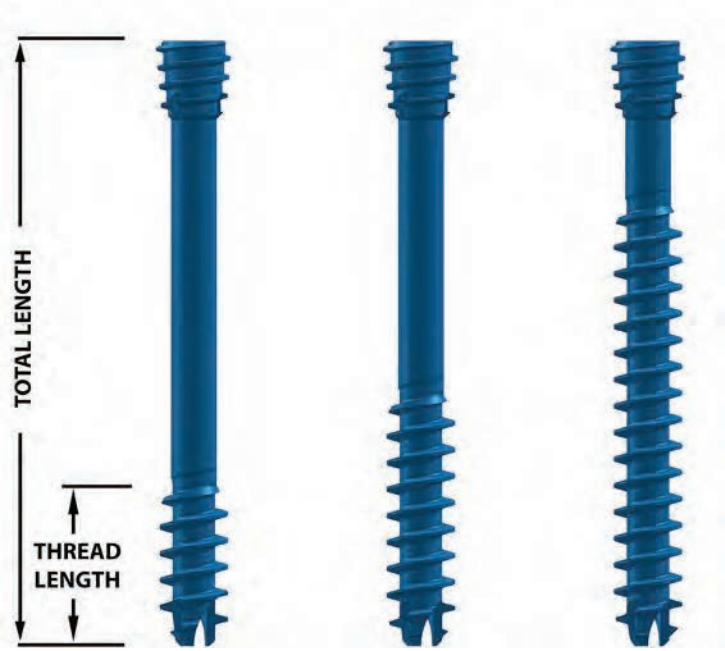


FIGURE 6

Screw - Ø4.5mm



Length	Ø4.5mm Headless Cannulated Screw		
	Short	Long	Full
20	HTR-04-450120	HTR-04-450220	HTR-04-450320
22	HTR-04-450222	HTR-04-450322	HTR-04-450422
24	HTR-04-450324	HTR-04-450424	HTR-04-450524
26	HTR-04-450426	HTR-04-450526	HTR-04-450626
28	HTR-04-450528	HTR-04-450628	HTR-04-450728
30	HTR-04-450630	HTR-04-450730	HTR-04-450830
32	HTR-04-450732	HTR-04-450832	HTR-04-450932
34	HTR-04-450834	HTR-04-450934	HTR-04-450134
36	HTR-04-450936	HTR-04-451036	HTR-04-450236
38	HTR-04-451038	HTR-04-450138	HTR-04-450338
40	HTR-04-450140	HTR-04-450240	HTR-04-450440
42	HTR-04-450242	HTR-04-450342	HTR-04-4505442
44	HTR-04-450344	HTR-04-450444	HTR-04-4506464
46	HTR-04-450446	HTR-04-450546	HTR-04-450746
48	HTR-04-450548	HTR-04-450648	HTR-04-450848
50	HTR-04-450650	HTR-04-450750	HTR-04-450950
52	HTR-04-450752	HTR-04-450852	HTR-04-451052
54	HTR-04-450854	HTR-04-450954	HTR-04-450154
56	HTR-04-450956	HTR-04-451056	HTR-04-450256
58	HTR-04-451058	HTR-04-450158	HTR-04-450358
60	HTR-04-450160	HTR-04-450260	HTR-04-450460
65	HTR-04-450265	HTR-04-450365	HTR-04-450565
70	HTR-04-450370	HTR-04-450470	HTR-04-450670
75	HTR-04-450475	HTR-04-450575	HTR-04-450775
80	HTR-04-450580	HTR-04-450680	HTR-04-450880
85	HTR-04-450685	HTR-04-450785	HTR-04-450985
90	HTR-04-450790	HTR-04-450890	HTR-04-451090
95	HTR-04-450895	HTR-04-450995	HTR-04-450195
100	HTR-04-450900	HTR-04-451000	HTR-04-450200
105	HTR-04-451005	HTR-04-450105	HTR-04-450305
110	HTR-04-450110	HTR-04-450210	HTR-04-450410

NOTES:

Thread Length

Short Thread= 25% Total Length
Long Thread= 40% Total Length
Full Thread= Total Length - 11mm

Sterile Implants are denoted with an "-S" after the Part #

Standard in Non-Sterile Tray

Screw - Ø6.5mm

Length	Ø6.5mm Headless Cannulated Screw		
	Short	Long	Full
30	HTR-04-650130	HTR-04-650930	HTR-04-651730
32	HTR-04-650232	HTR-04-651032	HTR-04-651832
34	HTR-04-650334	HTR-04-651134	HTR-04-651934
36	HTR-04-650436	HTR-04-651236	HTR-04-652036
38	HTR-04-650538	HTR-04-651338	HTR-04-650138
40	HTR-04-650640	HTR-04-651440	HTR-04-650240
42	HTR-04-650742	HTR-04-651542	HTR-04-650342
44	HTR-04-650844	HTR-04-651644	HTR-04-650444
46	HTR-04-650946	HTR-04-651746	HTR-04-650546
48	HTR-04-651048	HTR-04-651848	HTR-04-650648
50	HTR-04-651150	HTR-04-651950	HTR-04-650750
52	HTR-04-651252	HTR-04-652052	HTR-04-650852
54	HTR-04-651354	HTR-04-650154	HTR-04-650954
56	HTR-04-651456	HTR-04-650256	HTR-04-651056
58	HTR-04-651558	HTR-04-650358	HTR-04-651158
60	HTR-04-651660	HTR-04-650460	HTR-04-651260
65	HTR-04-651765	HTR-04-650565	HTR-04-651365
70	HTR-04-651870	HTR-04-650670	HTR-04-651470
75	HTR-04-651975	HTR-04-650775	HTR-04-651575
80	HTR-04-652080	HTR-04-650880	HTR-04-651680
85	HTR-04-650185	HTR-04-650985	HTR-04-651785
90	HTR-04-650290	HTR-04-651090	HTR-04-651890
95	HTR-04-650395	HTR-04-651195	HTR-04-651995
100	HTR-04-650400	HTR-04-651200	HTR-04-652000
105	HTR-04-650505	HTR-04-651305	HTR-04-650105
110	HTR-04-650610	HTR-04-651410	HTR-04-650210
115	HTR-04-650715	HTR-04-651515	HTR-04-650315
120	HTR-04-650820	HTR-04-651620	HTR-04-650420

NOTES:

Thread Length
Short Thread= 25% Total Length or 4mm
Long Thread= 40% Total Length
Full Thread= Total Length - 15mm

Sterile Implants are denoted with an "-S" after the Part #

Standard in Non-Sterile Tray

Instruments

Guidewire

HTR-04-009104	Ø1.6mm Guidewire (6”)
HTR-04-009206	Ø2.0mm Guidewire (9”)

Guidewire Dispenser*

HTR-04-009353	1.6mm Guidewire Dispenser (6”)
HTR-04-009455	2.0mm Guidewire Dispenser (9”)

Tissue Protector

HTR-04-009527	Tissue Protector 1.6mm x 3.0mm
HTR-04-009630	Tissue Protector 2.0mm x 4.5mm

Depth Gauge

HTR-04-009735	6” Depth Gauge
HTR-04-009736	9” Depth Gauge

Drill

HTR-04-139866	Ø3.0mm (6”) Drill
HTR-04-149909	Ø4.5mm (9”) Drill

Countersink

HTR-04-009143	4.5 Screw Countersink
HTR-04-009247	6.5 Screw Countersink

Torx Driver

HTR-04-009312	T15 (Ø1.6) Torx
HTR-04-009413	T25 (Ø2.0) Torx

Handle

HTR-04-009509	Ratcheting AO Handle

Tray and Caddy

HTR-04-009600	Common Tray Base
HTR-04-019604	4.5 Tray Insert
HTR-04-019705	6.5 Tray Insert
HTR-04-019806	4.5 / 6.5 Screw Caddy

The HNM Total Recon Headless Compression Screw implant is provided either sterile or non-sterile. All sterile implanys will be clearly marked “STERILE”. The sterile implant is gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize. Where specificed, do not use the device after expiration date.
the device after expiration date.

The HNM Total Recon Headless Compression Screw non-sterile implants and instrumentation are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to use.

The following steam sterilization parameters are recommended:

Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Time: 4 minutes
Drying time: 20 minutes
NOTE: Allow For Cooling

Consult the HNM Total Recon Headless Compression Screw Package Insert for additional cleaning and sterilization instructions.

Individuals not using the recommended method temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.