

Headless Compression Screw 2.5 / 3.0

Titanium or Stainless Steel

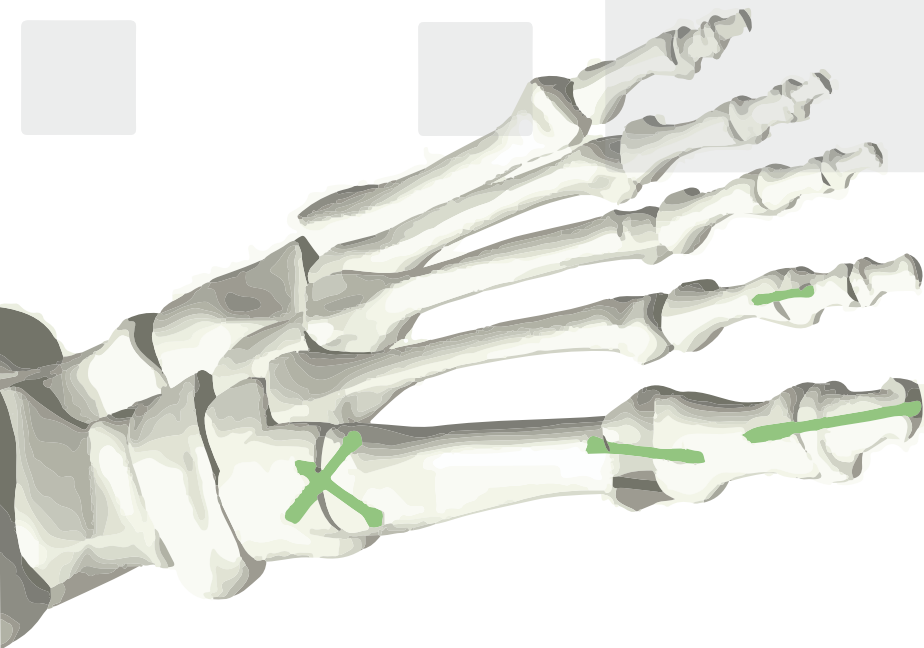
Cannulated Headless Design

Multiple Thread Options

Torx Driver

Sterile and Non-Sterile Options

Simple Instrumentation



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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

CONNECTION



TORX

THREAD LENGTH



SHORT



LONG



FULL

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 increased 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.

The implantation of screw systems should be performed only by experienced surgeons with specific 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 been in contact with body fluids or body tissues must not be resterilized.

The HNM Total Recon Trauma Screw System 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.

Correct 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 implant 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 that 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)

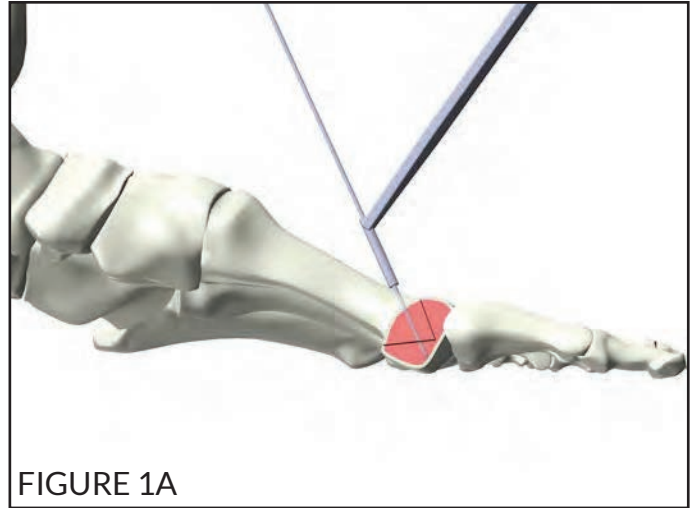


FIGURE 1A

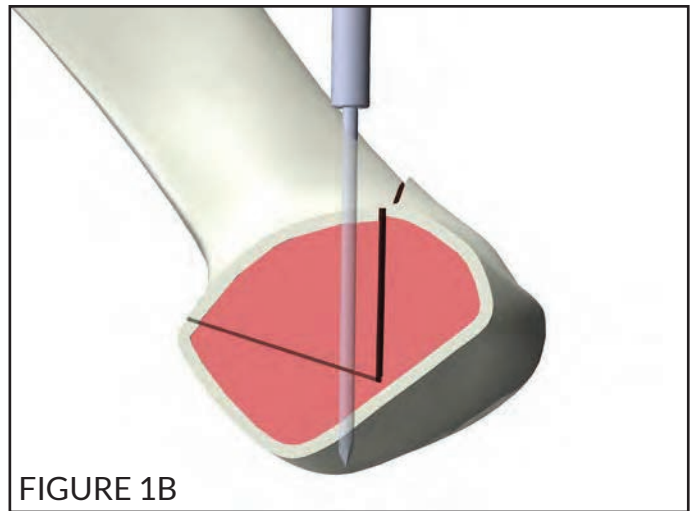


FIGURE 1B

TABLE 1 - GUIDEWIRE AND TISSUE PROTECTOR SIZING

Screw Diameter	Guidewire Diameter	Tissue Protector Size
Ø2.5mm	Ø1.1mm*	1.1mm x 2.0mm
Ø3.0mm	Ø1.1mm*	1.1mm x 2.0mm

* - Contained in Guidewire Dispenser

Determine Screw Length

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, unless using the Ø1.5mm solid screw. (Figures 2A and 2B)

Note: If using a non-cannulated Ø1.5mm screw; you can now remove 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.

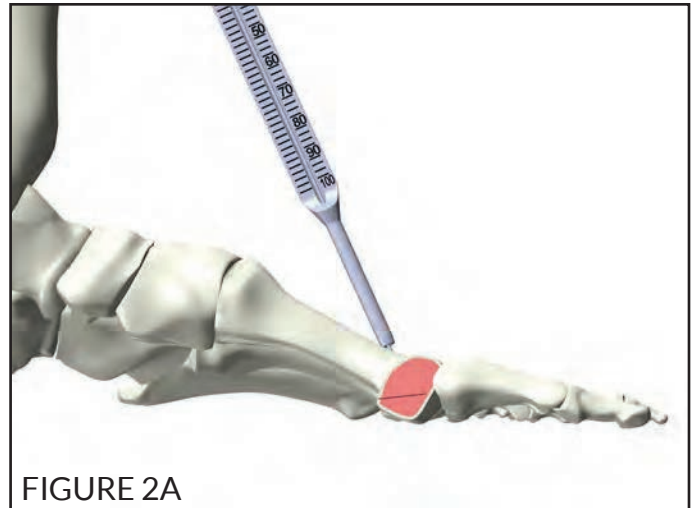


FIGURE 2A

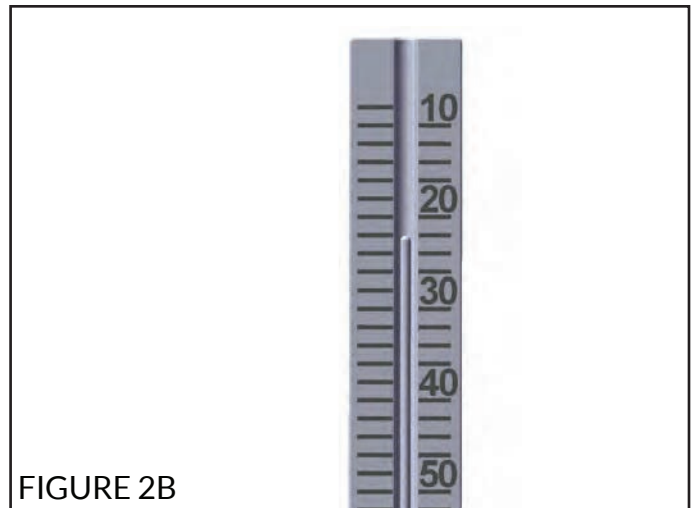


FIGURE 2B

TABLE 2 - GUIDEWIRE AND DEPTH GAUGE SIZING

Screw Diameter	Guidewire Diameter	Depth Gauge Size
Ø2.5mm	Ø1.1mm*	6" Depth Gauge
Ø3.0mm	Ø1.1mm*	6" Depth Gauge

* - Contained in Guidewire Dispenser

Pre-Drilling (Optional)

STEP 3 - Pre-Drilling (Optional)

If applicable, 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.

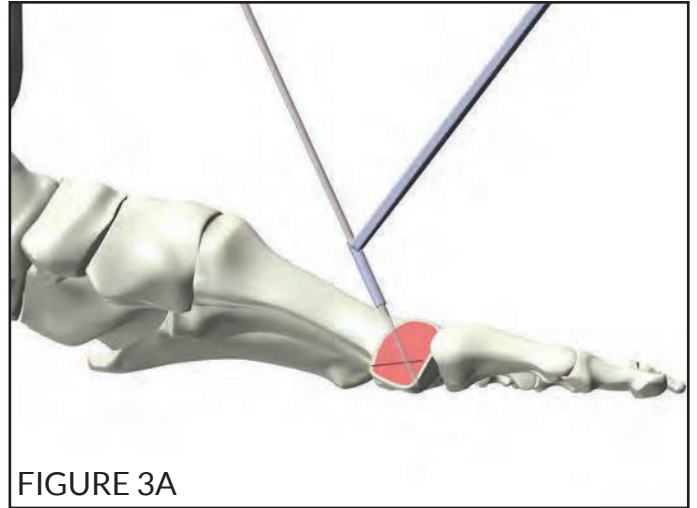


FIGURE 3A

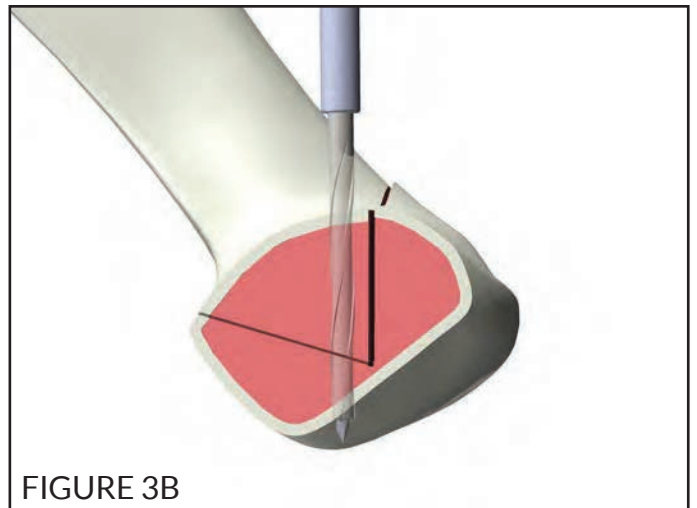


FIGURE 3B

TABLE 3 - GUIDEWIRE AND DRILL SIZING

Screw Diameter	Guidewire Diameter	Drill Diameter
Ø2.5mm	Ø1.1mm	Ø2.0mm
Ø3.0mm	Ø1.1mm	Ø2.0mm

Countersinking (Optional)

STEP 4 – Countersinking (Optional)

If applicable, 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)

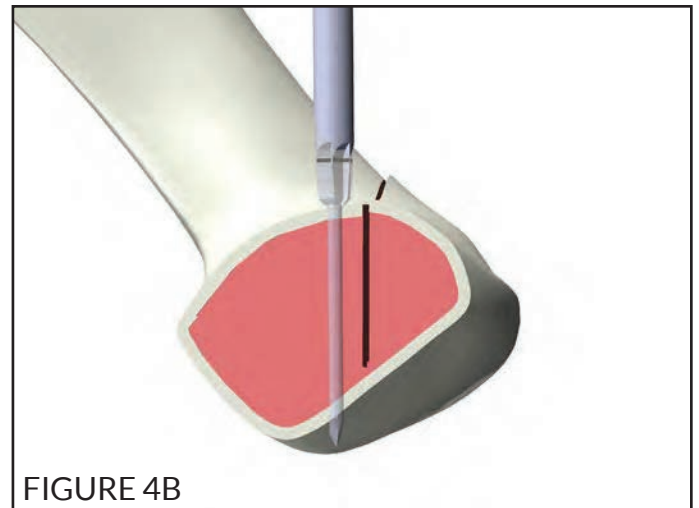
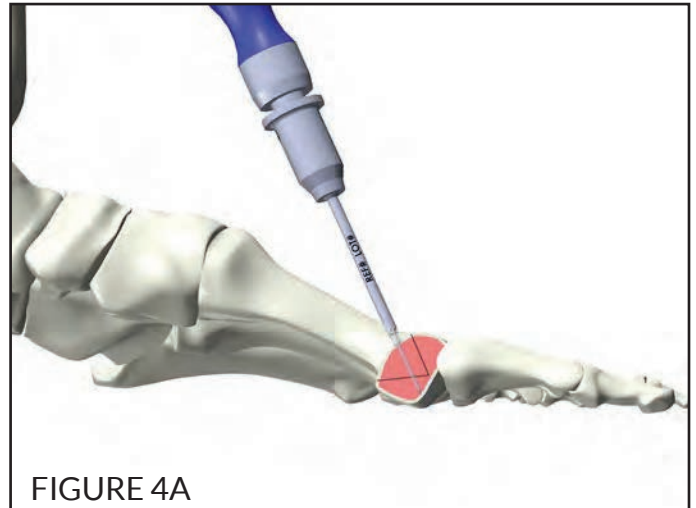


TABLE 4 - GUIDEWIRE AND COUNTERSINK SIZING

Screw Diameter	Guidewire Diameter	Countersink
Ø2.5mm	Ø1.1mm	3.0 Screw Countersink
Ø3.0mm	Ø1.1mm	3.0 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. (Figures 5B)

Remove the guidewire.

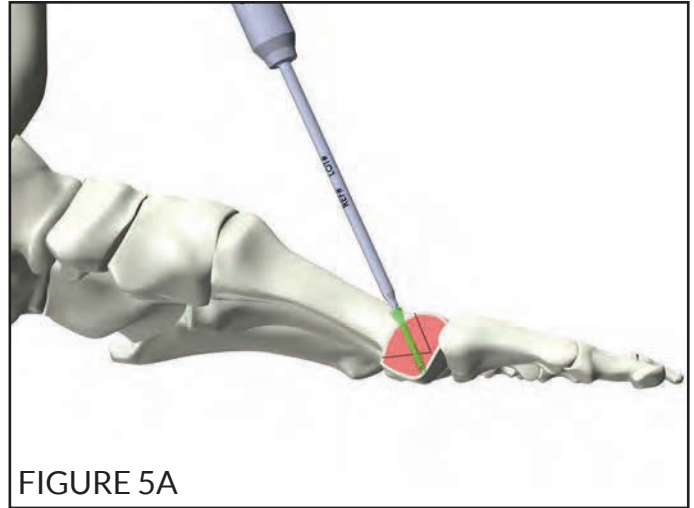


FIGURE 5A

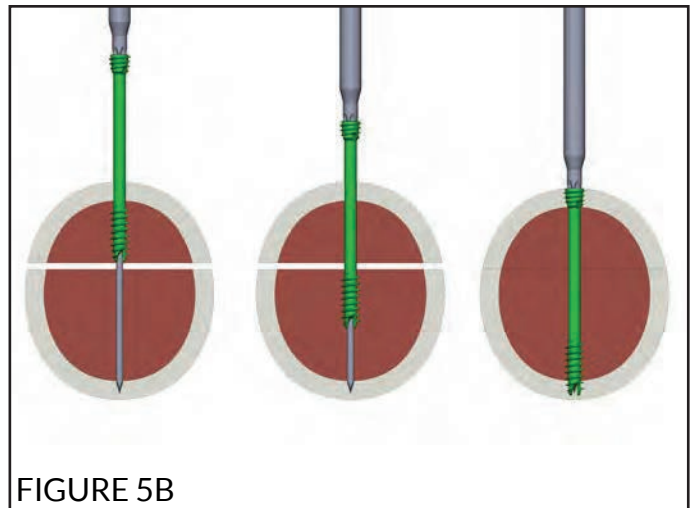


FIGURE 5B

TABLE 5 - GUIDEWIRE AND DRIVER SIZING

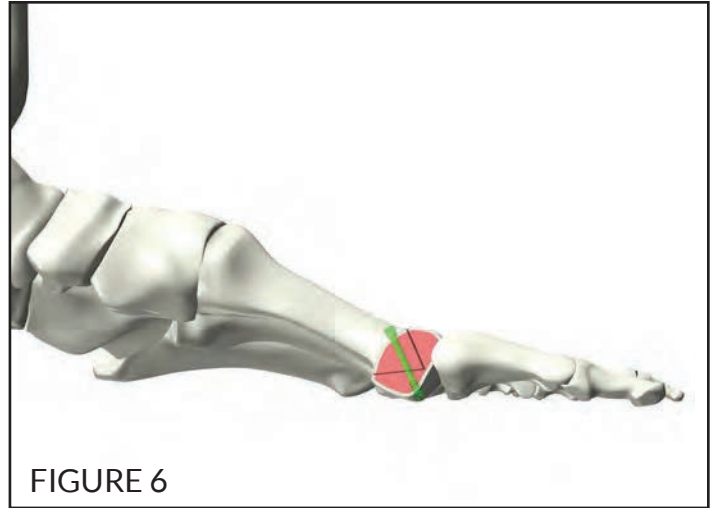
Screw Diameter	Guidewire Diameter	Driver Size
Ø2.5mm	Ø1.1mm	T8 Torx Driver
Ø3.0mm	Ø1.1mm	T8 Torx Driver

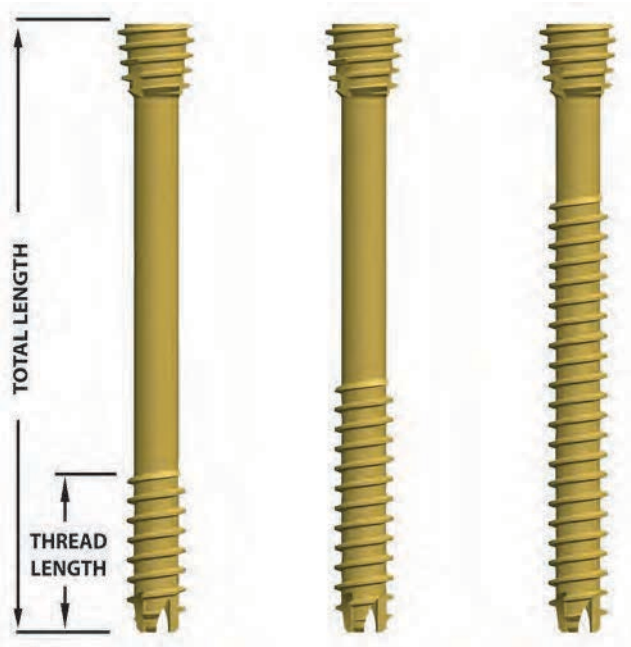
Removal

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





NOTES:

Thread Length

Short Thread= 4mm

Long Thread= 25% Total Length

Full Thread= Total Length - 4mm

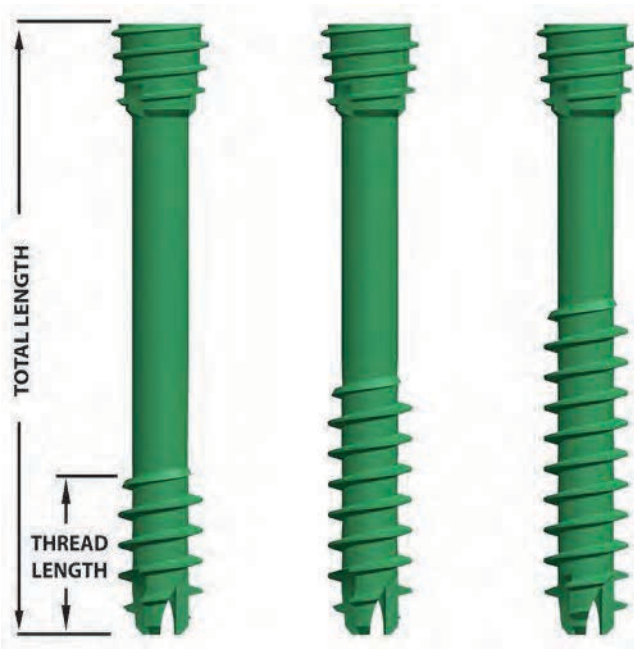
Sterile Implants are denoted with an “-S” after the Part #

Standard in Non-Sterile Tray

Length	Ø2.5mm Headless Cannulated Screw		
	Short	Long	Full
10	HTR-04-25431	HTR-04-254810	HTR-04-254410
11	HTR-04-254411	HTR-04-254911	HTR-04-254511
12	HTR-04-254512	HTR-04-254912	HTR-04-254612
13	HTR-04-254613	HTR-04-254213	HTR-04-254713
14	HTR-04-254714	HTR-04-254314	HTR-04-254814
15	HTR-04-254815	HTR-04-254415	HTR-04-254915
16	HTR-04-254916	HTR-04-254516	HTR-04-254116
17	HTR-04-254117	HTR-04-254617	HTR-04-254217
18	HTR-04-254218	HTR-04-254718	HTR-04-254318
19	HTR-04-254319	HTR-04-254819	HTR-04-254419
20	HTR-04-254120	HTR-04-254920	HTR-04-254620
21	HTR-04-254521	HTR-04-254121	HTR-04-254721
22	HTR-04-254822	HTR-04-254222	HTR-04-254922
23	HTR-04-254723	HTR-04-254323	HTR-04-254923
24	HTR-04-254824	HTR-04-254424	HTR-04-254124
25	HTR-04-254925	HTR-04-254525	HTR-04-254225
26	HTR-04-254126	HTR-04-254626	HTR-04-254326
27	HTR-04-254227	HTR-04-254727	HTR-04-254427
28	HTR-04-254328	HTR-04-254828	HTR-04-254528
29	HTR-04-254429	HTR-04-254929	HTR-04-254629
30	HTR-04-254530	HTR-04-254130	HTR-04-254730
31	HTR-04-254631	HTR-04-254231	HTR-04-254831
32	HTR-04-254732	HTR-04-254332	HTR-04-254932
33	HTR-04-254833	HTR-04-254433	HTR-04-254333
34	HTR-04-254934	HTR-04-254534	HTR-04-254634
35	HTR-04-254135	HTR-04-254635	HTR-04-254735
36	HTR-04-254236	HTR-04-254736	HTR-04-254836
37	HTR-04-254337	HTR-04-254837	HTR-04-254937
38	HTR-04-254438	HTR-04-254938	HTR-04-254138
39	HTR-04-254539	HTR-04-254139	HTR-04-254239
40	HTR-04-254640	HTR-04-254240	HTR-04-254340

* 4mm Minimum Thread Length

Screw - Ø3.0mm



NOTES:

Thread Length

Short Thread= 25% Total Length or 4mm

Long Thread= 40% Total Length

Full Thread= Total Length - 9mm

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

Standard in Non-Sterile Tray

Length	Ø3.0mm Headless Cannulated Screw		
	Short	Long	Full
10	HTR-04-300110	HTR-04-300310	HTR-04-300610
11	HTR-04-300211	HTR-04-300411	HTR-04-300711
12	HTR-04-300312	HTR-04-300512	HTR-04-300812
13	HTR-04-300413	HTR-04-300613	HTR-04-300913
14	HTR-04-300514	HTR-04-300714	HTR-04-301014
15	HTR-04-300615	HTR-04-300815	HTR-04-300115
16	HTR-04-300716	HTR-04-300916	HTR-04-300216
17	HTR-04-300817	HTR-04-301017	HTR-04-300317
18	HTR-04-300918	HTR-04-301118	HTR-04-300418
19	HTR-04-301019	HTR-04-300219	HTR-04-300519
20	HTR-04-300220	HTR-04-300320	HTR-04-300620
21	HTR-04-300321	HTR-04-300421	HTR-04-300721
22	HTR-04-300422	HTR-04-300522	HTR-04-300822
23	HTR-04-300523	HTR-04-300623	HTR-04-300923
24	HTR-04-300624	HTR-04-300724	HTR-04-301024
25	HTR-04-300725	HTR-04-300825	HTR-04-300125
26	HTR-04-300826	HTR-04-300926	HTR-04-300226
27	HTR-04-300927	HTR-04-301027	HTR-04-300327
28	HTR-04-301028	HTR-04-300428	HTR-04-300728
29	HTR-04-300129	HTR-04-300529	HTR-04-300829
30	HTR-04-300230	HTR-04-300630	HTR-04-300930
31	HTR-04-300331	HTR-04-300731	HTR-04-301031
32	HTR-04-300432	HTR-04-300832	HTR-04-300132
33	HTR-04-300533	HTR-04-300933	HTR-04-300233
34	HTR-04-300634	HTR-04-301034	HTR-04-300334
35	HTR-04-300735	HTR-04-300535	HTR-04-300435
36	HTR-04-300836	HTR-04-300636	HTR-04-300536
37	HTR-04-300937	HTR-04-300737	HTR-04-300637
38	HTR-04-301038	HTR-04-300838	HTR-04-300738
39	HTR-04-300139	HTR-04-300939	HTR-04-300839
40	HTR-04-300240	HTR-04-301040	HTR-04-300940

* 4mm Minimum Thread Length

Guidewire

HTR-04-009203 Ø1.1mm Guidewire (6")



Guidewire Dispenser*

HTR-04-009452 1.1mm Guidewire Dispenser (6")



Tissue Protector

HTR-04-009625 Tissue Protector 1.1mm x 2.0mm



Depth Gauge

HTR-04-009735 6" Depth Gauge



*Holds up to 5 guidewires

Instruments

Drill

HTR-04-129816 Ø2.0mm (6") Drill



Countersink

HTR-04-009140 3.0 Screw Countersink



Torx Driver

HTR-04-009411 T8 (Ø1.1) Torx



Handle

HTR-04-009508 Mini Fixed AO Handle



Tray and Caddy

HTR-04-009600 Common Tray Base
HTR-04-019802 3.0 Tray Insert
HTR-04-019903 1.5 / 2.0 / 3.0 Screw Caddy

The HNM Total Recon Headless Compression Screw implant is provided either sterile or non-sterile. All sterile implants 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 specified, do not use 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.