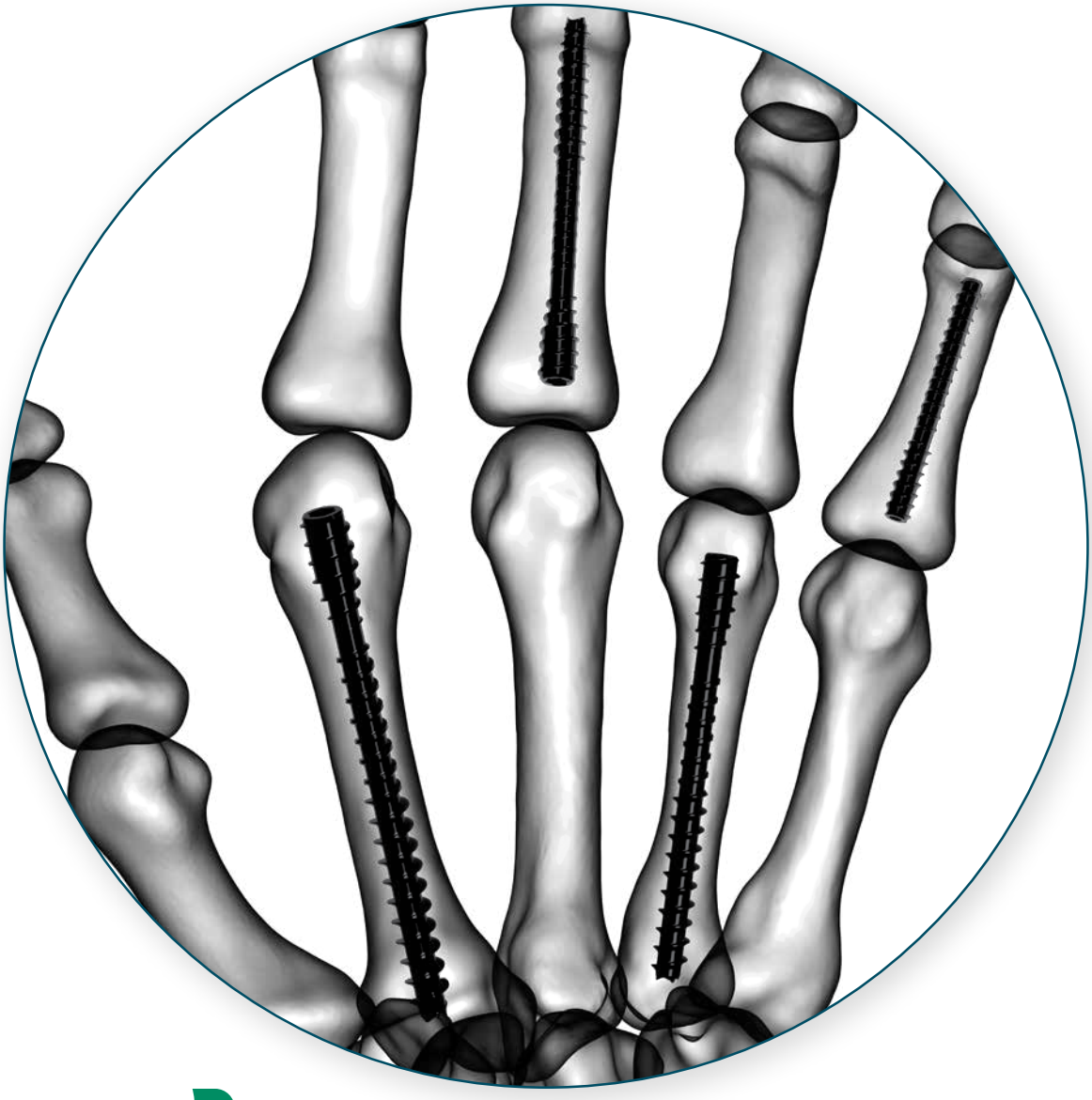
SURGICAL TECHNIQUE GUIDE

THREADED HAND NAIL



skeletal dynamics®

UNDERSTANDING THE UPPER EXTREMITY

As described by:
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THREADED HAND NAIL

Description

The Skeletal Dynamics Threaded Hand Nail System consists of titanium Nails and specialized instrumentation.

- 2.0mm non-cannulated Threaded Nails: 12mm - 28mm in 2mm increments.
- 2.0mm non-cannulated Threaded Nails: 32mm - 48mm in 4mm increments.
- 3.0mm cannulated Threaded Nails: 20mm - 70mm in 5mm increments.
- 3.5mm cannulated Threaded Nails: 25mm - 70mm in 5mm increments.
- 4.5mm cannulated Threaded Nails: 25mm - 70mm in 5mm increments.

The system is provided non-sterile and is sterilized in the user facility.

Indications for Use

The Skeletal Dynamics Threaded Hand Nail System is intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized Nail.

1 LOCATING THE INSERTION POINT

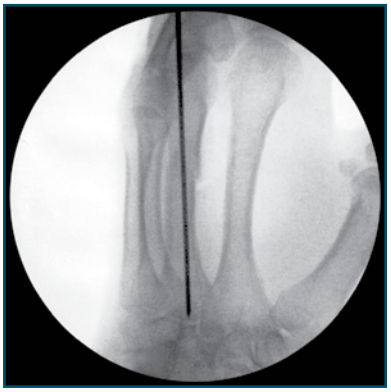
For both metacarpal and phalanx fractures, approaching from the metacarpal joint is recommended. Fully flex the metacarpophalangeal joint and make an incision to expose the metacarpal head (for metacarpal fractures) or the base of phalanx (for phalanx fractures), visualizing the tendon.

If delivering a 3.0mm diameter or larger cannulated Threaded Hand Nail , insert the 1.4mm K-Wire starting at the dorsal third of the bone being fixated.

If a 2.0mm non-cannulated Threaded Hand Nail is indicated, please refer to page 8 for technical steps specific to the instrumentation of this implant diameter.

KWIR-ST-14203: K-Wire, 1.4mm x 203mm, Single Trocar

2 K-WIRE INSERTION AND FRACTURE REDUCTION

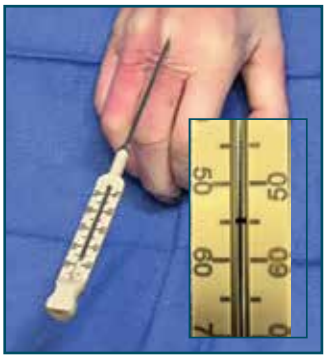


The Threaded Hand Nail can be introduced either in a retrograde or antegrade direction. Retrograde metacarpal Nail insertion may be simpler in most cases, but may create a larger defect in the metacarpal head and extensor tendon at the MP joint. Antegrade metacarpal Nail insertion may be preferable for fractures located near the proximal (to patient) aspect of the bone shaft or proximal metaphysis. This approach is less traumatic for the CMC joint but requires careful management of extensor tendons at the wrist.

Once the direction of Nail insertion has been determined, insert the 1.4mm K-Wire radial to the tendon, advancing it into the near fragment in line with the medullary canal of the opposing fragment under fluoroscopy. Reduce the fracture and advance the K-Wire into second fragment stopping short of the far cortex.

MEASURE NAIL LENGTH 3

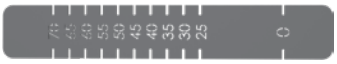
Measure the Nail length with one of the following methods:



Depth Gauge:
Using fluoroscopy, position the distal end of the K-Wire at the base of the bone. Pass the Depth Gauge over the K-Wire up to the articular surface of the bone. Using the laser etched band on the K-Wire, read and note the Nail length from the Depth Gauge measurement window.

Measurement Ruler:
Using fluoroscopy, align the "0 mark" of the Measurement Ruler with the base of the bone and note the length mark near the head.

Note:
When determining the appropriate Nail to use, select a length shorter than the measured length to ensure the Nail doesn't violate the articular surfaces (5 – 10mm shorter for a metacarpal Nail; approximately 4mm shorter for a phalanx Nail).



MSRT-RL: Measurement Ruler

DGA-RHS: Depth Gauge, Threaded Hand Nail

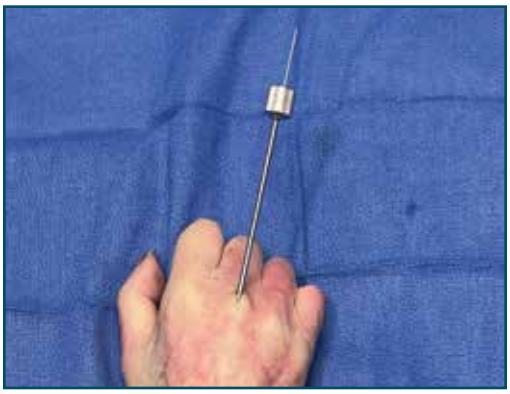
REAMING IM CANAL 4

Create a small incision around the K-Wire to ensure ease of reaming and Nail introduction. Slide the 2.4mm Reamer over the end of the K-Wire, advance gently through the soft tissues with an oscillating motion to the bone surface. Ream the medullary canal manually, stopping at least 5mm from to the distal articular surface. Continue reaming with the 2.7mm and 3.3mm Reamers until cortical engagement is achieved.

INSTRUMENTATION SIZING			
REAMER	COUNTERSINK	DRIVER	THREADED NAIL
2.4mm	3.3mm	T8	3.0mm
2.7mm			3.5mm
3.3mm	3.8mm	T10	4.5mm

RHS-RMR-XX: Reamer, XXmm, Cannulated

5 EXCHANGING K-WIRES

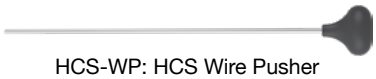


Once adequate canal preparation has been completed, remove the QC Handle from the Reamer and withdraw the 1.4mm K-Wire through the Reamer while maintaining fracture reduction. Once the 1.4mm K-Wire has been removed, the 0.9mm K-Wire should be inserted in its place through the Reamer. After the 0.9mm K-Wire is fully inserted past the fracture line, the Reamer may be removed while maintaining the position of the 0.9mm K-Wire.

Note:
If necessary, use Wire Pusher to keep K-Wire in place when removing the Reamer.

Optional:
If preferred, a K-Wire Exchanger is available for use in completing this step (shown above).

Place the K-Wire Exchanger over the proximal end of the 1.4mm K-Wire and advance cautiously through the soft tissues and past the fracture site up to the distal reamed portion of the canal. Leave the K-Wire Exchanger in place, then remove the 1.4mm K-Wire. Insert the 0.9mm K-Wire into the K-Wire Exchanger up to the distal end of the medullary canal. Remove the K- Wire Exchanger.



HCS-WP: HCS Wire Pusher

GDW-EXCH: K-Wire Exchanger

KWIR-ST-09203: K-Wire, 0.9mm x 203mm, Single Trocar

6 COUNTERSINK FOR TRAILING END OF NAIL

Insert the Countersink indicated in Table 1 over the K-Wire, then advance with an oscillatory hand motion. Countersink only the cortical region of the bone advancing no more than 10mm. Use the Wire Pusher to keep the K-Wire in place when removing Countersink.

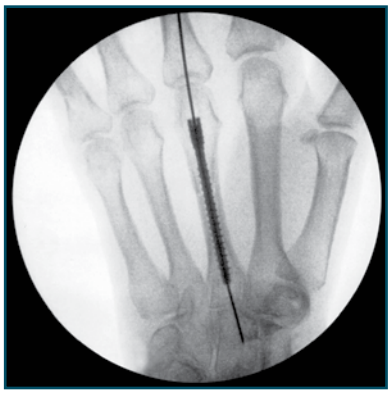
Caution:
Do not use the Countersink under power; use the provided manual handle. Do not countersink to ream the entire medullary canal.

RHS-CSK-XX: Countersink, X.Xmm, Cannulated

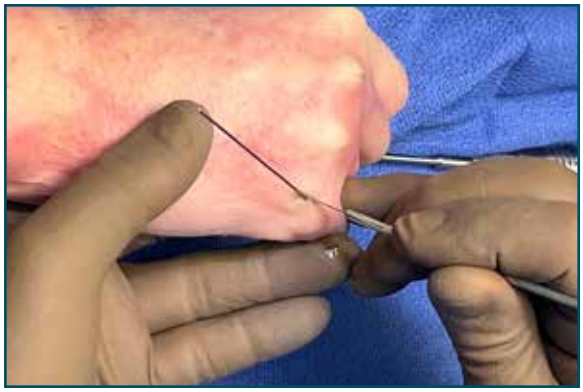
THREADED HAND NAIL INSERTION

7

Insert the selected sized Nail over the K-Wire and advance cautiously through the soft tissues to the bone surface. Thread into the bone. Verify proper reduction and Nail placement with radiographic imaging. Remove the K-Wire.

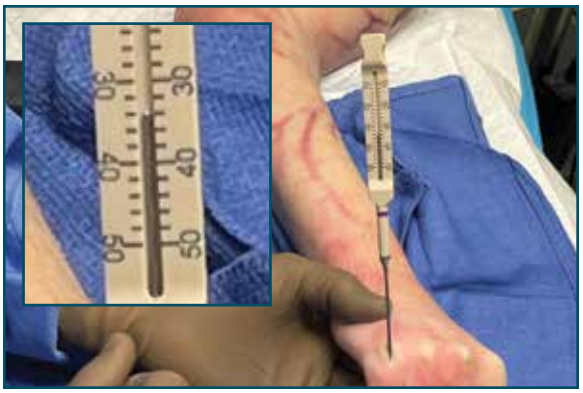


1 K-WIRE INSERTION AND FRACTURE REDUCTION



Sublux the proximal phalanx to insert the 0.9mm K-Wire provided in the 2.0 Threaded Nails caddy, and advance into the base of the proximal phalanx in line with the medullary canal of the proximal fragment. Reduce the fracture and advance the 0.9mm K-Wire into the distal fragment until the distal cortical margin has been reached. If desired, a 1.4mm K-Wire can be inserted parallel to this K-Wire to assist with maintaining reduction.

2 MEASURE NAIL LENGTH



Measure the Nail length with one of the following methods:

A. Depth Gauge:
Using fluoroscopy, position the distal end of the K-Wire at the base of the bone. Pass the 2.0 Threaded Nail Depth Gauge over the K-Wire up to the articular surface of the bone. Measuring from the end of the K-Wire, read and note the Nail length from the Depth Gauge measurement window. Subtract 4mm from the length reading to choose the appropriate size Nail.

B. Measurement Ruler:
Align the “0 mark” of the Measurement Ruler with the base of the bone and note the length mark near the head. Subtract 4mm from the length reading to choose the appropriate size Nail.

MSRT-RL: Measurement Ruler

DGA-THN-20: Depth Gauge, Threaded Hand Nail, 2.0

REAMING OF THE CANAL PREPARATION

3

To ensure ease of reaming and Nail introduction, create a small incision around the K-Wire entry point.

Slide 1.8mm Reamer over the proximal end of the K-Wire. Ream the medullary canal manually using an oscillating motion, stopping at least 2mm from the distal articular surface of the bone. If cortical engagement is not achieved with the 1.8mm Reamer, then a 3.0mm Threaded Hand Nail may be more appropriate. Remove the 1.8mm Reamer and refer to steps 4 through 7 above starting on page 5.

Note:
If necessary, use Wire Pusher to keep K-Wire in place when removing the reamer. Do not remove K-Wire.

RHS-RMR-18: Reamer, 1.8mm, Cannulated

THREADED HAND NAIL INSERTION

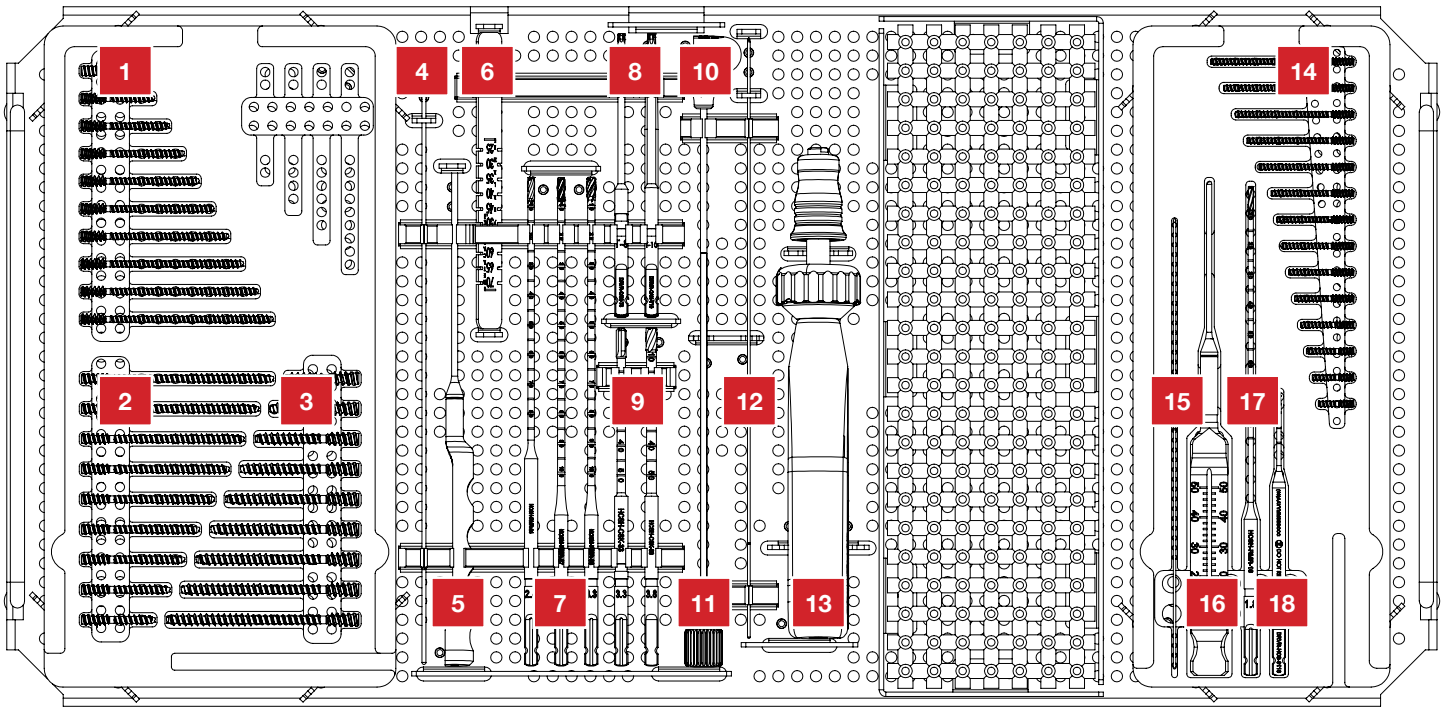
4

Fully flex the proximal interphalangeal joint. Continue to advance the 0.9mm K-Wire distally through the dorsal aspect of the phalangeal head. Advance the K-Wire through the soft tissues until exiting through the skin. Continue to advance the K-Wire until the distal end of the K-Wire can be easily grasped with surgical pick-ups to stabilize the wire position.

The cupped leading end of the 2.0mm Threaded Hand Nail can be mated onto the proximal end of the K-Wire and advanced using the non-cannulated Screw Driver to follow the exiting 0.9mm K-Wire. Continue to advance the Nail along the track of the K-Wire until it is in the desired position crossing the fracture line. Confirm final Nail position, reduction, and rotational alignment using fluoroscopy in the A/P and lateral planes. If position is correct, fully remove the K-Wire from the head of the proximal phalanx.

DRVR-HCS-0110: REDUCT Driver, 2.0

INSTRUMENT TRAY (Standard Configuration)



Loc#	Catalog#	Description
1	RHS-30020	Threaded Hand Nail, 3.0mm x 20mm, Ti
	RHS-30025	Threaded Hand Nail, 3.0mm x 25mm, Ti
	RHS-30030	Threaded Hand Nail, 3.0mm x 30mm, Ti
	RHS-30035	Threaded Hand Nail, 3.0mm x 35mm, Ti
	RHS-30040	Threaded Hand Nail, 3.0mm x 40mm, Ti
	RHS-30045	Threaded Hand Nail, 3.0mm x 45mm, Ti
	RHS-30050	Threaded Hand Nail, 3.0mm x 50mm, Ti
	RHS-30055	Threaded Hand Nail, 3.0mm x 55mm, Ti
	RHS-30060	Threaded Hand Nail, 3.0mm x 60mm, Ti
	RHS-30065	Threaded Hand Nail, 3.0mm x 65mm, Ti
	RHS-30070	Threaded Hand Nail, 3.0mm x 70mm, Ti (70mm optional, not shown)
2	RHS-35025	Threaded Hand Nail, 3.5mm x 25mm, Ti
	RHS-35030	Threaded Hand Nail, 3.5mm x 30mm, Ti
	RHS-35035	Threaded Hand Nail, 3.5mm x 35mm, Ti
	RHS-35040	Threaded Hand Nail, 3.5mm x 40mm, Ti
	RHS-35045	Threaded Hand Nail, 3.5mm x 45mm, Ti
	RHS-35050	Threaded Hand Nail, 3.5mm x 50mm, Ti
	RHS-35055	Threaded Hand Nail, 3.5mm x 55mm, Ti
	RHS-35060	Threaded Hand Nail, 3.5mm x 60mm, Ti
	RHS-35065	Threaded Hand Nail, 3.5mm x 65mm, Ti
	RHS-35070	Threaded Hand Nail, 3.5mm x 70mm, Ti (70mm optional, not shown)
3	RHS-40025	Threaded Hand Nail, 4.5mm x 25mm, Ti
	RHS-40030	Threaded Hand Nail, 4.5mm x 30mm, Ti
	RHS-40035	Threaded Hand Nail, 4.5mm x 35mm, Ti
	RHS-40040	Threaded Hand Nail, 4.5mm x 40mm, Ti
	RHS-40045	Threaded Hand Nail, 4.5mm x 45mm, Ti
	RHS-40050	Threaded Hand Nail, 4.5mm x 50mm, Ti
	RHS-40055	Threaded Hand Nail, 4.5mm x 55mm, Ti
	RHS-40060	Threaded Hand Nail, 4.5mm x 60mm, Ti
	RHS-40065	Threaded Hand Nail, 4.5mm x 65mm, Ti
	RHS-40070	Threaded Hand Nail, 4.5mm x 70mm, Ti (70mm optional, not shown)
4	KWIR-ST-14203	K-Wire, 1.4mm x 203 mm, Single Trocar
5	DGA-RHS	Depth Gauge, Threaded Hand Nail
6	MSRT-RL	Measurement Ruler
7	RHS-RMR-24	Reamer, 2.4mm, Cannulated
	RHS-RMR-27	Reamer, 2.7mm, Cannulated
	RHS-RMR-33	Reamer, 3.3mm, Cannulated
8	DRVR-CAN-T8	T8 Driver, AO, Cannulated
	DRVR-CAN- T10	T10 Driver, AO, Cannulated
	DRVR-UQC-T8	Driver, Universal QC, T8
	DRVR-UQC-T10	Driver, Universal QC, T10
9	RHS-CSK-33	Countersink, 3.3mm, Cannulated
	RHS-CSK-38	Countersink, 3.8mm, Cannulated
10	HCS-WP	HCS Wire Pusher
11	GDW-EXCH	K-Wire Exchanger
12	KWIR-ST-09203	K-Wire, 0.9mm x 203mm, Single Trocar
13	HNDL-UQC-RTC	Handle, Universal QC, Ratcheting
14	RHS-20012	Threaded Hand Nail, 2.0mm x 12mm, Ti
	RHS-20014	Threaded Hand Nail, 2.0mm x 14mm, Ti
	RHS-20016	Threaded Hand Nail, 2.0mm x 16mm, Ti
	RHS-20018	Threaded Hand Nail, 2.0mm x 18mm, Ti
	RHS-20020	Threaded Hand Nail, 2.0mm x 20mm, Ti
	RHS-20022	Threaded Hand Nail, 2.0mm x 22mm, Ti
	RHS-20024	Threaded Hand Nail, 2.0mm x 24mm, Ti
	RHS-20026	Threaded Hand Nail, 2.0mm x 26mm, Ti
	RHS-20028	Threaded Hand Nail, 2.0mm x 28mm, Ti
	RHS-20032	Threaded Hand Nail, 2.0mm x 32mm, Ti
	RHS-20036	Threaded Hand Nail, 2.0mm x 36mm, Ti
	RHS-20040	Threaded Hand Nail, 2.0mm x 40mm, Ti
	RHS-20044	Threaded Hand Nail, 2.0mm x 44mm, Ti
	RHS-20048	Threaded Hand Nail, 2.0mm x 48mm, Ti
15	KWIR-ST-09152	K-Wire, 0.9mm x 152mm, Single Trocar
16	DGA-THN-20	Depth Gauge, Threaded Hand Nail, 2.0
17	RHS-RMR-18	Reamer, 1.8mm, Cannulated
18	DRVR-HCS-0110	REDUCT Driver, 2.0
	GDW-INT	Guide Wire Introducer (optional, not shown)

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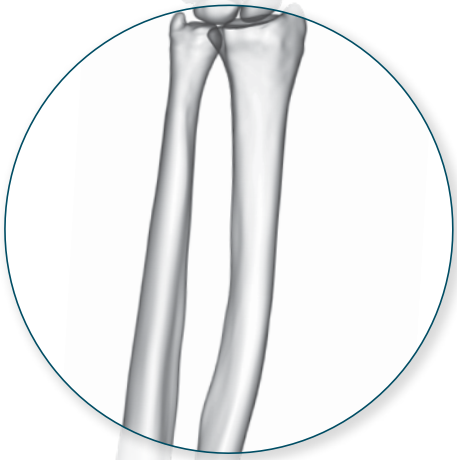

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