Smith+Nephew

LEOS◊ SMALL

Cannulated Screw System

Surgical Technique

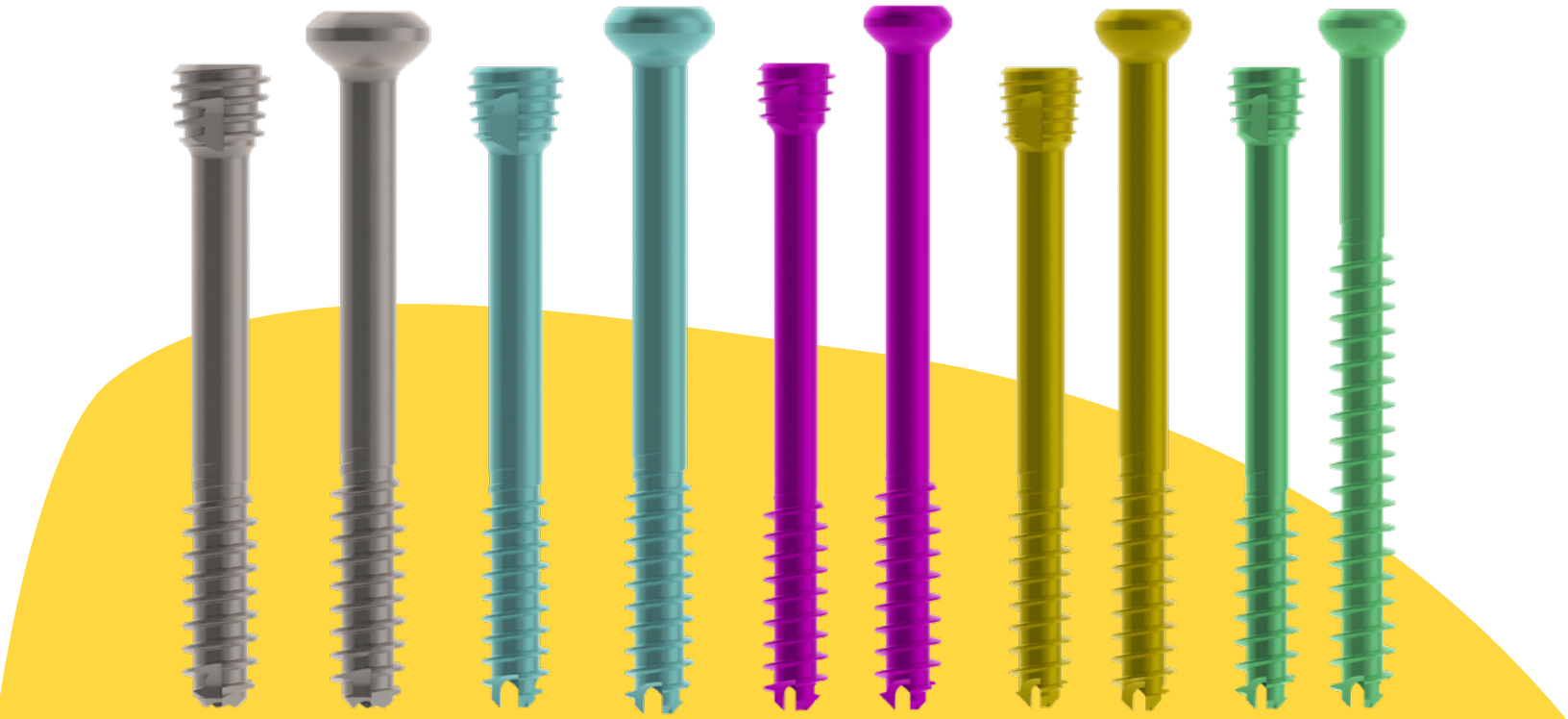
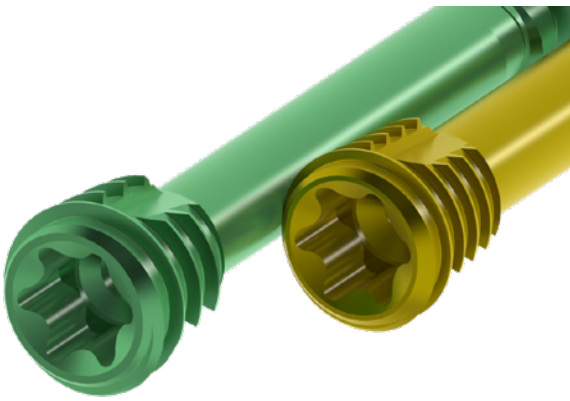


Table of contents

Nota Bene

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and Instructions for Use found at LEOS-eIFU.info.



System features

The comprehensive Smith+Nephew LEOS◊ Cannulated Screw System was designed to provide compression.[1] The compression screw exhibits the following:

- Multiple thread length options between headed and headless implants
- Tapered head to deliver compression for headless implants[1]
- Cannulation to allow for precise insertion using a K-wire[1]
- Self-drilling and self-tapping features[1]

Overview

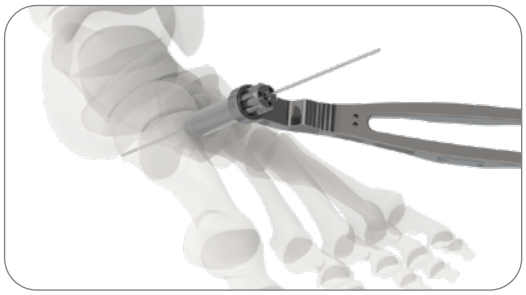
The LEOS Cannulated Screw System includes both headed and headless screws and accompanying instrumentation as outlined in the below table:

LEOS SMALL Cannulated Screw System

	2.0mm			2.5mm		3.0mm		3.5mm		4.0mm			
	QFX◊ (Snap off)	Headed	Headless	Headed	Headless	Headed	Headless	Headed	Headless	Headed ST	Headed LG	Headless ST	Headless LT
													
Part Number	7110228xS	763120xx	763420xx	763125xx	763425xx	763130xx	763430xx	763135xx	763435xx	763140xxSH	763240xxLG	763440xxSH	763540xxLT
K-wire		0.9mm		1.1mm						1.4mm			
Drill		1.6mm		2.0mm				2.7mm					
Driver		T6		T8				T15					
Screw Length	8-18	8-30	8-50	8-30	8-50	10-40		12-50mm		12-70mm			
Thread Length	Full	1/3 total length								1/3, Max 16mm	2/3, Max 32mm	1/3, Max 16mm	2/3, Max 32mm

LEOS Auxiliary Cannulated Screw System

	3.5mm		4.0mm			
	Headed	Headless	Headed ST	Headed LG	Headless ST	Headless LT
						
Part Number	763135xx	763435xx	763140xxSH	763240xxLG	763440xxSH	763540xxLT
K-wire	1.1mm		1.4mm			
Drill	2.7mm					
Driver	T15					
Screw Lengths	20-40mm		12-50mm			
Thread Length	1/3 total length		1/3, Max 16mm	2/3, Max 32mm	1/3, Max 16mm	2/3, Max 32mm



Surgical technique

Preparation and K-wire insertion

Dissect a clean approach to the desired region of the bone where the screw will be inserted.

Select the appropriate K-wire and wire guide for the chosen screw diameter and indication (See table on page 2).

When using the Tissue Protector as the chosen guide, select appropriate wire sleeve combination and assemble in outer sleeve.

Align Wire Guide

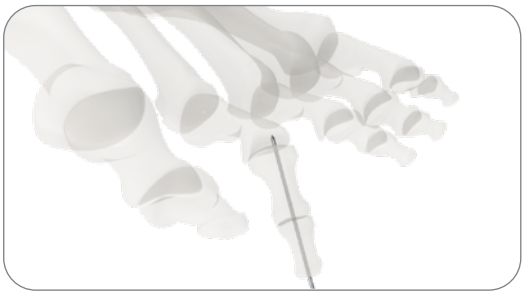
Insert the percutaneous sleeve assembly through the incision down to bone. Align the guide in the desired direction for the screw insertion.

K-wire insertion

Insert the appropriately sized K-wire through the wire sleeve and into bone to the desired depth. Confirm positioning under fluoroscopy.

Once positioning is confirmed, remove wire sleeve.

Note: For indications that require interfragmentary screw placement compatible with the LEOS◊ Plating System, see Page 11.

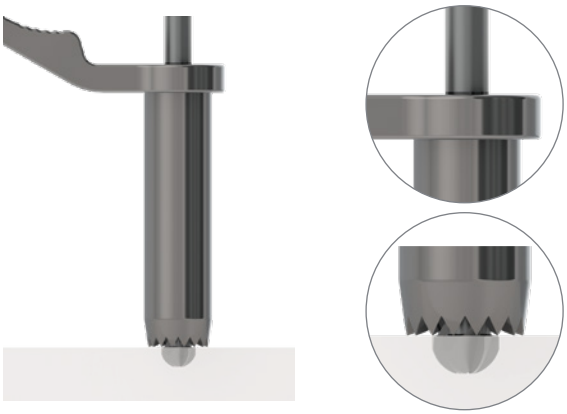


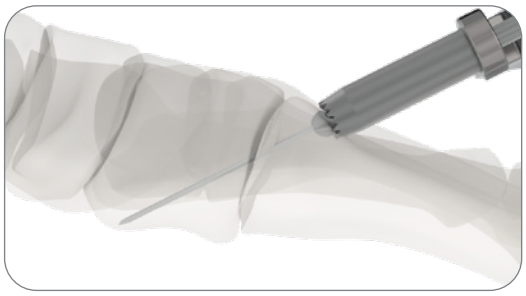
Preparation and K-wire insertion for Hammertoe

Dissect a clean approach to the desired region of the bone where the screw will be inserted. Select the approppriate K-wire for the chosen screw diameter and indication.

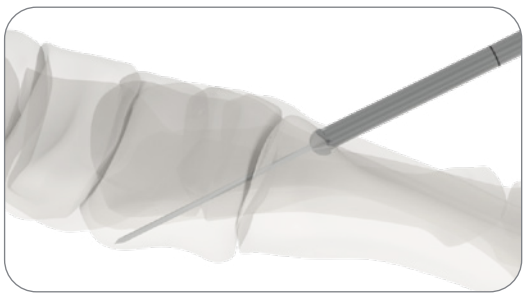
Distal K-wire insertion
Insert K-wire centrally through the middle and distal phalanges. Advance wire until enough length is available distally to pull the wire retrograde from the distal phalange. Minimal wire length should remain in the joint space.

Proximal K-wire insertion
Position the toe into the preferred anatomical alignment and drive the wire into the center of the proximal phalanx to the depth of the intended screw location. Confirm positioning under fluoroscopy.





With Tissue Protector



Without Tissue Protector

Headed Countersink (Optional)

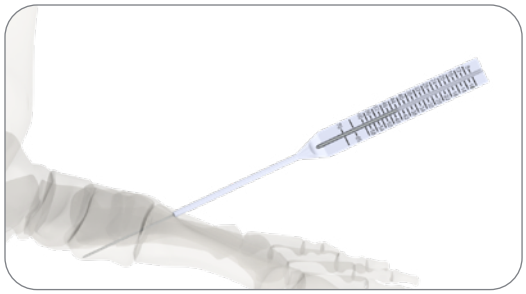
Select the correct countersink for the chosen screw diameter and indication for headed implants (See table on page 2).

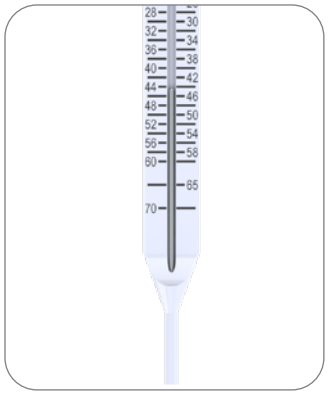
Advance the countersink tip into the bone by applying pressure and repeatedly rotating the countersink construct back and forth until the flat of the countersink head is flush with the bone.

Note: When using the Tissue Protector as the chosen guide, the laser marked band on the countersink corresponds to the depth of the head of the countersink. Rotate the countersink construct back and forth until the black line on the shaft is reached.

Note: When choosing a headed screw approach, measurement using a depth gauge must occur after use of headed countersink to indicate the correct screw length.

Note: The head of the countersink represents the height of the screw head.





Determine screw length

Insert Depth Gauge

Feed the distal end of the depth gauge over the K-wire and place it flush against the bone.

When using the Tissue Protector as the chosen guide, insert the depth gauge through the outer sleeve.

Depth gauge is not intended to measure through 2.0/2.5/3.0 Drill Guide.

Record measurement

Record the measurement at the proximal end of the K-wire to determine the depth.

Notes:

- Wire may be further advanced after measurement is taken to ensure wire remains in bone for remaining steps of procedure.
- When measuring for screw length, take into account any possible compression that may occur as this will affect final screw position.
- When a headed countersink is used first, the depth gauge should be seated in the countersink hole.

With Tissue Protector

Without Tissue Protector

Headless Countersink (Optional)

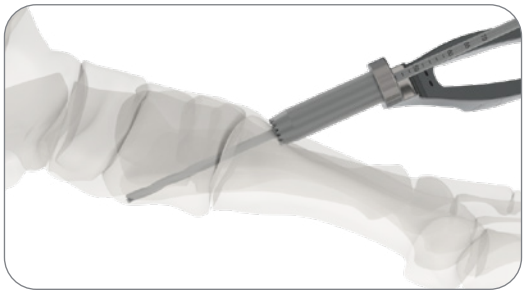
Select the correct countersink for the chosen screw diameter and indication for headless implants (See table on page 2).

Advance the countersink tip into the bone by applying pressure and repeatedly rotating the countersink construct back and forth until the black line on the countersink head is reached.

Note: When using the Tissue Protector as the chosen guide, the laser marked band on the countersink corresponds to the depth of the head of the countersink. Rotate the countersink construct back and forth until the black line on the shaft is reached.

Note: When using a headless screw approach, measurement using a depth gauge must occur prior to use of headless countersink to indicate the correct screw length.

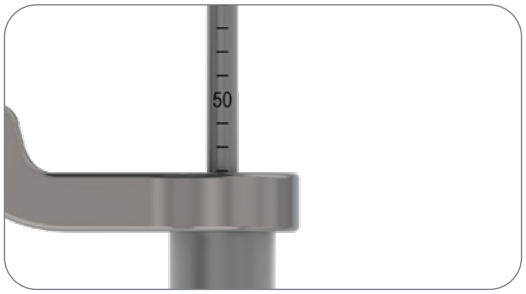
Note: The laser etch (groove under fluoroscopy) on the head of the countersink represents the height of the screw head.



Drill (Optional)

Select the correct drill size for the chosen screw diameter (See table on page 2). Select the correct drill guide for the chosen screw diameter.

Note: When using the Tissue Protector as the chosen guide, insert drill through outer sleeve.



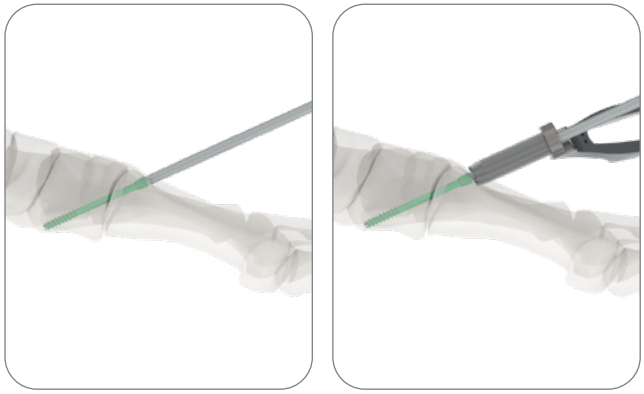
Drill bone

Place the appropriate cannulated drill over the guide wire and advance the drill until depth is achieved. Drill is calibrated to display drilled length from the near cortex to the tip of the drill and must be read from the top of the Tissue Protector or drill guide.

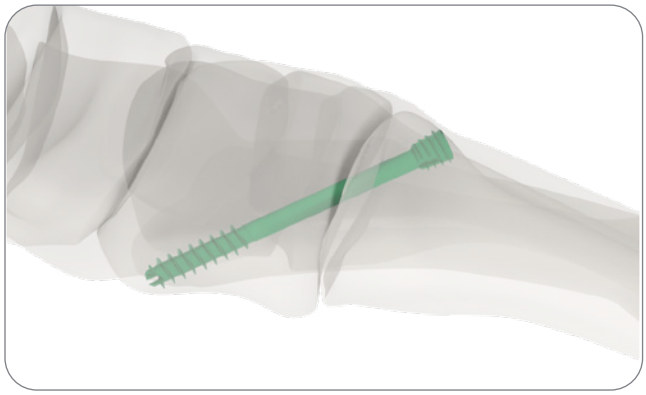
Confirm depth with fluoroscopy.

Notes:

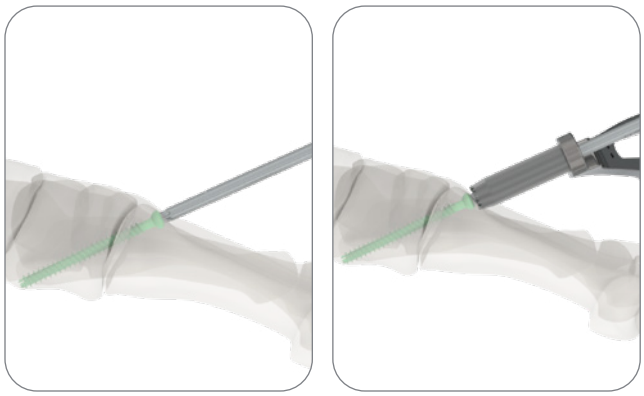
- Drilling is optional due to the self-drilling flute feature of implant tips.
- Drilling is beneficial for dense bone, as the axial force of self-drilling could distract the fragments of the compression site temporarily.
- When drilling under power, use power adapter for compatibility between Hall-Jacobs connections.



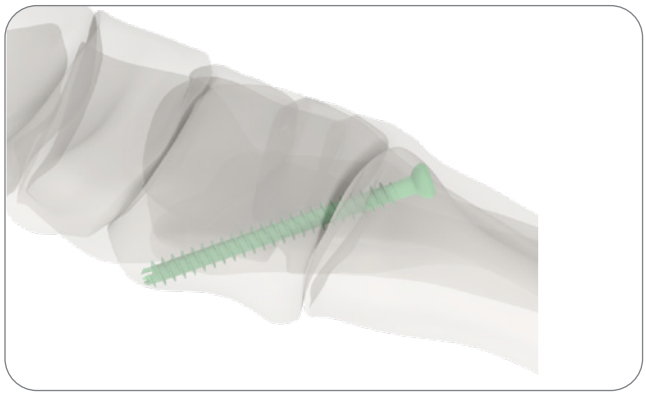
Headless Screw insertion



K-wire removed



Headed Screw insertion



K-wire removed

Insert screw and apply compression

Select the correct driver size for the chosen screw diameter (See table on page 2). Pass the screw over the K-wire, then use the driver to advance the screw into position.

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 or joint line.

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.

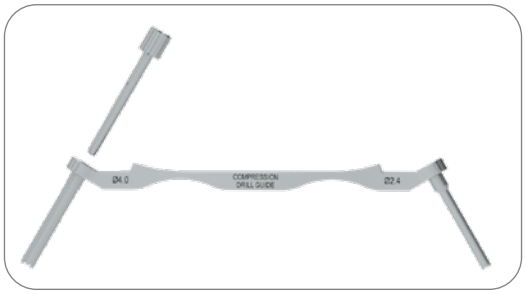
Advance the screw into the bone until the head of the screw sits just below the surface of the bone. Lastly, remove the K-wire.

Note: When using the Tissue Protector as the chosen guide, insert the driver and implant through the Outer Sleeve.

Implant removal (if required)

The implant may be removed by using the drivers indicated in the table on page 2. Clear any tissue overgrowth from the screw head recess and insert the driver. Next, turn the driver counterclockwise.

If alignment is difficult, a K-wire may be inserted through the screw cannula to facilitate driver alignment.



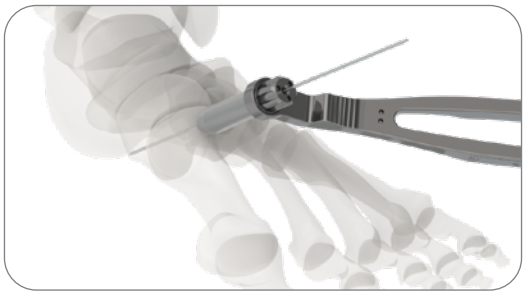
Interfragmentary Screw Insertion
Compatible with the LEOS Plating System

Follow preparation techniques outlined on page 5.

For placement of an interfragmentary screw compatible with the LEOS Plating System, the LEOS Compression Drill Guide, 1.4mm Wire Sleeve may be used for initial K-wire placement and soft tissue protection.

Select the appropriate K-wire (See table on page 2).

Assemble the 1.4mm Wire Sleeve into the Ø4.0 end of the LEOS Compression Drill Guide (7624-4940).



Align Assembled Guide

Align the assembled guide in the desired direction of screw insertion.

K-wire insertion

Feed the K-wire through the guide and advance it into the bone. Continue advancing the K-wire until it reaches the distal pole of the desired depth and position.

Following K-wire insertion, follow applicable surgical steps from the above technique using compatible instruments per page 3 Aux Set table. Follow plating technique for plate insertion.

2.0mm QFX◊ Screw

This screw has a built-in driver that bends off once the screw has been inserted.

Drill and measure (optional).

Due to the design of the 2.0mm QFX Screw, it is not necessary to drill prior to screw insertion. In areas of increased bone density, a 1.1mm Drill Tip Wire (71101413) may be used to pre-drill a pilot hole.

Using the 76308531 Wire Insert 2.5/3.0/3.5 Cann Screws and 76308539 Drill Guide 2.0/2.5/3.0 Cann Screws, insert a 1.1mm K-wire into the bone to the desired depth. Confirm positioning under fluoroscopy.

Measure with 76308510 152mm Depth Gauge over the guide wire until the near cortex is reached. The screw length can be determined at this point by reading the measurement off of the measuring device.

Remove and discard the wire.

Screw insertion

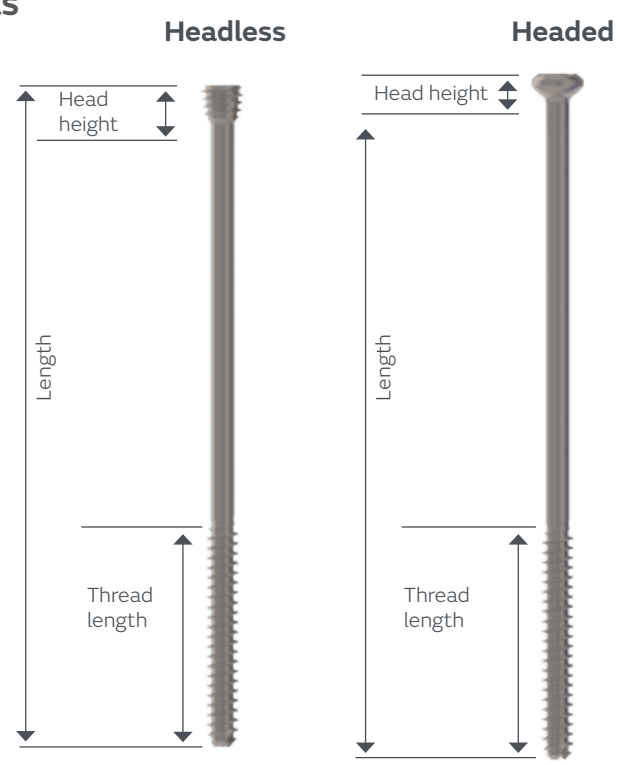
Insert the smooth driving shaft of the 2.0mm QFX◊ Screw into a pin driver. Insert the screw until the screw head is seated on the near cortex. Tilt the pin driver forward to detach the driver shaft. If applicable, further insertion can be performed using the 2.0mm QFX Screw Removal Driver (71177169).

2.0mm QFX Screw Removal Driver

Connect the 2.0mm QFX Screw Removal Driver to the Small Cannulated Handle with Quick Connect. Engage the three tabs on the tip of the screw remover with the three slots on the screw head. Continue insertion until final seating has been achieved.

Please note that this device can also assist with implant removal.

2.0 Implant details

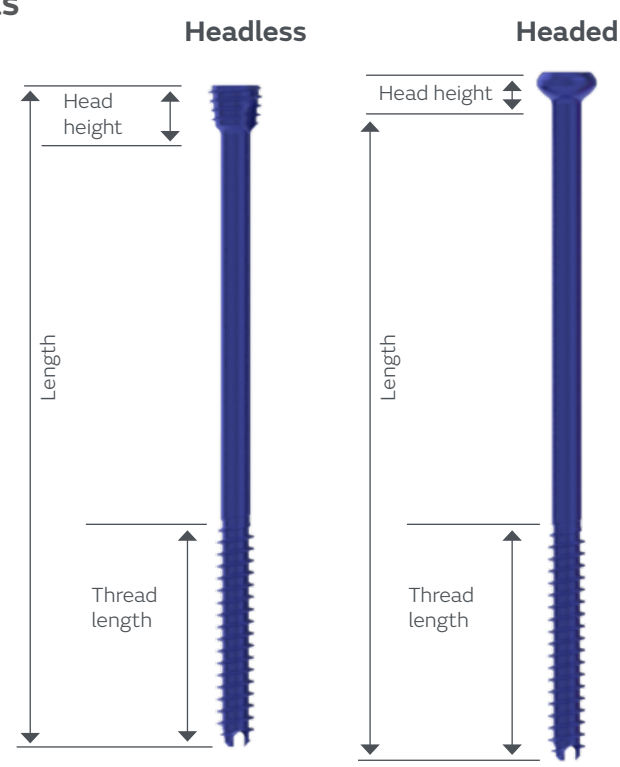


Thread length:
Short Thread = 1/3 Total Length
Min 4mm

Head Height:
Headless= 5.45mm
Headed= 1.65mm

Part Number		Length
Headless	Headed	
76342008	76312008	8mm
76342010	76312010	10mm
76342012	76312012	12mm
76342014	76312014	14mm
76342016	76312016	16mm
76342018	76312018	18mm
76342020	76312020	20mm
76342022	76312022	22mm
76342024	76312024	24mm
76342026	76312026	26mm
76342028	76312028	28mm
76342030	76312030	30mm
76342034	—	34mm
76342038	—	38mm
76342042	—	42mm
76342046	—	46mm
76342050	—	50mm

2.5 Implant details



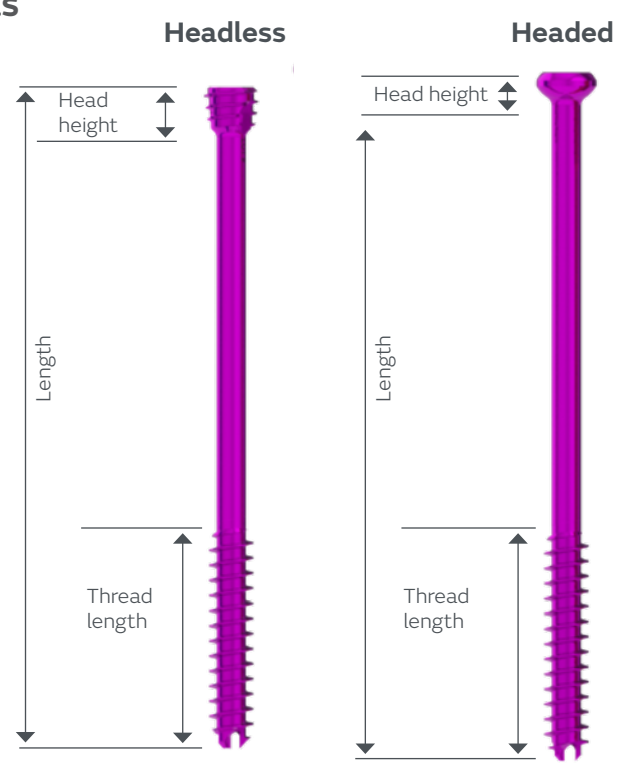
Thread length:
Short Thread = 1/3 Total Length
Min 4mm

Head Height:

Headless=	Headed=
3.12mm	1.90mm

Part Number		Length
Headless	Headed	
76342508	76312508	8mm
76342510	76312510	10mm
76342512	76312512	12mm
76342514	76312514	14mm
76342516	76312516	16mm
76342518	76312518	18mm
76342520	76312520	20mm
76342522	76312522	22mm
76342524	76312524	24mm
76342526	76312526	26mm
76342528	76312528	28mm
76342530	76312530	30mm
76342534	—	34mm
76342538	—	38mm
76342542	—	42mm
76342546	—	46mm
76342550	—	50mm

3.0 Implant details

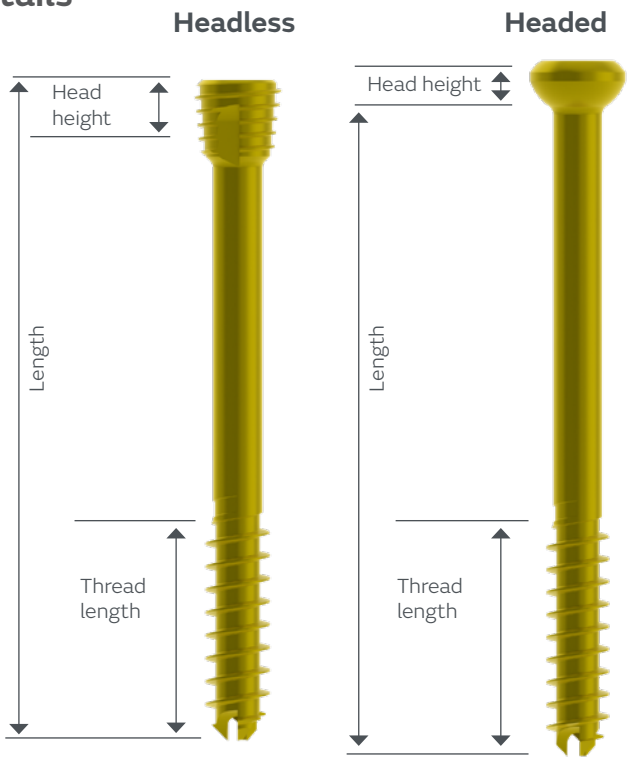


Thread length:
Short Thread = 1/3 Total Length
Min 4mm

Head Height:
Headless= 3.16mm
Headed= 1.90mm

Part Number		Length
Headless	Headed	
76343010	76313010	10mm
76343012	76313012	12mm
76343014	76313014	14mm
76343016	76313016	16mm
76343018	76313018	18mm
76343020	76313020	20mm
76343022	76313022	22mm
76343024	76313024	24mm
76343026	76313026	26mm
76343028	76313028	28mm
76343030	76313030	30mm
76343032	76313032	32mm
76343036	76313036	36mm
76343040	76313040	40mm

3.5mm Implant details



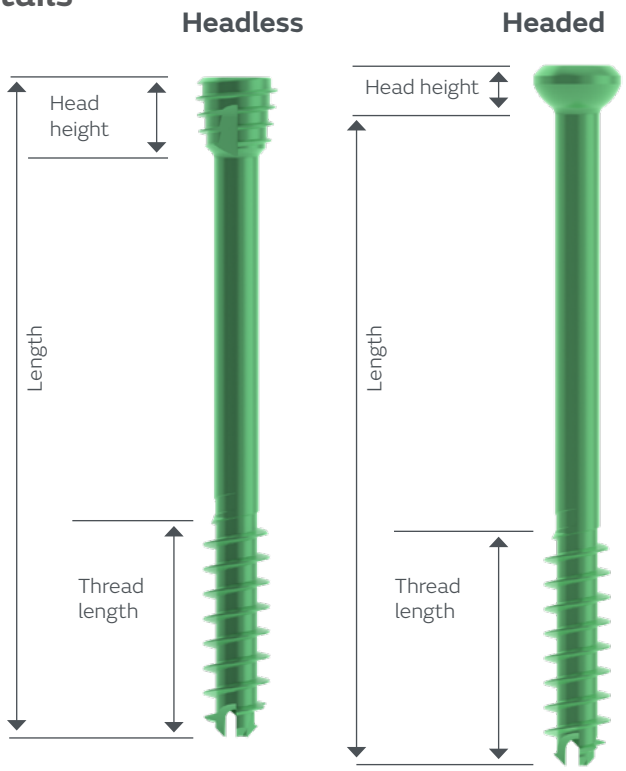
Thread length:
Short Thread = 1/3 Total Length
Min 4mm

Head Height:

Headless=	Headed=
4.58mm	2.70mm

Part Number		Length
Headless	Headed	
76343512	76313512	12mm
76343514	76313514	14mm
76343516	76313516	16mm
76343518	76313518	18mm
76343520	76313520	20mm
76343522	76313522	22mm
76343524	76313524	24mm
76343526	76313526	26mm
76343528	76313528	28mm
76343530	76313530	30mm
76343532	76313532	32mm
76343534	76313534	34mm
76343536	76313536	36mm
76343538	76313538	38mm
76343540	76313540	40mm
76343542	76313542	42mm
76343544	76313544	44mm
76343546	76313546	46mm
76343548	76313548	48mm
76343550	76313550	50mm

4.0mm Implant details



Thread length:
Short Thread = 1/3 Total Length
Max 16mm

Min 5mm

Long Thread = 2/3 Total Length
Max 32mm

Head Height:
Headless= 4.71mm
Headed= 2.70 mm

Washers:
For use with Headed Implants

Part number	Description
76308846	4.0mm Washer

Part Number				Length
Headless		Headed		
Short thread	Long thread	Short thread	Long thread	
76344012SH	—	76314012SH	—	12mm
76344014SH	—	76314014SH	—	14mm
76344016SH	—	76314016SH	—	16mm
76344018SH	—	76314018SH	—	18mm
76344020SH	—	76314020SH	—	20mm
76344022SH	—	76314022SH	—	22mm
76344024SH	—	76314024SH	—	24mm
76344026SH	—	76314026SH	—	26mm
76344028SH	—	76314028SH	—	28mm
76344030SH	76354030LG	76314030SH	76324030LG	30mm
76344032SH	76354032LG	76314032SH	76324032LG	32mm
76344034SH	76354034LG	76314034SH	76324034LG	34mm
76344036SH	76354036LG	76314036SH	76324036LG	36mm
76344038SH	76354038LG	76314038SH	76324038LG	38mm
76344040SH	76354040LG	76314040SH	76324040LG	40mm
76344042SH	76354042LG	76314042SH	76324042LG	42mm
76344044SH	76354044LG	76314044SH	76324044LG	44mm

4.0mm Implant details
(continued)

Part Number				Length
Headless		Headed		
Short thread	Long thread	Short thread	Long thread	
76344046SH	76354046LG	76314046SH	76324046LG	46mm
76344048SH	76354048LG	76314048SH	76324048LG	48mm
76344050SH	76354050LG	76314050SH	76324050LG	50mm
76344052SH	76354052LG	76314052SH	76324052LG	52mm
76344056SH	76354056LG	76314056SH	76324056LG	56mm
76344060SH	76354060LG	76314060SH	76324060LG	60mm
76344065SH	76354065LG	76314065SH	76324065LG	65mm
76344070SH	76354070LG	76314070SH	76324070LG	70mm

Aux set instrumentation

K-wires

Part Number	Description
76308831	1.1 X 152mm K-wire single end trocar tip
76308841	1.4 X 152mm K-wire

K-wire Dispensers

Part Number	Description
76308537	Dispenser 1.1mm K-wire single tip

Depth Gauge

Part Number	Description
76308510	152mm Depth Gauge

Drills

Part Number	Description
76308842	2.7 X 152mm Drill AO

Countersinks

Part Number	Description
76308534	Countersink 3.5/4.0mm Cann HLESS Screws
76308543	Countersink 3.5/4.0mm Cann HD Screws

Drivers

Part Number	Description
76308540	T15 Driver AO

Wire Guide

Part Number	Description
76308542	Wire Insert 3.5/4.0mm LEOS◊ Drill Guide

Cleaning Stylets

Part Number	Description
76308536	Cleaning Stylet 2.5/3.0/3.5/4.0mm Screws

Trays

Cannulated Auxiliary Trays for LEOS Plating

Part Number	Description
76309300	LEOS Cannulated 3.5/4.0mm Screws Aux Case
76309310	LEOS Cannulated 3.5/4.0mm Screws Aux Lid
76309440	Lid 3.5/4.0mm Implant Caddy
76309430	Caddy 3.5mm HD/HL Cann Screws
76309420	Caddy 4.0mm HD Cann Screws
76309410	Caddy 4.0mm HL Cann Screws

Small set instrumentation

K-wires

Part Number	Description
76308821	0.9 X 152mm K-wire single end trocar tip
76308822	0.9 X 152mm K-wire double end trocar tip
76308831	1.1 X 152mm K-wire single end trocar tip
76308832	1.1 X 152mm K-wire double end trocar tip
76308841	1.4 X 152mm K-wire

Depth Gauge

Part Number	Description
76308510	152mm Depth Gauge

Countersinks

Part Number	Description
76308522	Countersink 2.0 Cann HLESS Screws
76308533	Countersink 2.5/3.0 Cann HLESS Screws
76308534	Countersink 3.5/4.0 Cann HLESS Screws
76308523	Countersink 2.0 Cann HD Screws
76308535	Countersink 2.5/3.0 Cann HD Screws
76308543	Countersink 3.5/4.0 Cann HD Screws

Wire Guide

Part Number	Description
76308521	Wire Insert 2.0 Cann Screws
76308531	Wire Insert 2.5/3.0/3.5 Cann Screws
76308541	Wire Insert 4.0 Cann Screws
76308539	Drill Guide 2.0/2.5/3.0 Cann Screws
76308547	Drill Guide 3.5/4.0mm Cann Screws
76308546	Tissue Protector Outer Sleeve 3.5/4.0
76308555	Parallel Wire Guide 4.0/5.5 Cann Screws

Trays

Small Cannulated

Part Number	Description
76309000	LEOS Cannulated Small Screw System Case
76309020	LEOS Cannulated Small Screw System Lid
76309200	Instrument Tray 2.0/2.5/3.0/3.5/4.0
76309220	Caddy 2.0/2.5/3.0/3.5/4.0 HD Screws
76309240	Lid 2.0/2.5/3.0/3.5/4.0 HD Screws
76309210	Caddy 2.0/2.5/3.0/3.5/4.0 HLESS Screws
76309230	Lid 2.0/2.5/3.0/3.5/4.0 HLESS Screws

K-wire Dispensers

Part Number	Description
76308525	Dispenser 0.9mm K-wire single tip
76308526	Dispenser 0.9mm K-wire double tip
76308537	Dispenser 1.1mm K-wire single tip
76308538	Dispenser 1.1mm K-wire double tip

Drills

Part Number	Description
76308823	1.6 X 152mm Drill AO
76308833	2.0 X 152mm Drill AO
76308842	2.7 X 152mm Drill AO

Drivers

Part Number	Description
76308520	T6 Driver AO
76308530	T8 Driver AO
76308540	T15 Driver AO
71177169	QFX Removal Driver

Cleaning Stylets

Part Number	Description
76308524	Cleaning Stylet 2.0 Screws
76308536	Cleaning Stylet 2.5/3.0/3.5/4.0 Screws

Driver Handle

Part Number	Description
76245100	LEOS Ratcheting AO Handle
76308512	Handle AO - Jewelers

2.0mm QFX◊ Screw

Part Number	Description
71102280S	8mm
71102281S	10mm
71102282S	12mm
71102283S	14mm
71102284S	16mm
71102285S	18mm
71177169	2.0mm QFX Screw Removal Driver

Notes

Notes

Notes

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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References

1. Tyber Medical Data on file. Memo-X01-08-06A.