

6.5mm and 7.3mm Large Fragment Cannulated Screw System SCFE System

SURGICAL TECHNIQUE





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INDICATIONS

Large Cannulated Screws (6.5mm and 7.3mm diameters) are intended for fracture fixation of large bones and large bone fragments such as: slipped capital femoral epiphysis, pediatric femoral neck fractures, tibial plateau fractures, SI joint disruption, intercondylar femur fractures, subtalar arthrodesis and fixation of pelvis and iliosacral joint.

CONTRA-INDICATIONS

Metallic bone fixation devices **should not** be used in patients with:

- Active infections in or near the fixation site
- A demonstrated sensitivity to metals
- An inability to follow post-operative regimen

WARNING: These devices are not approved for screw attachment or fixation of the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

SYSTEM OVERVIEW

SCREWS

- 316L Stainless Steel
- Multiple thread length options

Diameter	Thread Length	Screw Length	Increments
6.5mm	16mm	30mm - 130mm	5mm
	32mm	45mm - 130mm	
	Fully Threaded	30mm - 90mm	2mm
		95mm - 130mm	5mm
7.3mm	16mm	30mm - 130mm	5mm
	32mm	45mm - 130mm	
	Fully Threaded	30mm - 90mm	2mm
		95mm - 130mm	5mm

Note: See Implant list in the back of this surgical technique for full part list.

- End cutting screw tip for ease of insertion
- Cancellous thread profile with optimized pitch to maximize threads across the physis
- Dual-lead thread to accelerate screw insertion and removal
- Reverse-cutting thread, threads end on screw head, and a threaded cannulation to facilitate implant removal

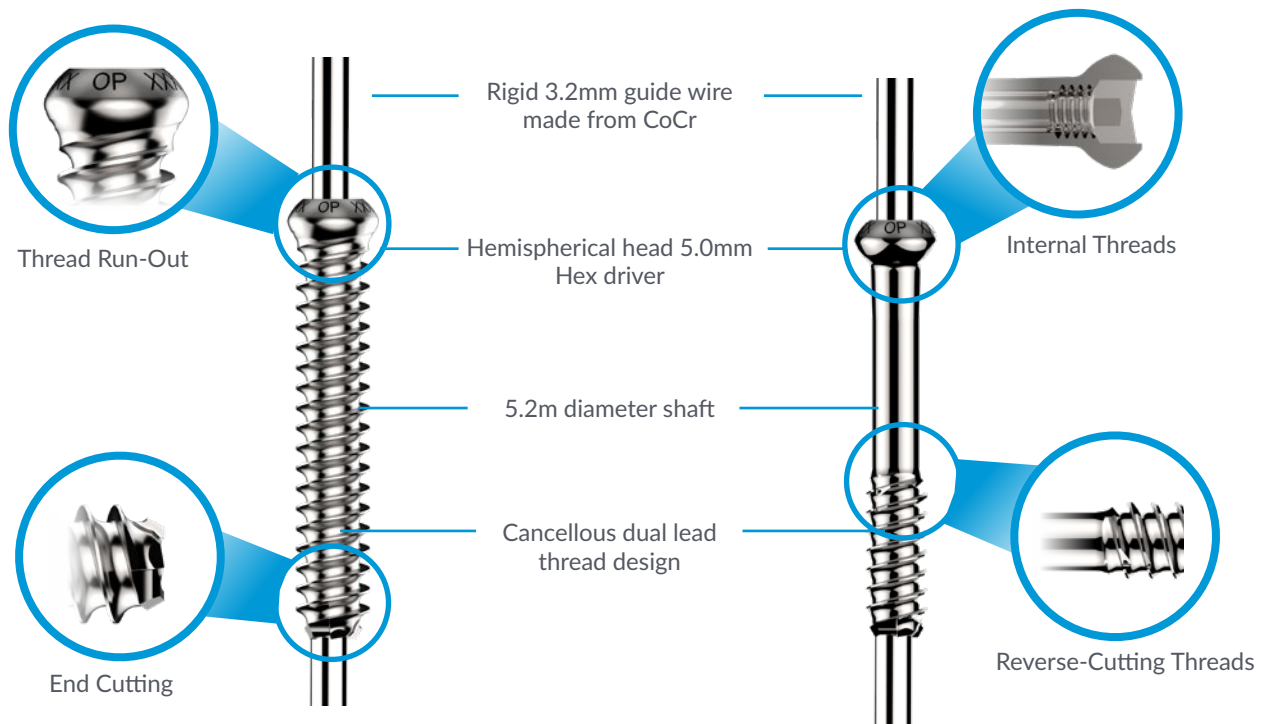


Figure 1: Screw design features.

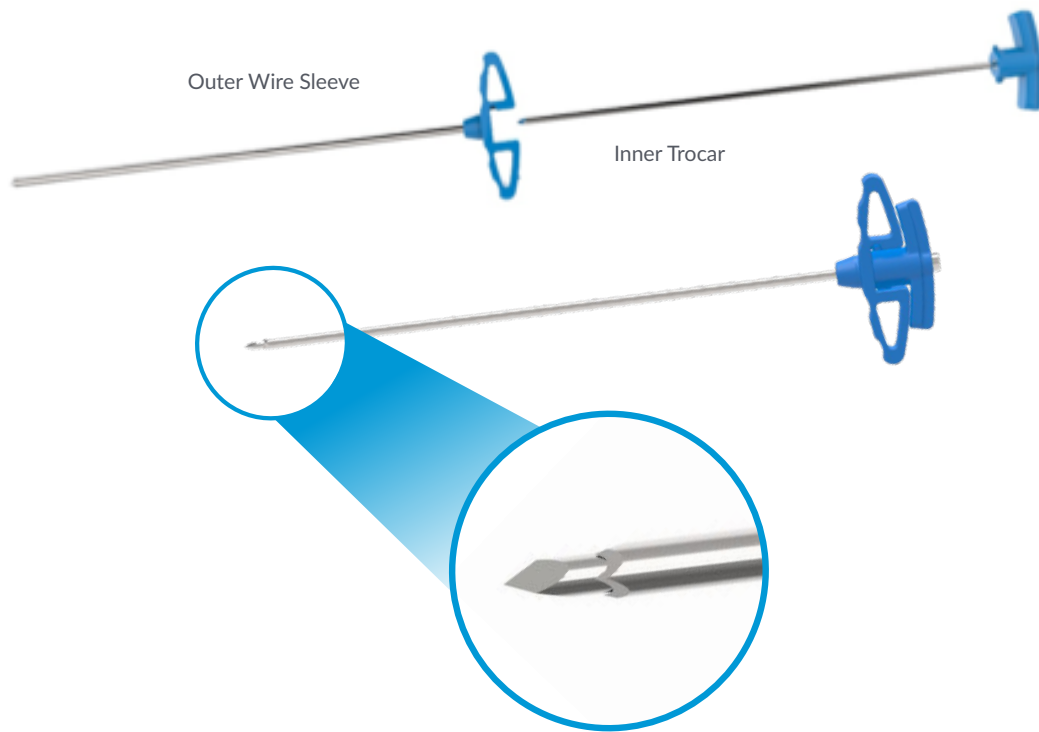


Figure 2: 3.2mm Wire Guide Assembly

Instruments

- Cobalt Chrome 3.2mm diameter guide wire for enhanced stiffness
- Long and short instrumentation to address varying soft tissue envelopes
- Shared instrumentation for intraoperative simplicity between 6.5mm and 7.3mm screw diameters
- Streamlined power drive connections (Zimmer Hudson quick connect)
- Multiple screw removal options
- Guide wire insertion re-thought and designed for accurate placement and reduced skiving

3.2mm Guide Wire Inserter

- This guide prevents the guide wire from skiving by first semi-introducing the guide wire into bone and enabling the surgeon to change trajectory without losing the entry point. The design and material of the 3.2mm wire guide inserter enables the surgeon to confirm the trajectory while reducing the potential for bending the guide wire during patient repositioning.
- The 3.2mm Guide Wire Inserter assembly consists of an outer wire sleeve and an inner trocar.

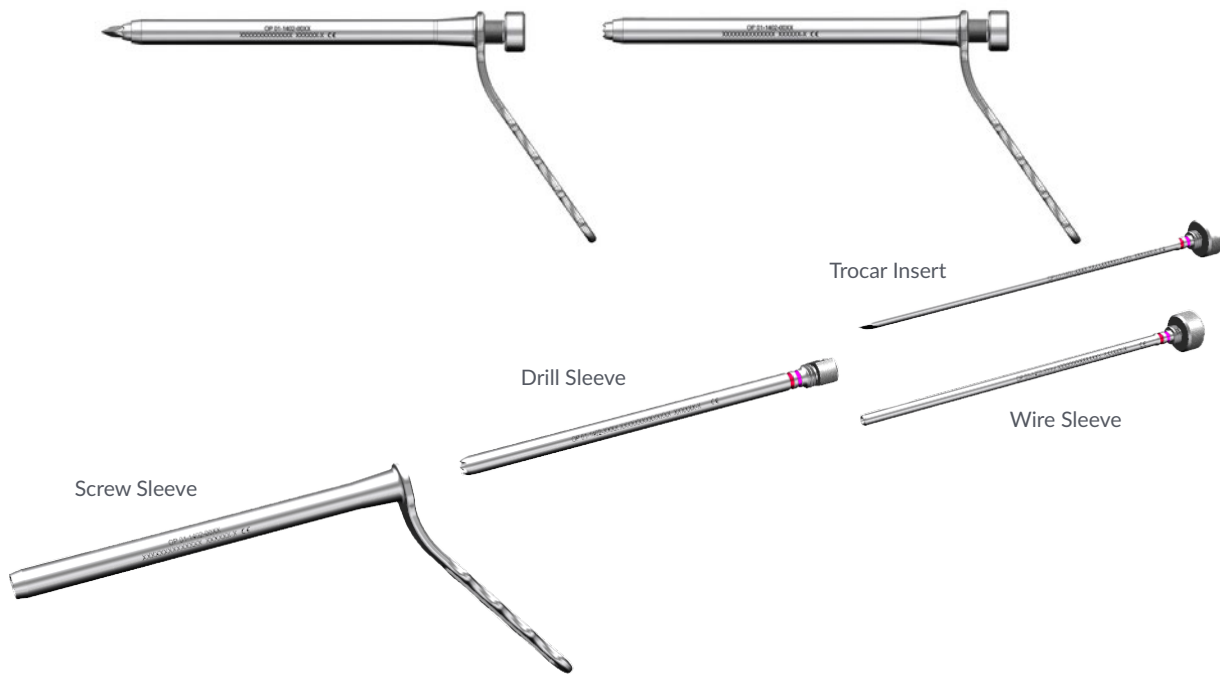


Figure 3: Percutaneous Sleeve Assembly

Percutaneous Sleeve Assembly

- The Percutaneous Sleeve provides the surgeon with a metal sleeve to protect soft tissue, through which every surgical step can be performed.
- The Percutaneous Sleeve Assembly includes 4 components: an outer screw sleeve and handle, a drill sleeve, a wire sleeve, and trocar insert. The trocar insert and wire sleeve fit within the drill sleeve, and cannot be used at the same time.

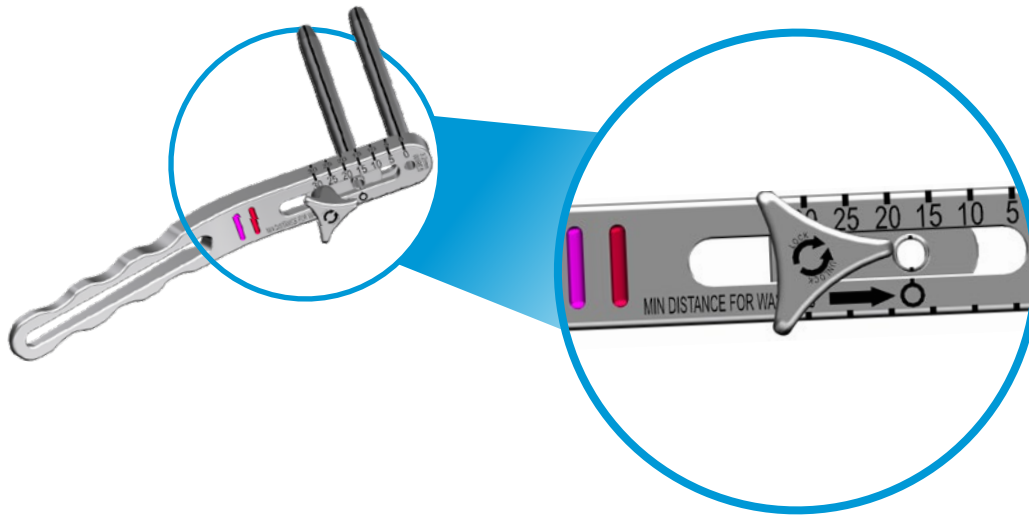


Figure 4: Parallel Wire Guide

Parallel Wire Guide

- If multiple screw fixation is desired, the Parallel Wire Guide can be used to insert an additional guide wire while referencing the first guide wire.
- The guide can be adjusted to place wires at varying distances apart. When two wires are placed as close together as possible the design ensures that the screw heads will not collide.
- If washers will be used, adjust the cannulation no closer than the 'o' symbol to ensure the washers do not collide.

SURGICAL TECHNIQUE



Figure 5: 3.2mm Wire Guide

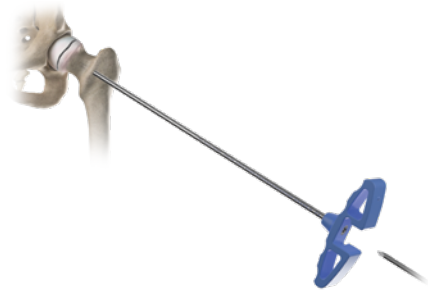


Figure 6: Remove the inner trocar and insert the guide wire

Guide Wire Insertion Options

Option 1

Insert the 3.2mm Wire Guide assembly down to bone and identify the desired start point. Advance the 3.2mm Wire Guide 1-2cm into the bone by hand or using a mallet. Using fluoroscopy confirm the desired trajectory of the wire. If the wire trajectory needs to be adjusted pull the 3.2mm Wire Guide back slightly, reorient the tip, and advance it slightly to hold the wire trajectory.

Remove the inner trocar and using a power driver, insert the guide wire through the outer sleeve to the desired position. Monitor guide wire insertion under fluoroscopy. After the wire is inserted remove the 3.2mm Wire Guide.

NOTE: When properly assembled the trocar tip should advance past the crown tip geometry of the outer sleeve



Figure 7: Percutaneous Screw Sleeve with trocar



Figure 8: Percutaneous Screw Sleeve with Wire Sleeve



Figure 9: Insert guide wire through Wire Sleeve

Guide Wire Insertion Options (cont.)

Option 2

Assemble the Percutaneous Screw Sleeve, Drills Sleeve, and trocar. Make a stab incision at the site of screw entry. Insert the Percutaneous Sleeve assembly through the incision down to bone.

Remove the trocar and insert the Wire Sleeve.

Using a power driver, insert the guide wire through the Wire Sleeve to the desired position. Monitor guide wire insertion under fluoroscopy.

NOTE: All surgical steps can be performed through the Percutaneous Sleeve assembly.

NOTE: If the wire(s) become bent, broken, or damaged in any way during the surgical procedure, this could lead to seizing of any of the cannulated instruments or screw on the wire; it could also impact pull out of the wire from the bone. Guide wire compatibility for wire guides is marked on each device.

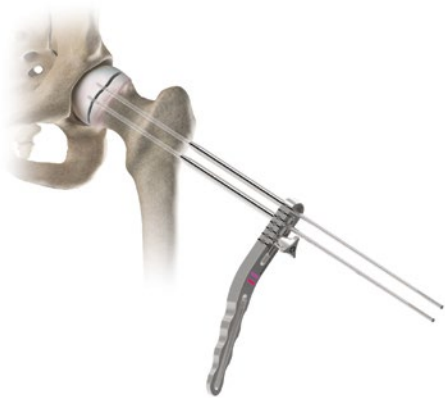


Figure 10: Insert second parallel guide wire



Figure 11: Countersink



Figure 12: Drill through the Percutaneous Drill Sleeve

If A Second Parallel Screw Is Desired

Insert additional guide wire (Optional)
Otherwise skip to the next step

Remove the Percutaneous Sleeve Assembly or 3.2mm Wire Guide from the incision and slide the Parallel Wire Guide over the existing guide wire. Adjust the wire spread to the desired distance by turning the cannulation knob on the back of the Parallel Wire Guide and move the cannulation to the desired location. Ensure that the cannulation knob is locked before inserting another guide wire.

Countersink (Optional)

If desired, carefully countersink over the guide wire to the appropriate depth.

Drill

Insert the Drill Sleeve and use the appropriate length 5.2mm cannulated drill to drill over the guide wire to the desired depth. In soft bone, it may not be necessary to drill the entire length of the screw.

PRECAUTION: Be careful of binding and unwanted progression of the guide wire.



Figure 13: Measure through the screw sleeve from the back of the guide wire

MEASURE

Remove the Drill Sleeve and slide the narrow end of the Direct Measuring Device over the wire and through the Percutaneous Wire Sleeve down to bone. For the Direct Measuring Device included in the 6.5mm/7.3mm set, reference the numerical markings on the flat side of the Direct Measuring Device that is associated with the appropriate wire.

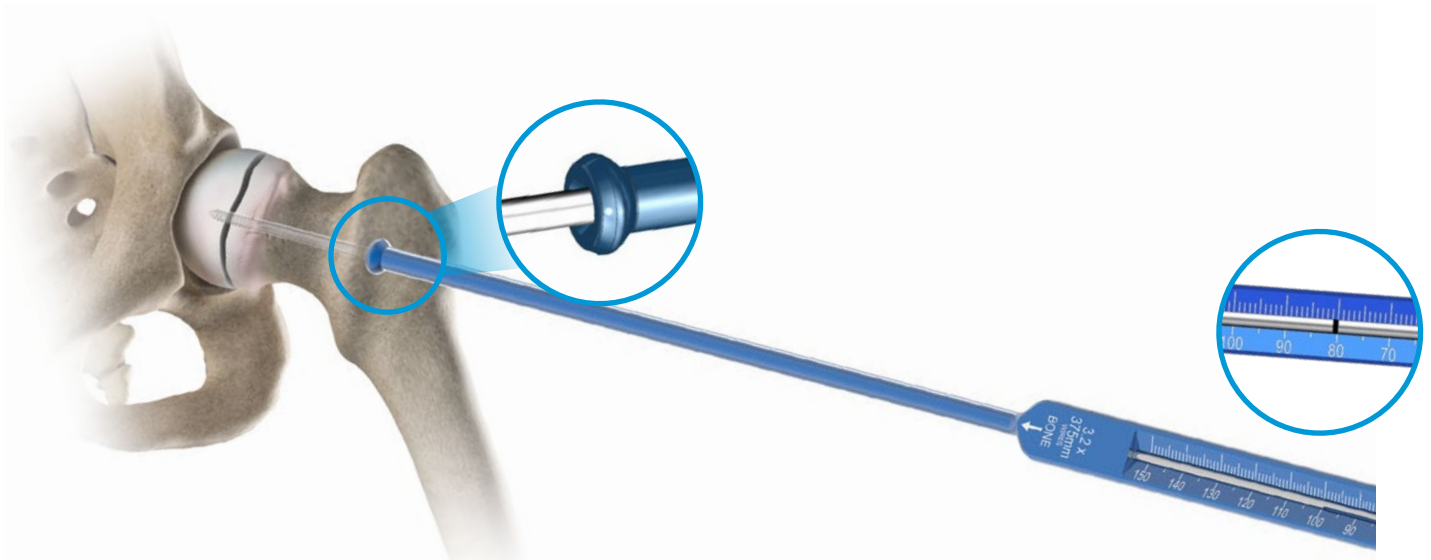


Figure 14 : Measure from the back of the guide wire. Tip geometry matches the screw head profile and is visible under flouroscopy

MEASURE (cont.)

The narrow end of the Direct Measurement Device will fit through the percutaneous screw sleeve. The tip of the narrow end of the Direct Measurement Device includes an identical geometry to the 6.5mm and 7.3mm screw head. This is for visualization of how the screw head will sit against the bone under fluoroscopy.

When using the 3.2mm x 800mm threaded guide wire (#01-1402-0532) and 3.2mm x 375mm direct measurement device (#01-1402-0013) measure from the back edge of the black reference line on the guidewire to determine the appropriate implant length.

NOTE: The reading indicates the screw length that will place the screw at the tip of the guide wire.

NOTE: Only use the guide wire in its original length to ensure a correct reading.

NOTE: If planning to countersink, this should be done prior to installing the Direct Measurement Device to ensure correct implant selection.



Figure 15: Tap through the Percutaneous Screw Sleeve



Figure 16: Tap without Percutaneous Screw Sleeve

Tap (optional)

In very dense bone or for an unstable SCFE, it may be helpful to tap the cortex. Slide the appropriate size tap for the desired screw diameter over the guide wire through the Percutaneous Screw Sleeve. Advance (turning clockwise) the tap to the desired depth and remove on reverse (counter clockwise). The tap may be used with or without the percutaneous sleeve as shown below.

NOTE: The tap should not be used under power

WARNING: Each screw diameter has a corresponding tap. Use of the compatible tap is recommended to prevent loss of fixation.



Figure 17 : Percutaneous Screw Sleeve with Driver and Ratcheting Handle

Insert Screw

Optional- A washer can be used with a screw to provide additional cortical stability.

Using the Retaining Cannulated Driver engage the tip in the desired length screw. The back end of the driver/handle can be lightly tapped to aid in the retaining functionality. Insert the screw over the guide wire and take care not to over-torque the driver and screw.

Care should be taken when inserting screws near a growth plate, joint space or another screw/implant.

Use fluoroscopy to check final placement.

Color coding and diameter gages are included in the screw caddies to help distinguish between screw diameters.

NOTE: The washer cannot pass through the Percutaneous Screw Sleeve if electing to use a washer with the screw.

NOTE: Laser line on driver indicates when screw is near final seating when used with the Percutaneous Screw Sleeve.

NOTE: Dot indicates that the driver is retaining.

PRECAUTION: Multiple thread options are included to aid in the proper reduction of the bones and/ or bone fragments. Improper reduction can lead to a non-union or screw overload.



Figure 18: Solid Hex Driver



Figure 19: 5.0mm Hex Easy Out (cannulated)



Figure 20: Screw Removal Driver

Screw Removal

The following screw removal instruments are included in the system:

Hex Drivers

- Intended to be used when the screw & female hex feature is completely intact.
- Solid and cannulated options available.

5.0mm Hex Easy Out (cannulated)

- Intended to engage and cut into the female hex of the screw if it has been stripped out.
- Use only in reverse.

Screw Removal Driver

- Intended to thread into the cannulation of the screw that has a female hex that is stripped.
- Thread in by hand to avoid cross threading removal tool with cannulation threads of the screw.
- Use only in reverse.



FIGURE 21: Cannulation Easy Out (Christmas Tree)



FIGURE 22: Trephines

Screw Removal (cont.)

The following screw removal instruments are included in the system:

Cannulation Easy Out (Christmas Tree)


- Intended to engage into the cannulation of a screw that has been stripped beyond the use of a Hex Easy Out, or if a portion of a screw head is missing.
- Use only in reverse.

Trephines (6.75mm & 7.55mm, cannulated)


- Intended to ream bone just slightly oversized to the major diameter of the screw threads. If any portion of the screw head is remaining, consider using the Screw Removal Driver or Cannulation Easy Out.
- Use only in reverse.

APPENDIX


6.5MM SCREWS FULLY THREADED (Lengths Refer To Working Thread Length)

Product	Item Number	Description
	00-1402-6030	6.5mm Cannulated Screw, Fully Threaded, 30mm
	00-1402-6032	6.5mm Cannulated Screw, Fully Threaded, 32mm
	00-1402-6034	6.5mm Cannulated Screw, Fully Threaded, 34mm
	00-1402-6036	6.5mm Cannulated Screw, Fully Threaded, 36mm
	00-1402-6038	6.5mm Cannulated Screw, Fully Threaded, 38mm
	00-1402-6040	6.5mm Cannulated Screw, Fully Threaded, 40mm
	00-1402-6042	6.5mm Cannulated Screw, Fully Threaded, 42mm
	00-1402-6044	6.5mm Cannulated Screw, Fully Threaded, 44mm
	00-1402-6046	6.5mm Cannulated Screw, Fully Threaded, 46mm
	00-1402-6048	6.5mm Cannulated Screw, Fully Threaded, 48mm
	00-1402-6050	6.5mm Cannulated Screw, Fully Threaded, 50mm
	00-1402-6052	6.5mm Cannulated Screw, Fully Threaded, 52mm
	00-1402-6054	6.5mm Cannulated Screw, Fully Threaded, 54mm
	00-1402-6056	6.5mm Cannulated Screw, Fully Threaded, 56mm
	00-1402-6058	6.5mm Cannulated Screw, Fully Threaded, 58mm
	00-1402-6060	6.5mm Cannulated Screw, Fully Threaded, 60mm
	00-1402-6062	6.5mm Cannulated Screw, Fully Threaded, 62mm
	00-1402-6064	6.5mm Cannulated Screw, Fully Threaded, 64mm
	00-1402-6066	6.5mm Cannulated Screw, Fully Threaded, 66mm
	00-1402-6068	6.5mm Cannulated Screw, Fully Threaded, 68mm
	00-1402-6070	6.5mm Cannulated Screw, Fully Threaded, 70mm
	00-1402-6072	6.5mm Cannulated Screw, Fully Threaded, 72mm
	00-1402-6074	6.5mm Cannulated Screw, Fully Threaded, 74mm
	00-1402-6076	6.5mm Cannulated Screw, Fully Threaded, 76mm
	00-1402-6078	6.5mm Cannulated Screw, Fully Threaded, 78mm
	00-1402-6080	6.5mm Cannulated Screw, Fully Threaded, 80mm
	00-1402-6082	6.5mm Cannulated Screw, Fully Threaded, 82mm
	00-1402-6084	6.5mm Cannulated Screw, Fully Threaded, 84mm
	00-1402-6086	6.5mm Cannulated Screw, Fully Threaded, 86mm
	00-1402-6088	6.5mm Cannulated Screw, Fully Threaded, 88mm
	00-1402-6090	6.5mm Cannulated Screw, Fully Threaded, 90mm
	00-1402-6095	6.5mm Cannulated Screw, Fully Threaded, 95mm
	00-1402-6100	6.5mm Cannulated Screw, Fully Threaded, 100mm
00-1402-6105	6.5mm Cannulated Screw, Fully Threaded, 105mm	
00-1402-6110	6.5mm Cannulated Screw, Fully Threaded, 110mm	
00-1402-6115	6.5mm Cannulated Screw, Fully Threaded, 115mm	
00-1402-6120	6.5mm Cannulated Screw, Fully Threaded, 120mm	
00-1402-6125	6.5mm Cannulated Screw, Fully Threaded, 125mm	
00-1402-6130	6.5mm Cannulated Screw, Fully Threaded, 130mm	


SHORT THREAD (All Short Thread Screws Have Thread Working Length Of 16MM)

Product	Item Number	Description
	00-1402-5030	6.5mm Cannulated Screw, 30mm SS, 16mm Thread
	00-1402-5035	6.5mm Cannulated Screw, 35mm SS, 16mm Thread
	00-1402-5040	6.5mm Cannulated Screw, 40mm SS, 16mm Thread
	00-1402-5045	6.5mm Cannulated Screw, 45mm SS, 16mm Thread
	00-1402-5050	6.5mm Cannulated Screw, 50mm SS, 16mm Thread
	00-1402-5055	6.5mm Cannulated Screw, 55mm SS, 16mm Thread
	00-1402-5060	6.5mm Cannulated Screw, 60mm SS, 16mm Thread
	00-1402-8065	6.5mm Cannulated Screw, 65mm SS, 16mm Thread
	00-1402-8070	6.5mm Cannulated Screw, 70mm SS, 16mm Thread
	00-1402-8075	6.5mm Cannulated Screw, 75mm SS, 16mm Thread
	00-1402-8080	6.5mm Cannulated Screw, 80mm SS, 16mm Thread
	00-1402-8085	6.5mm Cannulated Screw, 85mm SS, 16mm Thread
	00-1402-8090	6.5mm Cannulated Screw, 90mm SS, 16mm Thread
	00-1402-8095	6.5mm Cannulated Screw, 95mm SS, 16mm Thread
	00-1402-8100	6.5mm Cannulated Screw, 100mm SS, 16mm Thread
	00-1402-8105	6.5mm Cannulated Screw, 105mm SS, 16mm Thread
	00-1402-8110	6.5mm Cannulated Screw, 110mm SS, 16mm Thread
	00-1402-8115	6.5mm Cannulated Screw, 115mm SS, 16mm Thread
	00-1402-8120	6.5mm Cannulated Screw, 120mm SS, 16mm Thread
	00-1402-8125	6.5mm Cannulated Screw, 125mm SS, 16mm Thread
00-1402-8130	6.5mm Cannulated Screw, 130mm SS, 16mm Thread	


LONG THREAD (All Long Thread Screws Have Threaded Working Length Of 32MM)

Product	Item Number	Description
	00-1402-6345	6.5mm Cannulated Screw, 45mm SS, 32 mm Thread
	00-1402-6350	6.5mm Cannulated Screw, 50mm SS, 32 mm Thread
	00-1402-6355	6.5mm Cannulated Screw, 55mm SS, 32 mm Thread
	00-1402-6360	6.5mm Cannulated Screw, 60mm SS, 32 mm Thread
	00-1402-6365	6.5mm Cannulated Screw, 65mm SS, 32 mm Thread
	00-1402-6370	6.5mm Cannulated Screw, 70mm SS, 32 mm Thread
	00-1402-6375	6.5mm Cannulated Screw, 75mm SS, 32 mm Thread
	00-1402-6380	6.5mm Cannulated Screw, 80mm SS, 32 mm Thread
	00-1402-6385	6.5mm Cannulated Screw, 85mm SS, 32 mm Thread
	00-1402-6390	6.5mm Cannulated Screw, 90mm SS, 32 mm Thread
	00-1402-5095	6.5mm Cannulated Screw, 95mm SS, 32 mm Thread
	00-1402-5100	6.5mm Cannulated Screw, 100mm SS, 32 mm Thread
	00-1402-5105	6.5mm Cannulated Screw, 105mm SS, 32 mm Thread
	00-1402-5110	6.5mm Cannulated Screw, 110mm SS, 32 mm Thread
	00-1402-5115	6.5mm Cannulated Screw, 115mm SS, 32 mm Thread
	00-1402-5120	6.5mm Cannulated Screw, 120mm SS, 32 mm Thread
	00-1402-5125	6.5mm Cannulated Screw, 125mm SS, 32 mm Thread
	00-1402-5130	6.5mm Cannulated Screw, 130mm SS, 32 mm Thread


7.3MM Screws Fully Threaded (Lengths Refer To Working Thread Length)

Product	Item Number	Description
	00-1402-2030	7.3mm Cannulated Screw, Fully Threaded, 30mm
	00-1402-2032	7.3mm Cannulated Screw, Fully Threaded, 32mm
	00-1402-2034	7.3mm Cannulated Screw, Fully Threaded, 34mm
	00-1402-2036	7.3mm Cannulated Screw, Fully Threaded, 36mm
	00-1402-2038	7.3mm Cannulated Screw, Fully Threaded, 38mm
	00-1402-2040	7.3mm Cannulated Screw, Fully Threaded, 40mm
	00-1402-2042	7.3mm Cannulated Screw, Fully Threaded, 42mm
	00-1402-2044	7.3mm Cannulated Screw, Fully Threaded, 44mm
	00-1402-2046	7.3mm Cannulated Screw, Fully Threaded, 46mm
	00-1402-2048	7.3mm Cannulated Screw, Fully Threaded, 48mm
	00-1402-2050	7.3mm Cannulated Screw, Fully Threaded, 50mm
	00-1402-2052	7.3mm Cannulated Screw, Fully Threaded, 52mm
	00-1402-2054	7.3mm Cannulated Screw, Fully Threaded, 54mm
	00-1402-2056	7.3mm Cannulated Screw, Fully Threaded, 56mm
	00-1402-2058	7.3mm Cannulated Screw, Fully Threaded, 58mm
	00-1402-2060	7.3mm Cannulated Screw, Fully Threaded, 60mm
	00-1402-2062	7.3mm Cannulated Screw, Fully Threaded, 62mm
	00-1402-2064	7.3mm Cannulated Screw, Fully Threaded, 64mm
	00-1402-2066	7.3mm Cannulated Screw, Fully Threaded, 66mm
	00-1402-2068	7.3mm Cannulated Screw, Fully Threaded, 68mm
	00-1402-2070	7.3mm Cannulated Screw, Fully Threaded, 70mm
	00-1402-2072	7.3mm Cannulated Screw, Fully Threaded, 72mm
	00-1402-2074	7.3mm Cannulated Screw, Fully Threaded, 74mm
	00-1402-2076	7.3mm Cannulated Screw, Fully Threaded, 76mm
	00-1402-2078	7.3mm Cannulated Screw, Fully Threaded, 78mm
	00-1402-2080	7.3mm Cannulated Screw, Fully Threaded, 80mm
	00-1402-2082	7.3mm Cannulated Screw, Fully Threaded, 82mm
	00-1402-2084	7.3mm Cannulated Screw, Fully Threaded, 84mm
	00-1402-2086	7.3mm Cannulated Screw, Fully Threaded, 86mm
	00-1402-2088	7.3mm Cannulated Screw, Fully Threaded, 88mm
	00-1402-2090	7.3mm Cannulated Screw, Fully Threaded, 90mm
	00-1402-2095	7.3mm Cannulated Screw, Fully Threaded, 95mm
	00-1402-2100	7.3mm Cannulated Screw, Fully Threaded, 100mm
00-1402-2105	7.3mm Cannulated Screw, Fully Threaded, 105mm	
00-1402-2110	7.3mm Cannulated Screw, Fully Threaded, 110mm	
00-1402-2115	7.3mm Cannulated Screw, Fully Threaded, 115mm	
00-1402-2120	7.3mm Cannulated Screw, Fully Threaded, 120mm	
00-1402-2125	7.3mm Cannulated Screw, Fully Threaded, 125mm	
00-1402-2130	7.3mm Cannulated Screw, Fully Threaded, 130mm	


SHORT THREAD (All Short Thread Screws Have Thread Working Length Of 16MM)

Product	Item Number	Description
	00-1402-1030	7.3mm Cannulated Screw, 30mm SS, 16mm Thread
	00-1402-1035	7.3mm Cannulated Screw, 35mm SS, 16mm Thread
	00-1402-1040	7.3mm Cannulated Screw, 40mm SS, 16mm Thread
	00-1402-1045	7.3mm Cannulated Screw, 45mm SS, 16mm Thread
	00-1402-1050	7.3mm Cannulated Screw, 50mm SS, 16mm Thread
	00-1402-1055	7.3mm Cannulated Screw, 55mm SS, 16mm Thread
	00-1402-1060	7.3mm Cannulated Screw, 60mm SS, 16mm Thread
	00-1402-7065	7.3mm Cannulated Screw, 65mm SS, 16mm Thread
	00-1402-7070	7.3mm Cannulated Screw, 70mm SS, 16mm Thread
	00-1402-7075	7.3mm Cannulated Screw, 75mm SS, 16mm Thread
	00-1402-7080	7.3mm Cannulated Screw, 80mm SS, 16mm Thread
	00-1402-7085	7.3mm Cannulated Screw, 85mm SS, 16mm Thread
	00-1402-7090	7.3mm Cannulated Screw, 90mm SS, 16mm Thread
	00-1402-7095	7.3mm Cannulated Screw, 95mm SS, 16mm Thread
	00-1402-7100	7.3mm Cannulated Screw, 100mm SS, 16mm Thread
	00-1402-7105	7.3mm Cannulated Screw, 105mm SS, 16mm Thread
	00-1402-7110	7.3mm Cannulated Screw, 110mm SS, 16mm Thread
	00-1402-7115	7.3mm Cannulated Screw, 115mm SS, 16mm Thread
	00-1402-7120	7.3mm Cannulated Screw, 120mm SS, 16mm Thread
	00-1402-7125	7.3mm Cannulated Screw, 125mm SS, 16mm Thread
00-1402-7130	7.3mm Cannulated Screw, 130mm SS, 16mm Thread	

LONG THREAD (All Long Thread Screws Have Threaded Working Length Of 32MM)

Product	Item Number	Description
	00-1402-7345	7.3mm Cannulated Screw, 45mm SS, 32 mm Thread
	00-1402-7350	7.3mm Cannulated Screw, 50mm SS, 32 mm Thread
	00-1402-7355	7.3mm Cannulated Screw, 55mm SS, 32 mm Thread
	00-1402-7360	7.3mm Cannulated Screw, 60mm SS, 32 mm Thread
	00-1402-7365	7.3mm Cannulated Screw, 65mm SS, 32 mm Thread
	00-1402-7370	7.3mm Cannulated Screw, 70mm SS, 32 mm Thread
	00-1402-7375	7.3mm Cannulated Screw, 75mm SS, 32 mm Thread
	00-1402-7380	7.3mm Cannulated Screw, 80mm SS, 32 mm Thread
	00-1402-7385	7.3mm Cannulated Screw, 85mm SS, 32 mm Thread
	00-1402-7390	7.3mm Cannulated Screw, 90mm SS, 32 mm Thread
	00-1402-1095	7.3mm Cannulated Screw, 95mm SS, 32 mm Thread
	00-1402-1100	7.3mm Cannulated Screw, 100mm SS, 32 mm Thread
	00-1402-1105	7.3mm Cannulated Screw, 105mm SS, 32 mm Thread
	00-1402-1110	7.3mm Cannulated Screw, 110mm SS, 32 mm Thread
	00-1402-1115	7.3mm Cannulated Screw, 115mm SS, 32 mm Thread
	00-1402-1120	7.3mm Cannulated Screw, 120mm SS, 32 mm Thread
	00-1402-1125	7.3mm Cannulated Screw, 125mm SS, 32 mm Thread
	00-1402-1130	7.3mm Cannulated Screw, 130mm SS, 32 mm Thread

WASHER

Product	Item Number	Description
	00-1402-1000	6.5mm/7.3mm Cannulated-Screw Washer

INSTRUMENTS

CASE 1, TRAY 1, LONG INSTRUMENTS

Item Number	Description
01-1402-0015	5.0mm Hex Cannulated Driver, Non Retaining, Long
01-1402-0008	5.0mm Hex Cannulated Driver, Retaining, Long
01-1402-0332	3.2mm Threaded k-wire, 375mm
01-1402-0132	3.2mm Smooth k-wire, 375mm
01-1402-0005	5.2mm Cannulated Drill, Long
01-1402-0002	6.5mm Cannulated Tap, Long
01-1402-0004	7.3mm Cannulated Tap, Long
01-1402-0013	Direct Measuring Device - 3.2mm x 375mm Wire
01-1402-0069	Percutaneous Screw Sleeve w/Handle, Long
01-1402-0369	Percutaneous Wire Sleeve, Long
01-1402-0269	Percutaneous Trocar Insert, Long
01-1402-0169	Percutaneous Drill Sleeve Insert, Long
01-1402-0020	3.2mm SCFE Wire Guide Inserter, Long
01-1402-0121	3.2mm Cleaning Stylet, Long
01-1071-011	Screw Holding Forceps
01-1071-005	Zimmer Inline Ratchet

INSTRUMENTS

CASE 2, TRAY 2, SHORT INSTRUMENTS

Item Number	Description
01-1402-0011	5.0mm Hex Cannulated Driver, Non-Retaining, Short
01-1402-0007	5.0mm Hex Cannulated Driver, Retaining Short
01-1402-0432	3.2mm Threaded k-wire, 300mm
01-1402-0232	3.2mm Smooth k-wire, 300mm
01-1402-0006	5.2mm Cannulated Drill, Short
01-1402-0017	Cannulated Countersink 6.5mm/7.3mm screw, Short
01-1402-0014	Direct Measuring Device - 3.2mm x 300mm Wire
01-1402-0070	Percutaneous Screw Sleeve w/Handle, Short
01-1402-0370	Percutaneous Wire Sleeve, Short
01-1402-0270	Percutaneous Trocar Insert, Short
01-1402-0170	Percutaneous Drill Sleeve Insert, Short
01-1402-0023	Cannulation Easy Out
01-1402-0037	5.0mm Hex Easy Out, Cannulated
01-1402-0025	7.55mm Trephine
01-1402-0027	6.75mm Trephine,
01-1402-0028	Screw Removal Driver
01-1071-005	Zimmer Inline Ratchet
01-1400-0100	3.2mm Parallel Wire Guide, Adjustable
01-1071-011	Screw Holding Forceps

SPECIAL ORDER INSTRUMENTS

Item Number	Description
01-1402-0129	Over Screw Head Trephine
01-1402-0532	3.2mm x 800mm Threaded Guide Wire
01-1402-0029	5.0mm Hex Solid driver, short
01-1402-0030	5.0mm Hex Solid driver, long

IMPORTANT MEDICAL INFORMATION

Warnings

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
- The OrthoPediatics' Cannulated Screw System is not intended to support the patient's weight as excessive loads may cause the device to fail. Weight bear will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.
- Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant and instrument system.
- Repeat use of a surgical implant is strictly forbidden. Each implant used once must be disposed of properly. This is the same even where it appears to be intact. The device may have small faults or internal stresses that if the item is re-used may lead to fatigue failure.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from different sources being mixed.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, OrthoPediatics recommends the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening. This is especially important for young and active patients. Routine removal of the internal fixation devices after healing may also reduce the occurrence of symptomatic complications of implant breakage, implant loosening or implant related pain.

- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from different sources being mixed.

MRI Safety Information

In non-clinical testing of OrthoPediatics implants were determined to be MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 1.5 Tesla and 3.0 Tesla
- The Maximum spatial gradient magnetic field of 2000 Gauss/cm or less
- Maximum whole-body average specific absorption rate (SAR) of 1.0 W/kg or less for 15 minutes of scanning per pulse sequence.

MRI-Related Heating

- Based on measurements and calculations of RF heating according to ASTM F2182-11a, the Orthopediatrics' Cannulated Screw System is expected to produce a maximum temperature rise of 6.4°C for a whole-body SAR of 1.0W/Kg for a 15-minute scan.

Artifact Information

- MR image quality may be comprised if the area of interest is in the same area or relatively close to the position of OrthoPediatics implants. The maximum artifact beyond the implant was 55mm for the spin echo sequence and 60mm for the gradient echo sequence in a 3.0 Tesla MR system (GE Signa HDxt MR System). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The presence of other implants or the health state of the patient may require a modification of the MR conditions.

IMPORTANT MEDICAL INFORMATION

Adverse Effects:

The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

- Delayed or non-union that may lead to breakage of the implant
- Loss of fixation, attributable to non-union, osteoporosis, unstable comminuted fractures
- Bending, fracture, or migration of the implant
- Metal sensitivity, or allergic reaction to a foreign body
- Limb shortening, or decrease in bone density, due to compression of the fracture or bone resorption
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis of bone
- Infection, both deep and superficial
- Death
- Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis

These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.



CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

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