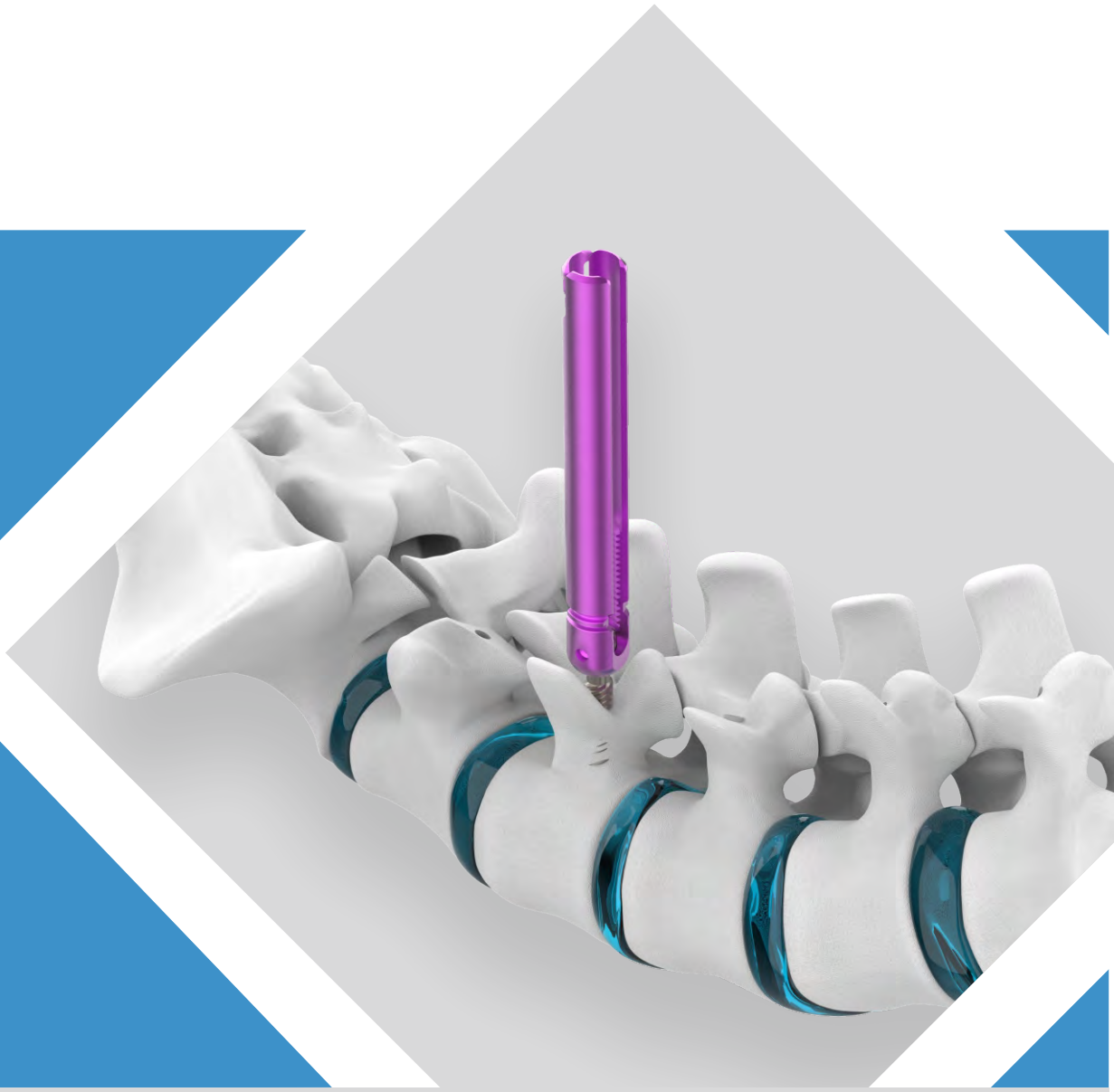
Auxein®



Surgical Technique

VERTAUX MIS Screw Spine System

www.auxein.com

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Our Achievements

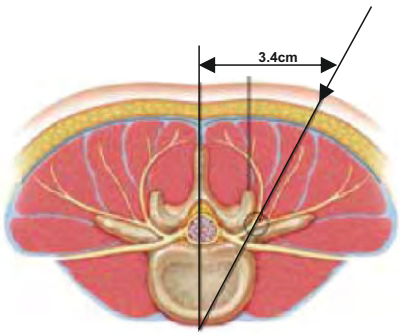
Accessing the Pedicle

Patient Positioning

The patient should be positioned prone, lying flat on the table. Some tables have pedestals that make it difficult to get a true AP view of the pedicles. While adjustments in patient positioning can be made, tables that limit good AP and lateral fluoroscopy should be generally avoided.

Preoperative Planning

- Verifying that adequate fluoroscopic images of the pedicles can be obtained in both AP and lateral views before proceeding.
- On AP and lateral fluoroscopy, the endplates should be parallel and the spinous processes should lie midway between both pedicles.

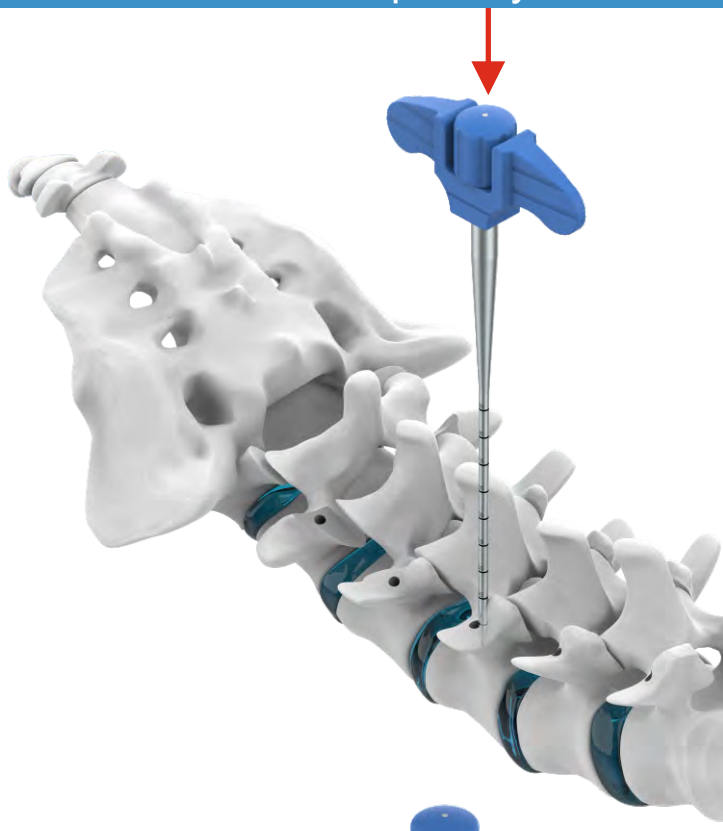


Skin Incision

- The Guide Pin may be used to verify the appropriate location of the skin incisions. The Guide Pin is first positioned on the skin perpendicular to the spinal column and directly through the projection center of the pedicles on an AP image. Mark the location of the pin with the surgical marker.
- Place the Guide Pin parallel to the spinal column to lay the projection of Guide Pin laterally to the lateral edge of targeted and adjacent pedicles on an AP image. Mark the location of the pin with the surgical marker.
- The incision should be at least lcm lateral to intersection line and adjusted according to different patient anatomy.

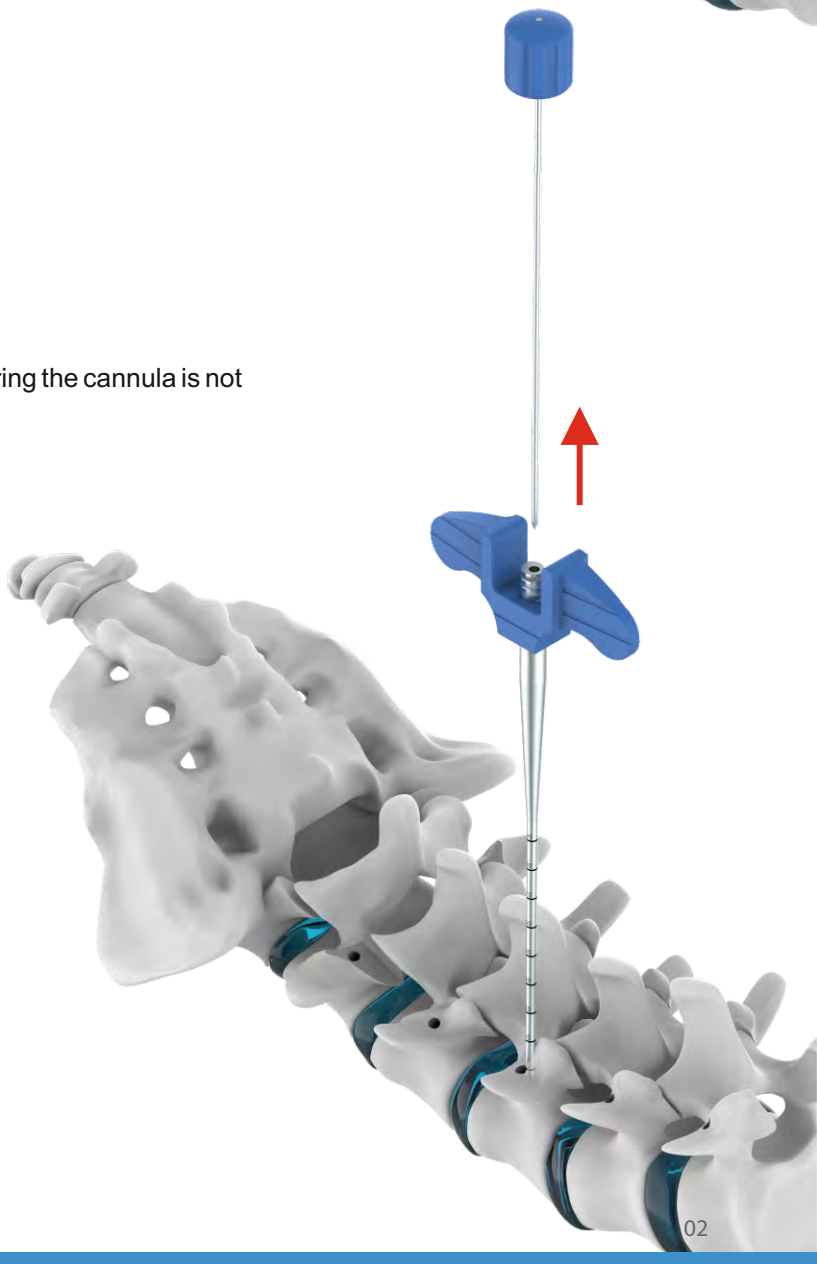
Pedicle Access

Once the position is confirmed, a skin and fascia! incision is then made approximately 15mm in length. A Starting Needle is used to gain access to the pedicle. After placing the Starting Needle at tthe intersection of the facet and the transverse process, and confirming direction on fluoroscopy, the needle is advanced into the pedicle.

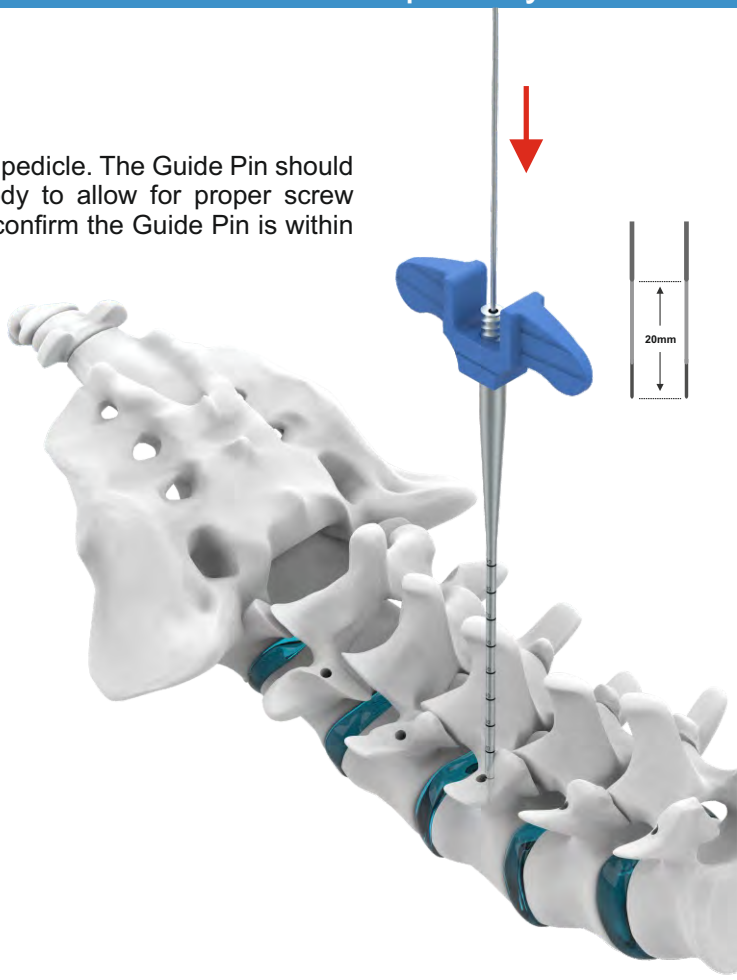


AP and lateral fluoroscopy should be used intermittently as needed to confirm direction. An AP image should show the needle tip initially at the lateral margin of the pedicle. As the needle advances towards the base of the pedicle on the lateral image, it should approach the pedicle center on the AP image. The Starting Needle should be advanced across the junction of the pedicle and the vertebral body to allow easier placement of the Guide Wire. AP and lateral fluoroscopy should be used to confirm the needle is within pedicle confines.

- Remove the inner stylet of the Starting Needle, ensuring the cannula is not removed from the pedicle.



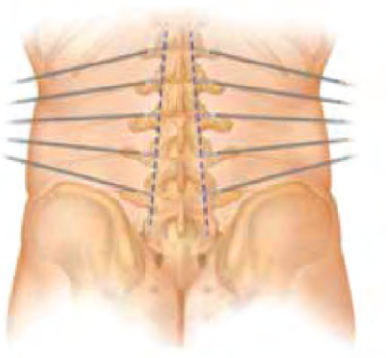
- The Guide Pin is inserted through the cannula and into the pedicle. The Guide Pin should be advanced approximately 20mm into the vertebral body to allow for proper screw placement. AP and lateral fluoroscopy should be used to confirm the Guide Pin is within pedicle and vertebral body confines.

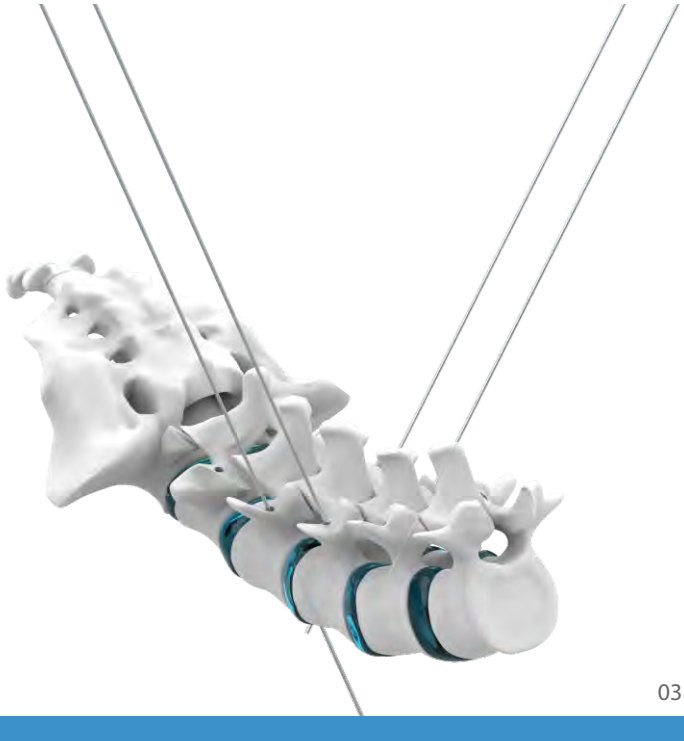


- Care should be taken when insert the Guide Pin. Depth marks of Smm each on the Guide Pin helps contribute to confirm the insertion depth.

- When the Guide Pin has been advanced into the proper place, the cannula of the Starting Needle is carefully removed, leaving only the Guide Pin in place.

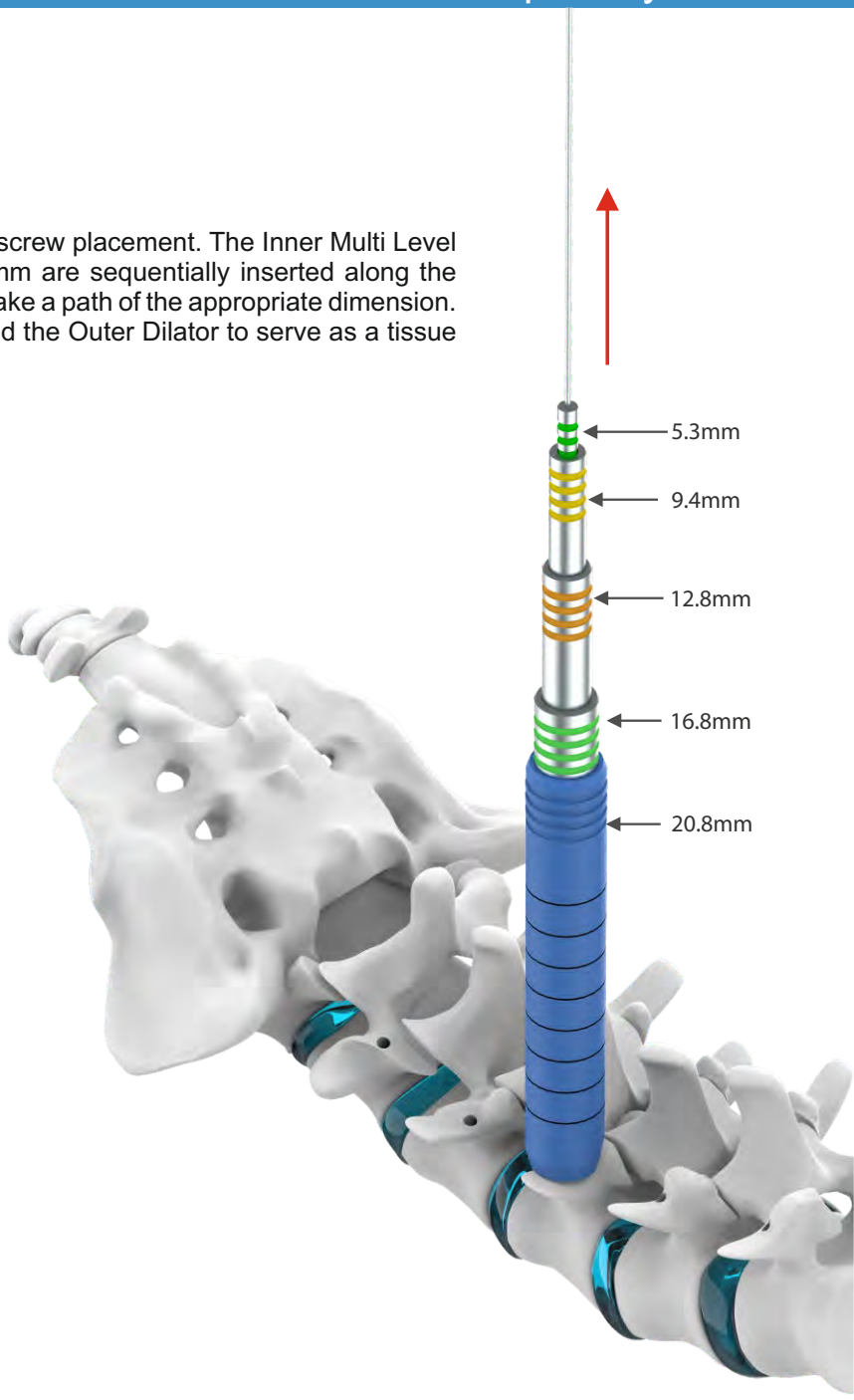
Note:
for multi-level surgery, it is suggested to place the Guide Pins into all levels before inserting pedicle screws.



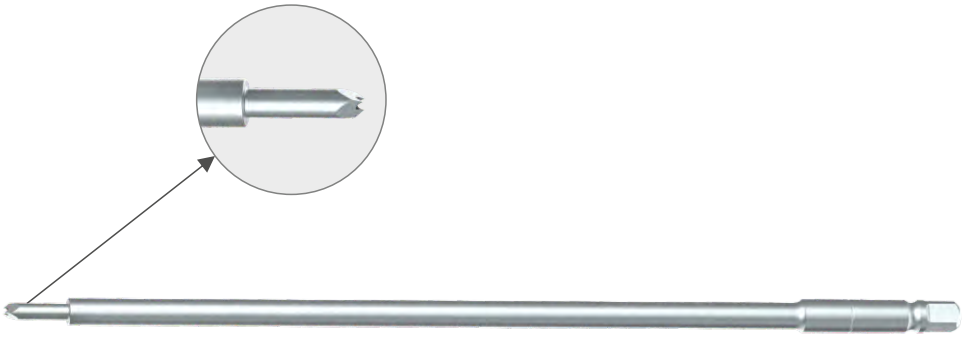


Pedicle Preparation

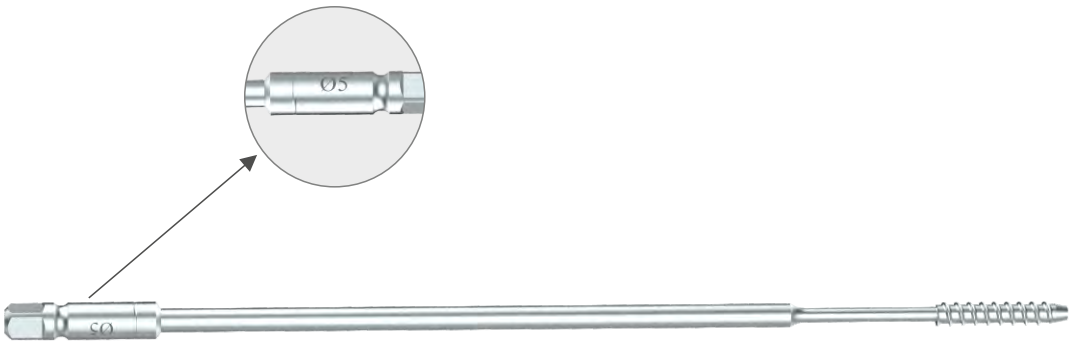
The fascia and muscle must be dilated to allow for screw placement. The Inner Multi Level Dilator 9.4mm and Outer Multi Level Dilator 12.8mm are sequentially inserted along the Guide Pin and docked on bony anatomy to gently make a path of the appropriate dimension. Remove the Inner Dilator, leaving the Guide Pin and the Outer Dilator to serve as a tissue protection sleeve during tapping.



Over the Guide Pin and through the Outer Multi Level Dilator 12.8mm, insert the Awl Cannulated to make an opening on the cortical bone at the starting point.



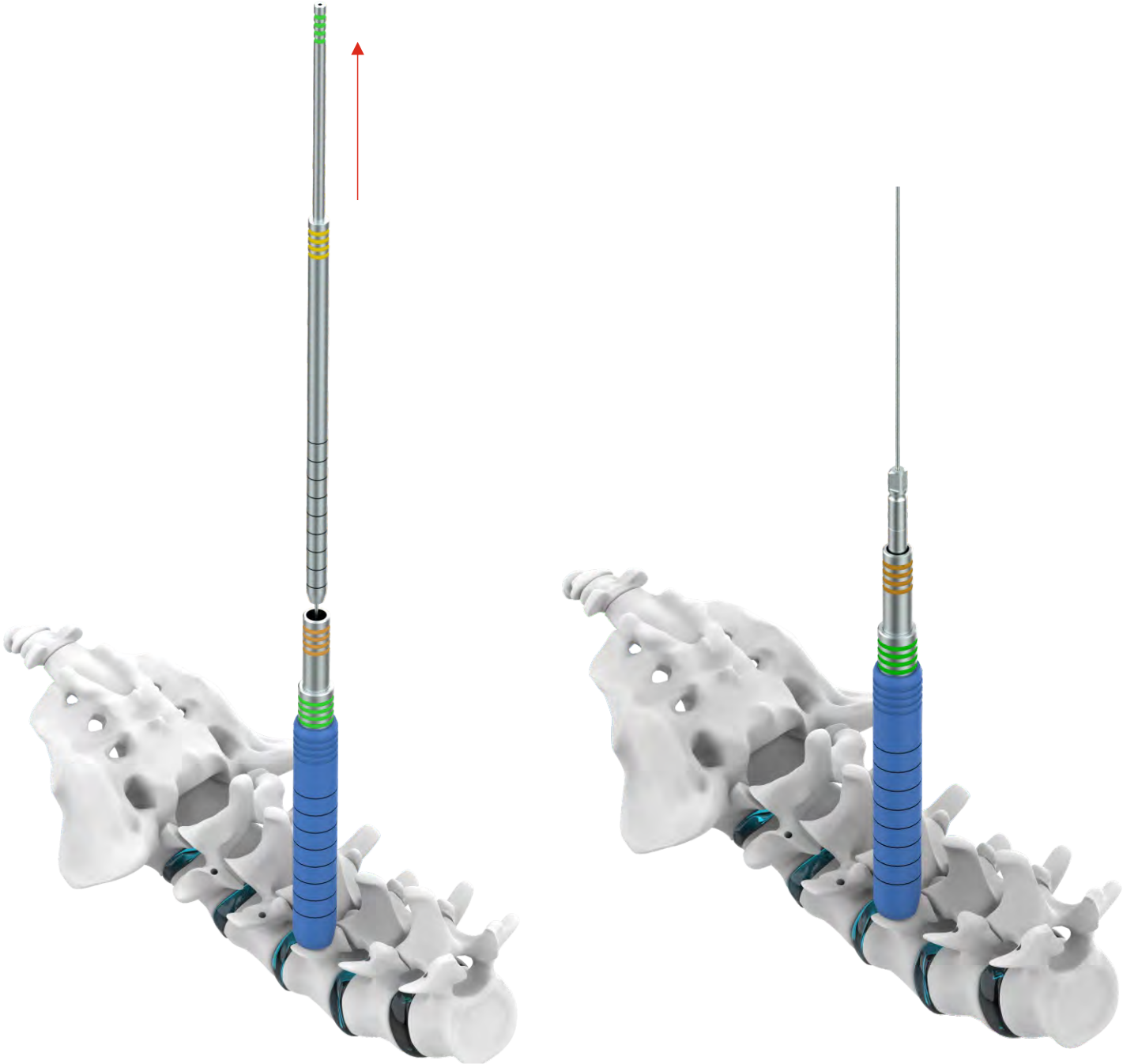
The pedicle is then prepared by driving the Tap Cannulated over the Guide Pin and through the Outer Multi Level Dilator 12.8mm. When tapping, the depth marks on both Tap and Guide Pin should be noticed to avoid unintentional advancement or back-out of the Guide Pin.



- Ensure not to tap beyond the tip of the Guide Pin because the bone within the end of the Tap may cause the Guide Pin to pull out as you remove the Tap.

- Screw length can be estimated by referencing the depth marks on the Tap Cannulated.

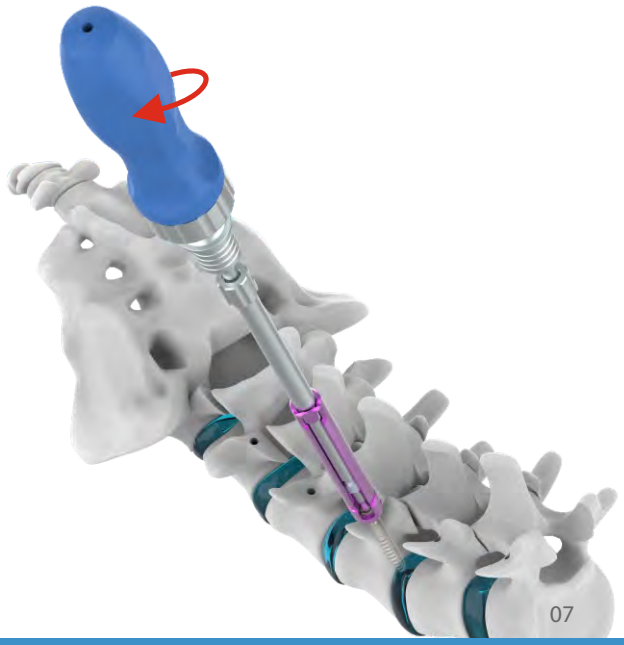
Remove the Tap exercising great care to not remove the Guide Pin.



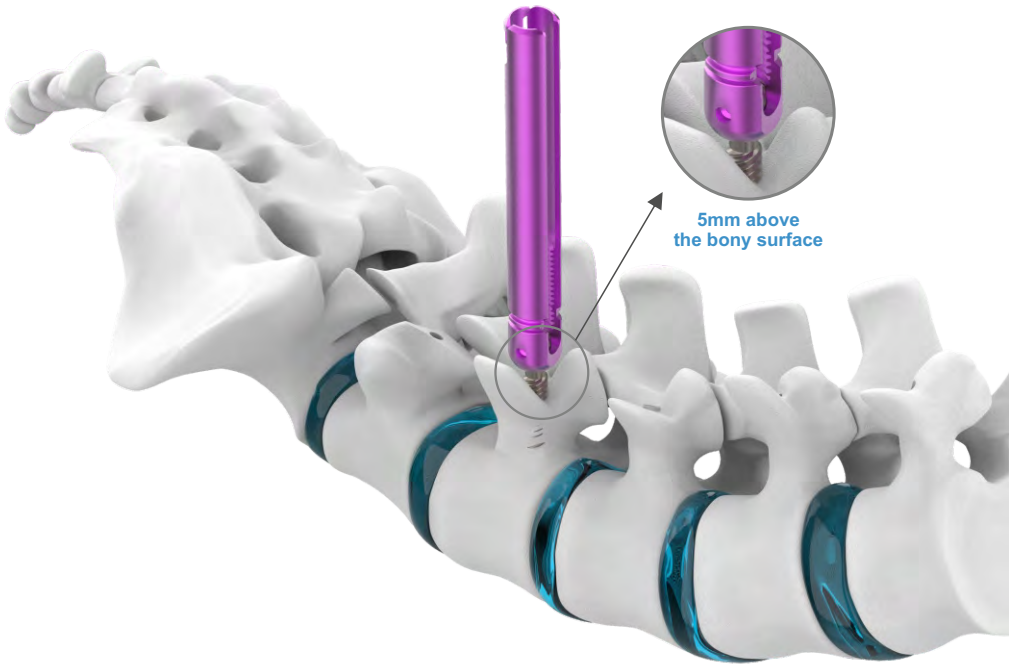
Screw Insertion

Connect the Screwdriver to the Handle with Quick Coupling. Select the appropriate screw and insert the tip of the Screwdriver into the screw head until the Screwdriver fully engages the screw. Thread the outer sleeve of the Screwdriver into the head of the screw until tight.

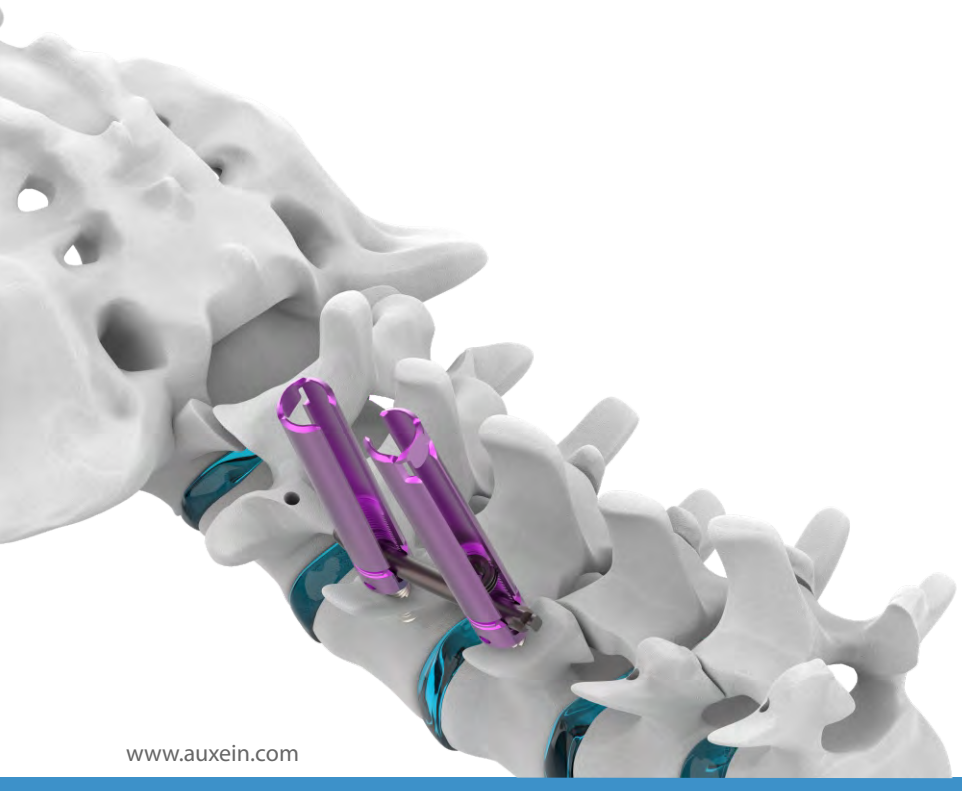
- One of the three Outer Sleeves can be selected according to patient skin thickness and placed over the Outer Dilator to protect the surrounding tissues when insert the screw.
- The screw is inserted over the Guide Pin and into pedicle after remove the Outer Dilator.



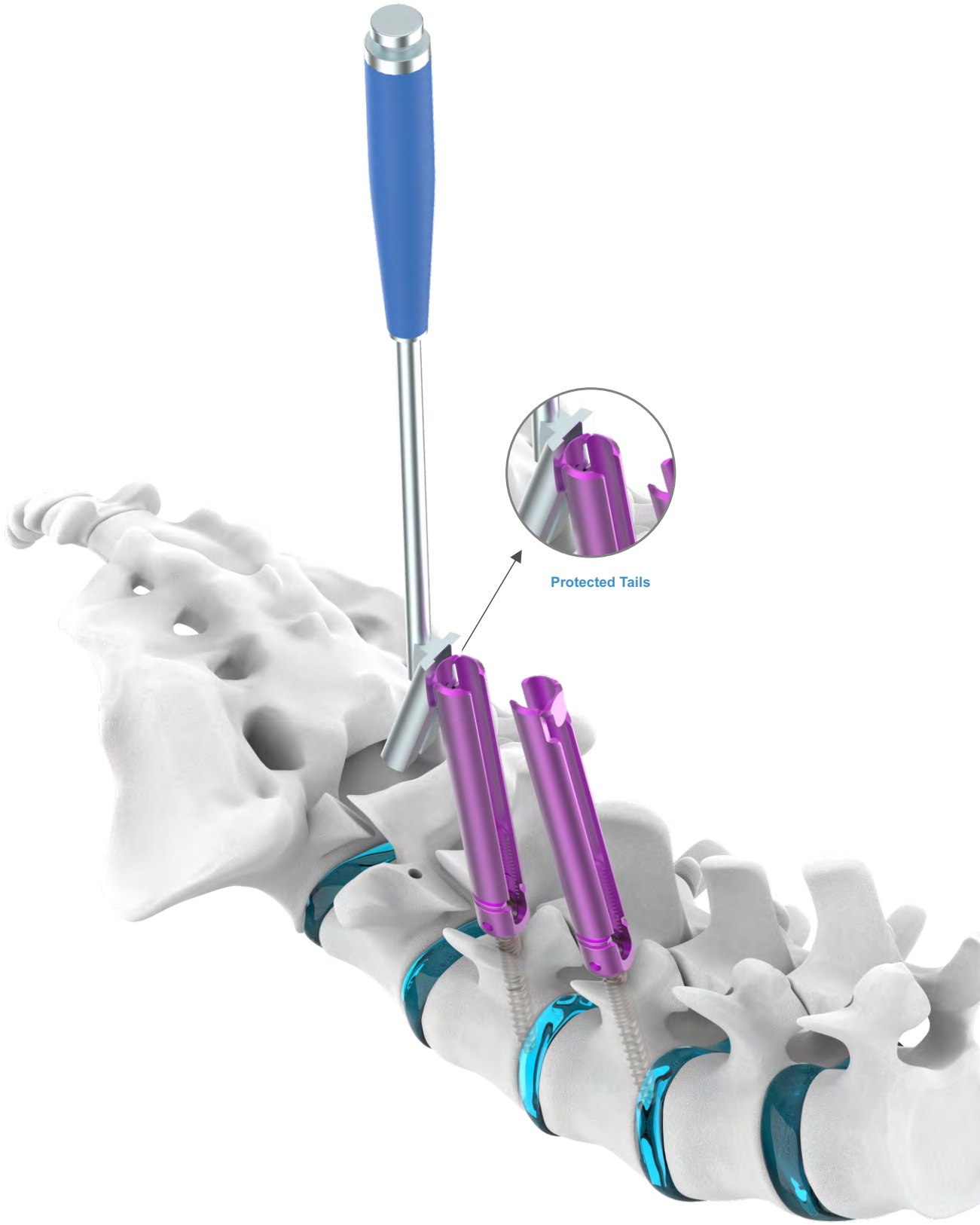
- After gaining initial purchase of the pedicle with the screw(about 20mm in depth), remove the Guide Pin to prevent it from being advanced too far. Then continue the screw insertion to the appropriate depth. It is suggested not to insert the screw too far, and to keep the bottom of t he screw tulip head above the bony surface about 5mm. If the multiaxial head of the Vertaux MIS Screw is inserted flush with the bone, it will lose its multiaxial capability .



- Repeat the above steps to insert the remaining screws. Check the screw multiaxial capability and adjust the screw height to match the rod curve. Under fluoroscopy, visualize screws to ensure they line up coronally as much as possible.

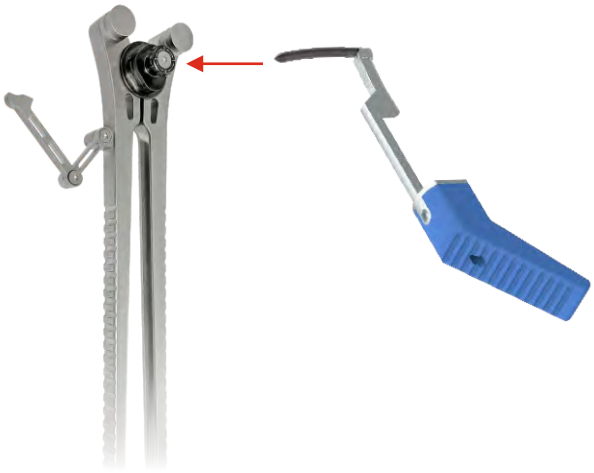


- Once all the screws are in place, use the Tulip Break Off Iron to break off the two protected tails on the screw long arms.



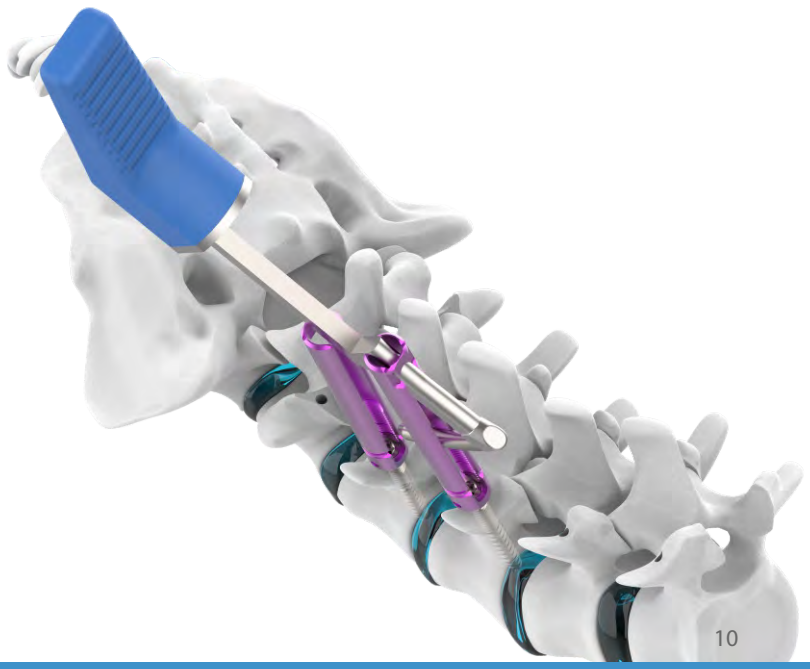
Rod Placement

- Select the appropriate-length rod, and connect the rod to the Rod Holder. Use the Rod Holder Screwdriver to help lock the rod to the Rod Holder.

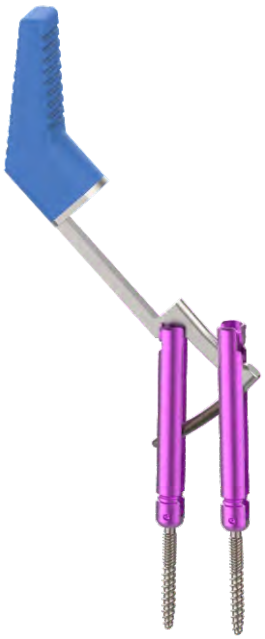


- If needed use the Rod Bender to bend the rod according to patient anatomy. As there is connecting clasp on the Rod Holder, it is suggested not to bend the rod prior to placing it in the Rod Holder.

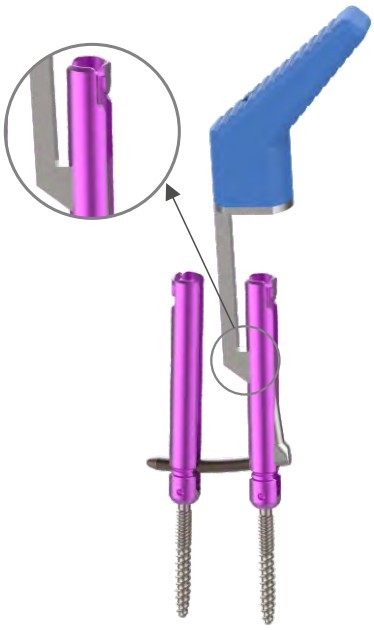
- Perpendicular to the skin pass the rod through the cannulated long arms of the first screw until the rod tip reaches the bottom of the screw saddle.



- Advance the rod below the fiscia to the second screw and seat the rod along the first screw long arms and down to the screw saddle bottom.



- To ensure the Rod Holder blocking part is parallel to the long arms of the first screw which can help guarantee the rod has passed through the first screw long enough and the screw cap will not press down on the connecting clasp of the Rod Holder.



- Rotate the second screw by hand to test the rod passage. If the second screw rotates freely, then the rod has not passed through the second screw.

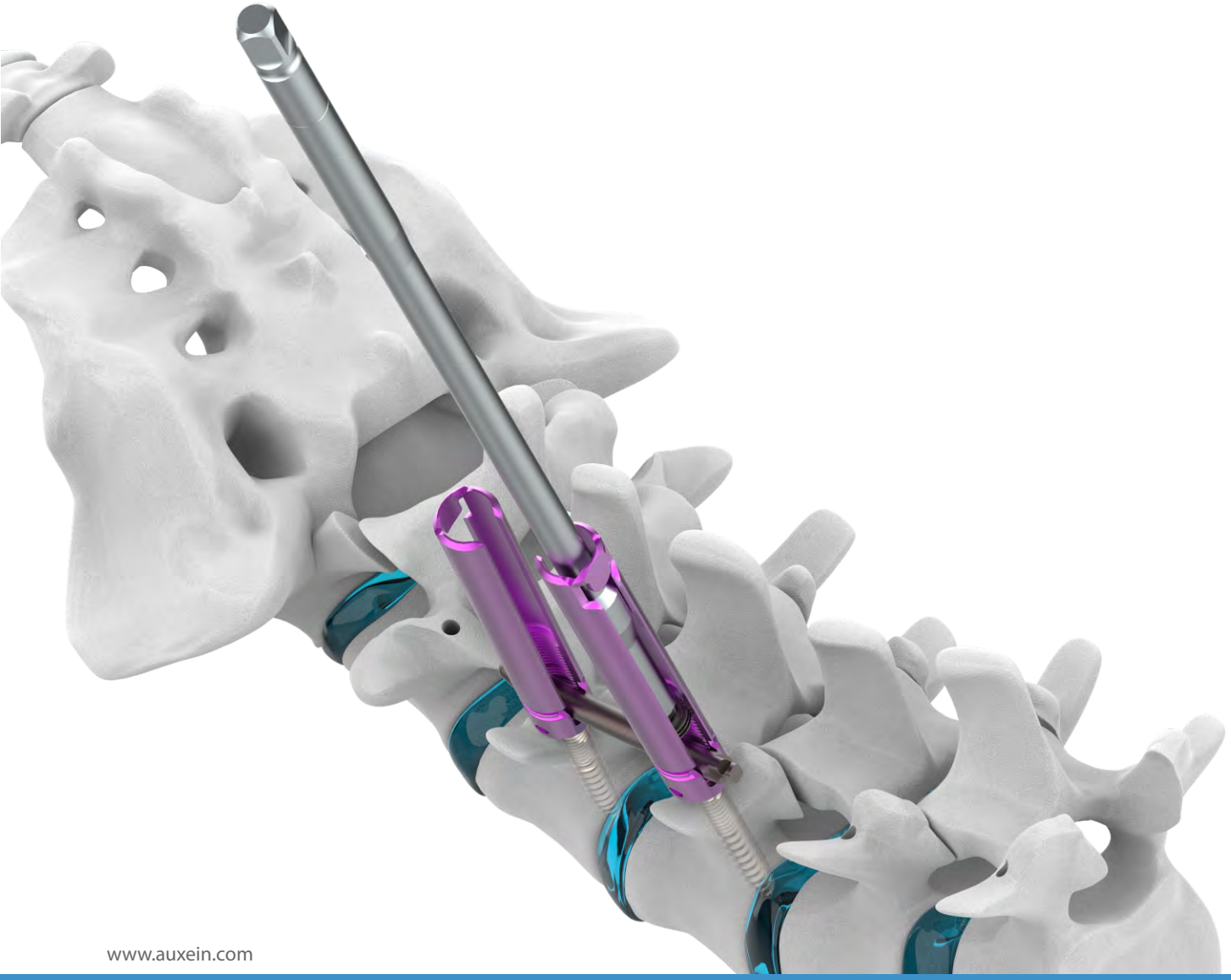
- For multilevel operation, it is suggested to use the Long Rod Holder.

Cap Insertion

- Attach a screw cap to the Reduction Multiaxial Screwdriver, and rotate the caudal knob to help hold the screw cap more stable. Do not over-tighten the Reduction Multiaxial Screwdriver which may cause damage to it.

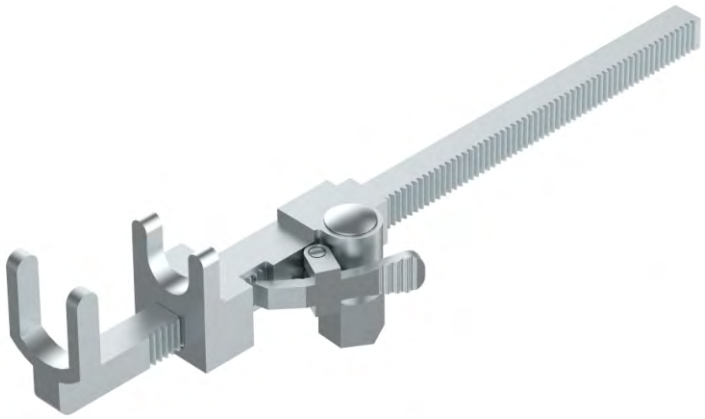
- Insert all the screw cap into the screws and moderately tighten those caps to maintain the screw multiaxial capability which ensures the screw long arm can still be adjusted during the later steps.

- Attention should be paid to the two marker lines on the Reduction Multiaxial Screwdriver. When the bottom mark line comes flush with screw long arms, it means the screw cap has come in touch with the screw thread; when the upper marker line sinks below screw long arms, it means the screw cap has been inserted to the bottommost thread. Rotate the caudal knob anticlockwise to remove the Reduction Multiaxial Screwdriver.

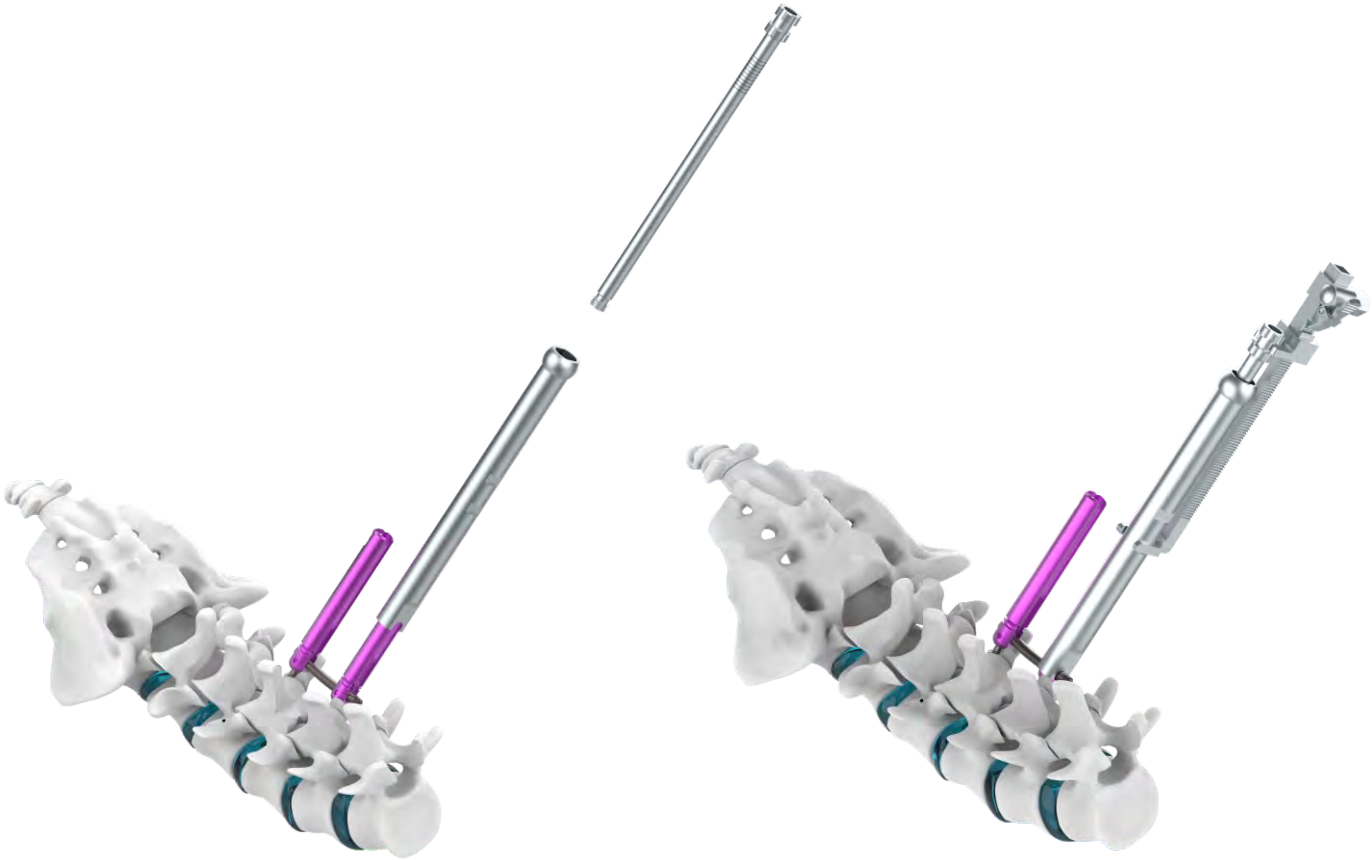


Reduction

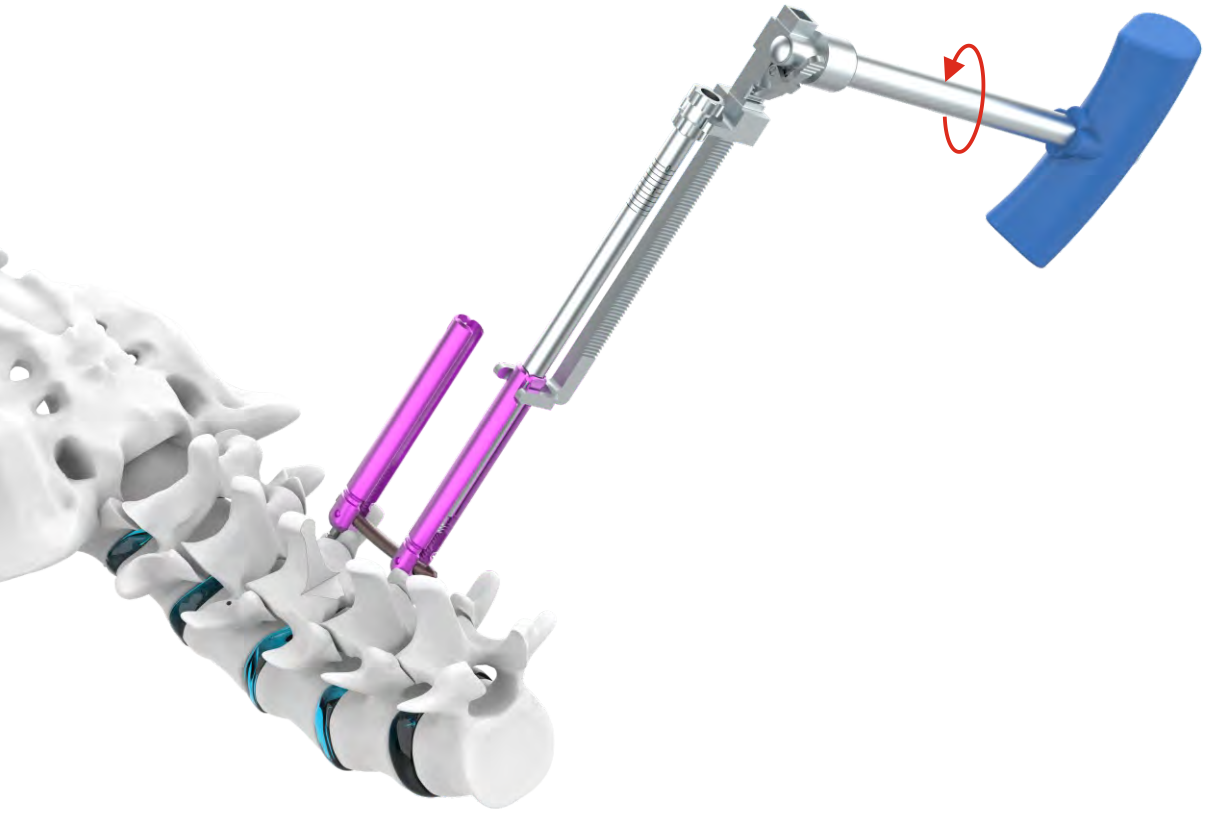
- Generally, it can help seat the rod and achieve reduction when we insert the screw cap. The Reducer can be used as well to achieve reduction if required.



- Place the Reduction Extension A for Vertaux MIS Instrument Set over the screw long arms and down to the rod. Draw close the Reducer and assemble it onto the screw: there are two U-shaped openings on Reducer. First hem the screw arm in the bottom U-shape opening which is then seated onto the Reduction Extension A for Vertaux MIS Instrument Set. Slightly press the screw long arms to plug two teeth of the upper U-shape opening into the reduction slots on the screw arms.

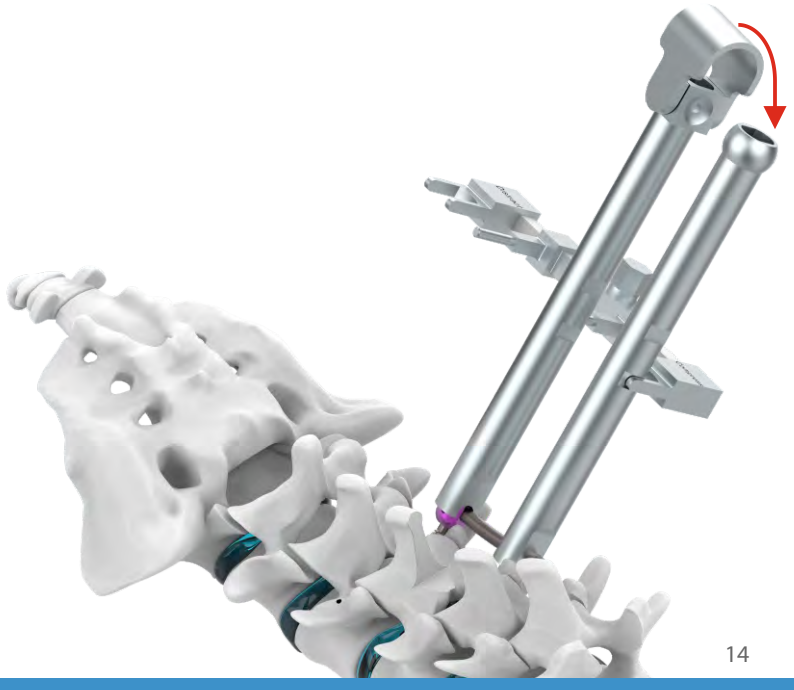


- Rotate the hex knob on Reducer by using the T Handle Screwdriver, Hex 11mm to reduce the screw.

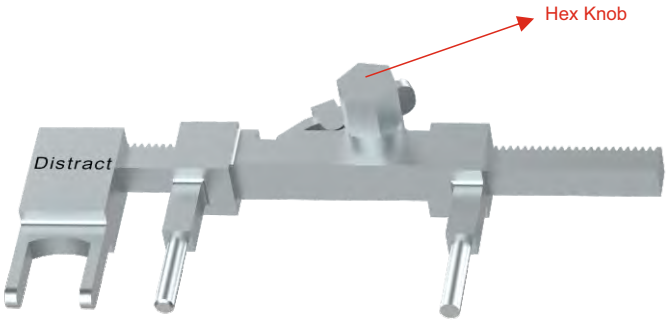


Distraction/Compression

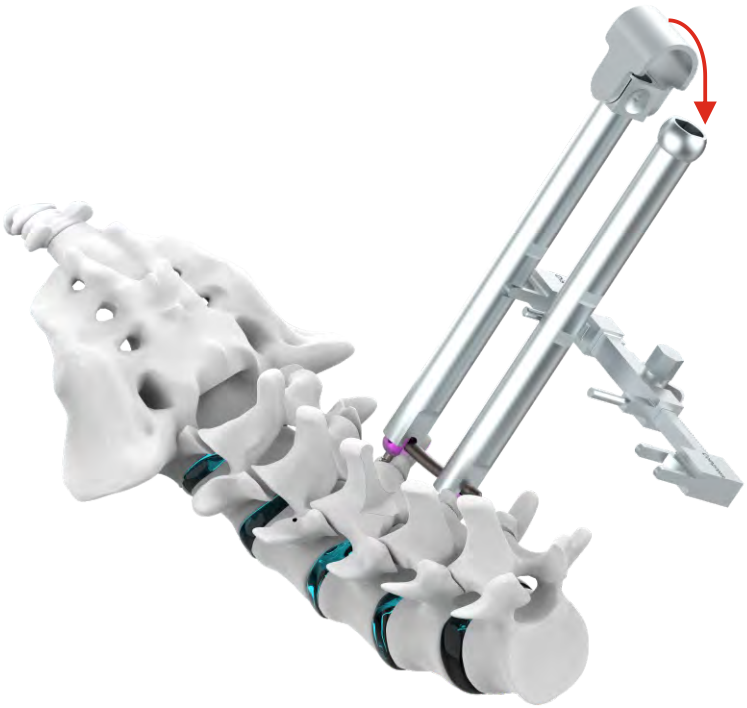
- The Counter Torque can work as a lever when perform distraction or compression. Over the screw long arms slide the Counter Torque down to the rod. Reduction Extension B for Vertaux MIS Instrument Set, padle locks onto Reduction Extension A for Vertaux MIS Instrument Set, before distraction or compression.



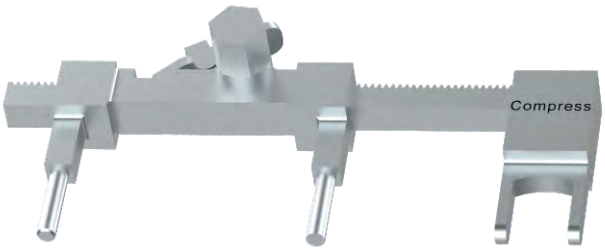
- Adjust the two U-shaped openings on Distractor to the appropriate distance to fit the two adjacent Counter Torques in. When assemble the Distractor, keep the side with hex knob on the top.



- Hold the upper ends of the Counter Torques together as a pivot. Rotate the hex knob on the Distractor by using the T Handle Screwdriver, Hex 11mm to perform distraction.



- Replace the Distractor with Compressor, and take the above steps to perform compression if needed.

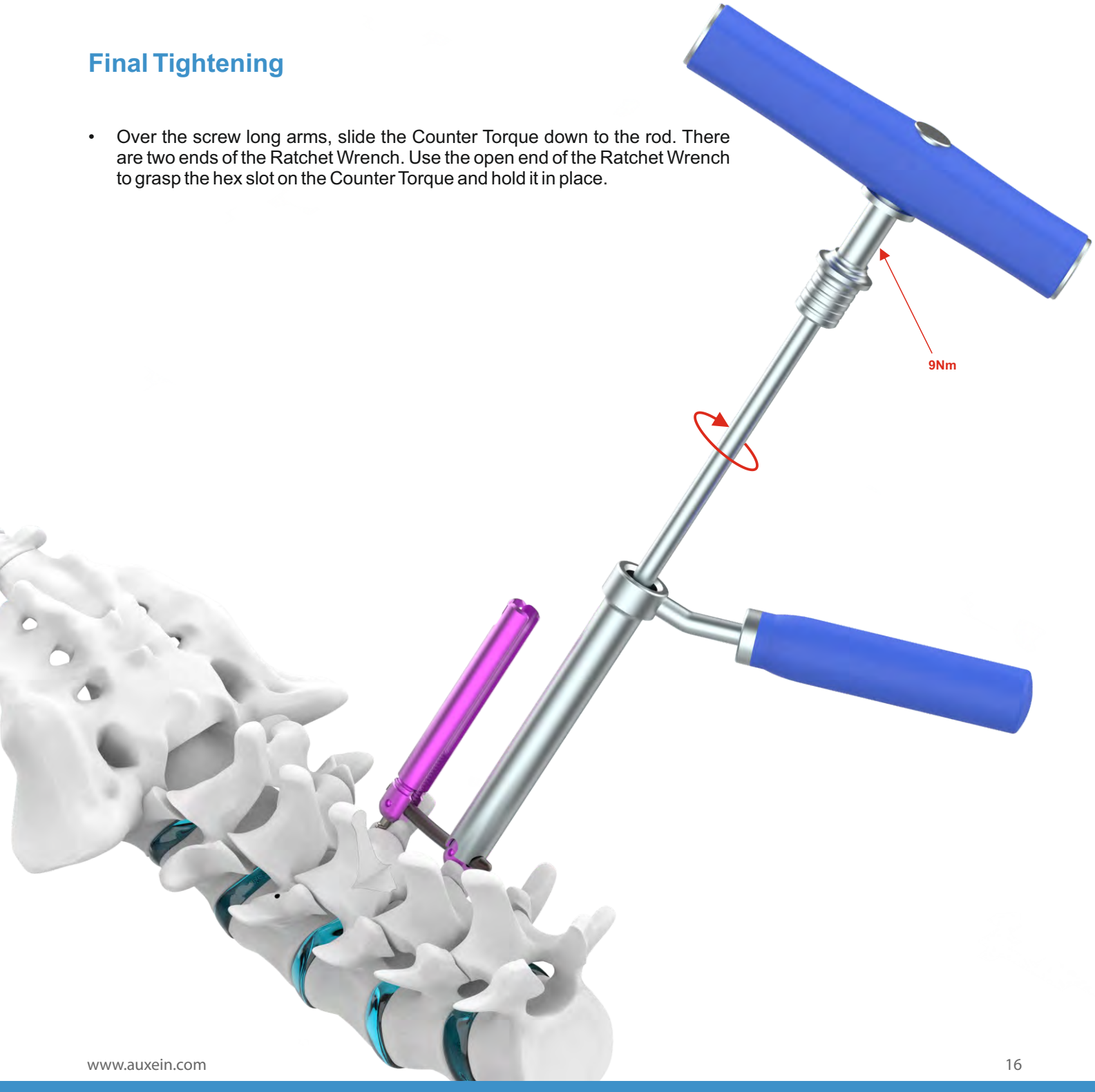


Remove Rod Holder

- Before remove the Rod Holder, confirm with fluoroscopy that both ends of the rod have passed through screw saddles about 5mm.
- Insert the Rod Holder Screwdriver and rotate anticlockwise to loosen the clasp on the Rod Holder. Release the rod and remove the Rod Holder from body.

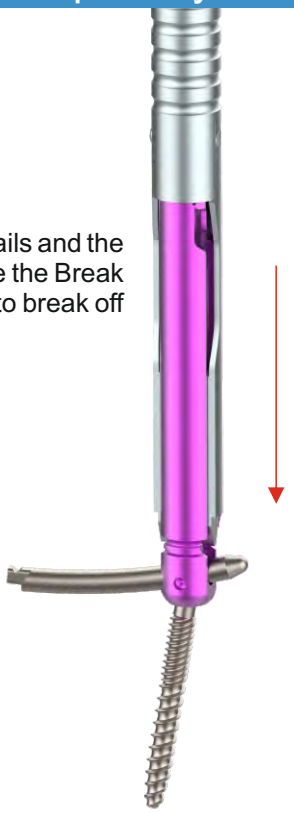
Final Tightening

- Over the screw long arms, slide the Counter Torque down to the rod. There are two ends of the Ratchet Wrench. Use the open end of the Ratchet Wrench to grasp the hex slot on the Counter Torque and hold it in place.

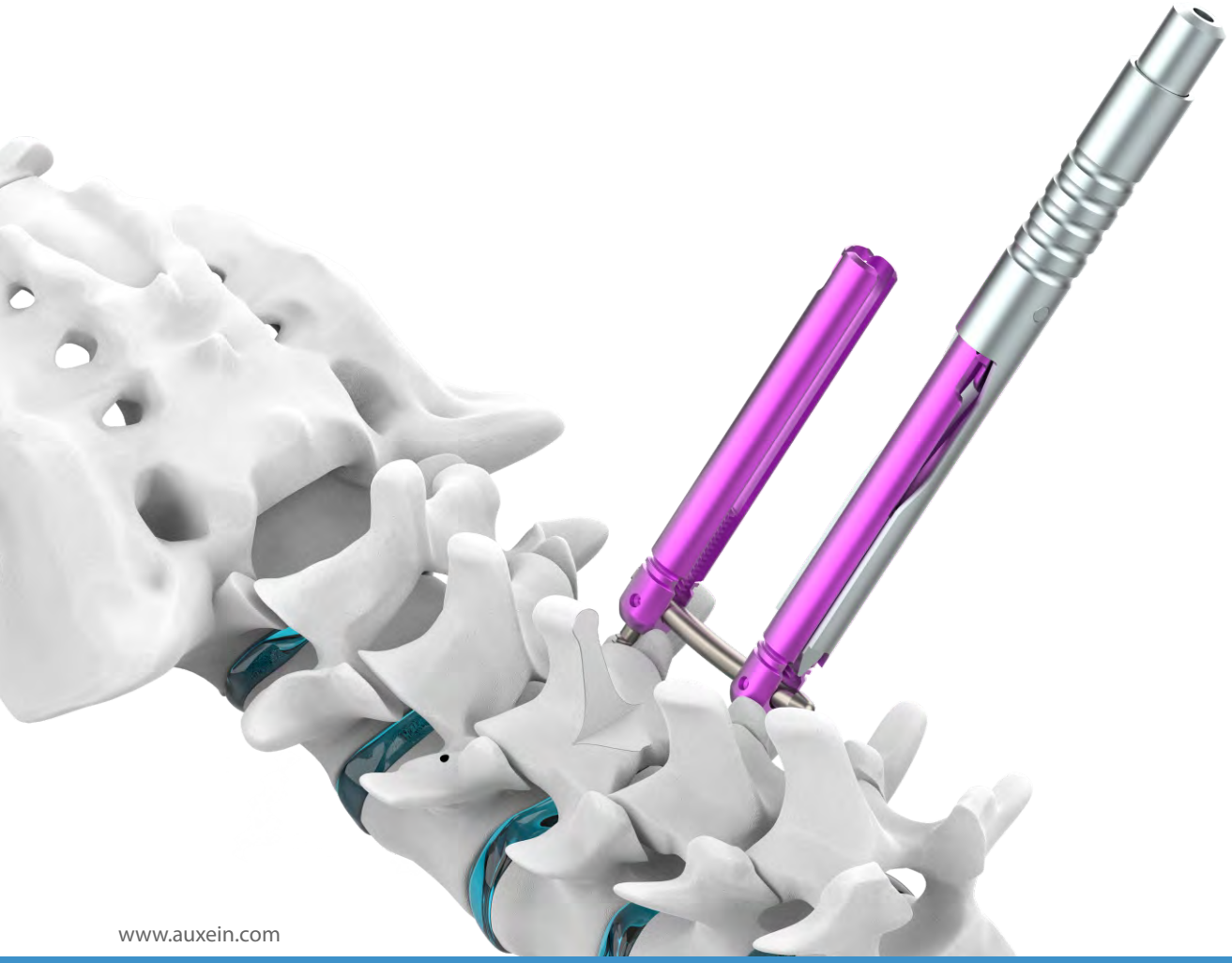


Break Off Screw Long Arms

- There are two ends of the Break Off Iron, one side used to break off the screw protected tails and the other side to break off the screw long arms. Under the protection of Counter Torque, slide the Break Off Iron along the groove on screw long arm down to the bottom. Pull the Break Off Iron to break off the screw long arm. Break off the other side screw arm in the same maneuver.



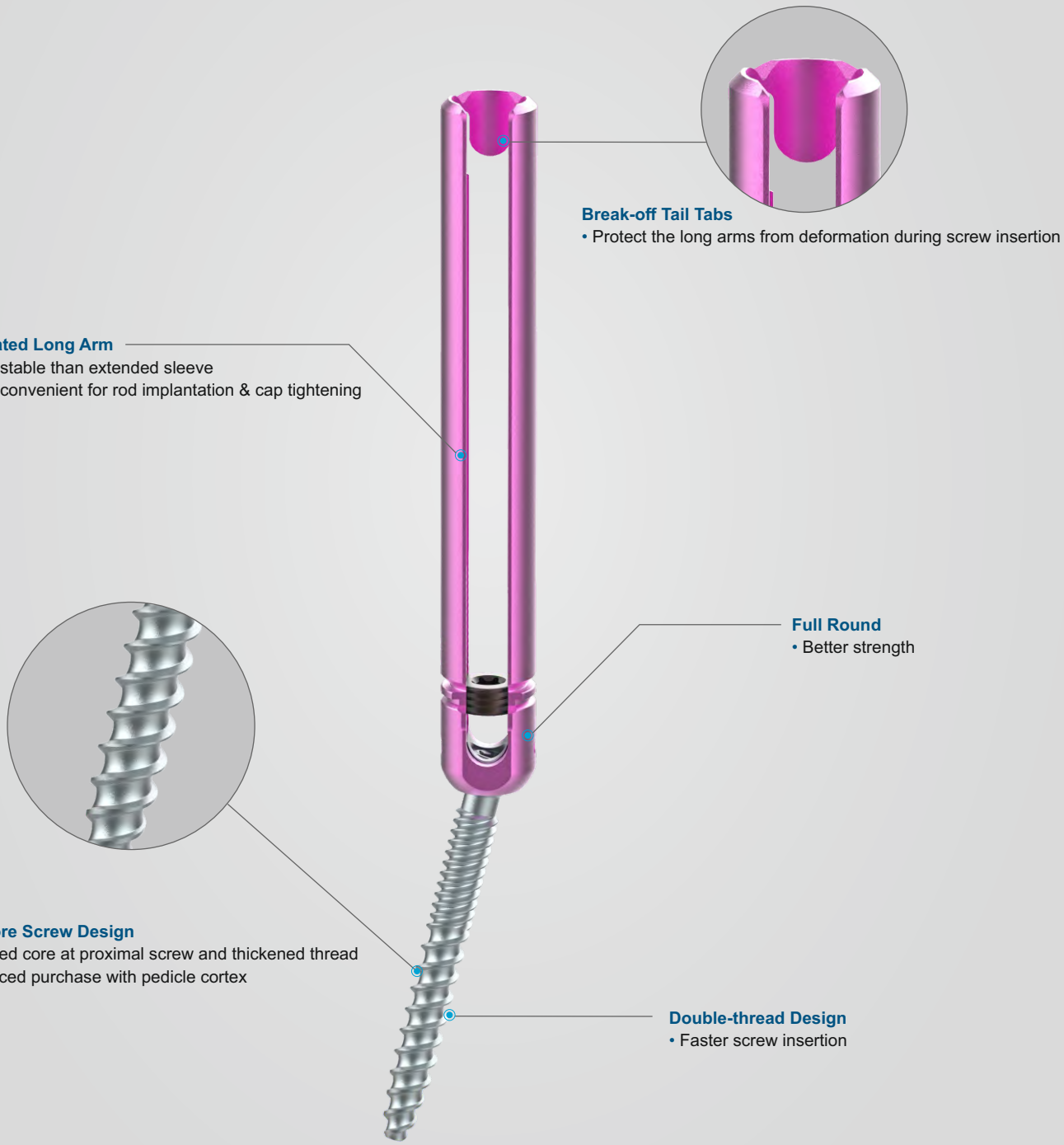
- It is suggested to double tighten the screw cap using Torque-limiting Screwdriver after screw long arms are broken off. Repeat the above steps to break off remaining screws.



VERTAUX MIS SCREW SYSTEM

Colour Parameters as per Ø

Silver	Green	Blue	Pink	Brown
Ø 5.0	Ø 5.5	Ø 6.0	Ø 6.5	Ø 7.0



Break-off Tail Tabs
- Protect the long arms from deformation during screw insertion

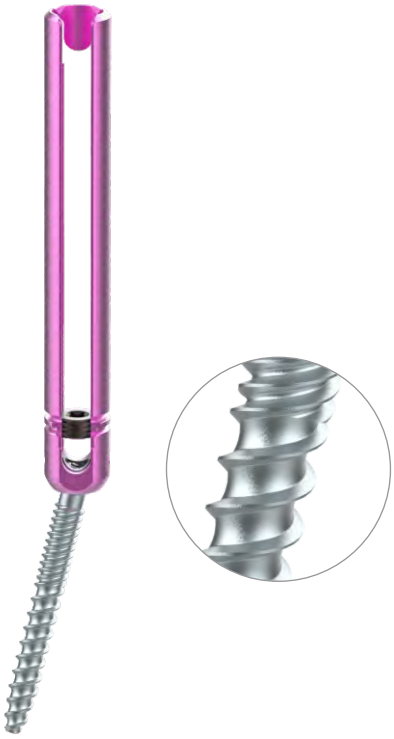
Integrated Long Arm
- More stable than extended sleeve
- More convenient for rod implantation & cap tightening

Full Round
- Better strength

Dual-core Screw Design
- Enlarged core at proximal screw and thickened thread
- Enhanced purchase with pedicle cortex

Double-thread Design
- Faster screw insertion

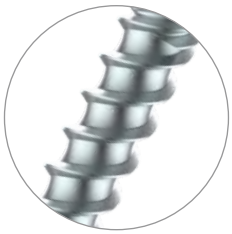
VERTAUX MIS Polyaxial Screw with Cap



Code	Dia X Length
4-109-01TI	Ø5mm x 30mm
4-109-02TI	Ø5mm x 35mm
4-109-03TI	Ø5mm x 40mm
4-109-04TI	Ø5mm x 45mm
4-110-01TI	Ø5.5mm x 30mm
4-110-02TI	Ø5.5mm x 35mm
4-110-03TI	Ø5.5mm x 40mm
4-110-04TI	Ø5.5mm x 45mm
4-110-05TI	Ø5.5mm x 50mm
4-111-01TI	Ø6mm x 30mm
4-111-02TI	Ø6mm x 35mm
4-111-03TI	Ø6mm x 40mm
4-111-04TI	Ø6mm x 45mm
4-111-05TI	Ø6mm x 50mm
4-111-06TI	Ø6mm x 55mm

Code	Dia X Length
4-112-01TI	Ø6.5mm x 30mm
4-112-02TI	Ø6.5mm x 35mm
4-112-03TI	Ø6.5mm x 40mm
4-112-04TI	Ø6.5mm x 45mm
4-112-05TI	Ø6.5mm x 50mm
4-112-06TI	Ø6.5mm x 55mm
4-112-07TI	Ø6.5mm x 60mm
4-113-01TI	Ø7mm x 35mm
4-113-02TI	Ø7mm x 40mm
4-113-03TI	Ø7mm x 45mm
4-113-04TI	Ø7mm x 50mm
4-113-05TI	Ø7mm x 55mm
4-113-06TI	Ø7mm x 60mm

Vertaux MIS Monoaxial Screw with Cap



Code	Dia X Length
4-117-01TI	Ø5mm x 30mm
4-117-02TI	Ø5mm x 35mm
4-117-03TI	Ø5mm x 40mm
4-117-04TI	Ø5mm x 45mm
4-118-01TI	Ø5.5mm x 30mm
4-118-02TI	Ø5.5mm x 35mm
4-118-03TI	Ø5.5mm x 40mm
4-118-04TI	Ø5.5mm x 45mm
4-118-05TI	Ø5.5mm x 50mm
4-119-01TI	Ø6mm x 30mm
4-119-02TI	Ø6mm x 35mm
4-119-03TI	Ø6mm x 40mm
4-119-04TI	Ø6mm x 45mm
4-119-05TI	Ø6mm x 50mm
4-119-06TI	Ø6mm x 55mm

Code	Dia X Length
4-120-01TI	Ø6.5mm x 30mm
4-120-02TI	Ø6.5mm x 35mm
4-120-03TI	Ø6.5mm x 40mm
4-120-04TI	Ø6.5mm x 45mm
4-120-05TI	Ø6.5mm x 50mm
4-120-06TI	Ø6.5mm x 55mm
4-120-07TI	Ø6.5mm x 60mm
4-121-01TI	Ø7mm x 35mm
4-121-02TI	Ø7mm x 40mm
4-121-03TI	Ø7mm x 45mm
4-121-04TI	Ø7mm x 50mm
4-121-05TI	Ø7mm x 55mm
4-121-06TI	Ø7mm x 60mm

VERTAUX MIS Screw Cap

Code
4-114-01TI

Star Head

VERTAUX MIS Rod Ø5.5mm

Code	Length
4-122-01	30mm
4-122-02	35mm
4-122-03	40mm
4-122-04	45mm
4-122-05	50mm
4-122-06	55mm
4-122-07	60mm
4-122-08	65mm
4-122-09	70mm
4-122-10	75mm
4-122-11	80mm
4-122-12	85mm
4-122-13	90mm
4-122-14	95mm
4-122-15	100mm
4-122-16	105mm
4-122-17	110mm
4-122-18	115mm
4-122-19	120mm
4-122-20	125mm
4-122-21	130mm
4-122-22	135mm
4-122-23	140mm
4-122-24	145mm
4-122-25	150mm
4-122-26	155mm
4-122-27	160mm
4-122-28	165mm
4-122-29	170mm
4-122-30	175mm
4-122-31	180mm
4-122-32	185mm
4-122-33	190mm
4-122-34	195mm
4-122-35	200mm
4-122-36	205mm
4-122-37	210mm
4-122-38	215mm
4-122-39	220mm
4-122-40	225mm
4-122-41	230mm
4-122-42	235mm
4-122-43	240mm
4-122-44	245mm
4-122-45	250mm
4-122-46	255mm
4-122-47	260mm
4-122-48	265mm
4-122-49	270mm

Code	Length
4-122-50	275mm
4-122-51	280mm
4-122-52	285mm
4-122-53	290mm
4-122-54	295mm
4-122-55	300mm
4-122-56	305mm
4-122-57	310mm
4-122-58	315mm
4-122-59	320mm
4-122-60	325mm
4-122-61	330mm
4-122-62	335mm
4-122-63	340mm
4-122-64	345mm
4-122-65	350mm
4-122-66	355mm
4-122-67	360mm
4-122-68	365mm
4-122-69	370mm
4-122-70	375mm
4-122-71	380mm
4-122-72	385mm
4-122-73	390mm
4-122-74	395mm
4-122-75	400mm
4-122-76	405mm
4-122-77	410mm
4-122-78	415mm
4-122-79	420mm
4-122-80	425mm
4-122-81	430mm
4-122-82	435mm
4-122-83	440mm
4-122-84	445mm
4-122-85	450mm
4-122-86	455mm
4-122-87	460mm
4-122-88	465mm
4-122-89	470mm
4-122-90	475mm
4-122-91	480mm
4-122-92	485mm
4-122-93	490mm
4-122-94	495mm
4-122-95	500mm

7-145-01 Guide Wire,Ø1.5X500 for Vertaux MIS Screw

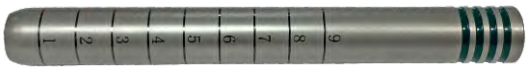
7-145-02 Inserted needle for Vertaux MIS Screw

7-145-03 Multiple Level Dilator 5.3mm for Vertaux MIS Screw

7-145-04 Multiple Level Dilator 9.4mm for Vertaux MIS Screw

7-145-05 Multiple Level Dilator 12.8mm for Vertaux MIS Screw

7-145-06 Multiple Level Dilator 16.8mm for Vertaux MIS Screw



7-145-07 Multiple Level Dilator 20.8mm for Vertaux MIS Screw

7-145-08 Cannulated Tap Ø1.5/Ø5.0 for Vertaux MIS Screw

7-145-09 Cannulated Tap Ø1.5/Ø5.5 for Vertaux MIS Screw

7-145-10 Cannulated Tap Ø1.5/Ø6.0 for Vertaux MIS Screw

7-145-11 Cannulated Tap Ø1.5/Ø6.5 for Vertaux MIS Screw

7-145-12 Cannulated Tap Ø1.5/Ø7.0 for Vertaux MIS Screw

7-145-13 Cannulated Tap Ø1.5/Ø7.5 for Vertaux MIS Screw

7-145-14 Cannulated Quick Change Handle for Vertaux MIS Screw

7-145-15 Awl for Vertaux MIS Screw

7-145-16 Bone Reamer Ø8 for Vertaux MIS Screw

7-145-17 Reduction Multi-axial Screwdriver for Vertaux MIS Screw

7-145-18 Counter Torque for Vertaux MIS Screw

7-145-19 Ratchet Handle for Vertaux MIS Screw

7-145-20 Screwdriver for Vertaux MIS Screw

7-145-21 Break Off Iron for Vertaux MIS Screw

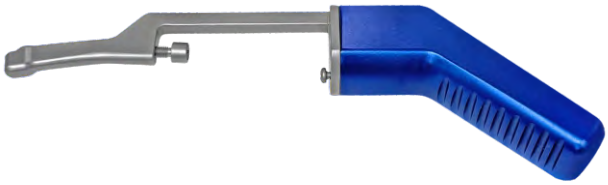
7-145-22 Plug Screwdriver (Self Hold with Inner Locking Pin) for Vertaux MIS Screw

7-145-23 Screwdriver Shaft for Vertaux MIS Screw

7-145-24 Torque-limiting Handle, 9Nm for Vertaux MIS Screw

7-145-25 Rod Bender for Vertaux MIS Screw

7-145-26 Rod Holder, Straight for Vertaux MIS Screw

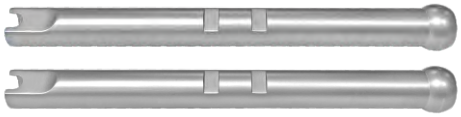


7-145-27 Rod Holder, Long for Vertaux MIS Screw

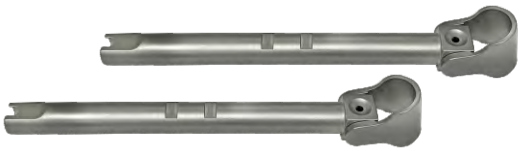
7-145-28 Break Off Iron for Vertaux MIS Screw

7-145-29 Reduction Sleeve for Vertaux MIS Screw

7-145-30 Reduction Extension A for Vertaux MIS Screw



7-145-31 Reduction Extension B for Vertaux MIS Screw



7-145-32 Torx Screwdriver for Vertaux MIS Screw

7-145-33 Distractor/Compressor for Vertaux MIS Screw

7-145-34 Puller for Vertaux MIS Screw

7-145-35 Screwdriver SW11 for Vertaux MIS Screw

7-145-36 Rod Gauge for Vertaux MIS Screw

Instruments

7-145-37 Template for Vertaux MIS Screw

7-145-38 Rod Inserter for Vertaux MIS Screw

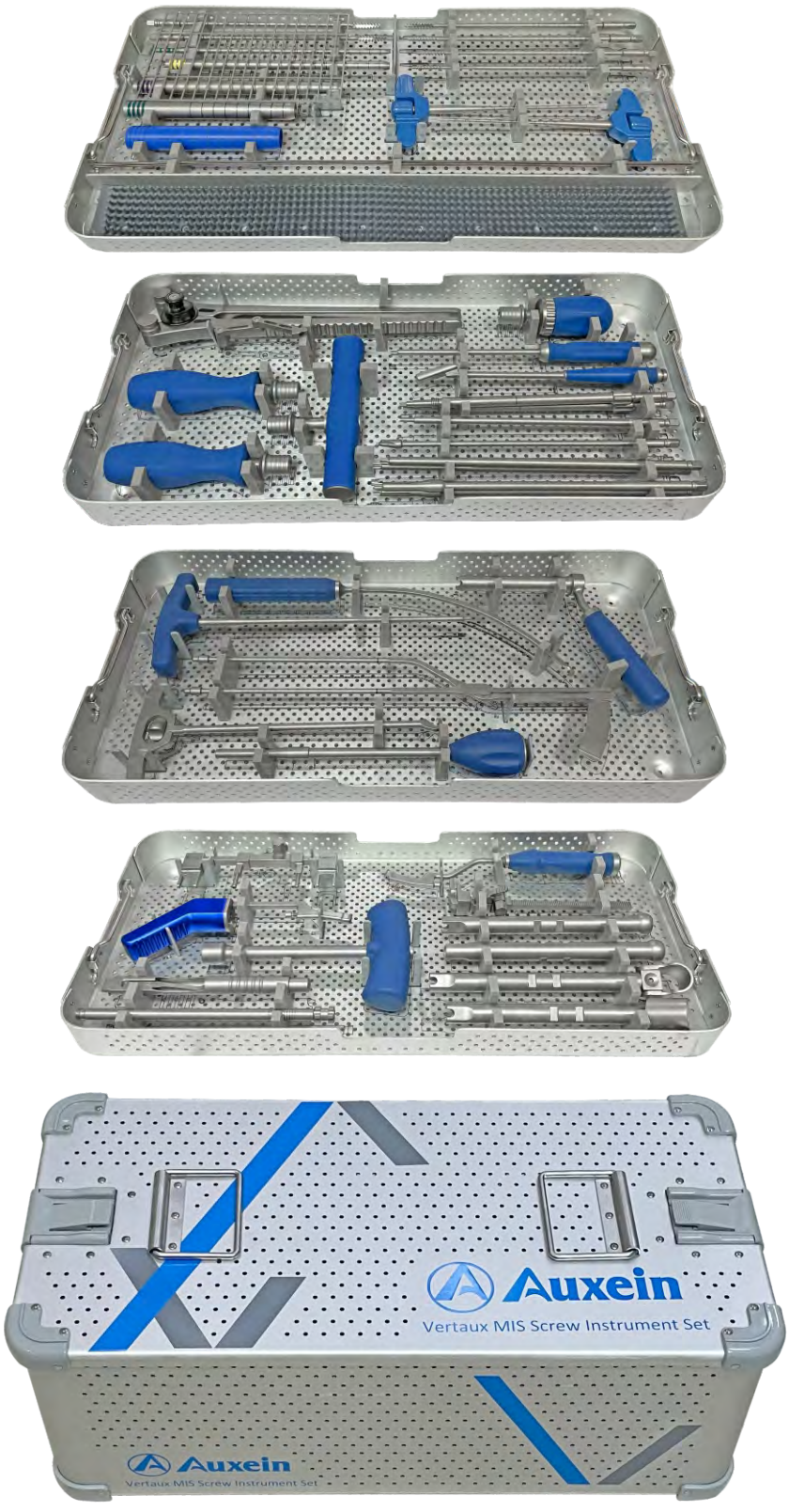
7-145-39 Rod Pusher for Vertaux MIS Screw

7-145-40 Tissue Dissector for Vertaux MIS Screw

7-145-41 Instrument Trays for Vertaux MIS Screw

7-145-42 Container for Vertaux MIS Screw

7-145 Vertaux MIS Instrument Set



7-145 Vertaux MIS Instrument Set

Code	Set Consisting of	Qty.
7-145-01	Guide Wire,Ø1.5X500 for Vertaux MIS Screw	6
7-145-02	Inserted needle for Vertaux MIS Screw	2
7-145-03	Multiple Level Dilator 5.3mm for Vertaux MIS Screw	1
7-145-04	Multiple Level Dilator 9.4mm for Vertaux MIS Screw	1
7-145-05	Multiple Level Dilator 12.8mm for Vertaux MIS Screw	1
7-145-06	Multiple Level Dilator 16.8mm for Vertaux MIS Screw	1
7-145-07	Multiple Level Dilator 20.8mm for Vertaux MIS Screw	1
7-145-08	Cannulated Tap Ø1.5/Ø5.0 for Vertaux MIS Screw	1
7-145-09	Cannulated Tap Ø1.5/Ø5.5 for Vertaux MIS Screw	1
7-145-10	Cannulated Tap Ø1.5/Ø6.0 for Vertaux MIS Screw	1
7-145-11	Cannulated Tap Ø1.5/Ø6.5 for Vertaux MIS Screw	1
7-145-12	Cannulated Tap Ø1.5/Ø7.0 for Vertaux MIS Screw	1
7-145-13	Cannulated Tap Ø1.5/Ø7.5 for Vertaux MIS Screw	1
7-145-14	Cannulated Quick Change Handle for Vertaux MIS Screw	2
7-145-15	Awl for Vertaux MIS Screw	1
7-145-16	Bone Reamer Ø8 for Vertaux MIS Screw	1
7-145-17	Reduction Multi-axial Screwdriver for Vertaux MIS Screw	2
7-145-18	Counter Torque for Vertaux MIS Screw	1
7-145-19	Ratchet Handle for Vertaux MIS Screw	1
7-145-20	Screwdriver for Vertaux MIS Screw	1
7-145-21	Break Off Iron for Vertaux MIS Screw	1
7-145-22	Plug Screwdriver (Self Hold with Inner Locking Pin) for Vertaux MIS Screw	2
7-145-23	Screwdriver Shaft for Vertaux MIS Screw	2
7-145-24	Torque-limiting Handle, 9Nm for Vertaux MIS Screw	1
7-145-25	Rod Bender for Vertaux MIS Screw	1
7-145-26	Rod Holder, Straight for Vertaux MIS Screw	1
7-145-27	Rod Holder, Long for Vertaux MIS Screw	1
7-145-28	Break Off Iron for Vertaux MIS Screw	1
7-145-29	Reduction Sleeve for Vertaux MIS Screw	1
7-145-30	Reduction Extension A for Vertaux MIS Screw	2
7-145-31	Reduction Extension B for Vertaux MIS Screw	2
7-145-32	Torx Screwdriver for Vertaux MIS Screw	1
7-145-33	Distractor/Compressor for Vertaux MIS Screw	1
7-145-34	Puller for Vertaux MIS Screw	1
7-145-35	Screwdriver SW11 for Vertaux MIS Screw	1
7-145-36	Rod Gauge for Vertaux MIS Screw	1
7-145-37	Template for Vertaux MIS Screw	1
7-145-38	Rod Inserter for Vertaux MIS Screw	1
7-145-39	Rod Pusher for Vertaux MIS Screw	1
7-145-40	Tissue Dissector for Vertaux MIS Screw	1
7-145-41	Instrument Trays for Vertaux MIS Screw	4
7-145-42	Container for Vertaux MIS Screw	1

AMPL-ST-107-02, Effective Date, 25-01-2022

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