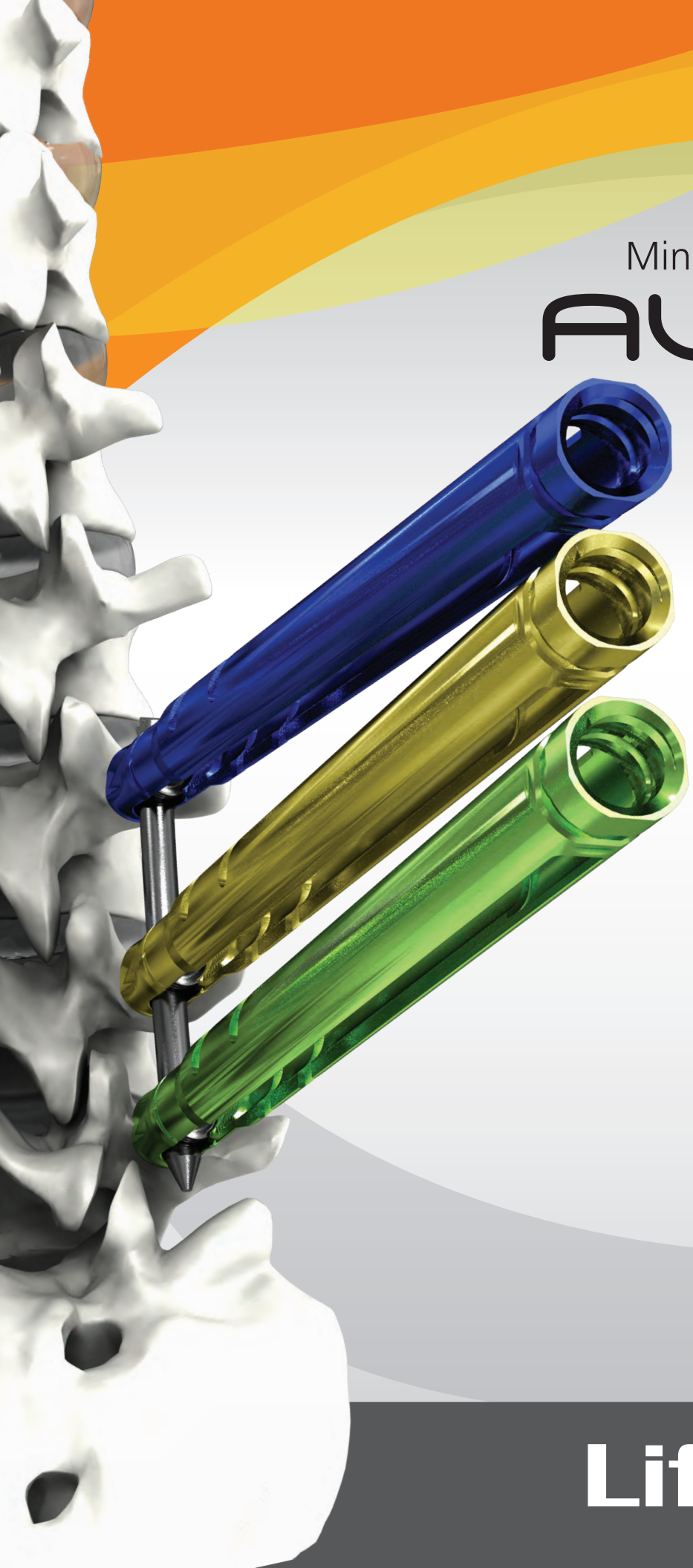
Minimally Invasive Spinal System

AVATAR®



SURGICAL TECHNIQUE GUIDE

LifeSpine® Designs For Life.®

Minimally Invasive Spinal System

AVATAR®

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Minimally Invasive Spinal System

AVATAR®

INTRODUCTION

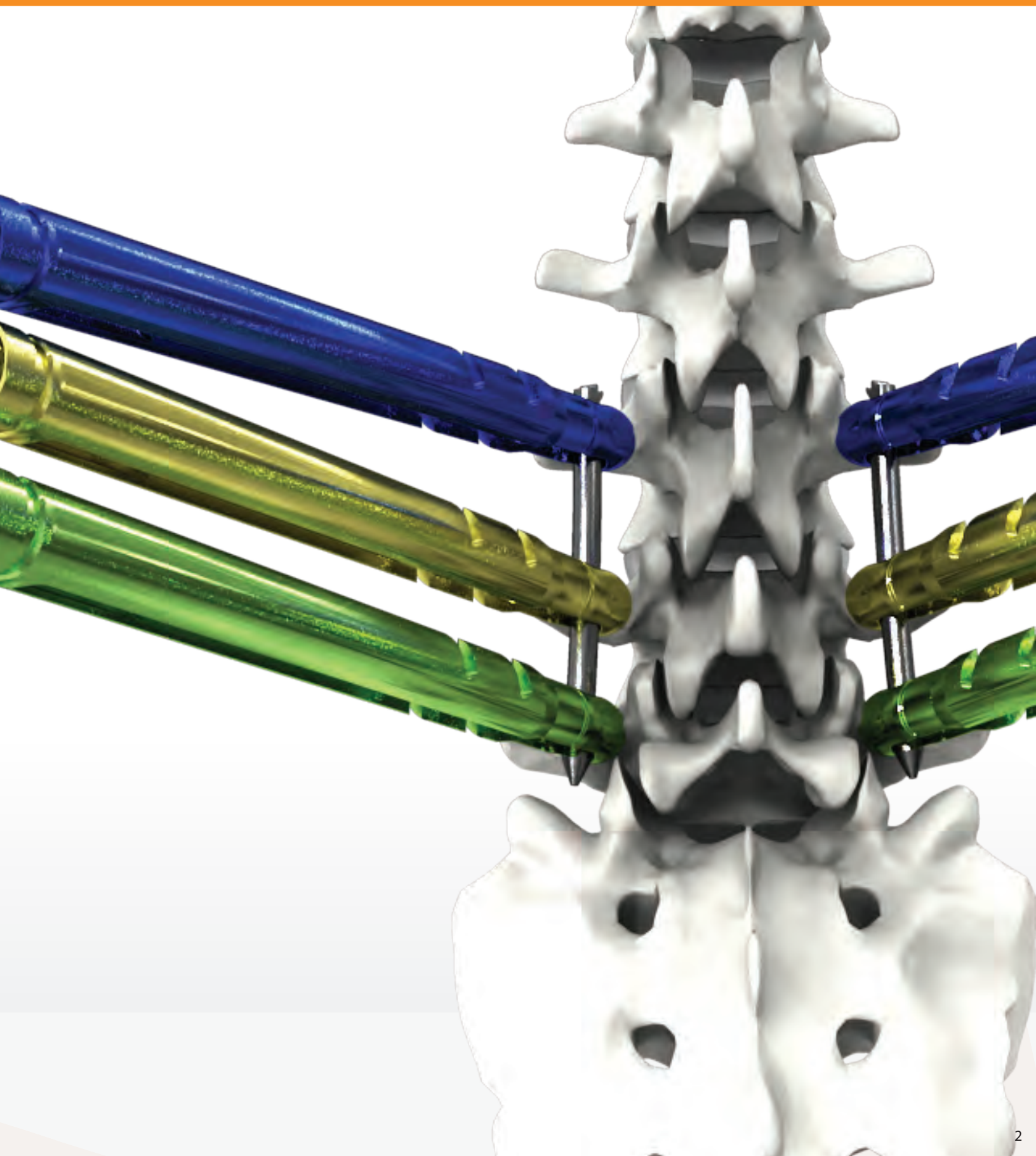
The AVATAR Extended Tab MIS System is a comprehensive system intended to treat an unparalleled range of pathologies for the thoracic and lumbar spine. The system eliminates unnecessary muscle and tissue trauma by offering integrated extended screw tab options to provide a pathway for secure implantation of the rod. Multiple types of color-coded, titanium implants provide significant intraoperative options and reliability. Comprehensive reduction, compression, and distraction are achieved effectively with intuitive instrumentation.

Features	Benefits
Slots in the Extended Screw Tabs	Provides pathway for percutaneous rod delivery while minimizing skin incision and tissue dissection
Integrated Extended Screw Tabs	Eliminate the need for extension assembly and offers a rigid connection to instruments for implantation of the set screws
Simple Percutaneous Reduction Driver	Provides significant internal rod reduction options without compromising incision size
Double Helical Screw Thread Design	Speed of insertion and bone purchase
Streamlined, Surgeon-Inspired Instrumentation	Provides intraoperative assurance and reliability

Indications

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing. The AVATAR MIS System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion. When used as a posterior spine thoracic/lumbar system, the AVATAR MIS System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

INTRODUCTION



AVATAR Configurations - Implant

Ø5.5mm AVATAR Screw

Ø6.5mm AVATAR Screw

Ø7.5mm AVATAR Screw

AVATAR 5.5mm Screws		AVATAR 6.5mm Screws		AVATAR 7.5mm Screws	
NUMBER	DIAMETER x LENGTH	NUMBER	DIAMETER x LENGTH	NUMBER	DIAMETER x LENGTH
7255-30-55	5.5mm x 30mm	7265-30-55	6.5mm x 30mm	7275-30-55	7.5mm x 30mm
7255-35-55	5.5mm x 35mm	7265-35-55	6.5mm x 35mm	7275-35-55	7.5mm x 35mm
7255-40-55	5.5mm x 40mm	7265-40-55	6.5mm x 40mm	7275-40-55	7.5mm x 40mm
7255-45-55	5.5mm x 45mm	7265-45-55	6.5mm x 45mm	7275-45-55	7.5mm x 45mm
7255-50-55	5.5mm x 50mm	7265-50-55	6.5mm x 50mm	7275-50-55	7.5mm x 50mm
7255-55-55	5.5mm x 55mm	7265-55-55	6.5mm x 55mm	7275-55-55	7.5mm x 55mm

5.5mm Pre-Lordosed Rods	
NUMBER	LENGTH
4551-035	35mm
4551-040	40mm
4551-045	45mm
4551-050	50mm
4551-055	55mm
4551-060	60mm
4551-065	65mm
4551-070	70mm
4551-075	75mm
4551-080	80mm
4551-085	85mm
4551-090	90mm

5.5mm Pre-Lordosed Rods	
NUMBER	LENGTH
4551-095*	95mm
4551-100*	100mm
4551-105*	105mm
4551-110*	110mm
4551-115*	115mm
4551-120*	120mm
4551-125*	125mm
4551-130*	130mm
4551-135*	135mm

5.5mm Straight Rods	
NUMBER	LENGTH
3557-140*	140mm
3557-150*	150mm
3557-160*	160mm
3557-170*	170mm
3557-180*	180mm
3557-190*	190mm
3557-200*	200mm

Locking Cap
NUMBER
148-003

* Items are special order. Please contact customer service at 847.884.6117.

AVATAR Standard Instrumentation

Instruments available for use with the AVATAR Extended TAB MIS System to facilitate implantation

Jamshidi Needle

MIS Polyaxial Screw Driver

Reduction Driver

Locking Cap Driver

Initial Cap Tightener

Cannulated Awl

Detachable Counter Torque Handle

Detachable Counter Torque Wrench

Bulleted Rod Inserter

Extension Tab Remover

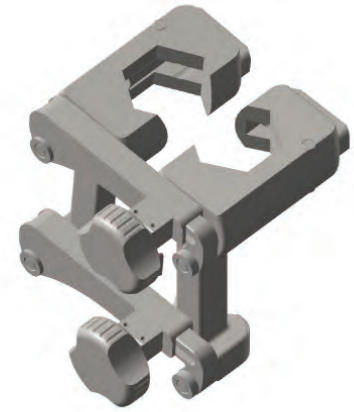
Gray Ø4.5mm Tap

Blue Ø5.5mm Tap

Gold Ø6.5mm Tap

Ø
Green 7.5mm Tap

Distractor Tips

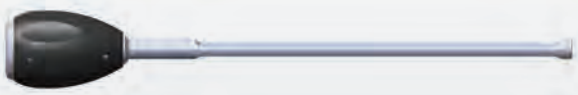


Compression/Distraction Cuffs

Compressor Tips

Compressor Tips, Wide

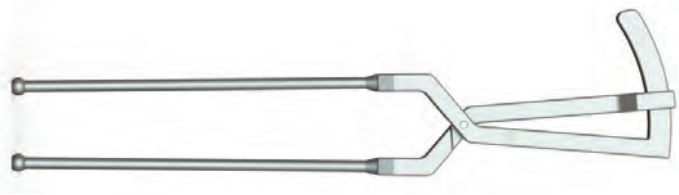
Ratcheting Handle, T-handle, 1/4 sq



Rod Pusher

IMPLANTS AND INSTRUMENTATION

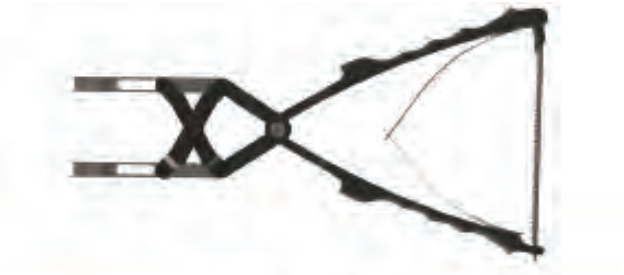
Ancillary Driver



Calipers

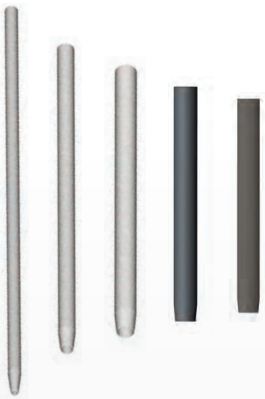
Blunt Dissector

MIS Distractor

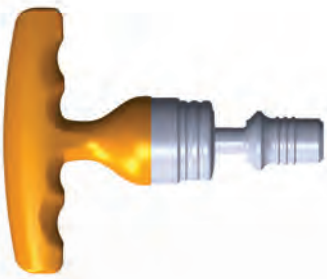


MIS Compressor

Rod Holder



Dilator #1, Stainless Steel
Dilator #2, Stainless Steel
Dilator #3, Stainless Steel
Dilator #4, Non-Conductive
Dilator #5, Non-Conductive



Torque Limiting Handle

Straight Ratcheting Handle

Nitinol Guidewire

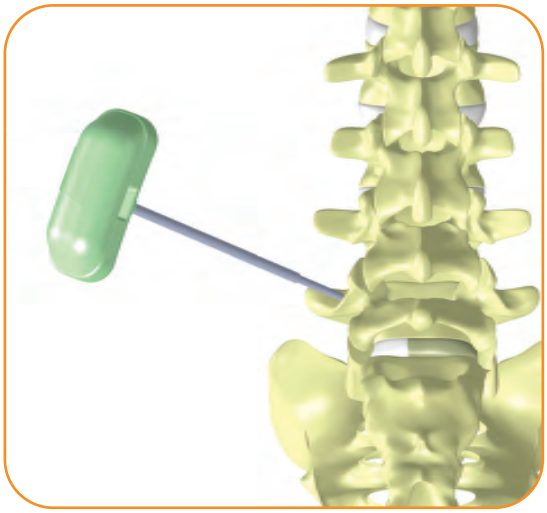
AVATAR Surgical Technique

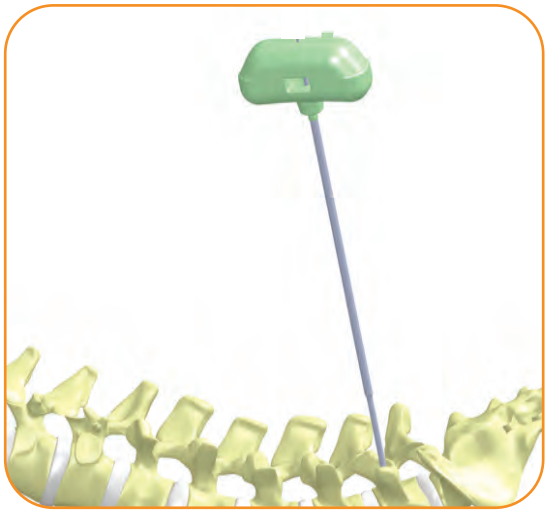
1. Preparation and Exposure

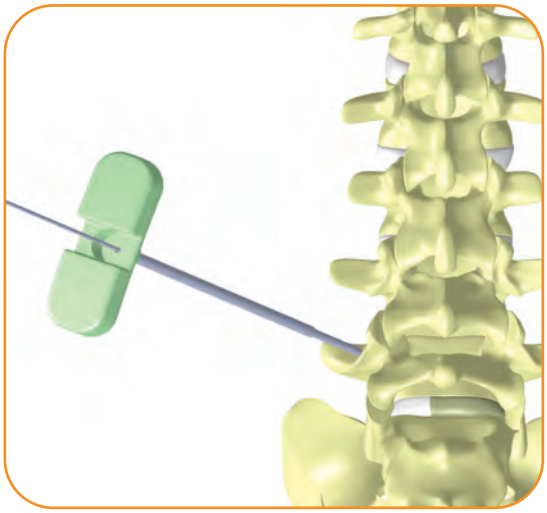
Preoperative planning is critical in the preparation for spinal surgery. A complete radiographic evaluation (A/P and lateral films) of the patient should be completed for proper diagnosis prior to surgery. Carefully place the patient in the prone position in normal lordosis following induction of anesthesia.

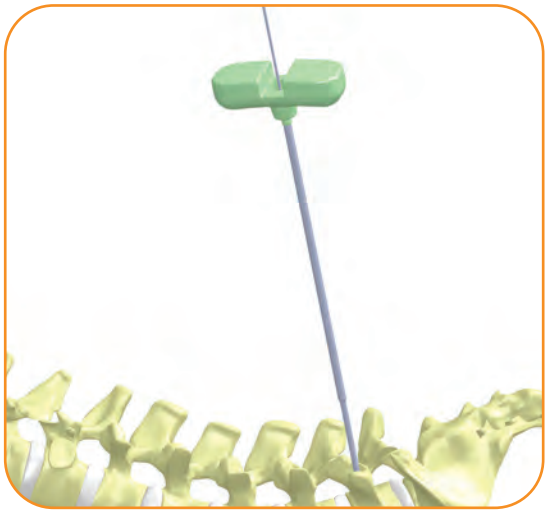
2. Access Needle and K-wire Insertion

Create an incision slightly larger than the outer diameter of the radiolucent sleeve, approximately 18mm. Using fluoroscopy, insert the Access Needle Stylet and Access Needle Sheath into the pedicle. Remove the stylet and insert the K-wire through the Access Needle Sheath. Confirm the position of the K-wire with A/P and lateral views. Once the K-wire position is determined, remove only the Access Needle Sheath.



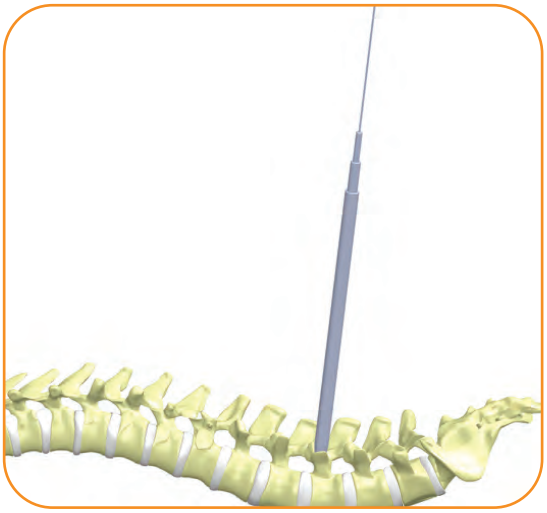






3. Awl

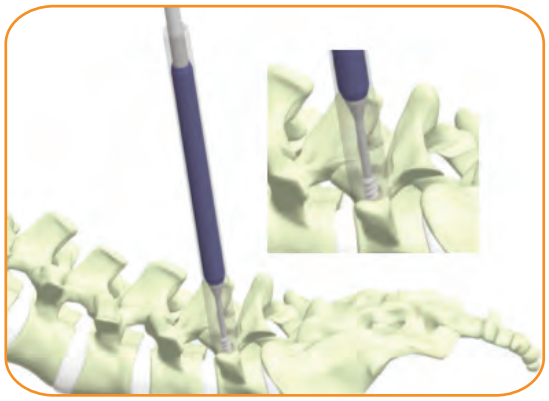
Advance Dilators #1-3 over the K-wire until the distal tip of the Dilators contact the pedicle. Remove Dilators #1 and #2 and insert the Bone Awl over the K-wire and through Dilator #3 to penetrate the cortex.



4. Tap

Remove the Bone Awl and insert the radiolucent Dilator #4 over Dilator #3. Remove Dilators #1-3. The radiolucent Dilator #4 assists with increased visualization under fluoroscopy and nerve monitoring. Securely attach the Ratcheting Handle to the cannulated Tap. Pass the Tap over the K-wire and through Dilator #4. Utilizing fluoroscopy to ensure that the K-wire does not advance, tap to the desired depth. Confirm depth measurement on the Tap against the top of Dilator #4 and select the appropriate screw length.

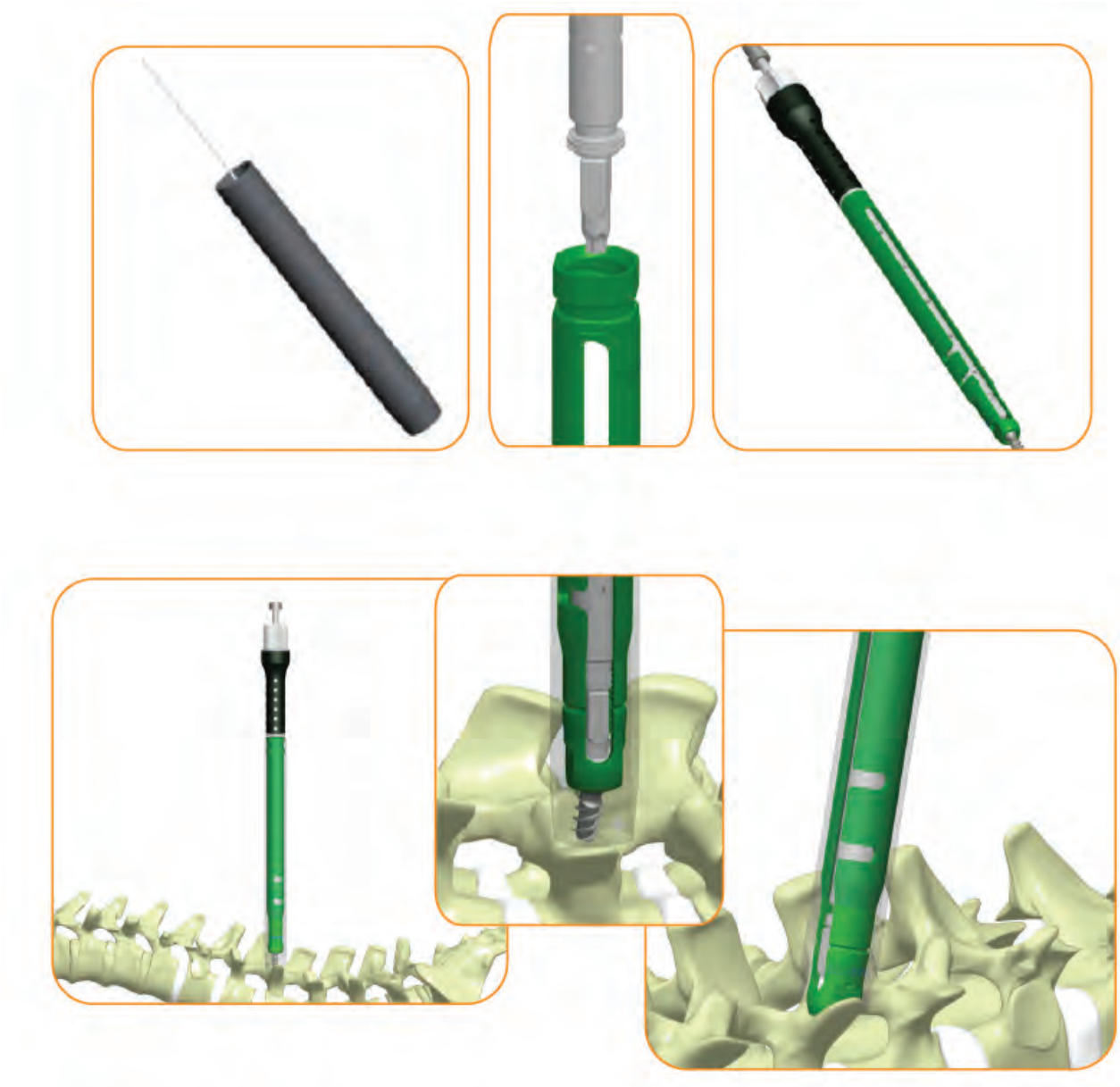
NOTE: The thread length at the distal end of the tap is measured at 25mm.



5. Screw Impant

Once tapping is complete, remove the Tap and insert the radiolucent Dilator #5 over Dilator #4. Remove Dilator #4. Securely attach the Ratcheting Handle to the Screwdriver. Securely align the Screwdriver tip with the saddle and hex of the polyaxial screw. Rotate the proximal knob on the Screwdriver clockwise to secure the polyaxial screw to the Screwdriver. Utilizing fluoroscopy, insert the polyaxial screw over the K-wire to the appropriate depth. The K-wire should be removed as soon as the polyaxial screw is advanced into the pedicle to the desired depth. Once the screw is inserted, turn the proximal knob on the Screwdriver counter-clockwise and remove the Screwdriver from the screw. Place remaining screws using the same technique.

NOTE: Always have visibility of K-wire. When removing the Tap, retrieve tap until threads are out of bone, detach and remove Ratcheting Handle, then carefully remove the Tap with the assist of a K-wire.



6. Rod Measuring

Insert one arm of the rod measuring Caliper into each of the outermost extended tabs until each leg is fully seated in the polyaxial screw head. Check placement via fluoroscopy. Once correctly positioned, read the rod length measurement indicated at the top of the Caliper.

NOTE: When the arrow on the Caliper is between two numbers, (i.e. 65mm – 75mm), always choose the longer rod length.
.

7. Rod Insertion

Turn the knob on the Rod Inserter counter clockwise and attach the selected rod at the distal end. Turn the knob on the Rod Inserter clockwise to secure the rod. If required, use the Initial Cap Tightener to engage and turn the knob to secure the rod.

8. Locking Cap Insertion

Securely engage the Locking Cap onto the Initial Locking Cap Tightener. While holding the rod in position with the Rod Inserter, advance the Initial Locking Cap Tightener through the extended tabs and rotate clockwise to seat the Locking Cap and secure the rod in place. It is imperative that the connection feature and bulleted profile at the ends of the rod are located outside of the tulip head to ensure the appropriate screw/rod interface is established. Confirm rod position fluoroscopically with A/P and lateral views. Place remaining Locking Caps using the same technique.

9. Final Tightening

Option 1

Slide the CT/Tower Breaker over the extended tabs of the screws. Secure the Locking Cap onto the Locking Cap Driver and insert it through the extended tabs. Attach the Torque Limiting Handle and apply a clockwise torque of 80 in-lbs. to secure the construct (an audible and tactile confirmation will alert the user that 80 in-lbs is achieved). Perform final tightening on all the Locking Caps using the same technique.

Start = Initial engagement between Locking Cap and internal threads

End = The Locking Cap is fully advanced and rod is seated on the tulip head.

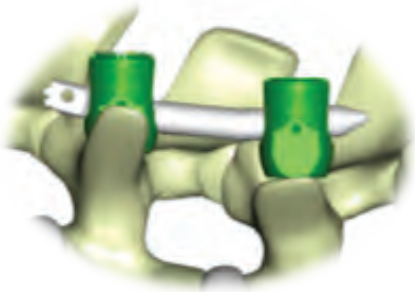
The Blue Collar will assist in identifying the initial engagement of the Locking Cap with internal threads of tulip head and confirm rod is fully seated

Option 2

While pressing the button on the Torque Handle, securely attach it to the Counter Torque Wrench. Slide the Counter Torque Wrench over the extended tabs of the screws. Secure the Locking Cap onto the Locking Cap Driver and insert it through the extended tabs. Attach the Torque Limiting Handle and apply a clockwise torque of 80 in-lbs. to secure the construct (an audible and tactile confirmation will alert the user that 80 in-lbs is achieved). Perform final tightening on all the Locking Caps using the same technique.

Note: Using fluoroscopy, verify that the rod overhangs the outermost screws by the bulleted profile at one end and full visualization of the circle of the connection feature at the other end.

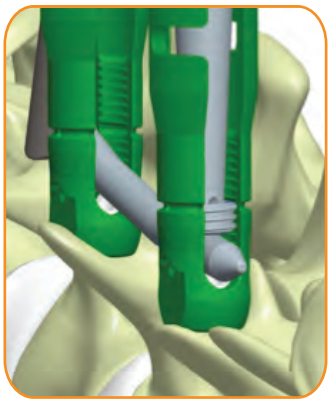
Press button and hold during attachment to the shaft



10. Reduction

The screw allows 10mm of rod reduction while the Reducer accommodates up to 20mm of additional rod reduction. Internal threads within the tabs promote additional reduction capability.

Securely engage the Locking Cap onto the Rod Reducer. While holding the rod in position with the Rod Inserter, advance the Rod Reducer through the extended tabs and rotate clockwise to reduce the rod into the saddle of the screw. Continue to advance the Rod Reducer to seat the Locking Cap and secure the rod in place.



Option 1

Once reduction is achieved, the Rod Reducer can be utilized to apply 80 in-lbs. torque and secure the construct. Remove the handle (black) from the Rod Reducer and slide the CT/Tower Breaker over the extended tabs of the screws. Attach a Torque Limiting Handle (orange) on the Rod Reducer. While holding the CT/Tower Breaker in place, turn the Torque Limiting Handle clockwise until 80 in-lbs. torque is achieved (an audible and tactile confirmation will alert the user that 80 in-lbs. is achieved).

Option 2

Once reduction is achieved, the Rod Reducer can be utilized to apply 80 in-lbs. torque and secure the construct. Remove the handle (black) from the Rod Reducer and slide the Counter Torque Wrench over the extended tabs of the screws. Attach a Torque Limiting Handle (orange) on the Rod Reducer. While holding the Counter Torque in place, turn the Torque Limiting Handle clockwise until 80 in-lbs. torque is achieved (an audible and tactile confirmation will alert the user that 80 in-lbs. is achieved).

11 Compression/Distraction

Prior to compression/distraction, perform final tightening to secure one of the constructs at the outermost polyaxial screws.

Press and hold the button on each Compression/Distraction Cuff and slide over the Counter Torque Wrenches. Release the buttons and assure the Compression/Distraction Cuffs are attached to the Counter Torque Wrenches.

Simply finger tighten the top bolt and loosen the bottom bolt of the Compression/Distraction Cuffs. Attach the Compressor/Distractor to the Counter Torque Wrenches. Apply desired compression or distraction.

Perform final tightening on the 2nd polyaxial screw construct.

Note: Distractor tips can be used with compressor for closer constructs.

Compression/Distraction can be done without cuffs.

12. Tab Removal

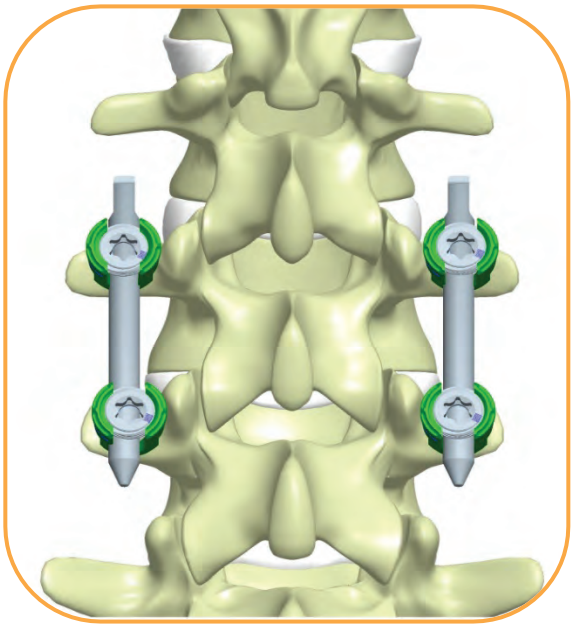
Option 1

Upon final tightening of the locking cap, the CT/Tower Breaker can be used to break off the extended tab of the screw. While holding onto the Torque Handle, turn the CT/Tower Breaker counter-clockwise to break off the extended tab of the screw.

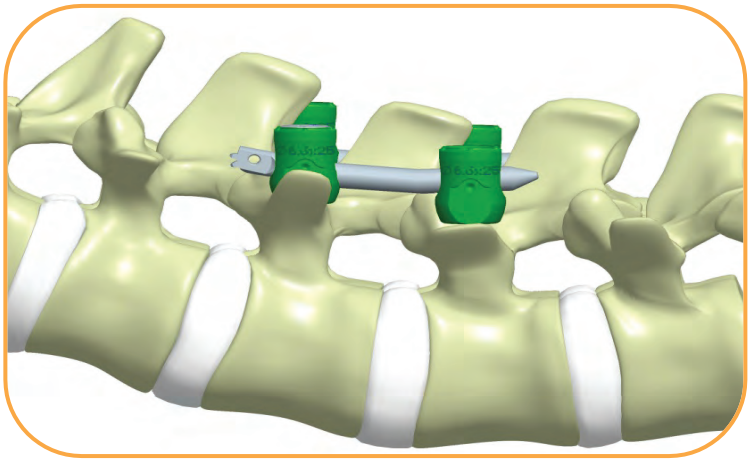
Option 2

With the Counter Torque Wrench seated over the extended tabs and the rod, insert the Extension Tab Remover through the screws. Once inserted completely, turn the Remover clockwise until it engages the slots of the screw tabs. This is confirmed with tactile feedback. Continue turning the Remover clockwise and applying torque until tabs have separated from the screw.

Final Construct



A/P View of the Final Construct



Lateral View of the Final Construct

13. Removal

If revision is required, remove the Locking Cap from the saddle of the screw using the Counter Torque Wrench, T-Handle and Locking Cap Driver. Ensure the Locking Cap Driver is fully seated in the Locking Cap. Apply downward pressure and rotate the T-Handle counter clockwise until the Locking Cap is completely unthreaded. Repeat for all the screws and remove the rod. Securely insert the Ancillary Driver to the screw and turn counter clockwise to remove the screw.

LIFE SPINE®

AVATAR® Extended Tab MIS System

Standard Product Insert

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USA

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Fax: 847-884-6118
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Important Information on the AVATAR Extended Tab MIS System

Purpose:
The AVATAR Extended Tab MIS System consists of screws, longitudinal rods, and cross connectors intended to provide temporary stabilization and immobilization following surgery to fuse a portion of the thoracic, lumbar, and/or sacral spine.

Description:
The AVATAR Extended Tab MIS System consists of an assortment of rods, screws, and cross connectors. The bone screw, head, and taper lock are assembled together during manufacturing to create the AVATAR Extended Tab MIS System screw assembly component. The cross connectors are also assembled during manufacturing. The AVATAR Extended Tab MIS System implant components are made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.Do not use any of the AVATAR Extended Tab MIS System components with the components from any other system or manufacturer.

Indications, Contraindications, and Possible Adverse Effects.

Indications:
Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The AVATAR Extended Tab MIS System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the AVATAR Extended Tab MIS System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Contraindications:
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness, alcoholism, drug abuse.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis
14. Any case not described in the Indications.
15. Any patient unwilling to cooperate with the post-operative instructions.
16. Any time implant utilization would interfere with anatomical structures or expected physiological performance

Potential Adverse Events:
A listing of possible adverse events includes, but is not limited to:
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery
14. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
15. Graft donor site complications including pain, fracture, or wound healing problems.
16. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
17. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
18. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
19. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
20. Change in mental status
21. Non-union (or pseudarthrosis). Delayed union. Mal-union.
22. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
23. Inability to perform the activities of daily living.
24. Paralysis
25. Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:
The AVATAR Extended Tab MIS System has not been evaluated for safety and compatibility in the MR environment. The AVATAR Extended Tab MIS System has not been tested for heating or migration in the MR environment.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The AVATAR Extended Tab MIS System is only a temporary implant used for the correction and stabilization of the spine. This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the AVATAR Extended Tab MIS System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the AVATAR Extended Tab MIS System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

WARNING: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Implant Selection:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

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Preoperative:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The AVATAR Extended Tab MIS System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:
1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.
7. Recheck the tightness of all screws after finishing ensuring that none have loosened during the tightening of the other screws. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.
8. Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.
9. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
10. To insert a screw properly, a guide wire should first be used, followed by a sharp tap.
11. Do not overtap or use a screw/bolt that is either too long or too large. Overtapping or using an incorrectly sized screw/bolt may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screw/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
12. To assume maximum stability, two or more crosslink plates on two bilaterally placed, continuous rods should be used whenever possible.

Postoperative:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. The AVATAR Extended Tab MIS System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position possibly resulting in injury, (3) Risk of additional injury from post-operative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the AVATAR Extended Tab MIS System components should ever be reused under any circumstances.

Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to LIFE SPINE.

Cleaning and Decontamination:
Precleaning:

Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Cleaning:
All instruments and trays must first be cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. A room temperature enzymatic cleaner bath (soak) or a solution of room temperature water and neutral pH detergent are effective in removing organic material from instruments. Use distilled (demineralized) water if possible. Instruments should be fully submerged for at least 10 minutes.

Instruments and trays must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Immerse instruments fully opened and flush all cannulas with room temperature water until rinse water runs clear. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments and trays. If there is any visual contamination, repeat the steps as necessary until the instruments and trays are visually clean. Rinse instruments and trays under running room temperature water for at least 1 minute to remove solutions.

If contamination is unable to be removed, return the instrument and/or tray to Life Spine in a sealed container clearly marked “contaminated.”

Instruments and trays should never be exposed to cleaning agents containing any peroxides.
Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
Unless noted otherwise on the package labeling, the AVATAR Extended Tab MIS System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Gravity Displacement	270°F(132°C)	30 minutes	60 minutes
Method	**Cycle**	**Temperature**	**Exposure Time**	**Dry Time**
Steam	Prevacuum	270°F(132°C)	4 minutes	60 minutes

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods.

No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Do not stack trays during sterilization. Use only sterile products in the operative field.

Always immediately re-sterilize all implants, instruments, and trays used in surgery. This process must be performed before handling or (if applicable) returning to Life Spine.

This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Product Complaints:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, LIFE SPINE. Further, if any of the implanted AVATAR Extended Tab MIS System component(s) ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any LIFE SPINE product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence.

When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

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