Arsenal™ Degenerative

Spinal Fixation System

FEATURES

- Ergonomically designed instrumentation
- Low-Profile Screws
- Dual-Lead Threads
- Color-coded shanks
- 76 degrees of variability
- Sacral and Reduction Screws
- Revision Connectors

Alphatec Spine®

THORACOLUMBAR | Surgical Technique Guide

PREFACE

Posterior Spinal fusion to treat thoracolumbar pathologies has been performed since the early 1900's and continues to evolve today. The desire for improved patient outcomes and enhanced surgical experience has continued to drive innovation in this segment of spinal surgery. Today's spinal fixation systems are more advanced than ever, and require increased mechanical advantage, simplified instrumentation, a better anatomical fit, and the necessary strength to achieve a solid fusion.

Alphatec strives to move spinal fixation forward and continues innovation by further enhancing the surgeon and patient surgical experience. The Arsenal™ Degenerative Spinal Fixation System was thoughtfully designed to provide operational efficiency, biomechanical strength, and surgical simplicity while providing a complete solution to combat complex degenerative pathologies.

The combination of low-profile implants, intuitive instrumentation, and proven strength are certain to quickly become allies.

CONTENTS

A SYSTEM OVERVIEW

Features

The Arsenal Spinal Fixation System was designed to enhance the surgical experience by providing surgeons the following:

- A comprehensive system capable of handling complex degenerative pathologies.

- Ergonomically designed instrumentation
  - Improved mechanical advantage with lighter weight materials
  - Improved tactile feel and comfort

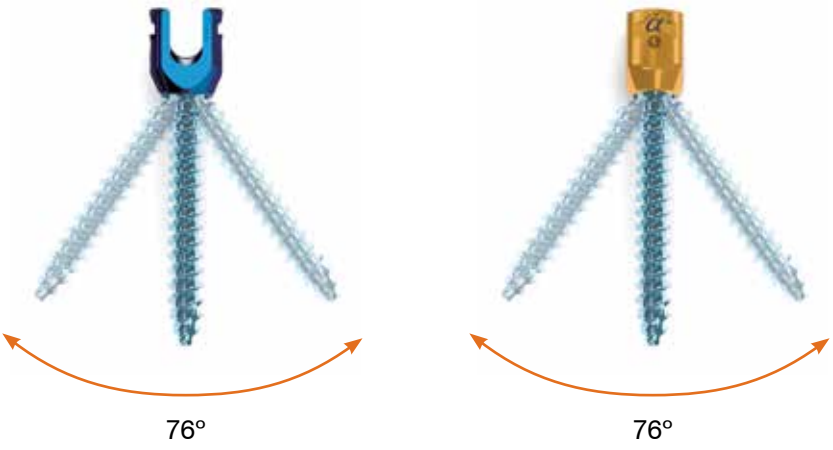
- Low-Profile Screws
  - Minimized implant profile for a better anatomical fit.

A

- Dual Lead Threads
  - Provides faster screw delivery
  - Reduces OR time
  - Reduces surgeon fatigue

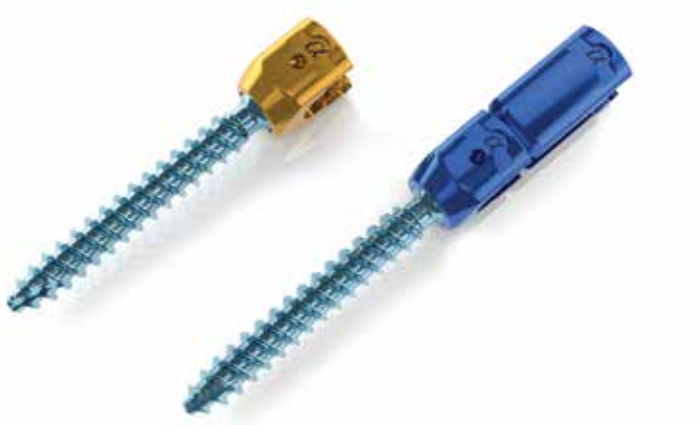
- Color-coded screw shanks
  - For quick identification of shank diameter

- 76 degrees of variability
  - To better accommodate varying anatomy



A

- Sacral and Reduction Screws
  - Facilitate long constructs to the pelvis
  - Spondylolisthesis reduction



- Revision Connectors
  - Simplify connection to adjacent level constructs
  - Provide flexibility in complex anatomical situations

Optional

NOTE: Blue indicates compatibility with 5.5mm rod, silver indicates compatibility with 6.35mm.

1 INTRA-OP IMAGING

- Prior to preparing the pedicles for screw insertion, determine the Sagittal and Coronal orientation of the pedicles for the vertebrae to be instrumented. Utilize a true A/P and lateral radiograph or C-Arm image (Figure 1a and 1b).

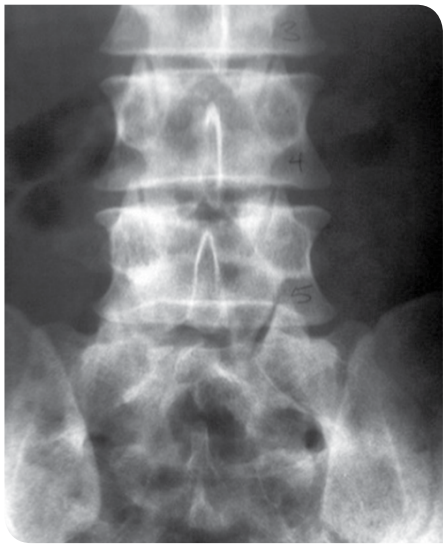


Figure 1a - A/P Image showing lumbar vertebral bodies

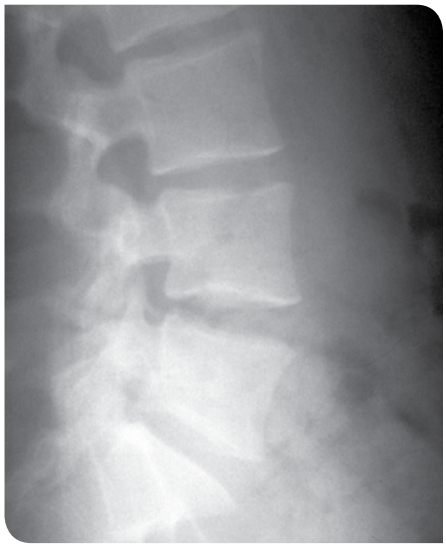


Figure 1b - Lateral Image showing lumbar vertebral bodies

- Identify the appropriate anatomical landmarks to create the entry points and pilot holes for screw insertion (Figures 2a and 2b).

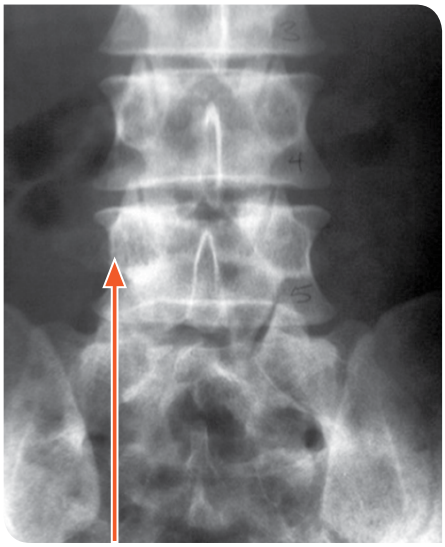


Figure 2a - A/P Image showing entry point for lumbar probe

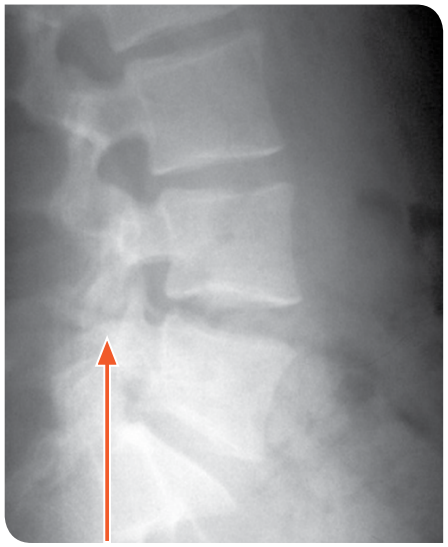


Figure 2b - Lateral Image showing entry point for lumbar probe

2 PEDICLE PREPARATION

- Create a pilot hole in the pedicle at the junction of the transverse process and the superior articular process using a high speed burr.

- Next, use a pedicle probe to complete the cannulation of the pedicle (Figures 3a & 3b).

Figure 3a

Figure 3b

- Following preparation of the pedicle, a Ball Tip Probe can be used to palpate the pedicle wall to ensure its integrity. (Figures 4a & 4b)

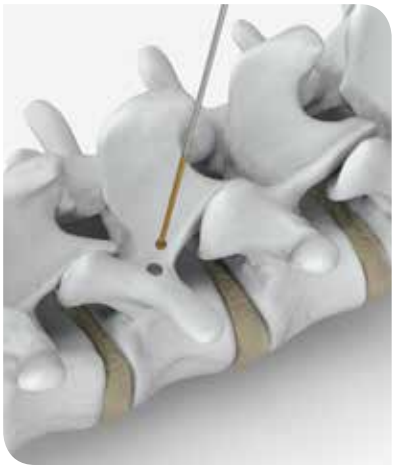


Figure 4a

Figure 4b

TIP: The **GOLD** portion of all Arsenal instruments is 30mm long for quick reference to depth.

2 PEDICLE PREPARATION (CONTINUED)

- Arsenal Polyaxial Screws have self-tapping triple cutting flutes to obviate the need for tapping should the surgeon so choose. Therefore, pedicle screws may be inserted immediately following the preparation and verification of pedicle wall integrity. However, in cases of dense, sclerotic, or osteoporotic bone, tapping is recommended.
- Select the appropriate diameter tap, insert it into the pedicle and stop at the desire depth. (Figures 5a).

Figure 5a

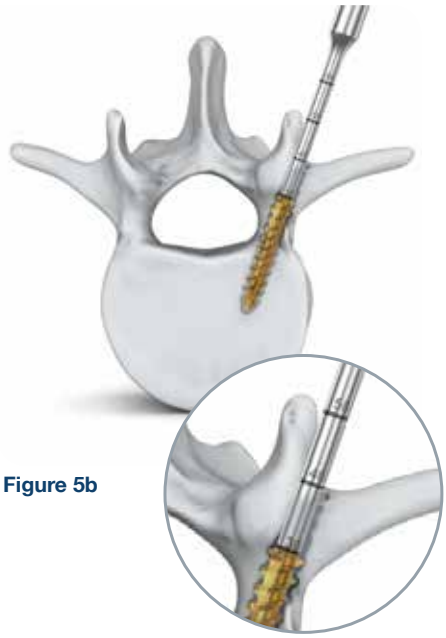


Figure 5b

- Following final preparation of the pedicle, a Ball Tip Probe can again be used to follow the tapped threads through the cancellous bone and palpate for any perforations in the pedicle wall or anterior vertebral body (Figures 6a & 6b).

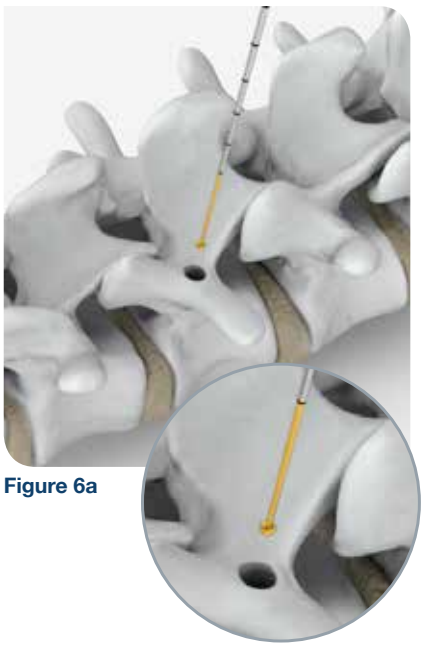


Figure 6a

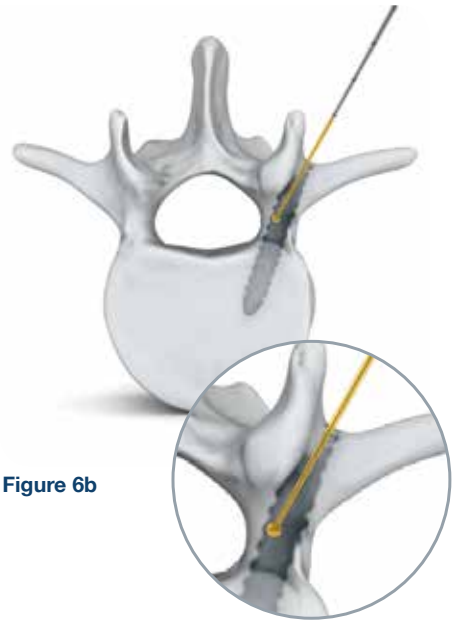


Figure 6b

3 SCREWDRIVER AND SCREW ASSEMBLY

- Assemble the Axial Ratcheting handle and the appropriate length pedicle screw onto the Locking Polyaxial Screwdriver.
  - **STEP 1.** Connect the Axial Ratcheting Handle onto the proximal end of the screwdriver and ensure the 1/4" square drive of the shaft is fully engaged with the handle (Figure 7).
  - **STEP 2.** With the screw in the caddy, insert the hexalobe end of the screwdriver into the screw and thread the silver locking collar clockwise into the head of the screw (Figures 8a, 8b, 8c).
  - **STEP 3.** Once the outer sleeve is fully tightened, slide the locking collar distally into the locked position. A green indicator ring confirms the driver is loaded, locked & ready (Figure 9).
- The T25 Self Retaining Screwdriver may also be used to insert a polyaxial pedicle screw.

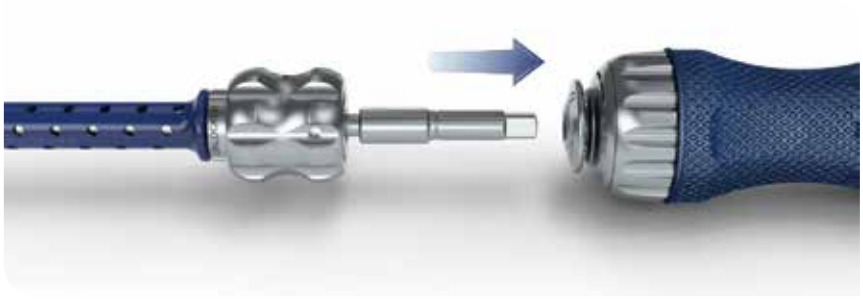


Figure 7

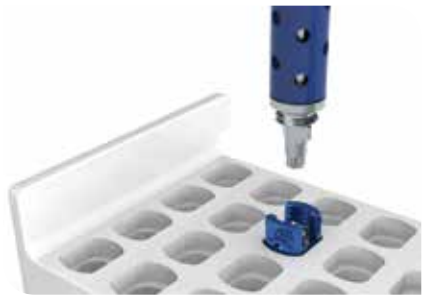


Figure 8a

Figure 8b

Figure 8c

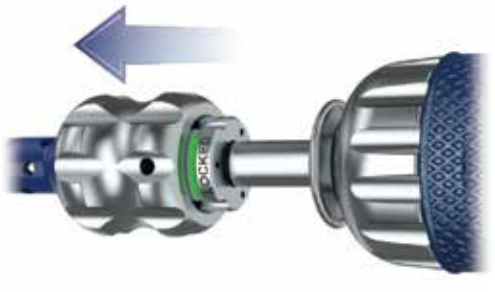


Figure 9

4 SCREW INSERTION

- Once the screwdriver and screw assembly is complete, insert the screw into the pedicle. Set the Axial Ratcheting Handle in the forward position and ratchet clockwise until the screw has reached the desired depth.
- To disengage the screwdriver, slide the locking collar proximally to the unlocked position and unthread the outer shaft from the screw head. (Figure 10)

Figure 10

5 ROD MEASUREMENT & CONTOURING

- Use the Head Positioner to align polyaxial screws for easier rod insertion (Figure 11a). If additional screw depth adjustment is needed, the T25 Self Retaining Screwdriver can be used (Figure 11b).
- With the screws in place, the Rod Template can be used to determine the appropriate rod contour and length.
- If required, a Rod Cutter and French Rod Bender may be used to achieve the desired rod length and contour.

Figure 11a

Figure 11b

NOTE: Contoured rods cannot be cut using a Tabletop Rod Cutter.

NOTE: It is recommended that rods be bent in one direction only. Over manipulation and bending may cause eventual breakage of the rod.

TIP: Prior to rod placement, the operating table can be adjusted to restore lumbar lordosis.

6 ROD INSERTION

- Place the rod using the Multipurpose Forceps (Figure 12).

Figure 12

- Once the rod is properly in place, load the set screws from the caddy using either the Double Ended or T27 Set Screw Starter (Figure 13). Place the set screws into the screw heads and rotate clockwise until provisionally tightened.

Figure 13

TIP: Rotate the set screw counterclockwise a ¼ turn to ensure a smooth start every time.

7 ROD REDUCTION

- The Arsenal Spinal Fixation System provides the surgeon with a variety of rod reduction options: High Top Screws, Rod Pusher, Rod Rocker, Axial Reducer, and Pistol Persuader*. Depending on the anatomy and the perceived force required, the surgeon may utilize any one of these methods to fully seat the rod into the implant and allow engagement of the set screw.
- Reduction screws may be utilized to facilitate a rod reduction of 20mm in cases with difficult anatomy or if spondylolisthesis reduction is required. (Figure 14)

Figure 14

- If the rod is slightly proud with respect to the implant, the Rod Pusher or Rod Rocker can be used. Slide the Rod Rocker pins into the lateral chevron features of the implant and rock the handle back to make contact with the rod and leverage it into the implant (Figure 15a). When the rod is fully seated, insert the set screw using the T27 Set Screw Starter (Figure 15b).

Figure 15a

NOTE: The Rod Rocker has approximately 9mm of reduction capability.

NOTE: The High Top Screws have 20mm of reduction capability.

Figure 15b

* Optional

7 ROD REDUCTION

- Use the Axial Reducer when additional force and distance is required to seat the rod into the screw head.
- With the rod in place, position the Axial Reducer over the implant and snap it into place using the “drop and lock” technique. The reducer will automatically lock onto the screw (Figure 16a). Confirm proper engagement by giving a light tug upward.
- To reduce the rod, turn the handle of the Axial Reducer clockwise until the rod is fully seated into the screw head, as indicated by the laser mark lines. If needed, the Hex Drive Adapter with Ratcheting Handle can be used to provide additional torque on the Axial Reducer (Figure 16b).
- Insert a set screw through the cannula of the Axial Reducer using the T27 Set Screw Starter and provisionally tighten.
- Remove the Axial Reducer by squeezing the gold release tabs and pull up. It is not necessary to unthread the reducer (Figure 16c).

Figure 16a

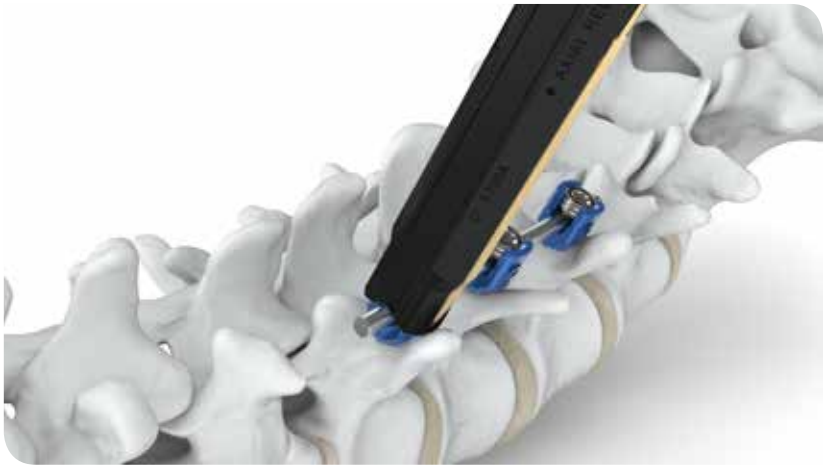


Figure 16b

Figure 16c

NOTE: The Axial Reducer has approximately 50mm of reduction capability.

7 ROD REDUCTION

- The Pistol Persuader* can also be used to reduce the rod. Position the Pistol Persuader over the screw and drop it over the top (Figure 17a). Next squeeze the handles to lock the Persuader to the screw. A green indicating line confirms the Pistol Persuader is locked to the screw. Confirm connection with a light tug upward.
- To reduce the rod, repeatedly squeeze the Ratcheting Handle until the rod is fully seated into the screw.
- Insert a set screw through the cannula of the Persuader using the Long T27 Set Screw Starter and provisionally tighten.
- Remove the Persuader by pressing the thumb release down (Figure 17b).

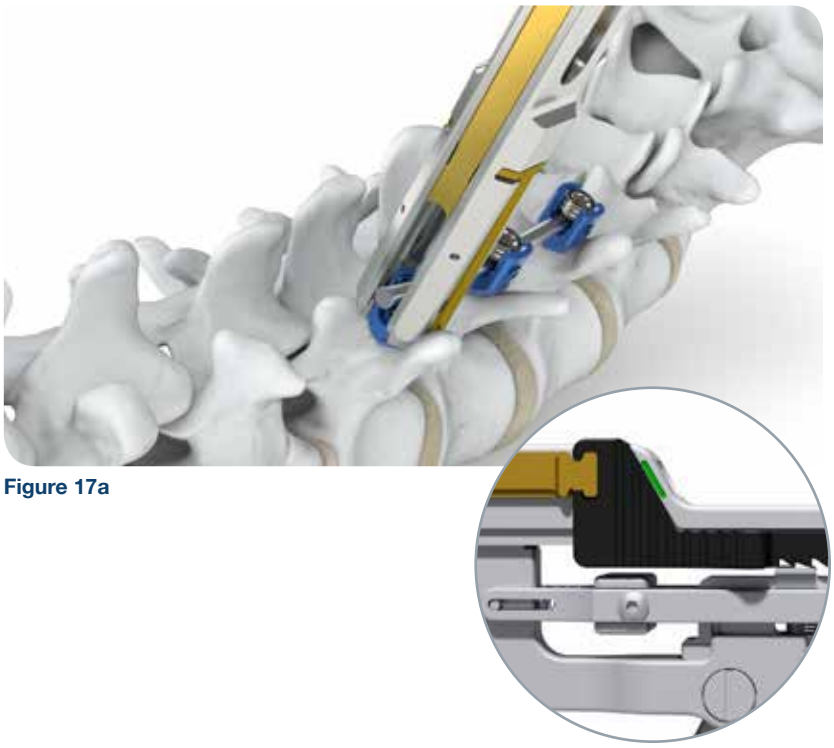


Figure 17a

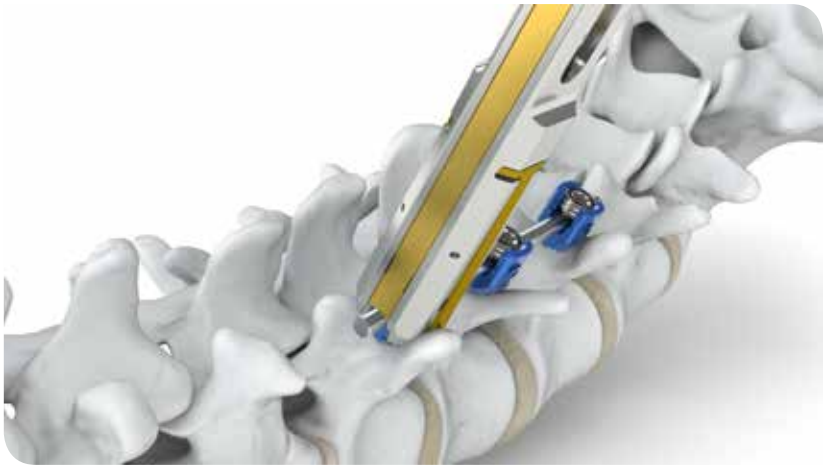


Figure 17b

NOTE: The Pistol Persuader has approximately 30mm of reduction capability.

* Optional

8 PARALLEL COMPRESSION

- Compression can be performed at any instrumented level to restore sagittal alignment. To begin, tighten the set screw on one side of the motion segment and leave the set screw loose in the adjacent segment to be compressed.
- Place the Parallel Compressor tips outside of the screw heads and over the rod. Squeeze the handles until adequate compression is attained.
- Finally, use the T27 Set Screw Starter to tighten the set screw and maintain compression (Figure 18).

Figure 18

9 PARALLEL DISTRACTION

- To begin, tighten the set screw on one side of the motion segment and leave the adjacent set screw loose. Place the tips of the Parallel Distractor over the rod and between the implants, and then squeeze the handles to distract. When adequate distraction is attained, use the T27 Set Screw Driver to tighten the set screw and maintain distraction (Figure 19).

Figure 19

10 FINAL TIGHTENING

- Final tightening of the construct should be performed when all screws and rods are in their final position.
- Connect the Torque Limiting T-Handle with aqua band to the T27 Set Screw Driver.
- Insert the torque driver assembly through the cannula of the Anti-Torque and engage the tip of the torque driver into the set screw (Figure 20).
- Slide the Anti-Torque down until the instrument is fully seated over the rod and implant. Turn the T-Handle clockwise to tighten. Final tightening is achieved when the T-Handle audibly clicks (Figure 21 & 22).

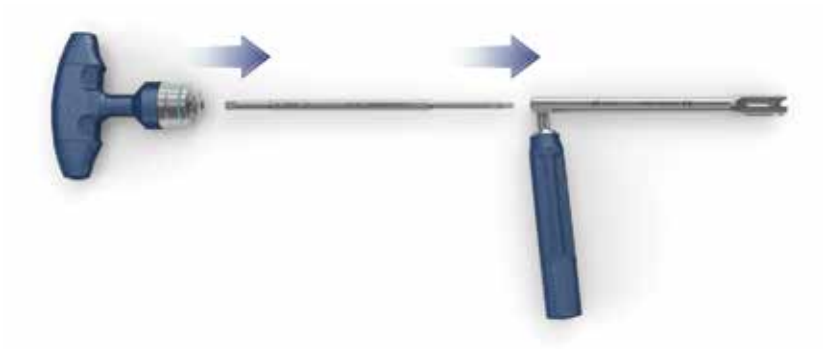


Figure 20

Figure 21

- Alternatively, the Torque Indicating T-Handle* can be used for final tightening. Assemble the T-Handle to the torque driver and insert the tip into the set screw. Turn the T-Handle clockwise, noting the position of the torque indicating arrows. Final tightening is achieved when the torque indicating arrows are aligned (Figure 22a).

Figure 22

Figure 22a

* Optional - must be ordered seperately

11 BRIDGE SYSTEM

- The Arsenal Variable Bridge implants can be used to increase the torsional stability of a construct. Variable Bridges should be placed at each end of longer constructs to increase construct rigidity.
- Use the Bridge Gauge to determine the proper length of the Variable Bridge. (Figure 23).

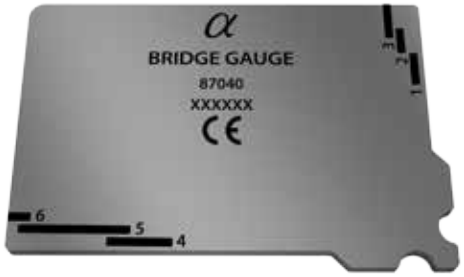


Figure 23

- Once the appropriate Variable Bridge is selected, use the Bridge Inserter to engage a lateral set screw. (Figure 24).
- The Bridge Inserter can then be used to hook and articulate the Variable Bridge around the rods (Figure 25). Once precise contact has been achieved between the bridge and the rods, the Bridge Inserter can be used to provisionally tighten the bridge to the rods.
- To final tighten the Variable Bridge, connect the Torque Limiting T-Handle with gold band to the T25 Bridge Driver.
- Insert the driver assembly into a lateral set screw. Turn the T-Handle clockwise. Final tightening is achieved when the T-Handle audibly clicks. Final tighten both lateral set screws prior to tightening the center set screw.
- To final tighten the center set screw, slide the driver assembly into the Variable Bridge Anti-Torque and place it over the center set screw. Turn the T-Handle clockwise. Final tightening is achieved when the T-Handle audibly clicks.

Figure 24

Figure 25

TIP: Prior to bridge placement, ensure that the bridge set screws are backed out to ensure ease of placement onto the rod.

12 DECORTICATION & GRAFT PLACEMENT

- Use of the Arsenal Spinal Fixation System requires supplementary bone graft. When using allograft or autograft bone to facilitate bony fusion, care should be taken to place the graft material directly onto the decorticated bony surfaces.
- To see Alphatec's bone graft extension offering, please see our brochures for 3D Profuse (LIT-83233) products.

13 IMPLANT REMOVAL

- Arsenal Set Screws may be removed using a T27 screw driver.
- The Pedicle Screws may be removed using a T25 screw driver.

TIP: Arsenal Polyaxial Screws may need to be remobilized to ease driver engagement.

- The Remobilizer may be used to restore variability to the polyaxial screws. To restore variability to the Polyaxial Screw remove the set screw and rod, place the tip of the Remobilizer in the head of the screw and squeeze the handle. Verify Polyaxial Head variability by rotating the Remobilizer instrument prior to releasing the handle.
- The Variable Bridge may be removed with a T25 Screw Driver.

14 REVISION IMPLANTS

- If revision procedures are required, the Arsenal Revision module offers Rod Connectors, Revision Rod Connectors, and larger diameter screws to help facilitate revision and adjacent level procedures.
- Rod Connectors (Figure 26) utilize the larger T27 set screw for additional strength when connecting to the rod. To final tighten the construct, assemble the Torque Limiting T-Handle with the T27 Set Screw Torque Shaft and drive the set screw clockwise until the T-Handle provides an audible click. No anti-torque is required.

NOTE: Blue indicates compatibility with 5.5mm rod, silver indicates compatibility with 6.35mm.

Axial Connector
Part # 47008-55-030

Axial Connector*
Part # 47008-65-030

Domino Rod Connector
Part # 47018-55-055

Domino Rod Connector*
Part # 47018-55-635

Rod Connector
Part # 47028-55-055

Rod Connector*
Part # 47028-55-635

Wide Rod Connector
Part # 47038-55-055

Wide Rod Connector*
Part # 47038-55-635

Open Side-loading Rod
Connector Part # 47048-55-055

Open Side-loading Rod Connector*
Part # 47048-55-635

Revision Connector
Part # 47068-55-080

In-line Revision Connector
Part # 47089-55-080

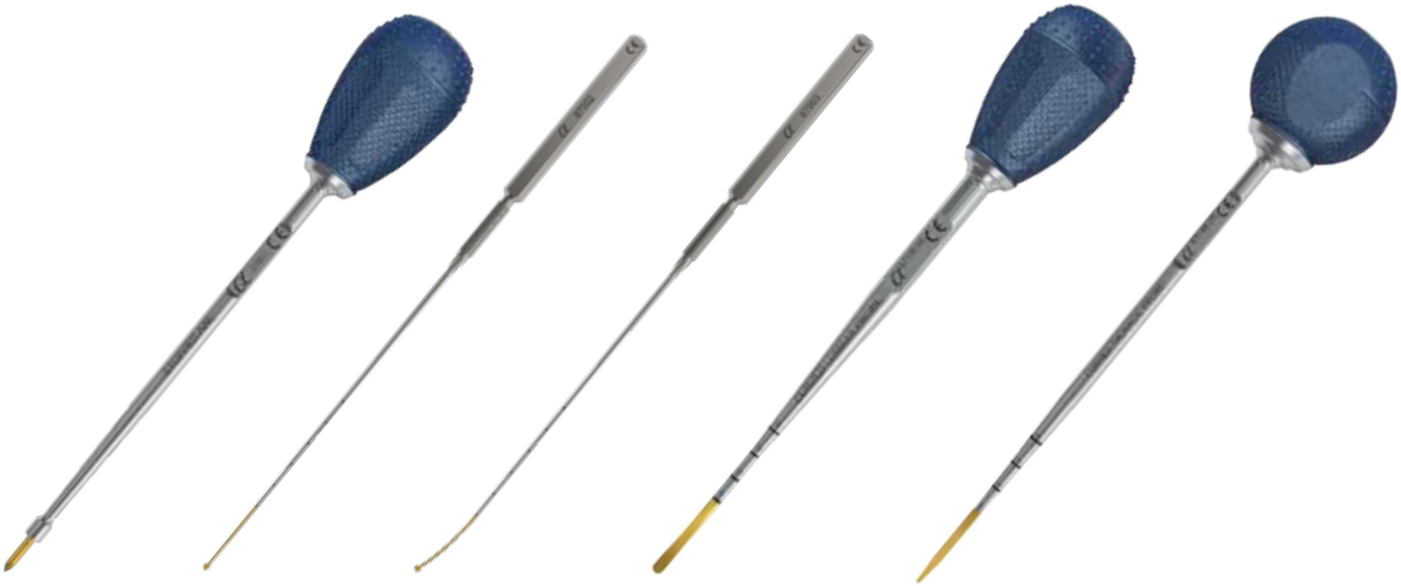
* Optional

Figure 26

15 PELVIC FIXATION IMPLANTS

- The Arsenal Pelvic Fixation module facilitates long constructs to the sacrum and ilium by providing multiple fixation options for the unique anatomy of the pelvis. Open Offset Connectors, Sacral and Polyaxial screws have been provided to help reduce cantilever and pull out stresses.

16 INSTRUMENTS



Stopped Awl*
Part # 87001

Straight Ball Tip Probe
Part # 87002

Curved Ball Tip Probe
Part # 87003

Curved Lumbar Probe
Part # 87105-05

Curved Thoracic Probe
Part # 87146-05

* Optional

16 INSTRUMENTS

4.0mm Tap
Part # 87107-040

4.5mm Tap
Part # 87107-045

5.5mm Tap
Part # 87107-055

6.5mm Tap
Part # 87107-065

7.5mm Tap
Part # 87107-075

8.5mm Tap
Part # 87107-085

Alphatec Ratcheting
Axial Handle
Part # 86073-1100

Polyaxial
Screwdriver*
Part # 87033

Reduction
Polyaxial
Screwdriver*
Part # 87038

Locking Polyaxial
Reduction
Screwdriver
Part # 87012

Locking Polyaxial
Screwdriver
Part # 87011

T25 Self Retaining
Driver
Part # 87013

Polyaxial Head
Adjuster
Part # 87014

* Optional

16 INSTRUMENTS

Double Sided Set Screw Inserter*
Part # 87030

T27 Set Screw Driver
Part # 87034

Torque Limiting T-Handle (Aqua Band)
Part # 86013-1200-080
Part # 86013-1200-090*

Torque Indicating T-Handle*
Part # 86903-0600-080

Alphatec Ratcheting T-Handle
Part # 86013-1100

Anti Torque
Part # 87031

French Rod Bender
Part # 87016

Multipurpose Forceps
Part # 87024

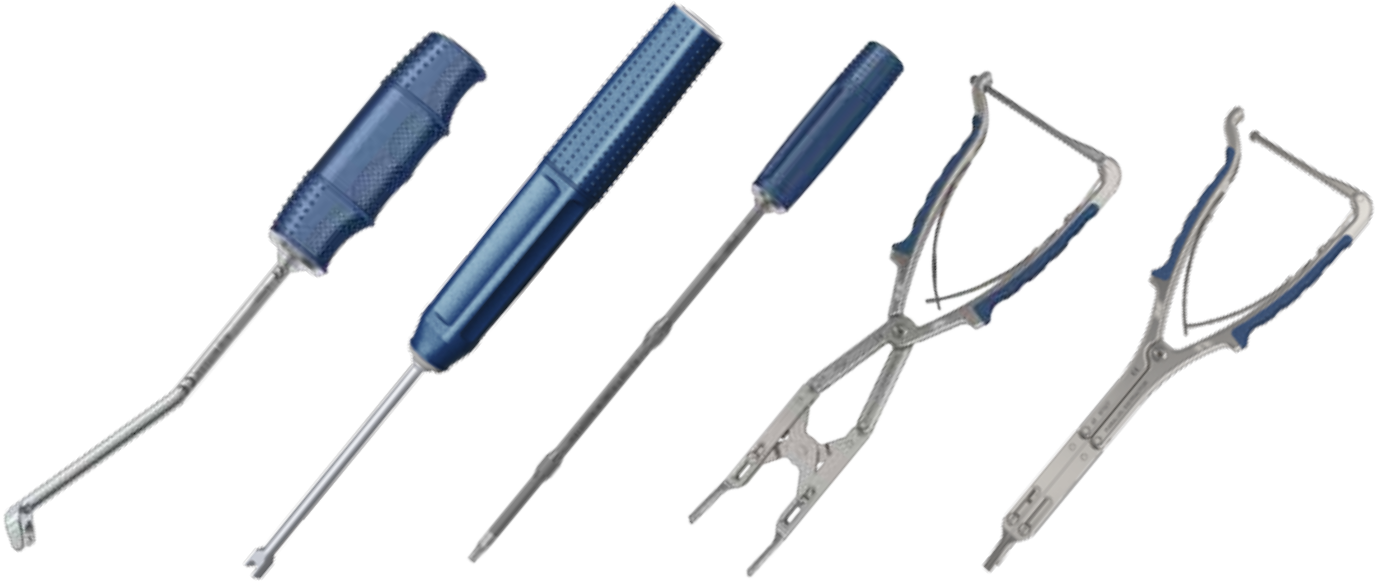
Axial Reducer
Part # 87066

Axial Reducer Anti Torque Adaptor
Part # 87064-13

25mm Hex Adaptor
Part # 87065

* Optional

16 INSTRUMENTS



Rod Rocker
Part # 87020

Rod Pusher
Part # 87022

T27 Set Screw
Inserter
Part # 87029

Compressor (Parallel)
Part # 87026

Distractor (Parallel)
Part # 87027

Rod Template
130mm
Part # 87015-130

Polyaxial Remobilizer
Part # 87036

Pistol Persuader*
Part # 87019-11

Rod Gripper*
Part # 87018

Polyaxial Provisional
Locking Tool*
Part # 87035

* Optional

16 INSTRUMENTS

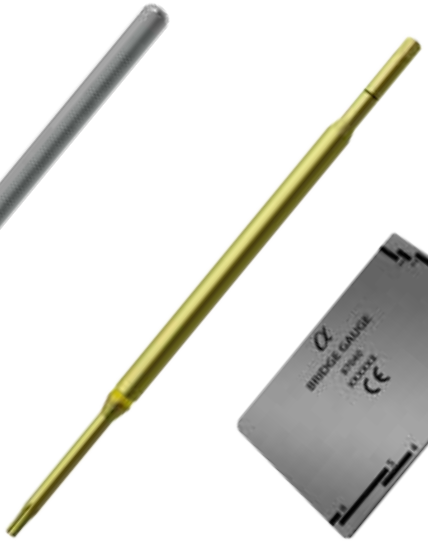
In situ Rod*
Bender Left
Part # 87060

In situ Rod*
Bender Right
Part # 87061

Long T27 Set
Screw Inserter*
Part # 87044

Bridge Anti Torque
Part # 87048

T25 Bridge Inserter
Part # 87063



T25 Bridge Driver
Part # 87039

Bridge Gauge
Part # 87040

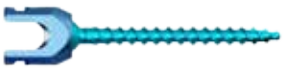
Bridge Caliper*
Part # 87041

Torque Limiting T-Handle
(Gold Band)
Part # 86012-1500-040

* Optional

17 IMPLANTS

Set Screw
Part # 47127



Polyaxial Screw
Part # 47000-040-XXX

Polyaxial Screw
Part # 47000-055-XXX

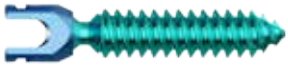
Polyaxial Screw
Part # 47000-065-XXX

Polyaxial Screw
Part # 47000-075-XXX

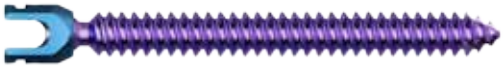
Polyaxial Screw
Part # 47000-045-XXX

Polyaxial Screw
Part # 47000-085-XXX

Polyaxial Screw
Part # 47000-095-XXX



Polyaxial Screw
Part # 47000-105-XXX



Polyaxial Screw
Part # 47000-XXX-XXX

Sacral Screw
Part # 47100-XXX-XXX

Reduction Screw
Part # 47200-XXX-XXX

Open Offset Connector
Part # 47008-XXX

Pre-contoured Rod
Part # 47003-55-XXX

Straight Rod
Part # 48001-055-XXX

Variable Bridge
Part # 47006-XX
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XX
XX
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XX

ARSENAL™ SPINAL FIXATION SYSTEM

GENERAL INFORMATION:
The Arsenal Spinal Fixation System is intended for posterior, non-cervical, spinal fixation as an adjunct to fusion for the treatment of degenerative disease, deformity, and trauma indications. The Arsenal System consists of a variety of shapes and sizes of rods, screws, hooks, connectors, and bridges that provide temporary internal fixation and stabilization during bone graft healing and/or fusion mass development. The screws, hooks, connectors, and bridges are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI). The rods are available in commercially pure titanium, titanium alloy, and cobalt chrome (CP Ti Grade 4, Ti-6Al-4V ELI, and Co-28Cr-6Mo).

The Arsenal System may be used in connection with Alphatec Spine's Solanas® Posterior System, which in turn connects with Avalon® Occipital Plate System creating additional levels of fixation. The Variable Bridges are appropriate for use with other Alphatec Spine 5.5 rod-based systems, which include both the Zodiac® Spinal Fixation System and the Xenon® Pedicle Screw System.

INDICATIONS FOR USE, DEGENERATIVE:
The Arsenal Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. Fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical screw fixation in pediatric patients, the Arsenal Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the Arsenal Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolistheis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach.

The Arsenal Spinal Fixation System is intended to be used with autograft and/or allograft.

INDICATIONS FOR USE, DEFORMITY:
The Arsenal Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. Fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Arsenal Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Arsenal Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The Arsenal Spinal Fixation System is intended to be used with autograft and/or allograft.

CONTRAINDICATIONS:
The system is contraindicated for:
1. Use in the cervical spine.
2. Use with bone cement.
3. Patients with allergy to Titanium or Cobalt Chrome.
4. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
5. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions, which would prohibit beneficial surgical outcome.
6. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
7. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
8. Reuse or multiple uses.

WARNINGS:
1. The implants and instruments of the system are provided non-sterile. Refer to the CLEANING and STERILIZATION sections.
2. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
3. The system implants are used only to provide temporary internal fixation during the bone fusion process with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
4. The implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.
5. The product implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
6. The instruments in the Arsenal System are reusable surgical devices except for the Single-Use CBx Pedicle Marker Taps and the guide wires used with the Arsenal System, which are single use only. Single use instruments are disposable devices, designed for single use and should not be re-used or re-processed. Reprocessing of Single Use Instruments may lead to instrument damage and possible improper function.
7. Do not comingle titanium and stainless steel components within the same construct.
8. The final operative procedure with the system must include tightening of the set screws in order to maintain construct integrity. Each locking mechanism must be rechecked for tightness before closing the soft tissues as noted in the Intraoperative Management section.
9. 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 (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological 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.
10. Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient conditions, which may impact the performance of the system when using this device. Use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants.
11. Risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.
12. Risk factors that may affect successful surgical outcomes include: Alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
13. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
14. It is critical that set screws are turned to the proper torque values as recommended in the Surgical Technique Guides, using the instruments provided. Failure to tighten the set screws to the recommended torque value could compromise the mechanical stability of the connector.
15. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
16. To prevent guide wire breakage, do not use a kinked or bent guide wire.
17. Guide wire advancement should be monitored using fluoroscopic imaging. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

PRECAUTIONS:
1. 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.
2. The Arsenal System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. The system has not been tested for heating or migration in the MR environment.
3. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
4. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may have an impact on the performance of the system.

POSSIBLE ADVERSE EFFECTS:
The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon must be discussed with the patient preoperatively.
1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components.
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, seroma, and possible tumor formation.
3. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur.
4. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
5. Infection and/or hemorrhaging.
6. Bone graft, vertebral body and/or sacral fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level.
7. Non-union and/or pseudarthrosis.
8. Neurological disorder, pain and/or abnormal sensations.
9. Revision surgery.
10. Death.

Excerpt from INS-076E

The Arsenal Spinal Fixation System is not in any way affiliated with Arsenal Medical.

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