Amendia

The Elements of Healing

SAVANNAH-T

HIGH TOP PEDICLE SCREW

Amendia

5.5
6.5
7.5

SVH

SAVANNAH-T
HIGH TOP PEDICLE SCREW

SURGICAL TECHNIQUE GUIDE

Savannah-T
High Top Pedicle Screw System

Table of Contents

Amendia
The Elements of Healing

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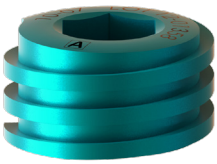
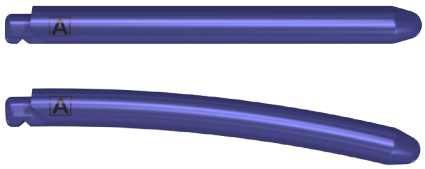
Disclaimer:
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon before and during surgery as to the best mode of treatment for each patient. Please reference the 510K or package insert for additional information and a complete list of intended indications, warnings, precautions, and other medical information.

Features & Benefits

- Constructed of implant grade Titanium Alloy (Ti 6Al-4V ELI)
- Cannulated screws
- Self-tapping "Grip Quick" Thread®
- 5.5 mm bulleted rods - straight or pre-lordosed
- Rods offered in 5 mm increments from 30 mm through 130 mm
- Rods offered in various increments from 140 mm through 300 mm (See catalog for available sizes)
- Set screw designed to prevent tulip splaying
- 13 mm extended thread for rod reduction
- Easy release break away towers
- Minimally invasive delivery reduces soft tissue disruption
- Anti-cross thread feature in tulip and set screw
- Connected Tab or Open Top options available



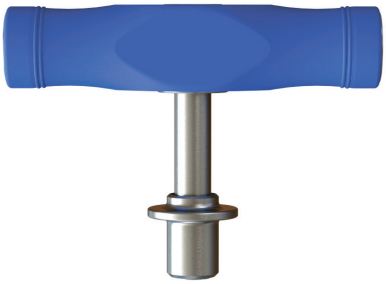


Available Sizes	
Diameter (mm)	Lengths (mm)
5.5	30-50
6.5	30-65
7.5	30-65

Handles

Axial Ratcheting Handle
11000-54

Palm Ratcheting Handle
11000-57



Torque-Limiting T-Handle
11000-55

Note: There are three handle types available for use with all quick connect instructions in the Savannah-T System. This includes the Taps, Pedicle Screw Driver, Screw Adjuster, and Set Screw Driver.

Instruments

Bone Awl (Non Cannulated)
11000-56

Straight Bone Probe (Duck Bill)
11000-51

Curved Bone Probe (DuckBill)
11000-52

Depth Sounder
11000-53

Instrument Guide

Taps

Part No.	Size
11000-8-45	4.5 mm
11000-8-50C*	5.0 mm (Cannulated
11000-8-55	5.5 mm
11000-8-55C	5.5 mm (Cannulated)
11000-8-65	6.5 mm
11000-8-65C	6.5 mm (Cannulated)

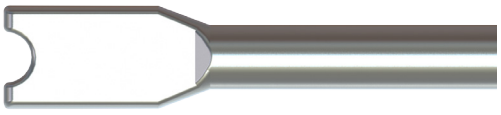
***Not Included In Standard Tray Configuration**

Pedicle Screw Driver
11000-14

Screw Adjuster
11000-7

Small Dilator
10650-2

Large Dilator
10650-3



Tulip Positioner
11000-3

Instrument Guide

Scissor Caliper
11000-13

Rod Bender
9095

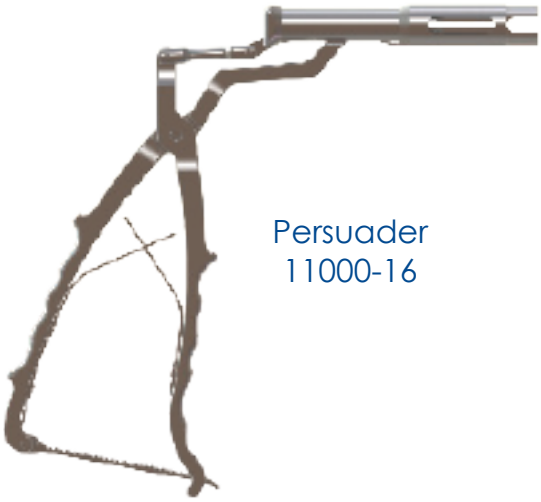
Rod Gripper
9091

Right Angle Rod Inserter
11000-11

Rod Inserter Driver (for Right Angle Rod Inserter)
11000-59

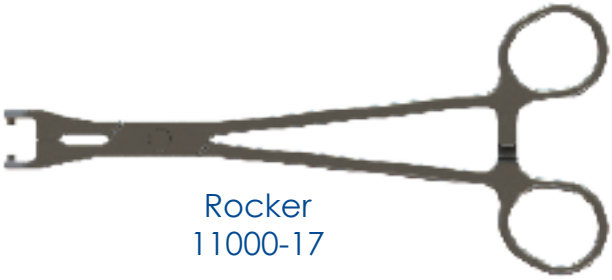
Instrument Guide

Set Screw Starter
11000-1



Persuader
11000-16

Counter Torque
11000-2

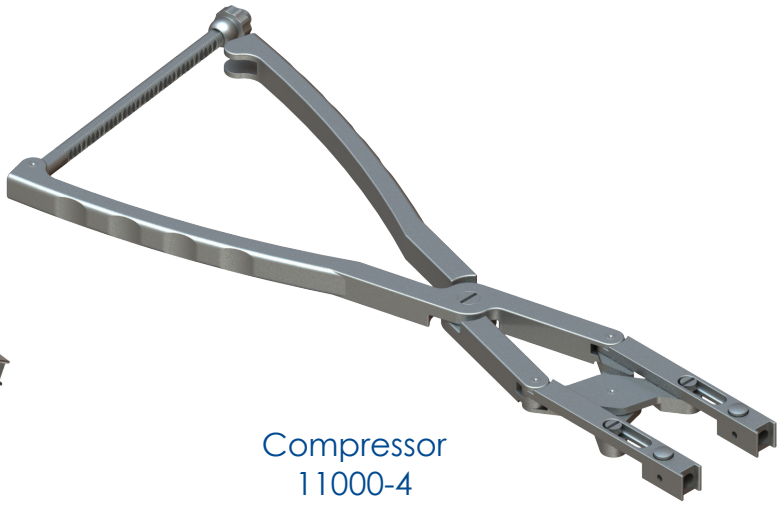


Rocker
11000-17

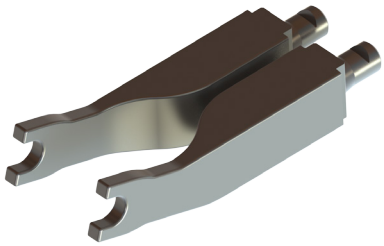
Set Screw Driver
11000-6

Instrument Guide

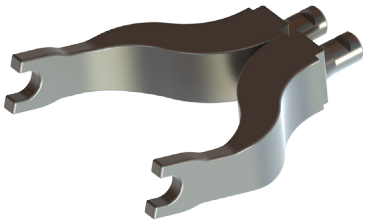
Distractor
11000-5



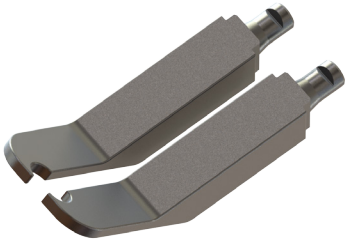
Compressor
11000-4



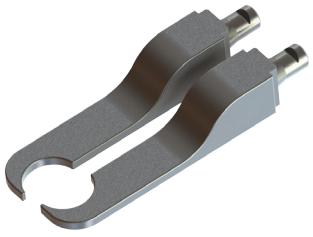
Curved Distractor/ Compressor Tip
11000-29



Offset Curved Distractor/ Compressor Tip
11000-30



Hook Distractor/ Compressor Tip
11000-31

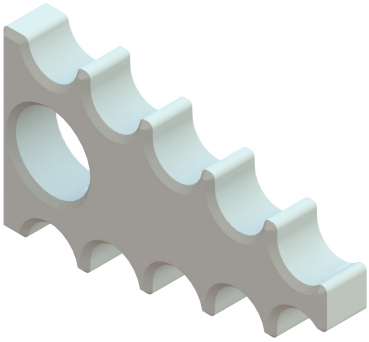


MIS Distractor/ Compressor Tip
11000-32

Instrument Guide

MIS Compressor
11000-20

MIS Sleeves
10-40



Compressor Fulcrum
10342-2

Tab Cutter (For Domed High Top)
11000-58

Tab Breaker (For High Top)
11000-12

Tab Breaker Pliers (For Mid Top)
11000-15

Bone Funnel
11000-18

Bone Tamp
11000-19

Optional

18 inch Guide Wire, Single Trocar Tip
9080-18U
(Single Use, Individual Sterile Packaged)

24 inch Guide Wire, Single Trocar Tip
9080-24U
(Single Use, Individual Sterile Packaged)

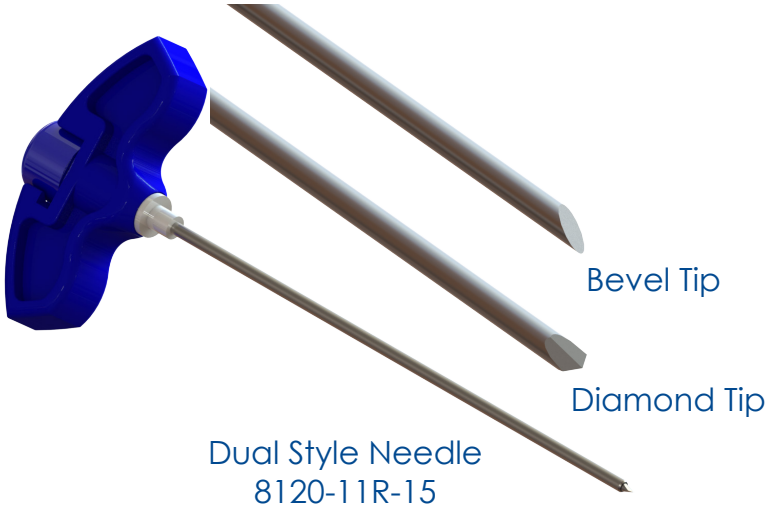
18 inch Threaded Guide Wire, Single Trocar Tip
9080-18T
(Single Use, Individual Sterile Packaged)

18 inch Banded Guide Wire, Single Trocar Tip
9080L-18U
(Single Use, Individual Sterile Packaged)

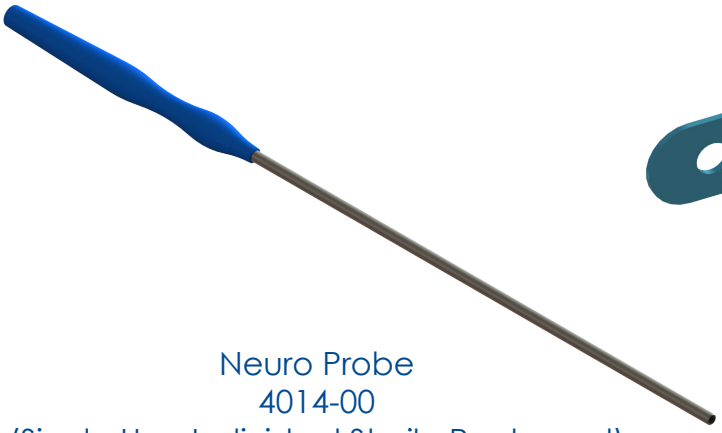
*Blunt Tipped Guide Wires are also available
9080B-18U, 9080B-24U, 9080B-18T

Optional

Crown
10-51
(For use with 10-06-DDLL-2)

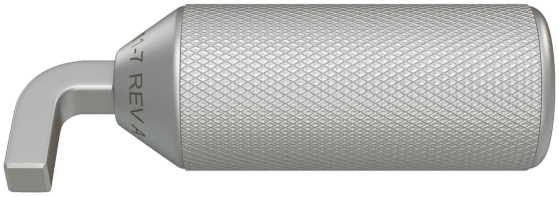


Dual Style Needle
8120-11R-15
(11 Gauge, 150 mm)
(Single Use, Individual Sterile Packaged)



Neuro Probe
4014-00
(Single Use, Individual Sterile Packaged)

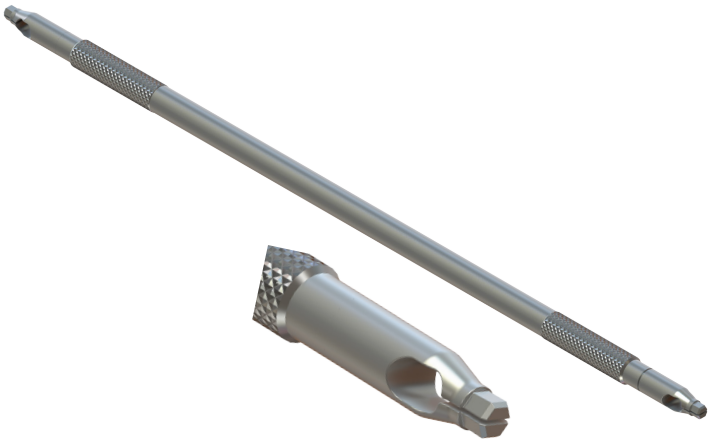
Lodestar
11000-40
(Single Use, Individual Sterile Packaged)



Anti Torque Handle
11000-11-7
(For use with Right Angle Rod Inserter)

Ratcheting T-Handle
9093

Optional



Extended Set Screw Starter
11000-36

Self Retaining Set Screw Driver
11000-24

Savannah-Link T20 Driver
11000-66
(For use with Savannah-Link)

Optional

Fulcrum Rocker
11000-26

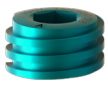
Lenke Tip Curved Bone Probe
337000

Lenke Tip Straight Bone Probe
336000

Large T-Handle with AO Connection
11000-67
(For use with Savannah-Link)

Flexible Rod Templates, 200 mm
11000-61

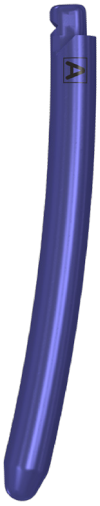
Part #	Size	Dome Topped Pedicle Screw, Cannulated
10-03-5530-2	5.5 mm x 30 mm	
10-03-5535-2	5.5 mm x 35 mm	
10-03-5540-2	5.5 mm x 40 mm	
10-03-5545-2	5.5 mm x 45 mm	
10-03-5550-2	5.5 mm x 50 mm	
10-03-6530-2	6.5 mm x 30 mm	
10-03-6535-2	6.5 mm x 35 mm	
10-03-6540-2	6.5 mm x 40 mm	
10-03-6545-2	6.5 mm x 45 mm	
10-03-6550-2	6.5 mm x 50 mm	
10-03-6555-2	6.5 mm x 55 mm	
10-03-6560-2	6.5 mm x 60 mm	
10-03-6565-2	6.5 mm x 65 mm	
10-03-7530-2	7.5 mm x 30 mm	
10-03-7535-2	7.5 mm x 35 mm	
10-03-7540-2	7.5 mm x 40 mm	
10-03-7545-2	7.5 mm x 45 mm	
10-03-7550-2	7.5 mm x 50 mm	
10-03-7555-2	7.5 mm x 55 mm	
10-03-7560-2	7.5 mm x 60 mm	
10-03-7565-2	7.5 mm x 65 mm	

Part #	Set Screw
10-07	

Part #	Size	Split Tower Tulip Pedicle Screw, Cannulated
10-06-5530-2	5.5 mm x 30 mm	
10-06-5535-2	5.5 mm x 35 mm	
10-06-5540-2	5.5 mm x 40 mm	
10-06-5545-2	5.5 mm x 45 mm	
10-06-5550-2	5.5 mm x 50 mm	
10-06-6530-2	6.5 mm x 30 mm	
10-06-6535-2	6.5 mm x 35 mm	
10-06-6540-2	6.5 mm x 40 mm	
10-06-6545-2	6.5 mm x 45 mm	
10-06-6550-2	6.5 mm x 50 mm	
10-06-6555-2	6.5 mm x 55 mm	
10-06-6560-2	6.5 mm x 60 mm	
10-06-6565-2	6.5 mm x 65 mm	
10-06-7530-2	7.5 mm x 30 mm	
10-06-7535-2	7.5 mm x 35 mm	
10-06-7540-2	7.5 mm x 40 mm	
10-06-7545-2	7.5 mm x 45 mm	
10-06-7550-2	7.5 mm x 50 mm	
10-06-7555-2	7.5 mm x 55 mm	
10-06-7560-2	7.5 mm x 60 mm	
10-06-7565-2	7.5 mm x 65 mm	

Implant Guide

Part #	Straight Notched Rod
10705-030*	
10705-035*	
10705-040	
10705-045	
10705-050	
10705-055*	
10705-060	
10705-065*	
10705-070	
10705-075*	
10705-080	
10705-085*	
10705-090	
10705-095*	
10705-100	
10705-105*	
10705-110*	
10705-115*	
10705-120*	
10705-125	
10705-130*	
10705-140*	
10705-150*	
10705-160*	
10705-170*	
10705-175*	
10705-180*	
10705-190*	
10705-200*	
10705-220*	
10705-240*	
10705-250*	
10705-260*	
10705-280*	
10705-300*	

Part #	Curved Notched Rod
10706-030*	
10706-035*	
10706-040	
10706-045	
10706-050	
10706-055	
10706-060	
10706-065	
10706-070	
10706-075	
10706-080	
10706-085	
10706-090	
10706-095	
10706-100	
10706-105*	
10706-110*	
10706-115*	
10706-120*	
10706-125*	
10706-130*	
10706-140*	
10706-150*	
10706-160*	
10706-170*	
10706-175*	
10706-180*	
10706-190*	
10706-200*	

***Not Included In Standard Tray Configuration**

1. Prepare the Pedicle

Make an incision to expose all the pedicles that will be used for the screw construct. Use the **Dual Stylet Needle** and radiographic imaging to find the optimal trajectory (**Figure 1**) for the **Pedicle Screw** and create a pilot hole in the pedicle (**Figure 2**).

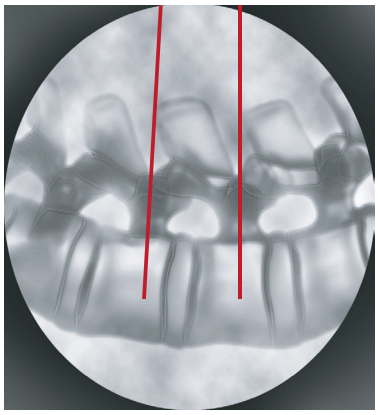


Figure 1

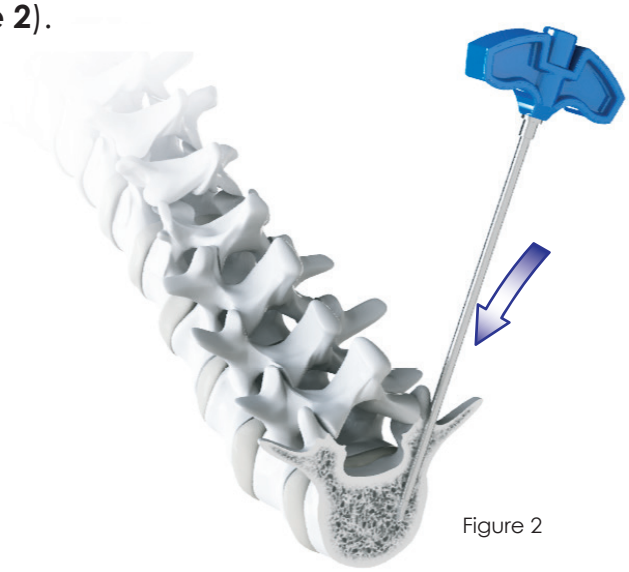


Figure 2

Remove the stylet from the **Dual Stylet Needle (Figure 3)**. Use the cannulation to introduce the **Guide Wire (Figure 4)**. Insert the **Guide Wire** through the cannulated handle, pressing it into the bone to anchor it. Remove the cannulated handle keeping the **Guide Wire** in place **(Figure 5)**. Use radiographic imaging to confirm placement and orientation within the pedicle. Repeat for all pedicles supporting the construct.

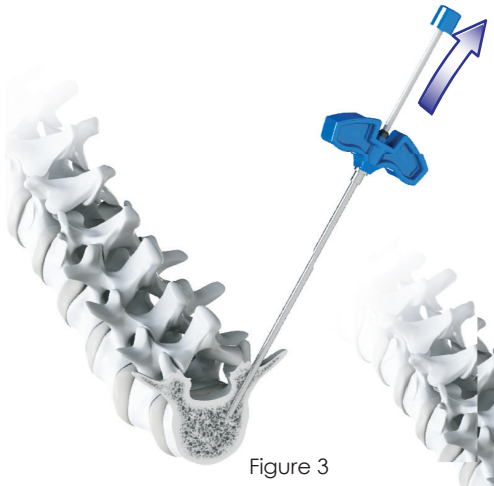


Figure 3

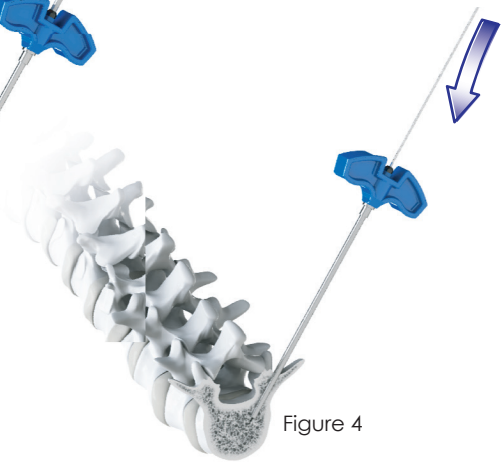


Figure 4

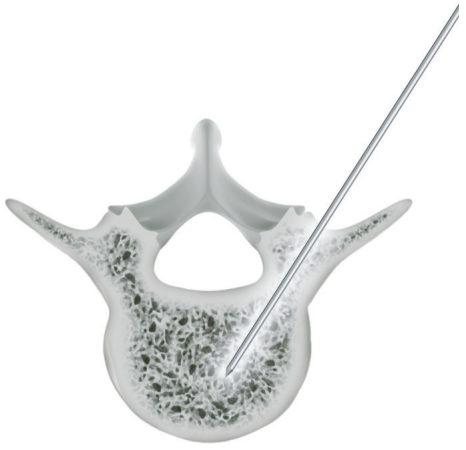


Figure 5

2. Screw Delivery

Optional

Savannah-T Cannulated Pedicle Screws have a self-tapping tip, therefore tapping is optional. If tapping is preferred, use the **Cannulated Tap** over the **Guide Wire** to prepare the pedicle for screw delivery **(Figure 6-A)**. It is recommended to prepare the pedicle using an undersized **Tap**. *Note: The **Taps** are labeled with their actual diameter. The threaded length of the **Tap** is 30 mm **(Figure 6-B)**.*

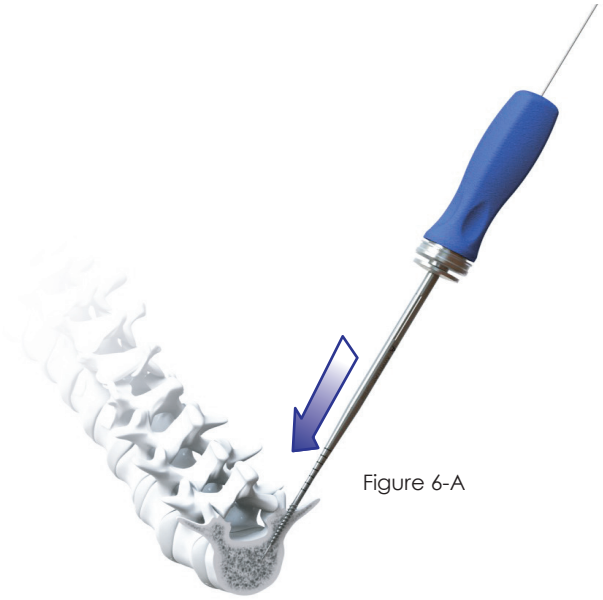


Figure 6-A

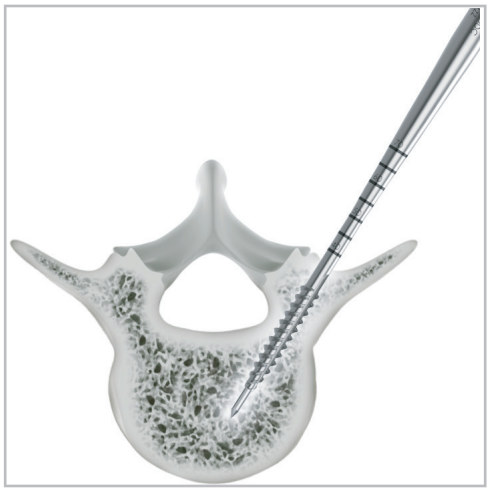


Figure 6-B

Load the appropriate size **Pedicle Screw** onto the **Pedicle Screw Driver (Figure 7)** by threading the outer shaft into the threads on the tulip **(Figure 8)**, making sure the inner shaft's hex is engaged in the screw **(Figure 9)**. Tighten for a secure fit. Alternatively, the **Screw Adjuster** may be used as a friction fit driver.

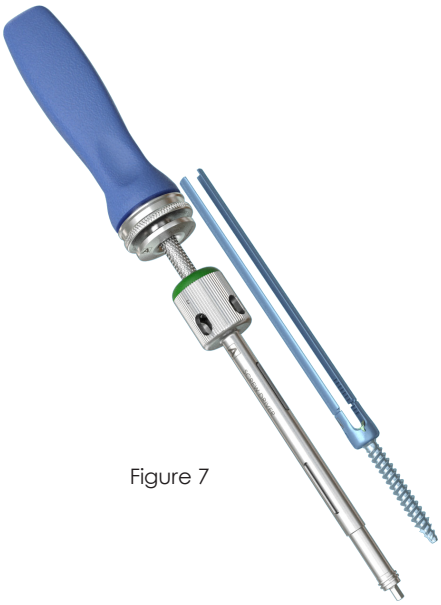


Figure 7

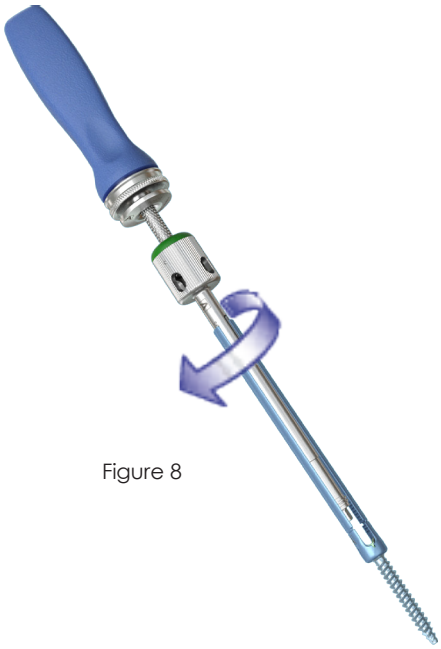


Figure 8

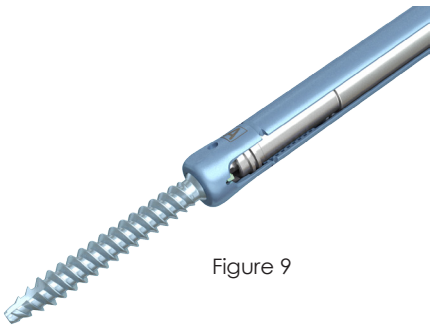


Figure 9

Using the handle of your choice on the **Pedicle Screw Driver**, send the **Pedicle Screw** over the **Guide Wire** and drive it into the prepared pedicle **(Figures 10-A, 10-B)**. Remove the **Driver** by backing out the outer shaft's threads and remove the **Guide Wire (Figure 11)**. Repeat for all pedicles supporting the construct.

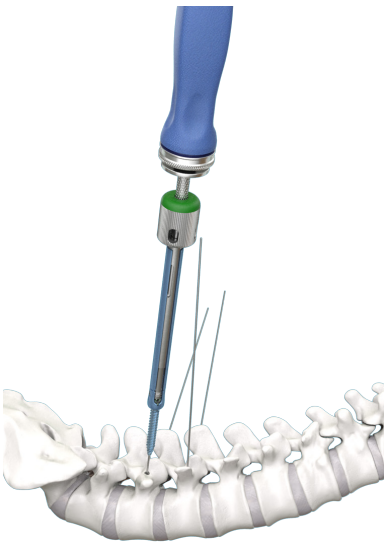


Figure 10-A

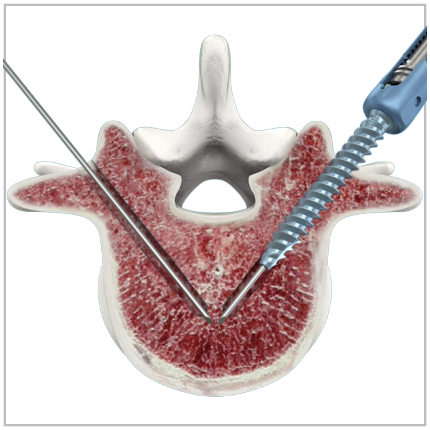


Figure 10-B

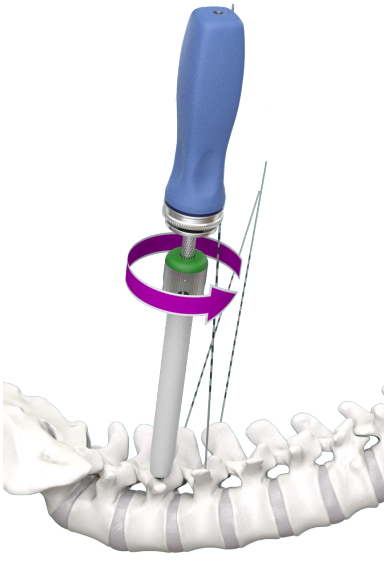


Figure 11

3. Introducing the Rod

Measure the distance between screws with the **Scissor Caliper**. Place the ends of the **Caliper** down through the towers of the **MIS Screws** into the tulips, where the **Rod** will ultimately be secured **(Figure 12-A)**. Read the indicator on the **Caliper (Figure 12-B)**. Each graduation is x10 mm. Read the upper scale for bullet tipped **MIS Rods**. *Note: This is only a guide for choosing the **Rod** length. The actual **Rod** length may vary depending on the specific case.*

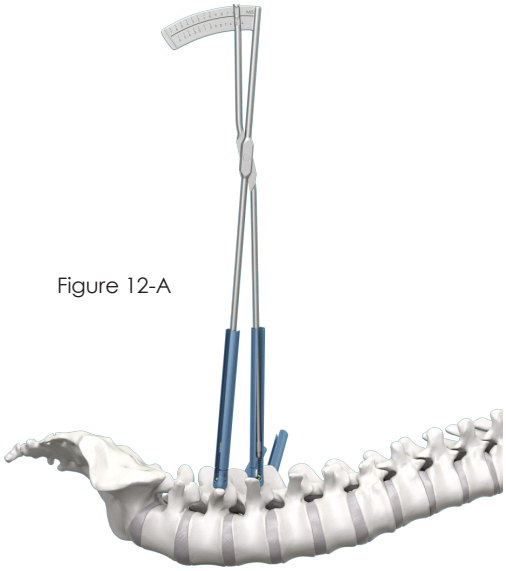


Figure 12-A

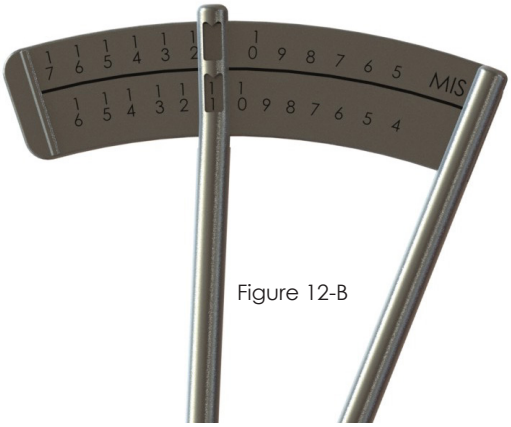


Figure 12-B

Place the selected **Rod** into the **Right Angle Rod Inserter**, mating the notched end of the **Rod** so it dovetails into the **Inserter (Figure 13-A)**. Then use the **Rod Inserter Driver** to turn the hex near the handle connection clockwise, to lock the **Rod** in place **(Figure 13-B)**.

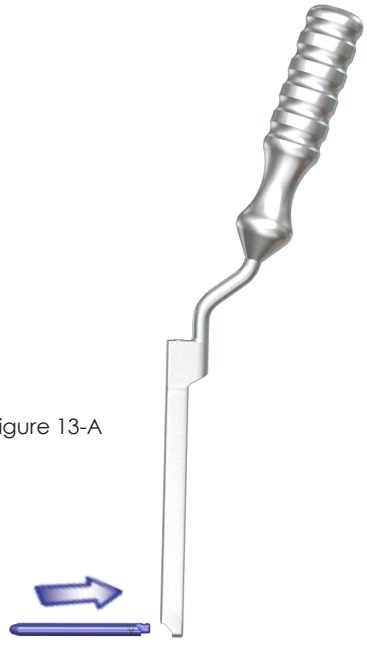


Figure 13-A

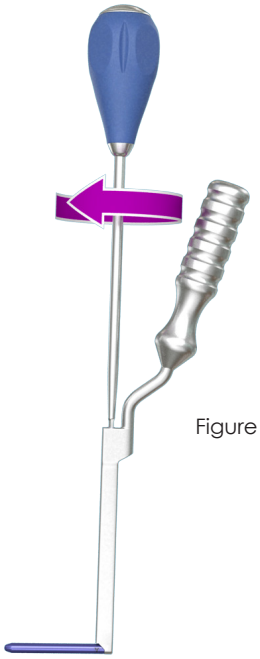


Figure 13-B

4. Rod Insertion

Use the **Right Angle Rod Inserter** to introduce the **Rod** through the incision, accessing the incision through the top of the **MIS Pedicle Screw** construct. Insert the bullet tip of the **Rod** until it is below the muscle fascia **(Figure 14)**.

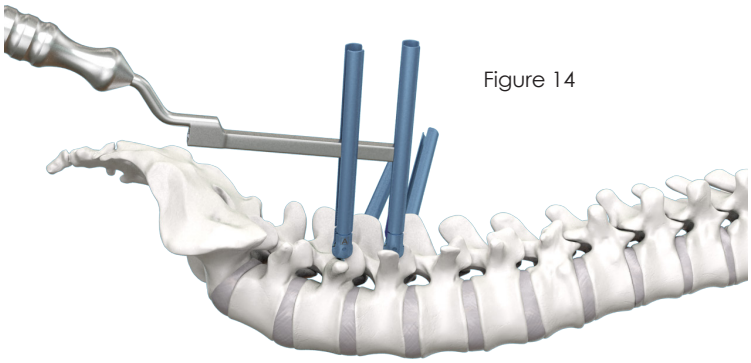


Figure 14

Pivot the **Rod Inserter** to direct the end of the **Rod** through the tower of the second **MIS Pedicle Screw (Figure 15)**.

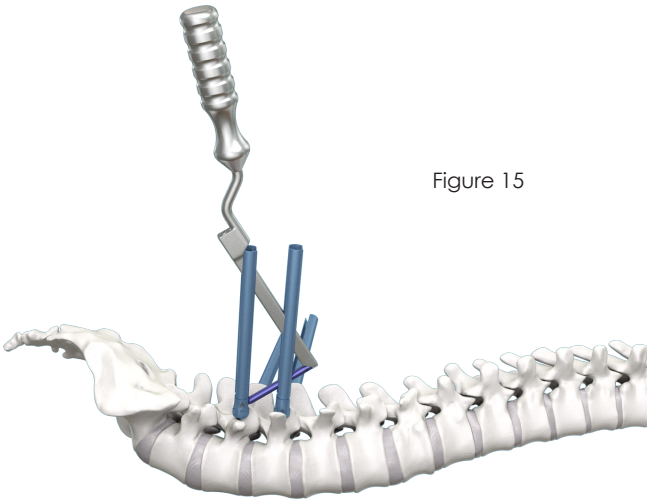


Figure 15

Rotate the **Rod** and sweep the handle upwards to seat the **Rod** into place within the saddles of the screw heads, staying within the incision and directing the **Rod** under the tissue **(Figure 16)**.

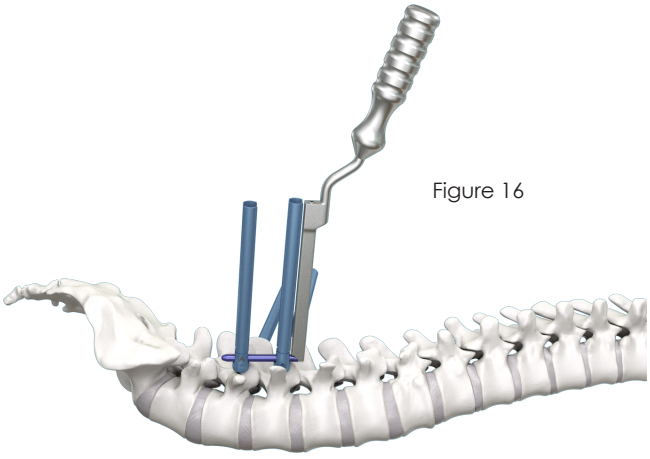


Figure 16

5. Securing the Rod and Final Tightening

Load both ends of the **Set Screw Starter** with **Set Screws (Figure 17)**. Place **MIS Sleeves** over the tulips **(Figure 18)**. With the **Right Angle Rod Inserter** still in place, send the loaded **Set Screw Starter** down the center of the **MIS Screws (Figure 19)**. Install the **Set Screws** into the tulips and thread down until they engage the **Rod**. Repeat for each tulip along the **Rod**. *Note: Excessive torque may damage the **Set Screw Starter**.*

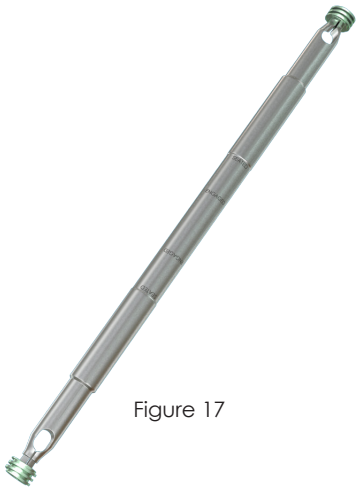


Figure 17

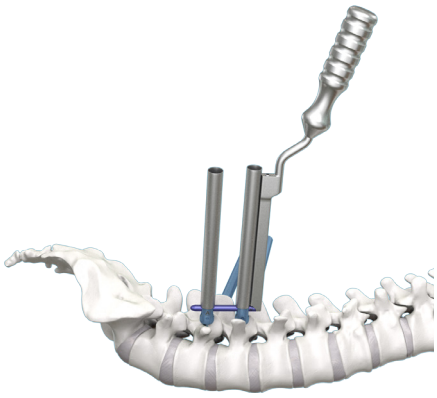


Figure 18

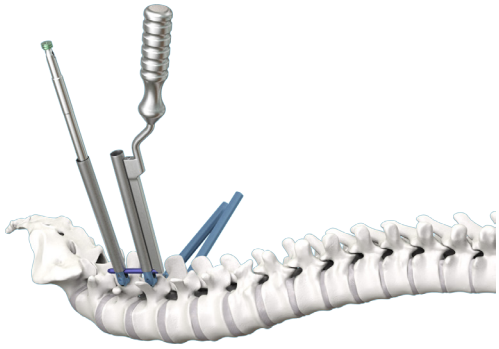


Figure 19

Incrementally tighten each **Set Screw**, assuring that the **Rod** is properly seated in every **Screw** before beginning final tightening.

(Optional) If compression is necessary, first use the **Set Screw Driver** with **Torque-Limiting T-Handle** to tighten the **Set Screw** farthest from the **Right Angle Rod Inserter**. Then remove the **Right Angle Rod Inserter**. Next, insert the **Compressor Fulcrum** between the towers. Apply compression below the **Compressor Fulcrum (Figure 20-A)**. Next, torque down the remaining **Set Screws** using the **Set Screw Driver (Figure 20-B)**.

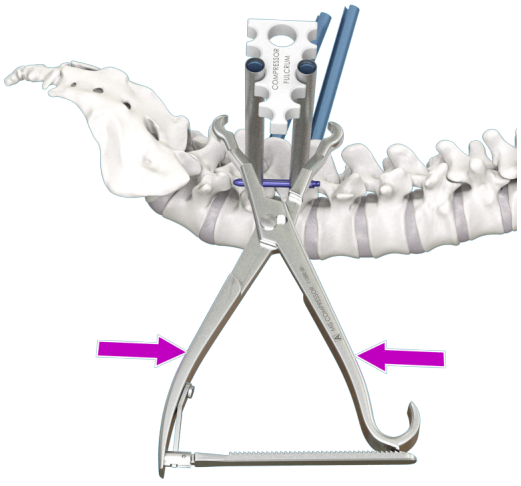


Figure 20-A

Figure 20-B

If Compression Was Not Used:

Once one **Set Screw** is tightened, remove the **Right Angle Rod Inserter** by turning the hex on the proximal end counter-clockwise **(Figure 21)** and pull the **Inserter** away from the **Rod** until it is released **(Figure 22)**. Tighten remaining **Set Screws** using the above method. Repeat steps 3, 4, and 5 on the other side of the construct. Remove the **Compression Sleeves (Figure 23)**.

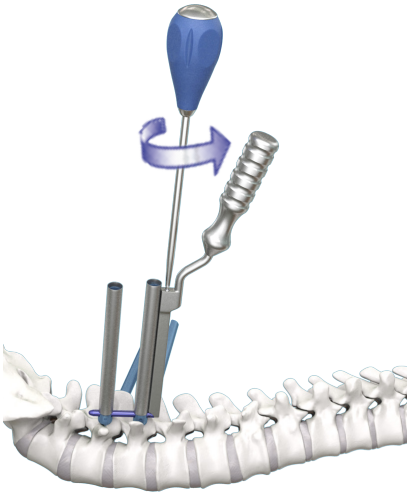


Figure 21

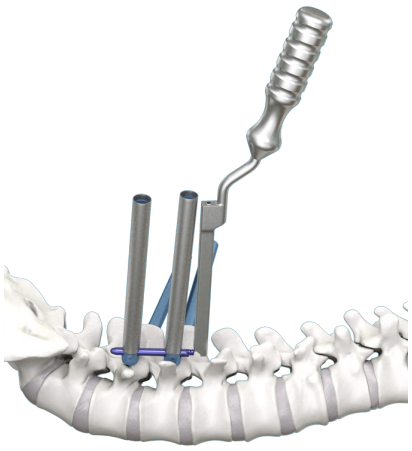


Figure 22

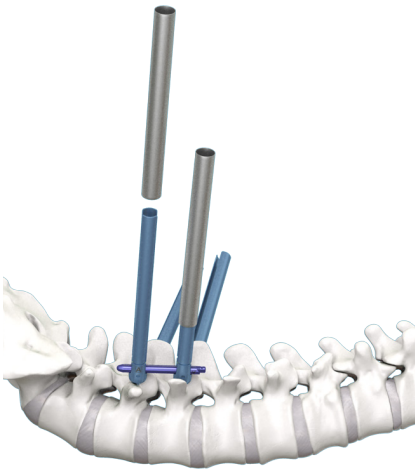


Figure 23

Perform final tightening with the **Torque Limiting T-Handle (Figure 24)**. The **Counter Torque** should be used at every level to ensure that excessive forces are not transmitted to the vertebral bodies when the **Torque Limiting Driver** "clicks" at the desired final torque.

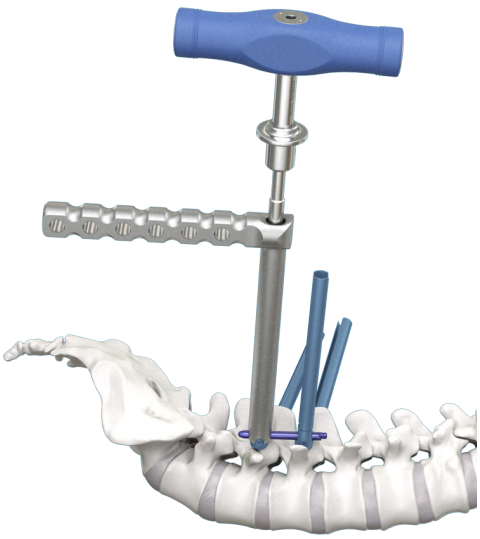


Figure 24

6. Tab Removal

Use the **Tab Breaker** to pry the extension tabs until they break off of the tulip and discard them **(Figure 25-A, 25-B, 25-C)**.

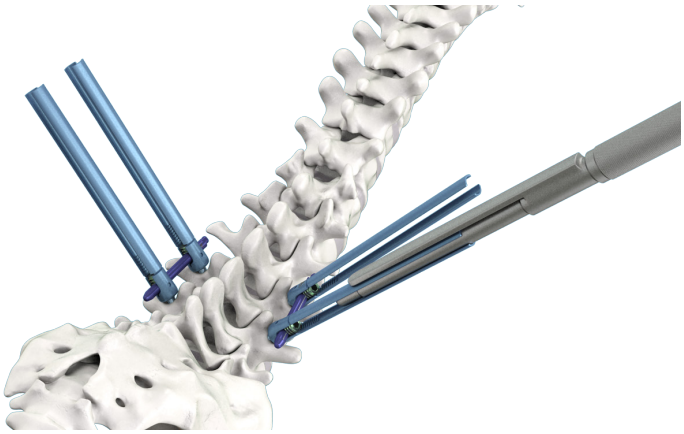


Figure 25-A

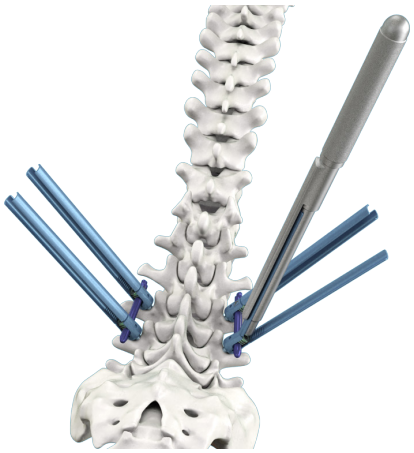


Figure 25-B

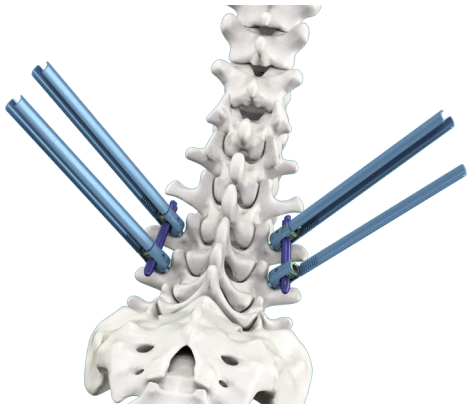


Figure 25-C

Important Product Information

CAUTION: Federal law (USA) restricts these devices to the sale by or on the order of a physician. Implants and disposable instruments single use only.
Description:
The Savannah® Lumbar Percutaneous Stabilization System is comprised of a variety of pedicle screws sizes, couplers, a ball swivel, rods and locking nuts that can be uniquely fitted for each individual case.
The Savannah-T® Pedicle Screw System consists of pedicle screws, mono-axial and poly-axial screw heads, connecting rods, set screws, and transverse crossmembers, called the Savannah-Link. The screws are available in various diameters and lengths, and the rods are available in straight and curved versions in various lengths.
All implantable components are manufactured from medical grade titanium alloy (Ti-6Al-4V per ASTM F136) and are provided non-sterile for single-use. (NOTE: Titanium and stainless steel implants should not be mixed in patients as corrosion may occur resulting in decreased mechanical performance.) The system is to be used with bone graft material to facilitate spinal fusion.

Indications for Use:
The Savannah® Lumbar Percutaneous Stabilization System (SLPSS) is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:
• When used as a pedicle screw fixation system of the posterior lumbar spine in skeletally mature patients, the SLPSS is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) spinal tumor, and/or (5) failed previous fusion (pseudarthrosis).
• In addition, when used as a pedicle screw fixation system, the SLPSS is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.
• The Savannah® Lumbar Percutaneous Stabilization System (SLPSS) is also intended to provide immobilization and stabilization of the spinal segments of the lumbar and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.
The Savannah-T® systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine, specifically as follows:
• When intended for pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients the Savannah-T® systems are indicated for one or more of the following: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and/or failed previous fusion (pseudarthrosis).
• In addition, when used as a pedicle screw fixation system, the Savannah-T® systems are indicated for skeletally mature patients having degenerative spondylolisthesis with objective evidence of neurologic impairment and/or severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and who are having the device removed after the development of a solid fusion mass.

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 (grades 3 and 4) of the L5–S1 vertebra, degenerative 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. The Savannah® and Savannah-T® system components are not to be used with systems or components of another manufacturer.

Important Product Information

Contraindications include, but are not limited to:
• Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
• Insufficient quality or quantity of bone which would inhibit rigid device fixation.
• Previous history of infection.
• Excessive local inflammation.
• Open wounds.
• Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
• Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
• Patients having inadequate tissue coverage of the operative site.
• Pregnancy.
• A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
• Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
• Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

Precautions:
• Surgical Implants should never be reused.
• Handle carefully to avoid damage to the implants or instruments.
• 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.
• A successful result is not always achieved in every surgical case. Surgeons should not implant the Savannah® and Savannah-T® spinal implants until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the Savannah® Lumbar Percutaneous Stabilization System Surgical Technique Manual and Savannah-T® Pedicle Screw System Surgical Technique Manual for more information on proper implantation technique.
• The Savannah® and Savannah-T® systems have not been evaluated for safety and compatibility in the MR environment. The Savannah® and Savannah-T® systems have not been tested for heating or migration in the MR environment.

Possible Adverse Effects:
Potential adverse effects may include, but are not limited to the following:
• Bending, disassembly, or fracture of any or all implant components.
• Pain, discomfort, or abnormal sensations due to the presence of the device.
• Pressure on the skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin, seroma or wound dehiscence.
• Dural leak, pseudomeningocele, or fistula requiring surgical repair.
• Loss of proper spinal curvature, correction, height and/or reduction.
• Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending, or fatigue fracture.
• Early or late loosening of spinal fixation implants.
• Peripheral neuropathies, nerve damage, neurovascular compromise, paralysis, loss of bowel or bladder function, or foot-drop. Other neurologic adverse events may include motor or sensory loss, spasms, parasthesia, paraparesis cauda equina syndrome, numbness and decrease or total loss of reflexes and/or muscle tone.
• Serious complications may be associated with any spinal surgery. These complications include but are not limited to: genitourinary disorders; gastrointestinal orders; vascular disorders; including thrombus; bronchopulmonary disorders, including emboli, atelectasis, pneumonia and ARD; bursitis, hemorrhage, seroma, myocardial infarction, infection, paralysis or death.
• Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
• Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
• Decrease in bone density due to stress shielding.
• Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of the bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.
• Heterotropic bone formation.
• Graft site pain, fracture or wound healing problems.
• Tissue reaction to the implant, debris or corrosion of the implant material.
• Disc herniation and degeneration of adjacent discs.
• Decreased ability to perform activities of daily living.

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510(k) Number: K132925
MM-066, Rev. 5