BridgePoint

Spinous Process Fixation System

FEATURES

- Telescoping Plates for Compression and Distraction
- Large Bone Graft Window
- Large Contact Area
- Preassembled Device
- Implant Angulation

Alphatec Spine®

PREFACE

BridgePoint Spinous Process Fixation System is a spinous process fixation system that was developed to address the disadvantages of traditional stabilization devices. The system allows surgeons to fixate the spine using a less invasive approach by attaching a plate to the spinous process of the vertebral body during spinal fusion surgery. Pedicle screws are time consuming to place, can interfere with the superior facet joint complex, and risk increased blood loss and the risk of nerve root injury. Also, there is a morbidity associated with aggressive dissection through the paraspinal musculature to the lateral aspect of the spine. This approach does not limit access to the pars and transverse processes and reduces the amount of soft tissue dissection and damage.

BridgePoint Spinous Process Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine for conditions including degenerative disc disease, spondylolisthesis, tumor, and/or trauma. The BridgePoint device is used as an adjunct to interbody fusion or posterior fusion with decompression treatment. It can be used for posterior interlaminar fusion, posterolateral fusion, ALIF, TLIF, TLIF with unilateral screws, hybrid constructs and revision procedures as well as direct lateral fusion.

IMPORTANT NOTE

As with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary. The surgical approach is dependent upon the surgeon's preference and level treated.

The BridgePoint Spinous Process Fixation System is intended for use with bone graft material.

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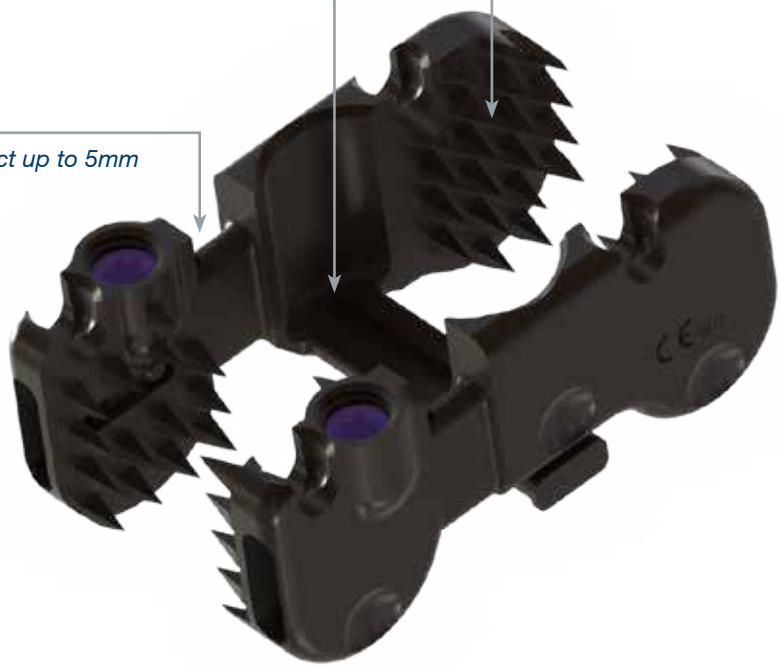
1 IMPLANT - 5 KEY FEATURES

1 Large Contact Area
Provides a strong anchor point and facilitates a reliable fusion

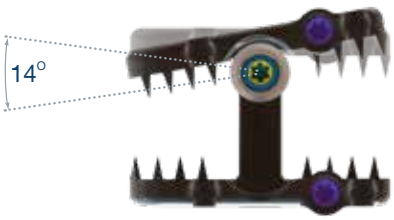
2 Large Bone Graft Window
Allows placement of bone graft for fusion

3 Telescoping Plate
Provides the ability to compress or distract up to 5mm

4 Preassembled Device
Minimizes operative time



5 Implant Angulation
Adapts to varying patient anatomy



2 PLATE SIZING

Plate sizing is dependent on surgeon preference. It is important not to oversize the plate. Avoid plate extension beyond the superior margin of the superior spinous process and the inferior margin of the inferior spinous process.

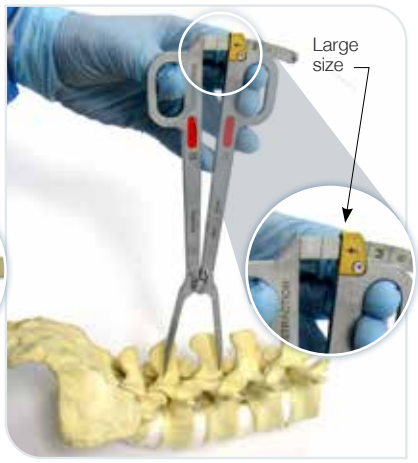
Calipers are provided to ensure proper sizing whether you choose to distract or compress the implant.

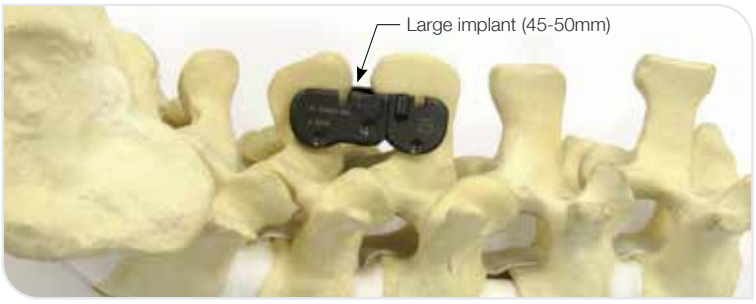
Distraction

If the level is to be distracted, the side laser marked “Distraction” may be used.

NOTE: Measure from the superior edge of the superior spinous process to the inferior edge of the inferior spinous process to position the tips of the calipers where the implant will be placed.

Read the scale on this side of the Calipers to determine implant size, which will be the largest size possible for the particular level.



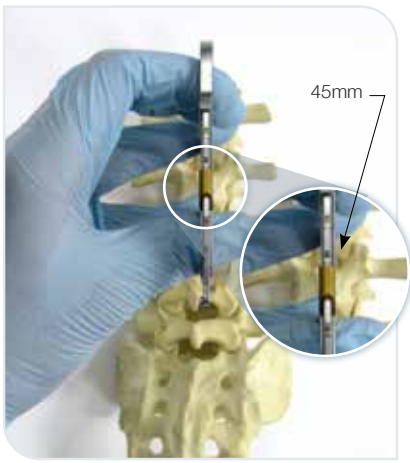


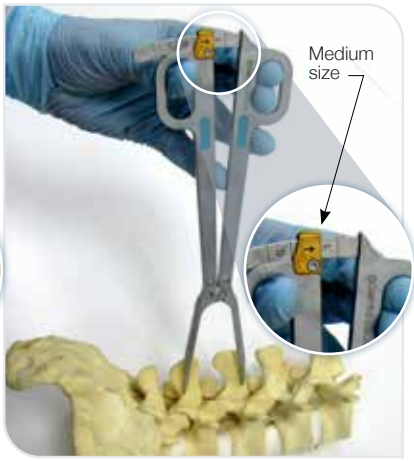
Compression

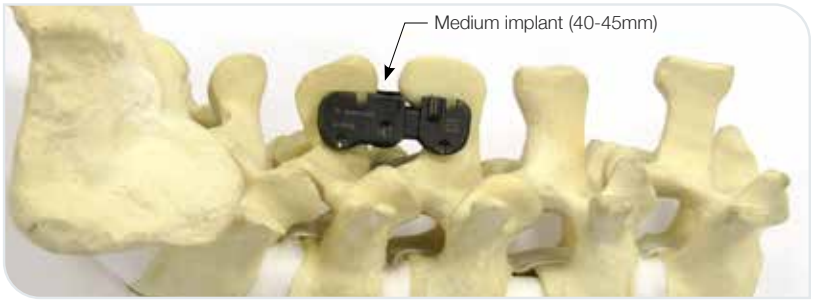
If the level is to be compressed, the side laser marked “Compression” may be used.

NOTE: Measure from the superior edge of the superior spinous process to the inferior edge of the inferior spinous process to position the tips of the Calipers where the implant will be placed.

Read the scale on this side of the Calipers to determine implant size, which will be the largest size possible for the particular level.







3 IMPLANT INSERTION AND PLACEMENT

1. Use the implant holder to select the appropriate size implant directly from the caddy.

2. **Optional:** Press the green locking button to ensure the ratchet does not slip.

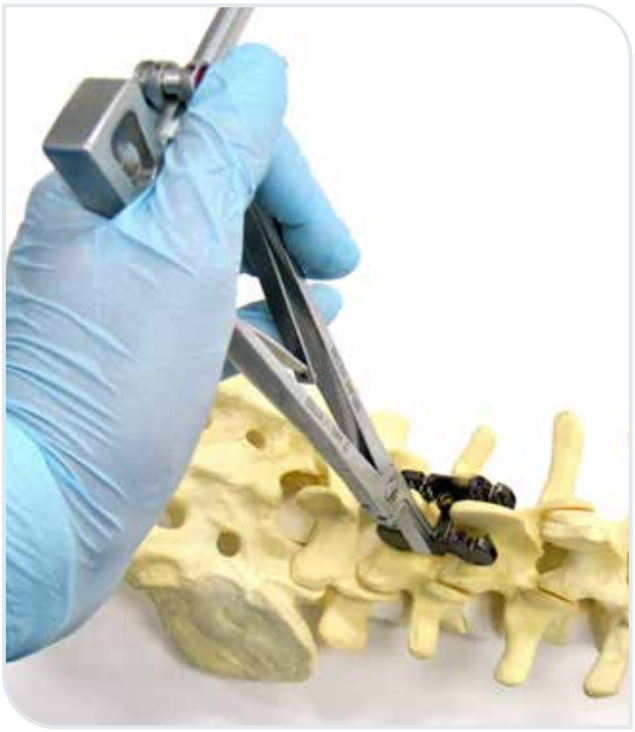
3. Place the implant around the spinous process.

   IMPORTANT: Ensure that the device is placed as far anteriorly as possible, but not so much that the posterior-most spikes do not engage sufficiently, and that the plate does not protrude above the lumbodorsal fascia.

   The lower contact points should be at the spinolaminar junction.

4. Confirm position in the sagittal plane, ensuring that the fixation spikes will securely engage both spinous processes.

5. Confirm correct placement with fluoroscopy.

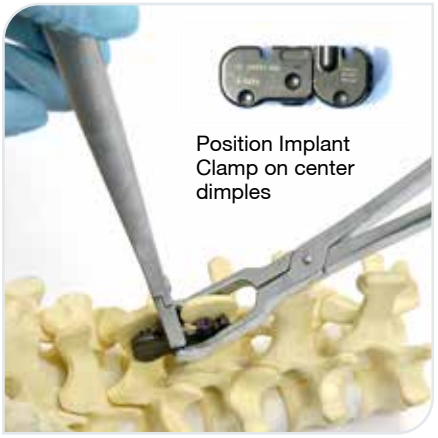


4 IMPLANT ENGAGEMENT

1. With the Implant Holder in place, use the Torque Shaft with the Torque Handle to loosen the medial set screw in order to allow the implant plates to move medially-laterally (1/4-1/2 set screw turn should be sufficient).
2. Confirm the Implant Clamp is unlocked and then mate it to the center dimples of the implant.
3. Use the Implant Clamp to press the implant spikes into the spinous processes.
4. Press the green locking button to ensure the ratchet does not slip. Remove the Implant Holder. (Fig. 1)
5. Place the second Implant Clamp on an outer set of dimples and then move the first Implant Clamp to the outer dimples on the opposite side.
6. Squeeze the clamps until the spikes are engaged and then press the green locking buttons to ensure the ratchets do not slip.
7. Use the Torque Shaft with the blue and purple bands with the Torque Handle to tighten the medial set screw to 25 in-lbs. Disengage the Implant Clamps

8a **IMPORTANT: Unless compression/ distraction will be performed, in which case the Implant Clamps should remain engaged to ensure optimal spike engagement during compression/distraction.**

8b If compression/distraction will NOT be performed, use the Torque Shaft with the blue and purple bands with the Torque Handle to tighten the lateral set screws to 25 in-lbs (the device is only tightened to 3 in-lbs straight out of the caddy).



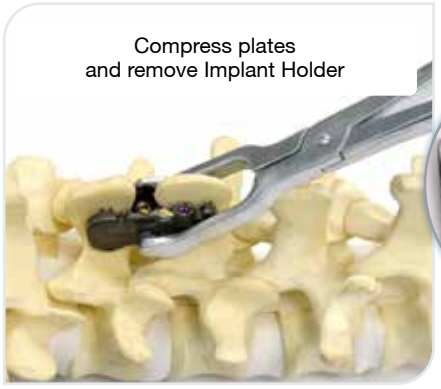
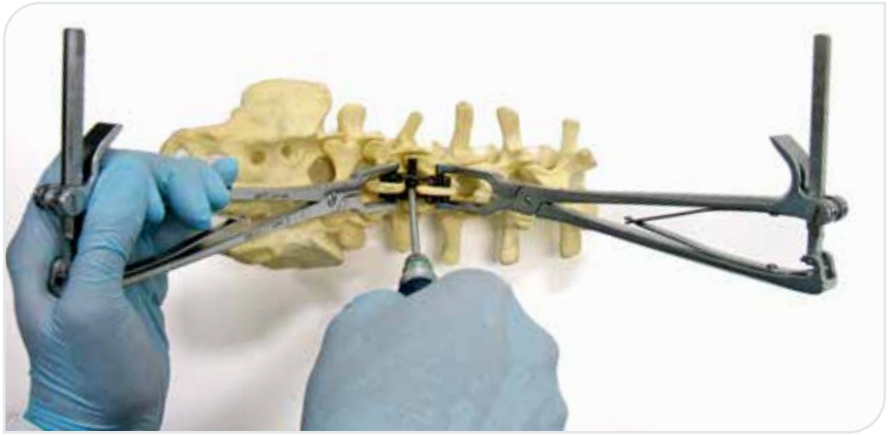


Figure 1

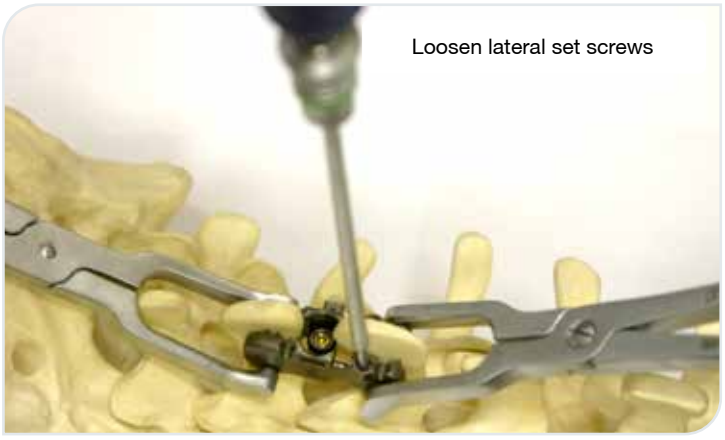
Place second Implant Clamp and then move first Implant Clamp to outer dimples.

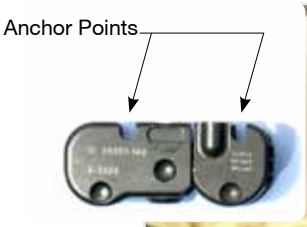


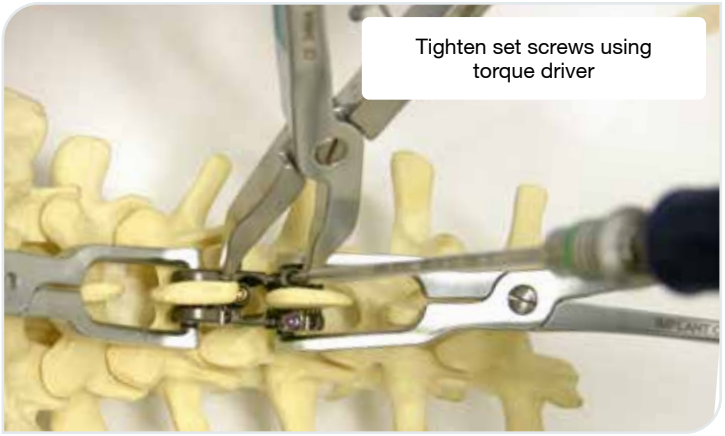
4a OPTIONAL: IMPLANT COMPRESSION/DISTRACTION

1. The Implant clamps should be engaged to ensure optimum spike engagement during compression/distraction.
2. Use the Torque Shaft to loosen the lateral set screws.
3. Engage the Compressor or Distractor with the implant anchor points and compress or distract the implant to the desired amount (up to 5mm).
4. Use the Torque Shaft with the Torque Handle to tighten the lateral set screws to 25 in-lbs.

NOTE: Even if compression/distraction is not performed, it is important to use the Torque Shaft with the blue and purple bands with the Torque Handle to tighten the lateral set screws to 25 in-lbs (the device is only tightened to 3 in-lbs straight out of the caddy).



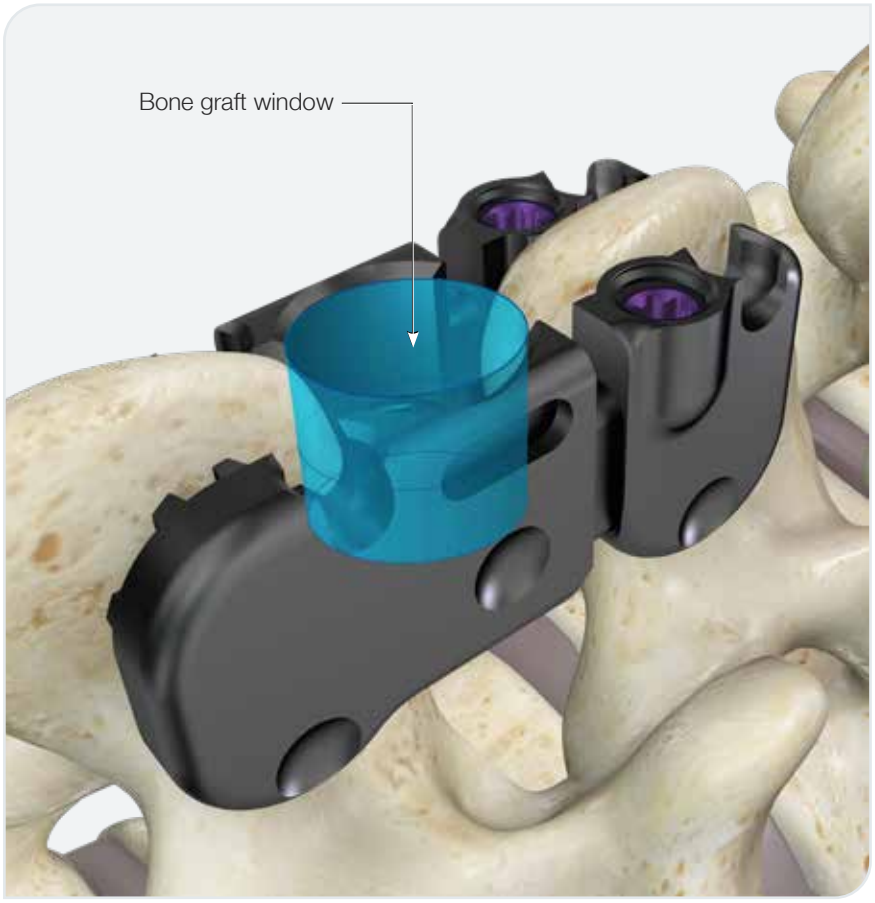




5 BONE GRAFTING AND CLOSURE

The BridgePoint Spinous Process Fixation System is **intended for use with bone graft** material and is **not intended for stand-alone use.**

NOTE: Interbody bone grafting technique is not covered in this technique guide. If performing an interbody fusion, disc preparation and interbody spacer placement is typically performed prior to placement of the BridgePoint device.



1 If not previously performed, decorticate the bone surfaces, prepare the fusion site for grafting and place the bone graft material. If bone graft will be placed between the spinous process through the implant window, the surgeon may choose to distract the level first, place bone graft, and then compress the spinous process onto the bone graft.

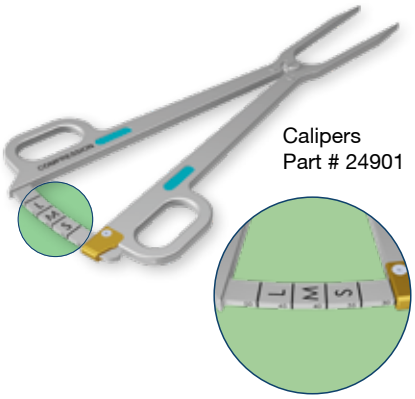
1a When fusing the spinous processes, bone graft material may be placed in the window of the device.

1b If fusing through the facets, decorticate articular surfaces and place bone graft in the usual manner.

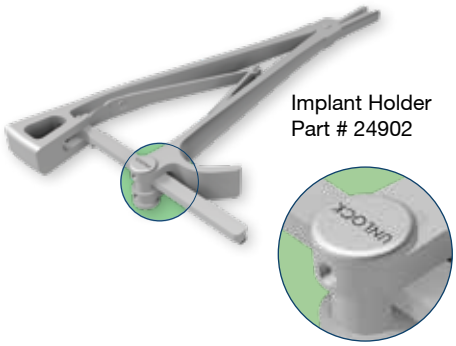
2 If desired, additional posterior bone grafting material may be placed around the implant, in the posterolateral gutter and/or across the interlaminar space.

3 After the construct is implanted and bone graft completed, close the surgical site using standard techniques.

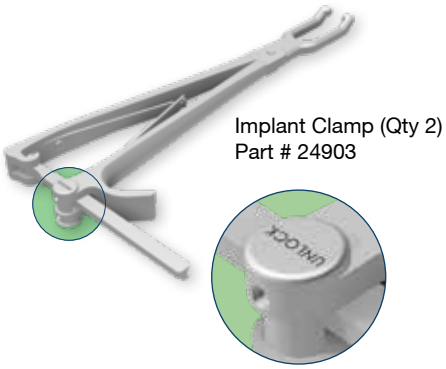
6 INSTRUMENTS



Calipers
Part # 24901

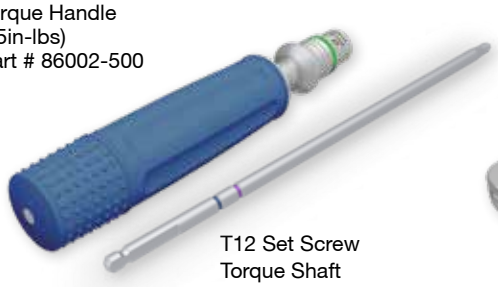


Implant Holder
Part # 24902

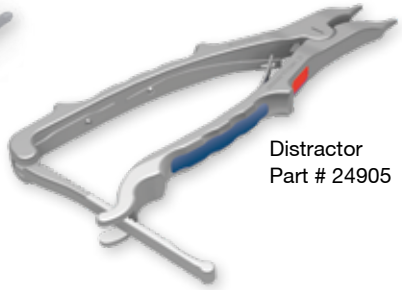


Implant Clamp (Qty 2)
Part # 24903

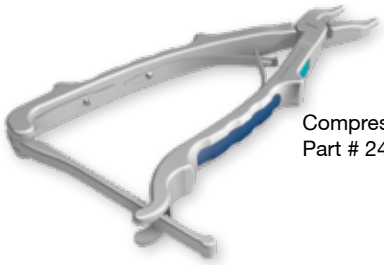
Torque Handle
(25in-lbs)
Part # 86002-500



T12 Set Screw
Torque Shaft
(Qty 2)
Part # 24909



Distractor
Part # 24905



Compressor
Part # 24904

7 REVISION INSTRUMENTS*

*Single use only.

Set Screw Torque Shaft
Part # 24908

8 IMPLANT SIZES

Part #	Description
24001-135	*Small 35mm - 40mm*
24001-140	*Medium 40mm - 45mm*
24001-145	*Large 45mm - 50mm*

Small 35-40mm

Medium 40-45mm

Large 45-50mm

INSTRUCTIONS FOR USE
BridgePoint® Spinous Process Fixation System

GENERAL INFORMATION:
BridgePoint is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: 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); and/or tumor. It is not intended for stand alone use.

The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

INDICATIONS FOR USE:
The BridgePoint Spinous Process Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: 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); and/or tumor. It is not intended for stand alone use.

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

WARNINGS:
1. The implants and instruments of the BridgePoint System are provided non-sterile and must be cleaned and sterilized before use. Refer to the CLEANING and STERILIZATION sections of this instruction for use.
2. The BridgePoint implants and set screw driver shafts 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.
    - Reuse of the single use set screw driver shaft may result in failure due to stripping of the implant set screws and/or shearing of the driver tip.
3. The BridgePoint 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, or bone failure.
4. The safety and effectiveness of BridgePoint System has been established only for the conditions listed in the indications for use. The safety and effectiveness of these devices for any other conditions are unknown.
5. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system.
6. Risk identified with the use of this device, which may require additional surgery, include spinous process fracture, loss of fixation/stabilization, non-union, neurological injury or vascular injury.
7. Risk factors that may affect successful surgical outcomes include alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality.
8. 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.
9. 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.
10. The system implants of the BridgePoint System should not be used with instruments from any other company's systems.

PRECAUTIONS:
1. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant are important considerations in the success of surgery.
2. It is critical that the device's teeth are fully seated into the bone for proper application of the device.
3. The BridgePoint implant has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The BridgePoint implant has not been tested for heating or migration in the MR environment
4. Device components should be received and accepted only in packages that have not been damaged. Damaged implants should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.

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, 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 pseudoarthrosis
8. Neurological disorder, pain and/or abnormal sensations
10. Revision surgery
11. Death

Excerpt from INS-043C

Associated Systems

Associated Alphatec Spine Systems include:

Alphatec solus
Anterior Lumbar Interbody Fusion

NOVEL® ALS
Anterior Lumbar Interbody Fusion
Spinal Spacer System

ILLICO® FS
Facet Fixation System

Alphatec Spine®

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