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Thoracolumbar Solutions

Vitality®+ Hook

Implant and Instrument Kit

Surgical Technique Guide

Vitality+ Hook Implant and Instrument Kit Highlights

The Vitality+ Hook Implant and Instrument Kit is the next leap forward, in the evolution of the Vitality Spinal Fixation System, and another addition to Zimmer Biomet Spine's expanding portfolio of surgical solutions for complex spine procedures.

Kit Features:

- *An assortment of additional fixation options designed for sublaminar, pedicle, and transverse process hook fixation techniques.*
- *Various throat depths to accommodate individual patient anatomy, surgeon preference, and to facilitate a complete spectrum of surgical techniques.*

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

SYSTEM OVERVIEW

The Vitality+ Hook Implant and Instrument Kit is a subset of the Vitality Spinal Fixation System and is intended for use with Vitality instruments and implants. It should be noted, however, that the counter-torque from the Vitality Locking Instruments Kit (Kit#: 07.02136.405) is not compatible with the implants found in the Vitality+ Hook Implant and Instrument Kit. The counter-torque handle included in the Vitality+ Hook Implant and Instrument Kit should be used during final tightening and revisions.

Hook Starters

An assortment of hook starters is available in the Vitality+ Hook Implant and Instrument Kit. These instruments are designed to assist the surgeon in preparing the implant site and separating ligamentous attachments from bone prior to affixing a hook. These hook starters may be used to facilitate the placement of hooks using sublaminar, transverse process, and pedicle fixation techniques.

NARROW LAMINAR HOOK STARTER	PART NUMBER
	730M0034

THORACIC HOOK STARTER	PART NUMBER
	730M0035

MEDIUM LAMINAR HOOK STARTER	PART NUMBER
Optional, does not come in standard kit configuration	730M0033

PEDICLE HOOK STARTER	PART NUMBER
	730M0031

WIDE LAMINAR HOOK STARTER	PART NUMBER
	730M0032

Hook Holders

All hooks may be inserted using a vertical, angled, or side hook holder (Figures 1, 2, 3). Attach the vertical and angled hook holders, via the dimples on the sides of the hook tulip (Figures 1, 2, 4).

The side hook holder attaches to any hook in the system via ipsilateral relief slots found on the front and rear aspect of each tulip wall (Figures 3, 4) .

Note: *A closure top can be pre-loaded into the hook's tulip before insertion, using any of the hook holders.*

Note: *The angled and side hook holders allow the surgeon to introduce, adjust, and remove a closure top, while the hook holder is still affixed to a hook (Figures 2, 3, 5, 6).*

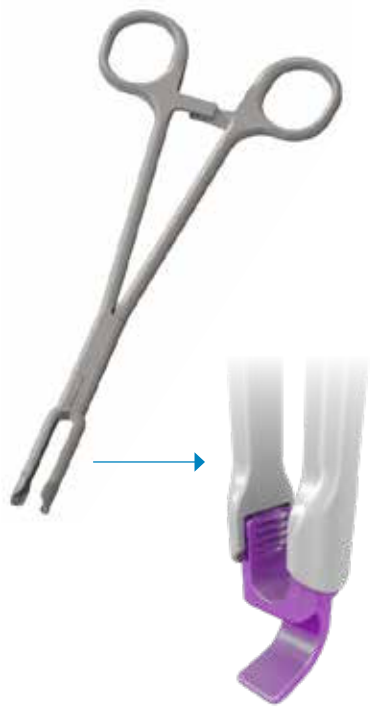


Figure 1
Vertical hook holder

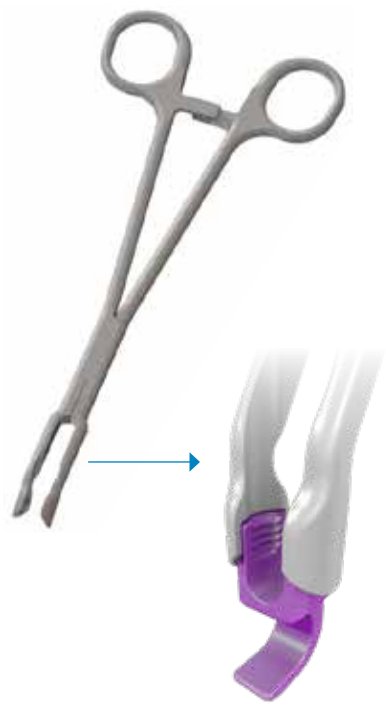


Figure 2
Angled hook holder

Figure 3
Side hook holder

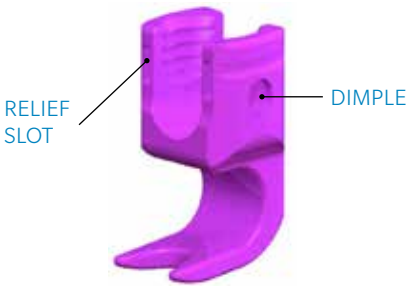


Figure 4
Hook tulip relief slot and dimple

Figure 5
Closure top introduced to hook, with angled hook holder attached

Figure 6
Closure top introduced to hook, with side hook holder attached

SYSTEM OVERVIEW *(continued)*

Implant Selection and Dimensions

	DESCRIPTION	DIMENSIONAL RANGE (MM)
A	Pedicle Hook, XXS, XS, S, M, L	4.0, 5.0, 6.0, 7.5, 9.0
B	Left Angled Hook, S, M, L	6.0, 7.5, 9.0
C	Right Angled Hook, S, M, L	6.0, 7.5, 9.0
D	Left Offset Hook, S, M, L	6.0, 7.5, 9.0*
E	Right Offset Hook, S, M, L	6.0, 7.5, 9.0*
F	Laminar Hook, S, M, L	6.0, 7.5, 9.0
G	Narrow Laminar Hook, S, M, L	6.0, 7.5, 9.0*
H	Narrow Reduced Laminar Hook, S, M, L	6.0, 7.5, 9.0*
I	Angled Blade Hook, S, M, L	6.0, 7.5, 9.0*
J	Extended Laminar Hook, S, M, L	6.0, 7.5, 9.0

**Denotes optional size*

Note: *All dimensions shown refer to throat depth, which is measured from the blade to the under side of the tulip.*

A

B

C

D

E

F

G

H

I

J

SURGICAL TECHNIQUE

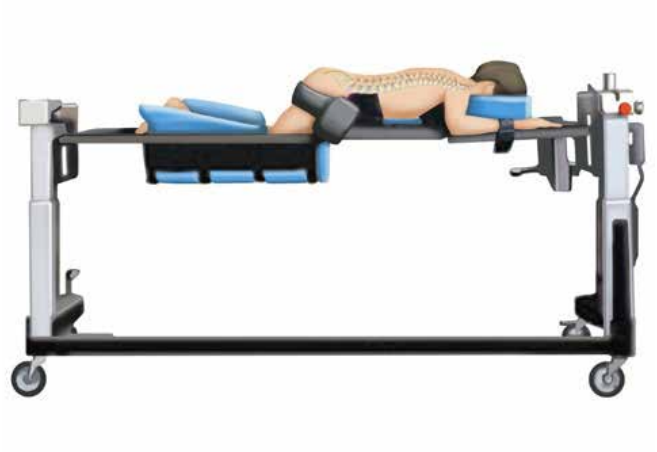


Figure 7
Patient positioning

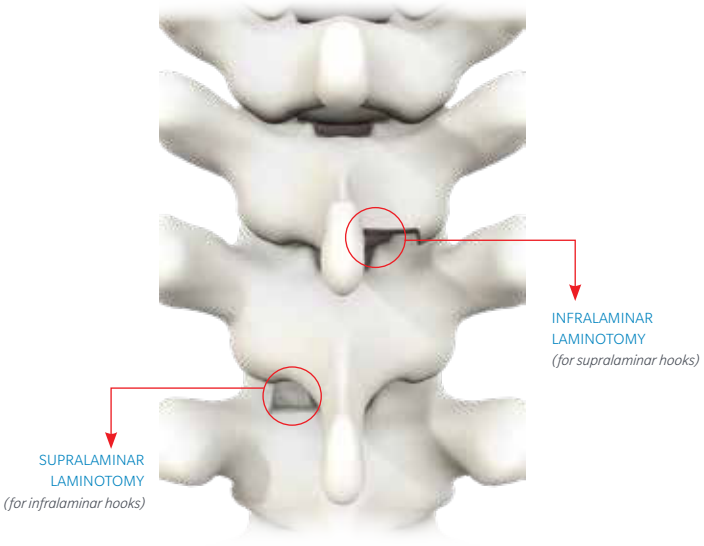


Figure 8
Laminotomies

Patient Preparation

- Place the patient in the prone or knee-chest position on a radiolucent operating table.
- Adjust the table (as needed) so that the C-arm provides true A/P images when at 90° and true lateral images at 0° (Figure 7).

Sublaminar Hook Technique

- In order to provide for the safe passage of a hook blade, into the central canal; laminar hooks are typically placed after removing an appropriate amount of ligamentum flavum and resecting some of the bone surrounding the fixation site, via infralaminar and supralaminar laminotomies (Figure 8).
- When extra room is needed, a partial or total removal of the thoracic spinous process may also be performed (Figures 9a, 9b). The extent of these bony resections is situation dependent and a matter of surgeon discretion.

SURGICAL TECHNIQUE *(continued)*

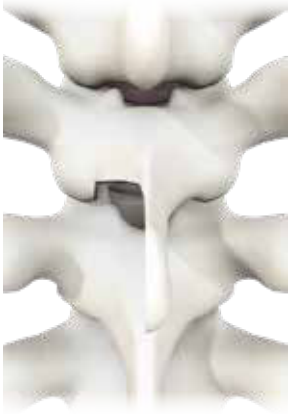


Figure 9a
Partial spinous process resection

Figure 9b
Full spinous process resection for hook fixation

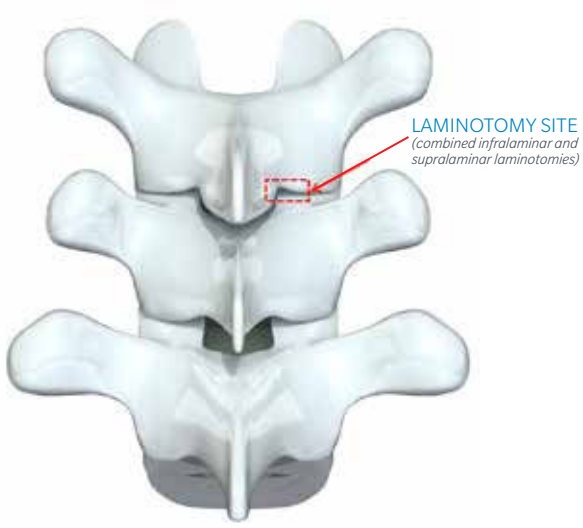


Figure 9c
Laminotomy hook site preparation involving resections of both lamina

Sublaminar Hook Technique *(continued)*

Thoracic Supralaminar ("down-going") Hook Site Preparation

- Due to the shingle-like properties of thoracic lamina and their spinous processes, resection of some bony anatomy is typically required.
- For safe insertion of a hook along the superior margin of the targeted lamina, a laminotomy is performed at the lamina superior to the intended fixation site. If more room is necessary, the surgeon may consider a small laminotomy along the margin of the lamina intended for instrumentation (Figure 9c).
- Care should be taken to protect the integrity of the instrumented lamina in order to preserve fixation. A partial, or total, removal of the superior spinous process may be necessary, to allow safe insertion of the hook's blade, in some cases (Figures 9a, 9b, 9c).

Important Note: When placing any instrumentation at the proximal end of a construct, take care to leave the interspinous ligament intact to avoid iatrogenic proximal junctional kyphosis.

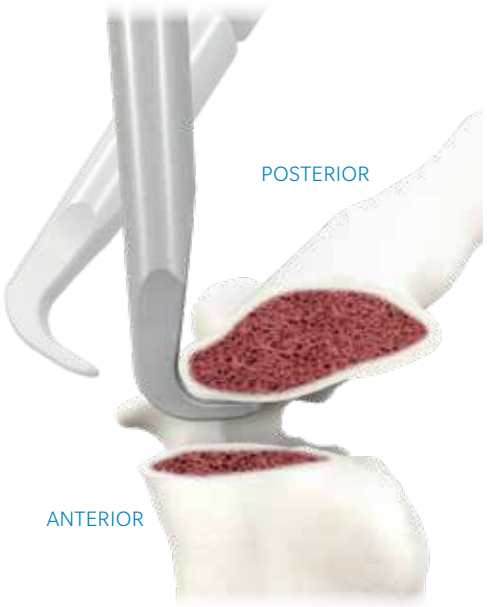


Figure 9c
Laminar hook site

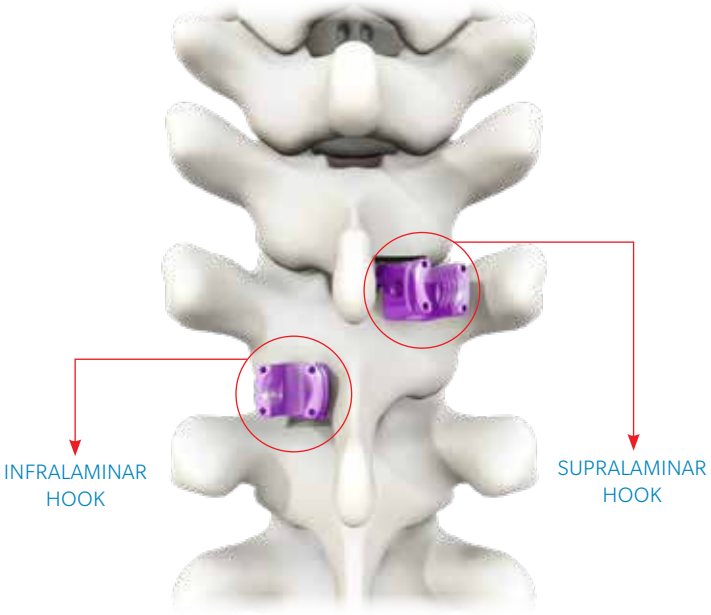


Figure 10
Infralaminar hook and supralaminar hooks inserted

- To ensure access for the supralaminar hook, perform a partial division and removal of the ligamentum flavum. Select a hook starter from the Vitality+ Hook Implant and Instrument Kit to help partially separate and/or remove the ligamentum flavum.
- Check that the space is adequate, between the laminar and peridural structures along the superior aspects of the lamina to be instrumented (Figure 9c).

Thoracic Infralaminar ("up-going")
Hook Site Preparation

- Infralaminar hooks are affixed to the inferior margin of the lamina (Figure 10).
- Perform osseous resections like those used for supralaminar hook insertion, to adequately seat the infralaminar hook.
- Before hook insertion, the ligamentum flavum is partially removed or separated from the inferior surface of the lamina using one of the hook starters.

SURGICAL TECHNIQUE *(continued)*

Figure 11a
Laminar hook

Figure 11b
Narrow laminar hook

Figure 11c
Narrow reduced laminar hook

Figure 11d
Angled blade hook

Figure 11e
Extended laminar hook

Figure 11f
Left angled hook

Figure 11g
Right angled hook

Figure 11h
Left offset hook

Figure 11i
Right offset hook

Sublaminar Hook Technique *(continued)*

Laminar Hook Insertion

- A wide selection of laminar hooks is included in the Vitality+ Hook Implant and Instrument Kit, available for use in different anatomic locations, depending on surgeon need and patient anatomy. Each laminar hook is compatible with vertical, angled, and side hook holders.
- The kit includes narrow reduced laminar hooks (Figure 11c). These hooks are often placed in the thoracic spine, in a down-going fashion. They are often used at the end of a scoliotic curve's concavity, or in a rigid segment. These hooks prevent unnecessary crowding of the hook blade into the spinal canal.
- The extended body laminar hooks are best used, in a down-going fashion in the mid-lumbar spine, to maintain the appropriate rod height at the proximal and distal aspects of the construct (Figure 11e).
- The kit also features offset and angled laminar hooks (Figures 11f, 11g, 11h, 11i). These hooks may be placed in either an up-going, or down-going, fashion; to maintain co-linearity of the implant tulip. In some situations, particularly when a sub-adjacent pedicle screw is in place, the offset and angled laminar hooks are ideal to ensure that the hook tulip will meet the rod. When placing down-going angled and offset hooks, left hooks are used on the right side and vice versa. This allows the tulip to be in-line with the other fixation implants already in place.

Note: *The angled and side hook holders allow for the introduction, adjustment, and removal of a closure top, while the inserter is still attached to a hook.*

Note: *Care should be taken to ensure that the bone captured by the hook completely fills the throat of the implant, preventing unnecessary penetration of the blade into the canal.*

Figure 12a
Hook site preparation for transverse process

Figure 12b
Hook site preparation for transverse process

Figure 12c
Hook fixation

Transverse Process Hook Technique

- The left and right angled laminar hooks are ideal for transverse process hook placement in either an up-going or down-going orientation.
- The transverse process hook technique is often used at the top of a thoracic construct. This technique is ideal for when patient anatomy prevents pedicle screw insertion.
- A transverse process hook technique is also particularly advantageous; when the surgeon requires a greater moment arm for leverage, to achieve the desired coronal correction at the upper instrumented level.

Transverse Process Hook Technique: Hook Site Preparation

- Use a laminar hook starter to separate the ligamentous attachments between the undersurface of the transverse process and the posterior arch of the rib, medial to the costotransverse joint (Figure 12a).

Note: When placing down-going angled laminar hooks, left hooks are used on the right side and vice versa. This allows the tulip to be in-line with the other fixation implants already in place.

Transverse Process Hook Technique: Hook Insertion

- After selecting the angled hook for implantation at the transverse process, place the hook on any of the hook holders available in the Vitality+ Hook Implant and Instrument Kit.
- When placing a down-going hook on a transverse process at the proximal end of the construct, some surgeons find it advantageous to attach the hook to an angled hook holder, so that the throat of the hook faces in the same direction as the bend in the holder (Figure 12b).
- The surgeon may then leave the hook holder attached to the hook, thus angling the handle away from the incision site.
- This technique also helps guide the rod into the hook's tulip and allows the surgeon to introduce a closure top without removing the holder.

SURGICAL TECHNIQUE *(continued)*

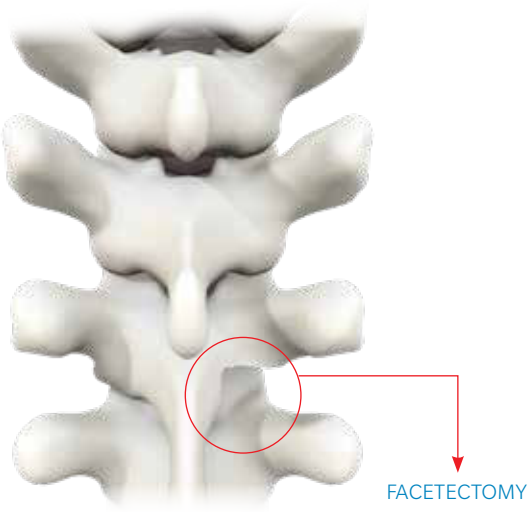


Figure 13
Facetectomy

Figure 14
Pedicle hook starter

Pedicle Hook Technique

- Site preparation for pedicle hooks and some laminar hooks typically involves partial facetectomies of the thoracic spine at the implantation level (Figure 13). Care should be taken to avoid injury to the neural elements during hook site preparation.
- Prepare the pedicle hook site by using either a quarter-inch, or a right angle, osteotome.
- Make two cuts on the superior vertebra's inferior articular process at the motion segment to be instrumented.
- Make a superior-to-inferior cut at the lateral margin of the ligamentum flavum, 2-3 mm proximally.
- Make the second cut with a quarter-inch osteotome in a transverse plane from the lateral edge of the facet to the medial cut. Approximately 6 mm of the inferior vertebra's superior articular process should remain, when measured from the base of the transverse process.
- Remove the osteotomized bone and curette the facet cartilage.
- A pedicle hook starter may be used from T1 to T10. Place the hook blade cephalad in the infralaminar position (Figure 14).
- Divide the facet capsule. As previously mentioned, a portion of the inferior articular process may be removed to facilitate insertion of the hook.
- Once the pedicle has been clearly identified with the help of the pedicle hook starter, the hook may be inserted.

Note: *Use caution to prevent medial penetration of the canal with the pedicle hook starter.*

Pedicle Hook Insertion with Hook Holders

- Insert the pedicle hook using a vertical, angled, or side hook holder. The closure top can be pre-loaded into the hook's tulip before insertion via any of the hook holders found in the Vitality+ Hook Implant and Instrument Kit.

Figure 15
Hook impactor used for insertion

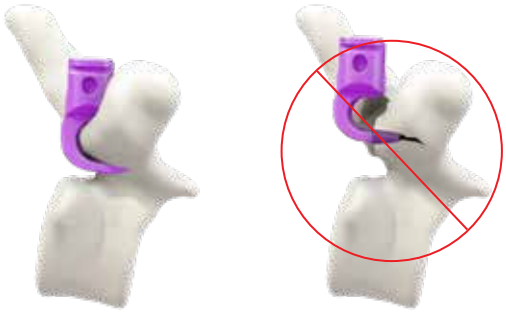


Figure 16
Pedicle hook insertion do and don't

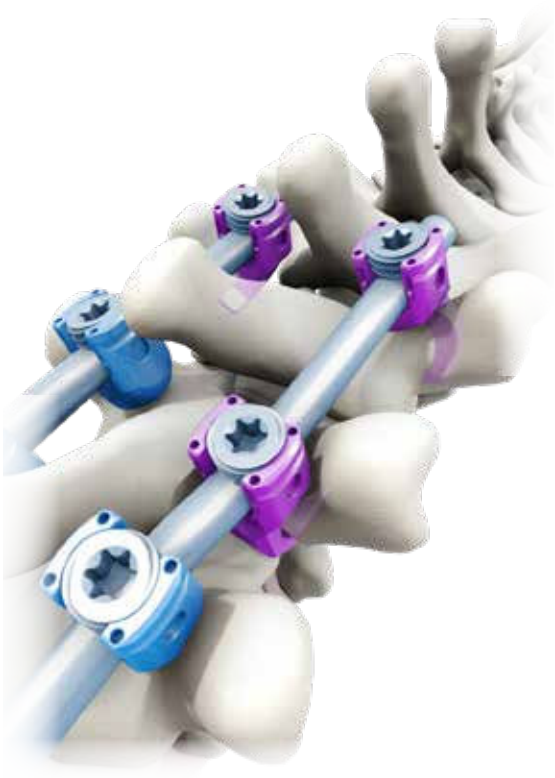


Figure 17
Pedicle and transverse process fixation technique with hooks — aka: claw hook construct

Transverse Process and Pedicle Hook "Claw" Technique

Pedicle Hook Insertion with Hook Impactor

- If needed, a hook may be inserted using the hook impactor. The impactor is designed to seat in the hook's tulip (Figure 15).
- After seating the impactor's distal end in the hook's tulip, insert a closure top and tighten, securing the hook to the impactor.
- Gently mallet the proximal end of the hook impactor to insert and seat the pedicle hook. If the surgeon chooses not to use a mallet, a hook holder may be attached to the hook for extra control and the hook may be pushed into place by hand using the grip of the hook impactor.

Note: *It is important that the pedicle hook is placed into the diarthroidial joint cavity of the facet and does not split the inferior articular process of the superior vertebra (Figure 16).*

- A down-going hook placed on the transverse process and a pedicle hook may be used in a "claw" hook construct (Figure 17). This technique allows for a greater degree of coronal correction, through compression and distraction of the levels captured by the claw construct and those levels adjacent to them.
- Use an angled hook in a down-going fashion on the transverse process at the level below an implanted pedicle hook. At this point the surgeon can compress and distract as needed on and against these fixation points, in order to gain the desired coronal correction.

SURGICAL TECHNIQUE *(continued)*

Figure 18a
Tightening step 1

Figure 18b
Tightening step 2

Final Tightening

- Once the rod has been seated into the hook's tulip and secured with a closure top, the closure top must be final tightened with the torque limiting driver handle.
- The counter-torque handle is placed over the head of the hook, so that the tines of the counter-torque are fully seated around the rod above and below the hook implant (Figure 18a).
- Once fully seated, using the T27 final tightening driver and the torque limiting driver handle from the Vitality Spinal Fixation System's Kit 5 (Kit#: 07.02136.405), pass the distal tip of the driver through the cannula of the counter-torque handle.
- Use the view port at the end of the handle to visually observe guiding the distal tip of the driver into the female T27 recess of the closure top or lift-up the counter-torque handle to insert the driver into the closure top and then re-seat the counter-torque.
- Once the closure top is engaged with the T27 driver and the counter-torque is fully seated, rotate the torque limiting driver handle clockwise (Figure 18b).
- Rotate the handle until an audible and tactile "click" is observed. This audible and tactile response indicates that the driver handle has reached 90in-lbs and the closure top is fully secured.

Note: *The counter-torque found in the Vitality Locking Instrument Kit (Kit#: 07.02136.405) is NOT compatible with the hooks and the upgraded version of the Vitality pedicle screw.*

Closure

- After implantation of the Vitality Spinal Fixation System is complete, complete layered closure according to standard protocol.

Implant Removal

- Remove the Vitality Spinal Fixation System by reversing the order of the implantation procedure.
- Attach the torque limiting driver handle to the T27 closure top driver in combination with the counter-torque handle to first remove the closure tops.

Postoperative Care

- To enhance recovery following implantation of the Vitality Spinal Fixation System, the patient should be immobilized a few days after surgery.
- A TSLO brace may be used postoperatively to decrease excessive movement.
- Restrict walking-intensive activities until advised by the surgeon.
- Take and review postoperative radiographs periodically to ensure fixation stability.

HOOKS

The Vitality+ Hook Implant and Instrument Kit has a complete selection of hooks. Hook styles are color-coded by throat size. All hooks are available in titanium.

BLADE SIZES
Narrow, 5.0 mm
Wide, 7.3 mm
Pedicle, 8.4 mm

THROAT SIZES	COLOR CODING
XX Small, 4.0 mm*	Teal
X Small, 5.0 mm*	Bronze
Small, 6.0 mm	Gold
Medium, 7.5 mm	Magenta
Large, 9.0 mm	Dark Blue

**Pedicle hook only*

PEDICLE HOOK	PART NUMBER
XX Small, 4.0 mm	720M0140
X Small, 5.0 mm	720M0150
Small, 6.0 mm	720M0160
Medium, 7.5 mm	720M0175
Large, 9.0 mm	720M0190

LAMINAR HOOK	PART NUMBER
Small, 6.0 mm	720M0460
Medium, 7.5 mm	720M0475
Large, 9.0 mm	720M0490

NARROW REDUCED LAMINAR HOOK	PART NUMBER
Small, 6.0 mm	720M0660
Medium, 7.5 mm	720M0675
Large, 9.0 mm**	720M0690

OFFSET HOOK	PART NUMBER
Left, Small, 6.0 mm	720M2060
Left, Medium, 7.5 mm	720M2075
Left, Large, 9.0 mm**	720M2090
Right, Small, 6.0 mm	720M2160
Right, Medium, 7.5 mm	720M2175
Right, Large, 9.0 mm**	720M2190

ANGLED HOOK	PART NUMBER
Left, Small, 6.0 mm	720M3060
Left, Medium, 7.5 mm	720M3075
Left, Large, 9.0 mm	720M3090
Right, Small, 6.0 mm	720M3160
Right, Medium, 7.5 mm	720M3175
Right, Large, 9.0 mm	720M3190

NARROW LAMINAR HOOK	PART NUMBER
Small, 6.0 mm	720M0560
Medium, 7.5 mm	720M0575
Large, 9.0 mm**	720M0590

ANGLED BLADE HOOK	PART NUMBER
Small, 6.0 mm	720M0960
Medium, 7.5 mm	720M0975
Large, 9.0 mm**	720M0990

EXTENDED LAMINAR HOOK	PART NUMBER
Small, 6.0 mm	720M1060
Medium, 7.5 mm	720M1075
Large, 9.0 mm	720M1090

***Denotes optional size*

INSTRUMENTS

VERTICAL HOOK HOLDER PART NUMBER

730M0027

ANGLED HOOK HOLDER PART NUMBER

730M0028

SIDE HOOK HOLDER PART NUMBER

730M0029

HOOK IMPACTOR PART NUMBER

730M0030

PEDICLE HOOK STARTER PART NUMBER

730M0031

WIDE LAMINAR HOOK STARTER PART NUMBER

730M0032

MEDIUM LAMINAR HOOK STARTER PART NUMBER

Optional, does not come in standard kit configuration 730M0033

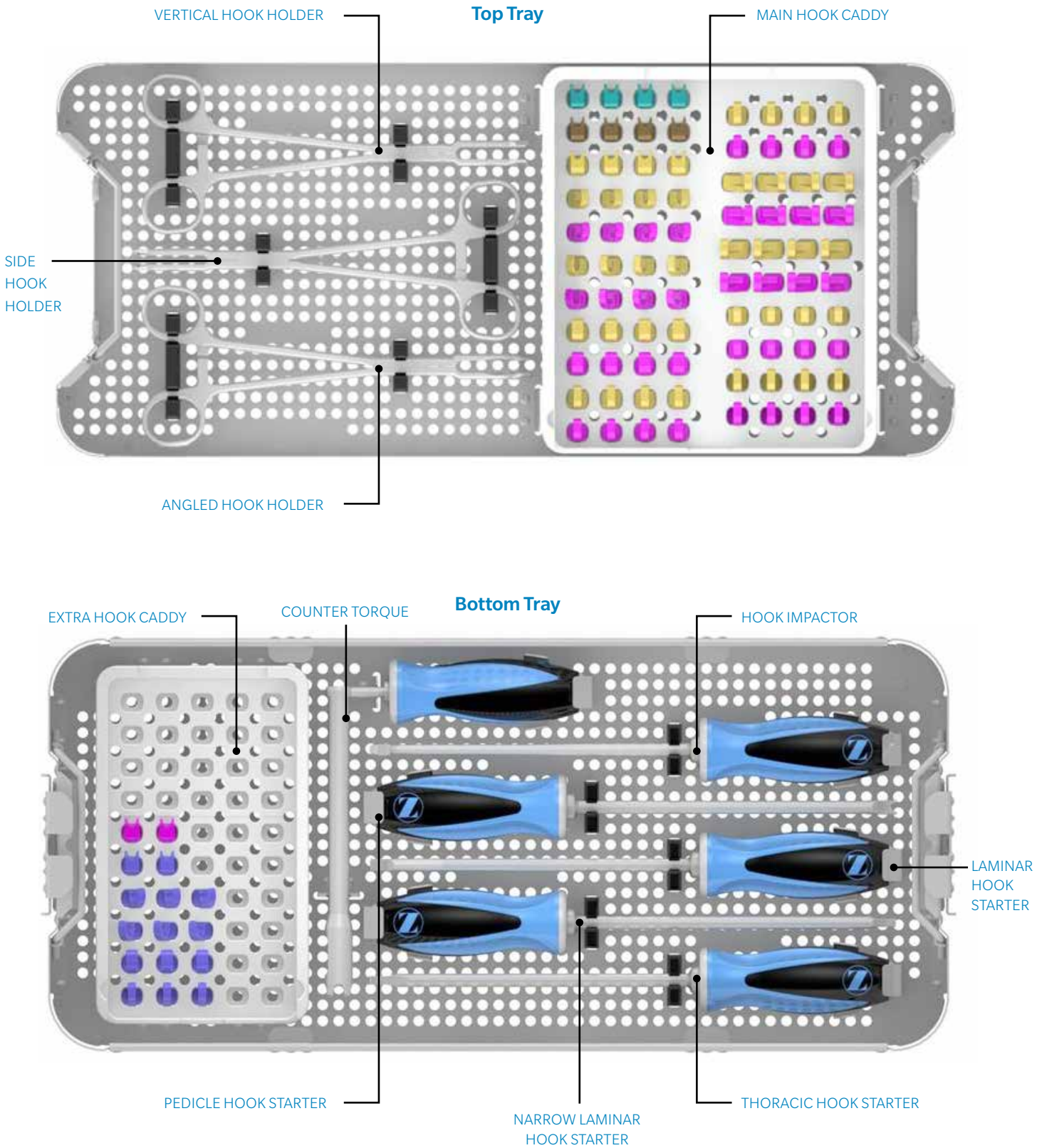
NARROW LAMINAR HOOK STARTER PART NUMBER

730M0034

THORACIC HOOK STARTER PART NUMBER

730M0035

KIT CONTENTS



Vitality+ Hook Implant and Instrument Kit Number: PCR700M5201

DESCRIPTION	QTY	PART NUMBER
Pedicle Hook, XX Small	4	720M0140
Pedicle Hook, X Small	4	720M0150
Pedicle Hook, Small	4	720M0160
Pedicle Hook, Medium	2	720M0175
Pedicle Hook, Large	2	720M0190
Laminar Hook, Small	4	720M0460
Laminar Hook, Medium	4	720M0475
Laminar Hook, Large	3	720M0490
Narrow Laminar Hook, Small	4	720M0560
Narrow Laminar Hook, Medium	4	720M0575
Narrow Reduced Laminar Hook, Small	4	720M0660
Narrow Reduced Laminar Hook, Medium	4	720M0675
Angled Blade Hook, Small	4	720M0960
Angled Blade Hook, Medium	4	720M0975
Extended Laminar Hook, Small	4	720M1060
Extended Laminar Hook, Medium	4	720M1075
Extended Laminar Hook, Large	3	720M1090
Offset Hook, Small, Left	4	720M2060
Offset Hook, Medium, Left	4	720M2075
Offset Hook, Small, Right	4	720M2160
Offset Hook, Medium, Right	4	720M2175
Angled Hook, Small, Left	4	720M3060
Angled Hook, Medium, Left	4	720M3075
Angled Hook, Large, Left	3	720M3090
Angled Hook, Small, Right	4	720M3160
Angled Hook, Medium, Right	4	720M3175
Angled Hook, Large, Right	3	720M3190
Counter Torque	1	730M0016

DESCRIPTION	QTY	PART NUMBER
Vertical Hook Holder	2	730M0027
Angled Hook Holder	2	730M0028
Side Hook Holder	2	730M0029
Hook Impactor	1	730M0030
Pedicle Hook Starter	1	730M0031
Wide Laminar Hook Starter	1	730M0032
Narrow Laminar Hook Starter	1	730M0034
Thoracic Hook Starter	1	730M0035

Optional Items (NOT PART OF THE STANDARD KIT)

DESCRIPTION	PART NUMBER
Medium Laminar Hook Starter	730M0033
Narrow Laminar Hook, Large	720M0590
Narrow Reduced Laminar Hook, Large	720M0690
Angled Blade Hook, Large	720M0990
Offset Hook, Large, Left	720M2090
Offset Hook, Large, Right	720M2190

IMPORTANT INFORMATION ON THE VITALITY+ HOOK IMPLANT AND INSTRUMENT KIT

Device Description

The Vitality Spinal Fixation System is a thoracolumbar and sacroiliac fixation system designed to aid in the surgical correction of several types of spinal conditions. The system consists of a variety of spinal rods, pedicle screws, hooks, and connectors intended only to provide temporary stabilization during the development of a solid fusion of the spine with bone graft. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy. All implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

The system also includes instrumentation for insertion, securing and removal of the implants. All implants are made from medical grade titanium alloy; select rods are also available in medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct. The Vitality Spinal Fixation System is compatible with components from other cleared spinal fixation systems. See Indications below.

Refer to the Vitality Spinal Fixation System Surgical Technique Guide for additional information on how to use this device. Contact your Zimmer Biomet Spine Sales Representative or Zimmer Biomet Customer Service for a copy of the current Surgical Technique.

Indications

The Vitality Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition the Vitality Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct® Java™ Spinal Fixation System* hooks, APEX Spinal System™* hooks, or fixation of the Universal Clamp® Spinal Fixation System* to the rods of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage® OCT Spinal Fixation System* and the Instinct Java Spinal Fixation System offered by Zimmer Biomet Spine, using rod connectors.

Contraindications

The Vitality System is not designed or sold for any use except as indicated. DO NOT USE THE VITALITY SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

- Insufficient bone quantity, severe osteoporosis, or other condition that might compromise rigid fixation of the device.
- A history of infection, active systemic infection or infection localized to the site of the proposed implantation.
- Suspected or documented metal allergy or intolerance.
- A disorder affecting the normal process of bone remodelling, including but not limited to severe osteoporosis involving the spine, excessive bone reabsorption, osteopenia, a primary or metastatic tumor involving the spine, or certain metabolic disorders of osteogenesis.
- Iliac screws and offset connectors should not be used in cases of tumor or trauma of the sacrum, when additional screw fixation in S1 is not possible.

**These optional components are not approved in all regions*

- Other relative contraindications include obesity, pregnancy, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

Warnings and Precautions

Following are specific warnings, precautions, and adverse effects associated with use of the Vitality System that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

- Implantation of the Vitality System should be performed only by experienced spinal surgeons.
- All implants are intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
  - Mechanical malfunction
  - Transmission of infectious agents
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.
- Universal precautions should be observed by all end users that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges to prevent injuries during and after surgical procedures and reprocessing.
- 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Warning: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. The device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- Additional Warnings for Pediatric Patients: The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
- Precaution: 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.
- Additional Precautions for Pediatric Patients: The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
  Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
  The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

IMPORTANT INFORMATION ON THE VITALITY+ HOOK IMPLANT AND INSTRUMENT KIT *(continued)*

Preoperative

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- Zimmer Biomet does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to using, is the best way to determine whether or not an individual device should be used.

Intraoperative

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant. Do not reverse bend the rods.
- Pedicle bone integrity should be verified.
- Care should be taken during pedicle preparation to avoid penetrating too deep.
- Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.
- Care should be taken to minimize soft tissue damage during surgery.
- Care should be taken to avoid removing excess material from the lamina.
- Care should be taken to avoid cross-threading screws and closure tops.
- If any implant or instrument comes in contact with a non-sterile surface it should not be used.

Postoperative

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
- The Vitality System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.

Adverse Effects

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery.

- Non-union, delayed union
- Bending or fracture of implant. Fraying, kinking, loosening, bending or breaking of any or all implant components.
- Loosening of or migration of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Loss of the natural curvature of the spine
- Modification of the spinal geometric corrections of the vertebral and/or intervertebral height and/or of the reduction in spinal deformities
- Vascular and/or nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paraesthesia.

- Bursitis
- Dural leak
- Paralysis
- Death
- Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death
- Additional surgery may be required to correct any of these potential adverse effects
- Additional Potential Adverse Effects for Pediatric Patients:
  - Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
  - Pedicle screw malpositioning, with or without neurological or vascular injury
  - Proximal or distal junctional kyphosis
  - Pancreatitis

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.*

eLabeling: *The Instructions for Use can be accessed online by visiting the website and using the KEY-CODE provided on the product label and as shown below. Additional translations are also available in electronic format for download. To request a paper copy of the Instructions for Use, contact Zimmer Biomet Spine at the phone number provided.*

Consult Instructions for Use on this website:
http://IFU.zimmer.com
Key-Code: 07.02199.001

Manufactured by:
Zimmer Biomet Spine, Inc.
10225 Westmoor Dr.
Westminster, CO 80021 USA

EC REP *Zimmer GmbH*
Sulzerallee 8
CH-8404 Winterthur
Switzerland
+41 058.854.80.00

CE 0086

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800.447.3625/zimmerbiomet.com

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