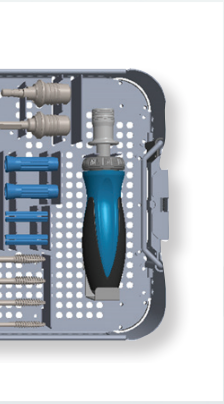
Vital™ Power

Instrument Kit

Surgical Technique Guide



ZimVie

Vital Power Instrument Kit Highlights

- The addition of powered pedicle preparation is a tremendous benefit to surgeons, as compared to traditional hand-driven pedicle preparation and insertion.
- The market's first drill bits and blunted reamers designed to resist cortical bone, provide tactile feedback, and ensure precision during pedicle preparation and implant insertion.
- Pedicle and iliac taps in modified lengths to facilitate ergonomic use.
- An assortment of pedicle screwdrivers in various lengths and styles all with optional soft tissue sleeves.
- Two different ¼" square adapters, designed to accommodate standard pedicle preparation and screw delivery options, from the Vitality Spinal Fixation System. These adapters are designed for use with ZimVie's Universal Power System.

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ZimVie 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 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

Assembly/Disassembly of Zimmer Biomet Universal Power System and Vital Power

Universal Power System Handpiece & Attachment Assembly

The Vital Power Instrument Kit features five types of instruments that are available for use with the ZimVie Universal Power System: drills, reamers, taps, drivers, and adapters. The Universal Power System is available in 2 handpiece styles: the single trigger handpiece and the double trigger handpiece. The Universal Power System also features various attachments that alter the speed and torque of the handpiece. Please refer to the Zimmer Biomet Universal Power System Instruction Manual (06001800100) for in-depth information on the system.

2.4 mm Pilot Drill Bit

2.0 mm Standard Drill Bit

3.0 mm Reamer Probe

1000RPM Small AO Attachment

Double Trigger Handpiece

Single Trigger Handpiece

Vital Power Drill/Reamer and Universal Power Small AO Attachment Assembly

The drills and reamers are intended for use with the Universal Power 1000 RPM Small AO Attachment. To assemble, insert the Universal Power Small AO Attachment into the Universal Power Handpiece of choice, ensuring the teeth of the attachment align with those of the handpiece. Once assembled, pull back the top sleeve of the attachment, to insert a drill or reamer. Following insertion, drills and reamers should be checked, so as to ensure proper mating with the Universal Power Small AO attachment.

Note: When using the double trigger handpiece, press the bottom trigger for clockwise rotation. For counter-clockwise rotation, first press the top trigger, followed by the bottom trigger.

Note: The toggle switch located above the trigger determines the direction of rotation, for the single trigger handpiece.

Note: If needed, the Vital Power Instrument Kit includes a straight, non-ratcheting handle that accepts Vital Power instruments that feature a male, Small AO connection.

Small AO Axial Handle

Vital Power Tap, Driver, and Universal Power System 250 RPM Zimmer/Hudson Attachment Assembly

All taps and drivers feature a Zimmer/Hudson Z-Connect mating feature for use with the Universal Power 250 RPM Zimmer/Hudson Attachment. Assemble the Universal Power Zimmer/Hudson Attachment with the handpiece in an identical manner to the Universal Power Small AO Attachment. Once the attachment and handpiece are assembled, pull back on the black collar of the attachment to insert the instrument.

Short Threaded (non-locking) T27 Driver

Stab-N-Grab T27 Driver

Standard Threaded (non-locking) T27 Driver

Double Trigger Handpiece

Note: If needed, the Vital Power System includes a straight ratcheting handle that accepts Vital Power instruments that feature a male Universal Power Z-Connect.

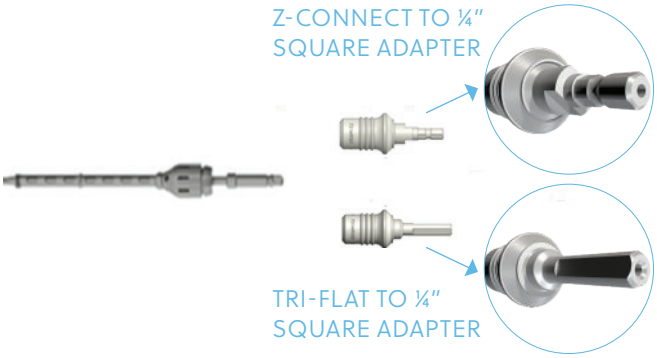
Ratcheting axial handle, Z-connect

Vital Power Adapter Assembly with Universal Power System 250 RPM Zimmer/Hudson Attachment

The taps and drivers from the Vitality Preparation Instrument Kit (Kit #07.02136.401) feature male ¼" square proximal ends and may be used in conjunction with two ¼" square adapters that are found in the Vital Power Instrument Kit:

- Universal Power Z-Connect to ¼" Square Adapter
- Universal Power Tri-flat to ¼" Square Adapter

The Universal Power Z-Connect to ¼" Square Adapter is used with the Universal Power 250RPM Zimmer/Hudson Attachment. When using either the Universal Power Z-Connect to ¼" Square Adapters, or the Universal Power Tri-flat to ¼" Square Adapters; the Vitality instruments may be loaded into the ¼" square receiver, by pulling back on the adapter collar and firmly inserting the proximal end of the instrument until fully seated.



Universal Power System and Vital Power Disassembly

To disassemble, pull on the attachment and/or adapter collars used for assembly and remove instruments. Press the two buttons located on either side of the handpiece's attachment receiver housing and pull the attachment out of the handpiece.

Surgical Technique

The following surgical technique guide describes how a surgeon may utilize the Vital Power Instrument Kit, for placing Vitality Spinal Fixation System Pedicle and Iliac Screws.

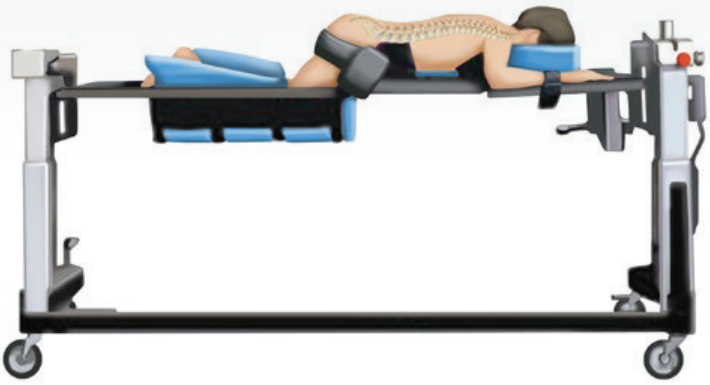


Figure 1
Patient positioning

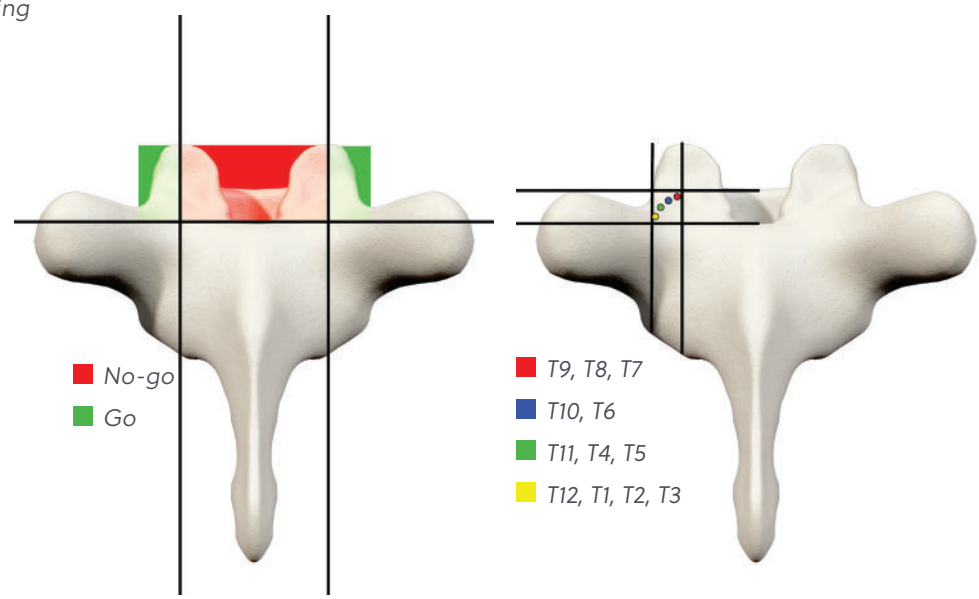


Figure 2
Anatomical reference points

Patient Positioning

- 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 1)**.

Powered Pedicle Preparation

Anatomical Reference Points

- Using standard anatomic markings, resect a small portion of dorsal cortex to create an entry point for the drill **(Figure 2)**.

Note: *The surgeon should ensure that the drill bit's trajectory is not inadvertently altered by soft tissue while attempting to cannulate the pedicle. Therefore, it is important that the surgeon provide sufficient tissue retraction when using either drill bit. As an example, the surgeon should take special care to provide adequate tissue retraction when attempting pedicle screw preparation at highly rotated vertebral segments, the Lowest Instrumented Vertebra (LIV), the Upper Instrumented Vertebra (UIV), and when attempting promontory trajectories at S1. If the surgeon observes a bend in the shank of either drill bit, he or she may either alter their retractor placement, increase exposure, or use a pedicle probe for initial pedicle cannulation.*

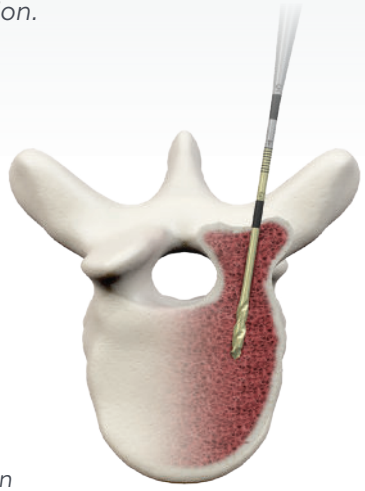


Figure 3a
Drill insertion

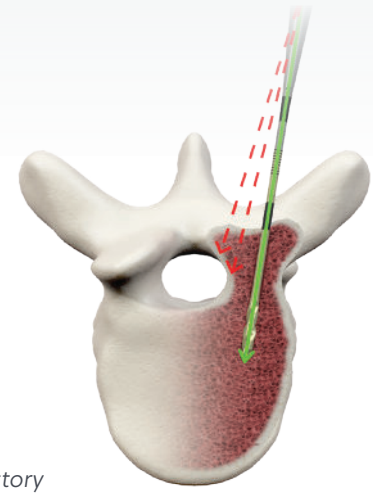


Figure 3b
Drill trajectory

Powered Pedicle Preparation and Screw Insertion with ZimVie Universal Power

- Using the Universal Power Handpiece with Universal Power Small AO Attachment secured, insert either the Vital Power 2.4 mm Pilot Drill or the Vital Power 2.0 mm Standard Drill to the attachment, to create a pilot trajectory that follows the pedicle canal. These drills are recommended for initiating the pilot trajectory, as they allow the surgeon to use tactile feedback, to find the pedicle channel **(Figures 3a, 3b)**.
- The drill bit should be spun very slowly during insertion–approximately 1 to 3 rotations per second is recommended. In most cases, the weight of the handpiece is entirely sufficient, to ensure progression of the drill bit through the pedicle channel. If necessary, carefully apply minimal force to the handpiece, while maintaining the recommended rotational speed of the drill bit. By maintaining low RPM and applying minimal force to the handpiece during this process, the cortical bone of the pedicle resists the pilot drill more than cancellous bone, thus providing tactile feedback to the surgeon. Using this technique, the surgeon should be able to tactilely determine the path of least resistance through the pedicle's cancellous channel.

Note: *Gentle application of pressure to the handpiece's trigger will give the desired speed. Some surgeons may find that paced, intermittent trigger presses of 1 to 2 seconds at a time, will help maintain low RPM and minimize downward pressure.*

Note: *Assuming sufficient tissue retraction has been achieved; if the shank of either drill bit bends during the pedicle cannulation process, release the trigger to stop drill progression. This bend is an indication that the distal tip of the drill is making contact with a pedicle cortex. Adjust the position of the handpiece until the bend in the drill shank is alleviated, reverse the drill bit slightly, and then continue forward drill progression through the pedicle channel.*

Surgical Technique *(continued)*

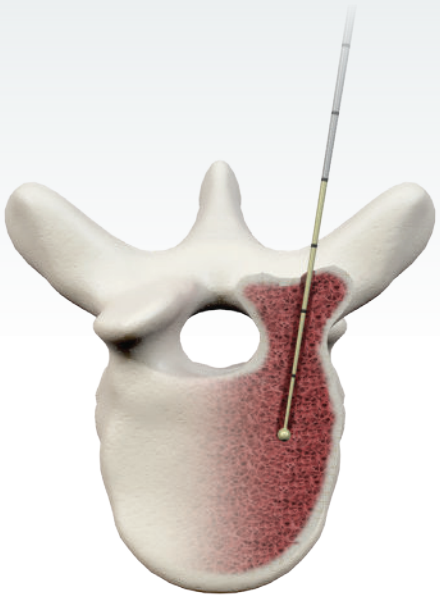


Figure 4
Ball-tipped, sounding probe check

- Use a ball-tipped, sounding probe to confirm that the pedicle has not been breached and that the depth is appropriate **(Figure 4)**.

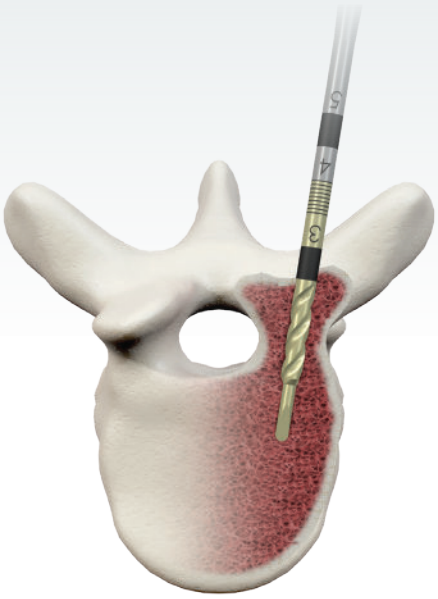


Figure 5
Secure reamer

- Secure either the Vital Power 3.0 mm Reamer Probe, or the optional Vital Power 3.2 mm Reamer Probe, to the Universal Power Small AO Attachment. Use the reamer to further dilate the channel that the pilot drill previously created through the pedicle canal. This reamer should self-center in the pilot hole created by the drill **(Figure 5)**.

  Note: *The 3.0 mm Reamer Probe matches the inner diameter of the 4.5 mm Vital Screw.*

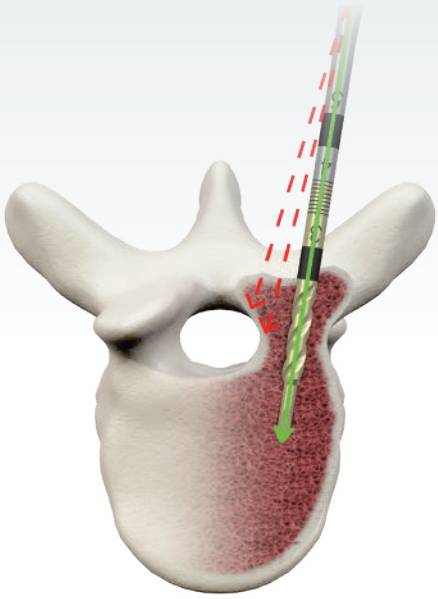


Figure 6
Reamer trajectory

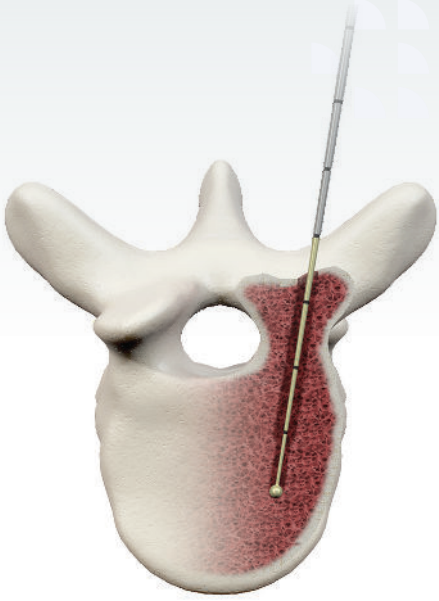


Figure 7
Ball-tipped, sounding probe check

- As with the drill bit from the previous step, the reamer should be spun very slowly during insertion–approximately 1 to 3 rotations per second is recommended. Just as before, apply minimal force to the handpiece and reamer, when deemed necessary. In most cases, the weight of the handpiece is entirely sufficient, to ensure progression of the drill bit through the pedicle channel **(Figure 6)**. By maintaining low RPM applying minimal force to the handpiece during this process, the cortical bone of the pedicle offers resistance to the blunted tip of the reamer more than cancellous bone and provides tactile feedback to the surgeon. Using this technique, the surgeon should be able to tactilely determine the path of least resistance through the pedicle's cancellous channel and establish the optimal path for pedicle screw insertion.

Note: *Gentle application of pressure to the handpiece's trigger will give the desired speed. Some surgeons may find that paced, intermittent trigger presses of 1 to 2 seconds at a time, will help maintain low RPM and minimize downward pressure.*

Note: *The reamers have a larger diameter than the drills and will dilate the pedicle further in preparation of pedicle screw placement.*

Note: *If using a 6.5 mm screw or larger in hard bone, a pedicle probe may be used to further widen the channel. This step is only necessary for the first 20 mm of screw length, as the cancellous bone of the vertebra does not need to be widened.*

- A ball-tipped, sounding probe may be used to check pedicle integrity, trajectory, and depth **(Figure 7).**

Surgical Technique *(continued)*

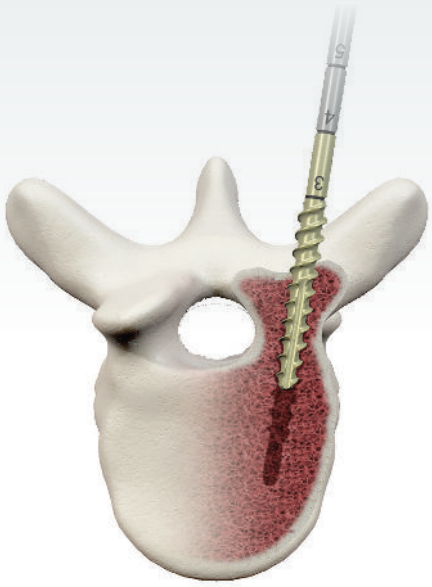


Figure 8
Tapping

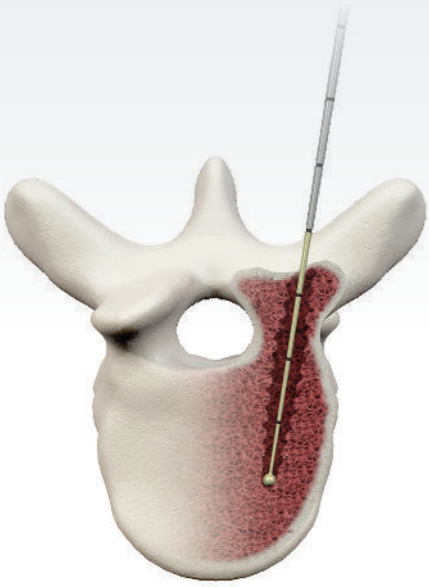


Figure 9
Sounding probe check

Optional: Tapping

- Some surgeons may elect to use a tap following use of the Vital Power 3.0 mm Blunt-tip Reamer. There is an assortment of taps available in various diameters to accommodate these surgeons. Care should be taken to ensure that the tap is inserted slowly into the pedicle **(Figure 8)**.

- A ball-tipped, sounding probe may be used to check pedicle integrity, trajectory, depth, and/or threads tapped into bone **(Figure 9)**.

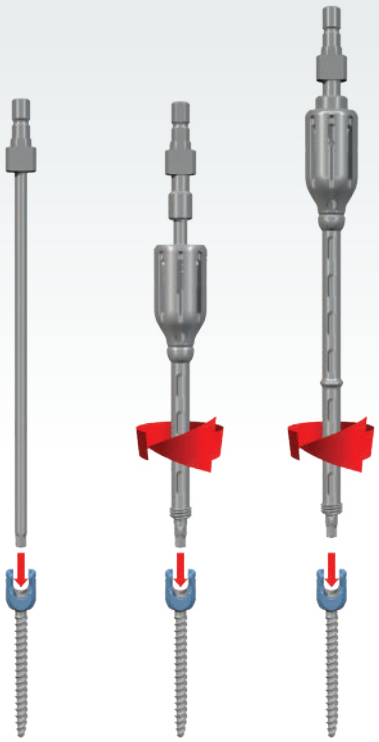


Figure 10
Attach the screw into selected pedicle screwdriver

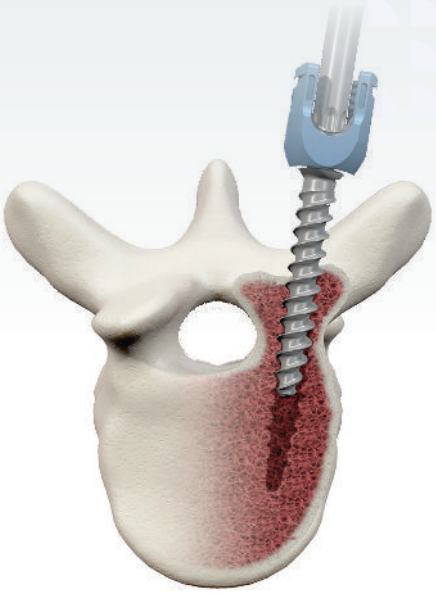


Figure 11
Drive screw into the pedicle

The Vital Power Instrument Kit comes with a comprehensive range of pedicle screwdrivers to satisfy a variety of surgeon preferences.

Attach desired pedicle screw to chosen driver:

1. Secure Zimmer/Hudson Attachment to Universal Power Handpiece (not pictured).
2. Secure proximal Universal Power Z-Connect end of the selected Vital Power Screwdriver into the Universal Power Zimmer/Hudson Attachment (not pictured).
3. Attach the screw to the selected Vital Power Pedicle Screwdriver by inserting the driver tip into the female T27 hexalobe on the screw shank. Make sure the screw shank is straight and aligned with the shaft of the inserter **(Figure 10)**.
4. For threaded, non-locking inserters, attach the screw by turning the driver's retention sleeve clockwise into the screw head.
5. Optional: A free floating tissue sleeve may be placed anywhere along the shaft of the Vital Power Stab-N-Grab Driver. The Vital Power Stab-N-Grab Tissue Sleeve will float freely and does not lock into place on the driver shaft.
6. Optional: A blue, free-spinning tissue sleeve may be placed over the driver's threaded retention sleeve. The tissue sleeve must be placed onto the threaded, non-locking driver retention sleeve before the screw is attached.

- Use the handpiece to slowly drive the selected screw into the pedicle. The screw should self-center in pilot hole previously created **(Figure 11)**.

Instruments

DESCRIPTION	PART NUMBER
Standard Threaded Driver (non-locking)	731M0000
Short Threaded Driver (non-locking) *not pictured*	731M0001

DESCRIPTION	PART NUMBER
Stab-N-Grab Driver	731M0010

DESCRIPTION	PART NUMBER
Stab-N-Grab Sleeve	731M0005

DESCRIPTION	PART NUMBER
Threaded Screwdriver Sleeve, Standard	07.02131.001
Threaded Screwdriver Sleeve, Short	07.02131.003

DESCRIPTION	PART NUMBER
Pilot Drill, ø2.4 mm	731M0040

DESCRIPTION	PART NUMBER
Standard Drill, ø2.0 mm	731M0021

DESCRIPTION	PART NUMBER
Reamer Probe, ø3.0 mm	731M0031
Reamer Probe, ø3.2 mm (OPTIONAL)	731M0030

DESCRIPTION	PART NUMBER
Adapter, Tri Flat t ¼" Sq	731M9000

DESCRIPTION	PART NUMBER
Adapter, Z-Connect to ¼" Sq	731M9001

DESCRIPTION	PART NUMBER
ø4.5 mm Tap, Z-Connect	731M0145
ø5.5 mm Tap, Z-Connect	731M0155
ø6.5 mm Tap, Z-Connect	731M0165
ø7.5 mm Tap, Z-Connect	731M0175
ø6.5 mm Iliac Tap, Z-Connect	731M0265
ø7.5 mm Iliac Tap, Z-Connect	731M0275
ø8.5 mm Iliac Tap, Z-Connect	731M0285
ø9.5 mm Iliac Tap, Z-Connect	731M0295

DESCRIPTION	PART NUMBER
Ratcheting Axial Handle, Z-Connect	731M9002

DESCRIPTION	PART NUMBER
Small AO Axial Handle	07.01788.001

Capital Equipment
(not available through ZimVie Spine, contact Zimmer Biomet Surgical Solutions)

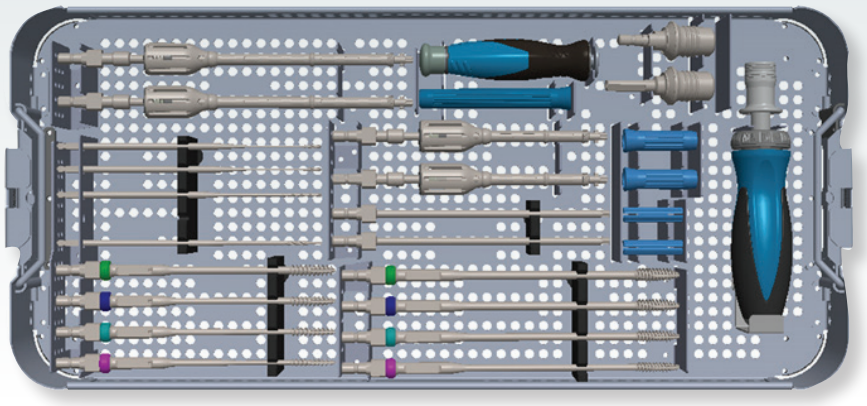
DESCRIPTION	PART NUMBER
Double Trigger Handpiece	89-8507-400-00

DESCRIPTION	PART NUMBER
Single Trigger Handpiece	89-8507-400-10

DESCRIPTION	PART NUMBER
1000RPM Small AO Attachment	89-8509-410-20

DESCRIPTION	PART NUMBER
250RPM Zimmer/Hudson Attachment	89-8509-425-80

Kit Contents



Kit Configuration Vital Power Instrument Kit Number: PCR700M2101

DESCRIPTION	QTY	PART NUMBER
Standard Threaded Driver (non-locking)	2	731M0000
Short Threaded Driver (non-locking)	2	731M0001
Stab-N-Grab Driver	2	731M0010
Stab-N-Grab Sleeve	1	731M0005
Threaded Screwdriver Sleeve, Standard	1	07.02131.001
Threaded Screwdriver Sleeve, Short	1	07.02131.003
Pilot Drill, ø2.4 mm	2	731M0040
Reamer Probe, ø3.0 mm	1	731M0031
Optional Reamer Probe, ø3.2 mm	1	731M0030
Standard Drill, ø2.0 mm	1	731M0021
Adapter, Tri Flat to ¼" Sq	1	731M9000
Adapter, Z-Connect to ¼" Sq	1	731M9001
ø4.5 mm Tap, Z-Connect	1	731M0145
ø5.5 mm Tap, Z-Connect	1	731M0155
ø6.5 mm Tap, Z-Connect	1	731M0165
ø7.5 mm Tap, Z-Connect	1	731M0175
ø6.5 mm Iliac Tap, Z-Connect	1	731M0265
ø7.5 mm Iliac Tap, Z-Connect	1	731M0275
ø8.5 mm Iliac Tap, Z-Connect	1	731M0285
ø9.5 mm Iliac Tap, Z-Connect	1	731M0295
Ratcheting Axial Handle, Z-Connect	1	731M9002
Small AO Axial Handle	1	07.01788.001

Capital Equipment (not available through ZimVie Spine, contact Zimmer Biomet Surgical Solutions)

DESCRIPTION	QTY	PART NUMBER
Double Trigger Handpiece	1	89-8507-400-00
Single Trigger Handpiece	1	89-8507-400-00
Small AO 1000 RPM	1	89-8507-400-00
Zimmer/Hudson Attachment 250 RPM	1	89-8507-400-00

Important Information on the Vital Power Instrument Kit

Vital™ Power

The Vital™ Power Instrument System is a subsystem of the Vitality Spinal Fixation System.

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.

Intended Use (Power)

Vital Power instruments and adapters are intended for use with the Zimmer Biomet Universal Power System to facilitate the preparation of the pedicle and ilium and insertion of Vitality Spinal Fixation System screws using a power surgical technique. Pedicle and iliac screws from the Vitality Spinal Fixation System may be implanted in the non-cervical spine using powered instrumentation during spinal surgery, including open and minimally invasive procedures.

Indications (Power)

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 ZimVie 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.

Important Information on the Vital Power Instrument Kit *(continued)*

- 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.

Additional preoperative, intraoperative, and postoperative warnings and precautions:

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.
- ZimVie 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.

Prior to use, instruments should be visually inspected for wear and tested to assure they are functioning properly. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, DO NOT USE. Instrumentation that appears damaged should be returned to the manufacturer.

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.

*These optional components are not approved in all regions.

For more information, visit ZimVie.com

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