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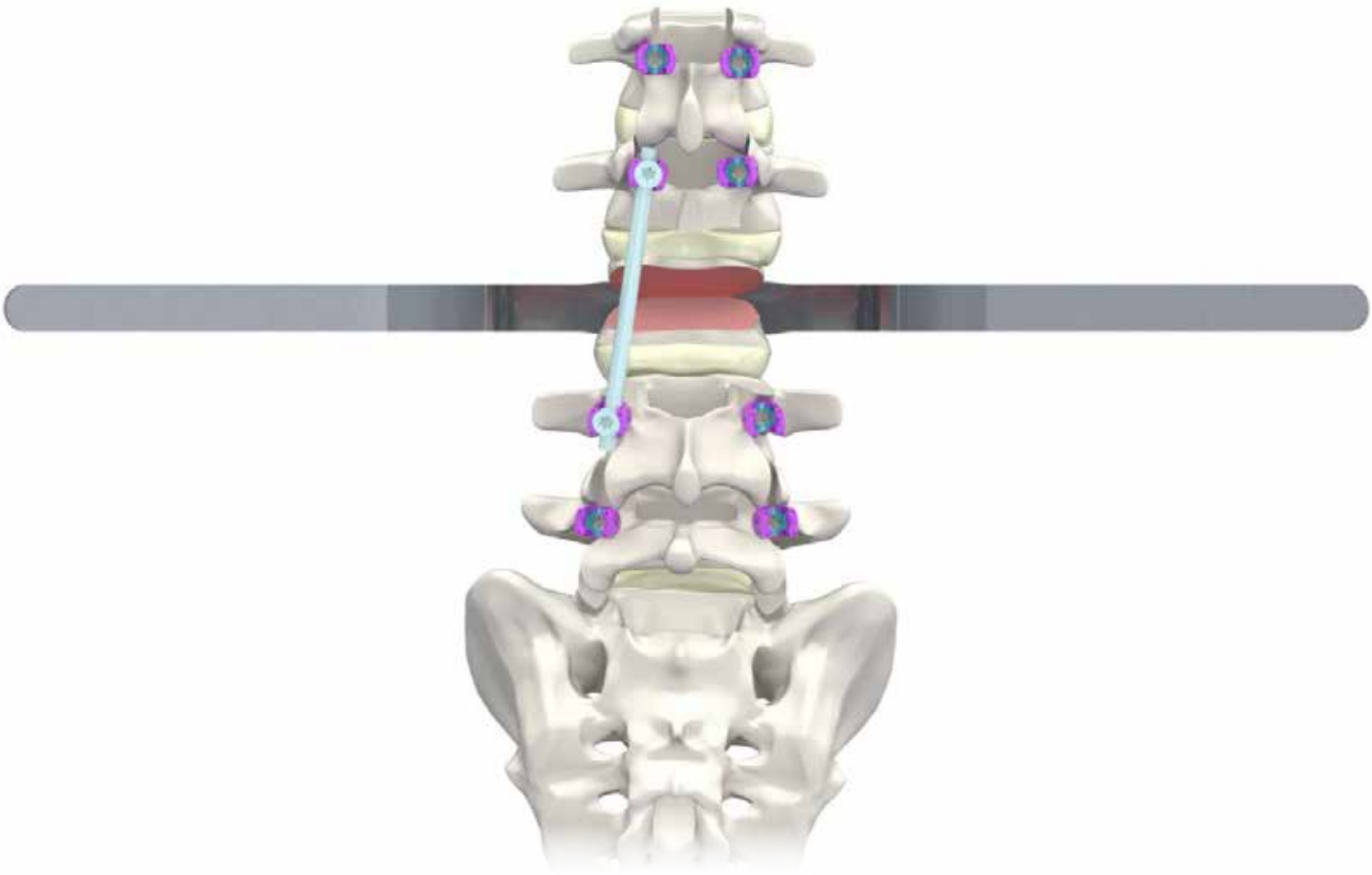
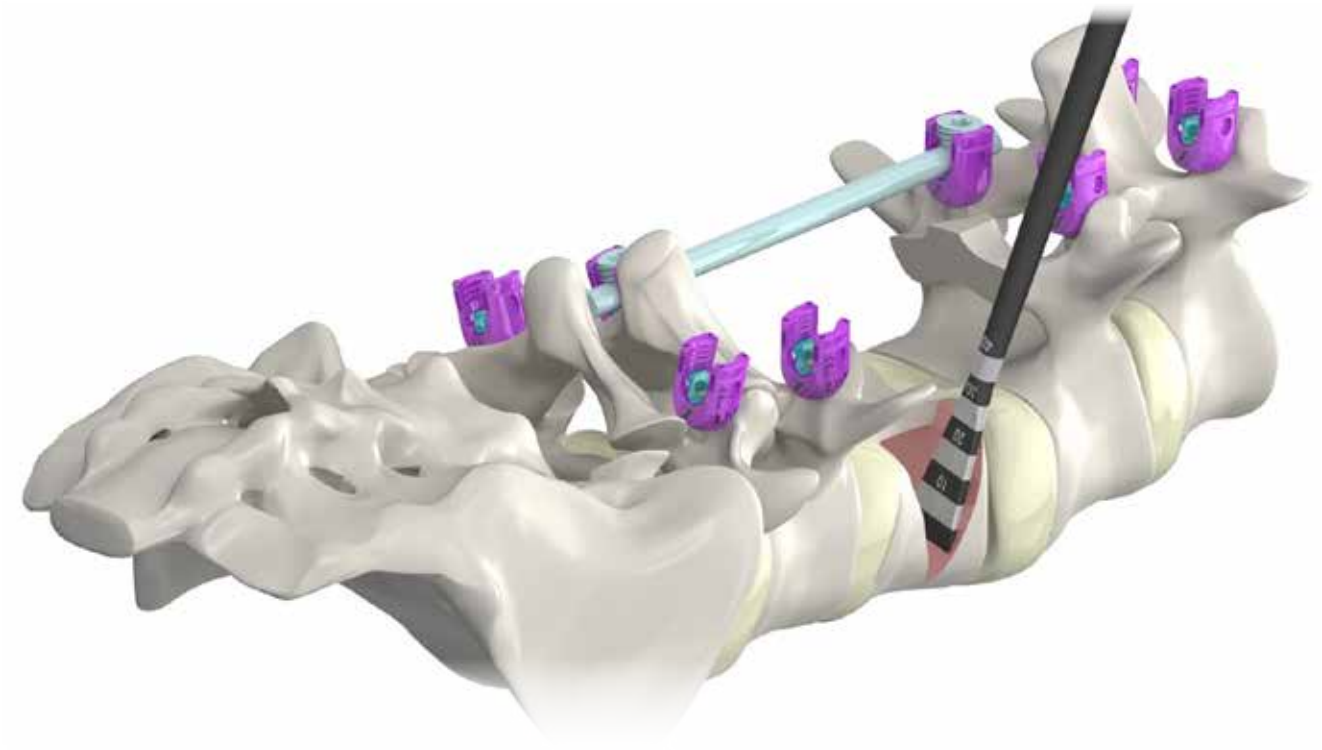


Thoracolumbar Solutions

Vitality®+ Osteotomy System

Surgical Technique Guide



The Pedicle Subtraction Osteotomy (PSO) and Vertebral Column Resection (VCR) procedures allow surgeons to correct spinal deformities related to sagittal and/or coronal imbalance. The Zimmer Biomet Vitality+ Osteotomy System has been designed in an effort to provide surgeons with viable, effective, and intuitive instrument options, in order to facilitate osteotomy procedures.

TABLE OF CONTENTS

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 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.

SURGICAL TECHNIQUE

While the instruments included in the Vitality+ Osteotomy System are often utilized in a wide variety of osteotomy procedures; this surgical technique serves to illustrate the surgical steps necessary for Pedicle Subtraction Osteotomy procedures. This system is designed to enhance surgical efficiency; by providing surgeons with instruments specifically intended for osteotomy procedures. However, it is beyond the scope and purpose of this manual to describe the full technique for all osteotomy variations.

PRE-SURGICAL PLANNING

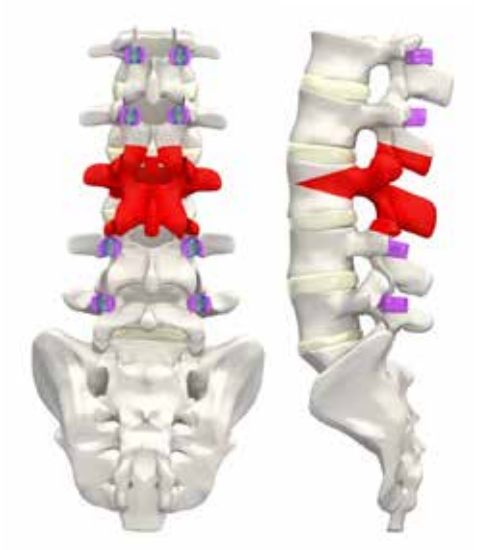


Figure 1
Dorsal and lateral views showing a Grade 3 Osteotomy

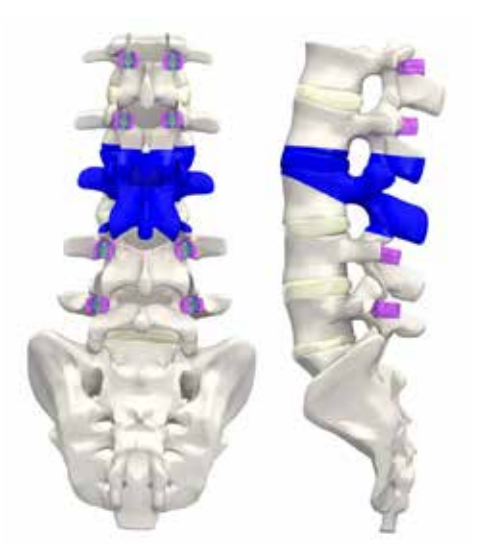


Figure 2
Dorsal and lateral views showing a Grade 4 Osteotomy

The extent to which lordosis and coronal correction may be achieved at any targeted vertebral level is dependent upon the size of the vertebra's pedicles, as pedicle size ultimately determines the amount of resection that can be accomplished. Because pedicle size differs from one patient to the next; pre-surgical planning is critical to the ultimate success of the intended surgical realignment.

There are two types of Pedicle Subtraction Osteotomies. The first, characterized as a Grade 3 Osteotomy, is achieved by removing the posterior elements, skeletonizing the pedicles, and performing a circumferential wedge resection; the apex of which forms a hinge at the anterior cortex of the vertebral body (Figure 1).

If a larger correction is required, the surgeon may choose to have the superior wall of the wedge resection include the endplates and disc of the motion segment cephalad to the accessed pedicles, classified as a Grade 4 Osteotomy (Figure 2).

PATIENT POSITIONING

Figure 3
Patient positioning

- It is recommended that a Jackson Table be used in conjunction with 6 attachable bolsters (Figure 3). The use of these bolsters allows the patient's lumbar region to hang freely, so as to introduce as much natural lordosis as possible and to minimize epidural bleeding.
- It is also suggested that the bed be put into a 10-15% reverse Trendelenburg position—a strategy intended to minimize the patient's risk of developing a dependent edema of the face during longer cases.

SURGICAL APPROACH, FIXATION, AND INITIAL DECOMPRESSION

Standard posterior exposure is recommended for this procedure.

- If the purpose of performing a PSO is to correct sagittal imbalance as a result of a previous surgery, the surgeon will likely have to work his, or her, way through significant scar tissue and a probable fusion mass.
- Once exposure is gained, it is recommended that the surgeon place instrumentation at the vertebral levels above and below the planned resection site. It is recommended that this spinal hardware be implanted prior to beginning the osteotomy, as the spine will become increasingly destabilized during the course of the procedure.
- Special care must be taken when decompressing the thecal sac, as the surgeon will likely encounter laminar defects and dural scarring. Epidural hemostasis may be achieved by the use of bipolar, hemostatic matrices, absorbable collagen hemostatic agents, and cottonoid patties.

FORAMINOTOMIES, TRANSVERSE PROCESS AMPUTATION, AND PEDICLE EXPOSURE

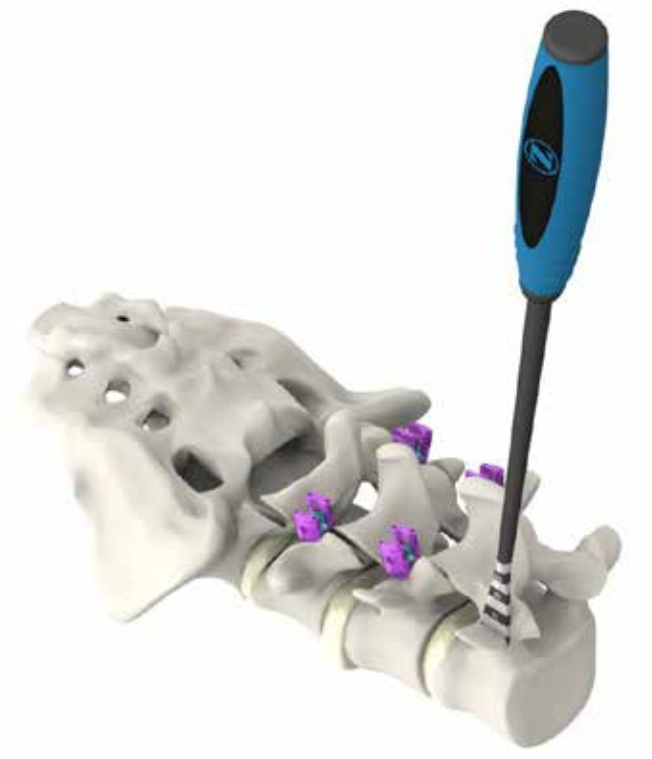


Figure 4
Transverse process amputation with straight osteotome

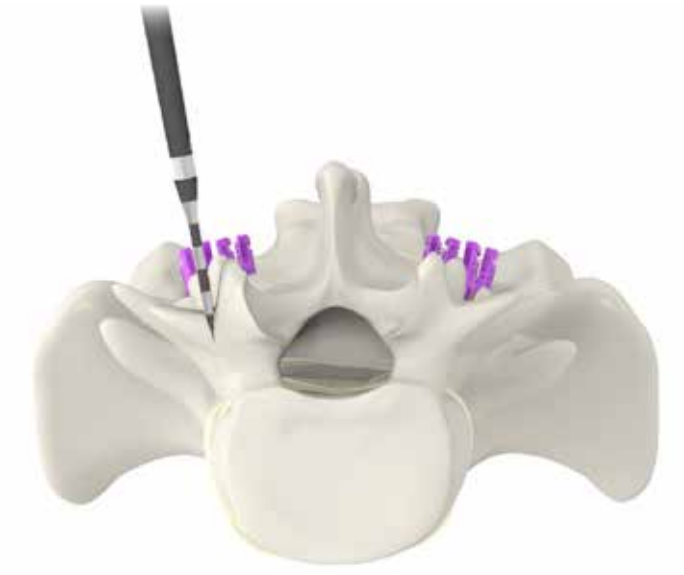


Figure 5
Axial view of transverse process amputation with straight osteotome

- Once the preliminary exposure of the thecal sac has been achieved, foraminotomies should be performed at the vertebral levels above and below the targeted pedicles. It is important that these foraminotomies be completed thoroughly, in order to prevent inadvertent nerve compression during the eventual closure of the osteotomy site.

The Vitality+ Osteotomy System includes a number of nerve root retractor options in order to work around the neural elements.

- Once the foraminotomies are finished, the thecal sac, pedicles, transverse processes, and exiting nerve roots should be clearly exposed. In some instances, the exiting nerve roots at the proximal level do not need to be entirely exposed. For example, if the inferior portion of the nerve root can be seen and protected, no additional exposure is necessary. However, the traversing nerve root must be exposed—e.g. L3 nerve root for an L3 PSO.
- Proceed by amputating the transverse process at its connection to the pedicle. This will lead to the lateral border of the vertebral body (Figure 4 and 5).

VERTEBRAL BODY RETRACTOR

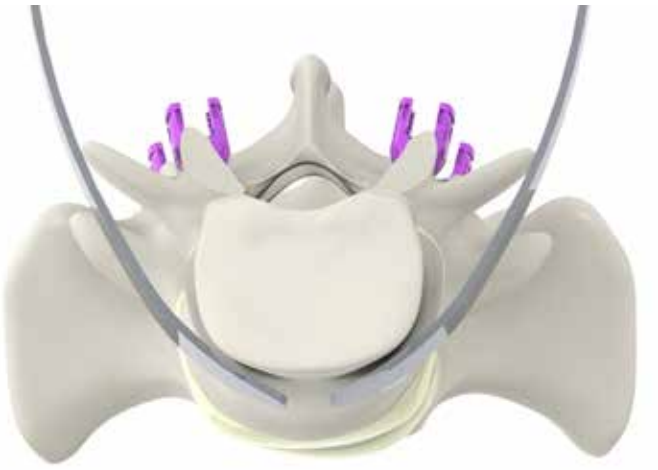


Figure 6
Malleable vertebral body retractors

- Dissection of the lateral border of the vertebral body should be periosteal, and judicious use of cautery can take care of the subsequent bleeding from segmental vessels. If seen, the segmental artery should be cauterized with a bipolar to prevent retraction and bleeding into the retroperitoneal space. The malleable vertebral body retractors can be helpful in this step.
- After selecting the appropriate malleable vertebral body retractor, the surgeon may perform a subperiosteal dissection of the targeted vertebral body. The malleable vertebral body retractors are radiolucent for maximum visualization of the surgical site under fluoroscopy. These retractors also feature a spoon-like blunt tip, ideal for dissection around the vertebral body (Figure 6).
- The ideal starting point for dissection is just caudal to the superior endplate of the targeted vertebral body. The segmental vessels should be swept anterior and lateral to the body, as the retractor is progressed around the anterior cortex.
- Begin dissection with the smallest vertebral body retractor and sequentially increase retractor width, as the dissection of the vertebral body progresses. The surgeon should take care to avoid inadvertently stretching the proximal exiting nerve root during dissection and retraction. Ultimately, the spoon tip should come to rest along the anterior cortex of the vertebral body.
- Once the vertebral body retractors are in place, the surgeon may choose to pack gauze between the retractor and the vertebral body. Doing so helps keep the retractor in place and helps to maintain separation of the psoas and the larger vessels, from the vertebral body. This gauze may also serve to protect the soft tissue once the lateral vertebral wall is resected just prior to final closure of the osteotomy.

PEDICLE RESECTION

Figure 7
Skeletonized pedicles

Figure 8
Fully resected pedicles

- Some surgeons prefer to first skeletonize the pedicles and work through them, in order to remove the cancellous bone from the targeted vertebral body (Figure 7). While this strategy restricts instrument access to the vertebral body; this technique does provide the means of protecting the neural elements during cancellous resection, without the need to use a nerve root and/or dural retractor. Others may prefer to either partially, or entirely, amputate the pedicle (Figure 8).
- As with any spine surgery, care must always be taken to guard against injury to the neural elements. To this end, the surgeon must ensure that no bony projections are left after pedicle amputation. If not properly addressed, these bony prominences could impinge upon the neural elements after closure of the osteotomy.
- The Vitality+ Osteotomy System includes a number of nerve root retractors to aid the surgeon in protecting the neural elements from inadvertent harm during the pedicle resection process.

PEDICLE RESECTION *(continued)*

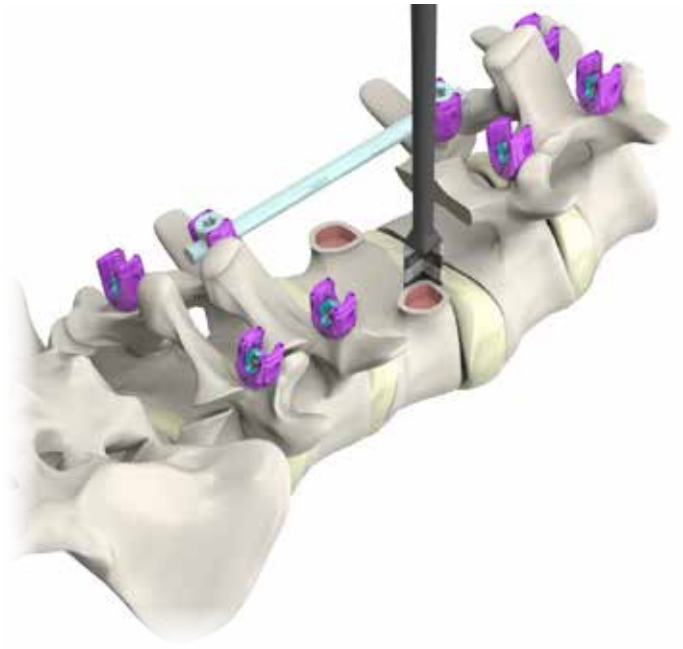


Figure 9
90° Osteotome

- 90° osteotomes are available, for resection of the superior-most aspects of the pedicles and the posterior cortical wall of the vertebral body. To avoid injury to the neural elements, this instrument should be placed so that the walls of the osteotome face superior and medial, respectively (Figure 9).

CANCELLOUS RESECTION

- At this point, resection of the vertebral body's cancellous bone should begin. The Vitality+ Osteotomy System includes instrumentation specifically designed for this cancellous bone removal. Care should be taken; to maintain the desired planes of resection that were determined during pre-surgical planning, so as to ensure the intended closure is achieved. The surgeon should remove as much trabecular bone as possible, along the intended resection planes. However, the surgeon must leave the anterior cortex intact, so as to serve as a pivot point during closure.
- It should be noted that the generous use of hemostatic agents and packing can significantly abate patient blood loss, during this stage of the procedure and those to follow. If bleeding precludes working in an area, the surgeon may choose to pack the troublesome area and work from the opposite side. This strategy can help move the case along more efficiently and the surgeon may repeat this process as needed.

LATERAL CORTICAL WALL RESECTION

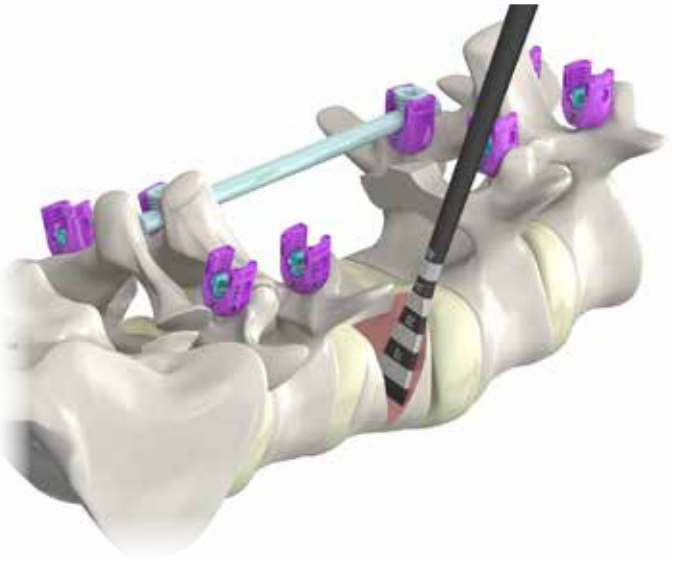


Figure 10
Lateral wall resection

- To prepare the vertebral body for closure, the lateral vertebral walls must be resected. The Vitality+ Osteotomy System provides instruments designed to aid in lateral cortical wall resection, including osteotomes in various widths. Care must be taken to maintain the integrity of the anterior cortex during the lateral wall resections, to prevent acute collapse and/or subluxation.
- Before proceeding with the lateral wall resections, it is recommended that the surgeon place at least one temporary rod, in order to prevent acute collapse, and/or subluxation of the surgical defect (Figure 10).

Note: *Some surgeons prefer to use two bilateral rods; to prevent acute collapse, or subluxation, as the lateral walls are being resected. This strategy provides more stability, but requires the surgeon to navigate around the implant construct, while both lateral walls are taken down.*

Other surgeons may choose to secure a single rod contralateral to the cortex that is being resected. This technique allows for some stability, while not requiring the surgeon to work around fixation instrumentation. To perform this technique a rod is first placed contralateral to the lateral wall intended for resection. Once the resection is completed, an ipsilateral rod is secured into place and the contralateral rod is removed. This allows the surgeon to access the second lateral wall without having to maneuver around a rod.

Regardless of which fixation strategy is used, before removing the posterior cortical wall; it is recommended to have two rods affixed to the spine. The presence of bilateral rods at this stage will help to prevent acute collapse and/or subluxation of the osteotomy site and ultimately allows the surgeon to access the wedge resection after the posterior wall has been removed. Having bilateral rods in place also provides the benefit of allowing the surgeon a more controlled closure of the osteotomy site through gradual and careful bilateral compression on the implant construct.

POSTERIOR VERTEBRAL BODY CORTEX REMOVAL

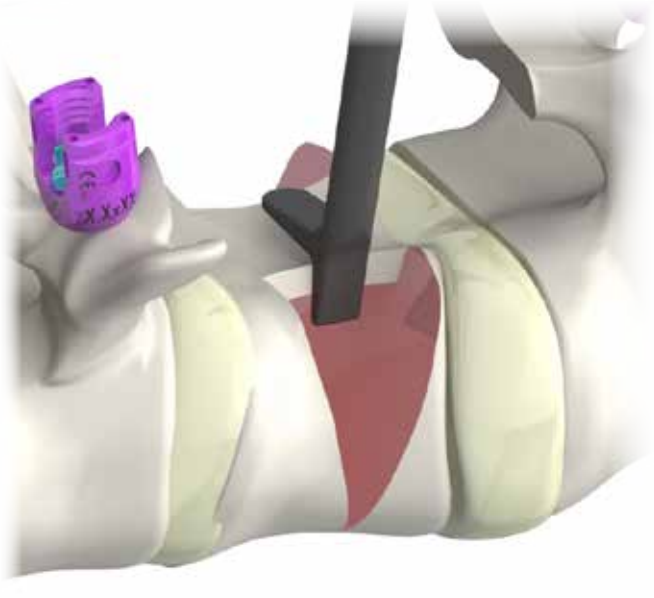


Figure 11
Posterior wall impactor used to fracture the posterior cortex

- Inspect the resection carefully before moving forward, so as to ensure that there are no residual bony fragments that could compress the thecal sac. Take care to ensure that the thecal sac and the exiting nerve roots above, below, and at the site of the osteotomy are free from any tissue that might create focal stenosis, or radiculopathy.
- The Vitality+ Osteotomy System includes both posterior wall impactors and osteotomes. The appropriate posterior wall instrument is that which spans the posterior wall beyond the lateral margins of the dura—as this will prevent the dura from injury during impaction. The dura should be dissected away from the posterior cortex, while the impactor is inserted into place. The impactor should be at the cephalad, or caudal, aspect of the missing pedicles (Figure 11). Carefully mallet the handle of the impactor to fracture the cortex.
- Repeat this impaction at the opposite side of the posterior wall to break the cortex completely free. Remove the posterior cortex from the resection site. The thecal sac should then be palpated with a Woodson, or Penfield, to ensure that no bone fragments are adhered to the dura.

CLOSURE

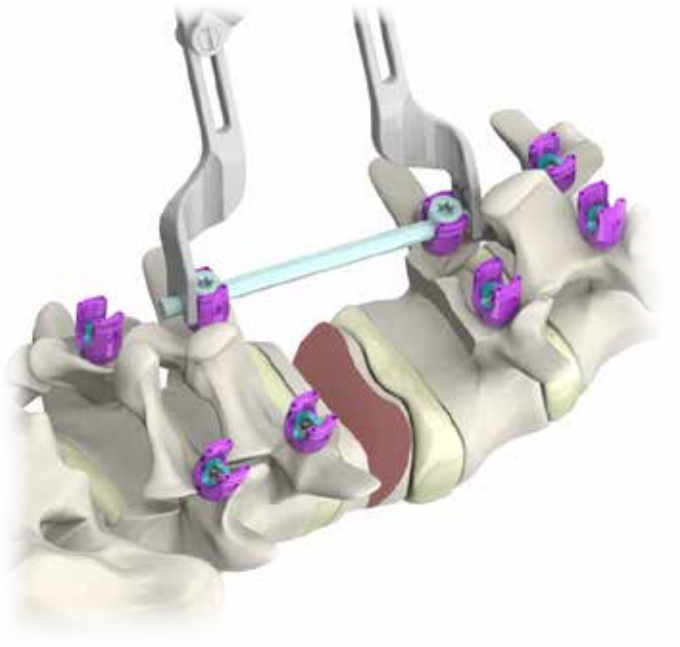


Figure 12
Final closure

- Carefully loosen the implant construct's closure tops, so that the weight of the abdomen provides initial closure of the osteotomy. While not required, if necessary there are multi-level compressors and distractors available in the Vitality Spinal Fixation System that can be used to control the closure of the osteotomy site.
- By placing the feet of the distractor between the screws immediately cephalad and caudal to the osteotomy site, the closure tops can be loosened without the weight of the abdomen abruptly closing the osteotomy site (Figure 12). The surgeon may then carefully guide closure by releasing the rack of the distractor, while still maintaining his/her grip on the distractor's handles. The surgeon may then use a compressor for final closure of the defect.
- Once the closure has been completed to the surgeon's satisfaction, the temporary rods should be replaced with the rods intended for the final construct. The closure tops of the construct should be final tightened and a standard arthrodesis should be performed, but only after ensuring that the neural elements remain free from compression by the surrounding bony and soft tissue.

Note: *Some dural kinking and buckling is common, but the degree to which is acceptable, must be determined by the surgeon. Comparison of neurophysiological data should be conducted to ensure no iatrogenic neurological complications. Performing small laminectomies above and below the closure site may minimize the risk of dural kinking due to closure and subluxation.*

INSTRUMENTS

Nerve Root Retractor, 7 mm	PART NUMBER
	142M0007

Angled Nerve Root Retractor	PART NUMBER
	732M0001

Malleable Nerve Root Retractor	PART NUMBER
	732M0002

90° Osteotome	PART NUMBER
6 x 6 mm	732M0406
8 x 8 mm	732M0408

Curved Osteotome	PART NUMBER
6 mm	732M1106
8 mm	732M1108
10 mm	732M1110

Straight Osteotome	PART NUMBER
6 mm	732M1206
8 mm	732M1208
10 mm	732M1210

Posterior Wall Impactor	PART NUMBER
21 mm	732M2121
24 mm	732M2124
26 mm	732M2126

Nerve Hook, Bayoneted 90° Up	PART NUMBER
6 mm	140M1000
8 mm	140M1001

Ball Probe, Bayoneted 90° Up, 10 mm	PART NUMBER
	140M1201

Woodson, Bayoneted	PART NUMBER
	140M1400

Penfield Push	PART NUMBER
Bayoneted #2	140M1602
Bayoneted #4	140M1604

Penfield Pull	PART NUMBER
Bayoneted #2	140M1702
Bayoneted #4	140M1704

PSO Curette, 60° Down	PART NUMBER
5.0 mm	732M1350
7.5 mm	732M1375

PSO Curette, 90° Down	PART NUMBER
5.0 mm	732M1450
7.5 mm	732M1475

Straight Curette	PART NUMBER
5.0 mm	733M1150
7.5 mm	733M1175

Cup Curette, Left 5.0 mm	PART NUMBER
	733M1550

Cup Curette, Right 5.0 mm	PART NUMBER
	733M1650

Rasp, Straight	PART NUMBER
	738M1101

INSTRUMENTS *(continued)*

Retractors *(order individually)*

Vertebral Body Retractor	PART NUMBER
Small	732M0033
Medium	732M0034
Large	732M0035

Optional Instruments

PSO Angular Template	PART NUMBER
25°	732M0225
30°	732M0230
35°	732M0235

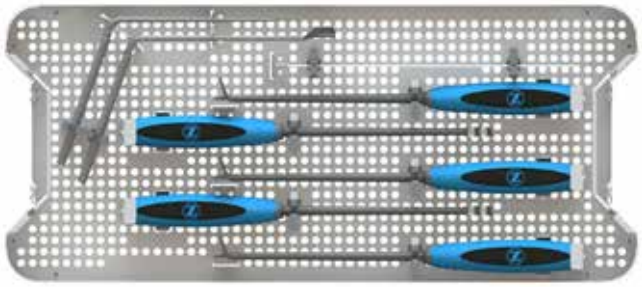
Osteotome Impactor	PART NUMBER
Right 21 mm	732M3121
Right 24 mm	732M3124
Right 26 mm	732M3126
Left 21 mm	732M3221
Left 24 mm	732M3224
Left 26 mm	732M3226

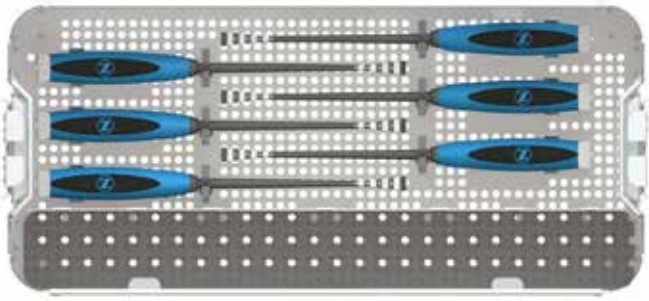
Wide Posterior Wall Impactor	PART NUMBER
21 mm	732M2221
24 mm	732M2224

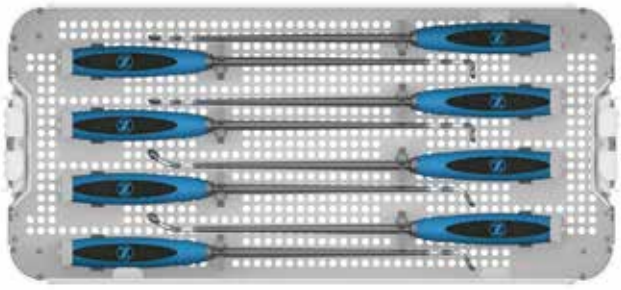
Posterior Wall Osteotome	PART NUMBER
21 mm	732M1721
24 mm	732M1724

Cobb Elevator	PART NUMBER
10 mm	732M0510
12 mm	732M0512

KIT CONTENTS







Vitality+ Osteotomy Instrument Kit
Kit Number: PCR700M3101

DESCRIPTION	PART NUMBER
Nerve Root Retractor, 7 mm	142M0007
Angled Nerve Root Retractor	732M0001
Malleable Nerve Root Retractor	732M0002
90° Osteotome, 6 x 6 mm	732M0406
90° Osteotome, 8 x 8 mm	732M0408
Curved Osteotome, 6 mm	732M1106
Curved Osteotome, 8 mm	732M1108
Curved Osteotome, 10 mm	732M1110
Straight Osteotome, 6 mm	732M1206
Straight Osteotome, 8 mm	732M1208
Straight Osteotome, 10 mm	732M1210
Posterior Wall Impactor, 21 mm	732M2121
Posterior Wall Impactor, 24 mm	732M2124
Posterior Wall Impactor, 26 mm	732M2126

Vitality+ Osteotomy Instrument Kit
Kit Number: PCR700M3111

DESCRIPTION	PART NUMBER
Nerve Hook, Bayoneted 90° Up, 6 mm	140M1000
Nerve Hook, Bayoneted 90° Up, 8 mm	140M1001
Ball Probe, Bayoneted 90° Up, 10 mm	140M1201
Woodson, Bayoneted	140M1400
Penfield Push, Bayoneted #2	140M1602
Penfield Push, Bayoneted #4	140M1604
Penfield Pull, Bayoneted #2	140M1702
Penfield Pull, Bayoneted #4	140M1704
PSO Curette, 60° Down 5.0 mm	732M1350
PSO Curette, 60° Down 7.5 mm	732M1375
PSO Curette, 90° Down 5.0 mm	732M1450
PSO Curette, 90° Down 7.5 mm	732M1475
Straight Curette, 5.0 mm	733M1150
Straight Curette, 7.5 mm	733M1175
Cup Curette, Left 5.0 mm	733M1550
Cup Curette, Right 5.0 mm	733M1650
Rasp, Straight	738M1101

IMPORTANT INFORMATION FOR VITALITY®+ OSTEOTOMY

Before using the Vitality®+ Osteotomy non-sterile instruments, the operating surgeon should study carefully the following recommendations, warnings, and instructions; as well as the available product-specific information (e.g., product literature, written surgical technique). We are not liable for complications that may arise, from the use of the device, in circumstances outside of our control including, but not limited to, product selection, deviations from the device's intended uses, or surgical technique.

Device Description

The Vitality+ Osteotomy non-sterile surgical instruments are manual surgical instruments; designed for use in Pedicle Subtraction Osteotomy (PSO) and Vertebral Column Resection (VCR) procedures, outlined by the Vitality+ Osteotomy Surgical Technique Guide. The reusable and/or disposable instruments were designed specifically to facilitate the preparation of the operative site and to aid in the implantation of associated surgical implants. As with all orthopedic surgical procedures, detailed preoperative planning is essential. Preoperative diagnostic evaluation, followed by carefully executed surgical technique is required. Postoperative care, individualized to suit the particular injury/disease requirements, is essential for optimum outcome. The surgeon must be fully aware of the risks and complications inherent to this type of surgery. Only those individuals with specialized training and experience in spinal surgery should attempt use of the instruments.

Intended Use

The Vitality+ Osteotomy non-sterile surgical instruments are intended for use in surgical procedures to manipulate tissue, bone, or for use with our other devices in orthopedic surgery.

Warnings and Precautions

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

- Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.
- Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose or even dangerous to the patient or surgical staff.
- The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials, and if any broken fragments of instruments remain in the body of a patient, the patient could have allergic or infectious consequences.
- It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.
- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery, where many extenuating circumstances may compromise the results.
- Special precautions are needed for pediatric cases. Care should be taken when using instrumentation with pediatric patients, since these patients are generally more susceptible to stresses involved in their use.
- Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. Read and follow the instructions for use and surgical technique guide provided by the manufacturer for this product.
- Under no circumstances are these instruments to be implanted.

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.
- 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.
- 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

- Over-bending, notching, striking and scratching with any instruments should be avoided to reduce the risk of breakage.
- If any instrument comes in contact with a non-sterile surface it should not be used.
- Extreme care must be taken when used near vital organs, nerves or vessels.

Possible Complications

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
- Infection, if instruments are not properly cleaned and sterilized.
- Nerve damage due to surgical trauma.
- Impingement of close vessels, nerves, and organs by slippage or misplacement of the instrument.
- Cutting of skin or gloves of operating staff.
- Bony fracture in cases of deformed spine or weak bone
- Involuntary crack, fracture or perforation of the bone
- The methods of use of instruments are to be determined by the user's experience and training in surgical procedures. A successful result is not always achieved in every surgical case.
- Proper Patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. Read and follow all other product information supplied by manufacturer of the implants or instruments.
- Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.

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 refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.*

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