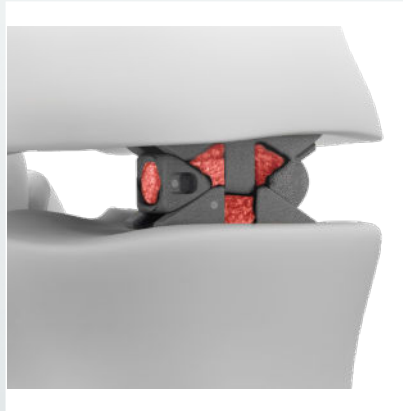
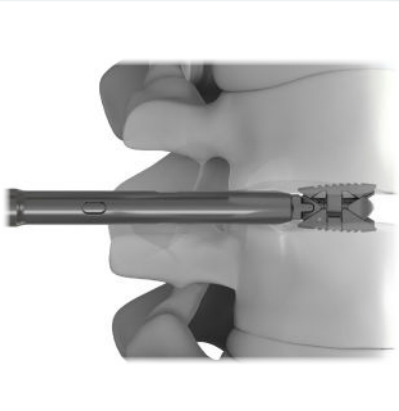




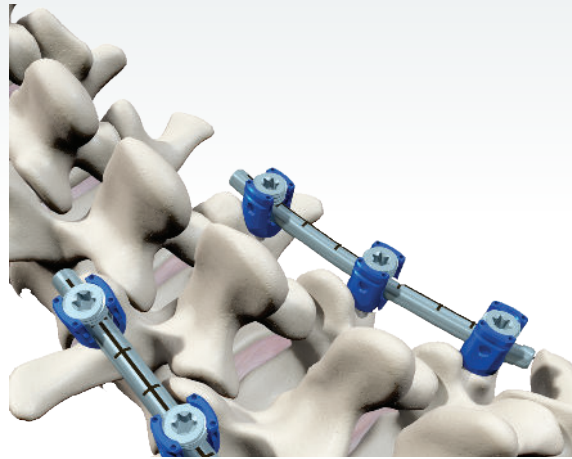
Prolift[®]

Expandable Spacer System

Surgical Technique Guide



Complete MIS Procedural Solution



Vital™ Spinal Fixation System



Viewline® Posterior MIS Retractor Sets



ProLift® Expandable Spacer System

Minimized Retraction • Disc Height Restoration • Controlled Distraction

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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

The ProLift Expandable interbody system with Osseo-Loc™ Surface Technology, provides a micro-invasive solution for TLIF and PLIF procedures with in situ expansion for restoration of normal anatomic disc height and decompression of neural elements. Streamlined instrumentation provides the surgeon minimal tissue disruption and nerve retraction while achieving surgical goals and restoring patient alignment.

Features and Benefits

- Controlled in situ expansion with continuous adjustability allows for foraminal and disc height restoration, as well as physiological levels of lordosis
- Bulleted tip simplifies insertion in collapsed degenerative discs without compromising the apophyseal ring
- Tactile and visual confirmation of expansion prevents over distraction
- Multiple lordotic options to assist in the restoration of normal spino-pelvic alignment
- Post pack design allows for insertion of graft material after expansion to assist with sentinel and columnar fusion through implant
- Designed to be used with the Osteo-Line™ Graft Delivery System

Implant Specifications

- 400-600 micron porosity
- 3 mm bulleted tip
- 0°, 7°, 12°, and 15° lordosis
- 28 mm pre-expansion length, 22 mm post-expansion length
- 8 mm - 13 mm height options in small implant
- 10 mm - 16 mm height options in large implant
- 10 mm and 12 mm width options



Lordotic



Parallel

3 mm bulleted tip



Surgical Technique

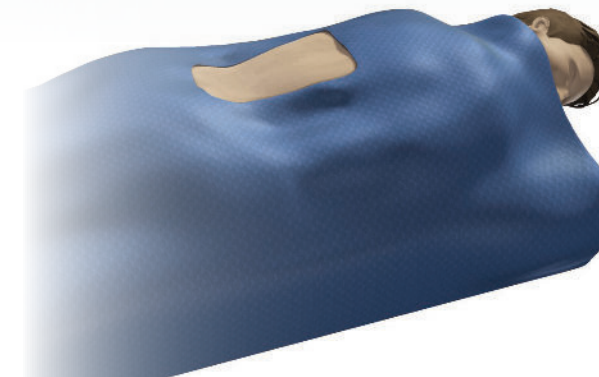


Figure 1
Patient positioning



Figure 2
Anatomical reference points at the respective vertebral levels

Step 1: Patient Positioning

- The patient is positioned in the prone position, and the appropriate surgical site is identified. Preoperative planning is critical in the preparation for spinal surgery and lateral fluoroscopy should be utilized to determine the precise implant size and intraoperative positioning (Figure 1).

Step 2: Exposure

Anatomical Reference Points

- Create an incision lateral off the midline for either a posterior lumbar interbody fusion (PLIF) or a transforaminal lumbar interbody fusion (TLIF) (Figure 2).

PLIF: Identify the relevant anatomical landmarks and perform a laminectomy and facetectomy to decompress the spinal canal.

TLIF: Remove the inferior facet of the superior vertebra and the superior facet of the inferior vertebra.

Note: If utilized with the Cypher MIS Screw System, retraction to the lateral aspect of the pars is recommended to prevent degeneration of the multifidus.

Surgical Technique (continued)



Figure 3
Discectomy

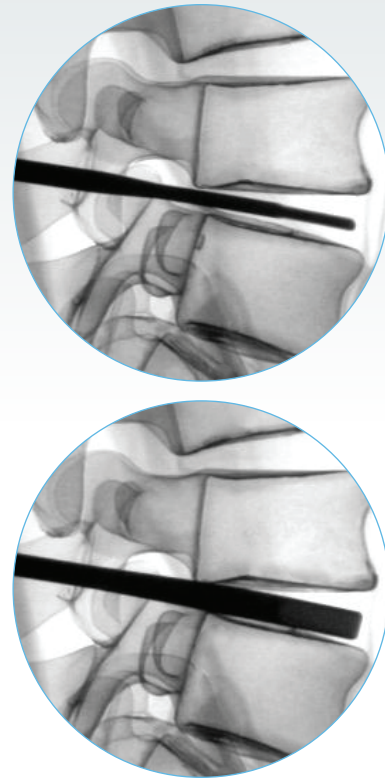


Figure 4
Endplate preparation



Figure 5
Confirm fit and position via fluoroscopy



Unlocked Position Locked Position

Figure 6a
Unlocked and locked position

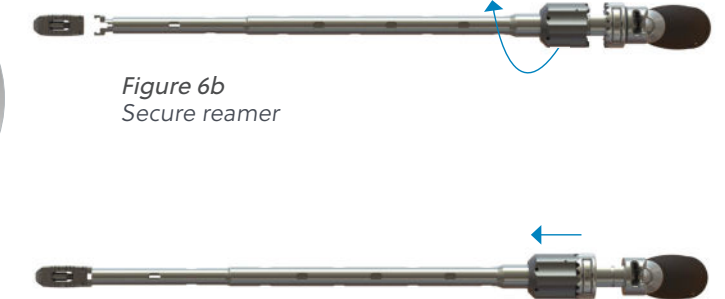


Figure 6b
Secure reamer



Figure 6c
Secure mechanism by pushing button and sliding lock down

Step 3: Discectomy

- Perform a complete discectomy on the desired disc using standard surgical instruments.
- When utilized bilaterally in a PLIF technique, it is important to remove the far lateral disc to allow for lateral placement along the lateral apophyseal ring (**Figure 3**).

Step 4: Endplate Preparation

- Remove the superficial layers of the endplates and expose bleeding bone. Paddle shavers and shapers may be used to assist with preparation of the vertebral endplates. Appropriate endplate preparation on each vertebral body will optimize surface contact with the selected interbody implant (**Figure 4**).

Note: Care should be taken not to remove excessive bone as this may weaken the endplates, possibly resulting in subsidence and segmental instability.

Tip: To remove cartilaginous endplates prior to ProLift placement, use a paddle shaver one size smaller than measured trial.

Step 5: Implant Size Selection

- Select the appropriate trial sizer and securely attach it to the T-handle. Lightly impact the trial sizer into the disc space and confirm proper fit and position via fluoroscopy. Remove the trial sizer and select the implant that corresponds to the appropriate size (**Figure 5**).

Tip: ProLift Lordotic implants should be trialed with either the parallel large or small sizer to insure ability to place contracted implant.

Note: Implant is not packaged in fully collapsed position. There will be a slight toggle until torque-limiting handle is used to fully collapse implant.

Step 6: Implant Attachment to Installer

- Select the implant that corresponds to the previously selected trial size and securely attach the implant to the installer.
- Ensure locking mechanism is in its unlocked state (**Figure 6a**) then turn the gray outer sleeve of the installer counterclockwise to open the distal end of the installer.
- To secure the implant to the installer, insert the pins of the installer onto the implant. While holding the implant in place, turn the black outer sleeve clockwise over the inner sleeve to secure the implant (**Figure 6b**).
- Push button on locking mechanism and slide the lock down to secure the gray outer sleeve (**Figure 6c**).
- Once the implant is in position, attach the installer driver to the torque-limiting handle. Turn the torque-limiting handle counterclockwise until the implant is fully collapsed.

Surgical Technique (continued)



Figure 7
Pack autograft

Step 7: Autograft Placement

- Prior to implant placement, pack the anterior 1/3 of disc space with autograft.
- Once the driver is securely engaged to the implant insert autograft within the graft window from one direction until it flows into opposite window. This will ensure that the implant is filled with bone graft (Figure 7).

Note: ProLift is intended for use with autograft.

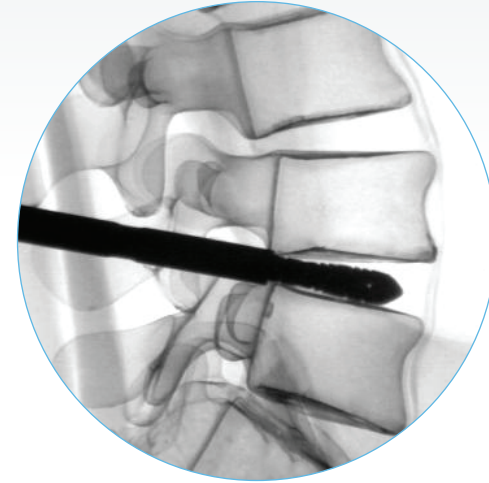


Figure 8
Confirm proper fit and position via lateral fluoroscopy

Step 8: Implant Insertion

- Lightly impact the implant in the disc space. Confirm proper fit and position via lateral fluoroscopy (Figure 8).
- Tip:** Countersinking of the implant 2-3 mm past the posterior cortex of the vertebral body is recommended for stability on the apophyseal rim.

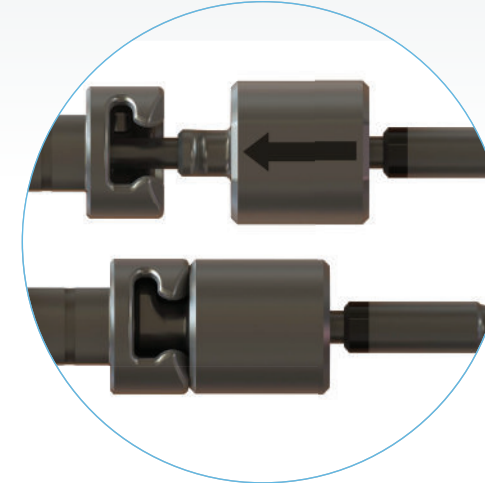


Figure 9
Remove the internal drive shaft from the installer assembly

Step 8: Implant Insertion (continued)

- Insert installer driver into the implant installer and match up arrow with the locking mechanism and turn clockwise to lock into place (Figure 9).
- Once the driver is engaged with the implant, turn the torque-limiting handle clockwise to expand the implant until desired position is reached or an audible click is heard and tension is released in the handle.
- Confirm implant position and endplate contact via lateral fluoroscopy (Figure 10a, 10b).

Note: 2.5 turns roughly equates to 1 mm of expansion.

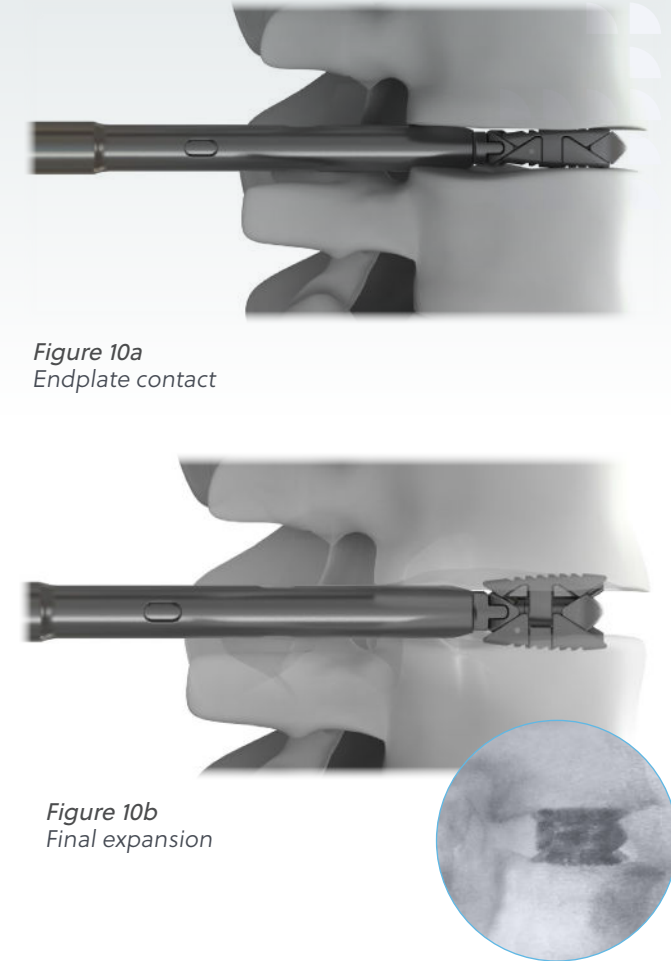


Figure 10a
Endplate contact

Figure 10b
Final expansion

Step 9: Drive Shaft Removal

- After final expansion of ProLift, and verification of placement, remove the internal drive shaft from the installer assembly.

Implants

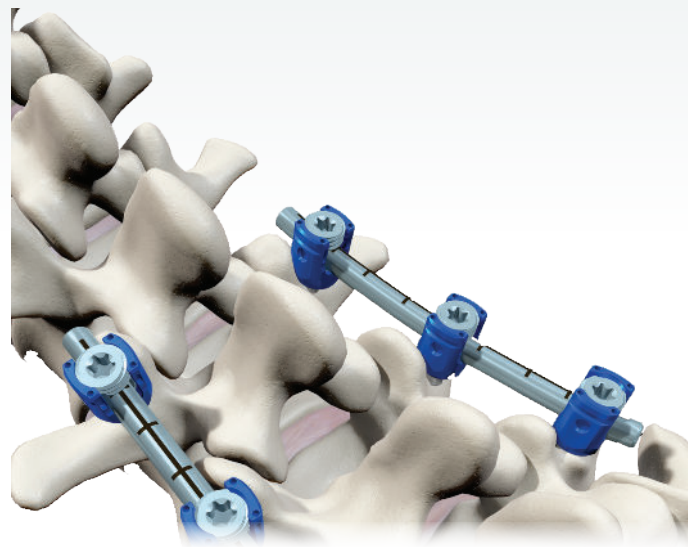


Figure 11
Vital Spinal Fixation System

Step 10: Supplemental Fixation

- Supplemental internal fixation, such as the Cypher MIS Screw System should be used for additional stabilization (**Figure 11**).

Step 11: Closure

- Properly irrigate the surgical site and close the incision utilizing standard subcuticular sutures.

Removal

- If removal or revision is required, securely attach the installer and installer driver to the implant. Once the installer is securely attached, remove the implant and replace with the new implant. If required, the slap hammer may be attached to the installer to assist in implant removal.



Lordotic



Parallel

ProLift Sizing

W x L, EXPANSION RANGE, LORDOSIS	ANTERIOR HEIGHT COLLAPSED	MAXIMUM HEIGHT COLLAPSED	POSTERIOR HEIGHT COLLAPSED	ANTERIOR HEIGHT EXPANDED	MAXIMUM HEIGHT EXPANDED	POSTERIOR HEIGHT EXPANDED	PART NUMBER
10 mm x 28 mm, 8 mm-13 mm, 0°	7.6 mm	8 mm	7.6 mm	12.1 mm	13 mm	12.1 mm	58-1028-0813Z
10 mm x 28 mm, 8 mm-13 mm, 7°	7.7 mm	8 mm	7.2 mm	12.3 mm	13 mm	11.1 mm	58-1028-0708Z
10 mm x 28 mm, 8 mm-13 mm, 12°	7.7 mm	8 mm	7.2 mm	12.3 mm	13 mm	10.8 mm	58-1028-1208Z
10 mm x 28 mm, 8 mm-13 mm, 15°	7.7 mm	8 mm	7.2 mm	12.3 mm	13 mm	10.4 mm	58-1028-1508Z
10 mm x 28 mm, 10 mm-16 mm, 0°	9.1 mm	10 mm	9.1 mm	15.1 mm	16 mm	15.1 mm	58-1028-1016Z
10 mm x 28 mm, 10 mm-16 mm, 7°	9.2 mm	10 mm	8.2 mm	15.2 mm	16 mm	14.1 mm	58-1028-0710Z
10 mm x 28 mm, 10 mm-16 mm, 12°	9.2 mm	10 mm	8.2 mm	15.2 mm	16 mm	13.7 mm	58-1028-1210Z
10 mm x 28 mm, 10 mm-16 mm, 15°	9.2 mm	10 mm	8.2 mm	15.2 mm	16 mm	13.3 mm	58-1028-1510Z
12 mm x 28 mm, 8 mm-13 mm, 0°	7.6 mm	8 mm	7.6 mm	12.1 mm	13 mm	12.1 mm	58-1228-0813Z
12 mm x 28 mm, 8 mm-13 mm, 7°	7.7 mm	8 mm	7.2 mm	12.3 mm	13 mm	11.1 mm	58-1228-0708Z
12 mm x 28 mm, 8 mm-13 mm, 12°	7.7 mm	8 mm	7.2 mm	12.3 mm	13 mm	10.8 mm	58-1228-1208Z
12 mm x 28 mm, 8 mm-13 mm, 15°	7.7 mm	8 mm	7.2 mm	12.3 mm	13 mm	10.4 mm	58-1228-1508Z
12 mm x 28 mm, 10 mm-16 mm, 0°	9.1 mm	10 mm	9.1 mm	15.1 mm	16 mm	15.1 mm	58-1228-1016Z
12 mm x 28 mm, 10 mm-16 mm, 7°	9.2 mm	10 mm	8.2 mm	15.2 mm	16 mm	14.1 mm	58-1228-0710Z
12 mm x 28 mm, 10 mm-16 mm, 12°	9.2 mm	10 mm	8.2 mm	15.2 mm	16 mm	13.7 mm	58-1228-1210Z
12 mm x 28 mm, 10 mm-16 mm, 15°	9.2 mm	10 mm	8.2 mm	15.2 mm	16 mm	13.3 mm	58-1228-1510Z

Biologics

Osteo-Line Graft Delivery System

Engineered to deliver up to 15 cc of autograft and/or allogenic bone graft directly to orthopedic site in situ



PART NUMBER: LS-1015-150Z

Instruments



DESCRIPTION	PART NUMBER
6 mm Modified Hudson Paddle Shaper	129-1006
7 mm Modified Hudson Paddle Shaper	129-1007
8 mm Modified Hudson Paddle Shaper	129-1008
9 mm Modified Hudson Paddle Shaper	129-1009
10 mm Modified Hudson Paddle Shaper	129-1010
11 mm Modified Hudson Paddle Shaper	129-1011
12 mm Modified Hudson Paddle Shaper	129-1012
13 mm Modified Hudson Paddle Shaper	129-1013



DESCRIPTION	PART NUMBER
6 mm Modified Hudson Paddle Shaver	151-262
7 mm Modified Hudson Paddle Shaver	151-265
8 mm Modified Hudson Paddle Shaver	151-268
9 mm Modified Hudson Paddle Shaver	151-271
10 mm Modified Hudson Paddle Shaver	151-274
11 mm Modified Hudson Paddle Shaver	151-277
12 mm Modified Hudson Paddle Shaver	151-280
13 mm Modified Hudson Paddle Shaver	151-283



DESCRIPTION	PART NUMBER
Expandable Implant Installer	151-596



DESCRIPTION	PART NUMBER
Slap Hammer, Long	112-351



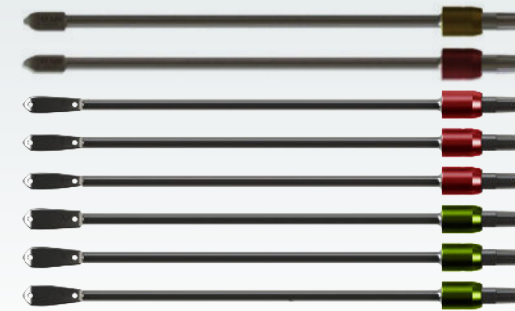
DESCRIPTION	PART NUMBER
Modified Hudson T-handle	112-345



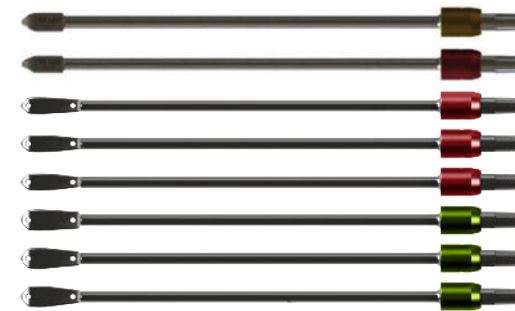
DESCRIPTION	PART NUMBER
Expandable Implant Installer Driver	151-219



DESCRIPTION	PART NUMBER
Torque-limiting Handle, 20 in-lbs	112-222



DESCRIPTION	PART NUMBER
Static Expandable Cage Trial, 12 mm x 28 mm x 8 mm, 0°	151-160
Static Expandable Cage Trial, 12 mm x 28 mm x 10 mm, 0°	151-162
Static Expandable Cage Trial, 12 mm x 28 mm x 8 mm, 7°	151-234
Static Expandable Cage Trial, 12 mm x 28 mm x 8 mm, 12°	151-235
Static Expandable Cage Trial, 12 mm x 28 mm x 8 mm, 15°	151-236
Static Expandable Cage Trial, 12 mm x 28 mm x 10 mm, 7°	151-237
Static Expandable Cage Trial, 12 mm x 28 mm x 10 mm, 12°	151-238
Static Expandable Cage Trial, 12 mm x 28 mm x 10 mm, 15°	151-239



DESCRIPTION	PART NUMBER
Static Expandable Cage Trial, 10 mm x 28 mm x 8 mm, 0°	151-400
Static Expandable Cage Trial, 10 mm x 28 mm x 10 mm, 0°	151-402
Static Expandable Cage Trial, 10 mm x 28 mm x 8 mm, 7°	151-455
Static Expandable Cage Trial, 10 mm x 28 mm x 10 mm, 7°	151-457
Static Expandable Cage Trial, 10 mm x 28 mm x 8 mm, 12°	151-510
Static Expandable Cage Trial, 10 mm x 28 mm x 10 mm, 12°	151-512
Static Expandable Cage Trial, 10 mm x 28 mm x 8 mm, 15°	151-565
Static Expandable Cage Trial, 10 mm x 28 mm x 10 mm, 15°	151-567

Kit Contents

ProLift 10 mm Instrument Kit Kit Number: 114-477

DESCRIPTION	QTY	PART NUMBER
ProLift Tray Lid	1	114-204-1
ProLift Tray Top	1	114-204-2
ProLift Tray Bottom	1	114-204-3
ProLift Tray Base	1	114-204-4
Expandable Implant Installer	2	151-596
Expandable Implant Installer Driver	2	151-219
Torque-limiting Handle, 20 in-lbs	2	112-222
Modified Hudson T-Handle	2	112-345
Slap Hammer, Long	1	112-351
6 mm Modified Hudson Paddle Shaper	1	129-1006
7 mm Modified Hudson Paddle Shaper	1	129-1007
8 mm Modified Hudson Paddle Shaper	1	129-1008
9 mm Modified Hudson Paddle Shaper	1	129-1009
10 mm Modified Hudson Paddle Shaper	1	129-1010
11 mm Modified Hudson Paddle Shaper	1	129-1011
12 mm Modified Hudson Paddle Shaper	1	129-1012
13 mm Modified Hudson Paddle Shaper	1	129-1013
6 mm Modified Hudson Paddle Shaver	1	151-262
7 mm Modified Hudson Paddle Shaver	1	151-265

ProLift 10 mm Implant Kit Kit Number: 114-478

DESCRIPTION	QTY	PART NUMBER
10 mm x 28 mm, Small, 0°	3	58-1028-0813Z
10 mm x 28 mm, Small, 7°	3	58-1028-0708Z
10 mm x 28 mm, Small, 12°	3	58-1028-1208Z
10 mm x 28 mm, Small, 15°	3	58-1028-1508Z
10 mm x 28 mm, Large, 0°	3	58-1028-1016Z
10 mm x 28 mm, Large, 7°	3	58-1028-0710Z
10 mm x 28 mm, Large, 12°	3	58-1028-1210Z
10 mm x 28 mm, Large, 15°	3	58-1028-1510Z

8 mm Modified Hudson Paddle Shaver	1	151-268
9 mm Modified Hudson Paddle Shaver	1	151-271
10 mm Modified Hudson Paddle Shaver	1	151-274
11 mm Modified Hudson Paddle Shaver	1	151-277
12 mm Modified Hudson Paddle Shaver	1	151-280
13 mm Modified Hudson Paddle Shaver	1	151-283
Static Expandable Cage Trial 10 mm x 28 mm x 8 mm, 0°	1	151-400
Static Expandable Cage Trial 10 mm x 28 mm x 10 mm, 0°	1	151-402
Static Expandable Cage Trial 10 mm x 28 mm x 8 mm, 7°	1	151-455
Static Expandable Cage Trial 10 mm x 28 mm x 10 mm, 7°	1	151-457
Static Expandable Cage Trial 10 mm x 28 mm x 8 mm, 12°	1	151-510
Static Expandable Cage Trial 10 mm x 28 mm x 10 mm, 12°	1	151-512
Static Expandable Cage Trial 10 mm x 28 mm x 8 mm, 15°	1	151-565
Static Expandable Cage Trial 10 mm x 28 mm x 10 mm, 15°	1	151-567

ProLift 12 mm Instrument Kit Kit Number: 114-475

DESCRIPTION	QTY	PART NUMBER
ProLift Tray Lid	1	114-204-1
ProLift Tray Top	1	114-204-2
ProLift Tray Bottom	1	114-204-3
ProLift Tray Base	1	114-204-4
Expandable Implant Installer	2	151-596
Expandable Implant Installer Driver	2	151-219
Torque-limiting Handle, 20 in-lbs	2	112-222
Modified Hudson T-Handle	2	112-345
Slap Hammer, Long	1	112-351
6 mm Modified Hudson Paddle Shaper	1	129-1006
7 mm Modified Hudson Paddle Shaper	1	129-1007
8 mm Modified Hudson Paddle Shaper	1	129-1008
9 mm Modified Hudson Paddle Shaper	1	129-1009
10 mm Modified Hudson Paddle Shaper	1	129-1010
11 mm Modified Hudson Paddle Shaper	1	129-1011
12 mm Modified Hudson Paddle Shaper	1	129-1012
13 mm Modified Hudson Paddle Shaper	1	129-1013
6 mm Modified Hudson Paddle Shaver	1	151-262
7 mm Modified Hudson Paddle Shaver	1	151-265

ProLift 12 mm Implant Kit Kit Number: 114-476

DESCRIPTION	QTY	PART NUMBER (OLD)	PART NUMBER (NEW)
12 mm x 28 mm, Small, 0°	3	58-1228-0813D	58-1228-0813Z
12 mm x 28 mm, Small, 7°	3	58-1228-0708D	58-1228-0708Z
12 mm x 28 mm, Small, 12°	3	58-1228-1208D	58-1228-1208Z
12 mm x 28 mm, Small, 15°	3	58-1228-1508D	58-1228-1508Z
12 mm x 28 mm, Large, 0°	3	58-1228-1016D	58-1228-1016Z
12 mm x 28 mm, Large, 7°	3	58-1228-0710D	58-1228-0710Z
12 mm x 28 mm, Large, 12°	3	58-1228-1210D	58-1228-1210Z
12 mm x 28 mm, Large, 15°	3	58-1228-1510D	58-1228-1510Z

8 mm Modified Hudson Paddle Shaver	1	151-268
9 mm Modified Hudson Paddle Shaver	1	151-271
10 mm Modified Hudson Paddle Shaver	1	151-274
11 mm Modified Hudson Paddle Shaver	1	151-277
12 mm Modified Hudson Paddle Shaver	1	151-280
13 mm Modified Hudson Paddle Shaver	1	151-283
Static Expandable Cage Trial 12 mm x 28 mm x 8 mm, 0°	1	151-160
Static Expandable Cage Trial 12 mm x 28 mm x 10 mm, 0°	1	151-162
Static Expandable Cage Trial 12 mm x 28 mm x 8 mm, 7°	1	151-234
Static Expandable Cage Trial 12 mm x 28 mm x 10 mm, 7°	1	151-237
Static Expandable Cage Trial 12 mm x 28 mm x 8 mm, 12°	1	151-235
Static Expandable Cage Trial 12 mm x 28 mm x 10 mm, 12°	1	151-238
Static Expandable Cage Trial 12 mm x 28 mm x 8 mm, 15°	1	151-236
Static Expandable Cage Trial 12 mm x 28 mm x 10 mm, 15°	1	151-239

Important information on the prolift expandable spacer system

Description

The ProLift Expandable System is available in a range of sizes and footprints and can expand to the desired height (8 mm to 16 mm) to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. The implant allows packing of autogenous bone graft to help promote fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral bodies to prevent rotation and/or migration.

All implants are provided sterile and intended for SINGLE USE ONLY and should not be reused under any circumstances. Do not use any of the ProLift Expandable System components with components from any other system or manufacturer. The ProLift Expandable System components should never be reused under any circumstances.

Indications

When used as an interbody fusion device, the ProLift Expandable System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is used in patients who have had at least six months of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level(s) may be treated with the device. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

Contraindications

Contraindications include, but are not limited to:

- Active systemic infection or infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.

- Morbid obesity.
- Pregnancy.
- Mental illness, alcoholism, drug abuse.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Suspected or documented material allergy or intolerance.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
- Symptomatic cardiac disease.
- Spondylolisthesis of Grade II or greater.
- Systemic or terminal illness.
- Prior fusion at the level(s) to be treated.

Potential Adverse Events

A listing of possible adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, loosening, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.

- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Paralysis
- Death

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions

- ProLift implants are provided STERILE. Do not use if the package is opened or damaged, or if the expiration date has passed. DO NOT re-sterilize these implants as this could result in injury or require reoperation due to breakage.
- SINGLE USE ONLY — ProLift Expandable System implants are intended for Single Use Only. No surgical implants should be reused. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure. Reuse could result in injury or require reoperation due to breakage or infection.

Non-Sterile; the ProLift Expandable System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized after each use.

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. The ProLift Expandable System is only an implant used for the correction and stabilization of the spine. This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device system is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the ProLift Expandable System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Important information on the prolift expandable spacer system

Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the ProLift Expandable System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

MRI Safety Information

The ProLift Expandable System has not been evaluated for safety and compatibility in the MR environment. The ProLift Expandable System has not been tested for heating or migration in the MR environment.

Warning: The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Warning: Dissimilar materials (e.g. titanium and stainless steel) should not be used.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Based on device testing results, the physician should always consider a variety of patient conditions including but not limited

to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Implant Selection

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The ProLift Expandable System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative

- Any instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the devices should be securely seated.
- Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

Postoperative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of fatigue and/or

breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

- To allow the maximum chances for a successful z surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- The ProLift Expandable System implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process while a solid fusion forms. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal should be followed by adequate postoperative and the difficulty of removal. Implant removal should be followed by adequate postoperative
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the ProLift Expandable System components should ever be reused under any circumstances.

For more information, visit [ZimVie.com](https://www.zimvie.com)

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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.

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