Part No. 030-1762
Rev. E

OSTEOMED SPINE
PrimaLIF™ RETRACTOR SYSTEM
Product Information and Instructions for Use

Description
The OSTEOMED SPINE PrimaLIF™ RETRACTOR system is a radial retraction/dilation instrumentation system that provides soft tissue retraction to perform a variety of spinal fixation procedures. Dilation and retraction is accomplished through a circular frame with five attached blades that simultaneously retract radially through a small initial incision. The system includes instruments such as guide wires, retractor blades, dilators, access rings, access tubes, tissue shim, pushers, disc shims, disc shim holder, and body pins.

Material
The OSTEOMED SPINE PrimaLIF™ RETRACTOR System is made from chrome coated stainless steel, anodized aluminum and medical grade plastic.

Clinical Indications
The OSTEOMED SPINE PrimaLIF™ RETRACTOR System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine, either from an anterior or posterior direction, the PrimaLIF™ RETRACTOR System is intended to aid in the surgeon's visualization of the surgical area. This allows the surgeon to perform any type of surgical spinal procedure such as discectomy, nucleotomy, visualization of the circumferential decompression of the nerve roots, spinal fusion, and insertion of spinal implants. Other examples of generic surgical use of the system may be acceptable, but have not been evaluated, and are not included in the current indications.

Contraindications
Contraindications may be relative or absolute. The choice to utilize the OSTEOMED SPINE PrimaLIF™ RETRACTOR System must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

1. Allergy or sensitivity to the instrument system materials or foreign body allergic reaction
2. Active or suspected infection
3. Patients who are immune compromised
4. Morbid obesity
5. Signs of local infection or inflammation
6. Alcoholism
7. Heavy smoking
8. Pregnancy
9. Certain lumbar deformities
10. Patients with internal abdominal scarring on both their left and right sides due to abscess or prior surgery
11. Any condition not described in the indications for use

Possible Complications
Possible complications specific to the system may include:

1. Nerve stretching or transection
2. Vascular stretching or transection
3. Other soft tissue damage
4. Allergic reaction to the instrument system materials

Other General Complications (associated with any spinal surgery)

1. Pain
2. Revision surgery
3. Bleeding
4. Infection, early or late
5. Bone damage
6. Tissue or nerve damage
7. Scar formation

Warnings
1. If the OSTEOMED SPINE PrimaLIF™ RETRACTOR System is repositioned for multiple spine level procedures, the retractor system should be removed and re-inserted. The retractor system should then be reintroduced over the Guide Wire with the Blade Retention Clip in place according to the Surgical Technique Guide. Do not reposition to another spine level without removing the retractor system.
2. Failure to properly align the Access Rings or Access Tubes in the blade assembly during insertion may cause binding or premature wear of the retractor system components.
3. If utilizing the system to access a spinal disc space, do not advance the depth probe, blades, guide wires, or dilators beyond the ipsilateral annulus of the disc space.
4. The PrimaLIF™ RETRACTOR System has not been evaluated for safety and compatibility in the MR environment, and has not been tested for heating or migration in the MR environment. In evaluating the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

Maintaining System Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of tissue retractors and spine access techniques.
2. The OSTEOMED SPINE PrimaLIF™ RETRACTOR System is not intended to endure excessive abnormal functional stresses.
3. Failure to use the OSTEOMED SPINE PrimaLIF™ RETRACTOR System in accordance with the Surgical Technique Guide may compromise the integrity of the system, leading to instrument failure and subsequent patient injury.
4. Carefully inspect and test the OSTEOMED SPINE PrimaLIF™ RETRACTOR System components before and after each procedure to ensure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OSTEOMED SPINE for disposition and repair.
5. OSTEOMED SPINE recommends the use of OSTEOMED SPINE products in a sterile environment.
6. The depth marking tolerances on the Depth Probe, Dilators, and Access Ring Inserters are ±.25mm.

Instructions for Use – PrimaLIF™ Retractor System
Attention, See Instructions for Use located in the Surgical Technique Guide, P/N 030-0840, available upon request at no charge

1. Place the patient in a direct lateral decubitus position on the operating room table to ensure suitable visualization of the trajectory of the retraction through the soft tissue. Secure the patient in position.
2. Using Fluoroscopy, verify the location of the spinal fixation site with anterior-posterior and lateral images.
3. Repeat fluoroscopy using two guide wires to determine initial skin incision location. If multiple levels will be retracted, the initial incision should be biased in the direction of the vertebral body between the desired levels.
4. Make a skin incision and palpate using a finger and blunt instruments to locate specific tissues or muscles, including the psoas. Use the provided neuromonitoring probe and neuromonitoring accessories to detect and avoid critical neural structures. Refer to the neuromonitoring probe and accessories IFUs for specific instructions for neuromonitoring.
5. Use finger palpation to move critical soft tissues or structures out of the path of retractor instruments.
6. Use the Depth Probe to palpate to site of the spinal fixation through the incision. Ensure the peritoneum is anterior to the Depth Probe during insertion.
7. Verify the positioning of the probe using a lateral fluoroscopy image.
8. Use the markings on the depth probe to determine the required blade length at the level of the skin.
9. Assemble the required length Retractor Blades to the Radial Retractor by aligning the mating dovetail at the top of the blades with each of the blade clamps on the frame and pulling it into position until the blade lock feature engages.
   Note: Ensure the Retractor Blades are fully inserted into the frame and the blade lock is captured so the blades cannot be removed without actuating the release button.
10. Secure the Retractor Blades in position by placing the Blade Retention Clip over the mating grooves on the outside of the blades until it is fully seated.
11. Insert a Guide Wire through the Depth Probe into the center of the intervertebral space.
12. Verify the position of the Guide Wire using fluoroscopy and remove the Depth Probe, leaving the Guide Wire in place.
13. Visually confirm that the Blade Retention Clip is in place, and insert the Retractor Blades and Radial Retractor over the Guide Wire. The provided neuromonitoring probe will assist in avoiding critical neural structures.
14. Confirm the blade tips are fully seated and against the annulus using fluoroscopy.
15. Mount the Table Arm and Radial Clamp to the surgical table and attach it to the modular connection of the Radial Retractor. Tighten the knob on the Table Arm and confirm rigidity to ensure the Radial Retractor remains in position.
16. Remove the Blade Retention Clip.
17. Insert the 7.5mm First Dilator over the Guide Wire and inside the Retractor Blades.
    Note: Ensure that dilators are inserted in sequence according to diameter (smallest to largest), and do not insert the dilators past the tips of the blades.
18. Confirm appropriate depth with index markings on the dilator or fluoroscopy.
19. Insert the 14mm Second Dilator, and confirm the appropriate depth in the same manner.
20. Determine the appropriate Access Ring size necessary to visually expose the spinal fixation site depending on the needs of the patient. Insert each sequential Dilator one at a time until the appropriate size has been achieved. Placement of each Access Ring requires its corresponding Dilator of the same color and each preceding size dilator.
21. The Access Ring also must also be assembled to the Access Ring Inserter of the same color. Align the mating tabs and rotate clockwise..
22. Slide the Access Ring assembly over the Dilator that corresponds with the Inserter size and color up to the Retractor Blades. Align the grooves of the Access Ring with the inner face of each Retractor Blade. Advance the Access Ring Inserter until the appropriate depth is indicated. The metal ring around the base of the Access Ring will contact the inner tip of the Retractor Blades when fully seated and may be confirmed with fluoroscopy. If necessary, a dilator pusher or ring inserter pusher may be used to assist with dilation
23. Remove Dilators and verify adequate visualization of the surgical area is achieved.
24. Twist the Access Ring Inserter counter-clockwise and remove, leaving the Access Ring in place.
25. Verify correct positioning of the Access Ring and Retractor Blades using lateral and anterior-posterior fluoroscopy.
26. Alternatively, Access Tubes that are the full length of the Retractor Blades may be used. Align the grooves of the Access Tube with the inner face of each Retractor Blade. The metal ring around the base of the Access Tube will contact the inner tip of the Retractor Blades when fully seated and may be confirmed with fluoroscopy. Remove Dilators and verify adequate visualization of the surgical area is achieved.
27. Use the Table Arm to adjust the position of the Radial Retractor if necessary. The retractor handle can be used to steer the PrimaLIF™ Retractor in various directions.
28. Complete the surgical spinal procedure through the PrimaLIF™ RETRACTOR System. Disc shims and body pins can be used to keep instruments away from structures near the anterior intervertebral disc and stabilize the vertebral body during discectomy and insertion of the PrimaLIF™ LLIF interbody device.
29. To remove, insert the Access Ring Inserter through the Retractor Blades and twist clockwise until the mating connection is aligned.
    Note: Do not attempt to remove the Radial Retractor from the soft tissue without removing the Access Ring (or Access Tube) and collapsing the Retractor Blades to the closed position.
30. Remove the Access Ring/Tube and the Access Ring Inserter from the skin incision.
31. Use the thumb knob to collapse the Retractor Blades to the closed position.
32. Release the Radial Retractor from the Table Arm.
33. Remove the Radial Retractor and Retractor Blades from the skin incision.

Cleaning
- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- OSTEOMED recommends the following cleaning and sterilization instructions for the PrimaLIF™ RETRACTOR System:
  1. Rinse the articles to be cleaned under running cool tap water to remove visible soil until visibly clean. Use a sterile syringe to flush water through any cracks, crevices, lumens, or hard to reach areas.
  2. Disassemble the Retractor Blades from the Radial Retractor and hold each blade under running water at the proximal end, ensuring that water is flowing freely through the cleaning holes.
  3. Prepare an enzymatic cleaner, such as Enzol®, per manufacturer's recommendations at 1 oz/gal using lukewarm tap water. Fully immerse the articles in the solution and soak for a minimum of 2 minutes. Actuate the articles while immersed in the solution to ensure complete penetration of cleaning solution.
  4. Using a soft bristled brush, clean the entire article, paying close attention to threads, crevices, and hard-to-reach areas until all evidence of soil is removed. Use a pipe cleaner to brush the lumen of the dilator. While brushing, actuate the articles in order to clean matted surfaces and movable parts.
  5. Using a sterile syringe, flush the enzymatic cleaner through any cracks, crevices, lumens, and hard to reach areas. While flushing, actuate the articles in order to clean matted surfaces and movable parts.
  6. Prepare a mild detergent, such as Prolystica® 2X Concentrate Neutral, per manufacturer's recommendations at 1/8 oz/gal using lukewarm tap water in an ultrasonic cleaner. Fully immerse the articles in the prepared detergent and sonicate the articles for a minimum of 10 minutes.
  7. Remove the articles from the detergent and rinse them under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed. A sterile syringe may be used to aid in rinsing.
  8. Dry the articles using a clean soft cloth and filtered pressurized air at ≤ 40 psi. Visually inspect each test article for visible soil. If visible soil remains, repeat cleaning process.
  9. Steam Autoclave per the following Sterilization Instructions.

Sterility
1. Product is supplied NON-STERILE.
2. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
3. The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
4. Non-sterile devices should be sterilized by steam sterilization (autoclaving). For sterilization of the PrimaLIF™ RETRACTOR System, the following parameters should be used.

   TRAY SYSTEM:

Pre-Vacuum Steam Sterilization	
Temperature:	270°F (132°C)
Time:	4 minutes
Dry Time:	30 minutes

Configuration: Individually wrapped in two layers of FDA cleared 1-ply polypropylene wrap such as Kimguard KC600 (510(k) K082554) using sequential wrapping techniques, with a towel placed between the bottom of the tray and the wrap. Do not exceed 275°F (135°C) to avoid compromising functions of polymeric instrumentation. Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.

Caution
- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001 USA
Customer Service:
800-456-7779
Outside USA:
972-677-4600

CE 0086
EC REP
European Representative:
Shotwell & Carr, LLC
2 St. Paul's Road
Clifton Bristol
BS8 1LT, U.K.
Tel: +44 (0) 117 9738944

Symbols and Definitions

Rx ONLY	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.		REF	Catalogue Number
NON STERILE	Non-sterile		EC REP	Authorized Representative in the European Community
LOT	Batch Code (Lot Number)			Consult Instructions for Use
	Date of Manufacture			Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents			

OSTEOMED SPINE, Inc. is a wholly owned subsidiary of OsteoMed
Printed in U.S.A.
OSTEOMED September 2014