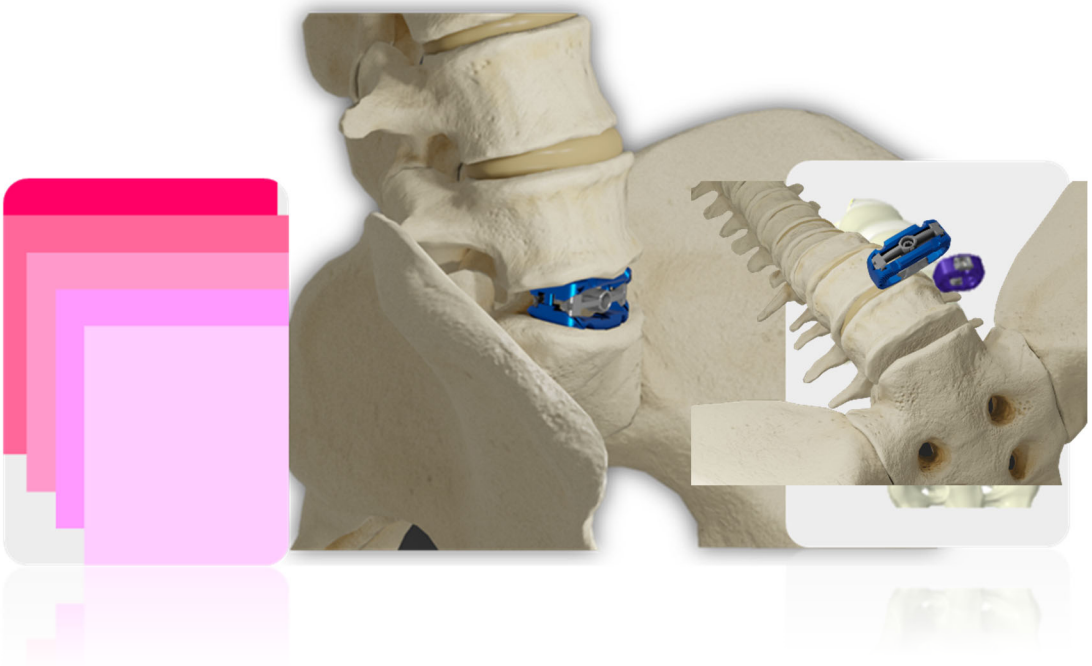
PathLoc-TA

SURGICAL TECHNIQUE



Introduction

Device Description

The PathLoc-TA is interbody fusion devices. This cage system is made of Titanium 6AL-4V Alloy (ASTM F136). And cages are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies.
The cage can be expanded in height using the system instrument after being inserted in the unexpanded state. The cages have serrations on the superior endplate and inferior endplate surfaces area to contact vertebrae bone endplate. The device system is designed for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) to facilitate fusion. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbrosacral spine (e.g., posterior pedicle screw and rod systems, anterior or lateral plate systems, and anterior screw and rod systems). All implants are provided sterile and intended for SINGLE USE ONLY and should not be reused under any circumstances.

Features:

The PathLoc-TA is interbody fusion devices. This cage system is made of Titanium 6AL-4V Alloy (ASTM F136). And cages are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies.

The cage can be expanded in height using the related Height adjustable driver after being inserted in the unexpanded state. The cages have serrations on the superior endplate and inferior endplate surfaces area to contact vertebrae bone endplate.

Bone graft material should be filled with as much bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) as possible and may be placed in the interbody space before/or after insertion of the PathLoc-TA.

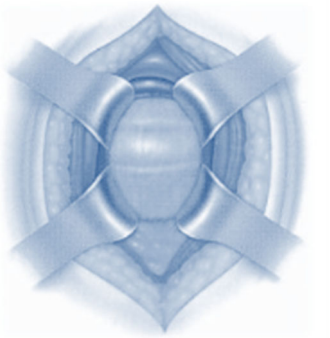
Indication:

PathLoc-TA is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) to facilitate fusion. PathLoc-TA is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Surgical Technique

1. Skin incision and Exposure of Disc Space

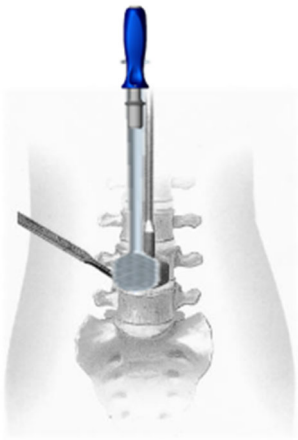
For anterior insertion, expose to intervertebral disc, so that there is clear space on either side of the vertebral midline equal to one-half the width of the Expandable ALIF Cage.



Create a window by cutting the anterior longitudinal ligament and annulus fibrosus in a rectangular shape with its width equal to that of the Expandable ALIF Cage.

2. Disc Space Preparation

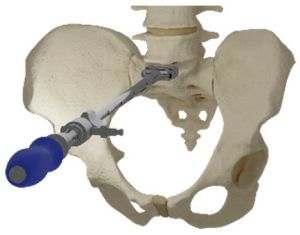
Through the window in the anterior longitudinal ligament and annulus fibrosus, the disc material is resected, and the superficial layers of the cartilaginous endplates are prepared until endplate bleeding is attained.
Adequate cleaning of the endplates is important for vascular supply to the bone graft; however, preparation cleaning may disrupt the endplate due to removal of the dense bony layer of the endplate.
The endplate should be prepared to match the shape of the curvature of the superior and inferior surfaces of the implant.



3. Cage Size Selection

To find the correct Cage size, begin with the trial cage that corresponds to the Expandable Cage size determined during preoperative planning. Attach the Trial to the cage inserter.

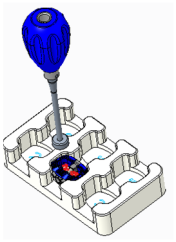
When the segment is fully distracted, the Expandable ALIF Trial must fit firmly with a tight press-fit between the endplates such that disc height is not lost when the distractor is removed.



Once the cage size has been determined, temporarily relax the distraction.
Take the Expandable ALIF Cage that corresponds to the selected Trial Cage and secure it to the Expandable ALIF Cage Inserter.
With the correct Expandable ALIF Cage, it is held with the Expandable ALIF Cage inserter.

4. Bone Packing

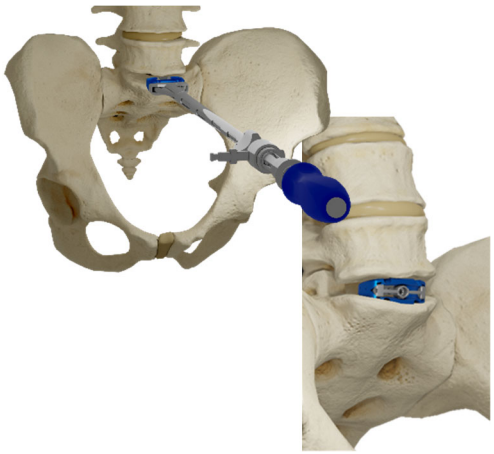
Bone graft material should be filled with as much bone graft as possible and may be placed in the interbody space before insertion of the implant.
The device should be filled with autogenous or allograft bone graft.
Additional bone graft material may be placed anterior to the implanted Expandable ALIF Cage using the Bone Graft Cannula and Pusher



5. Implant Placement

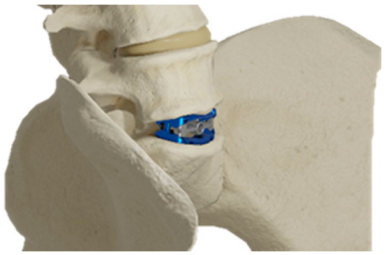
Loading the implant with inserter
once the proper implant size has been determined, attach the implant to the cage inserter.
slide the implant onto the prongs of the inserter. thread the knob clockwise to lock the inserter and secure the implant.

Carefully and gently insert the unexpanded Expandable ALIF Cage into the disc space using the mallet when necessary. Optimal positioning may be facilitated by directing the implant obliquely until it contacts the ventral annulus. Check for adequacy of the discectomy and be sure distraction is maintained.
Then, reposition the implant as needed. The distraction should be released to facilitate optimal placement of the implant and to permit expansion.
The correct position of the implant should be confirmed by direct visualization of implant location. Fluoroscopy may be useful in determining the appropriate trajectory for insertion and appropriate final positioning.



6. Implant Extension

Once the implant is confirmed to be in the appropriate position in the intervertebral disc space, inset the Driver in conjunction with the Torque limiting handle (max 3Nm) until engaged with the implant. Expand the implant as needed by rotating the Torque limiting Handle (max 3Nm) clockwise.
If repositioning is necessary, Torque Limiting Handle can be simply rotated counterclockwise to lower the Device to allow for repositioning. Once the desired position is achieved again, the Device should be expanded to the desired height
Once the Device is implanted successfully, remove the Driver and Torque Limiting Handle from Cage Holder.



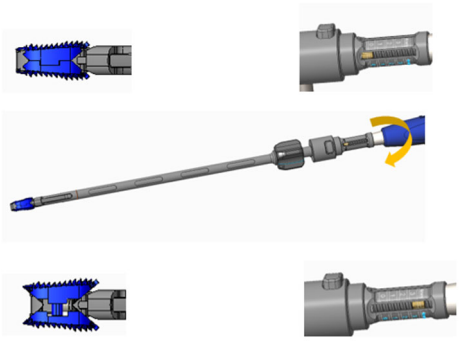
The Tether must then be removed by rotating counterclockwise while holding the Outer Sleeve until it has become loosened from the implant. Remove Tether and outer sleeve by gently pulling them away from the implant.

Attach the Height Adjustment Driver to the Torque Limiting I-Handle.

With the cage and Expandable Cage Inserter still fully engaged, insert the Height Adjustment Driver/ Torque Limiting I-Handle assembly through the proximal opening of Expandable Cage Inserter, until it is fully seated.

Tip: Make sure that the expansion indicator on the Expandable Cage Inserter is at the initial position of 0 mm. If it is not in the 0mm position, disengage the cage from the Expandable Cage Inserter, and then insert the Height Adjust Driver into the Expandable Cage Inserter and rotate it counterclockwise to move it to 0mm.

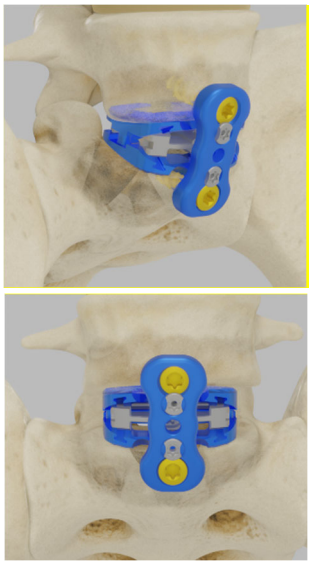
Turn the Height Adjust Driver/Torque Limiting I-Handle clockwise to expand the cage to desired height. As the cage expands, you will be able to see the height expanded on the indicator.



7. Apply supplemental Fixation System

Supplemental internal fixation is required when using the PathLoc-TA. The Elatus Plate system is available for use with the PathLoc-TA and is the supplemental fixation available for use in situations where a construct is appropriate.

The system may be augmented with additional supplemental fixation, as needed and determined by the user. The instructions for use for any additional supplemental fixation system(s) should be followed according to the manufacturer's guidelines.



8. Closure

Check the left L4-L5 foramen and Lumbar Interbody Fusion site for any bone fragments or extraneous soft tissue. Once satisfactory decompression of the exiting and traversing nerve roots is confirmed the wound should be closed.

9. Revision

For Revision Surgery or to changes in device positioning after seated, the surgeon must use his/her professional judgment to determine appropriate treatment for the patient.

The Cage Holder should be used to facilitate removal of the Implant. The device should be collapsed by rotating the Torque limiting handle counterclockwise when attached to the Driver and engaged to the implant. The implant can then be removed. It may be helpful to use X-ray, Fluoroscopy, a surgical microscope or endoscope for this process.

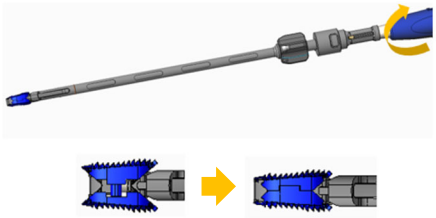
10. Implant Remover

1. Insertion Implant Remover into the implant grooves.

2. Turn the knob to lock the implant.

3. After fastening the driver to the implant, turn it to lower the cage height.

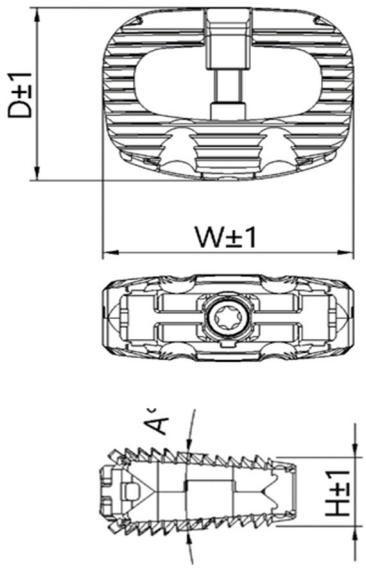
4. Pull up on the sleeve of the Sliding Hammer to remove the implant.

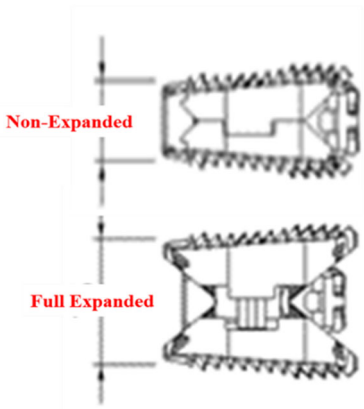


General surgical instruments can be used for curved implant removal.

Implants

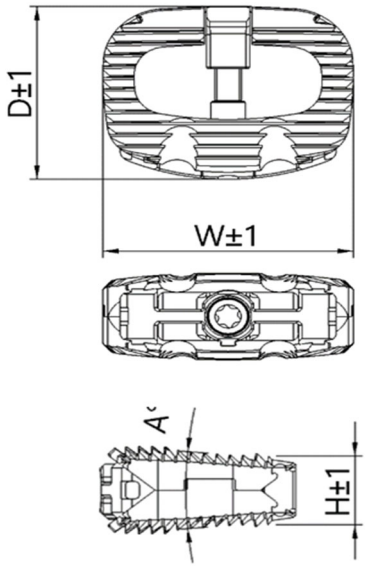
Each device is expanded up to 4 mm with 1mm increment.

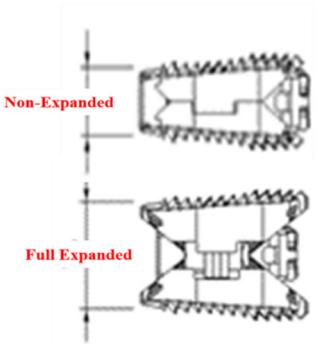




Cat. No.	Dimension (mm)									Color	Remark
Sterile	D (Depth)	W (Width)	A (Angle)	H (Height range) mm							
				Non-expanded	1mm Increment				Expandable range		
2432-0809S	24	32	8	9	10	11	12	13	9~13	Purple	Subject Device
2432-0812S	24	32	8	12	13	14	15	16	12~16	Gold	Subject Device
2432-0815S	24	32	8	15	16	17	18	19	15~19	None	Subject Device
2432-1209S	24	32	12	9	10	11	12	13	9~13	Purple	Subject Device
2432-1212S	24	32	12	12	13	14	15	16	12~16	Gold	Subject Device
2432-1215S	24	32	12	15	16	17	18	19	15~19	None	Subject Device
2432-1506S	24	32	15	6	7	8	9	10	6~10	Blue	Subject Device
2432-1509S	24	32	15	9	10	11	12	13	9~13	Purple	Subject Device
2432-1512S	24	32	15	12	13	14	15	16	12~16	Gold	Subject Device
2432-1515S	24	32	15	15	16	17	18	19	15~19	None	Subject Device
2432-2006S	24	32	20	6	7	8	9	10	6~10	Blue	Subject Device
2432-2009S	24	32	20	9	10	11	12	13	9~13	Purple	Subject Device
2432-2012S	24	32	20	12	13	14	15	16	12~16	Gold	Subject Device
2432-2015S	24	32	20	15	16	17	18	19	15~19	None	Subject Device
2432-2506S	24	32	25	6	7	8	9	10	6~10	Blue	Subject Device
2432-2509S	24	32	25	9	10	11	12	13	9~13	Purple	Subject Device
2432-2512S	24	32	25	12	13	14	15	16	12~16	Gold	Subject Device
2432-2515S	24	32	25	15	16	17	18	19	15~19	None	Subject Device
2432-3006S	24	32	30	6	7	8	9	10	6~10	Blue	Subject Device
2432-3009S	24	32	30	9	10	11	12	13	9~13	Purple	Subject Device
2432-3012S	24	32	30	12	13	14	15	16	12~16	Gold	Subject Device
2432-3015S	24	32	30	15	16	17	18	19	15~19	None	Subject Device

Each device is expanded up to 4 mm with 1mm increment.



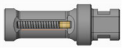


Cat. No.	Dimension (mm)									Color	Remark
Sterile	D (Depth)	W (Width)	A (Angle)	H (Height range) mm							
				Non-expanded	1mm Increment				Expandable range		
2938-0809S	29	38	8	9	10	11	12	13	9~13	Purple	Subject Device
2938-0812S	29	38	8	12	13	14	15	16	12~16	Gold	Subject Device
2938-0815S	29	38	8	15	16	17	18	19	15~19	None	Subject Device
2938-1209S	29	38	12	9	10	11	12	13	9~13	Purple	Subject Device
2938-1212S	29	38	12	12	13	14	15	16	12~16	Gold	Subject Device
2938-1215S	29	38	12	15	16	17	18	19	15~19	None	Subject Device
2938-1506S	29	38	15	6	7	8	9	10	6~10	Blue	Subject Device
2938-1509S	29	38	15	9	10	11	12	13	9~13	Purple	Subject Device
2938-1512S	29	38	15	12	13	14	15	16	12~16	Gold	Subject Device
2938-1515S	29	38	15	15	16	17	18	19	15~19	None	Subject Device
2938-2006S	29	38	20	6	7	8	9	10	6~10	Blue	Subject Device
2938-2009S	29	38	20	9	10	11	12	13	9~13	Purple	Subject Device
2938-2012S	29	38	20	12	13	14	15	16	12~16	Gold	Subject Device
2938-2015S	29	38	20	15	16	17	18	19	15~19	None	Subject Device
2938-2506S	29	38	25	6	7	8	9	10	6~10	Blue	Subject Device
2938-2509S	29	38	25	9	10	11	12	13	9~13	Purple	Subject Device
2938-2512S	29	38	25	12	13	14	15	16	12~16	Gold	Subject Device
2938-2515S	29	38	25	15	16	17	18	19	15~19	None	Subject Device
2938-3006S	29	38	30	6	7	8	9	10	6~10	Blue	Subject Device
2938-3009S	29	38	30	9	10	11	12	13	9~13	Purple	Subject Device
2938-3012S	29	38	30	12	13	14	15	16	12~16	Gold	Subject Device
2938-3015S	29	38	30	15	16	17	18	19	15~19	None	Subject Device

Instruments

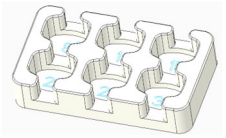
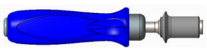
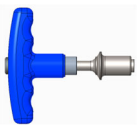
The Driver and Inserter of PathLoc-TA Instruments are Class II device

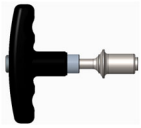
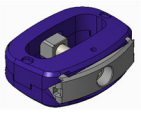
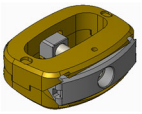
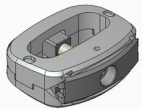
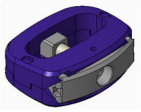
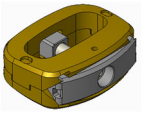
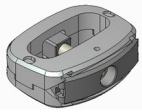
Trade Name	PathLoc-TA Instruments
Common Name	Orthopedic Manual Surgical Instrument
Product Code	MAX
Regulation	888.3080
Device Class	Class II
Panel	Orthopedic

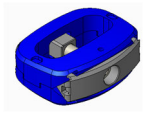
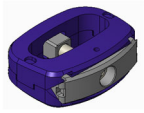
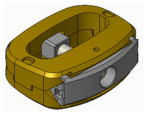
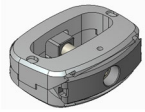
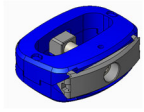
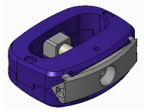
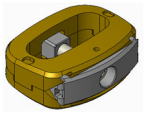
No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
1	S06001	Expandable Cage Inserter		Insertion for Cage	STS630, STS304, Ti alloy, PPSU	Yes
2	S06002	Height Indicator		Insertion for Cage	STS630, STS445, Ti alloy, PPSU	No
3	S06003	Height Adjust Driver		Cage expanding	STS445	Yes

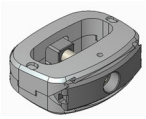
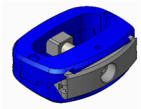
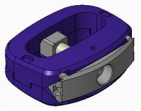
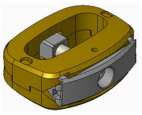
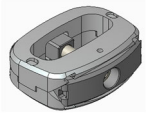
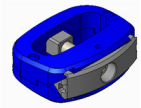
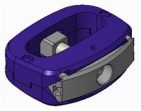
Other Instruments are Class I – Contact Bone tissue ≥ 24hours

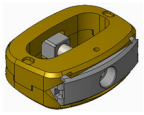
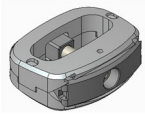
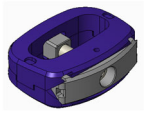
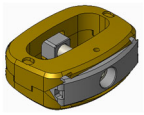
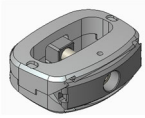
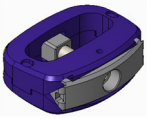
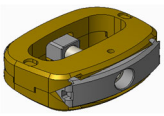
Trade Name PathLoc-TA Instruments
Common Name Orthopedic Manual Surgical Instrument (21CFR888.4540)
Product Code LXH
Device Class Class I
Panel Orthopedic

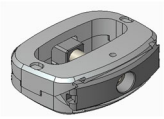
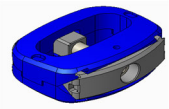
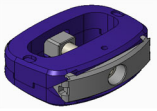
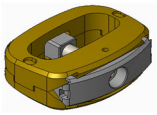
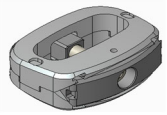
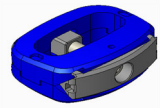
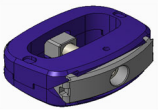
No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
4	S06004	Bone packing Block		Bone Delivery	PP(Polypropylene)	Yes
5	S06005	Bone packing Impactor		Bone Plunging	SUS304 Silicone	Yes
6	S06006	Slotted Hammer		Hammering	STS630, Silicone	Yes
7	S06007I	Torque Limit I-Handle 3Nm		Handle	STS630, Silicone	No
8	S06008I	Torque Limit I-Handle 5Nm		Handle	STS630, Silicone	No
9	S06007T	Torque Limit T-Handle3Nm		Handle	STS630, Silicone	No

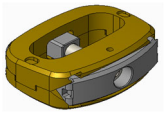
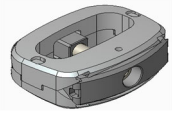
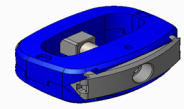
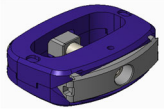
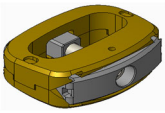
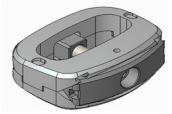
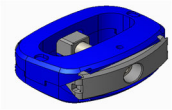
No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
10	S06008T	Torque Limit T-Handle5Nm		Handle	STS630, Silicone	No
11	S06009	Trial (24x32x8Dx9H)		Sizing	Ti alloy	Yes
12	S06010	Trial (24x32x8Dx12H)		Sizing	Ti alloy	Yes
13	S06011	Trial (24x32x8Dx15H)		Sizing	Ti alloy	Yes
14	S06012	Trial (24x32x12Dx9H)		Sizing	Ti alloy	Yes
15	S06013	Trial (24x32x12Dx12H)		Sizing	Ti alloy	Yes
16	S06014	Trial (24x32x12Dx15H)		Sizing	Ti alloy	Yes

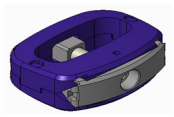
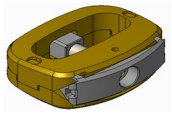
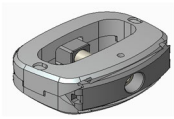
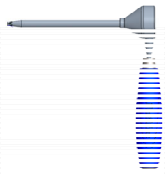
No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
17	S06015	Trial (24x32x15Dx6H)		Sizing	Ti alloy	Yes
18	S06016	Trial (24x32x15Dx9H)		Sizing	Ti alloy	Yes
19	S06017	Trial (24x32x15Dx12H)		Sizing	Ti alloy	Yes
20	S06018	Trial (24x32x15Dx15H)		Sizing	Ti alloy	Yes
21	S06019	Trial (24x32x20Dx6H)		Sizing	Ti alloy	Yes
22	S06020	Trial (24x32x20Dx9H)		Sizing	Ti alloy	Yes
23	S06021	Trial (24x32x20Dx12H)		Sizing	Ti alloy	Yes

No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
24	S06022	Trial (24x32x20Dx15H)		Sizing	Ti alloy	Yes
25	S06023	Trial (24x32x25Dx6H)		Sizing	Ti alloy	Yes
26	S06024	Trial (24x32x25Dx9H)		Sizing	Ti alloy	Yes
27	S06025	Trial (24x32x25Dx12H)		Sizing	Ti alloy	Yes
28	S06026	Trial (24x32x25Dx15H)		Sizing	Ti alloy	Yes
29	S06027	Trial (24x32x30Dx6H)		Sizing	Ti alloy	Yes
30	S06028	Trial (24x32x30Dx9H)		Sizing	Ti alloy	Yes

No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
31	S06029	Trial (24x32x30Dx12H)		Sizing	Ti alloy	Yes
32	S06030	Trial (24x32x30Dx15H)		Sizing	Ti alloy	Yes
33	S06031	Trial (29x38x8Dx9H)		Sizing	Ti alloy	Yes
34	S06032	Trial (29x38x8Dx12H)		Sizing	Ti alloy	Yes
35	S06033	Trial (29x38x8Dx15H)		Sizing	Ti alloy	Yes
36	S06034	Trial (29x38x12Dx9H)		Sizing	Ti alloy	Yes
37	S06035	Trial (29x38x12Dx12H)		Sizing	Ti alloy	Yes

No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
38	S06036	Trial (29x38x12Dx15H)		Sizing	Ti alloy	Yes
39	S06037	Trial (29x38x15Dx6H)		Sizing	Ti alloy	Yes
40	S06038	Trial (29x38x15Dx9H)		Sizing	Ti alloy	Yes
41	S06039	Trial (29x38x15Dx12H)		Sizing	Ti alloy	Yes
42	S06040	Trial (29x38x15Dx15H)		Sizing	Ti alloy	Yes
43	S06041	Trial (29x38x20Dx6H)		Sizing	Ti alloy	Yes
44	S06042	Trial (29x38x20Dx9H)		Sizing	Ti alloy	Yes

No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
45	S06043	Trial (29x38x20Dx12H)		Sizing	Ti alloy	Yes
46	S06044	Trial (29x38x20Dx15H)		Sizing	Ti alloy	Yes
47	S06045	Trial (29x38x25Dx6H)		Sizing	Ti alloy	Yes
48	S06046	Trial (29x38x25Dx9H)		Sizing	Ti alloy	Yes
49	S06047	Trial (29x38x25Dx12H)		Sizing	Ti alloy	Yes
50	S06048	Trial (29x38x25Dx15H)		Sizing	Ti alloy	Yes
51	S06049	Trial (29x38x30Dx6H)		Sizing	Ti alloy	Yes

No.	Cat. No.	Name	Photo	Intended use	Material	Contact Bone tissue (Yes/No)
52	S06050	Trial (29x38x30Dx9H)		Sizing	Ti alloy	Yes
53	S06051	Trial (29x38x30Dx12H)		Sizing	Ti alloy	Yes
54	S06052	Trial (29x38x30Dx15H)		Sizing	Ti alloy	Yes
55	S06053	Bone Funnel		Graft Delivery	STS304, Silicone	Yes
56	S06054	Bone Funnel Inserter		Graft Plunging	STS 304	Yes
57	G99001	I-Handle		Handle	STS630, Silicone	No

Instruction For Use (IFU)

PathLoc Lumbar Interbody Fusion Cage System (Sterile)

PURPOSE

This device is a Lumbar Interbody Fusion Cage device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The PathLoc Lumbar Interbody Fusion Cage System's implants are interbody fusion devices intended for use as an aid in spinal fixation. These hollow, rectangular implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. The implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants have serrations on the superior and inferior surfaces designed for fixation, ergonomically shaped anterior edges, and flat posterior edges.

Surgical approach

• PathLoc – TA is to be implanted via anterior approach.

Raw Material: Cage Body (Ti-6Al-4V ELI Alloy - ASTM F136)

INDICATIONS

PathLoc Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous level(s) from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allogenous bone graft composed of cancellous and/or corticocancellous bone. PathLoc Lumbar Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include, but are not limited to:

1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Suspected or documented allergy or intolerance to composite materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. Spondylolisthesis unable to be reduced to Grade 1.
14. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
15. Any case that requires the mixing of metals from two different components or systems.
16. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
18. Prior fusion at the level to be treated.

Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. Severe bone resorption

2. Osteomalacia
3. Severe osteoporosis

POTENTIAL ADVERSE EFFECTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and stabilization may increase in cases where associated complementary support is not employed.

Potential adverse events include but are not limited to:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
10. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
11. Haemorrhage of blood vessels and/or hematomas.
12. Discitis, arachnoiditis, and/or other types of inflammation.
13. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
14. Bone graft donor site complication.
15. Inability to resume activities of normal daily living.
16. Early or late loosening or movement of the device(s).
17. Urinary retention or loss of bladder control or other types of urological system compromise.
18. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
19. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
20. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
21. Loss of or increase in spinal mobility or function.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Cessation of any potential growth of the operated portion of the spine.
26. Death.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion.

These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

The PathLoc Lumbar Interbody Fusion Cage System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The PathLoc Lumbar Interbody Fusion Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

This system should not be used with components of any other systems or manufacturers.

Based on fatigue testing results, when using this system, the physicians /surgeons should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

PHYSICIAN NOTE:

Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient. Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up. The surgeon must warn the patient of the surgical risks and make the patient aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PREOPERATIVE PRECAUTIONS

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests must be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- •Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

INTRAOPERATIVE PRECAUTIONS

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by L&K Biomed.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

POSTOPERATIVE PRECAUTIONS

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompany clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

IMPLANT REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the PathLoc Lumbar Interbody Fusion Cage System is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration for such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
- Pain or abnormal sensations due to the presence of the implants.
- Infection or inflammatory reactions.
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

PACKAGING

Components should only be accepted if received with the factory packaging and labeling intact. All sets should be carefully inspected before use. In particular, check for completeness of the set and integrity of the components and/or instruments. Any damaged packaging and/or product must be returned to L&K BIOMED.

STORAGE AND HANDLING

PathLoc Lumbar Interbody Fusion Cage device should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

EXAMINATION

Instruments must always be examined by the user prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise un-functional.

1. VISUAL INSPECTION

Make certain of the following:

- Laser markings are legible.
- No cracks are present in instrument handles or any part of the instrument.
- Discoloration, corrosion, stains, or rust do not exist. If present, attempt to wipe clean in accordance with the instructions in the Manual Cleaning section of this document.
- There is no handle/shaft separation in instrument should not be separate, and that the handle-to-shaft connection is secure.
- No cuts or gouges in silicone are present.
- There is no damage (cuts, tears, etc.) to the insulation.
- There is no damage to the working ends or tips. The working end should be free of cracks, sharp edged gouges, and other damage. (When applicable, the working end should be sharp.)
- There is no damage to threads.
- All parts are present and free of damage and deterioration. Examples of parts that may be missing, loose, or damaged include screws, springs and pins.
- Mating ends are free of damage (nicks, gouges, bends, etc.) that would interfere with the mating function.
- Cannulated instruments with a guide wire or other insertion tool are visually checked.

2. FUNCTIONAL INSPECTION

Make certain of the following:

- The parts intended to move will do so freely, without sticking, binding, or grinding.
- Springs return the handle of the instrument to its original position.

- Retention tabs hold appropriate mating parts and are not damaged.
- The instrument will function as intended with the appropriate mating parts.
- Ball detents will hold mating parts and are free from damage.
- Sharp edges are sharp to the touch and are not dull, have no nicks, or any other damage.
- Tips meet when appropriate.
- Ratcheting mechanisms are functional. This includes handles, latches, and other mechanisms. All teeth should be present and functional.
- Driver tips are not worn beyond functional use. If necessary, mate the instrument with the appropriate part.

CLEANING AND STERILIZATION

Implants are supplied sterile and are for single use only. Re-sterilization of the implants is strictly forbidden, regardless of the method that might be employed. Otherwise, Instruments are supplied non-sterile and may be re-used. Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.

Unless just removed from an unopened L&K BIOMED package, all instruments must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to L&K BIOMED.

• Cleaning Instruction – Point of use

- Remove all visible soil from instruments using non-shedding wipes.
- Place instruments in a tray of water or cover with damp towels.
- Instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.

NOTE: Three cleaning methods are provided, a Manual Cleaning and a Semi Auto Cleaning and an Automated Cleaning Method, and at least one shall be performed.

1. Manual Cleaning procedure

(1) Soak the instrument in the tap water for 1 minute.

(2) Prepare cleaning solution at the concentration (0.8%～1.6 %) suggested by the detergent manufacturer, and soak the instrument in the prepared cleaning solution for 5 minutes, and then remove the contamination from the instrument surface with a soft brush. However, the operating part should be operated to clean the contamination.

(3) Rinse the instrument for at least 3 minutes with tap water. However, the small diameter hole is rinsed using a syringe or the like.

(4) Rinse the instrument by shaking with purified water for at least 5 minutes.

(5) Wipe off water in the instruments with a clean cloth. However, compressed air can be used for the device with complex structures.

(6) Prepare for storage and sterilization.

2. Semi auto cleaning procedure

(1) Prepare cleaning solution at the concentration (0.8%～1.6 %) suggested by the detergent manufacturer, and soak the instrument in the prepared cleaning solution for 20 minutes. Clean the instrument with a soft brush. (Especially, carefully wipe the gaps, interiors, and surfaces that are difficult to clean.) The inside of the instrument should be cleaned with a long, narrow, and soft brush.

(2) Rinse with purified water for 3 minutes to remove the cleaning solution. Use rinsing water temperature between 35℃ and 45℃ for part and holes that are difficult to clean.

(3) Immerse the product in the cleaning solution and clean using ultrasonic cleaner at 45 kHz to 50 kHz for 10 minutes.

(4) Rinse with purified water for at least 3 minutes until there is no blood or contaminants. If contaminants remain, ultrasonic cleaning (step 3) and rinsing (step 4) are performed once more

(5) Wipe the instrument cleaned with a clean, absorbent disposable wipe to dry instrument. If additional drying is needed after drying step, use medical compressed air (psi 20～30) to dry it. Check that the instrument is visually cleaned.

3. Automated cleaning procedure

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

CAUTION:

- Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
- Verify that the instruments are in visually clean.

STERILIZATION

For implants delivered Gamma irradiation sterile:

The implants are sterilized by Gamma radiation at doses of 25k Gray. Sterilization is valid 5 years from the date of manufacturing. The expiry date of sterile parts is indicated on the packaging.

For instruments delivered non-sterile:

All instruments are supplied non-sterile and may be re-used. Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.

Unless just removed from an unopened L&K BIOMED package, all instruments must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to L&K BIOMED.

Instruments must be sterilized prior to initial use, and as part of these reprocessing instructions, before re-use. The following sterilization instructions have been validated to a sterility assurance level of 10^{-6}.

Initial Instruction for sterilization

1. All instruments should be placed in the instrumentation which will be either wrapped in an FDA cleared sterilization wrap or placed in a rigid sterilization container.
2. Inspect the packaging to ensure no rips, punctures, or seal failures are present in or on the packaging prior to loading into the sterilizer.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	270°F(132°C)	15Minutes (Dry time, 30 Minutes)
Steam	Pre-Vacuum	270°F(132°C)	4Minutes (Dry time, 20 Minutes)
		275°F(135°C)	3Minutes (Dry time, 16 Minutes)

Implants previously implanted should not be re-used. Inspect visually for damage or contamination by biological residue. If damage or biological residue is observed on the Implant, it must be discarded.

GUARANTEE

The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in this instruction and in conformity with the recommended surgical technique.

CAUTION

Federal (USA) Law restricts this device to sale by or on the order of a physician.

PRODUCT COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance should notify L&K BIOMED. Moreover, if a device malfunctioned, L&K BIOMED or its distributor must be advised immediately. If a L&K BIOMED product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor must be informed as soon as possible by telephone, fax or in writing, For all complaints, please include the device name and reference along with the lot number of the component(s), your name and address and an exhaustive description of the event to L&K BIOMED understand the cause of the complaint. For further information or complaints, please contact as below address:

STORAGE

At room temperature (1~35℃)

SHELF-LIFE

5 years under recommended conditions

FURTHER INFORMATION

Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact L&K BIOMED Co., Ltd.

Manufactured by:

L&K BIOMED Co., Ltd.
: #101, 201, 202, 16-25, Dongbaekjungang-ro 16 beon-gil, Giheung-gu, Yongin-si,
Gyeonggi-do, 17015, Korea
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SYMBOL TRANSLATION					
LOT	LOT NUMBER	REF	CATALOGUE NUMBER	QTY	QUANTITY
	SINGLE USE ONLY	STERILE R	Sterilized Using Irradiation		MANUFACTURER
	See package insert for labeling limitation	℞ ONLY	Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.		DATE OF MANUFACTURE
	Consult instruction for use		KEEP DRY		DO NOT USE IF PACKAGE IS DAMAGED
	USE BY	1°C 35°C	STORE AT ROOM TEMPERATURE		KEEP AWAY FROM SUNLIGHT

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