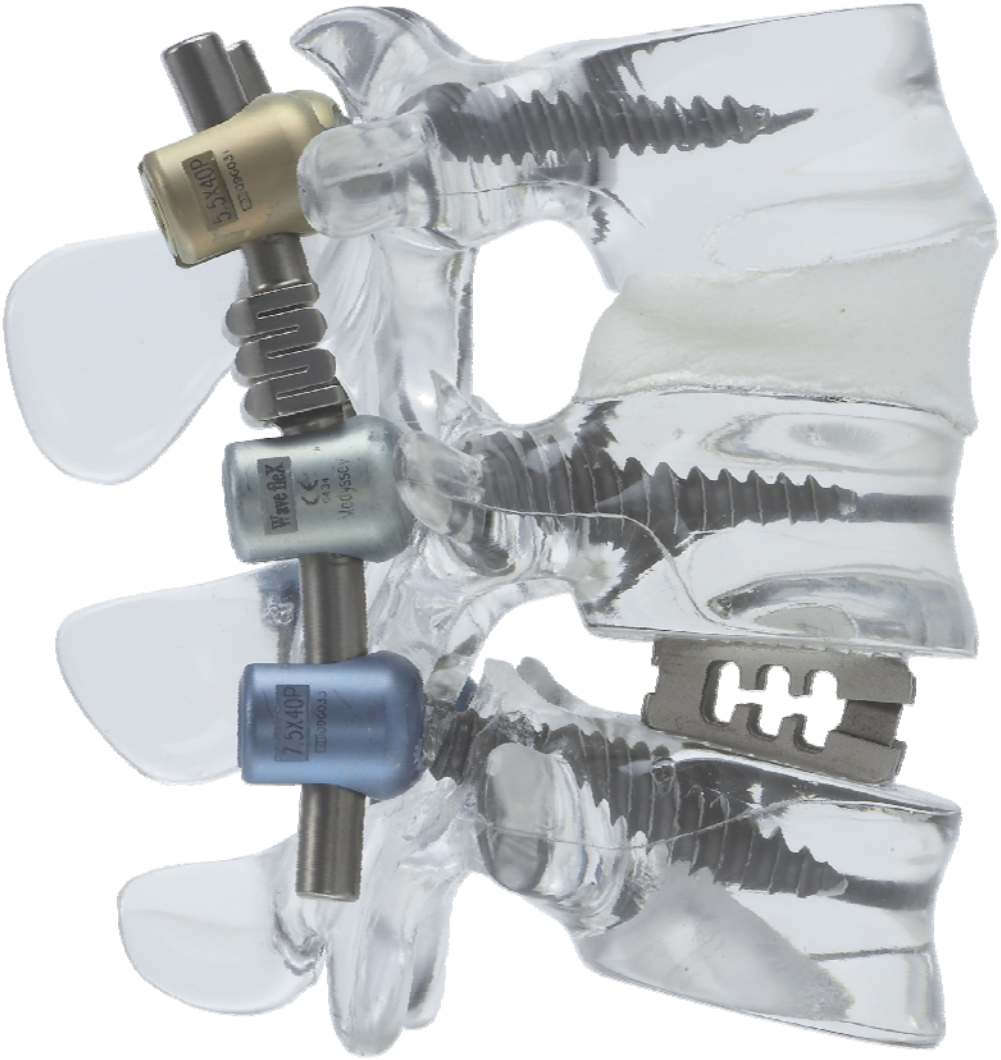
VariAn™ Expandable Cage System

Surgical Technique



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COMPANY INFORMATION

Medyssey designs, develops, manufactures and markets products for the surgical treatment of spine disorders through novel instrumentation and advanced orthobiologic solutions designed to improve spinal fusion rates, preservation of mobility and clinical outcomes.

Founded in 2003 by Edward J.W. Jang, Medyssey is privately owned and headquartered in Seoul, Korea. The Company has a pioneering focus on bringing leading orthopaedic and neurosurgical spinal implants to market. Medyssey's technological advancement of spinal surgery has accelerated growth in Asia Pacific, the Americas, the EU and emerging international markets. As a pioneer of motion preservation and dynamic stabilization, Medyssey has staked a position as a global leader with an innovative product portfolio, robust research and development pipeline, and a distribution footprint that now spans 17 countries covering six continents.

In the Company's quest to become a market leader, Medyssey is committed to generating, developing, and commercializing intellectual property that improve the quality of patients' lives while designed under the mantra of simple and reproducible.

VariAn Expandable Cage System

VariAn Expandable Cage System

The purpose of this VariAn Expandable Cage is designed to utilize the management on the degenerative disc disease of the extensive spinal column, from thoracic to sacral spine, include isolated disc resorption, primary and secondary instability, recurrent disc herniation, and pseudarthosis.

The VariAn Expandable Cage System is indicated for the following:

- ***Primary surgery for advanced discopathies or extensive decompressions(laminectomy, facetectomy, foraminotomy, etc.)***
- ***Spondylotic spinal stenosis***
- ***Revision surgery for failed disc operation***
- ***Post-operative instability***
- ***Disc herniation***
- ***Spondylosis with bone spurring, foraminal narrowing and nerve root impingement***
- ***Chronic and disabling discogenic low back pain***
- ***Spinal pseudarthrosis***

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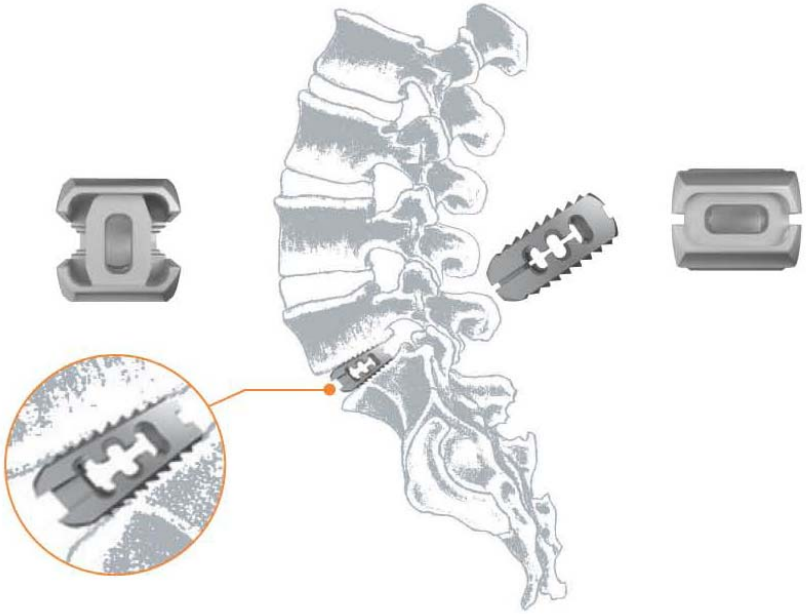
VariAn Expandable Cage

Easy Turn Expandable Interbody Device!!

As surgeons look for an easier to handle, easier to implant, safe and reliable interbody device, Medyssey has developed the revolutionary VariAn Expandable Cage that corresponds to their needs.



When the VariAn Expandable Cage is implanted into the interdiscal space, it is expanded with a simple 90° turn in the clockwise direction with a simple tuning device. Once expanded the cage offers either 8° or 10° of additional lordosis to help maintain the body's natural lordotic curvature.

Advantatges of the VariAn Expandable Cage:

- Accurate and Complete Anchor System
- Efficiency of Bone Graft Implantation
- Simplified Insttrumentation
- Minimizes Operational Time
- Easy Removal if Necessary
- Wide Range of Sizes

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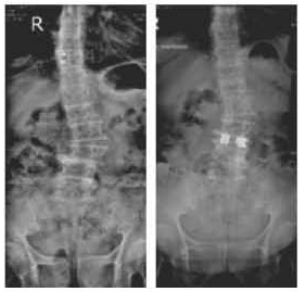
Clinical Cases

Indication

1. Symptomatic Disc Degeneration
2. Angular Kyphosis
3. Spondylolithesis
4. Arthrictic Instability
5. Decompression of the vertebral canal

Low-grade Spondylolisthesis

High-grade Spondylolisthesis
(w/ Severe Disc Space Narrowing)



Lateral Wedging (Scoliotic Change)

Clinical Follow-Up

POD #1

3 Mth

6 Mth

51/F, Severe Listhesis
Preoperation

1 Yr.

2 Yrs.

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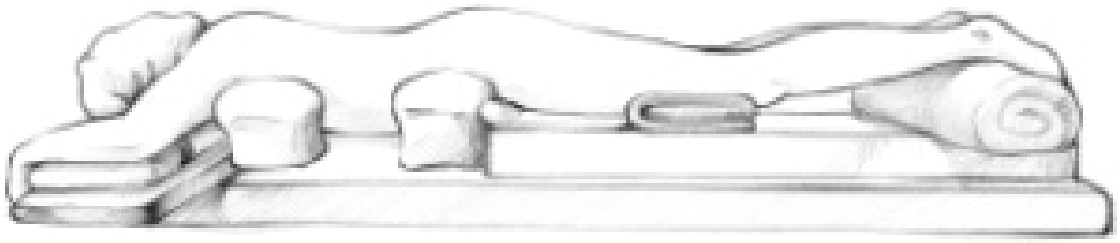
STEP 1 : PATIENT POSITIONING

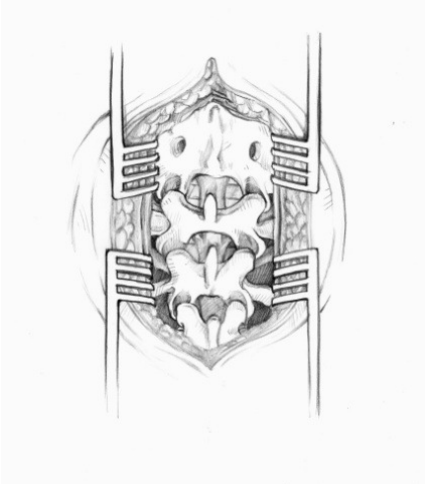
The patient is positioned on the operating table in the prone position. There are numerous frames that can be used including, but not limited to The Wilson Frame, Chest Rolls, Relton Hall Frame, Hasting Frame, Heffington Frame, and the Andrews Frame. Intra-abdominal pressure must be minimized to avoid venous congestion and excess intra-operative bleeding, while allowing adequate ventilation of the anesthetized patient. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.



STEP 2 : INCISION AND EXPOSURE

A midline 4-5cm incision offers the approach and the exposure of the interlaminar space as well as the facet joints, using the X-ray to make sure the appropriate level is reached.

Lamina should be removed from the vertebra to relieve the pressure on the spinal cord or nerve root that is being caused by a slipped or herniated disk in the lumbar spine.



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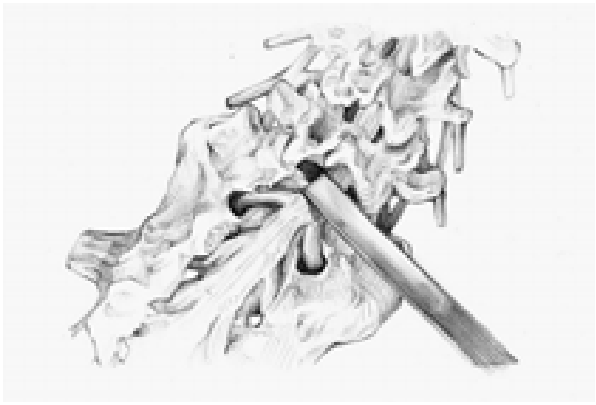
STEP 3 : MEDICAL DISCECTOMY

After exposing the intervertebral disc by retracting the nerve roots with the Nerve Retractor, the discectomy is carried out to remove the disc and cartilage from the interdiscal space by using the Shaver assembled with the T-Handle (Quick Holder) in order to remove the extruded fragments and to make the entry to the disc space of the VariAn Cage.

Shaver can be used with T-Handle (Quick Holder) assembled.



STEP 4 : TRIAL AND DISC SPACE DISTRACTION

Trial used to distract the disc space for the planned disc space height and for the foraminal opening of the VARIAN Cage. Trial shall be inserted parallel to the endplate of the vertebral body and be turned round 90° to distract the disc space with the Trial measurement to determine which size of the VARIAN Cage should be inserted.

Trial can also be with the T-Handle (Quick Holder) assembled the same as Shaver figured below.

And finally, make sure disc space is exactly occupied by using the Rasp or Curette just before inserting the VARIAN Cage.

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STEP 5 : CAGE PREPARATION

After all the procedures are done until the step 4, choose the appropriate size of cage and remove the end cap in the backside of the VARIAN Cage with the slotted End Cap Driver. Then, assemble the each part of the Cage Holder Set at first. To assemble the cage, load the appropriate size of Expandable Cage onto the part 1 and then turn the part 2 in the clockwise after inserting it into the hole of part 1.

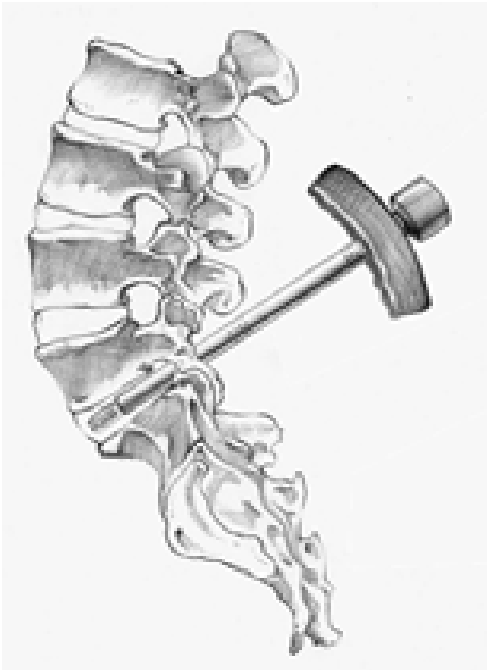
CAGE HOLDER

EXPANDER

CAGE HOLDER
WITH EXPANDER

STEP 6 : CAGE IMPLANTATION

Implant the determined size of the VARIAN Cage into the intervertebral body and impact the head of Cage Holder Set. Once the VARIAN Cage is completely embedded inside the intervertebral body, put the Cage Expander through the hole in the part 2 assembled with the part 1 until the tip of the Cage Expander is fully inserted in the end plate hole of VARIAN Cage.



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STEP 7 : CAGE EXPANDING

When the tip of the Cage Expander is anchored securely inside the end plate hole, turn the Cage Expander handle 90° in the clock-wise direction. And then, take the part 2 off from the part 1 for the next
procedure.

STEP 8 : BONE GRAFT PACKING

After taking the Cage Expander off from the Cage Holder Set, the Bone Impactor is used for the bone graft. The Bone should be also inserted through the hole of the part 1 and after then, taking the Bone Impactor into the hole of the part 1 and press them continually to the arrow direction figured on the left side in order for the completion of the bone graft. When the bone is fully packed inside the VARIAN Cage, the assembly status of the Bone Impactor and the Cage Holder Set will be below shown on the left-handed photo.

Conventionally, the cancellous bone taken from the iliac crest is used for the bone graft.

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STEP 9 : END CAP CLOSING

After the Bone Graft is completely performed, assemble the end cap which was removed at the first step of the surgical procedure shown on the left-handed photo. In order to pick the removed end cap up, the slotted End Cap Driver should be used at this stage.

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Instrument Photos	Instrument Name	Product Code	Description
	Cage Holder Set	CINS 001	Dynamic Cage only
	T-holder (Quick holder)	CINS 002	Dynamic & VariAn Cage
	Trial (7mm ~ 15mm)	CINS 003~011	Dynamic & VariAn Cage
	Shaver (7mm ~ 15mm)	CINS 012~020	Dynamic & VariAn Cage
	Bone Impactor	CINS 023	Dynamic Cage only
	Final Impactor	CINS 024	Dynamic Cage only
	Curret (General type)	CINS 025	Dynamic & VariAn Cage
	Curret (Open type)	CINS 026	Dynamic & VariAn Cage
	Rasp (7mm ~ 10mm)	CINS 027~029	Dynamic & VariAn Cage
	Platform	CINS 030	Dynamic Cage only
	Nerve Retractor (Small size)	CINS 031	Dynamic & VariAn Cage
	Nerve Retractor (Large size)	CINS 032	Dynamic & VariAn Cage
	VariAn Cage Holder Set	CINS 033	VariAn Expandable Cage only
	Cage Expander	CINS 034	VariAn Expandable Cage only
	End-cap Driver	CINS 035	VariAn Expandable Cage only
	Ratchet	CINS 039	
	Cage Tray	CINS 036	Tray for Instruments and Implants

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Product List

VariAn Cage

Code	Specification (mm)			
	Heighe	Expanding Heighe	Width	Length
VB-0911S	9	11	11	22
VB-0911M	9	11	11	24
VB-0911L	9	10.5	11	27
VB-0912S	9	12	11	22
VB-0912M	9	12	11	24
VB-0912L	9	11.5	11	27
VB-1012S	10	12	11	22
VB-1012M	10	12	11	24
VB-1012L	10	11.5	11	27
VB-1013S	10	13	11	22
VB-1013M	10	13	11	24
VB-1013L	10	12.5	11	27
VB-1113S	11	13	11	22
VB-1113M	11	13	11	24
VB-1113L	11	12.5	11	27
VB-1114S	11	14	11	22
VB-1114M	11	14	11	24
VB-1114L	11	13.5	11	27
VB-1214S	12	14	11	22
VB-1214M	12	14	11	24
VB-1214L	12	13.5	11	27
VB-1215S	12	15	11	22
VB-1215M	12	15	11	24
VB-1215L	12	14.5	11	27
VB-1315S	13	15	11	22
VB-1315M	13	15	11	24
VB-1315L	13	14.5	11	27
VB-1316S	13	16	11	22
VB-1316M	13	16	11	24
VB-1316L	13	15.5	11	27
VB-1416S	14	16	11	22
VB-1416M	14	16	11	24
VB-1416L	14	15.5	11	27
VB-1417S	14	17	11	22
VB-1417M	14	17	11	24
VB-1417L	14	16.5	11	27
VB-1517S	15	17	11	22
VB-1517M	15	17	11	24
VB-1517L	15	16.5	11	27
VB-1518S	15	18	11	22
VB-1518M	15	18	11	24
VB-1518L	15	17.5	11	27

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