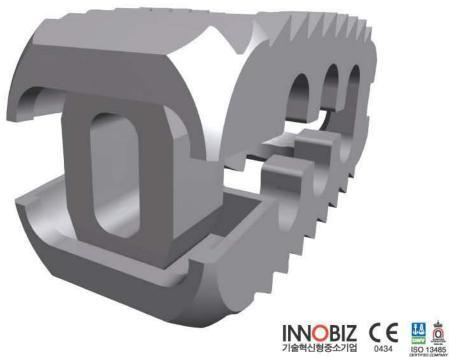


VariAn Cage Surgical Technique





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Company Information

Thinking Up! Passion Up! Soaring Up! possible through MEDYSSEY



Medyssey Co., Ltd. is the company specialized in the orthopedic and neurosurgery fields considering the human life as well as the human health as the most valuable assets under the company motto of 'Thinking Up, Passion Up, Soaring Up Possible through Medyssey'.

Ever since 2003, Medyssey's effort for these ideal has led us to the rapid growth in the past short term in both the domestic market and the overseas market with our best top-notched and brand-new unique product line.

- 1. Novel & Zenius System: Dove Tail Joint locking system and Linear Slot effect in the set screw
- 2. VariAn Expandable Cage: One-Turning Expanding mechanism with simplified implantation
- 3. Dynamic Cage: Easier insertion Cage with Flexibility
- 4. WX(WaveFlex) Dynamic Stabilization Rod System

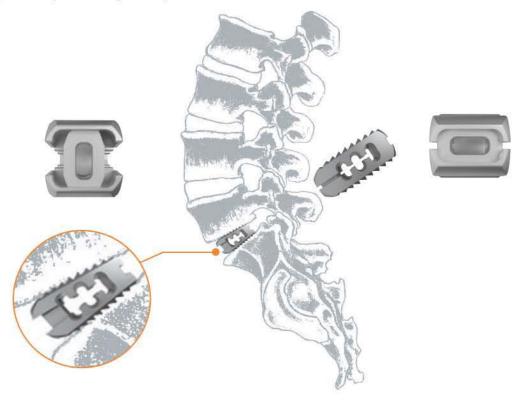
All these Medyssey's accomplishment has been done based on our revolutionary products and our tight QC, QM system with the accumulated long-term experiences.

As the results of our constant aim-oriented and self-volunteered attitude, we were designated as the Inno-Biz Company under the quality certificates of ISO13485, CE0434 and GMP (Good Manufacturing Practice).

Finally, Medyssey promises all of you to be the best business partner and the future leader by opening the evolutionary era in this field with our never-stopping efforts and better services by enhancing our new products and new technology all the time.

One-Touchable Easy Expandable Spacer!

As the surgeons look for the cage fusion spacer with the more simple and reliable surgery recently, Medyssey developed the revolutionary VariAn Expandable Cage correspondent to their needs.



When the VariAn Expandable Cage is implanted in the interdiscal space, it is expanded to 90° in the clock-wise direction by the one-turning mechanism and when it is fully expanded, it offers 8°-10° to maintain the natural lordotic angle.

Consequently, it has the following remarkable advantages.

Accurate and Complete Anchor

Different to other expandable cage, VariAn Expandable Cage allows the complete insertion up to the desired position because the angulated anterior shape allows the easier insertion and protects the bony cortex.

The posterior parts of VariAn Expandable Cage also sits stable.

Efficiency of Bone Graft

Different to the other expandable cage, VariAn Expandable Cage makes the early and efficient bone union with no dead space and hardware fracture as the bone chip is cleanly and widely spread.

Simplified Instrumentation

Instrumentation is simplified resulting from the one-turning mechanism

Minimized Operation Time

Operative time can be minimized with the simplified instrumentation

Easy Removal if Needed

Cage is easily removed by turning the end plate back in the counter clockwise

Appropriate Dimension

9mm-14mm in Height & 24mm, 27mm, 30mm in Length

Intelligent Linear Slot for Easy Insertion and Early Bone Fusion!

Dynamic Cage 0.5mm linear slot in the front has the effect to make possible for the easier insertion and the early bone fusion by the dynamic micro-movement.

Dynamic Cage linear slot is closed when it is fully inserted in the spinal vertebra.

Additionally, Dynamic Cage surface is also devised to be angulated to fit into the curvature of the spinal vertebra end plate and Dynamic Cage sawteeth on the upside and the downside make the outstanding feature.

Linear Slot is Closed When Dynamic Cage is inserted in the spinal vertebra





4° & 8° of Two Different Lordotic Angles are Available





Easier Insertion and Early Bone Fusion by the Slot in the front

Diverse Dimension for the Appropriate Surgery is Available



General Cage without Slot is also available

Clinical Cases

Indication

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



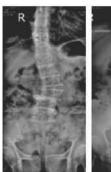


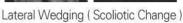
Low-grade Spondylolisthesis





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





Clinical Follow-Up







51/F, Severe Listhesis Preoperation



POD#1



3 Mth



6 Mth



1 Yr.



2 Yrs.



| Instrument Photos | Instrument Name | Product Code | Description |
|-------------------|--------------------------------|--------------|-----------------------------------|
| | Cage Holder Set | CINS 001 | Dynamic Cage only |
| 4 | 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 |
| 0 | 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 |
| <u></u> | Platform | CINS 030 | Dynamic Cage only |
| | Nerve Retractor (Small size) | CINS 031 | Dynamic & VariAn Cage |
| | Nerve Retractor (Large size) | CINS 032 | Dynamic & VariAn Cage |
| Å | 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 |



Surgical Technique



STEP 1: PATIENT POSITIONING

The patient is placed in the prone position under the hypotension controlled with the general anesthesia. The patient also should be taken care with the abdominal free in this position to avoid the excess venous and epidural pressure.

Fluoroscopy also can be available for the interoperative check-up.



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.



STEP 3: MEDIAL 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 cartiliage 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 Expandable Cage.

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

- CINS 031 (Nerve Retractor) : Small size - CINS 032 (Nerve Retractor) : Large size - CINS 012 - 020 (Shaver) : 7mm - 15mm - CINS 002 : T-Holder (Quick Holder)





STEP 4: TRIAL AND DISC SPACE DISTRACTION

Trial is used to distract the disc space for the planned disc space height and for the foraminal opening of the VariAn Expandable Cage.

Trial shall be inserted parallel to the endplate of the vertebral body and be turned round 90° to distract the disc space after full insertion.

Also, carefully check the disc space with the Trial measurement to determine which size of the VariAn Expandable Cage should be inserted.

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

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

- CINS 003 - 011 (Trial) : 7mm ~15mm

- CINS 029 (Rasp): 10mm





STEP 5: SPACER 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 Expandable 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 VariAn Expandable Cage onto the part 1 and then turn the part 2 in the clockwise after inserting it into the hole of part 1.

- CINS 001 : Cage Holder Set

- CINS 035: End Cap Driver (w/ slot & w/o slot)





What is the standard to choose the appropriate size ?

Below 40mm: 24mm Cage is proper 40mm-50mm: 27mm Cage is proper Above 50mm: 30mm Cage is proper



STEP 6: SPACER IMPLANTATION

Implant the determined size of the VariAn Expandable Cage into the intervertebral body and impact the head of CageHolder Set.

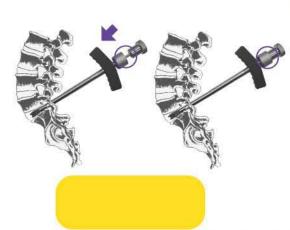
Once the VariAn Expandable Cage is completely embedded inside the intervertebral body, put the Cage Expander through the hole in the part 2 assembled with the part 1 until the tip of the Cage Expander is fully inserted in the end plate hole of VariAn Expandable Cage.



STEP 7: SPACER 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

After taking the Cage Expander off from the Cage Holder Set, the Bone Impactor(CINS024) 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 Expandable 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.



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.

Product List - DYNAMIC™ Cage



| Product Classification : [| Oynamic Cage with Slot | Raw Materials : Ti6Al-4V ELI Alloy | | | |
|----------------------------|------------------------|------------------------------------|-------------|-------------------|--|
| Product Code - | Specification | | | | |
| | Degree (°) | Width (mm) | Length (mm) | Front Height (mm) | |
| DC41A08 | 4 | 11 | 25 | 8 | |
| DC41A09 | 4 | 11 | 25 | 9 | |
| DC41A10 | 4 | 11 | 25 | 10 | |
| DC41A11 | 4 | 11 | 25 | 11 | |
| DC41A12 | 4 | 11 | 25 | 12 | |
| DC41A13 | 4 | 11 | 25 | 13 | |
| DC41A14 | 4 | 11 | 25 | 14 | |
| DC41A15 | 4 | 11 | 25 | 15 | |
| DC41A16 | 4 | 11 | 25 | 16 | |
| DC81A09 | 8 | 11 | 25 | 9 | |
| DC81A10 | 8 | 11 | 25 | 10 | |
| DC81A11 | 8 | 11 | 25 | 11 | |
| DC81A12 | 8 | 11 | 25 | 12 | |
| DC81A13 | 8 | 11 | 25 | 13 | |
| DC81A14 | 8 | 11 | 25 | 14 | |
| DC81A15 | 8 | 11 | 25 | 15 | |
| DC81A16 | 8 | 11 | 25 | 16 | |



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