



SURGICAL TECHNIQUE

EXPANDABLE CAGE





SYSTEM OVERVIEW

<u>EXPANDABLE CAGE</u>	
<p>Catalogue Number: Stainless Steel 316L: SS 457 Titanium Grade 5: TT 457 Length: For 10mm diameter - length 20-75mm. For 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm diameter - length 10 – 100 mm</p>	
INSTRUMENT SET DETAILS	
SIS 126	Eco & Expandable Cage Instruments Set
SIS 126-001	Cage Holder
SIS 126-002	Cage Pusher (Curved)
SIS 126-003	Cage Pusher (Straight)
SIS 126-004	Cage Expansion Bar (Straight)
SIS 126-005	Cage Expansion Bar (Curved)
SIS 126-006	Cage Lock Screw Holder
SIS 126-007	Box with Silicon Base

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 2 of 12

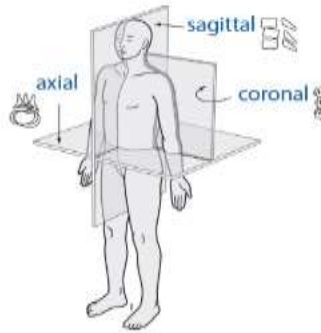


AO SPINE PRINCIPLES

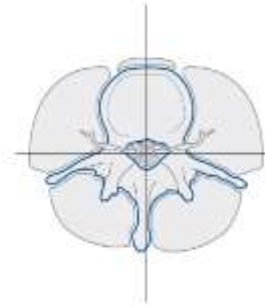
The four AO Spine Principles that create the foundation for proper spinal patient management lie at the core of the design and delivery of the curriculum: Safety, Alignment, Biology, Function



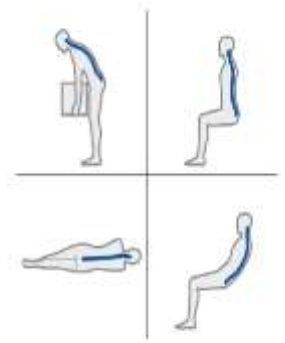
Stability:
Stabilization to achieve a therapeutic outcome.



Alignment:
Balancing the spine in three dimensions.



Biology:
Etiology, pathogenesis, neural protection and tissue healing.



Function:
Preservation and restoration of function to prevent disability.

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 3 of 12



INDICATIONS AND CONTRAINDICATIONS

INDICATIONS:

Intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body or vertebra resected or excised during total and partial corpectomy and vertebrectomy procedures due to tumor or trauma (i.e., fracture).

CONTRAINDICATION:

- Infection, local to operative site
- Not to be used for interbody fusion
- Vertebral body fracture
- Spinal tumors
- Major spinal instabilities
- Primary spinal deformities
- Signs of local inflammation
- Metal hypersensitivity
- Marked local inflammation
- Obesity
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Open wounds.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.

PRECAUTIONS

Pre-Operative:

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.
- Patients should be instructed 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.

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 4 of 12



- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Patients who smoke have been shown to have an increased incidence of nonunions. Such patients should be advised of this fact and warned of the potential consequences.

Intra-Operative:

- Discard all damaged or mishandled implants.
- Spine implants must not be reshaped, unless otherwise indicated in the surgical technique instructions. The use of inappropriate instruments may result in scratches, notches, and sharp bending, causing the breakage of the implants. Improper seating of the implant may result in implant failure.
- Never reuse an implant, even though it may appear undamaged.
- Do not mix metals.

Post-Operative:

Physician instructions regarding full weight-bearing activities must be complied with until maturation of the fusion mass is confirmed. Failure to comply with physician instructions may result in failure of the implant, the fusion, or both.

WARNINGS:

- Potential risk associated with use of this system may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of vertebrae, neurological injury, vascular or visceral injury.
- Under no circumstances may the implants be re-used.
- Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.
- Implants removed from a patient that contact bodily tissues or fluids should never be reused at risk of contamination of the patient.
- The device can break if subjected to increased load associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant.

ADVERSE EVENT:

- Late bone fusion or no visible fusion mass and pseudarthrosis.
- Superficial or deep-set infection and inflammatory phenomena.
- Allergic reactions to the implanted materials, although uncommon, can occur.
- Decrease in bone density due to stress shielding.
- Dural leak requiring surgical repair.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 5 of 12



foot-drop may occur.

- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Neurological and spinal dura mater lesions from surgical trauma.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary.

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 6 of 12



EXPANDABLE CAGE SURGICAL TECHNIQUE

1. PATIENT POSITION:

Patient positioning on the operating table is dependent on the level(s) to be operated. For levels T1-T3 and L5, the patient is typically placed in the anterior supine position. For levels T4-L4, the patient is typically placed in the lateral decubitus position

2. EXPOSURE

Through a trans-sternal, trans-thoracic, retroperitoneal, or combined thoracolumbar approach, the lateral or anterior aspect of the spine column is exposed. X-ray or fluoroscopy should be used to confirm the appropriate level.

A total or partial corpectomy or vertebrectomy procedure as needed is performed.

The bony endplates are prepared for implant insertion using standard surgical procedures and instrumentation.



Example of corpectomy on L5 vertebra



Example of vertebrectomy on thoracic vertebra

3. IMPLANT MEASUREMENT

The appropriate size implant can be determined preoperatively, by measuring the defect from the patient's films or CT scans. However, the measurement should be confirmed in situ with a caliper or ruler. It is recommended to measure in situ from the posterior aspect of the inferior endplate of the vertebral body above the affected level to the posterior aspect of the superior endplate of the vertebral body below the affected level



Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 7 of 12



4. IMPLANT SELECTION

The measured implant height can be cross-referenced with a sizing template to choose the appropriate implant construct, depending on diameter.

5. BONE GRAFT PACKING

The use of bone graft is optional.

6. IMPLANT INSERTION

After selection proper implant and packing with bone graft, the implant is ready for insertion.

The expander is used to insert the implant and distract the implant to its final height. Once the expander is in proper alignment with the implant, the implant can be placed into the defect and distracted to the appropriate height.

Once the optimal implant height is reached via in situ distraction, the outer distraction ring can be locked with a pre-assembled locking screw to prevent the implant height from changing.

IMPLANT REMOVAL

Standard instruments may be used to hold and disengage the device from the vertebrae. Any decision by a physician to remove the device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 8 of 12



CAUTION

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fails to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. **Therefore, reuse of implants is strictly not recommended.**

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

Packaging Materials Disposal:

The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keep out of reach of children and stray animals.

Single Brand Usage:

Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 9 of 12




MRI SAFETY INFORMATION

- Samay Surgical implants are manufactured from Titanium Gr.5, SS316L material are non-magnetic material, hence it does not pose any safety risk.
 - Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.
 - Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
 - The Samay Surgical implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI
 - The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
 - The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.
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Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 10 of 12



PRODUCT NAME	SS316L CATALOG NO.	TITANIUM GRADE 5 CATALOG NO.	LENGTH (MM)	DIAMATER (MM)
	SS 457-001	TT 457-001	20 To 75	ø 24.0
Expandable Cage	SS 457-002	TT 457-002	10 To 100	ø 12.0
	SS 457-003	TT 457-003	10 To 100	ø 14.0
	SS 457-004	TT 457-004	10 To 100	ø 16.0
	SS 457-005	TT 457-005	10 To 100	ø 18.0
	SS 457-006	TT 457-006	10 To 100	ø 20.0
	SS 457-007	TT 457-007	10 To 100	ø 22.0
	SS 457-008	TT 457-008	10 To 100	ø 24.0

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 11 of 12



Implants Certified by: **CE**
XXXX

Instruments Certified by Self Declaration : **CE**



SAMAY®
Surgical

Samay Surgical

Survey no- 212, plot no.-06 NH 08B,

Veravel- Shapar 360024

Dist- Rajkot, Gujrat, India.

Email- info@samaysurgical.com

- Samaysurgical@yahoo.com

Mobile no:- 9978104395(for international market)

:- 9429115008(for Domestic Market)

Doc Name	Doc No	Issue No/Rev No	Dated	Page No
Expandable Cage System	SS/ST/EXCS	01/00	26/09/2019	Page 12 of 12