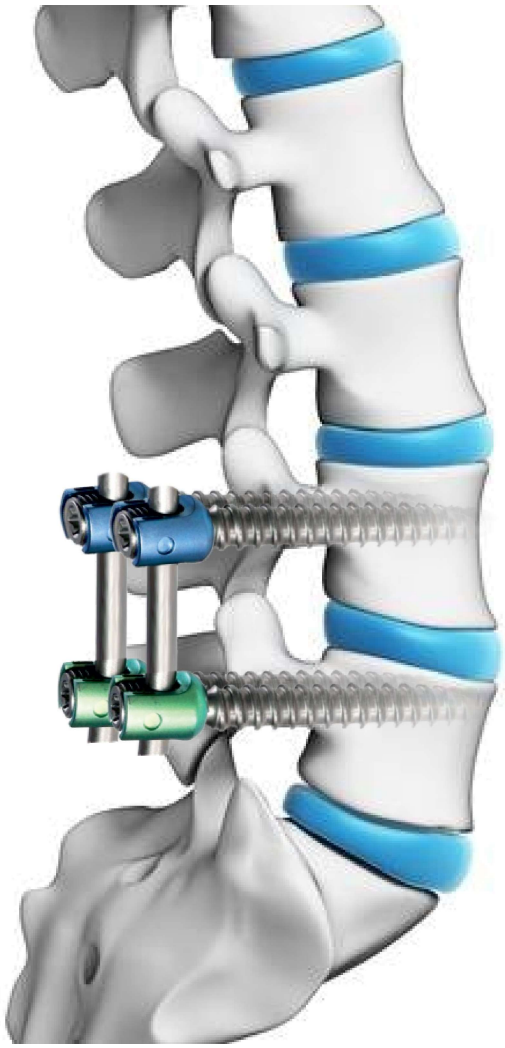
Kentro

SPINE IMPLANTS



Rivarp MEDICAL

ABOUT US

Rivarp Medical Private Limited is a Bangalore based medical devices company established in 2016; which specialised in R&D, manufacture and sales of high – quality medical devices in therapeutic areas of Spinal implants, Interventional cardiology & Critical care management

Quality Policy

Rivarp Medical Pvt Ltd is committed to provide innovative Medical devices that meet our customer requirement, applicable regulatory and statutory requirements.

We maintain an effective quality system by mitigating product and process risk. The quality system is reviewed for continuing suitability by executing objectives related to:

- Product development and improvement.
- Quality system planning and improvement.
- Supplier quality assurance.
- Personnel training and competence.
- Applicable Regulatory compliance and internal/external audits.
- Process effectiveness and efficiency.

KENTRO PRODUCT RANGE

Kentro PSS
Premium Pedicle Screw System

Kentro D-gen
Value Segment Pedicle screw system

Kentro TLIF / Banana Cage
Transforaminal Posterior Lumbar Interbody Cage System

Kentro PLIF / Bullet Cage
Posterior Lumbar Interbody Cage System

Kentro ACP
Anterior Cervical Plate

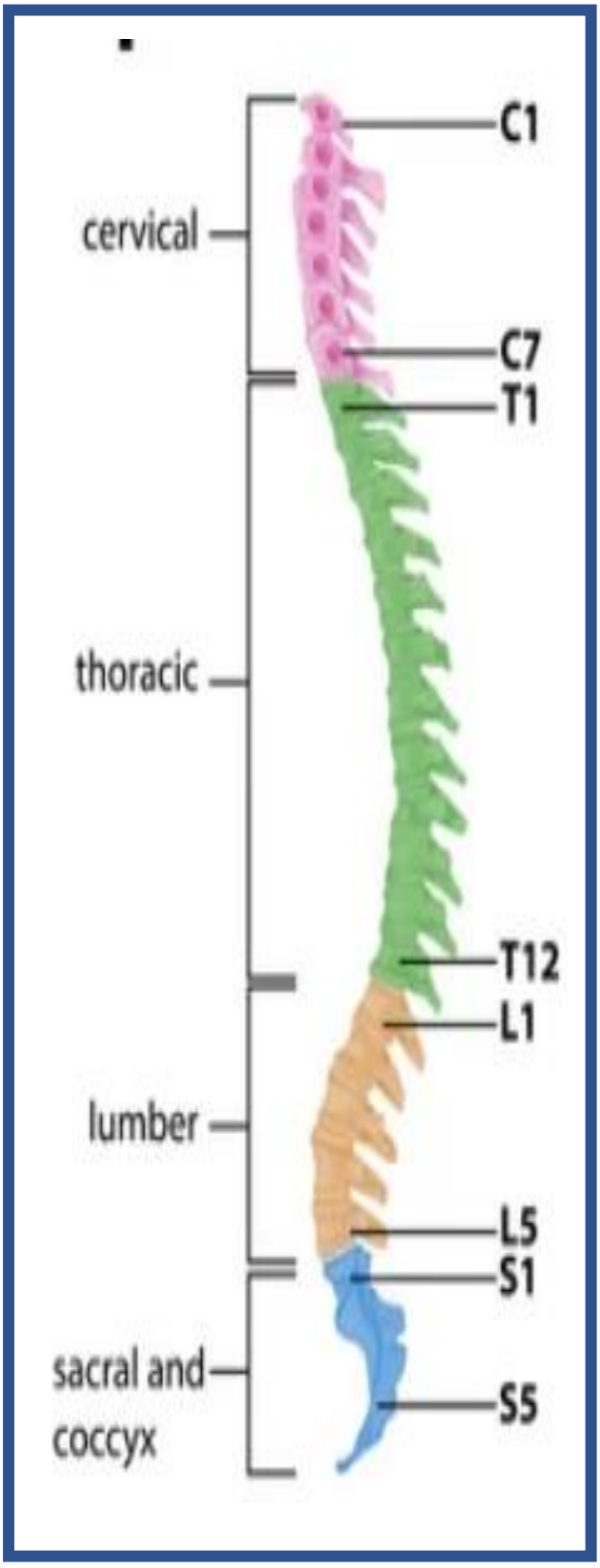
Kentro ACC
Anterior Cervical Cage

Kentro PCF
Posterior Cervical Fixation

Kentro SELF
Stand Alone Anterior Cervical Cage

Kentro KYPHONIX
Balloon Kyphoplasty

Kentro CCM
Mesh Cages



COMING SOON

KENTRO MIS SYSTEM

Kentro - PSS

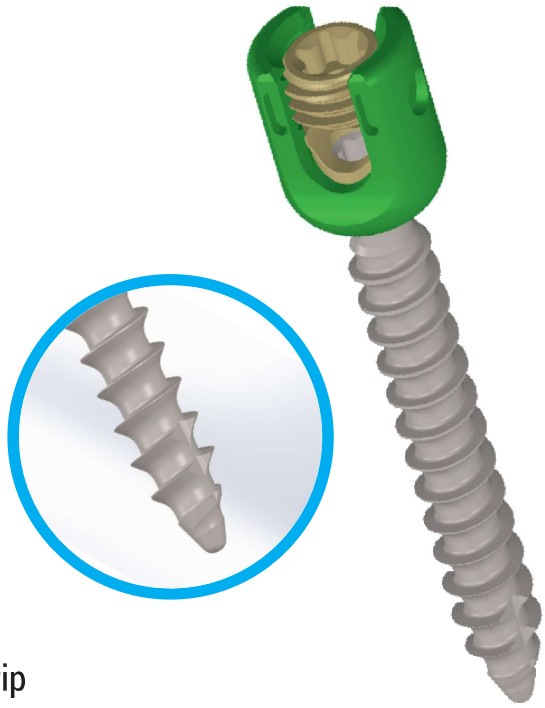
Pedicle Screw System

Great combination of quality screws & excellent instrumentation at affordable pricing

Low Profile Implant

Kentro - PSS

Pedicle Screw System



- Low profile head reducing possibility of soft tissue irritation
- 6 points contact for the ease of reduction
- Deep thread pitch for more screw purchase
- Sharp & thin thread flanks for cancellous bone in vertebral body
- Reverse buttress thread enhance screw pullout strenth
- Flutes for early bone purchase & for quick initial grip
- Star drive poly screw head & locking cap

Tested for Mechanical Strength & Biocompatibility

5.5 mm pre-cut rods

Buttress thread locking screw avoids cross threading

Hexagon end for in-situ rod rotation

Kentro - PSS

Pedicle Screw System

Polyaxial screwdriver with silicon ratchet handle gives effortless & Speedy screw insertion

Final tightening with 10NM Torque Indicating Handle

Perfectly matched persuader at 4 points of contact for enhanced reduction

Indications and Contraindications

The Kentro - Pss is a posterior pedicle screw system (T1-S2) Intended for use in skeletally mature patients.

Indications

- Deformities (i.e. Scoliosis, Kyphosis and/or lordosis)
- Degenerative Disc Disease
- Spondylolisthesis
- Trauma (i.e. fracture or dislocation)
- Tumor
- Stenosis
- Pseudarthorosis
- Failed previous fusion

Compact Instrument Set

Contraindications

- In fractures and tumors with severe anterior vertebral body disruption, an additional anterior support or column reconstruction is required
- Osteoporosis

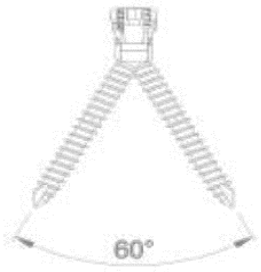
Available Sizes - Poly & Mono

Dia : 4.5 mm, 5.5 mm, 6.5 mm, 7 mm
Length : 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, 55 mm, 60 mm

Kentro D-gen

VALUE SEGMENT PEDICLE SCREW SYSTEM

Posterior Spinal Fixation System for Thoracic and Lumbar Region



- Semi conical shaft with cortico cancellous threading – In turns helps to increase pull out strength.
- Flutes at proximal tip.
- Tulip Design accommodates easy engagement of persuader at 2-point contact.
- Set Screw: Reverse buttress threading & hexagonal slot prevents splaying.
- Extended Angle of 60 degree which is specifically useful to accommodate from T1 to S1.

Kentro D-gen

VALUE SEGMENT PEDICLE SCREW SYSTEM

INSTRUMENTS

Poly-Axial Screwdriver

Poly-axial screwdriver with silicon rachet handle gives effortless & speedy screw insertion

Persuader

2-point contact persuader for reduction

Torque Handle

Final tightening with 10 NM torque limiting handle.

Ergonomic & Smart Instruments

High Quality Sturdy, Simple & User-Friendly Instruments.

Kentro - TLIF

Transforaminal Posterior Lumbar Interbody cage system

Self - distraction nose of the implant, guide and turn the cage between the vertebral bodies into the desired position

Pyramidal teeth

Provide resistance to implant migration

Rails on the surface

Guide and turn the cage into the desired position

Self - distraction nose

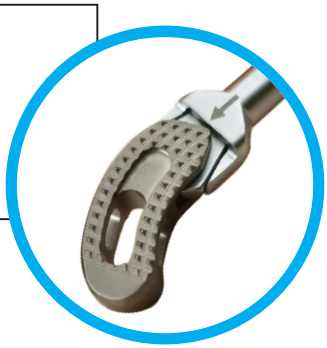
Allows for ease of insertion

Connection Cylinder

Permits the pivoting mechanism in combination with the applicator

Axial window

Accommodates autogenous bone graft or bone graft substitute to allow fusion to occur through the cage

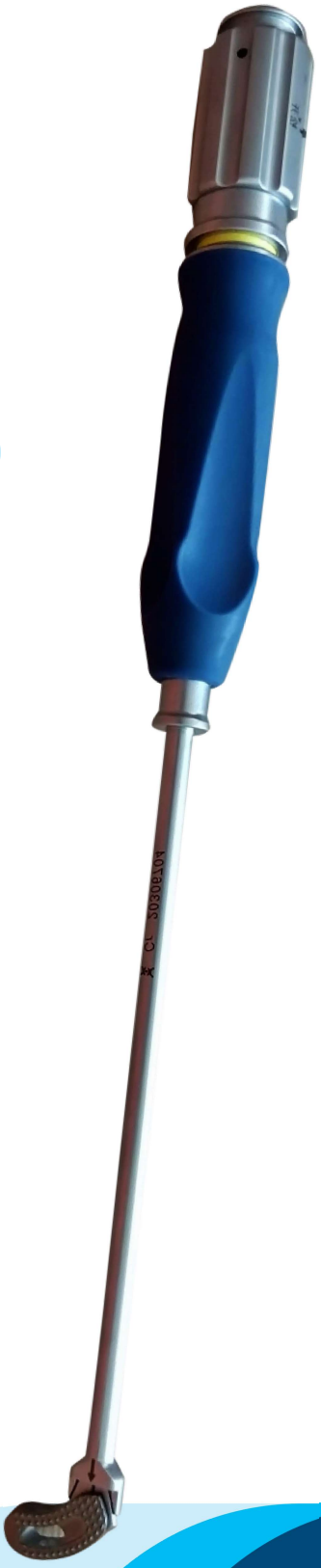


Material

Titanium alloy

Lordotic angle

5° to restore the natural spine lordotic curve



One Surgery, One instrument

- One key instrument for insertion of implant
- Applicator allows a controlled and guided insertion based on the pivoting option
- Security button to prevent implant disengagement
- applicator is designed for minimally invasive surgeries

Kentro - TLIF

Transforaminal Posterior Lumbar Interbody cage system

Attach Position

Pull the security ring down and simultaneously turn the knob counterclockwise. Ensure no gap between the handle, security ring and the applicator knob should be present. The yellow color band should not be visible.

Pack disc space

After the Kentro - TLIF cage is implanted, fill the posterior disc space and the lateral disc space with bone graft or bone graft substitute to create optimal conditions for fusion

Supplemental fixation

the Kentro - TLIF cage is intended to be used with Kentro - PSS supplemental posterior fixation,

Indication and Contraindications

The Kentro - TILF is intended to replace lumbar intervertebral discs and to fuse the adjacent vertebral bodies together at vertebral levels L1-S1. The Kentro -TILF implant is designed for a transforaminal approach

Indication

Indications are lumbar and lumbosacral pathologies in which segmental spondylodesis is indicated, For example

- Degenerative Disc Diseases and spinal instabilities
- Revision procedures for post discectomy syndrome
- Pseudarthroisis or failed spondylodesis
- Degenerative spondylolisthesis
- Isthmic spondylolisthesis

Contraindications

- Vertebral body fractures
- Spinal tumors
- Major spinal instabilities
- Primary spinal deformities
- Osteoporosis

Available Size & Foot Print

Foot Print : 10 mm x 27 mm
Size : 8mm, 9mm, 10 mm, 11 mm, 12mm 13mm, 14mm

Important :

Kento - TLIF must be applied in combination with posterior fixation

Kentro - PLIF

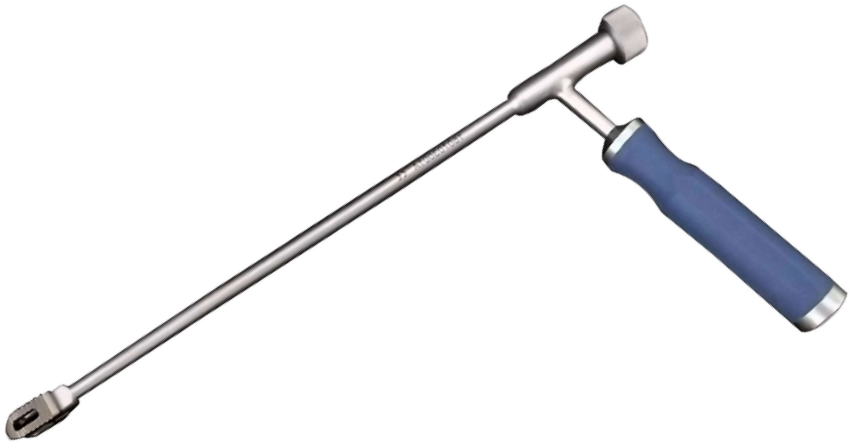
Posterior Lumbar Interbody cage system

- Tapered entry
- Curved edges for smooth entry
- Groves for additional stability
- Wider bone graft window
- 5 degree of angulations to maintain lordosis
- High quality narrow user friendly applicator

Indication

Indications are lumbar and lumbosacral pathologies in which segmental spondylodesis is indicated, For example

- Degenerative Disc Diseases and spinal instabilities
- Revision procedures for post discectomy syndrome
- Pseudarthroisis or failed spondylodesis
- Degenerative spondylolisthesis
- Isthmic spondylolisthesis



Contraindications

- Vertebral body fractures
- Spinal tumors
- Major spinal instabilities
- Primary spinal deformities
- Osteoporosis

Important :

Kentro - PLIF must be applied in combination with posterior fixation

Available Size & Foot Print

Foot Print : 10 mm x 25 mm
Size : 7mm, 8mm, 9mm, 10 mm, 11 mm, 12mm 13mm, 14mm

Kentro - ACC

Anterior Cervical Cage

- Perfect design to match anatomy
- Groves on the end plate for better grip
- Decent bone graft window
- Small arrow representing cranial side of the cage .
- Sturdy applicator with indicators
- Simple instrumentation

Indication

- Ruptured and herniated discs
- Degenerative Disc Diseases and instabilities
- Pseudarthrosis or failed spondylodesis
- For multisegmental fusion additional stabilization with a plate is recommended

Contraindications

- Severe Osteoporosis
- Extreme Instabilities

Available Size & Foot Print
Foot Print : 15 mm x 12.5 mm
Size : 5mm, 6mm, 7mm, 8mm, 9mm, 10 mm

Kentro - ACP

Anterior Cervical Plate

- Kentro-ACP is intended for anterior cervical fixation (C2-C7).
- 2mm thickness & 17mm width pre-contoured plate perfectly matching the anatomy .
- Built in Cam Locking Mechanism provides visual , tactile assurance of the lock .
- Uniquely shaped graft visualization window .
- Self drilling variable angle screw with 4mm & 4.5mm dia provides up to 20 degree angulation .
- The design of plate holder helps position the plate perfectly .
- Unique design of plate bender and other supporting instruments will make the surgery more comfort.

Indication

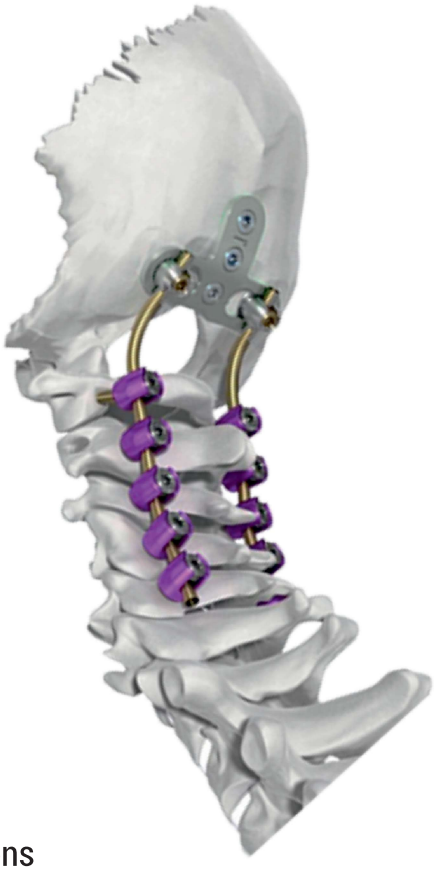
- Fracture
- Disc Prolapse with mylopathy
- Tumour

Contraindications

- Osteoporosis
- Plate without spacer /bone graft

Kentro - PCF
Posterior Cervical Fixation

Best in Class Instruments



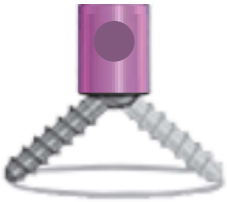
Up to 40° Screw Angulation

Complete OCT Solution

Best in Class Instruments

Kentro PCF

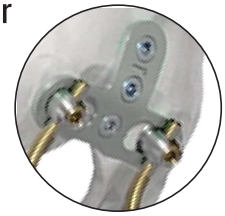
- Polyaxial screws with up to 40° angulation in all directions
- Enable advanced surgical techniques
- Pedicle screw setting
- C1/C2 fixation using Magerl Technique Simlifies operation
- Self-tapping for rapid insertion



A Complete Occipito-Cervico-thoracic Fixation Solution

Posterior Cervical fixation

Kentro - PCF is a top-loading implant system to stabilize the posterior cervical spine. It consists of top loading screws transconnectors and Ø 3.5 mm rods.



Kentro - PCF is compatible with the Occipito Cervical Fusion System which consists of occipatible plates, Clamps and pre-bent rods.

Kentro - PCF

Posterior Cervical Fixation

Occipital Fixation

The Ø3.5 mm rod connects the screws in the cervical spine with the plate in the occiput to achieve a stable occipito-cervical fixation

Trasition to thoracic spine

Open parallel connectors or tapered rods can be used to connect the Ø 3.5 mm rod with any 5.5 mm rod and thus extend the construct to the thoracic spine.

Indications

Occipito - cervical and upper cervical spine instabilities :

- Rheumatoid arthritis
- Congenital anomalies
- Post traumatic conditions
- Tumors
- Infections

- Instabilites in the lower cervical and upper thoracic spine :
- Post traumatic conditions
- Tumors
- Infections

Degenerative and painful posttraumatic conditions in the lower cervical and upper thoracic spine

Anterior cervical fusions requiring additional posterior stabilization

Available Size

Dia : 3.5mm, 4mm
Size : 12mm to 32 mm with 2 mm increment

Kentro - SELF

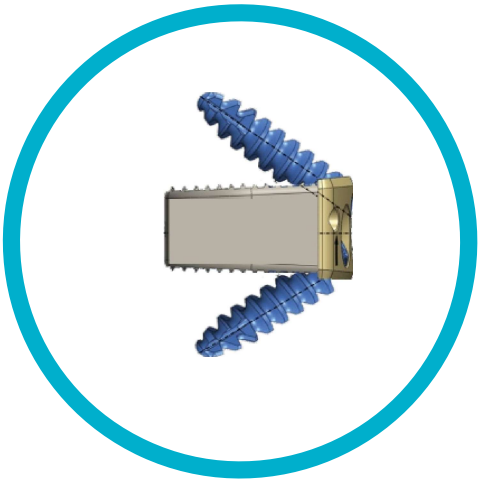
Stand Alone Anterior Cervical Cage

Stand Alone ACDF Implant

Kentro-Self as a stand-alone implant for use in cervical inter body fusions. Its design combines the functionality of a cervical inter body spacer and the benefits of an anterior cervical plate.

Reduces Risk of Dysphagia

The implant is contained within the excised disc space and does not protrude past the anterior wall of the vertebral body as do anterior cervical plates. This low anterior profile may be beneficial in reducing the occurrence and severity of postoperative dysphagia.



Ease of Use

Because plate and spacer are preassembled, the plate is automatically aligned upon implant insertion. This avoids the process of aligning and realigning an anterior cervical pltate.

Interbody Spacer

- Spacer component is made of Titanium alloy
- Teeth on the implant surface provide initial stability
- Available in different sizes

Kentro - SELF

- Provides a secure, rigid screw locking interface with cam-lock
- Stresses in plate are decoupled from spacer through an innovative interface

Stability similar to that of an anterior spacer and plate

Biomechanical testing has shown the stability of the implant to be similar to that of traditional plates and spacers

Locking Screws

- Screws form a bone wedge with a 40° ± 5° cranial/caudal angle
- One step locking screws
- Self tapping screws improve thread purchase
- Thread cutting flutes are self centering

The Kentro-Self Is intended for use following anterior cervical discectomy for reduction and stabilization of the cervical spine (C2-C7)

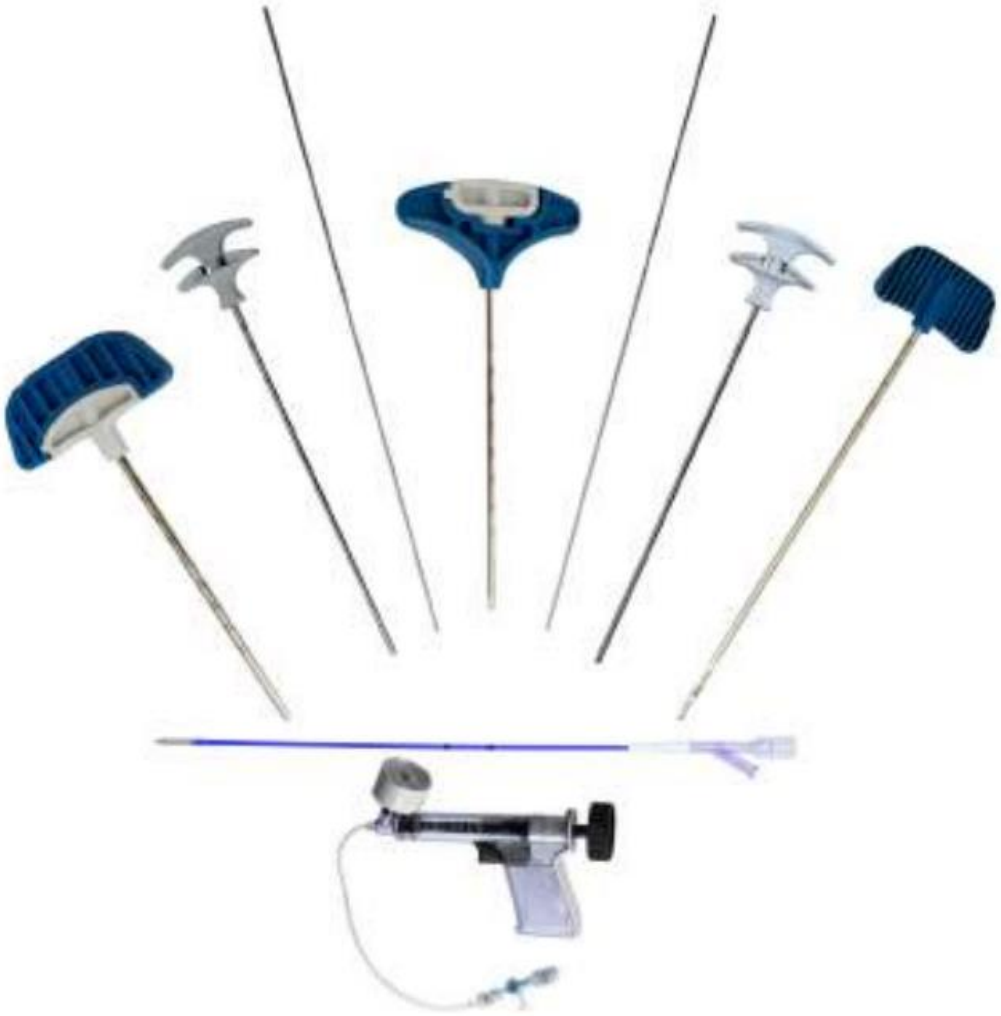
Indications include

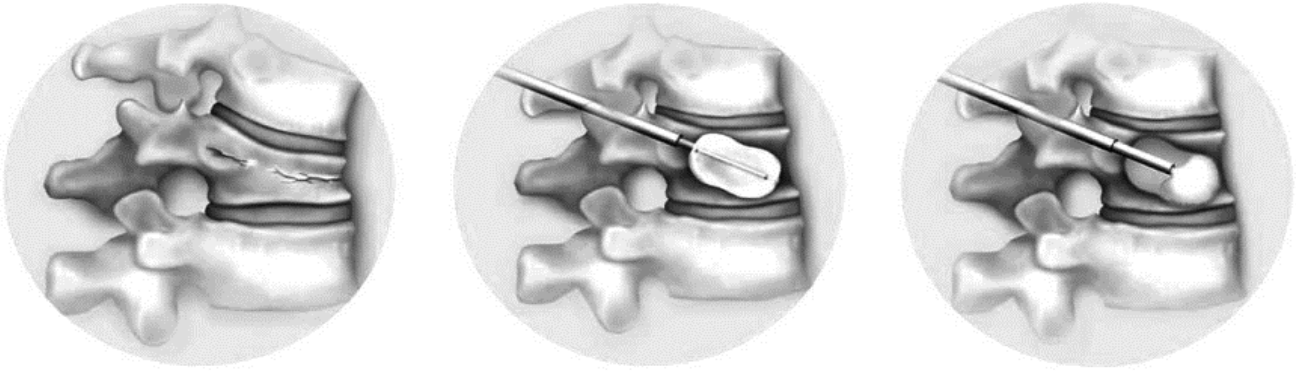
- Degenerative Disc Disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spinal Stenosis
- Failed previous fusions
- Pseudoarthrosis

Available Size & Foot Print

Foot Print : 15 mm x 13 mm
Size : 5mm, 6mm, 7mm, 8mm, 9mm, 10 mm

Kentro KYPHONIX | BALLOON KYPHOPLASTY



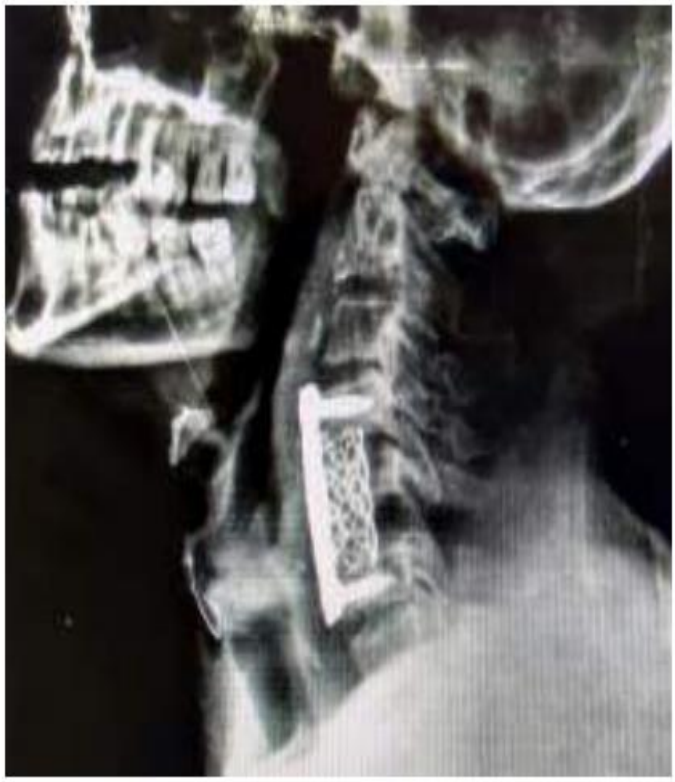


Kentro CCM | MESH CAGES

Usage

These Cylindrical Titanium Mesh Cage (TMC) are used for the replacement & reinforcement of anterior column, which provides support in kyphotic deformities as posterior Interlaminar spacer. Some features as follows:

- Restoring the height provided by the original intervertebral disc.
- Supporting the front (anterior) part of the spinal column.
- Expanding the bony openings between the vertebrae (foramina), providing more space for spinal nerves.



Mechanical test summary

Sl No.	Spinal implants	Test Name	Test results	Remarks
1	Pedicle screws and rods for pedicle screws	Static and Fatigue testing of spinal Implant Constructs	All tested samples withstood five million cycles without any failure (Test done as per the ASTM F1717-15)	COMPLIES
2	Lumbar Interbody fusion Cages (PLIF & TLIF)	Static Subsidence Test of spinal Implant Constructs	All tested samples were pushed into the PU-foam without any visible failure. The acceptance criteria of F yield, 2mm >400 N, as defined in ASTM standards (ASTM F2267-04: and ASTM F1839-08), was achieved, as well as a subsidence stiffness Kp >260 N/mm.	COMPLIES
3	Anterior Distractable cage	Static Subsidence Test of spinal Implant Constructs	All tested samples were pushed into the PU-foam without any visible failure. The acceptance criteria of F yield, 2mm >400 N, as defined in ASTM standards (ASTM F2267-04: and ASTM F1839-08), was achieved, as well as a subsidence stiffness Kp >260 N/mm.	COMPLIES
4	Mesh cages	Static Subsidence Test of spinal Implant Constructs	All tested samples were pushed into the PU-foam without any visible failure. The acceptance criteria of F yield, 2mm >400 N, as defined in ASTM standards (ASTM F2267-04: and ASTM F1839-08), was achieved, as well as a subsidence stiffness Kp >260 N/mm.	COMPLIES
5	Anterior cervical cage with screw	Static Subsidence Test of spinal Implant Constructs	All tested samples were pushed into the PU-foam without any visible failure. The acceptance criteria of F yield, 2mm >400 N, as defined in ASTM standards (ASTM F2267-04: and ASTM F1839-08), was achieved, as well as a subsidence stiffness Kp >260 N/mm.	COMPLIES
6	Anterior cervical plate system	Static and Fatigue testing of spinal Implant Constructs	The acceptance criteria, was complied with both tested specimens and all samples withstood five million cycle without any failure (Test done as per the ASTM F1717-15).	COMPLIES
7	Occipitall plates with screws	Static and Fatigue testing of spinal Implant Constructs	The acceptance criteria, was complied with both tested specimens and all samples withstood five million cycle without any failure (Test done as per the ASTM F1717-15).	COMPLIES
8	Cranial Fixation system	Static and Fatigue testing of spinal Implant Constructs	The acceptance criteria, was complied with both tested specimens and all samples withstood five million cycle without any failure (Test done as per the ASTM F1717-15).	COMPLIES

Biocompatibility Summary

Sl No.	Test name	Result	Remarks
1	Intra-cutaneous Reactivity Study of Spinal Implants in New Zealand White Rabbits	Non–irritant	PASS
2	13 Weeks Bone Implantation Study of Spinal Implants in New Zealand White Rabbits	Non-reactive/non-irritant	PASS
3	In Vitro Cytotoxicity Test on extracts of Spinal Implants	Non-cytotoxic	PASS
4	Skin Sensitization Study (GPMT) of Spinal Implants in Guinea Pigs	Weak sensitizer (Grade 1)	PASS
5	Acute Systemic Toxicity Study of Spinal Implants in Sprague Dawley Rats	Did not produce any adverse effect	PASS
6	Bacterial Reverse Mutation Assay of Spinal Implants in Salmonella typhimurium tester strains	Non-Mutagenic	PASS
7	In vivo Mammalian Bone Marrow Chromosomal Aberration Test of Spinal Implants in Mice	Did not induce structural chromosomal aberrations	PASS
8	In-Vitro evaluation of Hemolytic Properties of Spinal Implants	Non Hemolytic	PASS

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