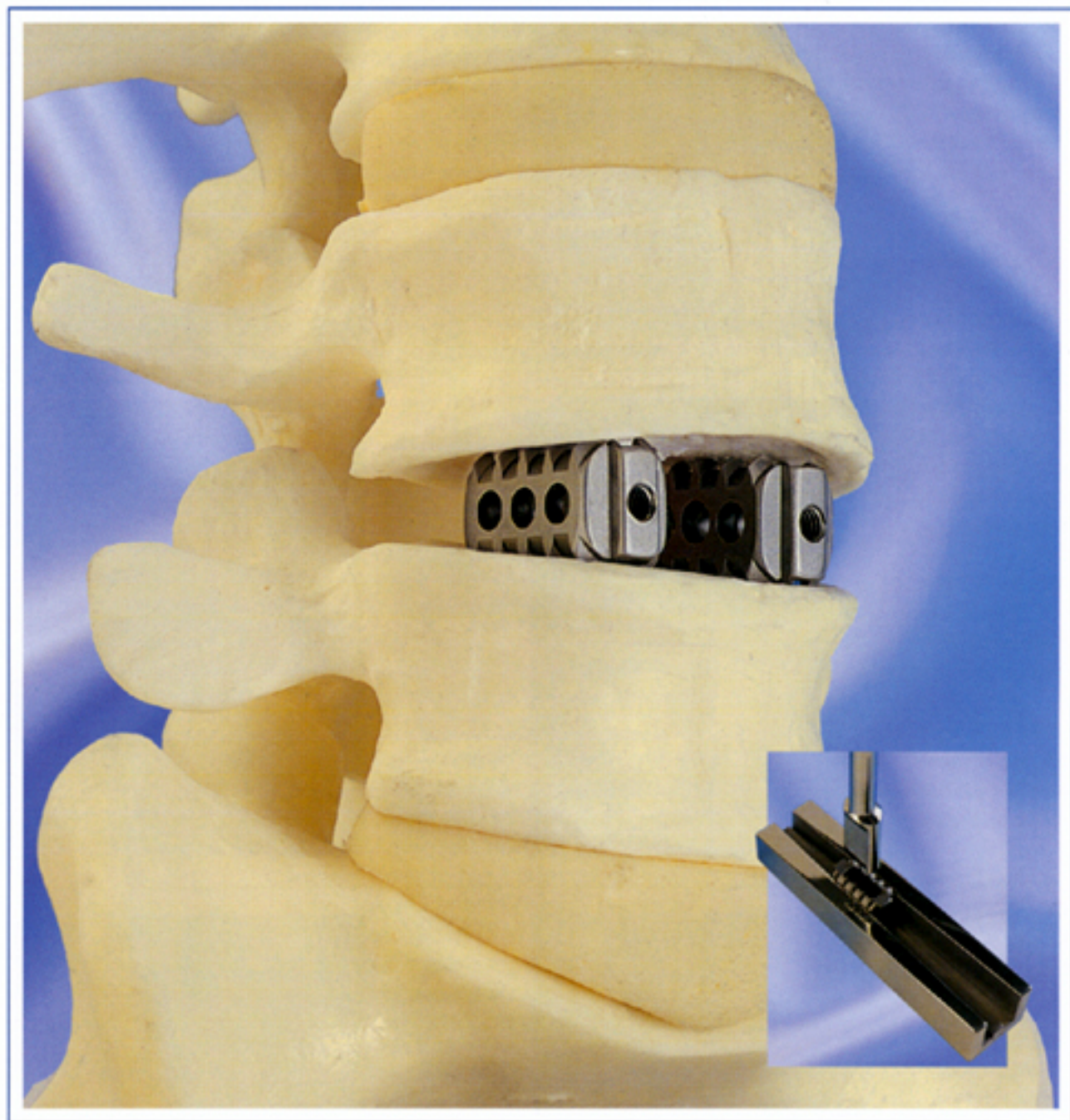


The Rotafix[®] Cage System

PLIF or ALIF

Stable and Anatomic Reconstruction of the Lumbar Spine



Developed in collaboration with Mr S M H Mehdian, Consultant Spinal Surgeon at the Queen's Medical Centre, Nottingham, England.



Corin Care



Corin Medical



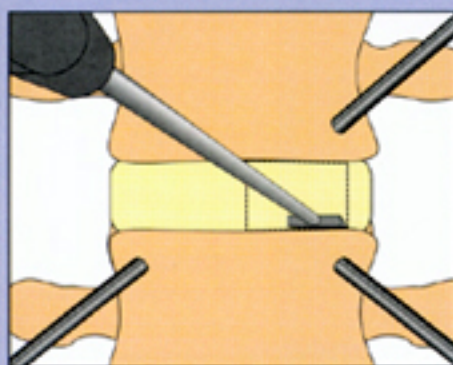
Corin



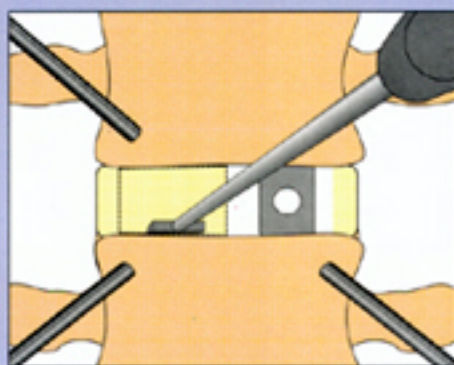
CORIN SPINAL
SYSTEMS
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The Rotafix® Cage System

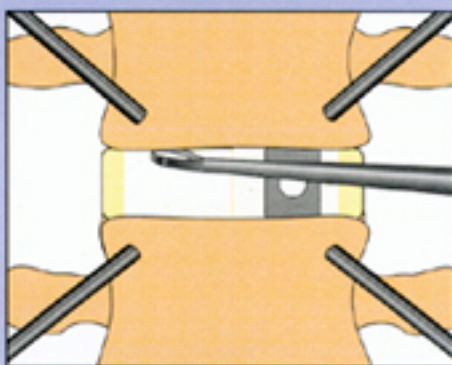
Anterior Lumbar Interbody Fusion Operative Technique



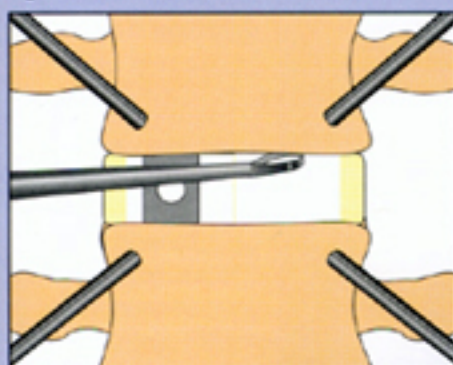
a. Having identified the correct level, visualisation is improved by retracting the soft tissues by inserting Steinmann pins as illustrated. Fine osteotomes are used to create a window in the annulus on the right side.



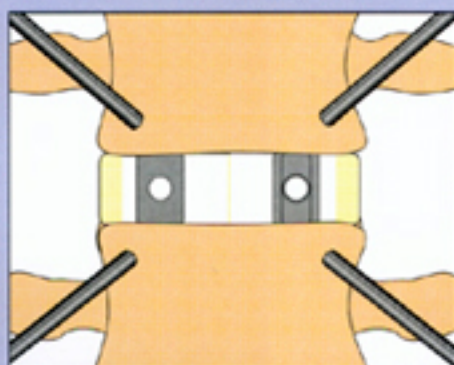
b. After removal of the disc material, a spacer is inserted on the right side in order to prepare the left side disc space. A second window is now created in the annulus on the left side.



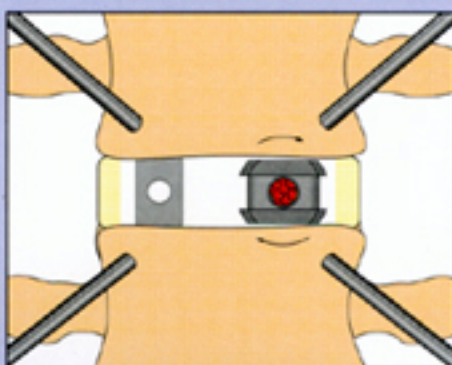
c. The vertebral end plates on the left side are cleaned to expose bleeding bone using a ring or spoon curette.



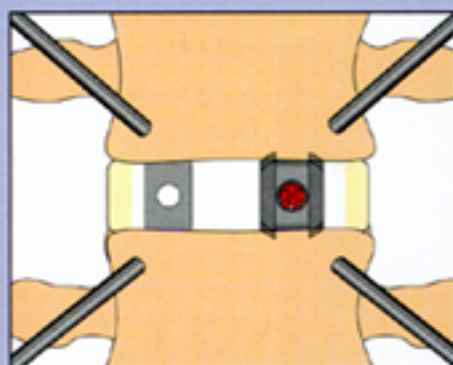
d. A larger spacer is inserted on the left side and the right side spacer removed. The end plates on the right side are cleaned as described in step c.



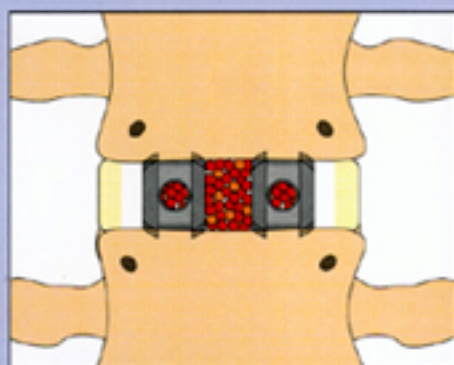
e. Following careful preparation of the end plates to expose bleeding bone for grafting purposes, a trial is inserted on the right side to assess size and rigidity of fit. The cage size used must be the same as the best fitting trial.



f. Cancellous bone graft is compacted into both cages utilising the tamping tool and jig. The cage introducer is attached to the first implant adjacent to the engraved letter A. The cage is then inserted on its side and its depth from the anterior edge of the vertebral body assessed using the 5mm gauge on the end of the introducer. The introducer handle is rotated **CLOCKWISE** through 90° so that the teeth engage with the end plates. An extreme lateral position of the cage must be avoided.



g. After final placement of the cage on the right side, the spacer from the left side is removed. The second cage is then inserted using the same technique as described in step f rotating the cage **ANTI-CLOCKWISE**.



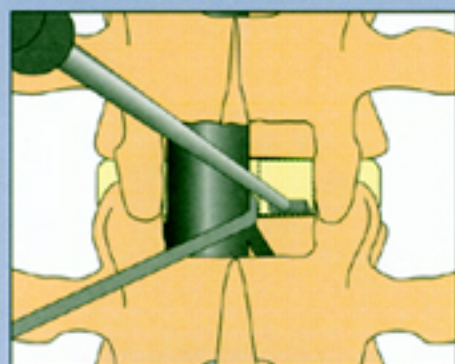
h. With both cages in position any remaining cancellous bone can be used for grafting between the implants. The Steinmann pins can now be removed and a standard closure performed.

ere posterior fixation has been used in conjunction with intervertebral cages.
n conjunction with the Mehdiian Pedicle Screw System.

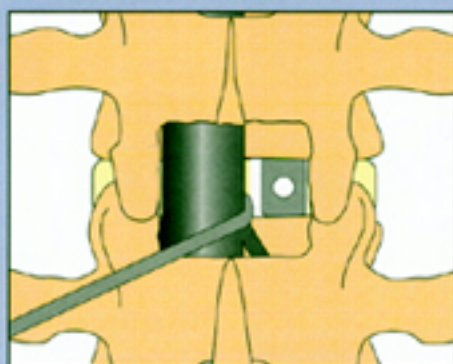
vice, intended use, instrumentation and the knowledge of the surgical techniques required. A full written operative technique is available upon request.

The Rotafix® Cage System

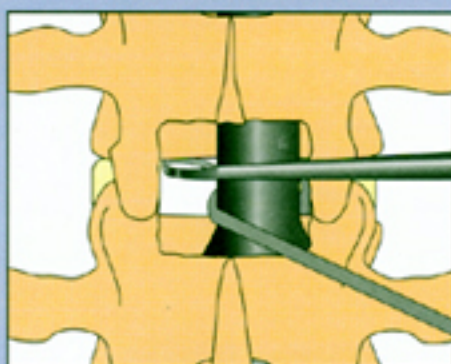
Posterior Lumbar Interbody Fusion Operative Technique



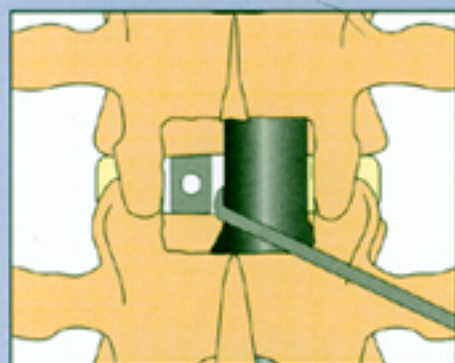
a. Following laminotomy the neural structures are retracted to the mid line. Fine osteotomes are used to create a window in the annulus on the right side.



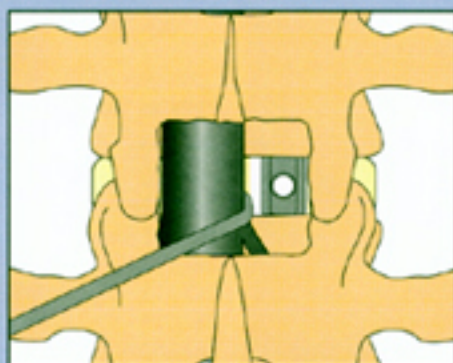
b. After removal of the disc material, a spacer is inserted on the right side in order to prepare the left side disc space.



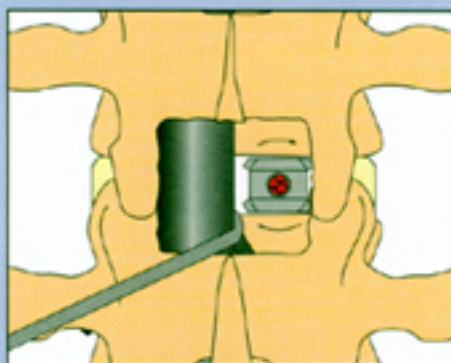
c. The vertebral end plates on the left side are cleaned to expose bleeding bone using a ring or spoon curette.



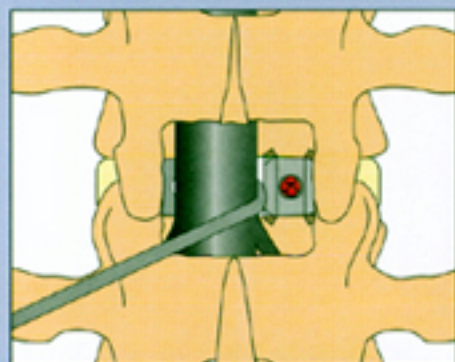
d. A larger spacer is inserted on the left side and the right side spacer removed. The end plates on the right side are cleaned as described in step c.



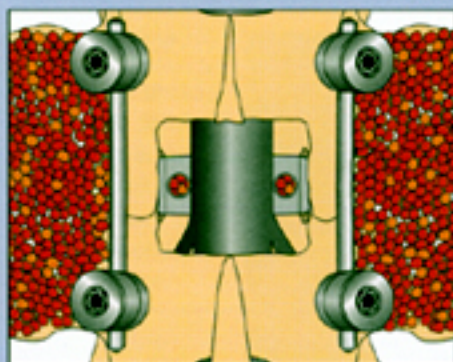
e. Following careful preparation of the end plates to expose bleeding bone for grafting purposes, a trial is inserted on the right side to assess size and rigidity of fit. The cage size used must be the same as the best fitting trial.



f. Cancellous bone graft is compacted into both cages, utilizing the tamping tool and jig. The cage introducer is attached to the first implant adjacent to the engraved letter P. The cage is then inserted on its side. A gauge positioned 5mm from the end of the introducer tip is used to assess the implant's depth from the posterior edge of the vertebral body. The introducer handle is perpendicular to the vertebral column and rotated **CLOCKWISE** through 90°. During rotation the teeth engage with the end plates. An extreme lateral position of the cage must be avoided.



g. After final placement of the cage on the right side, the spacer from the left side is removed. The second cage is then inserted using the same technique as described in step f rotating the cage **ANTI-CLOCKWISE**.



h. With both cages in place, Mehdian Pedicle screws and rods are implanted. Bone graft is placed in both lateral gutters for posterolateral fusion and a standard closure is performed.

Experience has shown that improved clinical results are obtained in patients with

The Rotafix® Cage System is designed to be used in

WARNING: Rotafix Cages must be a tight fit in the lumbar disc space. This device should be implanted only by a physician who is fully conversant with the

The Rotafix® Cage System

THE CONCEPT

Introduction

Interbody cages have been developed over the last few years for Posterior Lumbar Interbody Fusion (PLIF) and Anterior Lumbar Interbody Fusion (ALIF). The theoretical basis for interbody fusion is that it provides mechanical stability and restores disc height to open up the intervertebral foramen.

Threaded cylindrical cages have been used for both ALIF and PLIF indications but the design requires removal of load bearing bone and the parallel section of the implant fails to restore lumbar lordosis. Rectangular cages sit between the end plates of the vertebral body but rely on compressional forces in order to keep them in place.

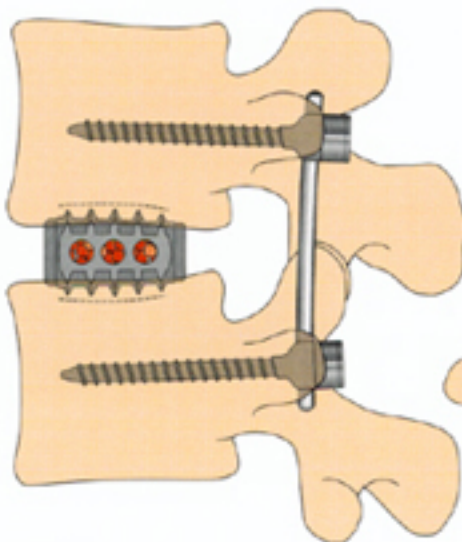
The Rotafix® Cage is designed for both ALIF and PLIF procedures for the treatment of degenerative disorders of the lumbar spine.

The Rotafix® Cage restores lordosis and the teeth interact with the bone to provide excellent stability and resistance to migration.

The Rotafix® Cage is a rigid one piece design, manufactured in MRI compatible titanium alloy.

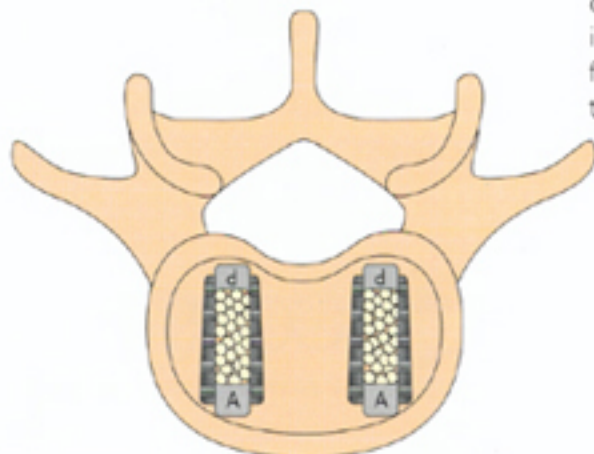
Anatomic

The Rotafix® Cage has 4° of lordosis to assist reconstruction of the natural lumbar anatomy. Contact between the implant and the vertebral body has been optimised by designing a progressive tooth height to conform with the concave bone surface. This feature allows the cage to fully engage with the end plates of the vertebral bodies.



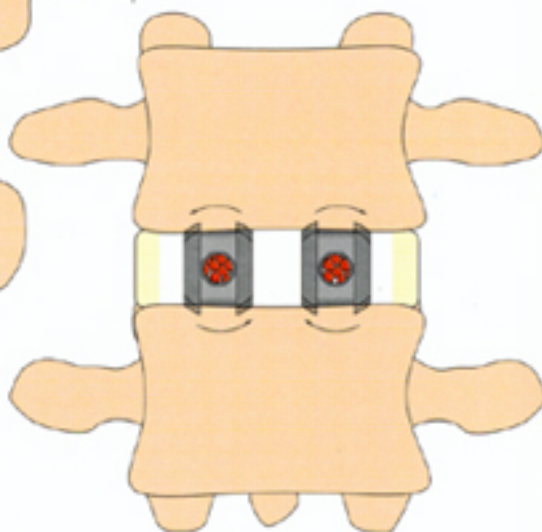
Stable

The immediate 3-dimensional changes in flexibility of the lumbar spine depend upon the cage design. The Rotafix® Cage has been successfully tested in a comparative study at the Queen's Medical Centre in Nottingham (ref 1). The additional stability imparted by the Rotafix® Cage was associated with the teeth engaging with the end plates of the vertebral bodies.



Fusion

The Rotafix® Cage is designed as a conduit for solid bony fusion. Large fragments of bone graft can be compacted into the implant cavity in the direction of loading. As the implant is rotated to its full height the teeth cut into the end plates exposing bleeding bone for grafting purposes. The large cavity within the implant provides a wide area of surface contact between the bone graft and vertebral end plates. Should the surgeon elect to place additional bone graft between the Rotafix® Cage implants, side holes allow excellent area contact for continuity of fusion development.

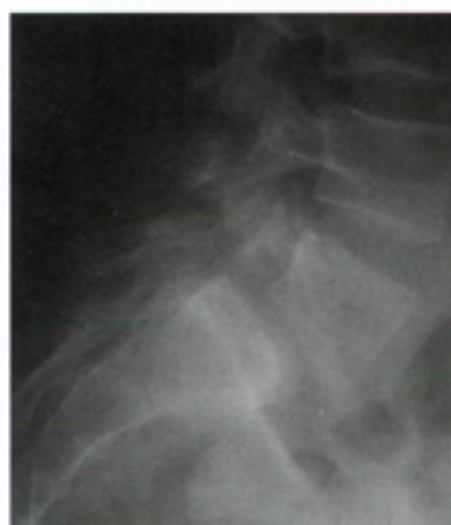


Implant Positioning

The smooth sides of the implant allow easy entry into the intervertebral disc space. The T-bar of the implant introducer controls implant orientation during the rotation manoeuvre. As the implant is rotated the physician can feel the teeth bite into the bone and the initial stability is self-evident.

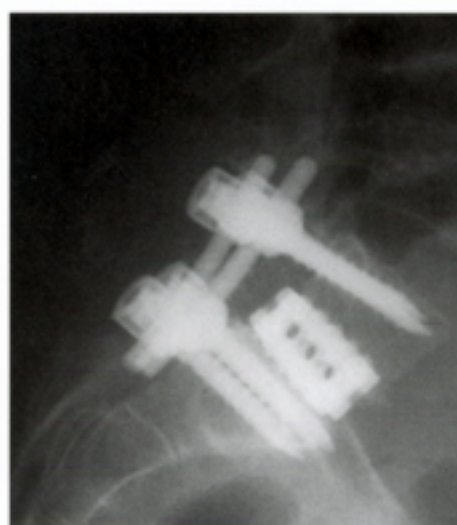
The Rotafix[®] Cage System

CLINICAL RESULTS



1. PRE-OP

A 15 year old patient with grade 2 lytic spondylolisthesis at L5/S1.



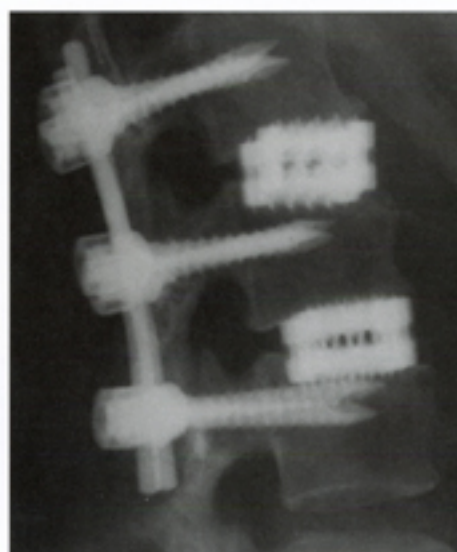
POST-OP

Posterior lumbar interbody fusion using Rotafix cages combined with instrumented posterolateral fusion. Anatomical reduction was achieved and the patient is asymptomatic at 18 months post-op.



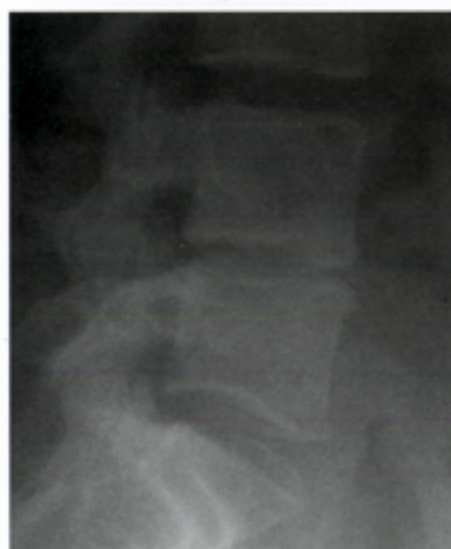
2. PRE-OP

A 25 year old female patient with upper lumbar Scheuermann's disease and with low back pain.



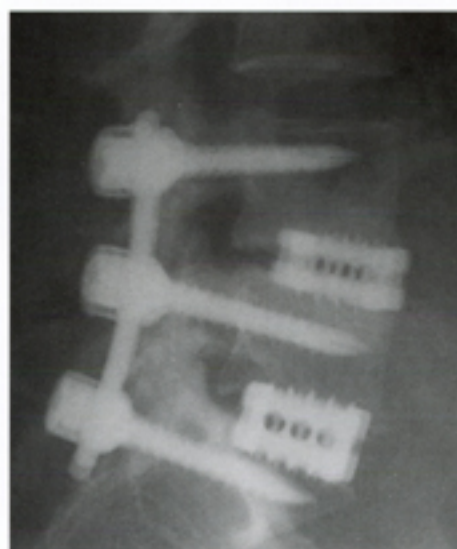
POST-OP

The x-ray shows satisfactory position of the anterior lumbar interbody fusion cages with pedicular fixation. The patient is asymptomatic at 12 months post-op.



3. PRE-OP

A 41 year old female patient with mechanical low back pain, secondary to postdiscectomy syndrome.



POST-OP

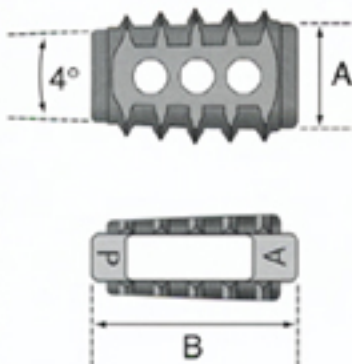
2 level combined anterior and posterior fusion was performed using Rotafix cages and pedicle screws. The patient is pain free and has resumed normal activities.

Note: For ALIF indications, the posterior fusion is conducted first in order to obtain sufficient bone graft from the posterior iliac crest which is used during both posterior and anterior fusion.

The Rotafix® Cage System

Mehdian Rotafix® Implants and Instruments

Part No.	A	B
167.908	8mm	24mm
167.909	9mm	24mm
167.910	10mm	24mm
167.911	11mm	24mm
167.912	12mm	24mm
167.913	13mm	24mm
167.914	14mm	24mm
198.108	8mm	20mm
198.109	9mm	20mm
198.110	10mm	20mm
198.111	11mm	20mm
198.112	12mm	20mm
198.113	13mm	20mm
198.114	14mm	20mm



Technical Support

The surgical technique used with the Rotafix® Spinal Cage System is fully supported by Corin's systematic approach to training.

Instrumentation

A comprehensive range of instruments has been designed as part of the Rotafix® Spinal Cage System. The specification for each instrument is the result of Mr Mehdiari's product development and extensive clinical experience.

Mehdian Rotafix® Spinal Interbody Implants

Part No.	Description	Unit
167.908	Rotafix Spinal Cage 8mm X 24mm Long	
167.909	Rotafix Spinal Cage 9mm X 24mm Long	
167.910	Rotafix Spinal Cage 10mm X 24mm Long	
167.911	Rotafix Spinal Cage 11mm X 24mm Long	
167.912	Rotafix Spinal Cage 12mm X 24mm Long	
167.913	Rotafix Spinal Cage 13mm X 24mm Long	
167.914	Rotafix Spinal Cage 14mm X 24mm Long	
198.108	Rotafix Spinal Cage 8mm X 20mm Long	
198.109	Rotafix Spinal Cage 9mm X 20mm Long	
198.110	Rotafix Spinal Cage 10mm X 20mm Long	
198.111	Rotafix Spinal Cage 11mm X 20mm Long	
198.112	Rotafix Spinal Cage 12mm X 20mm Long	
198.113	Rotafix Spinal Cage 13mm X 20mm Long	
198.114	Rotafix Spinal Cage 14mm X 20mm Long	

Reference 1

Biomechanical Evaluation of immediate stability with rectangular Vs cylindrical interbody cages in stabilisation of the lumbar spine:
 Dr D K Sengupta, Senior Spinal Fellow, Mr S M H Mehdiari, Consultant Orthopaedic Surgeon, Professor R C Mulholland, Special Professor in Orthopaedics and Trauma, Centre for Spinal Studies and Surgery, Queen's Medical Centre, Nottingham, UK
 Presented at ISSLES June 99 and NASS October 99

Mehdian Rotafix® Cage Instruments

Part No.	Description	Unit
267.100	Spacer Introducer (Set of 2)	
267.110	10mm Spacer	
267.111	11mm Spacer	
267.112	12mm Spacer	
267.113	13mm Spacer	
267.114	14mm Spacer	
267.302	Tamping Tool	
267.304	Tamping Jig	
267.032	Open Curette	
267.033	Spoon Curette	
267.041	Narrow Osteotome	
267.042	Wide Osteotome	
267.043	Angled Osteotome	
267.200	Spacer Handle	
267.208	8mm Spacer (Set of 2)	
267.210	10mm Spacer (Set of 2)	
267.212	12mm Spacer (Set of 2)	
267.214	14mm Spacer (Set of 2)	
267.992	Instrument Tray for Set 267.999	
267.999	Standard Rotafix Cage Instrument Set	



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