LDR

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Mobi™

MOBILE BEARING ARTIFICIAL DISC TECHNOLOGY

Mobi-C®

CERVICAL ARTIFICIAL DISC

Mobidisc® (Mobi-L™)

LUMBAR ARTIFICIAL DISC

Mobi™

MOBILE BEARING ARTIFICIAL DISC TECHNOLOGY

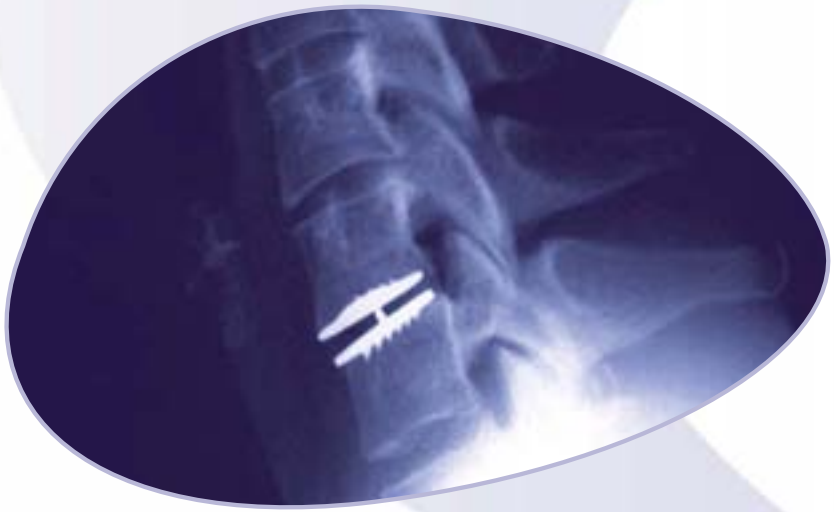
The controlled mobility of the mobile insert is the foundation of the Mobi artificial disc technology.
This platform of second generation artificial discs was designed by a team of surgeons specializing in spinal arthroplasty.

Mobi-C®

Mobidisc® (Mobi-L™)

CONTROLLED MOBILITY

Encourages restoration and respect of the instantaneous axes of rotation for a return to physiological mobility of the intervertebral disc.
Reduces the stresses on the posterior facet joints.



The reproducible surgical technique is assured by simple and safe instrumentation, notably by millimetric adjustment of implant positioning.

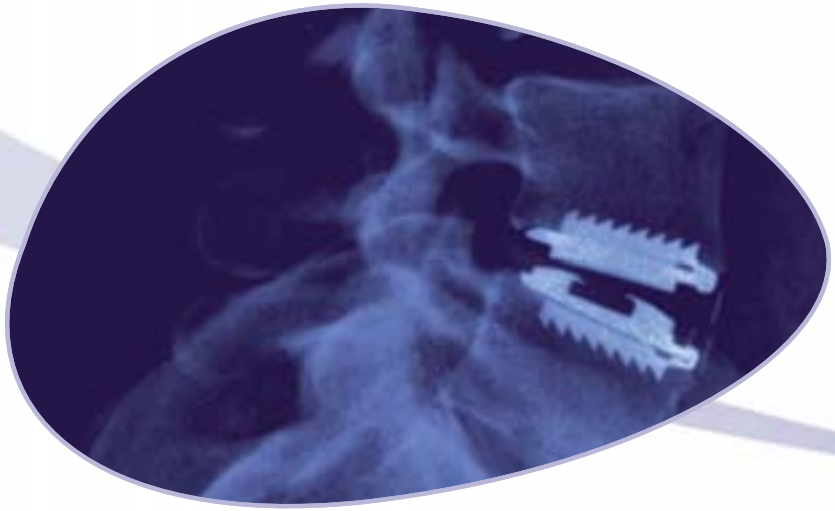
Maintenance of intervertebral height during implantation provides for optimal placement of the implant without trauma to the bone.

These advantages allow simple and safe implantation while reducing the operative time.

The reduction of stresses on the bone to implant interface allows for less invasive anchoring on the superior and inferior endplates.

The large range of implant sizes optimizes the implant coverage, thereby increasing the surface contact area on the vertebral plate, reducing the risk of subsidence.

In order to respond to the anatomical requirements of the vertebral segment, the Mobi system offers the lowest total implant height on the market.



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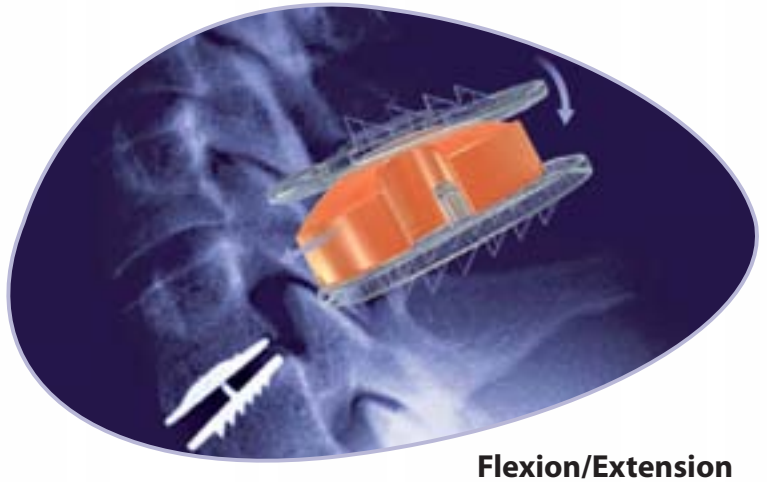
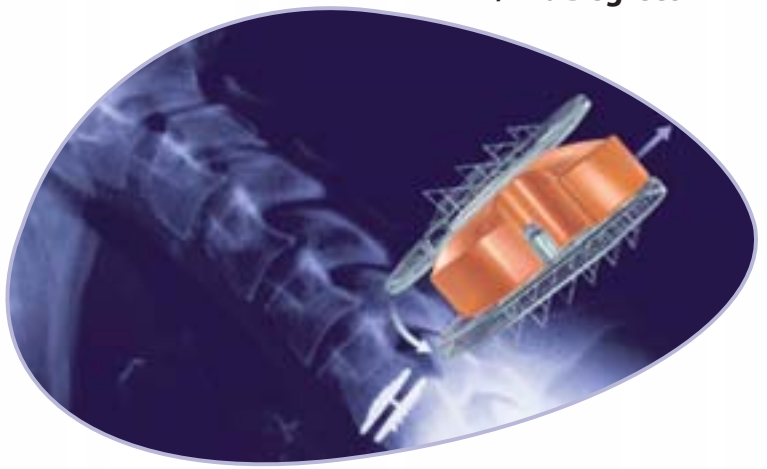
Mobi-C®

Restore Mobility

- Insert mobility provides six degrees of freedom and is self-controlled by the compression of the implant during flexion/extension and side bending.
- Two lateral stops on the inferior plate help to control mobility of the insert while preventing expulsion.



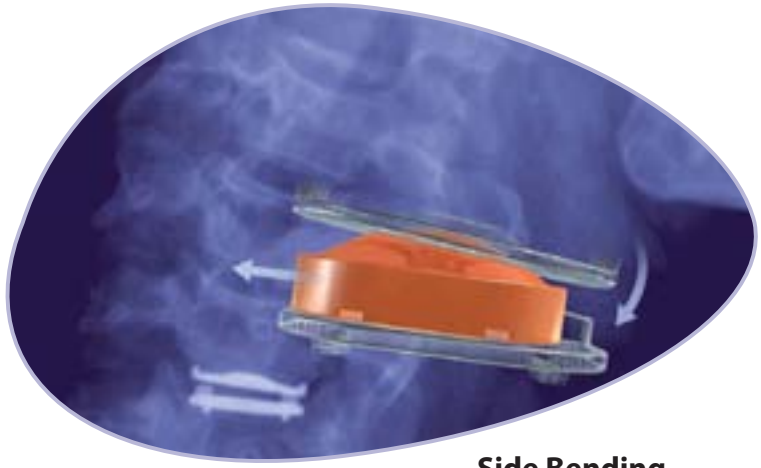
Flexion/Extension +/- 10 Degrees



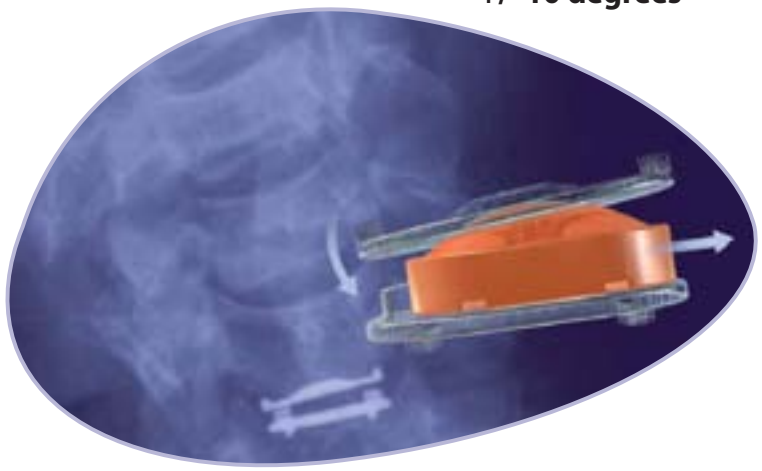
Design encourages physiologic movement - Facilitates restoration of height and lordosis

Mobility of insert decreases stress transmission on the bone/implant interface which in turn reduces stress transfer to the posterior facets.

- Insert mobility, including both translation and rotation, supports physiological movements.
- Mobility is self-controlled by the physiological forces applied to the insert during Flexion/ Extension and Side Bending.
- Cobalt chrome and polyethylene articulation provide optimal wear characteristics.



Side Bending
+/- 10 degrees



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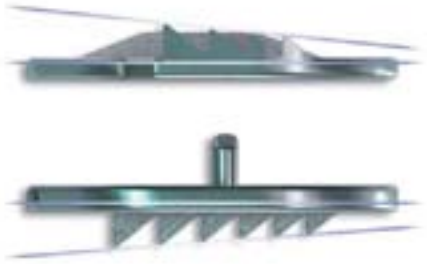
Provide Control

- Captured insert design resists expulsion.
- Design preserves the Instantaneous Axis of Rotation (IAR) allowing more natural physiological movement of the treated segment.

Secure yet conservative implant to bone fixation

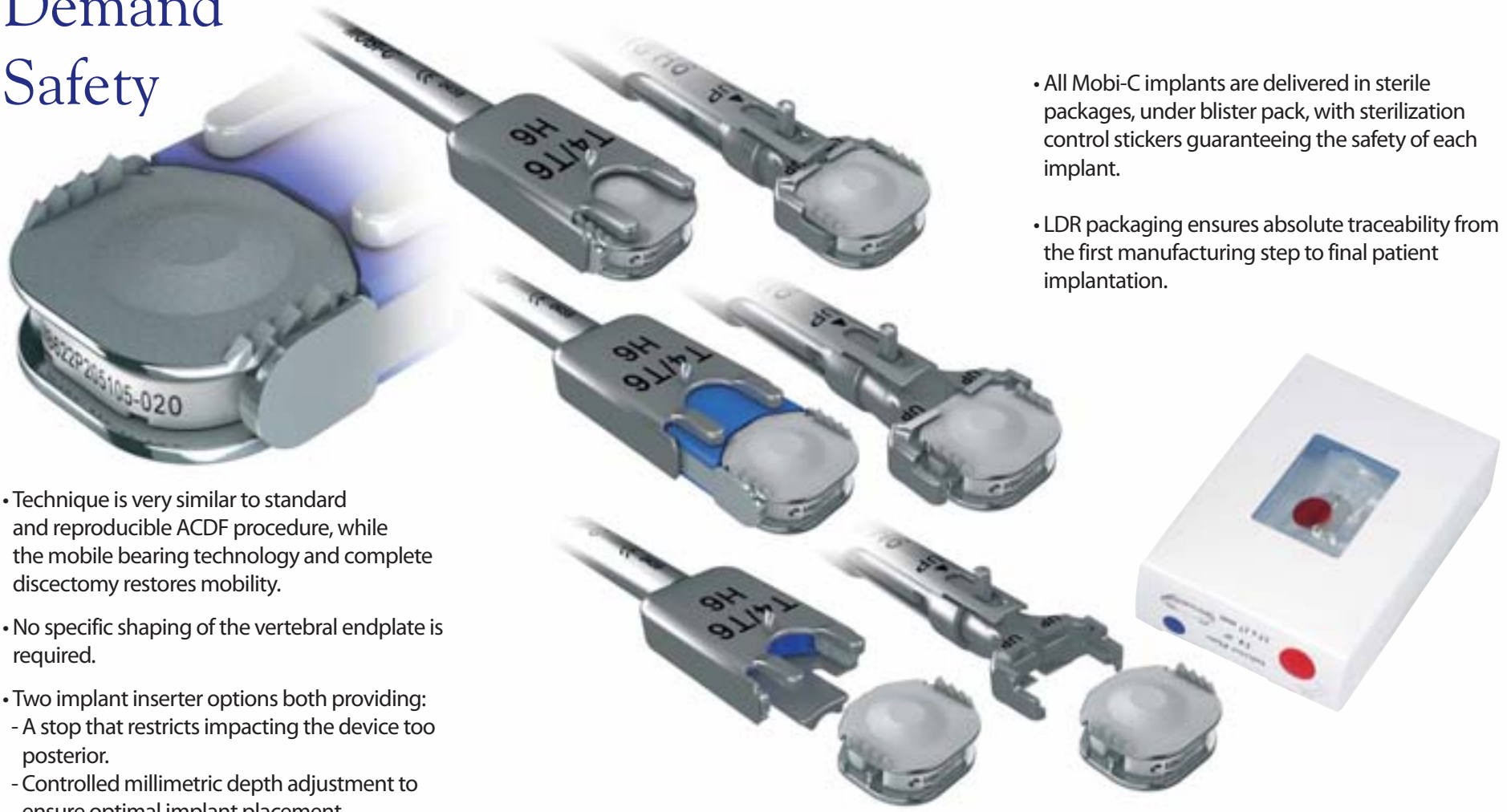


- Thin Cobalt Chrome endplates feature a roughened titanium surface and hydroxyapatite coating to encourage bony on-growth for long term stability.
- Contoured superior dome corresponds to concave vertebral endplate for intimate implant to bone contact.
- The inclined shape of the lateral teeth facilitate the introduction of the device while ensuring a reliable anchorage to the dense peripheral vertebral endplate.

- The contact area is optimized to provide improved lubrication of the articulation and is perfectly balanced between the flat and spherical surfaces.
- Four overall footprint sizes and insert height options for a total implant height of of 4.5, 5, 6 and 7mm allow for optimal anatomic congruency.

- Overall design allows for vertebral endplate conservation which safeguards anatomy of adjacent levels making it possible to perform an arthroplasty adjacent to a segmental fusion.

Demand Safety



- Technique is very similar to standard and reproducible ACDF procedure, while the mobile bearing technology and complete discectomy restores mobility.
- No specific shaping of the vertebral endplate is required.
- Two implant inserter options both providing:
  - A stop that restricts impacting the device too posterior.
  - Controlled millimetric depth adjustment to ensure optimal implant placement.
  - Incremental depth adjustment after initial insertion.

- All Mobi-C implants are delivered in sterile packages, under blister pack, with sterilization control stickers guaranteeing the safety of each implant.
- LDR packaging ensures absolute traceability from the first manufacturing step to final patient implantation.

- No over-distraction.
- One step implant insertion.
- Minimal invasion of vertebral endplates.
- Self-guided prosthesis.
- Very intuitive design.

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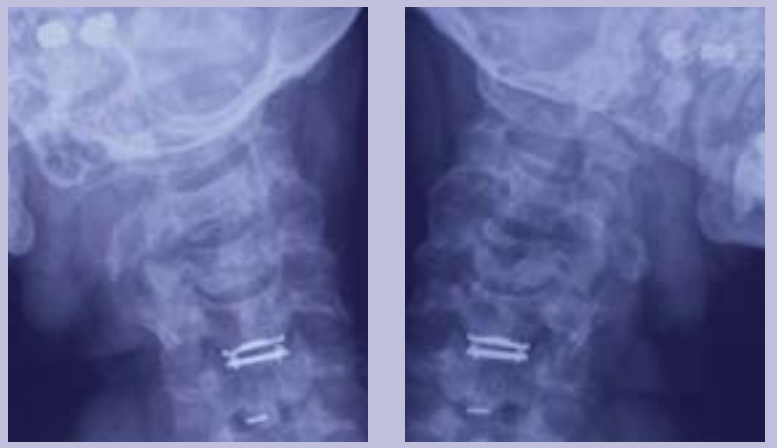
Mobi-C®

Expect Results

First implanted in November 2004, over 5000 Mobi-C arthroplasties were completed worldwide in the first three years of use. Follow-up of 275 patients with average follow-up of 17 months indicate exceptional results with 91.2% of patients being "Satisfied" or "Very Satisfied" with the surgery. 96.6% of the patients reported that they would undergo the surgery again.

Natural Design = Natural Motion

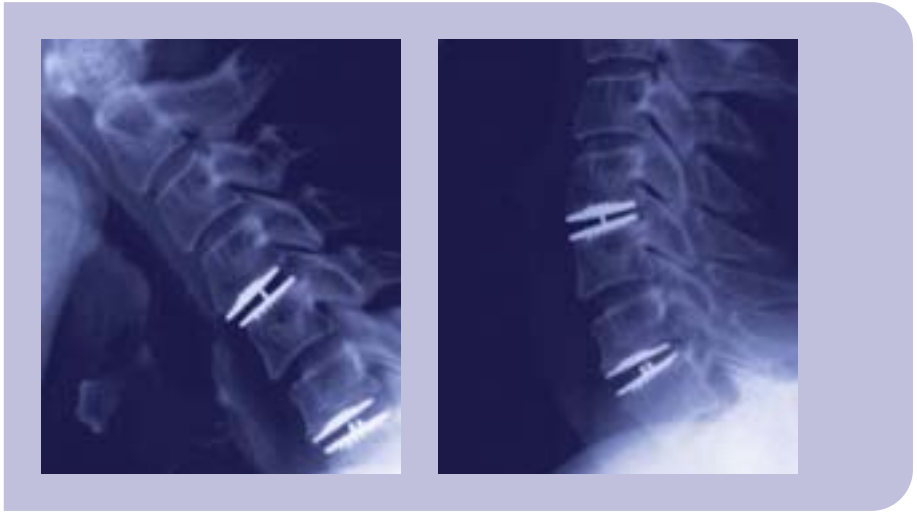


Natural movement is the result of our conservative implantation technique, superior device size range and our unique, specific to cervical, engineering specifications. All these features work together to replicate just the right amount of motion and constraint.

Clinical results summary

	Preoperative average	2-Year average	
VAS (Arm)	70.9	25.2	45.7 point average improvement at 2 years 75% of patients experienced an improvement of their radicular VAS score of at least 20 points
VAS (Neck)	61.3	21.5	39.8 point average improvement at 2 years 78% of patients experienced an improvement of their cervical VAS score of at least 20 points
NDI	49.9%	26.6%	23.3% average improvement at 2 years 64% of patients experienced an improvement of their NDI score of at least 15 points
SF-36 (PCS)	37.3	48.5	11.3 point average improvement at 2 years for the Physical Component Scale
SF-36 (MCS)	35.2	48.2	13.0 point average improvement at 2 years for the Mental Component Scale

The table above summarizes the results from a multicenter study on 275 patients with an average follow-up of 17.3 months. This includes 228 1-Level, 46 2-Level and 3 cases of 3-Level arthroplasty.



Range of Motion Analysis

Average ROM = 8.8 +/- 0.7° at 2 years
C5-C6 : mean ROM = 9.2° at 2 years
C6-C7 : mean ROM = 9° at 2 years

Clinical experience with the Mobi-C has proven that our fine balance of motion and constraint coupled with our stern requirement for safety has produced a top of the line, next generation disc replacement with superior straight forward instrumentation.

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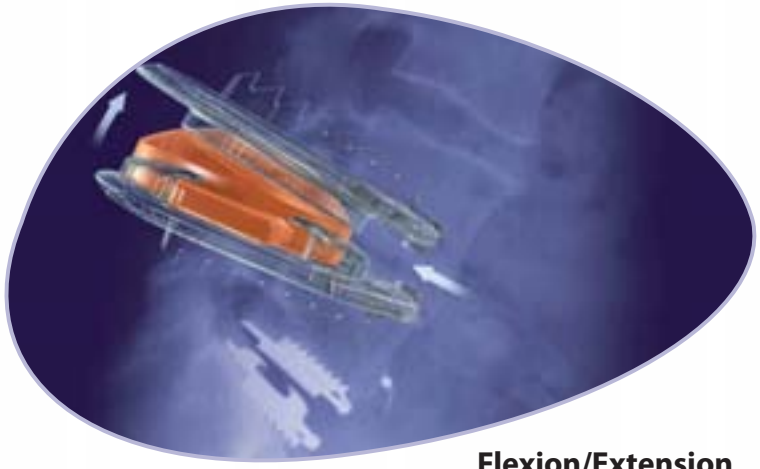
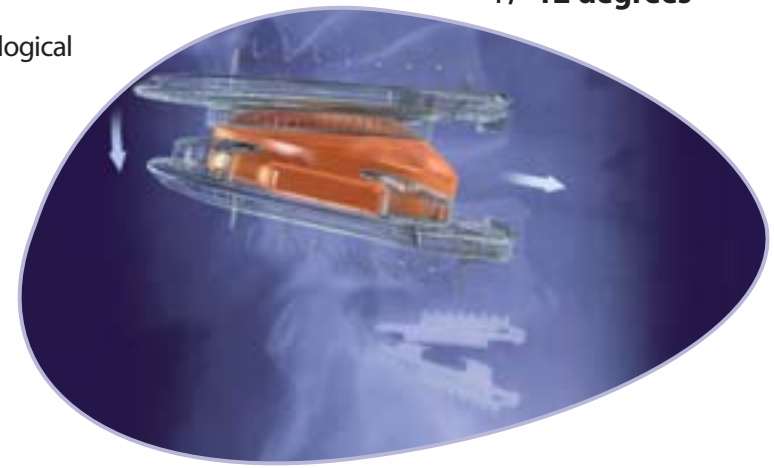
Mobidisc® (Mobi-L™)

Restore Mobility

- Cobalt chrome and polyethylene articulation provide optimal wear characteristics; while the insert mobility supports six degrees of freedom for the device.
- Mobility is self-controlled by the physiological forces applied to the insert during Flexion/Extension and Side Bending.
- Four peripheral stops control the mobility of the insert in all axes.



Flexion/Extension
+/- 12 degrees



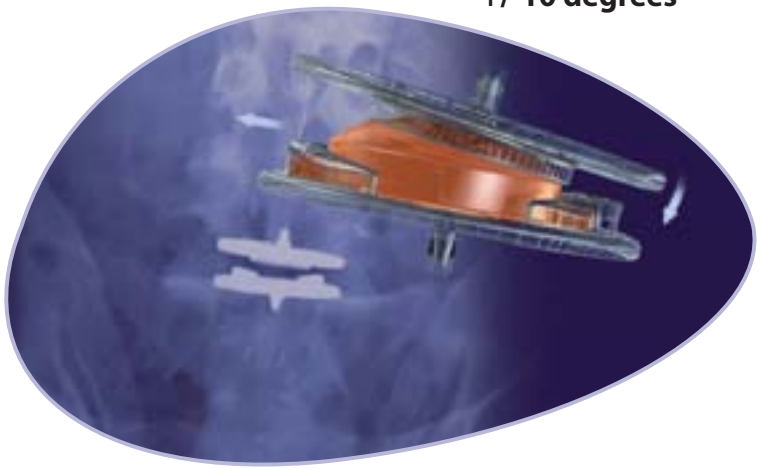
Instantaneous Axis of Rotation

The controlled mobility respects and adapts to the Instantaneous Axis of Rotation (IAR). This reduces the bone to implant forces ensuring stable fixation of the device and minimizes the stresses transmitted to the articular facets.

Physiological mobility

- The encouragement of natural motion while respecting constraint reduces strain on the posterior articular facet joints.
- The mobile bearing design reduces the stresses on the bone/implant interface, which allows for less invasive anchoring while providing optimal primary fixation.
- More natural biomechanical load sharing may increase the life of the implant.

Side Bending +/-10 degrees



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Mobidisc® (Mobi-L™)

Provide Control

- The mobile insert is free to translate and rotate on the inferior plate between the four peripheral stops which control mobility and prevent expulsion.

- The contact surface is optimized and perfectly balanced between the flat and spherical surfaces.
- The contact area is optimized to provide improved lubrication for the articulation; optimizing the wear characteristics between the Cobalt Chrome and Polyethylene.

- Modular keels are placed on implant endplates prior to disc assembly for implant to bone fixation.
- The pure Titanium outer surface with hydroxyapatite coating encourages bony on-growth for secondary fixation and long term stability.

- Optimal patient anatomy matching with nine implant foot print sizes available.

- Five insert height options represent an overall implant height range of 10mm to 14mm.

- Each plate is offered in three lordotic options 0°, 5° and 10°.

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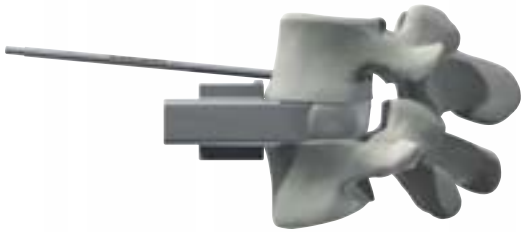
Mobidisc® (Mobi-L™)

Demand
Safety

Chamfers on the edges of the superior and inferior endplates help to ease insertion and help to ensure proper endplate conformity.

- Technique is very similar to standard and reproducible ALIF procedure, while the mobile bearing technology and complete discectomy restores mobility.

- No over distraction.
- Implantation "Guide" secures surgical approach by protecting the large blood vessels while maintaining the height during insertion.



- One-step implantation.
- Minimal invasion of vertebral endplates.
- Self-guided prosthesis.

Mobidisc was first implanted in November 2003. Since then, over 2000 arthroplasties were completed worldwide prior to 2008. Follow-up of approximately 300 patients (330 implants) with a average follow-up of 22.8 months indicates excellent results with 88% of patients with two years follow-up indicating "Satisfied" or "Very Satisfied" with the surgery.

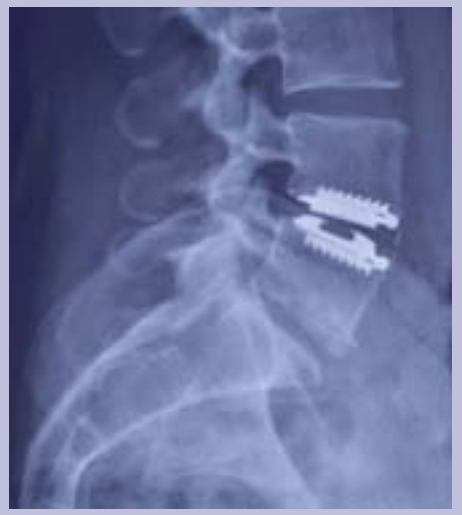
Clinical results summary

	Preoperative average	2-Year average	
VAS (Back)	6.4	2.3	4.1 point average improvement at 2 years 83.6% of patients have at least 2 points improvement at 2 years *vs* pre-op
VAS (Leg)	3.9	2.0	Mean improvement after 2 years : 1.6cm in the right leg 2.2cm in the left leg
Oswestry	49.4%	21.4%	28% average improvement after 2 years 75.7% of the patients have at least 15 point improvement at 2 years *vs* pre-op
SF-36 (PCS)	34.2	47.7	13.5 point average improvement at 2 years for the Physical Component Scale
SF-36 (MCS)	31.4	42.7	11.3 point average improvement at 2 years for the Mental Component Scale

Range of motion analysis

Mean ±SEM	Pre-op	1 year
All levels	4.2 ± 0.4	8.0 ±0.5
L5-S1	3.6 ± 0.5	8.1 ± 0.8
L4-L5	5.3 ± 0.6	7.8 ± 0.9

ROM ≥ 2° : 84.1% of the devices
ROM ≥ 5° : 64.7% of the devices



18 months post-operative

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