ROTAIO®
Cervical Disc Prosthesis

Implantable like a cage – moves like a disc

CLINIC
Nodding, shaking one’s head, looking up at the sky – a cervical disc prosthesis should allow one to enjoy the full range of life’s activities. This is one reason why the use of disc replacements that preserve movement has become increasingly established in recent years as an alternative to fusion (ACDF). Another reason is that, in spite of good clinical results with ACDF, there are indications that conventional ACDF may lead to increased stress on the adjacent segments with corresponding adjacent-segment degeneration.1,2

But merely preserving movement in the decompressed segment is not enough: Postoperative neck pain 3 and disproportionate stresses on the facet joints 4 have been described repeatedly following cervical disc arthroplasty. To achieve a high quality of movement, disc prostheses must therefore replicate the natural pattern of movement of a disc as precisely as possible. Thus, ROTAIO offers not only rotation, flexion/extension and lateral flexion, but also the possibility of uncoupled translation. In this way, ROTAIO optimally reproduces the natural centre of rotation and thereby provides physiological, facet-guided, segmental movement.

Although this may make the kinematics of ROTAIO highly complex, its surgical implantation nevertheless remains simple. Employing the standard Smith–Robinson technique, ROTAIO is implanted «in one piece» with no additional preparative steps. The posteriorly-oriented prosthesis design enables it to be securely positioned anterior to the posterior wall of the vertebral body and makes the implantation of ROTAIO comparable with that of a cage.

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Director Neurosurgery, University Hospital Innsbruck

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Physiological Mobility

Anatomical range of motion

The range of motion should be defined by the anatomical structures and not by the disc prosthesis. For this reason ROTAIO completely restores the physiological range of motion.

Flexion/Extension
C5-C6: 20°
ROTAIO: 20°
(ROTAIO 5 mm: 18°)

Axial rotation
C5-C6: 14°
ROTAIO: 360°

Lateral bending
C5-C6: 16°
ROTAIO: 16°

Due to the posteriorly oriented centre of rotation, the optimal position of the ROTAIO disc prosthesis is about 1–2 mm anterior to the posterior wall of the vertebral body, thus protecting the spinal cord from possible injury.

Centres of rotation of the cervical spine

Physiological Mobility

Controlled translation

The centre of rotation of the ROTAIO disc prosthesis adapts to the natural instantaneous centre of rotation depending on the movement performed. This is achieved by the ‘controlled translation’, in which the translation is uncoupled from flexion, extension and rotation movements so that it is directly controlled by the facet joints. This results in optimal replication of physiological movement. Thus, the facet joints are preserved, gaping of the joints is avoided.

Translation values of the cervical spine

<table>
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<tr>
<th>Movement</th>
<th>Value</th>
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<tr>
<td>Flexion/Extension (combined)</td>
<td>2.69 mm</td>
</tr>
<tr>
<td>Lateral bending (right)</td>
<td>0.48 mm</td>
</tr>
<tr>
<td>Axial rotation (left)</td>
<td>0.39 mm</td>
</tr>
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</table>

ROTAIO: Comparison with conventional prostheses

ROTAIO – Facet-guided movement, no abnormal gaping of the joints

Abnormal gaping of the facet joints with existing “ball-and-socket” prosthesis designs

Safety-first implant design

Long-term stability

Similar to our RABEA cage, which has an excellent clinical history spanning over 15 years due to its high primary stability, the fixation of the ROTAIO disc prosthesis is achieved by toothed end-plates which slope away posteriorly to protect the posterior walls of the vertebral body. This produces secure primary stabilisation of the segment while at the same time requiring minimal bone resection.

ROTAIO has a specially roughened surface to improve bony ingrowth. Various studies have shown that the adhesion of proteins to implants and their subsequent colonisation by bone cells (osteoblasts, osteoclasts etc.) is fundamentally influenced by the roughness of the material surface. The activity of osteoblasts is particularly increased if the roughness (Ra) is within the range from 1 to 7 μm. In various tests with blasted titanium surfaces, it was also demonstrated that the greater roughness achieved by this means is also accompanied by improved osteointegration. This was demonstrated both in animal experiments, and in studies on artificial hip replacements installed without cement and also in the field of dental implants.⁸

Four different implant footprints enable the prosthesis to achieve an optimal fit on different vertebral bodies. Maximum coverage of the vertebral body endplates is achieved, helping to prevent undesirable fusion of the segment.

The rectangular geometry of the ROTAIO facilitates its positioning on the strong lateral bony cortex, thus ensuring secure seating of the prosthesis and counteracting subsidence of the implant.

A cobalt-chrome-molybdenum alloy (CoCrMo) was selected for the bearing surfaces of the ROTAIO disc prosthesis. This metal is characterised by very good biomechanical and tribological properties. Abrasion was further reduced by a special surface finishing. In a wear test under axial loading and physiological kinematics the wear debris in volume was measured. For ROTAIO the average wear volume was very low with 1.29 mm³ after 10 million cycles (equivalent to approx. 80 years of everyday loading). In addition, no signs of functional fatigue were detectable.

### Product / bearing surfaces (lumbar prostheses)

<table>
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<tr>
<th>Material</th>
<th>Wear Volume (mm³) at 10 million simulated cycles</th>
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<tr>
<td>Medtronic A-MAV metal – metal</td>
<td>4.30</td>
</tr>
<tr>
<td>DePuy Charité metal – UHMWPE</td>
<td>208.00</td>
</tr>
<tr>
<td>Synthes ProDisc metal – UHMWPE</td>
<td>188.00</td>
</tr>
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### Safe handling

One-piece design, toothed endplates as used in spinal cages, posterior centre of rotation to position the prosthesis anterior to the rear wall of the vertebral body – in ROTAIO attention was paid to the tiniest detail for the sake of simple and safe handling. But this wasn’t only restricted to the implant itself: all relevant instruments are equipped with a variable depth stop to enable the optimal insertion depth for the patient’s anatomy leaving the spinal cord safely protected from possible injury.

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10 Quelle: ASTM F2624
Proven mechanics

Life is the hardest test. Everyday activities, sport, extreme stresses such as might occur during a fall – the cervical spine is exposed to constantly varying demands in daily life. A disc prosthesis must be equally capable of reliably meeting these requirements.

Therefore, ROTAIO has undergone an exceptionally extensive series of cyclic, dynamic and static tests. The studies required for registration were supplemented by further tests to understand the performance of the ROTAIO disc prosthesis as much as possible. These included loading conditions based on the actual loads on the cervical spine in order to draw direct conclusions about the mechanical safety of ROTAIO in the patient.

Cyclic fatigue tests

The aim of these tests is to duplicate the repetitive loads on the cervical spine in everyday life in order to simulate fatigue effects on the implant. The performance of the ROTAIO disc prosthesis in these tests lies significantly above daily loading conditions of the cervical spine. ROTAIO is even able to withstand ultimate loads.

The ROTAIO disc prosthesis withstood the applied stresses in a specially developed shear test without suffering a critical failure. In real life these loads represent about 80 years of above-average daily stresses and followed by 50,000 rear-end car collisions and 20,000 loading cycles that would result in injuries to the cervical spine if encountered in actual life.

Dynamic impulse test

In a fall or an accident large forces may occur suddenly on the cervical spine. The aim of this test is to simulate these momentary forces. The results show that the mechanical stability of the ROTAIO prosthesis is significantly above the injury threshold of a cervical spine segment.

Static tests

These tests cannot be directly related to everyday life on account of the very slow application of loads. They nevertheless enable one to quantify the essential mechanical properties of ROTAIO.

In addition to a large number of static tests which demonstrate the mechanical stability of the ROTAIO disc prosthesis, special attention was again paid to the fixation of the bearing unit in the endplates.

In the static torsion test, under worst-case conditions, the ROTAIO disc prosthesis withstood a torsional moment of 0.9 Nm without loosening. As the prosthesis is freely rotatable, it theoretically transmits no torsional moment. However, the cyclic test showed that this is not absolutely true: Small torsional moments, caused by friction, are indeed transmitted. After the simulated stress tests were completed, the bearing units were still securely fixed in the endplates.

We will be pleased to provide the detailed test records on request.

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**Proven Surgical Technique**

The implantation of ROTAIO is very similar to that of a cage, because it consists of only one component. Supplied sterile and pre-mounted on an insertion bracket, it is ready for immediate use, so no time-consuming assembly steps are needed during the operation. Further, ROTAIO requires no additional preparatory steps such as required for fins and keels. The instrument set is also clearly laid out, and the surgical technique is well established: The implantation of ROTAIO can be done according to the Smith-Robinson technique just as if it were a cage. In spite of its replicating the highly complex kinematics, our system is simple and excellent value for money.

**Implants**

4 prosthesis footprints and 3 heights:

- 5 mm
- 6 mm
- 7 mm
- 15x13 mm
- 17x13 mm
- 17x15 mm
- 19x15 mm

**Instruments**

- **Inserter with depth stop** for implanting the ROTAIO disc prosthesis
- **Pindriver with Orientation Pin** for vertical midline identification
- **Trials** for determining the height
- **Footprint templates** for determining the footprint
NOTICE:
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Cervical VBR