

PERSONALIZED MIS SOLUTIONS

The MySpine MC Experience

Redefining better in orthopaedics and spine surgery

"Our vision to improve the care and well-being of orthopaedic and spine surgery patients around the world stems from both experience and passion.

Our surgical innovations and surgeon education programs focus on getting patients back to their healthy, active lifestyles, without forgetting both the environmental and societal impacts of the products we create"

Francesco Siccardi

CEO



With the **patient** in mind, our
innovations are designed to become
part of their **life experience**



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Innovation is of paramount importance at Medacta

It is the **foundation of all our projects** and the basis of our growth strategy today and tomorrow. Personalized solutions, the primary focus of our innovation, are based on three pillars: a **complete and profound knowledge of human nature**, the use of cutting-edge technologies such as **3D printing**, and **continuous investments in long-term R&D and in medical education**, collaborating with surgeons and universities worldwide.

Innovation is expressed in the originality of our **minimally invasive** and **personalized surgical techniques** and our internationally patented implants, devices and surgery execution tools.



From **Minimally Invasive** Surgery
to **Personalized Medicine**
and beyond

MySpine MC

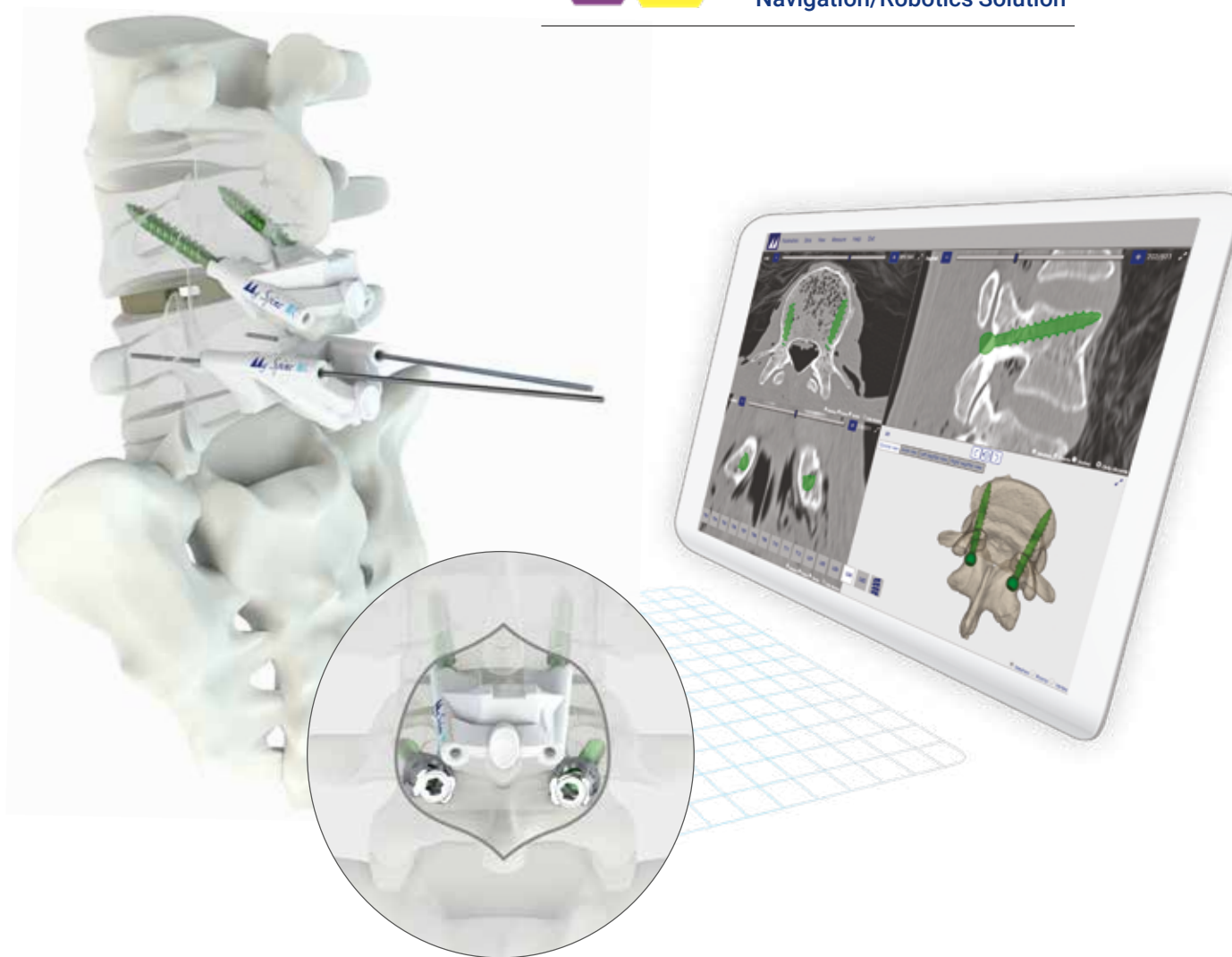
Personalized MIS solution

MySpine MC is a **3D printed patient matched solution** in the **midline cortical approach**. Posterior lumbar fusion is driven in a **minimally invasive**, muscle sparing way, enabling shorter operating times^[18] and a substantial **reduction of both radiation exposure^[16] and costs^[18]** compared with CT based navigation systems.



2019 AWARD

Medacta's MySpine MC Wins
MedTech Breakthrough Award
for Orthopaedics and Surgical
Innovation as **"Best Healthcare
Navigation/Robotics Solution"**

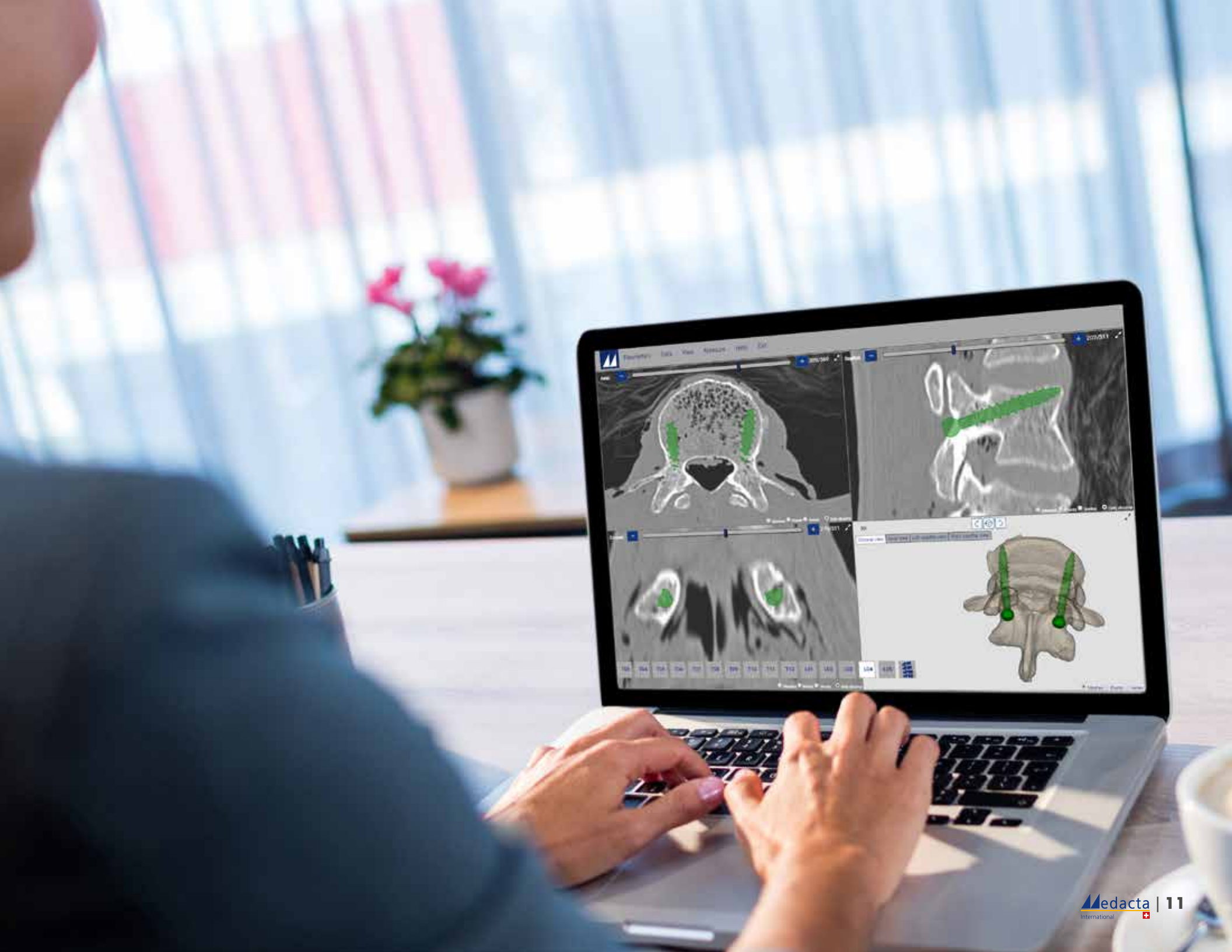


3D Preoperative Planning

Personalized by the surgeon... for the Patient

Thanks to this **accurate** tool the surgeon can optimize screws parameters, entry points and trajectories^[14], **avoiding potential intraoperative complications** for the patient, such as pedicle fractures and neurovascular injuries^[14,16].





Personalized Technique

MySpine MC entry points and trajectories are customized through pre-op trajectory management to enable the use of longer screws and larger diameters vs. free hand CBT, and are comparable to the conventional technique.

3D PRE-OPERATIVE PLAN



SURGERY



The final pedicle screw position reflects the pre-operative plan

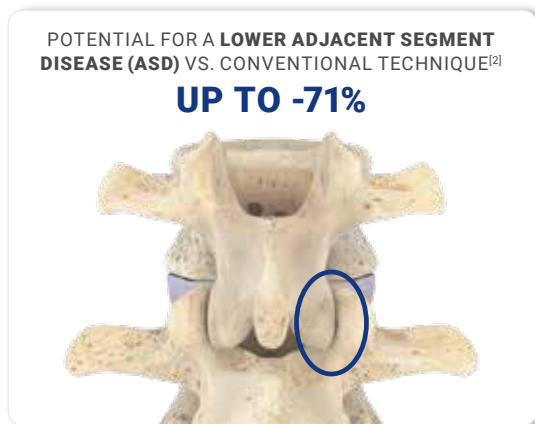
Minimally invasive



Posterior lumbar fusion is driven in a minimally invasive, muscle sparing way, allowing:

- Enhanced muscle preservation^[17]
- Reduced blood loss^[17]

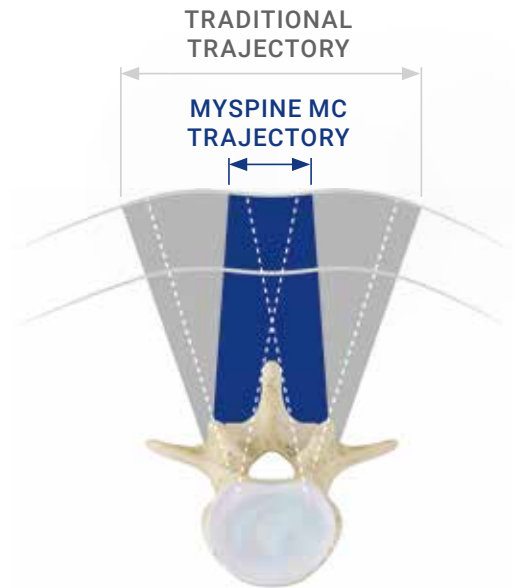
Compared with traditional open technique.



The benefits for the patient are:

- Supradjacent facet preservation^[1,17]
- Lower adjacent segment disease^[2]
- Faster discharge^[16]
- Less pain^[17]
- Fast patient recovery^[16,17]

Compared with traditional open technique.



Personalized around the patient

Following the pre-op trajectory a 3D patient matched guide is designed to match the patient's anatomy. This navigated tool provides **accurate intra-operative guidance** for **safe screw positioning**^[14] potentially **reducing the need of fluoroscopy**^[15].

3D PATIENT ANATOMY



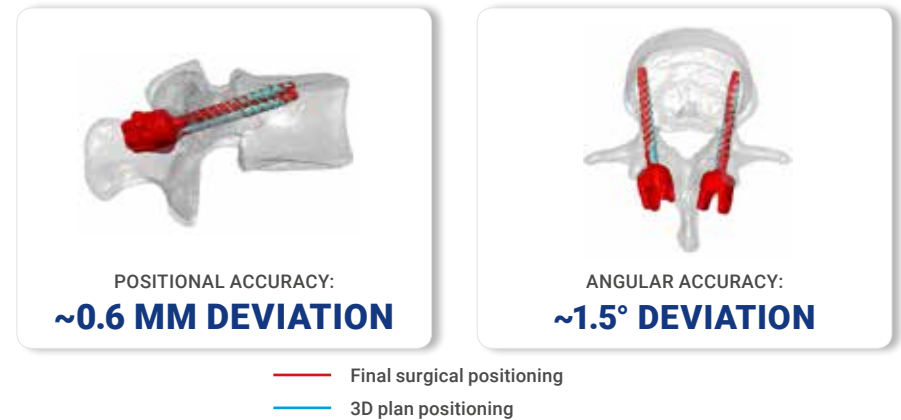
3D PATIENT MATCHED GUIDE



A personalized surgical instrument to match patient's anatomy

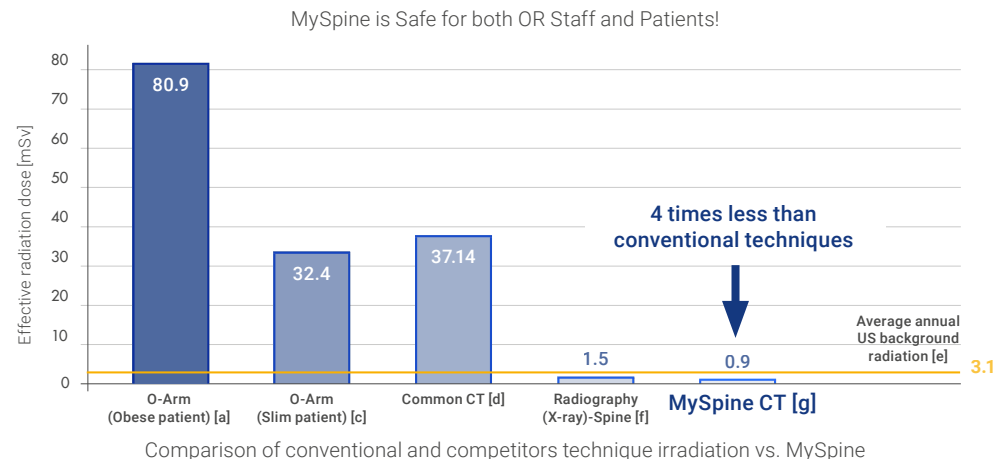
Accurate technology

The final screw positioning reflects the trajectories planned by the surgeon pre operatively^[14].



With **LOW** radiation dose

- Patients are exposed to a **low dose** pre-op CT scan, resulting in radiation exposure lower than a single full spine x-ray
- Pre-operative planning **potentially nullifies the need for intra-operative checks**, with dramatic reduction of irradiation^[16]
- Cumulative dose is potentially reduced vs. navigation assisted technique



[a] Lange et.al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery, Spine 2013 [b] US Nuclear Regulatory Commission's (USNRC) [c] Lange et.al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery, Spine 2013 [d] Biswas et.al. Radiation Exposure from Musculoskeletal Computerized Tomographic Scans, JBJS Am. 2009 [e] Health Physics Society Specialists in Radiation Safety, Lawrence Berkeley National Laboratory; Fact Sheet 2010 [f] Radiation Dose in X-Ray and CT Exams; 2013 Radiological Society of North America, Inc [g] MySpine, Charité University Hospital, Berlin, Germany

Excellent Clinical Outcome

99.5%

SAFE PEDICLE SCREW
POSITIONING^[14]

-24%

HOSPITAL STAY^[17]

-69%

REDUCED SCREW
LOOSENING RATE^[9]

-83%

STRONG ANTEROPOSTERIOR
SPONDYLOLISTHESIS
CORRECTION SLIP^[10]

+35%

SIGNIFICANT INCREASE
IN PULL-OUT RESISTANCE^[14]

-18%

BLOOD LOSS DURING
SURGERY^[17]

Better Muscular preservation^[17]

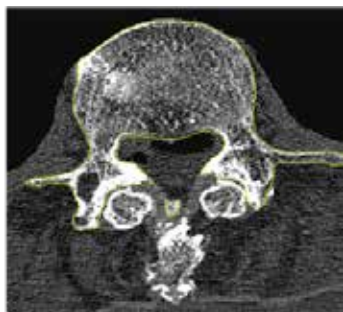
Uncompromised fusion rate^[17]

Less residual low back **pain** after surgery^[17]

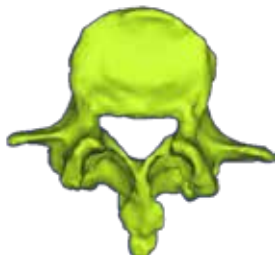




MySpine Case management



CT BASED SEGMENTATION



3D ANATOMY

1. IMAGE ACQUISITION

Low Dose CT scan to deliver 3D reconstruction of individual vertebral anatomy



2. 3D PRE-OP PLAN MANAGEMENT

The surgeon defines optimal implant parameters: screw diameter, length and trajectory



3. 3D PRINTING MYSPINE MC

3D patient matched Jigs are sent to the hospital



4. MYSPINE MC MIS SURGERY

Surgery with dedicated MySpine MC system

Courtesy of Melanie Kinchen, MD
Baylor Scott and White Medical Center, Grapevine, US



Medical Education

The M.O.R.E. Institute offers effective and continuous education to surgeons, with an aim to **improve patient outcomes** and **surgical proficiency**. Close collaboration between Experts and the M.O.R.E. Institute has resulted in the on-going development and evolution of the Educational programme.

The M.O.R.E. Institute was founded on, and encourages the concept of, **sharing experiences** across the international medical community. It has become a **unique** and **global** education platform, **tailored** to the individual's needs.



The surgeon is never alone
when discovering new technologies

MORE.MEDACTA.COM



Courtesy of Dr. Riccardo Cecchinato
Istituto Ortopedico Galeazzi, Milano, IT

INSTRUCTIONAL LEVEL



EVALUATE

Surgical Technique

EXPLORE

Medacta Products/
Services

By visiting a **Reference Centre**

1



EXPERIENCE

a network of Experts, with
mentoring of initial cases

EVOLVE

with the M.O.R.E. continuous
education program

By taking advantage of **Proctoring**

2

3



DEEPEN

the scientific knowledge
of the Approach

PRACTICE

the technique during assisted
cadaver workshops

By attending a **Learning Centre**

ADVANCED LEVEL

MASTER LEVEL



SHARE

your experience, improve
your technique and widen
patient selection

By meeting with **Experts**

4

5



MASTER

the MySpine MC Surgical
Technique and Medacta
Products

By dedicated podium and **Scientific Activities**

EXPECT MORE

with an Education Path
tailored to your needs

Multiple implants choice

A **comprehensive** screws and cages portfolio to work in **harmony** with the patient matched platform.

M.U.S.T.

Multiple choices of cannulated and solid screws to accommodate:

- Degenerative and deformity cases
- Primary and revision cases
- High degree reduction

The range of diameters covers the thoracolumbar, sacral and sacro-iliac fixation needs.



Polyaxial



Revision



Monoaxial



Reduction

MECTALIF

MectaLIF Oblique

MectaLIF Oblique cage that, with a 3D lordosis, is capable to deliver stable vertebral support and potentially reduced risk of subsidence.



MectaLIF Transforaminal

MectaLIF Transforaminal banana cage with a large contact area and a controllable system with a precise delivery.



MectaLIF Posterior

Thanks to the MectaLIF Posterior cage capable of facilitating stable support with a broader area of intervertebral contact.



Flexibility during the surgery

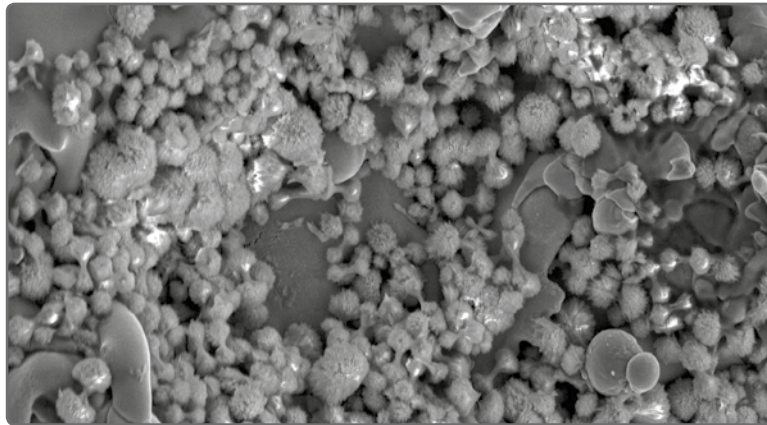
Enhanced Bone Contact

Next generation plasma sprayed Titanium coating for **optimal clinical results.**



BIOACTIVE SURFACE

Unique bioactivity boosts an early hydroxyapatite-like layer foundation, facilitating **bone formation** and allowing for direct bone-implant bond^[a,b].

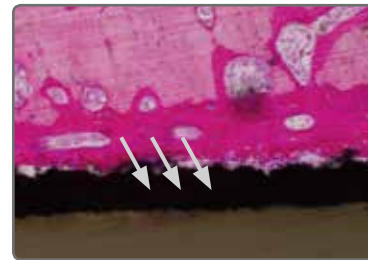


APATITE LAYER ON TIPEEK [1 DAY]

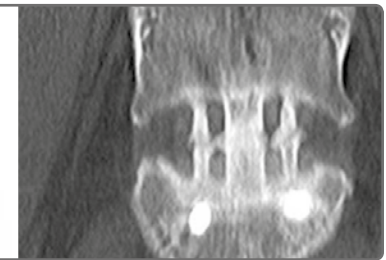
OSTEOCONDUCTIVE TECHNOLOGY

The unique TiPEEK cages may contribute to the bony fusion process and **enhance bone quality** at the implant interface^[b]:

- **Direct bone ongrowth** around the Ti-Coating surface texture^[b]
- **Bone ingrowth** with fusion mass formation throughout the inside of the cage^[c]



DIRECT BONE APPPOSITION ON TIPEEK SURFACE [12 WEEKS]



BONE ONGROWTH AND INGROWTH IN A TIPEEK CAGE [6 MONTHS]

^[a] M. Rickert et al. Transforaminal lumbar interbody fusion in PEEK oblique cages with and without titanium coating: results from a randomized clinical trial - <http://8more.medacta.com/video/508bb2e8-cae4-44c2-88f0-e4dbaf35a44f.mp4> ^[b] B. Walsh et al. Titanium coated interbody devices - <http://8more.medacta.com/video/26c24c91-2420-4aaf-aac2-88e25cab22f6.mp4> ^[c] Geert Mahieu et al. A retrospective analysis of patients treated with TIPEEK cages in the cervical and lumbar spine - <http://8more.medacta.com/video/2ad0c9c7-8164-4a2b-8bbe-4354c4fb0d73.mp4>

Flexibility during the **surgery**

Modular Design offers Freedom of Choice

Versatile solution provides freedom of choice in a **personalized platform**.



MECTALIF ANTERIOR



Flush

No anterior profile construct for minimal impact.



Hybrid

Greater cranial stability with a caudal flush profile provides a solution for L5-S1 implantation.



Long

Greater stability in extension and torsion with a 4 hole design.



L5-S1

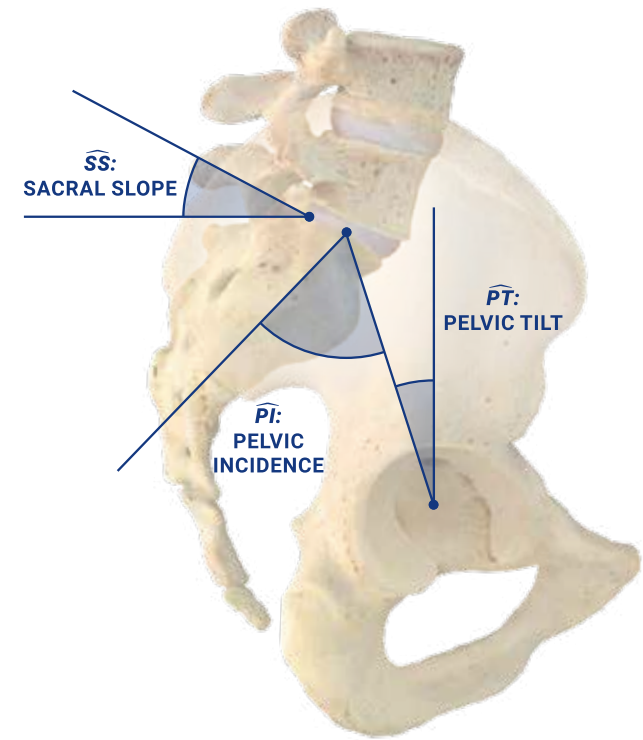
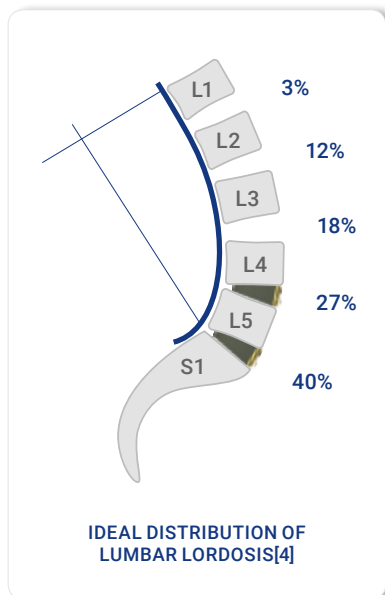
Greater stability in extension and torsion. 3 hole design provides flexibility with respect to the iliac artery bifurcation.

Flexibility during the **surgery**

A Unique Synergy

MySpine & MectaLIF Anterior, a unique synergy for optimal sagittal balance restoration.

- Proper **sagittal** and **coronal alignment** thanks to hyperlordotic cages in combination with posterior correction
- Recovery of the Spino **Pelvic harmony**
- Ideal **circumferential approach** in combination with MySpine MC Minimally invasive surgery
- **Decreased complications** than traditional pedicle subtraction osteotomies (PSO)



Surgeon Testimonies

“ Now I go into the operating room with a much more **unique understanding of the patient** that I’m about to operate on because I feel like I literally looked at their spine and turned it around and understood it in a way that helps me, when I’m there in the operating room. ”

(Dr. Jeffrey Henn, MD)

“ I feel that with **3D planning** there are some definite benefits. It is possible that blood loss, operative time, neurologic injury, vascular injury and possibly even infections can be reduced, if you have paid attention to the anatomy pre-operatively. ”

(Dr. Brian Nielsen, MD)

“ The one I actually like the best ... is pre-operative planning. That is the future ... You can plan it in advance. Very impressive technology. ”

(Dr. Rick Hynes, MD)



Healthcare Sustainability

Medacta was founded with the philosophy of creating medical devices that facilitate healthcare sustainability. This is the reason why sustainability is a fundamental pillar of our way of doing business, in environmental, economic and social terms. This philosophy translates into guidelines and internal regulations that guide our daily decisions and actions.

MySpine embodies this philosophy while providing a comprehensive navigation system with the following advantages over competitive systems:

- No capital investment is required
- No recurring maintenance fee is required
- Low per-case disposable cost
- Viability in out-patient / surgery center environments



2019 AWARD

Medacta's MySpine MC Wins MedTech Breakthrough Award for Orthopaedics and Surgical Innovation as **"Best Healthcare Navigation/Robotics Solution"**

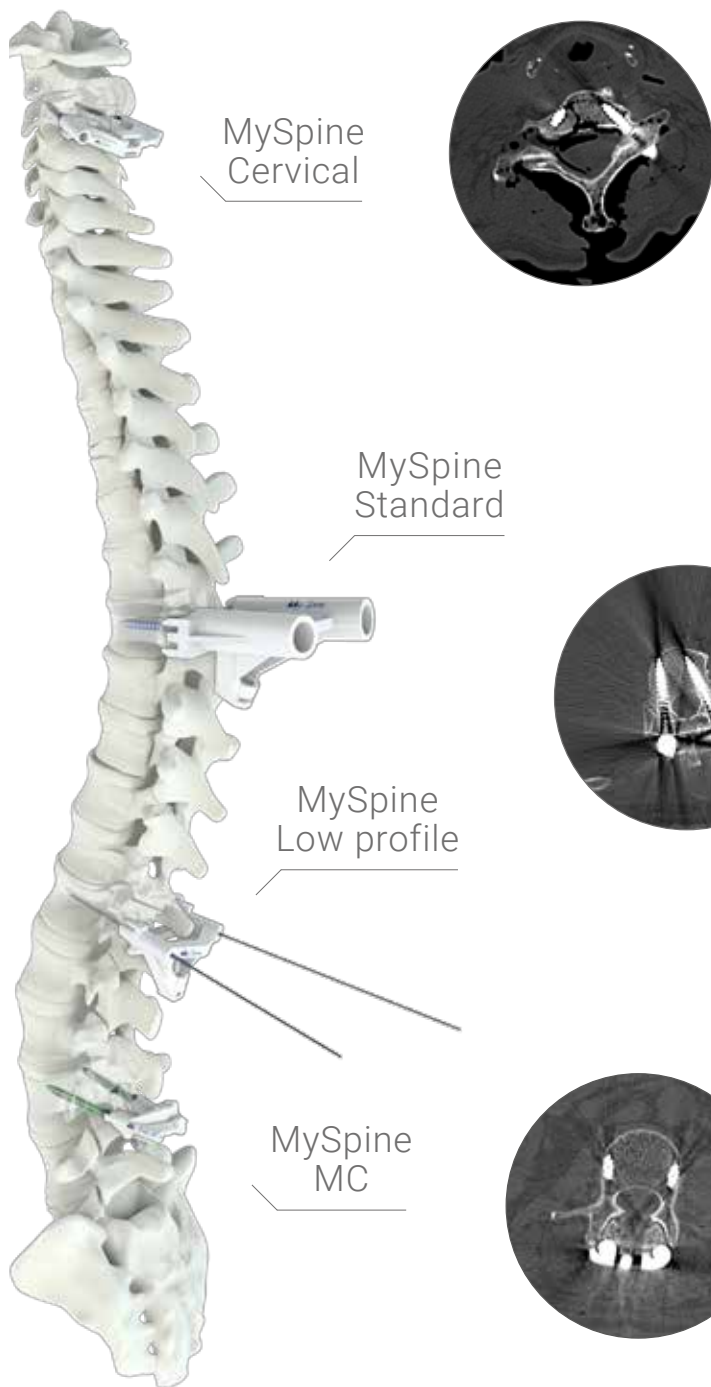
MySpine Platform

A comprehensive range of patient specific, pedicle screw placement guides allows for a personalized treatment depending on the patient pathology and the surgical approach. The system supports the surgeon pre and intra operatively for post op patient benefit.

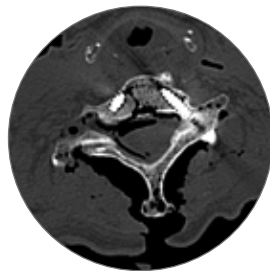
Multiple Surgical Options

for different indications.





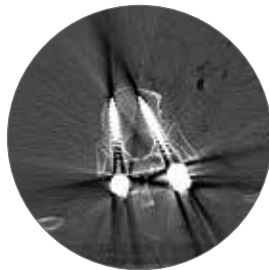
MySpine
Cervical



CERVICAL

Your solution for pedicle screw in cervical fixation.

MySpine
Standard



STANDARD

A unique platform to treat thoracolumbosacral segments in conventional technique.

MySpine
Low profile



LOW PROFILE

MySpine
MC



MIDLINE CORTICAL

MIS solution for cortical bone screw fixation.

Notes

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REFERENCES

1. Matsukawa K. et al., Incidence and Risk Factors of Adjacent Cranial Facet Joint Violation Following Pedicle Screw Insertion Using Cortical Bone Trajectory Technique, Spine, 2016
2. Sakaura H. et al., Posterior lumbar interbody fusion with cortical bone trajectory screw fixation versus posterior lumbar interbody fusion using traditional pedicle screw fixation for degenerative lumbar spondylolisthesis: a comparative study, JNS, 2016
3. Khanna N. et al., Spine (Phila Pa 1976). 2016 Apr;41 Suppl 8:S90-6. doi: 10.1097/BRS.0000000000001475. Medialized, Muscle-Splitting Approach for Posterior Lumbar Interbody Fusion: Technique and Multicenter Perioperative Results
9. Santoni B.G. et al., Cortical bone trajectory for lumbar pedicle screws, The Spine Journal, 2009
10. Mori K. et al., Short-Term Clinical Result of Cortical Bone Trajectory Technique for the Treatment of Degenerative Lumbar Spondylolisthesis with More than 1-Year Follow-Up, Asian Spine Journal, 2016
14. Matsukawa K. et al., Accuracy of cortical bone trajectory screw placement using patient-specific template guide system, Neurosurgical Review, July 2019
15. Matsukawa K. et al., Cortical pedicle screw trajectory technique using 3D printed patient-specific-guide, M.O.R.E. Journal, September 2018
16. Marengo N. et al., Cortical Bone Trajectory Screw Placement Accuracy with a Patient-Matched 3-Dimensional Printed Guide in Lumbar Spinal Surgery: A Clinical Study, WORLD NEUROSURGERY, June 2019
17. Marengo N. et al., Cortical Bone Trajectory Screws in Posterior Lumbar Interbody Fusion: Minimally Invasive Surgery for Maximal Muscle Sparing—A Prospective Comparative Study with the Traditional Open Technique, Clinical Study, February 2018
18. Kim J. et al., Three-Dimensional Patient-Specific Guides for Intraoperative Navigation for Cortical Screw Trajectory Pedicle Fixation, World Neurosurgery Volume 122 (674-679), February 2019



**REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY**

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Please verify approval of the devices described in this document with your local Medacta representative.