PERSONALIZED MIS SOLUTIONS

The MySpine MC Experience

Medacta International

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

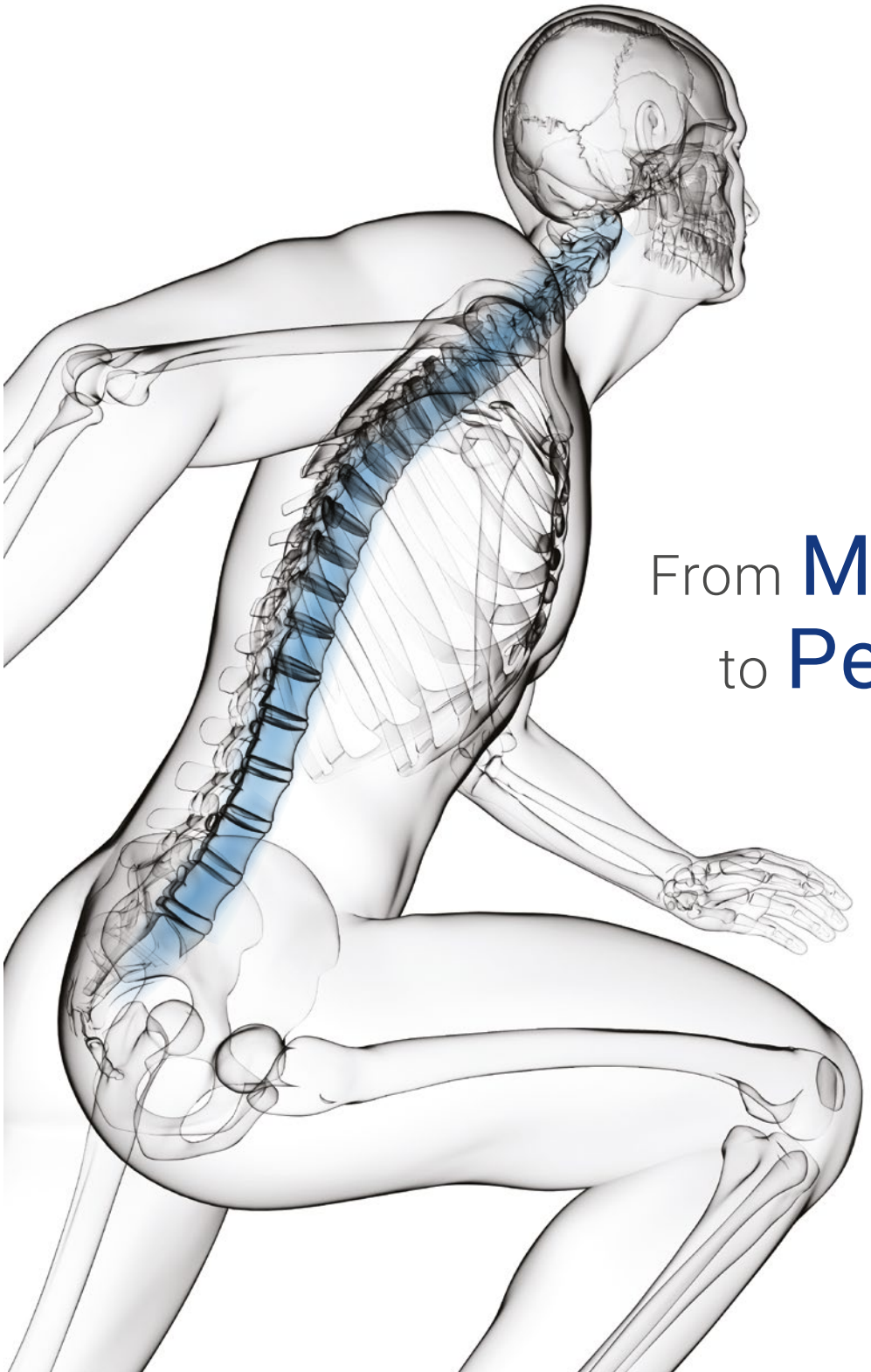
With the **patient** in mind, our **innovations** are designed to become part of their **life experience**

Contents

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

Swiss company. Your global partner

Medacta's mission is to transform the patient experience by advancing surgical approaches, implants and instruments through **responsible innovation** and **meticulous design** in **joint replacement, spine surgery** and **sports medicine**. Medacta is a unique company in its field, as it is the only one **founded by a patient**. It follows the experience of the Founder Alberto Siccardi, whose own journey as a patient convinced him of the importance of pioneering a new approach to joint replacement.

Established in 1999, Medacta has leveraged its orthopedic expertise and comprehensive understanding of the human body to develop the **"MySolutions" technology**, which offers surgeons personalized pre-operative planning and implant placement methodologies by creating **advanced personalized kinematic models** and **3D planning tools**.

Since 2009 a team of engineers has collaborated with international surgeons to develop innovative solutions for the treatment of various spine pathologies. The **MySpine platform**, along with **MC-Midline Cortical guides**, is a 3D printed patient matched solution that, together with the **M.U.S.T. Screw System**, the **MectaLIF Ti-coating family** of interbody fusion devices, creates a harmonized and complete system, meeting surgeon needs and patient care expectations.

Bieffe Biochimici Firenze was founded by Dr. Francesco Siccardi Sr.

1958

1997

Acquisition by Baxter of Bieffe Medital

1999

MEDACTA INTERNATIONAL WAS FOUNDED

2000

NEW HEADQUARTERS IN CASTEL SAN PIETRO

2004

M.O.R.E. INSTITUTE WAS FOUNDED

2008

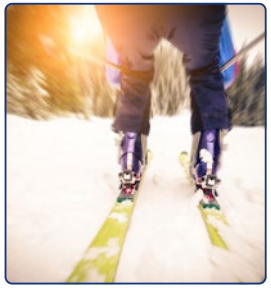
1st IMPLANT IN USA

2009

STRATEGIC DECISION TO ENTER SPINE MARKET

2015

STRATEGIC DECISION TO ENTER SPORTS MED MARKET



2016

NEW PLANT IN RANCATE AND STABIO LOGISTIC CENTER

2019

20th MEDACTA ANNIVERASRY OFFICIALLY ENTERING THE SIX SWISS EXCHANGE

2022

NEW OFFICES IN RANCATE

MySpine MC

Personalized MIS solution

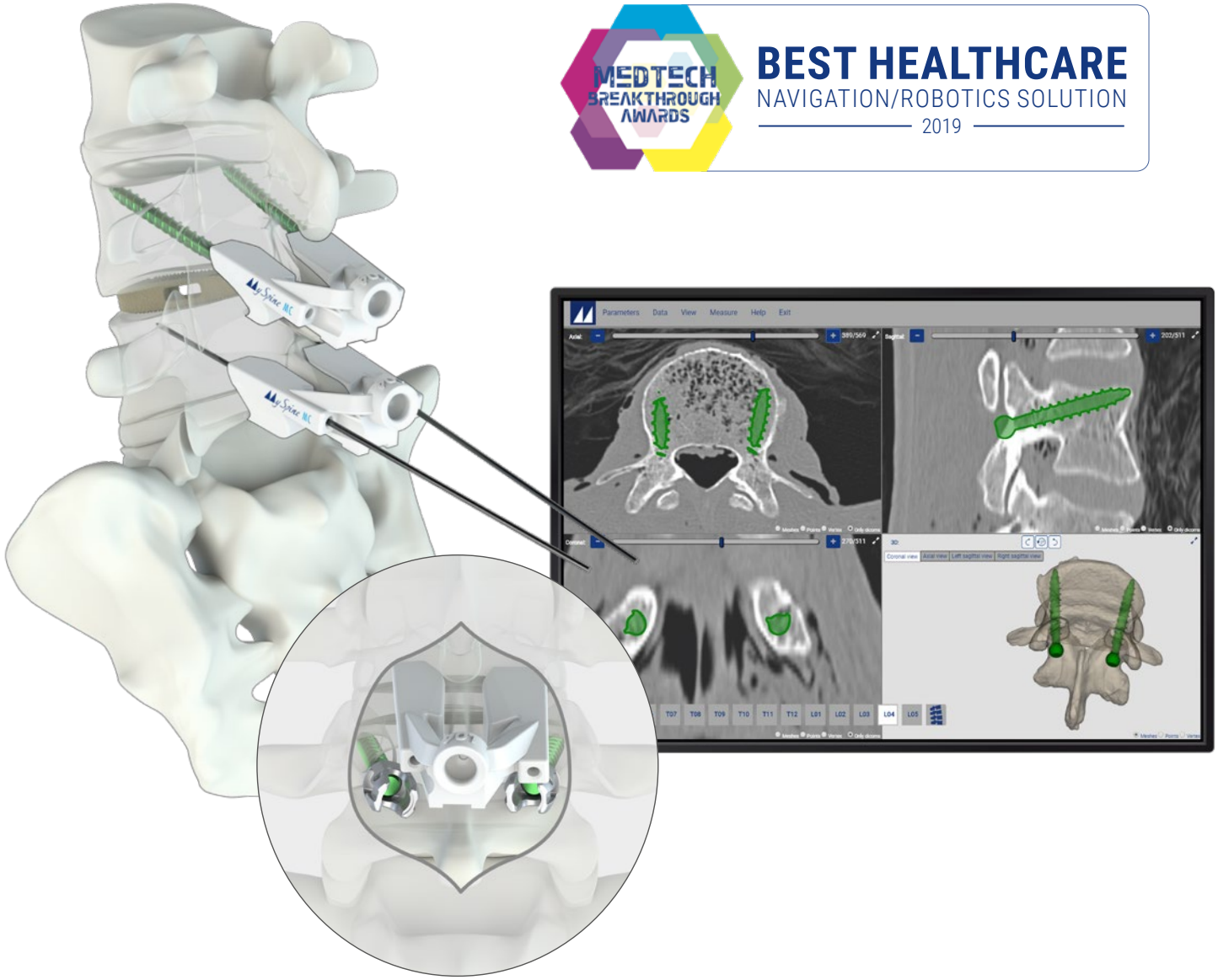
MySpine is Medacta's patient-specific navigation platform that provides pre-operative planning and intra-operative navigation, and integrates a comprehensive product portfolio of patient-matched technologies.
MySpine was born out of Medacta's commitment to three core philosophies:

MEDICAL EDUCATION

PATIENT WELL-BEING

HEALTHCARE SUSTAINABILITY

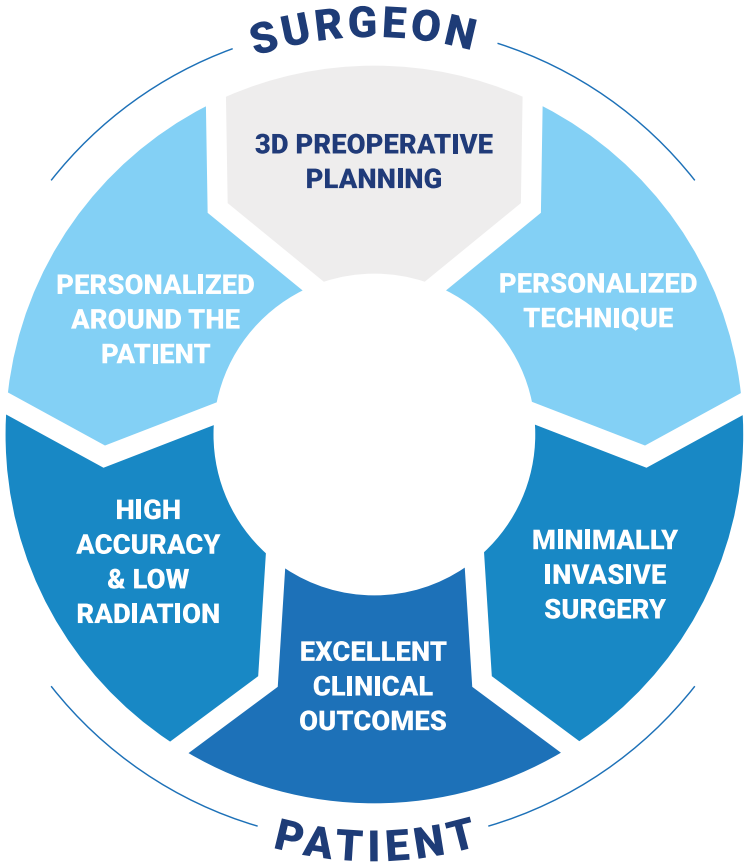
MySpine embodies these core philosophies by providing spine surgeons with patient-specific anatomical insights through its suite of pre-operative planning functionality, a safer surgery by helping reduce radiation exposure and incision size, and an affordable navigation platform with zero capital investment or restrictive purchasing agreements.


MEDTECH
BREAKTHROUGH
AWARDS
BEST HEALTHCARE
NAVIGATION/ROBOTICS SOLUTION
2019

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[1], **potentially avoiding intraoperative complications** for the patient, such as pedicle fractures and neurovascular injuries[1,2].



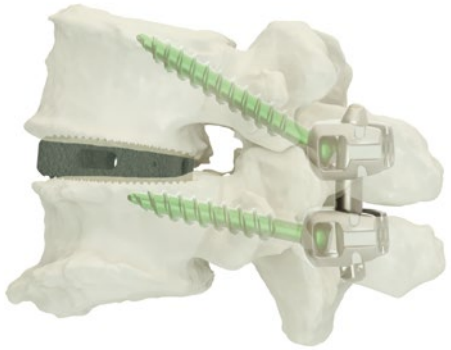

Parameters
Data
View
Measure
Help
Exit
Axial:
Sagittal:
Coronal:
2D:
Coronal view
Axial view
Left sagittal view
Right sagittal view
T02 T04 T05 T06 T07 T08 T09 T10 T11 T12 L01 L02 L03 L04 L05

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.

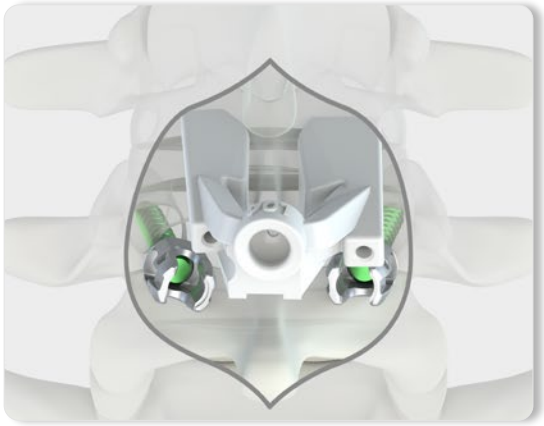
3D PRE-OPERATIVE PLAN

SURGERY



The final pedicle screw position reflects the pre-operative plan

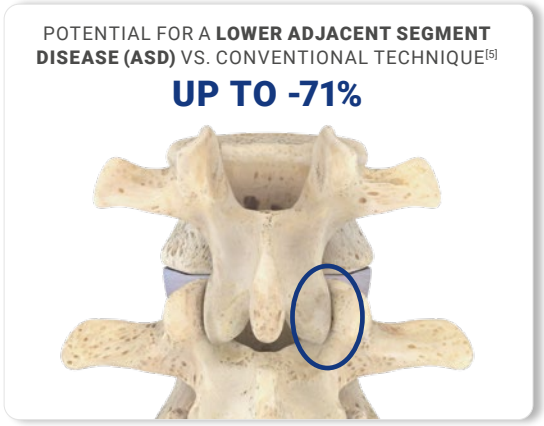
Minimally invasive



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

- Enhanced muscle preservation[3]
- Reduced blood loss[3]

Compared with traditional open technique.



The benefits for the patient are:

- Supradjacent facet preservation[3,4]
- Lower adjacent segment disease[5]
- Faster discharge[2]
- Less pain[3]
- Fast patient recovery[2,3]

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**[1] potentially **reducing the need of fluoroscopy**[6].

3D PATIENT ANATOMY

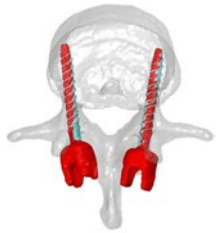
3D PATIENT MATCHED GUIDE

A personalized surgical instrument to match patient's anatomy

Accurate technology

The final screw positioning reflects the trajectories planned by the surgeon pre operatively[1].

POSITIONAL ACCURACY:
~0.6 MM DEVIATION

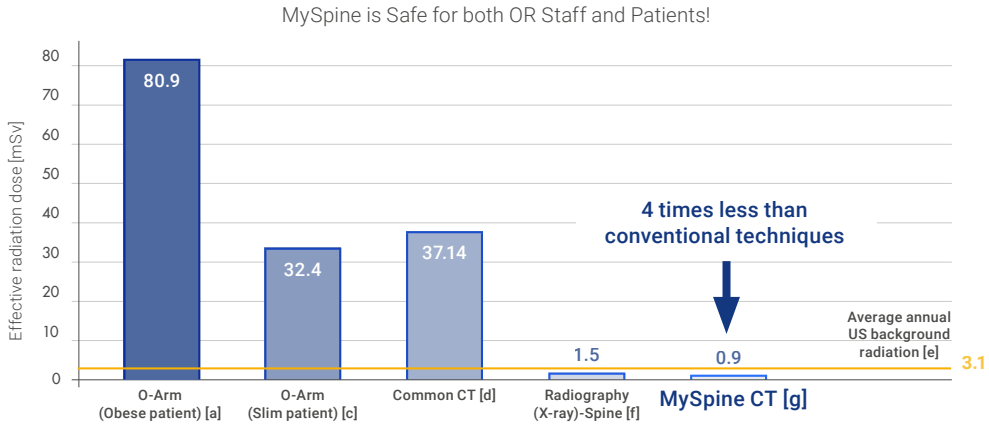


ANGULAR ACCURACY:
~1.5° DEVIATION

Final surgical positioning
3D plan positioning

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[2]
- Cumulative dose is potentially reduced vs. navigation assisted technique



Comparison of conventional and competitors technique irradiation vs. MySpine

[a] Lange et.al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in toracolumbar 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 toracolumbar 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[1]

-24%

HOSPITAL STAY[3]

-69%

REDUCED SCREW LOOSENING RATE[7]

-83%

STRONG ANTEROPOSTERIOR SPONDYLOLISTHESIS CORRECTION SLIP[8]

+35%

SIGNIFICANT INCREASE IN PULL-OUT RESISTANCE[1]

-18%

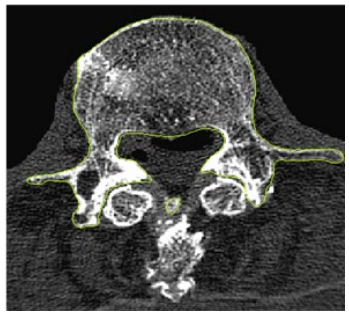
BLOOD LOSS DURING SURGERY[3]

Better Muscular preservation[3]

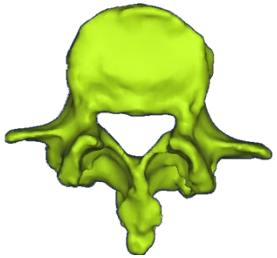
Uncompromised fusion rate[3]

Less residual low back **pain** after surgery[3]

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 effective 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.

M.O.R.E.
INSTITUTE

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

DEEPEN
the scientific knowledge
of the Approach

PRACTICE
the technique during assisted
cadaver workshops

By attending a **Learning Centre**

2

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**

3

ADVANCED LEVEL

MASTER LEVEL

SHARE
your experience, improve your technique and widen patient selection

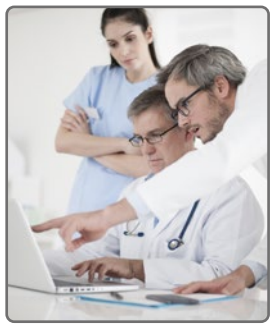
By meeting with **Experts**

4

5

EXPECT MORE

with an Education Path tailored to your needs

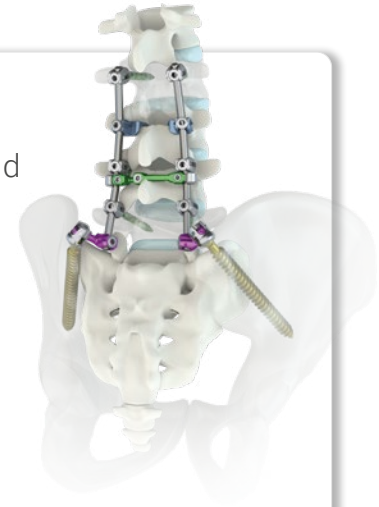


MASTER
the MySpine MC Surgical Technique and Medacta Products

By dedicated podium and **Scientific Activities**

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 to accommodate stable support with a broaden area of intervertebral contact

Flexibility during the surgery

MectaLIF® TIPEEK

TI-COATED INTERBODY FUSION DEVICE

Enhanced Bone Contact

Next generation plasma sprayed Titanium with **proven clinical results**.

TOPOGRAPHY

TiPEEK cages are plasma sprayed coated devices with a unique roughness and a 3D complex topography.

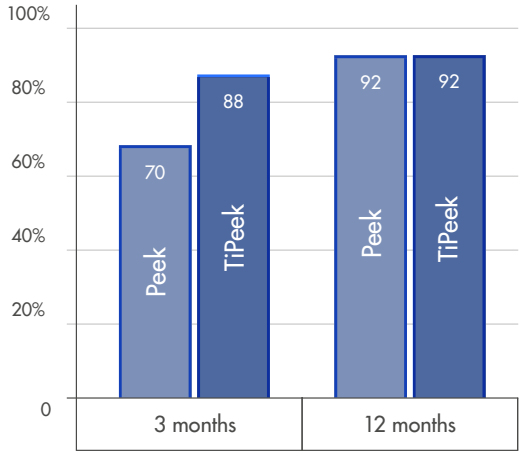
Rough Layer[c,d]

Hydrophilic Surface[d]

Low Inflammatory Response[b]

FUSION RATE

High level fusion rate: **~90% at 3 months** post-operative[a].

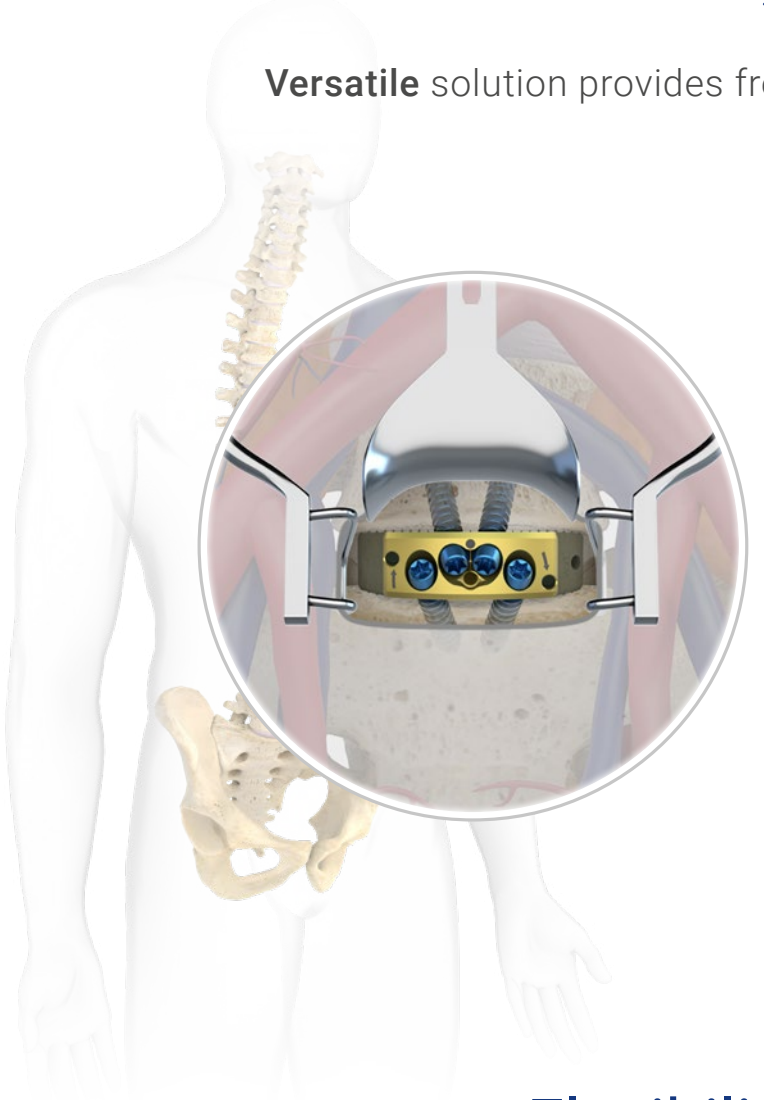


[a] M.Rickert et al. Transforaminal lumbar interbody fusion in PEEK oblique cages with and without titanium coating: results from a randomized clinical trial - http://8more.medacta.com/video/508bb2e8-cae4-44c2-88f0-e4dbaf35a44f.mp4 ***[b]*** *Buser D et al. J Biomed Mater Res 1991;25(7):889-902* ***[c]*** *Olivares-Navarrete et al. Implant materials generate different peri-implant inflammatory factors: poly-ether-ether-ketone promotes fibrosis and microtextured titanium promotes osteogenic factors. Spine (Phila Pa 1976). 2015 Mar 15;40(6):399-404* ***[d]*** *Olivares-Navarrete et al. Osteoblast maturation and new bone formation in response to titanium implant surface features are reduced with age. J Bone Miner Res. 2012; 27(8); 1773-1783*

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 provide a solution for L5-S1 implantation.

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

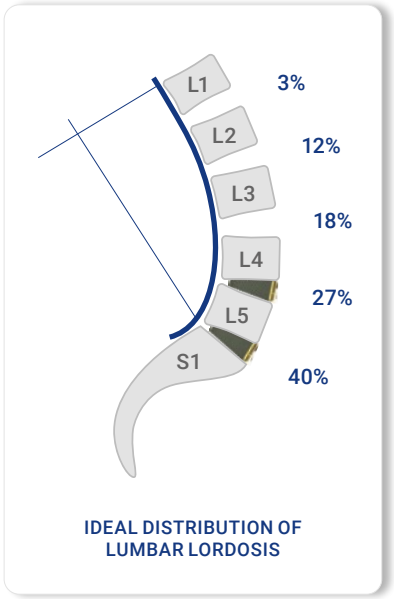
L5-S1
Greater stability in extension and torsion. 3 holes design provides flexibility with respect to the illiac artery bifurcation.

Flexibility during the surgery

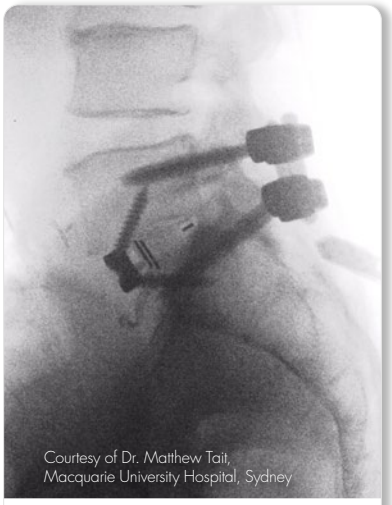
A Unique Synergy

MySpine & MectaLIF Anterior, a unique synergy for effective sagittal imbalance restoration.

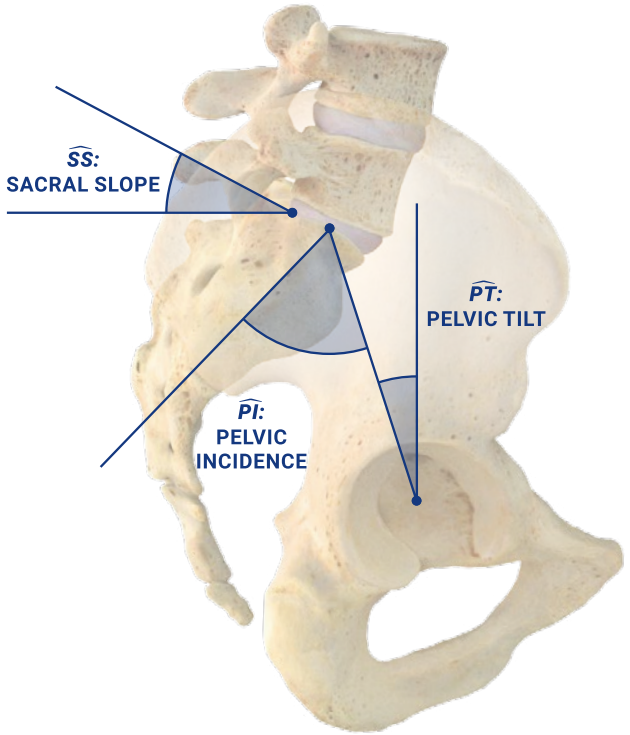
- Proper **sagittal** and **coronal alignment** thanks to hyperlordotic cages in combination with posterior correction
- Recovery of the Spino **Pelvic harmony**
- Ideal **circumferential approach** in combination with MySpine MC Minimally invasive surgery
- **Decreased complications** than traditional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



IDEAL DISTRIBUTION OF LUMBAR LORDOSIS



M.U.S.T. PEDICLE SCREWS COMBINED WITH MECTALIF ANTERIOR



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

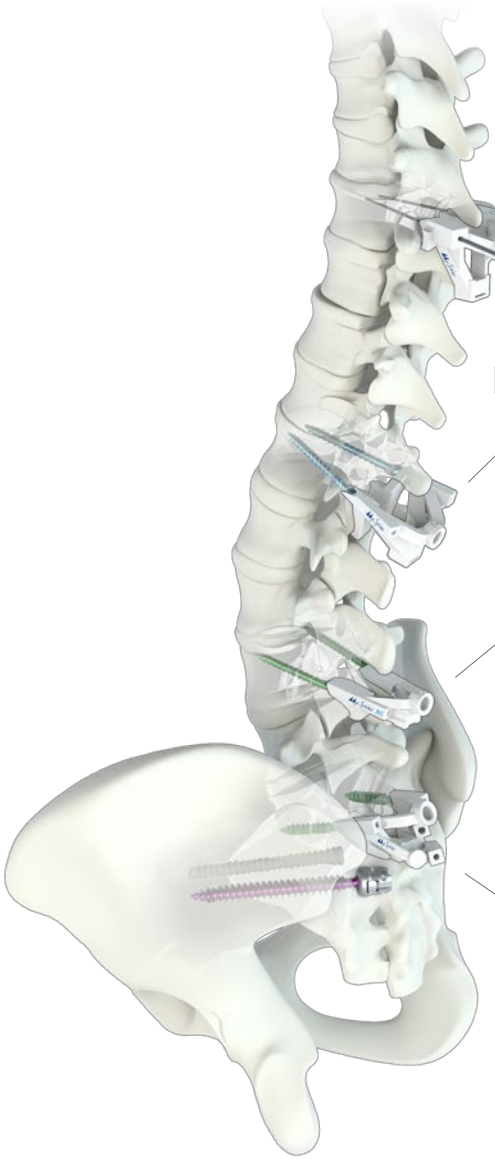
Medacta's MySpine MC Wins MedTech Breakthrough Award for Orthopaedics and Surgical Innovation as **"Best Healthcare Navigation/Robotics Solution"**

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.



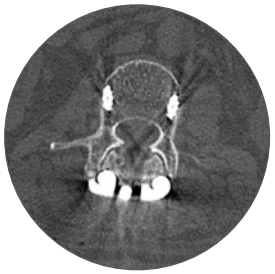
MySpine Low profile
(K-wire)

LOW PROFILE (LP)
DRILL PILOT / K-WIRE

A unique platform to treat thoracolumbosacral segments in conventional technique.

MySpine Low profile
(drill pilot)

MySpine MC



MIDLINE CORTICAL (MC)

MIS solution for cortical bone screw fixation.

MySpine Anchor
MySpine S2-AI

ANCHOR / S2AI

Patient-Matched Solution for posterior Sacro-Iliac fusion as an adjunct to thoracopelvic.

Medacta International

Strada Regina - 6874 Castel San Pietro - Switzerland

Phone +41 91 696 60 60 - Fax +41 91 696 60 66

www.medacta.com - info@medacta.ch

Medacta USA

6640 Carothers Pkwy - Franklin, TN 37067

Phone +1 866 830 1063 / +1 615 622 4715 - Fax +1 312 896 9138

www.medacta.us.com - info@medacta.us.com

REFERENCES

1. Matsukawa K. et al., Accuracy of cortical bone trajectory screw placement using patient-specific template guide system, Neurosurgical Review, July 2019
2. 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
3. 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
4. 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
5. 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
6. Matsukawa K. et al., Cortical pedicle screw trajectory technique using 3D printed patient-specific-guide, M.O.R.E. Journal, September 2018
7. Santoni B.G. et al., Cortical bone trajectory for lumbar pedicle screws, The Spine Journal, 2009
8. 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

REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY

MEDACTA.COM

This document is intended for the US market.

Ref: 99.MY46MCXP.11US Rev.01