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.
Medacta’s MySpine MC Wins MedTech Breakthrough Award for Orthopaedics and Surgical Innovation as “Best Healthcare Navigation/Robotics Solution”
Thanks to this **accurate** tool the surgeon can optimize screws parameters, entry points and trajectories\textsuperscript{[14]}, **avoiding potential intraoperative complications** for the patient, such as pedicle fractures and neurovascular injuries\textsuperscript{[14,16]}. 

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**3D Preoperative Planning**

Personalized by the surgeon... for the Patient
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.

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\textsuperscript{[17]}
- Reduced blood loss\textsuperscript{[17]}

Compared with traditional open technique.

The benefits for the patient are:

- Supradjacent facet preservation\textsuperscript{[1,17]}
- Lower adjacent segment disease\textsuperscript{[2]}
- Faster discharge\textsuperscript{[16]}
- Less pain\textsuperscript{[17]}
- Fast patient recovery\textsuperscript{[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\textsuperscript{14} potentially reducing the need of fluoroscopy\textsuperscript{15}.

A personalized surgical instrument to match patient’s anatomy
Accurate technology

The final screw positioning reflects the trajectories planned by the surgeon preoperatively\cite{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\cite{16}
- Cumulative dose is potentially reduced vs. navigation assisted technique

\begin{figure}
\centering
\includegraphics[width=\textwidth]{comparison_graph.png}
\caption{Comparison of conventional and competitors technique irradiation vs. MySpine}
\end{figure}

\begin{table}
\centering
\begin{tabular}{|c|c|c|c|}
\hline
Technique & Effective radiation dose [mSv] \\
\hline
O-Arm (Obese patient)\textsuperscript{[a]} & 80.9 & \textbf{3.1} & \textbf{3.1} \textsuperscript{\textsuperscript{e}} & \textbf{Average annual US background radiation} \textsuperscript{[e]} \textsuperscript{\textsuperscript{f}} \textsuperscript{\textsuperscript{g}} \\
O-Arm (Slim patient)\textsuperscript{[c]} & 32.4 & 1.5 & 0.9 & \textbf{4 times less than conventional techniques} \textsuperscript{\textsuperscript{h}} \textsuperscript{\textsuperscript{i}} \\
Common CT \textsuperscript{[d]} & 37.14 & & & \\
Radiography (X-ray)-Spine \textsuperscript{[f]} & & & & \\
MySpine CT \textsuperscript{[g]} & & & & \\
\hline
\end{tabular}
\caption{Comparison of conventional and competitors technique irradiation vs. MySpine}
\end{table}

\textsuperscript{a}[a] Lange et al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery, Spine 2012
\textsuperscript{b}[b] US Nuclear Regulatory Commission’s (USNRC)
\textsuperscript{c}[c] Lange et al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery, Spine 2012
\textsuperscript{d} Biswas et al. Radiation Exposure from Musculoskeletal Computerized Tomographic Scans, JBJS Am. 2009
\textsuperscript{e}[e] Health Physics Society Specialists in Radiation Safety, Lawrence Berkeley National Laboratory; Fact Sheet 2010
\textsuperscript{f}[f] Radiation Dose in X-Ray and CT Exams; 2013 Radiological Society of North America, Inc.
\textsuperscript{g}[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\[^{17}\]
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
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 ongoing 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.
**INSTRUCTIONAL LEVEL**

1. **EVALUATE**
   Surgical Technique
   By visiting a Reference Centre

2. **EXPLORE**
   Medacta Products/Services
   By taking advantage of Proctoring

3. **EXPERIENCE**
   a network of Experts, with mentoring of initial cases
   **EVOLVE**
   with the M.O.R.E. continuous education program

**DEEPEN**
the scientific knowledge of the Approach

**PRACTICE**
the technique during assisted cadaver workshops

By attending a Learning Centre
**SHARE**

your experience, improve your technique and widen patient selection

By meeting with **Experts**

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**MASTER**

the MySpine MC Surgical Technique and Medacta Products

By dedicated podium and **Scientific Activities**

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**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.

**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].

**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]

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**Flexibility during the surgery**

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\[a\] 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-cae4-44c2-8810-e44baf25a44f.mp4

\[b\] B.Walsh et al. Titanium coated interbody devices - http://8more.medacta.com/video/26c24c91-2428-4aa1-aac2-25a6cd322f6.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-89be-4564c4960d73.mp4
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)

![IDEAL DISTRIBUTION OF LUMBAR LORDOSIS](image)

![M.U.S.T. PEDICLE SCREWS COMBINED WITH MECTALIF ANTERIOR](image)
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)
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.
Your solution for pedicle screw in cervical fixation.

A unique platform to treat thoracolumbosacral segments in conventional technique.

MIS solution for cortical bone screw fixation.
REFERENCES

15. Matsukawa K. et al., Cortical pedicle screw trajectory technique using 3D printed patient-specific-guide, M.O.R.E. Journal, September 2018
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