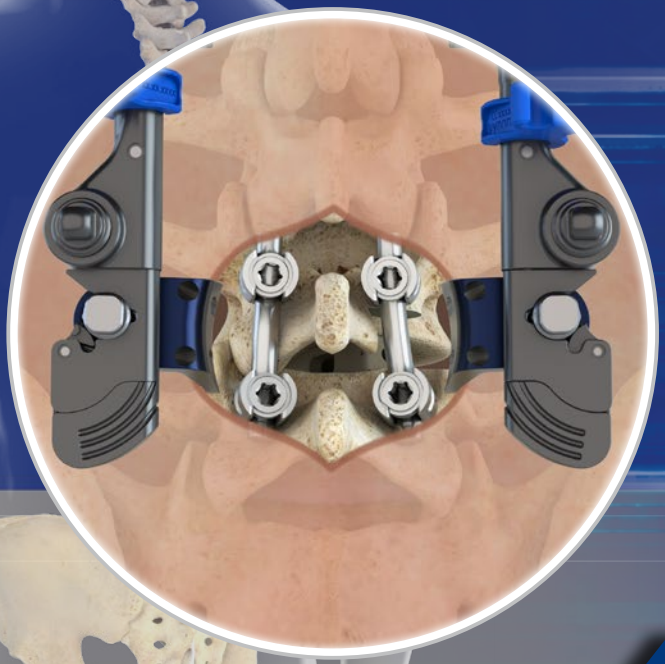
MySpine® MIS MC

PERSONALIZED MIDLINE CORTICAL PROCEDURE

COMPLETE SOLUTION IN THE MIDLINE CORTICAL APPROACH



Procedural Brochure

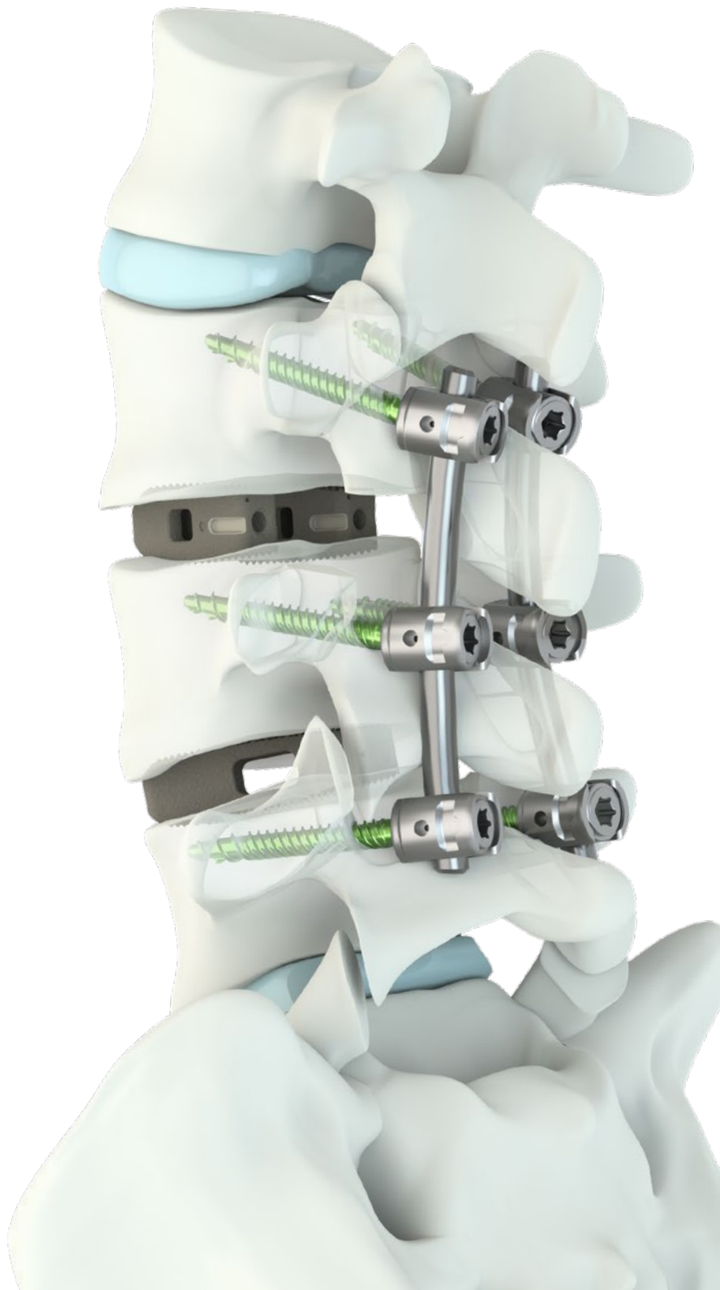
Joint | **Spine** | Sports Med

Medacta International

COMPLETE SOLUTION IN THE MIDLINE CORTICAL APPROACH

The **MySpine MIS MC procedure** is a complete solution for an **accurate minimally invasive** midline divergent screw positioning through a **small skin incision**. A **patient-specific preoperative plan** allows for creating **3D guides** which **physically navigate** the screw positioning also in **challenging anatomies**.

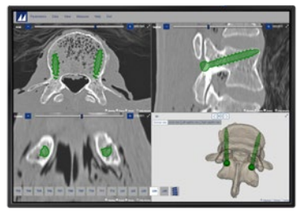
One of the **smallest screw tulips** in the market works in synergy with a comprehensive portfolio of **posterior TI-PEEK cages**.



M.U.S.T. MC

MectaLIF System

MySpine MC



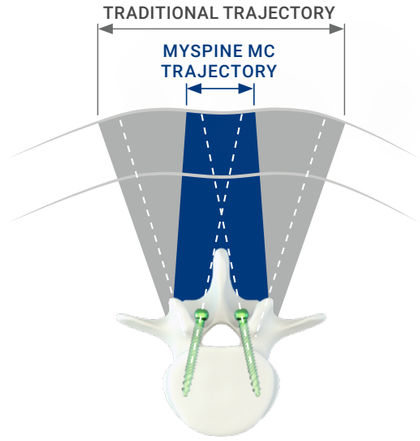
MySpine Webplanner

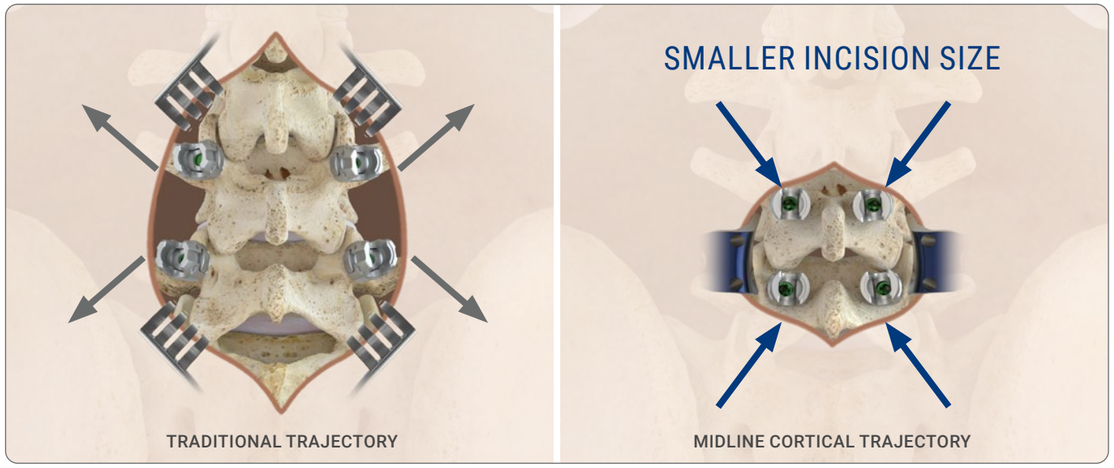
WHY A DIVERGENT SCREW POSITIONING?

Divergent screws allow for positioning the entry points at the pars interarticularis with favorable cortical bone quality[1], improving bone purchase and **significantly increasing the pull out resistance up to +30%** with respect to the conventional technique.[1]

The posterior lumbar fusion with a midline cortical trajectory is driven in a minimally invasive, muscle-sparing way, allowing for:

- **Enhanced muscle preservation**[2]
- **Reduced blood loss**[3]

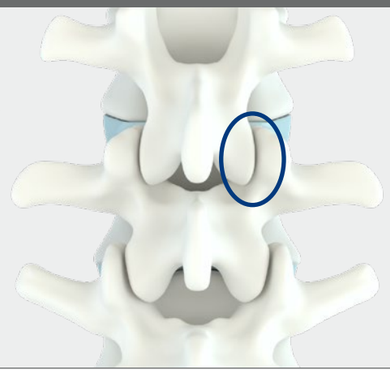




PATIENT BENEFITS OF THE MIDLINE CORTICAL APPROACH

Compared to the traditional open technique, this approach provides the following potential benefits for the patient:

- Supradjacent facet preservation[4,5]
- Lower adjacent segment disease[2]
- Faster discharge[6]
- Less pain[5]
- Fast patient recovery[5,6]



POTENTIAL FOR A **LOWER ADJACENT SEGMENT DISEASE (ASD)** VS. CONVENTIONAL TECHNIQUE[2]

UP TO -71%

PERSONALIZED 3D PLANNING

An **accurate 3D preoperative** planning based on a **low dose CT scan** delivers **patient-matched guides**, resulting in zero capital investment.

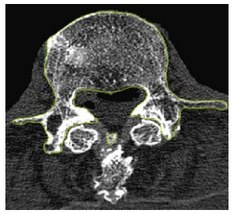
MYSPINE WEBPLANNER

The MySpine Webplanner allows for a **simple and accurate 3D preoperative planning**. The surgeon can simulate the final screw position from the patient's medical images and preview any potential surgical obstacles.

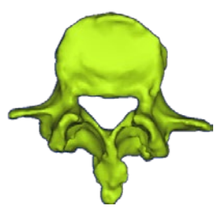
Thanks to **advanced 3D planning tool**, the surgeon can optimize screw parameters, entry points and trajectories[7] based on the patient anatomy **avoiding potentially intraoperative complications for the patient**, such as pedicle fractures and neurovascular injuries.[6,7]

LOW DOSE CT SCAN

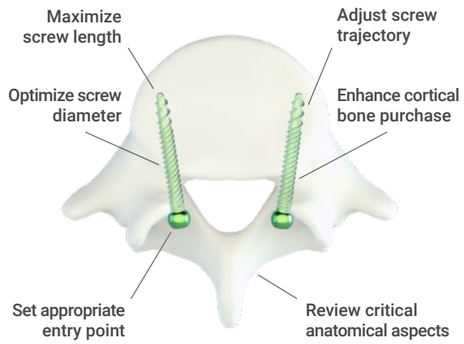
A specific **low dose CT protocol** ensures a safe image acquisition, reducing the amount of irradiation absorbed by the patient. Preoperative planning **potentially nullifies the need for intraoperative checks**, with a dramatic reduction of irradiation. **The cumulative dose is potentially reduced** compared to the navigation-assisted technique.



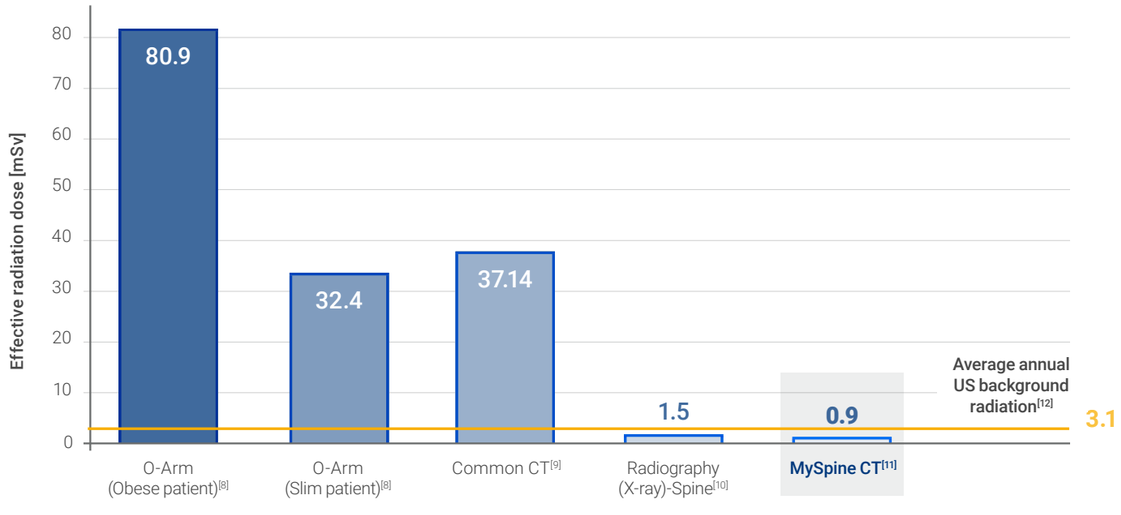
CT BASED SEGMENTATION



3D ANATOMY



COMPARISON OF CONVENTIONAL AND COMPETITORS TECHNIQUE IRRADIATION VS. MYSPINE



MySpine potentially reduces the dose exposure for both OR staff and patients!

From Minimally Invasive Surgery to Personalized Medicine and beyond

MYSPINE MC GUIDE

PATIENT-MATCHED TECHNOLOGY

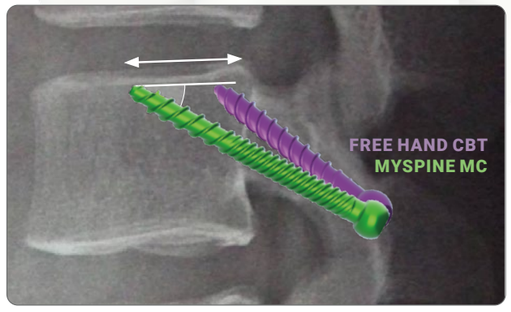
MySpine MC is a 3D printed patient-matched solution in the midline cortical approach. Following the preoperative trajectory a **3D patient-matched guide** is designed to match the patient's anatomy. This **navigation platform** provides accurate intraoperative guidance for safe screw positioning with no expensive capital investment or restrictive purchasing agreements.

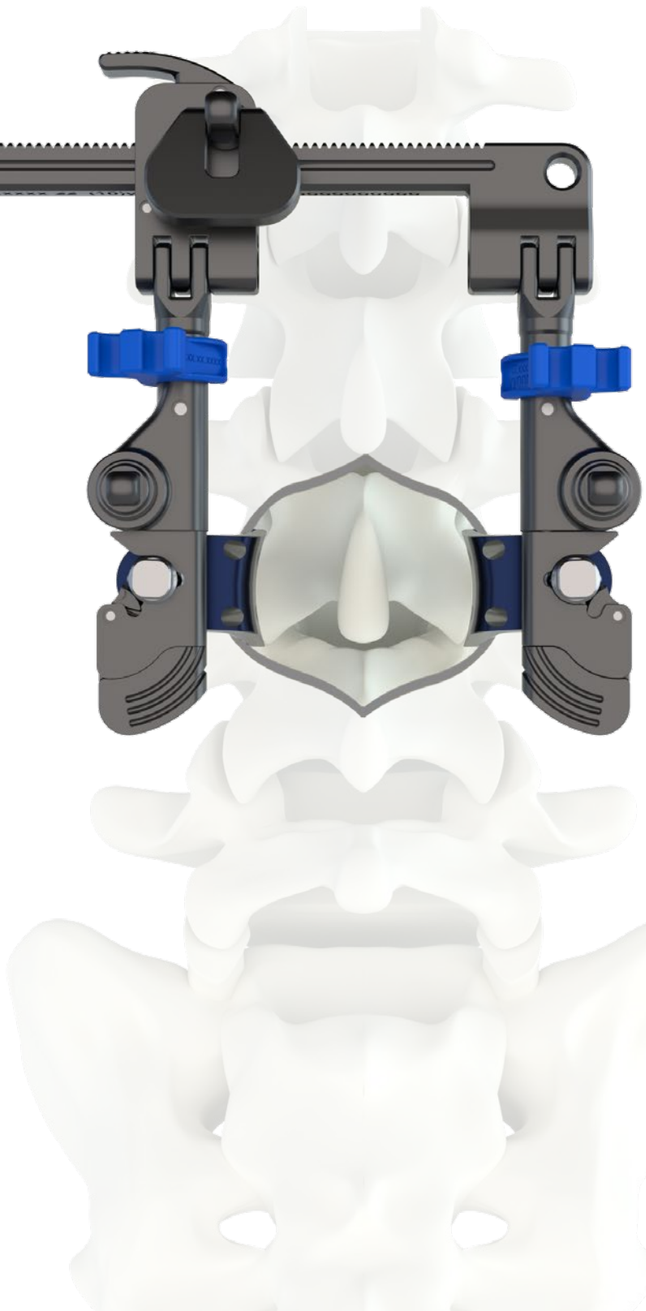
MYSPINE MC VS. FREE HAND CBT

The **MySpine MC guide** offers the possibility to position the **entry points at the pars interarticularis** with favorable cortical bone allowing for using **longer screws** and **larger diameters** compared to conventional CBT free hand.[13]

TIME SAVING TECHNIQUE

The 3D printed guides are ready to use. By positioning them on the planned vertebra the screw path can be created for a safe and fast implant positioning, potentially eliminating the need of perioperative image acquisition and offering a significant **reduction of procedural time**.[14]





MC RETRACTOR

A dedicated **MIS retractor** with **anatomical blades** for **minimally disruptive access**.

QUICK LATERAL MOUNTING

The retractor frame has been designed with a lateral mounting feature for **quick blade mounting**, which also allows for connection of the blades **in situ**.

EFFECTIVE MUSCLE RETRACTION

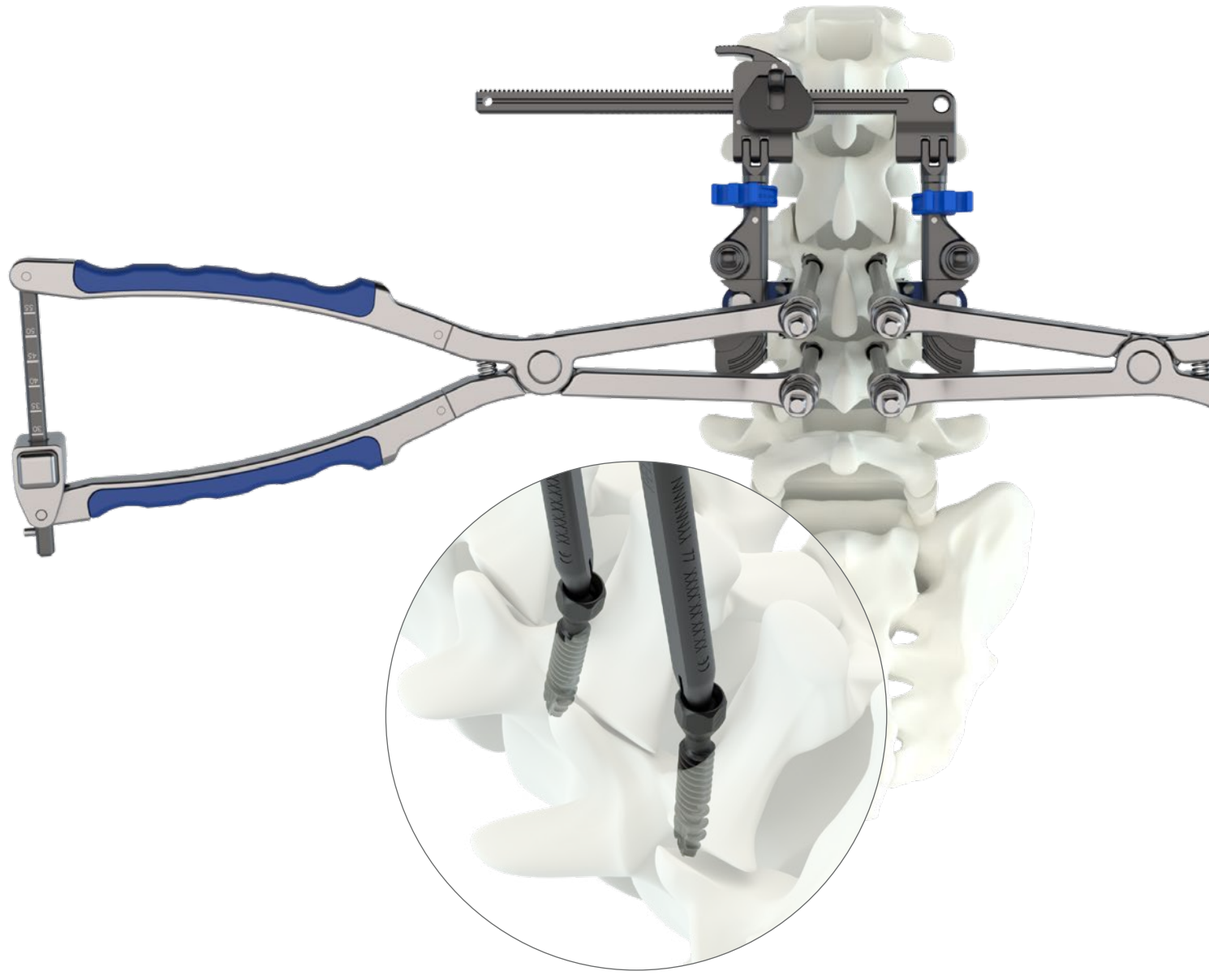
Further muscle retraction can be gently achieved by tilting the blades for an **optimal in situ visualization**.

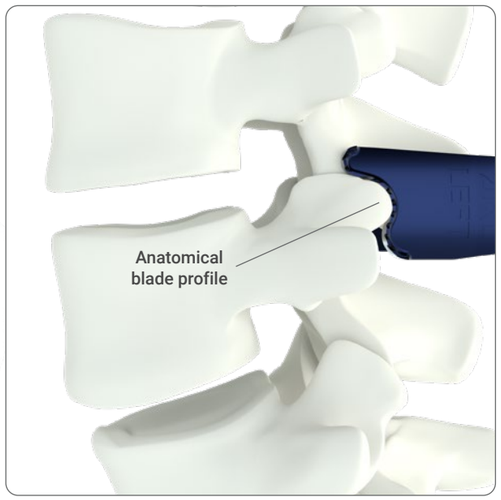
ANATOMICAL BLADE DESIGN

The favorable fit of the blade onto the posterior anatomy, provides **optimal tissue retraction** and helps prevent tissue creep, thus improving the field of view.

LIGHT SYSTEM

The compatible light system allows the surgeon to use **optical illumination** for **improved in situ visualization**.





MC MODULAR TAP AND DISTRACTOR

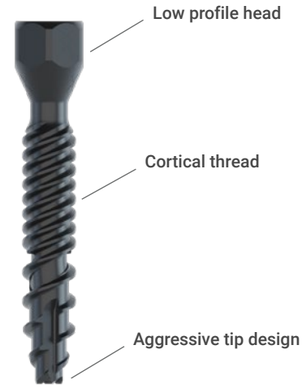
The **distractor system** with **modular & low profile taps** allows for a **straightforward technique** with an **effective distraction maneuver**.

MODULAR AND LOW PROFILE

The modular and low profile design allows for a quick distractor system connection.

VERSATILE AND ROBUST

The distractor system can be adapted to surgeon's **personalized technique**, to distract for an **easy intervertebral body device insertion** or to perform a **simple and effective decompression** maneuver.



MECTALIF SYSTEM - LUMBAR CAGES

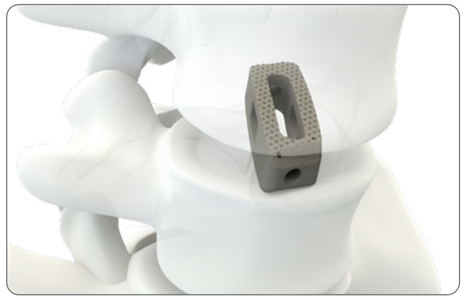
Medacta posterior lumbar cages are **versatile interbody fusion devices** designed for unilateral transforaminal approach or bilateral PLIF straight insertion.

COMPREHENSIVE CAGE PORTFOLIO

Thanks to the **anatomical design**, the Medacta posterior cages provide an **anterior-posterior support** with endplates in different shapes and allow for an **improved bicortical bridge support** aiming for a more physiological stress distribution compared to standard designs[15].

POTENTIAL BENEFITS

- Provide in situ stability
- Restore the native disc space height and lordosis[16]
- Contribute to the recovery of the spinal balance

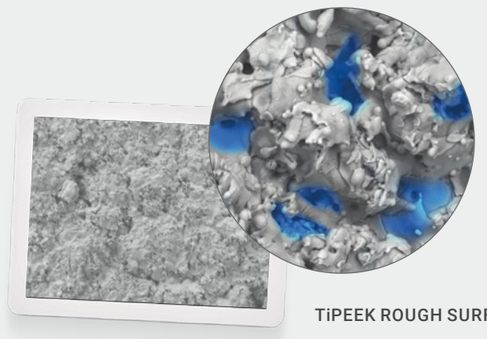


MectaLIF® SYSTEM

UNIQUE TITANIUM COATING

The Medacta posterior cages are plasma spray coated devices with a **unique roughness** and a **3D complex topography**.

- The micro scale roughness promotes **osteoblastic differentiation** potentially **promoting faster bone formation**.[17]
- The surface might improve neovascularization leading to **osteointegration**.[17]
- **Ti-coated surfaces** reduce inflammatory response with reduced risk of fibrous tissue layer around the implant while driving **direct bone formation**.[18]

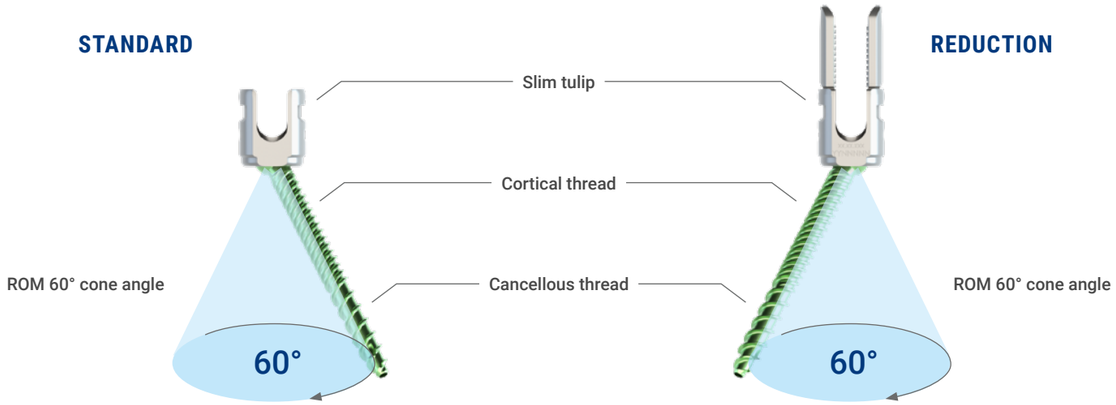


TiPEEK ROUGH SURFACE

The Titanium Coated Peek cages (TiPEEK) incorporate the advantages of both PEEK polymer and Titanium. This means that our cages may provide appropriate spine support, **preventing the risk of subsidence**[19] and allow for proper load force transmission at the implant-tissue interface[20] while offering a **good biocompatible implant**.

M.U.S.T. MC SCREW SYSTEM

The **cortical/cancellous** screw threads **differentiate bone purchase**, enhancing the posterior fixation.

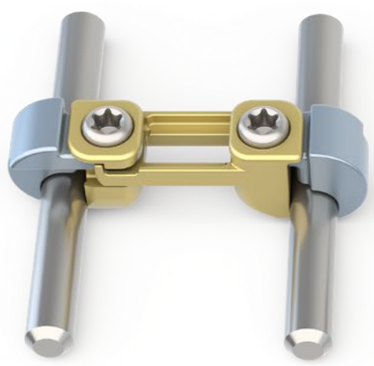


The M.U.S.T. MC screw minimizes the tulip dimensions, reducing the risk of interference with the surrounding bone and tissue

M.U.S.T. MC CROSS-CONNECTOR

The Medacta portfolio includes dedicated cross-connector, designed with a minimized profile and is intended for use with rods distant between 19 and 40mm in length. Two versions of the M.U.S.T. MC cross connector are available: straight and adjustable. In the straight version the hook can tilt ±5°, in the adjustable version ±15°.

STRAIGHT



ADJUSTABLE

MYSPINE MIS MC POTENTIAL POSTOPERATIVE BENEFITS

SHORTER RECOVERY TIME

While **not violating the neuro-muscular structures**, the MySpine MC technique may **decrease the muscular atrophy** leading to a **shorter rehabilitation**.[4,5]

*"My patients can **walk autonomously** the day after the surgery."*

***MD N. Marengo**, Italy*

REDUCED COMPLICATIONS

The MySpine MC technique **reduces the incidence of complications**, when compared to free-hand techniques, because of the **highly accurate implant positioning**.[21]

*"In our specific setting, the same surgical team **reduced complications from 16%** using the free-hand technique **to 0% with MySpine MC**."*

***MD N. Marengo**, Italy*

SHORTER HOSPITAL STAY

The MySpine MC technique usually significantly **reduces the duration of the hospital stay by 37%**.[21]

*"MySpine MC is a **Minimally Invasive technique** proven to be successful in Outpatient Setting."*

***MD I. LaMotta**, USA*

LONG-TERM OUTCOME

The MySpine MC 3D printed-specific solution may provide **better biomechanical performance**, allowing for an **improved long-term outcome**.[4,5,22]

*"At the 6-month follow-up, our patients show **important clinical improvements**, without new neurologic deficits or radiologic pathologic findings."*

***MD K. Matsukawa**, Japan*

MYSOLUTIONS PERSONALIZED ECOSYSTEM

A network of advanced digital solutions designed to improve patient outcomes and healthcare efficiency

MySolutions Personalized Ecosystem is designed around the patient's needs and expectations, in collaboration with an international network of expert surgeons, with the aim of delivering value throughout the entire patient journey.

Surgeons' advanced 3D planning is at the core of our platform, followed by highly accurate execution tools such as patient-matched surgical guides, as well as an augmented-reality-based surgical platform and verification software. To improve the patients' experience and support them during the continuum of care we set up a patient-optimized pathway tool. To let surgeons record and measure their clinical outcomes we offer a validated web-based archiving and analyzing system.

Why Medacta personalized enabling technologies?

PERSONALIZED 3D PLANNING

Leverage Medacta's experience and know-how in personalized **3D planning tools**. The preoperative planning suite offers solutions to accurately plan even the most challenging case.

PRECISE EXECUTION

Provide a **complete**, **precise**, **pre and intraoperative guidance** during the screw placement, allowing for personalized approaches based on each **patient's unique anatomy**.

STREAMLINED WORKFLOW

Integrate seamlessly into the surgeon's procedural workflow without bulky instruments, potentially **saving O.R. space setup time, and operative efficiency**.

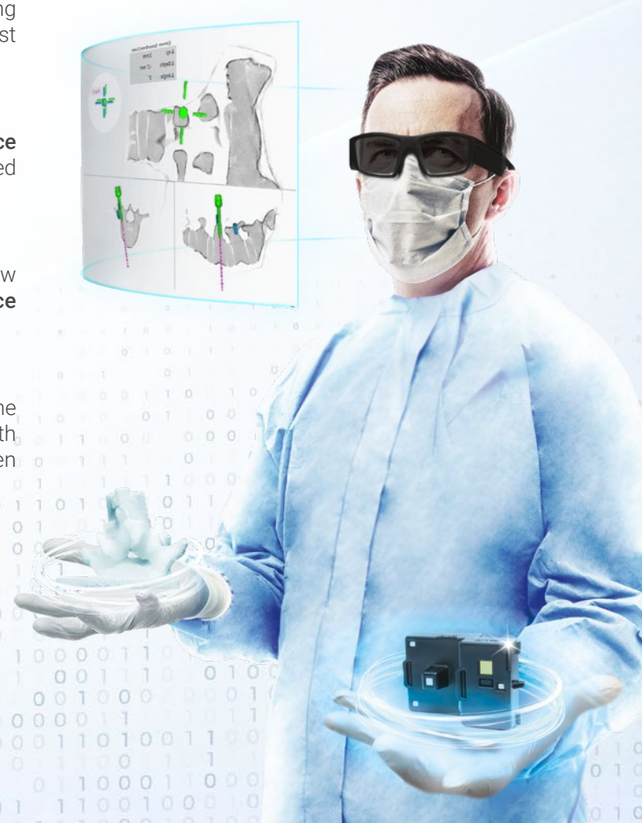
FULLY SUPPORTED ADOPTION

The **learning curve** can be limited to a few cases with the support of tailored **high-level educational pathways**. With the **M.O.R.E. Institute**, the surgeon is never alone when discovering new technologies.

SUSTAINABLE SOLUTION

- **Limited capital investment** required
- **No serving cost**

NEXTAR AUGMENTED REALITY SURGICAL PLATFORM | MySpine® PATIENT MATCHED TECHNOLOGY IN SPINE SURGERY



REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY

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MySpine® MIS MC
Procedural Brochure

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References: ***[1]*** *Santoni B.G. et al., Cortical bone trajectory for lumbar pedicle screws, The Spine Journal, 2009.* ***[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.* ***[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]*** *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.* ***[6]*** *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.* ***[7]*** *Matsukawa K. et al., Accuracy of cortical bone trajectory screw placement using patient-specific template guide system, Neurosurgical Review, 2019.* ***[8]*** *Lange et.al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery, Spine 2013.* ***[9]*** *Biswas et.al. Radiation Exposure from Musculoskeletal Computerized Tomographic Scans, JBJS Am. 2009.* ***[10]*** *Radiation Dose in X-Ray and CT Exams; 2013 Radiological Society of North America, Inc.* ***[11]*** *MySpine, Charité University Hospital, Berlin, Germany.* ***[12]*** *Health Physics Society Specialists in Radiation Safety, Lawrence Berkeley National Laboratory; Fact Sheet 2010.* ***[13]*** *Matsukawa -2nd MORE Japan MySpine cortical Bone Trajectory 2017. https://mysurgeon.medacta.com/uploads/presentation/attachments/d33a45ed-c550-438b-96b8-5e3fb1696725.mp4.* ***[14]*** *Farshad et. al. Accuracy of patient-specific template-guided vs. free-hand fluoroscopically controlled pedicle screw placement in the thoracic and lumbar spine: a randomized cadaveric study. Eur Spine J. 2016.* ***[15]*** *Influences of disc degeneration and bone mineral density on the structural properties of lumbar end plates; Yang Hou et.al: The Spine Journal 2012. Osteoporotic patients in spine surgery (Michael Rauschmann).* ***[16]*** *Biswas et.al. Radiation Exposure from Musculoskeletal Computerized Tomographic Scans, JBJS Am. 2009.* ***[17]*** *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.* ***[18]*** *Buser D et al. J Biomed Mater Res 1991;25(7):889-902.* ***[19]*** *Chen et al. Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: a prospective, randomized, control study with over 7-year follow-up. Eur Spine J. 2013 Jul;22(7):1539-46.* ***[20]*** *Sagomonyants KB, Biomaterials 29 (2008) 1563-1572.* ***[21]*** *Petrone S. et al., Cortical bone trajectory technique's outcomes and procedures for posterior lumbar fusion: A retrospective study, Journal of Clinical Neuroscience, 2020.* ***[22]*** *Matsukawa K. et al., Cortical pedicle screw trajectory technique using 3D printed patient-specific-guide, M.O.R.E. Journal, 2018.*