SPINE PORTFOLIO

A COMPLETE RANGE OF SOLUTIONS

Brochure

Joint | Spine | Sports Med

Medacta International

CERVICAL

Mecta-C SYSTEM

A **comprehensive system** of cervical interbody fusion **cages** and anterior **plates** for cases of degenerative disease, trauma, tumours and deformity.

Large range of implant sizes and lordosis to accommodate different patient anatomies.

Mecta-C STAND ALONE

The **MODULAR design** incorporates the benefits of an anterior plate and a separate radiolucent titanium coated interbody spacer.
The surgeon has the ability to choose intraoperatively from **four different plate designs** and the option of fixing the construct with **lag** or **locking screws**, according to the patient's individual anatomy.

COMING SOON

LUMBAR

MectaLIF ANTERIOR

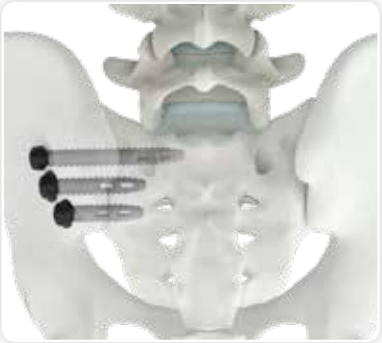
Modular cage and plate design provides the surgeon with intra-operative freedom of choice.

Multiple configurations to cover **different patient anatomy** and **surgical needs**.

SACRO-ILIAC

M.U.S.T. SACRO ILIAC

The M.U.S.T. Sacro Iliac System is designed for the **sacroiliac joint fusion** for patients suffering from degenerative sacroiliitis and sacroiliac joint disruptions.



GE OF SOLUTIONS

CERVICAL

M.U.S.T. MINI

A **simple and flexible** solution for **posterior cervical spine fixation** that allows the surgeon to assemble the desired construct according to the anatomy of the patient.

THORACOLUMBAR

M.U.S.T.

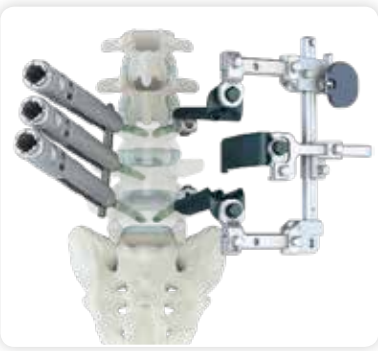
Versatile and **comprehensive** pedicle screw system designed to provide **flexibility** to the surgeon.

Harmonious, single-system approach for most spine stabilisation applications.

MectaLIF SYSTEM

A **complete system** of **cages** for solid initial fixation, and long term spine stabilisation.

Versatile interbody fusion devices platform with various anatomic shaping to **address your unique patients**.



M.U.S.T. MIS SYSTEM

M.U.S.T. MIS Platform: an **effective and harmonic** concept in terms of minimally invasive solutions.

The **Mini Open Retractor** together with the **Percutaneous System** can assist the surgeon to achieve efficient spine surgery results.

SPINE PORTFOLIO

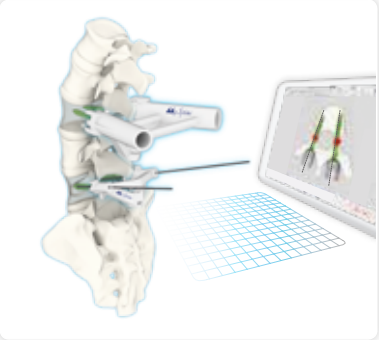
TECHNOLOGIES

MySpine

MySpine is a **patient specific** pedicle screw placement guide that, thanks to the 3D **pre-operative planning**, supports the surgeon during the critical steps of pedicle screw placement in order to:

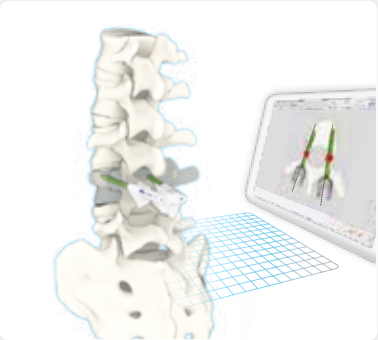
- improve accuracy
- reduce the surgical time
- reduce X-ray radiation to the patient and OR Staff

This innovative concept combines several different features to offer potential benefits to both the surgeon and the patient.



MySpine MC

MySpine MC is a **3D printed** patient matched solution in the **midline cortical** approach. Posterior lumbar fusion is driven in a **minimally invasive**[1], muscle sparing way, potentially allowing for shorter operating times[2,3] and a reduction of both radiation exposure[2] and costs[3].

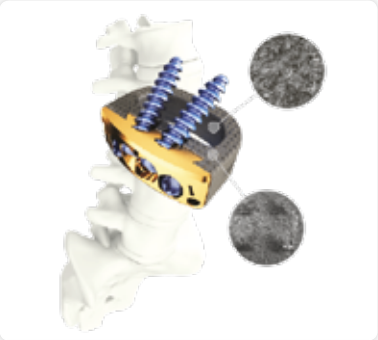


MectaLIF TIPEEK

Medacta's TiPEEK cages represent the next generation plasma sprayed Ti-Coated interbody fusion device designed to:

- promote bony on-growth
- provide optimal diagnostic assessment
- deliver improved stability

Titanium coated PEEK cervical and lumbar cages offer **superior properties** with regard to biocompatibility and biomechanical behaviour.



Cement & Biologics

A dedicated **cement system** that can provide pedicle screw augmentation and strong fixation.
Fully synthetic **moldable bone graft** that easily fits into different size and shaping of Medacata' cages. The microporous resorbable granules of calcium phosphate promotes a **faster bone growth**.

REFERENCES

[1] Matsukawa -2nd MORE Japan MySpine cortical Bone Trajectory 2017. [2] 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 [3] Landi et al. Spinal Neuronavigation and 3D-Printed Tubular Guide for Pedicle Screw Placement: A Really New Tool to Improve Safety and Accuracy of the Surgical Technique? J Spine 2015, 4:5

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rev. 01
Last update: October 2018

Mecta-C® STAND ALONE

ANTERIOR CERVICAL INTERBODY FUSION DEVICE

MODULAR DESIGN OFFERS FREEDOM OF CHOICE

Brochure

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MECTA-C STAND ALONE

Mecta-C Stand Alone is indicated for use in patients suffering from Degenerative Disc Disease at multiple contiguous levels from C2 to T1.

ANGULAR STABILITY

- Divergent & Convergent screws combination
- Increased **pull-out strength**
- Enhanced in-situ primary **stability**

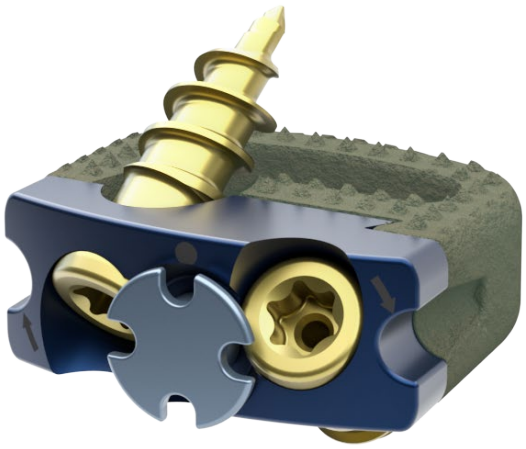
SIMPLICITY

Designed to simplify the surgical steps through an **easy and controlled implantation.**

Four plate configurations and angled instruments to cover different needs and **challenging anatomies**.

BONE GRAFT VOLUME

Wide central bone **graft area** may help to accelerate the occurrence of fusion through the implant.



CLEAR FUSION ASSESSMENT

- **Radiolucent TiPEEK** cage
- Titanium marker with **limited image artifact**
- Accurate reference for **diagnostic assessment**

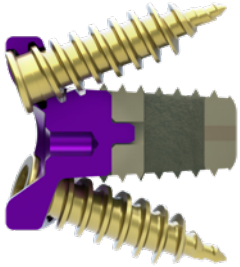
TIPEEK TECHNOLOGY

The modular Mecta-C Stand Alone system in conjunction with the TiPEEK bioactive[1] plasma-sprayed titanium coated cages, provides value to improved stability and enhanced **fusion** rate.

ALONE SOLUTION

VERSATILE SYSTEM

Two diffferent options allow the surgeons to select the one that will best suit their patient's needs.

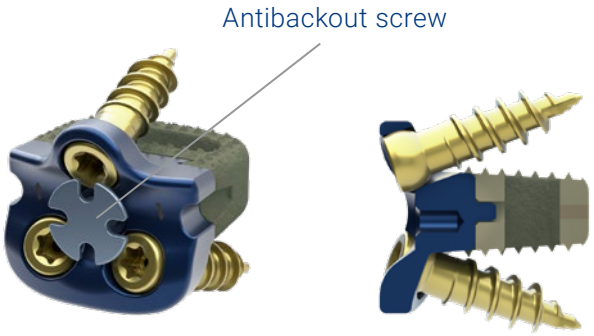


RIGID FIXATION

- **Locking Screw** & **Threaded Plate** for a secure rigid fixation of the construct
- **One step** screw lock system
- **Intrinsic Antibackout** system

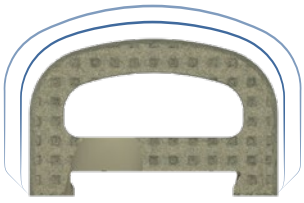
"VARIABLE" FIXATION

- Lag Screw & Unthreaded Plate to allow **micro-motion** and proper load distribution according to the Wolff's law [2]
- **Physiological-like support** that may lead to a stable configuration
- Easy insertion of the central **Antibackout screw** to safely fix the Lag screw



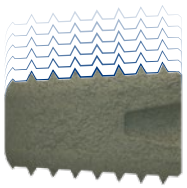
COMPREHENSIVE SYSTEM TO COVER DIFFERENT PATIENTS' NEEDS

Footprint [WxD]



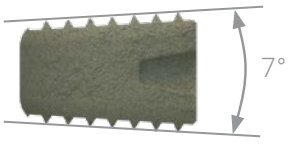
15x13 mm
16x14 mm
18x15 mm

Height [mm]



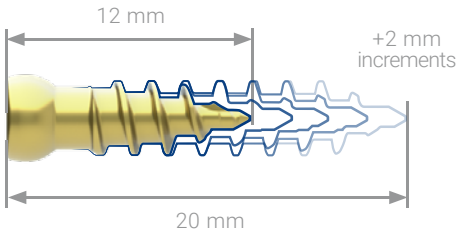
5mm - 12 mm
(+1mm increments)

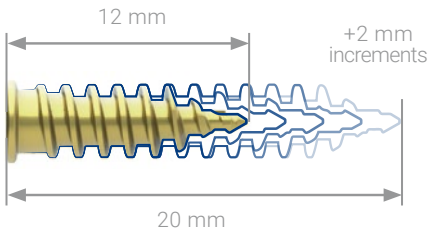
Lordosis



SCREWS

Self-Tapping & Self-Drilling screws are avaialble both for Locking and Lag screws.



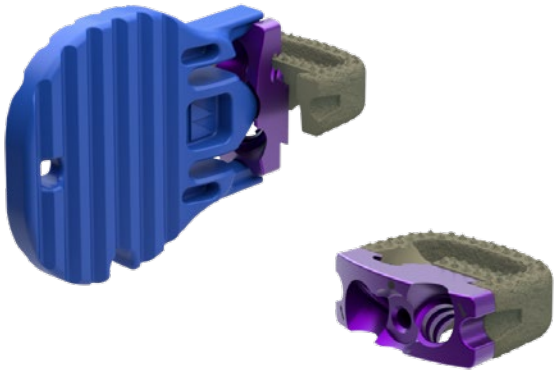


Mecta-C® STAND ALONE

MODULAR DESIGN OFFERS FREEDOM OF CHOICE

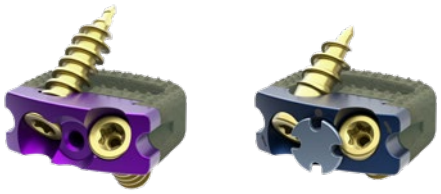
Universal cage to plate «snap-in» concept allows **1-click** construct **assembly**:

- Easy **intraoperative assembly** through the dedicated instrumentation
- Create an **indication-specific** interbody fusion device
- One cage **fits in four plate configurations**



MULTIPLE CONFIGURATIONS

FLUSH

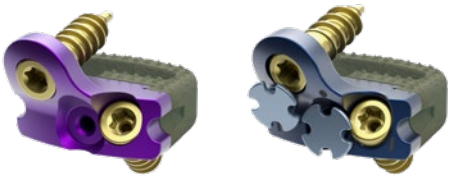


Zero-Profile construct, minimal impact, reduced irritation

TRIO

High **Stability** minimizing the number of screws

HYBRID



Reduces the risk of impingement with surronding anatomical structures. Best fit design for C7-T1 or C2-C3.

QUATTRO

Offers improved **Stability and Torsional Resistance**. The convergent/divergent screw trajectory minimize the adjecent level interference in multilevel fixation.

REFERENCES

[1] B.Walsh et el. Effect of titanium coating on PEEK osteoconductivity in an ovine model, 8° M.O.R.E. International Symposium [2] H.M. Frost, Wolff's Law and bone's structural adaptations to mechanical usage: an overview for clinicians, Angled Ortho 1994

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rev.01
Last update: February 2021

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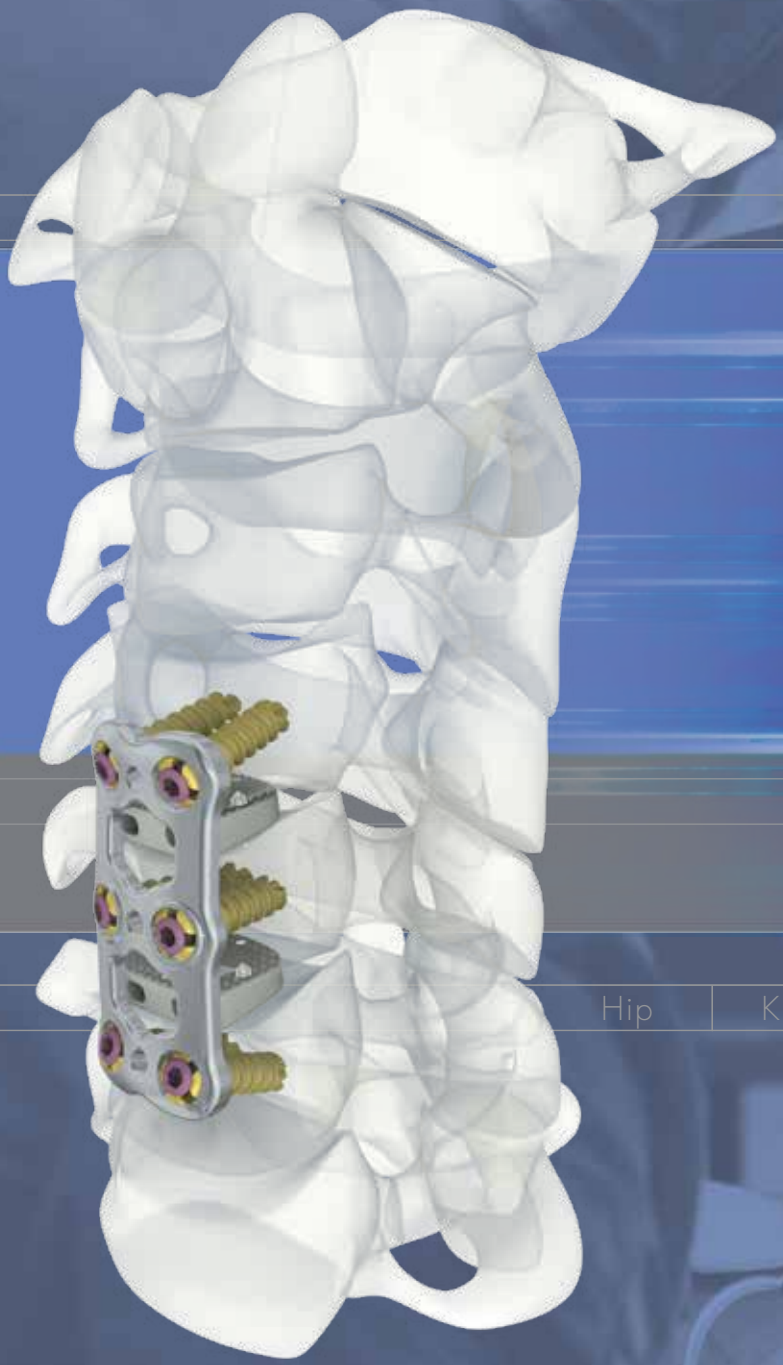
Mecta-C

CERVICAL INTERVERTEBRAL BODY FUSION DEVICE



Brochure

Hip | Knee | Spine | Navigation

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Mecta-C

UNIQUE PATIENTS - SPECIFIC INDICATIONS - ONE SYSTEM

Medacta Spine has developed a portfolio of spine implants that have been designed to complement one another.

The M.U.S.T. Pedicle Screw System, the MectaLIF Family of Interbody Fusion Devices and the Mecta C Plate-Cage system for cervical spine along with our suite of specialised surgical instruments, create a harmonised, single-system approach for most spine stabilisation applications.

Traditional and MIS surgical approaches are supported.

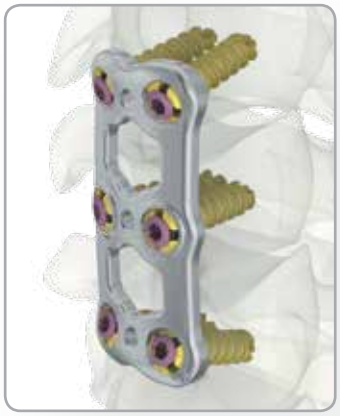
MECTA-C CERVICAL SYSTEM

The Mecta-C family of Cervical Interbody Fusion Cages and Anterior Plates represent a complete System to fuse and mechanically support the cervical spine in case of degenerative disease, trauma, tumors and deformity.

MECTA-C INTERBODY FUSION CAGES

- Made of PEEK and Titanium coated PEEK to offer effective load sharing and optimal biocompatibility. The Ti-Peek implant is entirely coated with Titanium plasma spray coating.
- Maintain modulus of PEEK, while addressing premium acute fixation and potential for long-term osseointegration of the entire implant.
- Options for selecting footprint, lordosis and profile parameters to address patients' unique anatomical needs.
- 12x14, 12x16, 14x14,14x16 and 15x18 footprints (Depth mm x Width mm) to provide structural support at cortical bone foundations
- Flat profile 7° lordosis for last stage of degeneration and Dome profile 5° lordosis to restore the anatomical alignment and mechanical stability for younger patients.
- Pyramidal shaped spikes to improve the primary stability and multi-dimensional pull-out resistance.
- Large central window to maximize the bone graft volume.

MECTA-C ANTERIOR PLATES



- Pre-lordosed plates to match the natural curvature of the spine and deliver secure fixation and stabilization for one, two, three and four level configurations
- Bone screw options include self-tapping or self-drilling designs, with variable and fixed angle locking to secure primary and revision surgeries (up to 20° cephalad/caudal screw angulation)
- Advantages of a polyaxial screw with the capability to convert it into a locking screw
- Preserve the option to build Fixed, Variable and Hybrid constructs to allow optimal load sharing and stability to match the specific needs of your patient
- Low 2mm profile design to reduce soft tissue irritation
- Large window to facilitate final bone graft placement, graft visibility and to assess bone growth via post-operative imaging.

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rev.00
Last update: April 2014

M.U.S.T. MINI

POSTERIOR CERVICAL SCREW SYSTEM

ONE SYSTEM, MULTIPLE OPTIONS

Brochure

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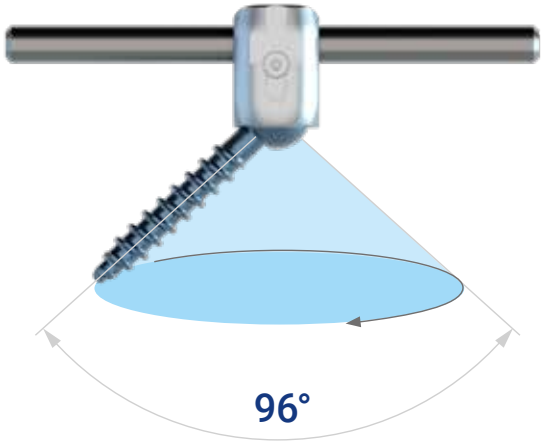
The **M.U.S.T. MINI** posterior cervical screw system is a **comprehensive solution** for fixation of the occipito-cervico-thoracic spine. The variety of screws, hooks, rods and connectors allows the surgeon to tailor the construct to the specific patient anatomy and pathology to be treated.

HIGH POLY-AXIALITY

The **broad range of motion**, up to 96° for the overall cone angle, eases the surgical practice in challenging anatomies.

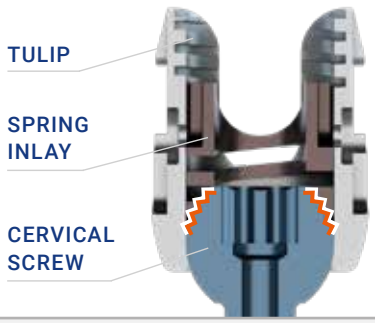


UNIQUE FRICTION HEAD

All the M.U.S.T. MINI screws have the **friction head** feature to facilitate **rod placement** and **ease** of **maneuvers** during surgery.

Orient the screw head

The screw head **maintains** the **position**



RATIONALE

Friction between the internal components allows to hold the screw head in the **desired position**.

MULTIPLE OPTIONS

COMPREHENSIVE SOLUTION

Screws:

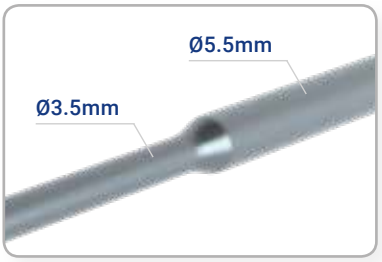
- **Solid** & **Cannulated** Ø3.5, 4, 4.5mm
- **Full** and **partial** threaded

Enhanced sharp tip for cannulated screws to facilitate implant insertion

Rods:

- **CoCr** for superior construct stability
- **Transition rods** for cervico-thoracic fixation

STRAIGHT



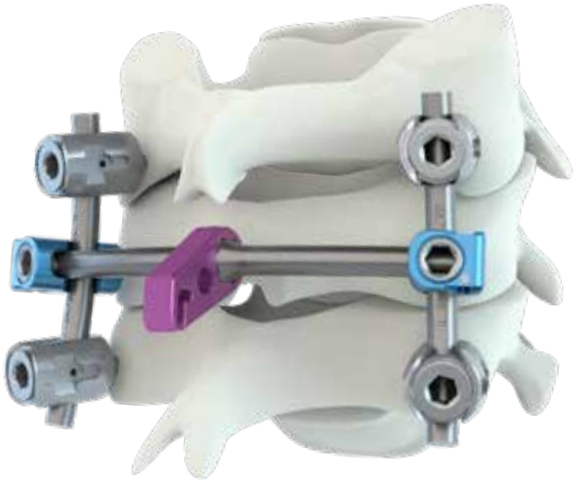
TRANSITION

ARTIFICIAL SPINOUS PROCESS

Seating between the neck muscles allows to:

- **Fix and adapt** the **neck muscles** in the midline
- **Safely secure** the **bone graft** with soft wires
- **Protect** in case of **spinous process** removal
- **Naturally reshape** the posterior aspect

MEDACTA
PROPRIETARY
TECHNOLOGY



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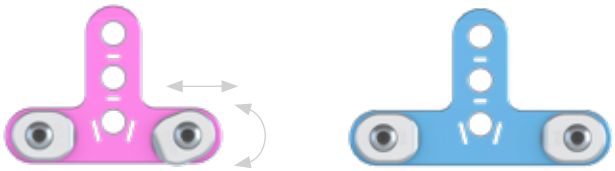
M.U.S.T. MINI

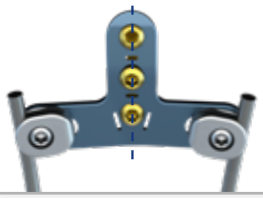
OCCIPITO-CERVICAL FUSION

The Occipital Plate offers **flexibility** to extend and further **stabilise** the posterior cervical construct.



OC PLATES

Small and large design to accommodate different patient anatomy



SCREW ALIGNMENT

Screws aligned along the external protuberance to **maximise** bone **purchase**

SNAP-IN

Adjustable OC Plate connectors **with Snap-in** feature to facilitate rod engagement

Primary

Rescue

SCREWS

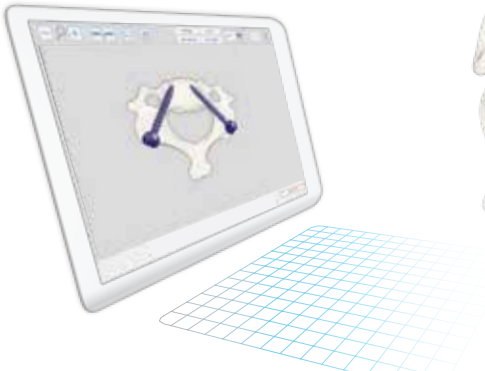
Flat tip design with aggressive groove to facilitate **screw insertion**

UNIQUE SYNERGY WITH MYSPINE CERVICAL

Guided insertion of the **M.U.S.T. MINI screws** thanks to the **MySpine Cervical**, a 3D patient matched technology based on pre-operative planning designed for **pedicle screw** positioning.

- **Steered pedicle screw** insertion
- **Increased stability** vs lateral masses screws trajectory
- **Drastic reduction** in radiation exposure for patients and OR Staff

COMING SOON



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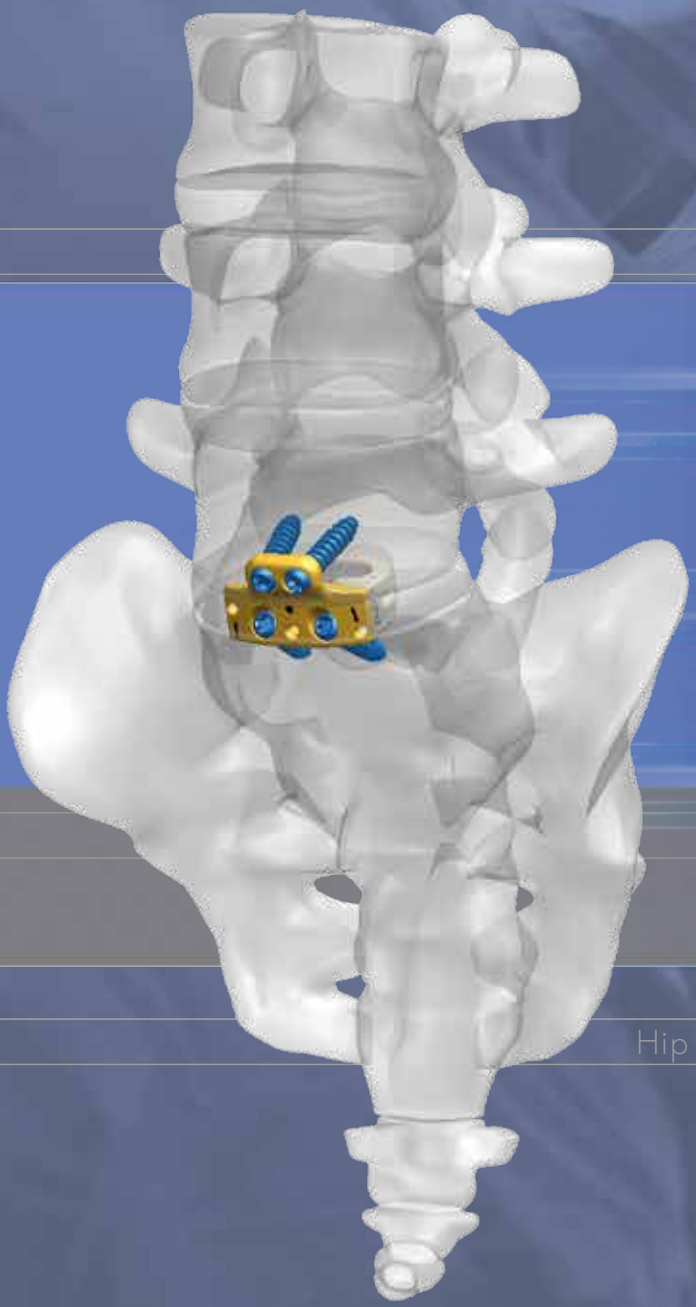
MectaLIF ANTERIOR

ANTERIOR LUMBAR INTERBODY FUSION DEVICE



Brochure

Hip | Knee | Spine | Navigation

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MECTALIF ANTERIOR HYBRID

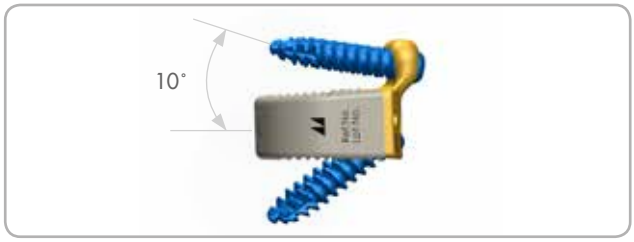
The MectaLIF **Hybrid** Interbody Fusion Device merges the mechanical features of the **Flush** zero anterior profile plate with the **Long** enhanced stability construct, thus providing added value in Anterior lumbar fixation.

MECTALIF ANTERIOR HYBRID RATIONALE

The MectaLIF **Hybrid** Interbody Fusion Device provides an aided solution for L5-S1 implantation where additional stability is required and low profile construct is necessary to deal with difficult tilted anatomies.

The **Flush** caudal profile avoids impingement and irritation of the soft tissues.

The **Long** cranial profile provides high level stability in extension and torsion.



The low-angle 10° screws offer easier insertion in challenging anatomies avoiding interference with the pubic symphysis. Low angle trajectory allows for screw insertion with straight instruments and a simple surgical technique.

Diverging screws provide enhanced stability and increased pull-out strength.

REFERENCES	
Hybrid Plate Height	Ref. code
H.12 mm	03.30.232
H.14 mm	03.30.233
H.16 mm	03.30.234
H.18 mm	03.30.235

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MectaLIF ANTERIOR

ANTERIOR LUMBAR INTERBODY FUSION DEVICE

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MECTALIF ANTERIOR SYSTEM, A COMPREHENSIVE SOLUTION FOR LUMBAR SPINE FUSION

SECURE LOCKING SYSTEM

- Controlled torque means securely locked screws with no need for a separate **anti-migration system**
- Threaded Titanium helps **avoid cross threading**
- **Horizontal screw** angle reduces the bending moments, preventing screw back out

ANGULAR STABILITY

- **Exclusive** divergent & convergent **screws**
- Enhanced in-situ system **stability**
- Increased **pull-out strength**

ENHANCED BONE GRAFT VOLUME

Large central bone **graft area** may help to accelerate the occurrence of fusion through the implant.

TIPEEK TECHNOLOGY

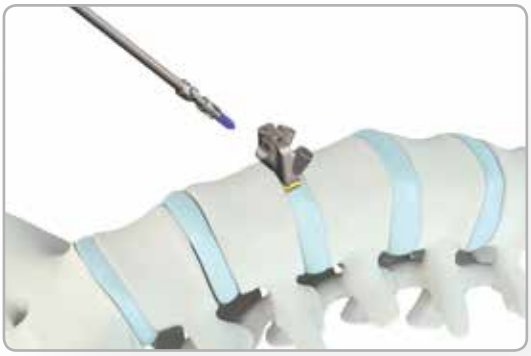
The MectaLIF Anterior system exploits Medacta's uniquely **bioactive** and **osteoconductive** Titanium coating technology.

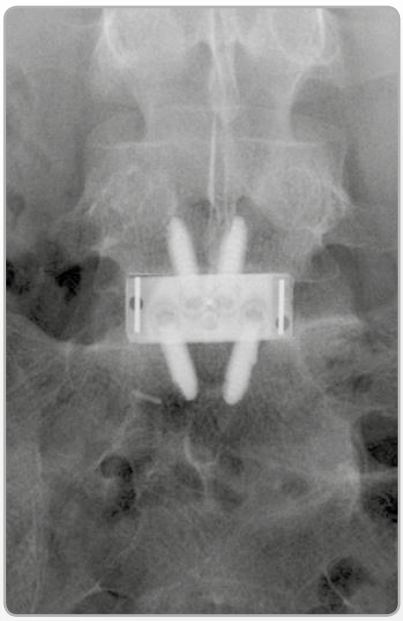
INTERBODY FUSION DEVICE

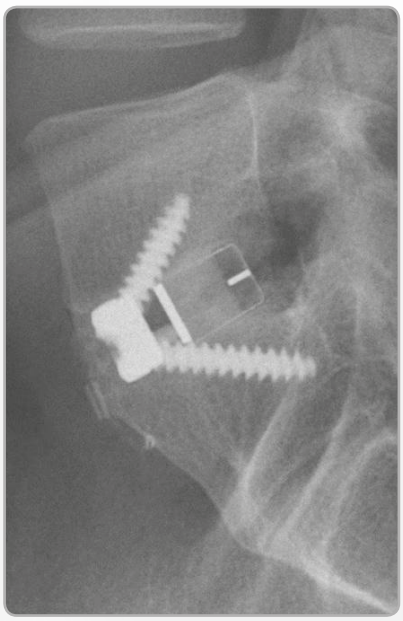
EASE OF IMPLANTATION

Dedicated instruments simplify surgical steps:

- in **challenging anatomies**
- in cases of **extreme** spine **curvature**
- in angled **L5-S1 anatomy**





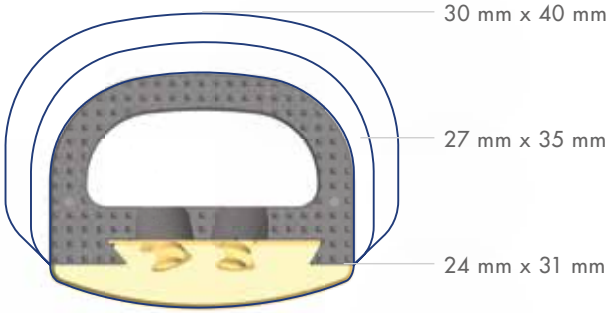


VERSATILE OFFERING

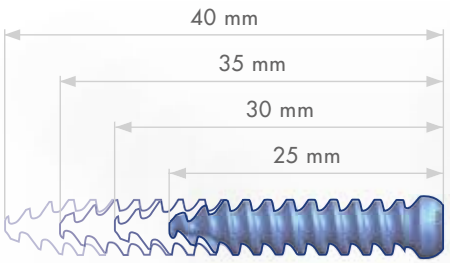
MectaLIF Anterior cages are offered with numerous implant heights, footprints and lordoses:

- ensuring an **optimal** anterior / posterior **support**
- providing patients with the **best** anatomical **fit**
- accommodating **surgeon's practice**

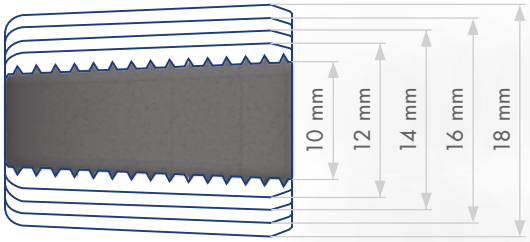
FOOTPRINT [D X W]



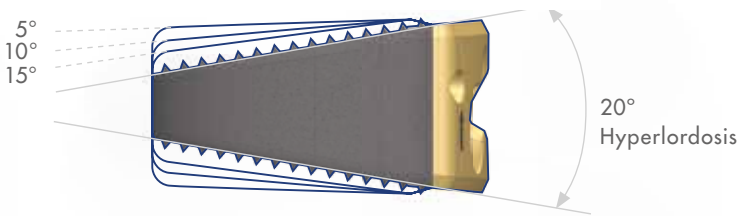
SCREWS LENGTHS



HEIGHT



LORDOSIS



MectaLIF ANTERIOR

UNIQUE MODULARITY

Universal cage to plate "snap in" concept allows the assembly of the construct in **1-click** to:

- Perform **intraoperative assembly**
- Create an **indication-specific** interbody fusion device

MULTIPLE CONFIGURATIONS - FREEDOM OF CHOICE

ANTERIOR STAND-ALONE SOLUTIONS to cover diverse patient anatomies and surgical needs.

FLUSH

No anterior profile, **minimal impact**, reduced irritation

HYBRID

Stable solution for L5-S1 **challenging anatomy**

LONG

Superior stability in extension and torsion

L5-S1

Flexible design for the iliac artery bifurcation

LATERAL

Offset profile, minimize vessels manipulation

ANTERIOR SOLUTION
requires supplementary fixation

SIMPLE

Simple! **Pure Anterior** approach

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MectaLIF

INTERVERTEBRAL BODY FUSION DEVICE

Brochure

Hip | Knee | Spine | Navigation

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MectaLIF

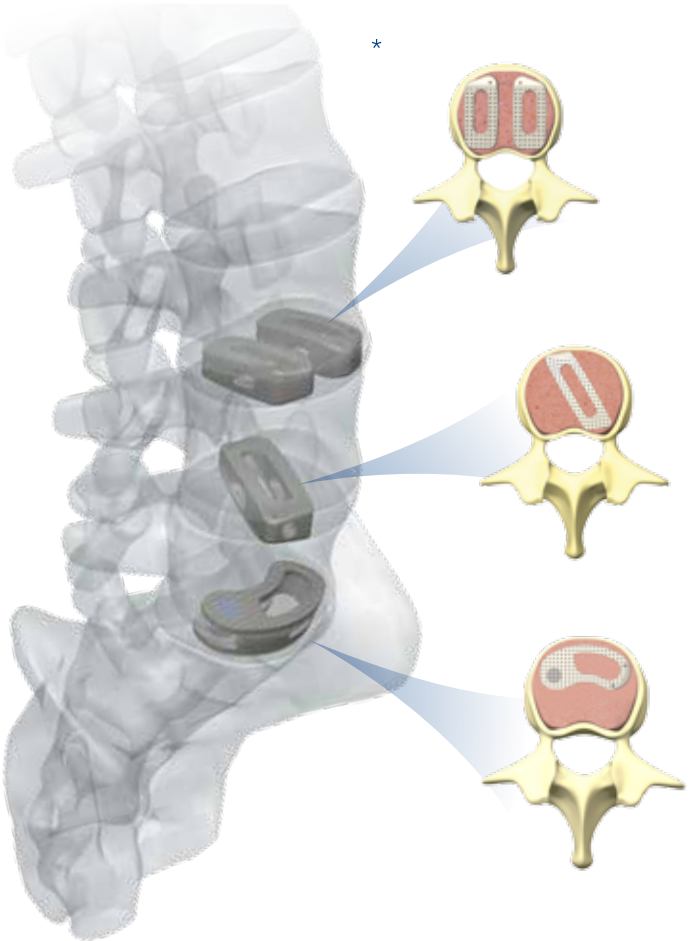
MEDACTA INTERNATIONAL

The foundation of Medacta International is built upon world-class hip and knee arthroplasty technology and leadership by the family Siccardi and a dedicated team of talented professionals based in Lugano, Switzerland.
The company began in the year 2000, and has proceeded on an accelerated growth curve that reflects our Customer's appreciation for Quality, Innovation and Service.
Bringing Swiss precision and engineering to the Spine Specialists, Medacta Spine, founded in 2009, is moving forward globally to deliver surgical technology solutions for degenerative, deformity and trauma/oncology indications through traditional open and MIS surgical approaches.
Medacta International has achieved FDA approval of a number of unique and effective spine implants. An active pipeline of technology development is being validated in worldwide markets and ultimately planned for eventual availability in the United States. Until then, we are proud to represent posterior and anterior fixation options designed with an important Philosophy: **Unique Patients - Specific Indications - One System.**

MECTALIF OLIF, TLIF AND PLIF FUSION DEVICES

The MectaLIF Family of Interbody Fusion Devices are shaped for solid initial fixation, and long term spine stabilization. Made of PEEK and Titanium coated PEEK material, the MectaLIF Fusion Devices offer biocompatibility and anatomic shaping to address your unique patients.

- Each implant features a chamfered leading edge for effective interbody distraction and less effort upon insertion.
- A variety of interbody heights, lordotic angles and footprints allow significant options when selecting the correct implant for your unique patients with bi-cortical bridging.
- Large autograft windows allow the delivery of significant volumes of bone to support bone growth through the cages.



* The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion.

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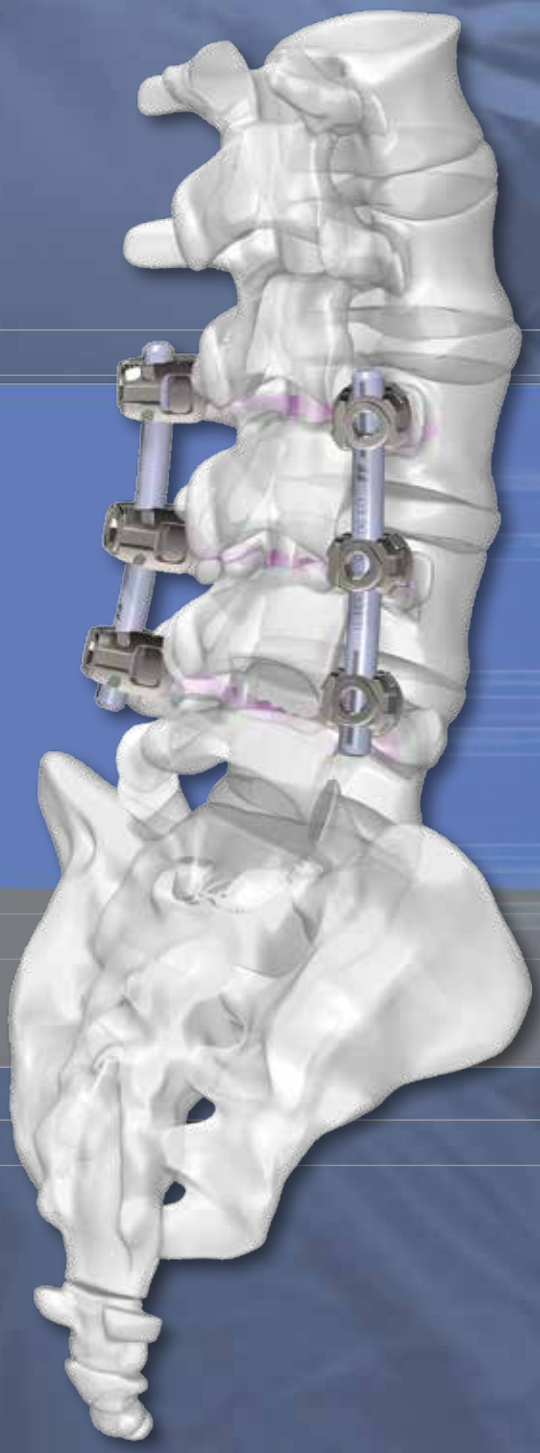
M.U.S.T.

MEDACTA UNCONSTRAINED SCREW TECHNOLOGY



Brochure

Hip | Knee | Spine | Navigation

Medacta International

UNIQUE PATIENTS - SPECIFIC INDICATIONS - ONE SYSTEM

Medacta Spine has developed a portfolio of spine implants designed to complement one another.

The M.U.S.T. Pedicle Screw System, the MectaLIF Family of Interbody Fusion Devices and our Suite of Specialized Surgical Instruments create a harmonized, single-system approach for most spine stabilization applications.

Traditional and MIS surgical approaches are supported.

M.U.S.T. PEDICLE SCREW SYSTEM

The M.U.S.T. Pedicle Screw System is an unconstrained polyaxial screw, rod & connector design applicable to degenerative, deformity and trauma indications using traditional open or MIS (mini-open) surgical approaches.

- Ultimate Versatility in One System.
- Ability to lock polyaxial head without in-situ rod to create monaxial rigidity for parallel compression/distraction.
- Pre-sterilized implants increase logistic efficiencies and reduce hospital preparation.
- Dual-thread lead advances screw with control and speed.
- Specialized enabling instruments for rod reduction and set-screw threading.
- Polyaxial and monoaxial in solid and cannulated versions.
- Range of diameters available to cover the thoracic, lumbar, sacral and sacro-iliac fixation needs.
- M.U.S.T. Link Cross Connectors provide an easy-to-use option to improve the stabilisation of the treated spine.

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U.S.T. SI

SACRO-ILIAC JOINT SCREW SYSTEM

A COMPLETE SYSTEM WITH DIFFERENT OPTIONS

Brochure

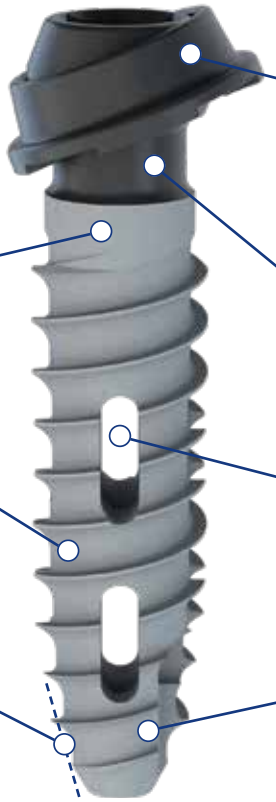
Joint | **Spine** | Sports Med

Medacta International

M.U.S.T. SI

The M.U.S.T. SI, Medacta Universal Screw Technology Sacro Iliac System, is intended for sacroiliac joint fusion of skeletally mature patients suffering from sacroiliac **joint disruptions**, degenerative **sacroiliitis** and degenerative sacroiliac **arthritis**, secondary to pelvic disruption.

IMPLANT FEATURES



Washer - "one-fits-all"
Several sizes to achieve suitable compression and proper load distribution

Hydroxyapatite rough plasma spray to promote arthrodesis

Titanium core screws

Long Pitch, Dual Lead Thread for rapid screw insertion

Windowed slots to enable surrounding bone access

Tapered tip aided guidance through hole

Self-Tapping screws to ease the insertion

PRODUCT RANGE

Comprehensive range of implants to accommodate several patients anatomies.

M.U.S.T. SI **Screws**:

- 25-80mm length
- Ø8, 9, 10 mm

M.U.S.T. SI **Washers**:

- **Standard** Ø13, 15, 17, 20 mm. ROM 22°
- **Favoured angle** Ø15, 17, 20 mm. ROM up to 28°

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MySpine® S2AI

PERSONALIZED SACROPELVIC FIXATION

UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS

Brochure

Joint | **Spine** | Sports Med

S2-ALAR/ALAR-ILIAC

Medacta International

S2-ALAR-ILIAC TECHNIQUE

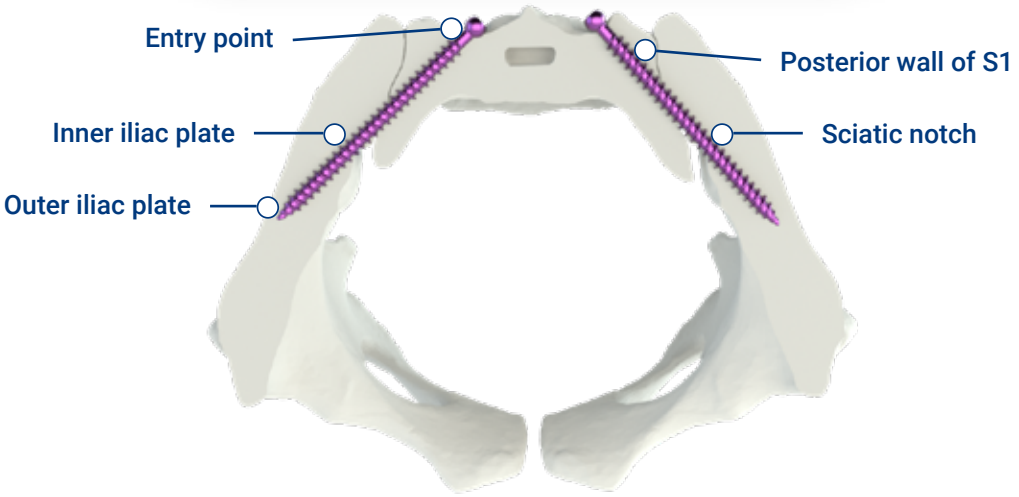
MySpine S2AI is the Medacta Patient-Specific Solution for **S2-Alar-Iliac fixation**: a **minimally invasive** solution at surgeon's hand for long constructs, designed to overcome the limits of a potentially insufficient lower spine fixation.

The S2-Alar-Iliac technique represents a valid solution since the trajectory crosses 5 cortical bone structures, resulting in a **strong bone fixation**, while the medial entry points **reduce** the need of **muscle dissection** leading to[5]:

- **Reduced screw loosening rate[5]***
- **Lower incidence of Sacro-Iliac Joint pain[5]***
- **Small incision[5]**
- **Less dissection[5]***

**compared with alternative lumbosacral instrumentations (S2-Alar and Iliac screws)*

5 CORTICAL BONE POINT FIXATION



Prominent conventional **Iliac screws** may lead to **irritation** and **pain** with **high revision rate.**[2,5]

MYSPINE IS DIFFERENT!

MySpine guided **S2-Alar-Iliac** trajectory may allow for a **small incision** and **less lateral retraction**, and the medial entry point allows for a **quick rod connection**, thus eliminating the need for additional connectors.[5]

PATIENT-MATCHED SOLUTIONS

MYSPINE S2AI VALUE PROPOSITION

MySpine is a **personalized surgical platform** that is **cost effective, efficient** and **intuitive**. MySpine provides pre-op planning, single-use patient-specific drill guides and intra-operative surgical plan.

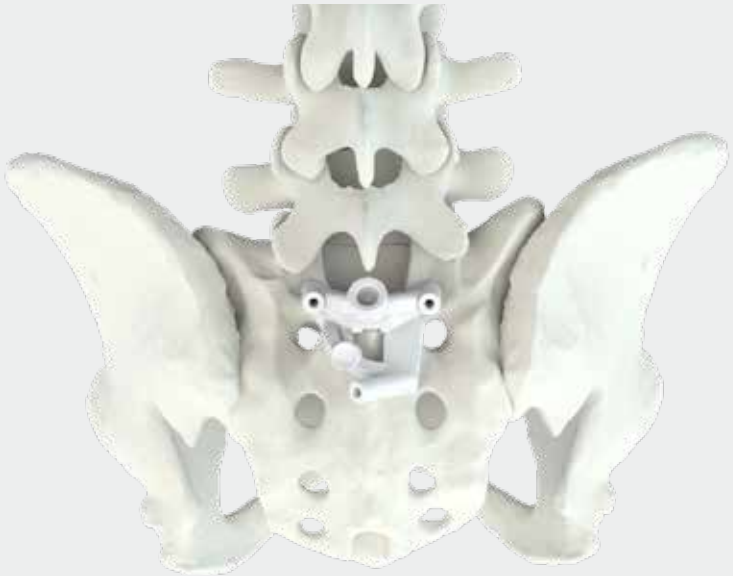
MySpine S2AI Pre-Op Plan

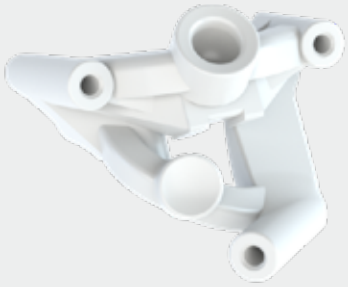
MySpine S2AI 3D Planning

MySpine S2AI can be used in those treatments where **strong bone fixation** is required, as it may provide[1]:

- Robust bone anchor and improved pelvic tilt correction in **Adult Spine Deformity**
- Spine balance recovery in rigid neuromuscular **Adolescent Idiopathic Scoliosis**
- Added value in fixing **fractured segments**

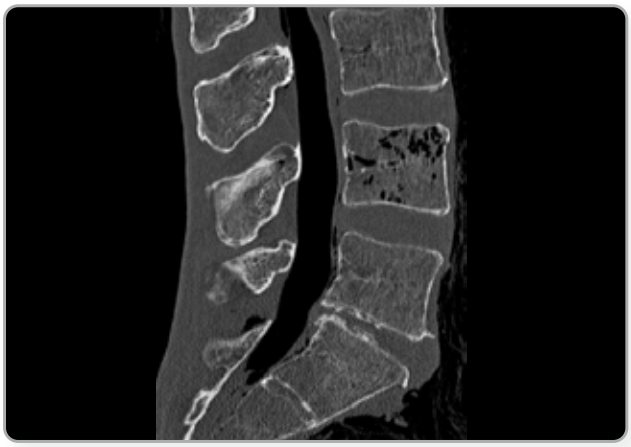
The guided technique leads to **precise screw placement**, comparable to that offered by gold standard navigation tools, while **reducing the radiation exposure and the surgical time.**[3,4]





- **HIGH ACCURACY**
- **LOW X-RAY RADIATION DOSE**
- **LOW PROFILE**

THE MYSPINE JOURNEY



1. IMAGE ACQUISITION

Low Dose CT scan to deliver 3D reconstructed vertebrae and the pelvic region

2. 3D PRE-OP PLAN MANAGEMENT

The surgeon defines optimal implant parameters

3. 3D PRINTING

Patient-matched Jigs are sent to the hospital

4. PROCTORED SURGERY

An experienced surgeon will support you during your first cases

REFERENCES

[1] Sponseller P. et al., "Low Profile Pelvic Fixation With the Sacral Alar Iliac Technique in the Pediatric Population Improves Results at Two-Year Minimum Follow-up", Spine, September 15, 2010
[2] Emami A. et al., "Outcome and Complications of Long Fusions to the Sacrum in Adult Spine Deformity: Luque-Galveston, Combined Iliac and Sacral Screws, and Sacral Fixation", Spine, April 1, 2002
[3] Matsukawa K. et al., Accuracy of cortical bone trajectory screw placement using patient-specific template guide system, Neurosurgical Review, July 2019
[4] Matsukawa K. et al., Cortical pedicle screw trajectory technique using 3D printed patient-specific-guide, M.O.R.E. Journal, September 2018
[5] Krieg S. et al., "Revision by S2-alar-iliac instrumentation reduces caudal screw loosening while improving sacroiliac joint pain—a group comparison", Neurosurgical Review, September 2020 study

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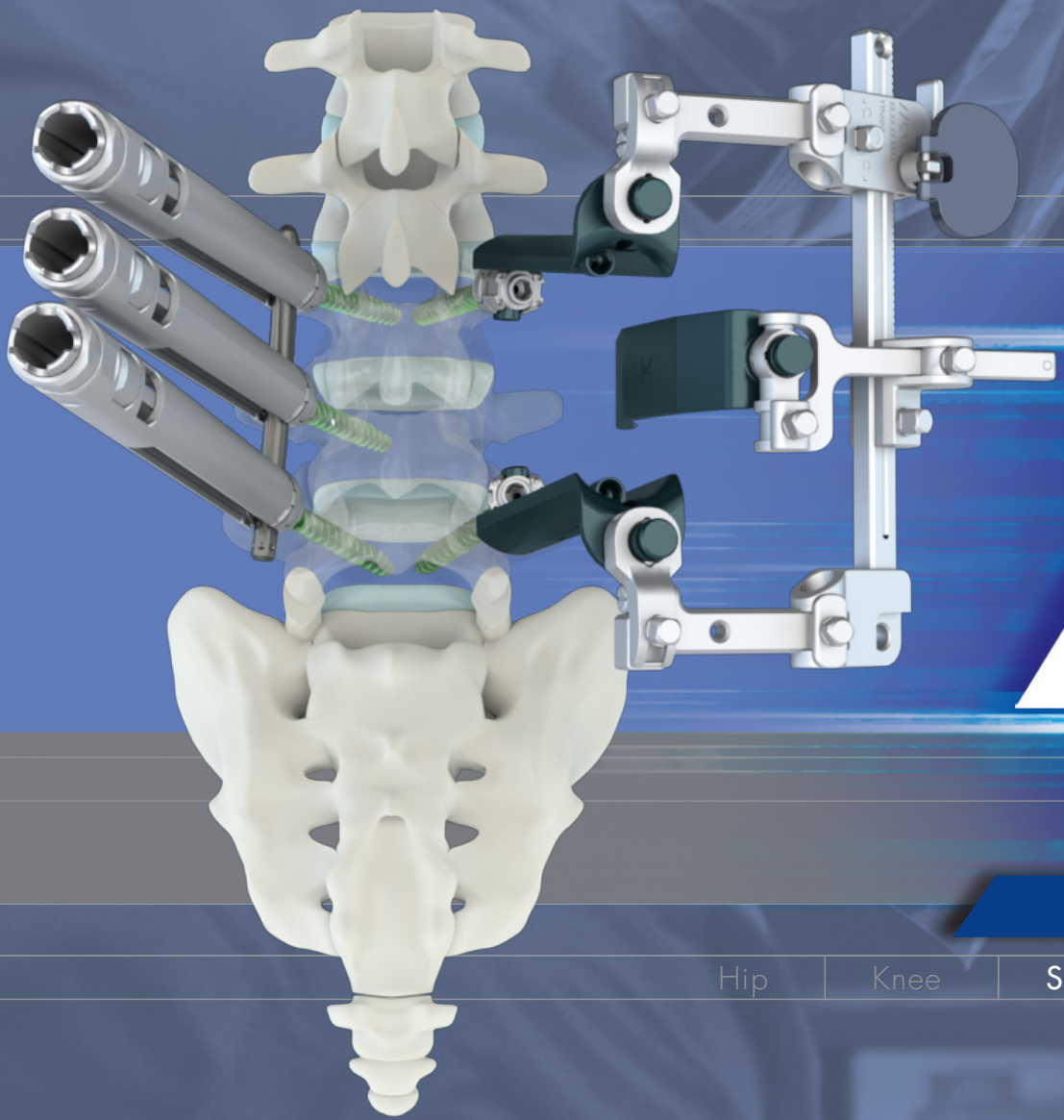
.U.S.T. MIS SYSTEM

MINIMALLY INVASIVE SOLUTIONS

M.I.S. MAKE IT SMART IN ONE SYSTEM



Brochure

Hip | Knee | Spine | Navigation

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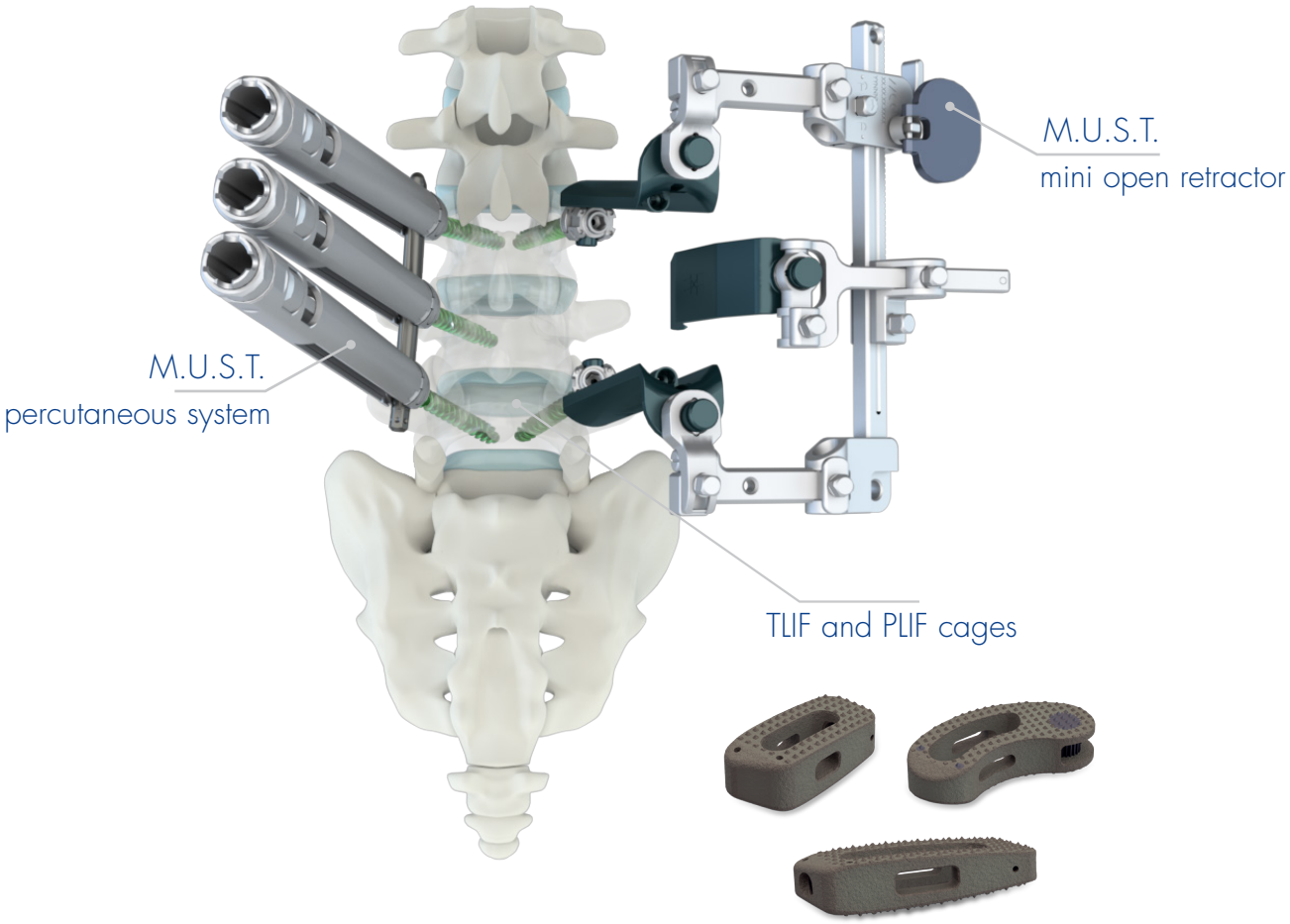
M.U.S.T. MIS SYSTEM

The **MUST MIS System** represents an effective and harmonic concept in terms of minimally invasive solutions. The MIS system is composed of:

- an innovative mini open retractor
- a percutaneous system
- TLIF and PLIF cages with dedicated MIS Instruments



A small incision, a gentle interface with soft tissues and an atraumatic technique may offer **valuable benefits to the patient**:

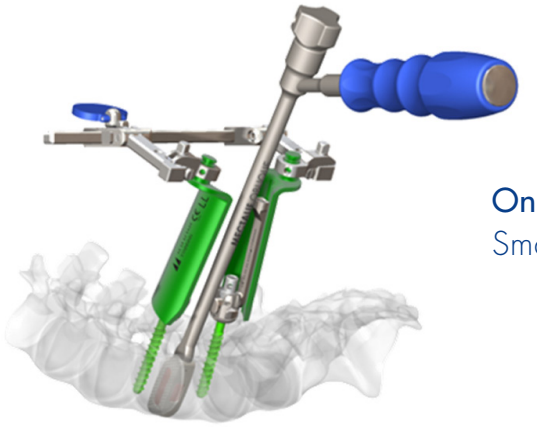
- Small incisions
- Reduced blood loss [1]
- Reduced site infection risks [3]
- Potential reduced vascular disruption
- Minimised soft tissue and muscle damages [2]
- Reduced post-op analgesic therapy [1]
- Minimum scar
- Improved recovery [1]
- Rapid hospital discharge [2]

SMART IN ONE SYSTEM

MUST. MINI OPEN

Specifically designed retractor for:

- decompression
- fusion and fixation
- optimal TLIF and PLIF cage placement with a comprehensive system of **dedicated MIS instruments**

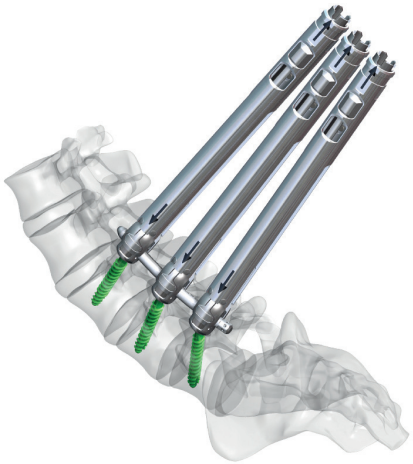


On the patient's side
Small incision, Large visualization

Low profile frame with ergonomic and radiolucent blade design to provide **better visual exposure with dedicated light cables for optimal site illumination**.

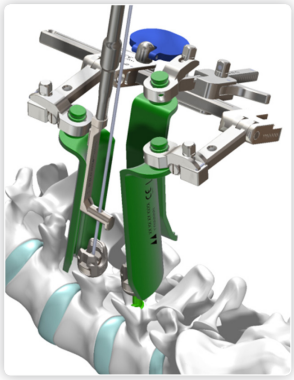
MUST. PERCUTANEOUS

A further step in the development of the well-established MIS approach.
The Medacta MIS system relies on a dedicated **MUST screw-based platform** assuring **superior stability**. Slim Percutaneous tubes provide **atraumatic access**.



An **effective** tool
in MIS treatments

ROBUST CONNECTION



A dedicated blade-to-screw connector gives the polyaxial screw monoaxial function, allowing for **direct and effective distraction of the vertebral bodies.**
Optimal application for minimally invasive PLIF Insertion and Wiltse TLIF approach with **TiPEEK** interbody fusion technology.

ENHANCED BONE CONTACT IN MIS SURGERIES

Optimal application for minimally invasive PLIF Insertion and Wiltse TLIF approach with **TiPEEK** interbody fusion technology.

High fusion rate, low subsidence
for accelerated fusion[1]
& fast bone remodelling[4]

Disc height preservation
for a substantial restoration
of interbody height and lordosis[1]

Improved stability
With an effective rough surface

Easy and clear fusion assessment
TiPEEK cages are compatible with
diagnostic bio-imaging techniques

REFERENCES

[1] S. Chusheng et al. Five-Year Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion: A Matched-Pair Comparison Study. Spine. 38(23):2049-2055, November 01, 2013. [2] Lee KH et al. Clinical and radiological outcomes of open versus minimally invasive transforaminal lumbar interbody fusion. Eur Spine J. 2012 Nov;21(11):2265-70. [3] McGirt et al. J Neurosurg Spine. 2011 Jun;14(6):771-8 Comparative analysis of perioperative surgical site infection after minimally invasive versus open posterior/transforaminal lumbar interbody fusion: analysis of hospital billing and discharge data from 5170 patients.[3] M.Rickert et al. Transforaminal lumbar interbody fusion in PEEK oblique cages with and without titanium coating: results from a randomized clinical trial [4] B.Walsh et al. Titanium coated interbody devices

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PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

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MYSPINE:

A new technology to reduce radiation exposure while maintaining high accuracy

MySpine®
PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

The tools and instruments used in spine surgery are continuously changing and improving. It has been shown and is accepted that the use of a navigation system is an extremely valuable tool in determining the **appropriate placement of pedicle screws**.

Everyone is exposed to natural radiation from food, water, radon gas, cosmic rays, and other naturally occurring radioactive materials resulting in an annual effective dose of approximately 3 mSv [e]. With the use of any ionizing radiation, such as x-ray, there are risks to the patient and to the staff in the operating room. Additional radiation from medical imaging augments the already present **risks of radiation-induced adverse consequences**, such as cancer, birth defects, and other deleterious occurrences.

PATIENT WISE

- **+91%** of breast cancer reported in women exposed to multiple diagnostic x rays [h] vs. normal population
- **+8%** risk of mortality among patients frequently exposed to radiographic exams [j] vs. normal population

SURGEON WISE

- **+190%** risk of breast cancer reported in orthopedic surgeons vs. normal population [k]
- **+100%** risk of all cancer reported in orthopedic surgeons vs. normal population [k]

There are measures that are taken to reduce the risk of radiation exposure, lead shields to cover the torso and neck, protective gloves and eye shields, and maintaining a safe distance from the radiation source. Even with appropriate measures taken, **the surgeon and the staff are still at risk of exposure from scatter radiation**. The newest imaging modalities such as the O-Arm™, have provided benefits, by utilizing intraoperative acquisition of 2D and 3D images of the spine and potentially allowing better placement of pedicle screws. However, these technologies are not without additional risks to the patient and operating room staff.

The effective dose limit for a non-occupationally exposed individual is 1 mSv per year above the background radiation dose of 3 mSv [e]. During a single O-Arm™ image acquisition, **the patient is exposed to an effective dose up to 81 mSv, a value over the documented annual dose limit [b]**. This can be over 50 times the regulated dose limit for a non-radiation worker.

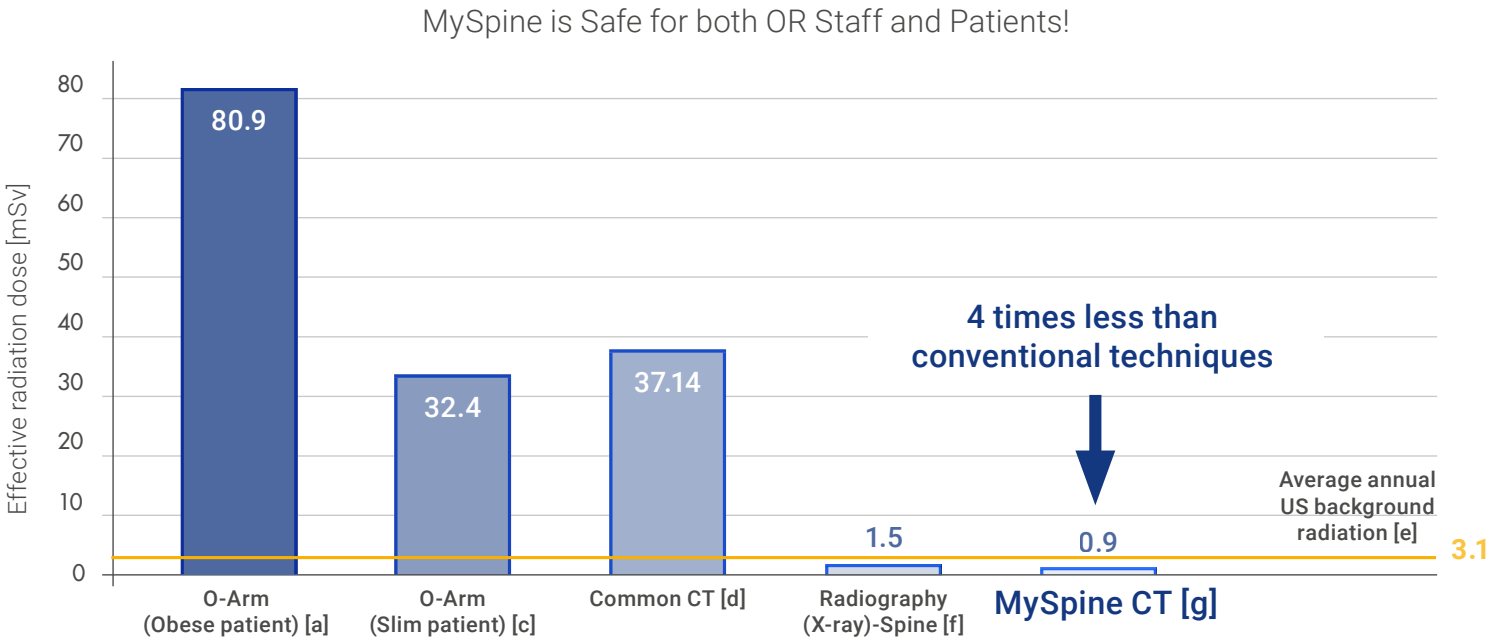
Though the risks of intraoperative radiation exposure to surgeons and staff are well documented within the peer reviewed literature, the perceived benefit in the accuracy of screw placement has made the use of intraoperative fluoroscopy and other sources of ionizing radiation in the operating room a fundamental requirement. The development of technologies to increase **surgical accuracy**, **reducing operative times**, and **improving outcomes** are the collaborative goals with industry and healthcare professionals. New instruments to aid in screw placement, imaging tools, and robotics have all been introduced in the last years with the goal of improving screw placement. Some of the most valuable tools, new imaging modalities and robotics, require a large capital investment for the facilities and therefore these options may not be available to all users.

MySpine Patient-Matched Technology by Medacta

MySpine technology utilizes a **low dose CT scan** of the patient's spine to create **patient specific instruments** designed and manufactured with the express intent of increasing accuracy when placing pedicle screws, thus reducing the need for the use of intra-operative fluoroscopy to confirm the appropriate placement of screws. The risks of exposure to high doses of radiation to both the patient and the surgical team can potentially be reduced through the utilization of this technology.

A patient who has been identified as needing a posterior, thoracolumbar fusion, is sent to a scanning facility and a low dose CT scan of their spine is performed. The data from this scan is transmitted securely to the manufacturer. The patient's anatomy is reconstructed and a **surgical plan is reviewed and approved by the surgeon**, determining the appropriate screw diameter, length and trajectory within the pedicle. 3D printed surgical guides are then created and provided for intraoperative use during the posterior fusion.

The figure below shows a comparison of radiation doses to the patient from different modalities in comparison to the MySpine technology.



Comparison of conventional and competitors technique irradiation vs. MySpine

The accuracy of MySpine technology is proven in a clinical study of pedicle screw placement utilizing post implantation CT scans. [l]

A total of **198 screws** were implanted, out of these **99.5%** were inserted in the safe zone. This result is comparable (or even better) to the values of robotic (97.8%) and navigated assisted techniques (95.6%) and greater than the traditional freehand approach (80%).

MySpine®
PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

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Conclusions

The pedicle screw is one of the spine surgeon's most commonly used tools, but its widespread prevalence doesn't make its proper placement any less challenging. The practice remains technically demanding, with a very small margin for error.
In order to assist the surgeons to accurately position the pedicle screws, intraoperative-based utilization of X-ray imaging tools and technologies have been successfully introduced. However these technologies expose the patient and the Operating Room team to the health risks associated with increased radiation exposure.

Recently introduced MySpine technology supports spine surgeons during the critical steps of pedicle screw placement by offering the potential for improved accuracy, as well as reduced radiation exposure.

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[a,c] 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) [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. Data on internal file - Medacta [h] Hoffman DA et al. "Breast cancer in women with scoliosis exposed to multiple diagnostic x rays" J Natl Cancer Inst. 1989 Sep 6; 81(17):1307-12 [j] Cécile M. Ronckers et al. « Cancer mortality among women frequently exposed to radiographic exams for spinal disorders" Radiat Res. 2010 Jul; 174(1): 83–90. [k] Chou et al. "Prevalence of Cancer in Female Orthopaedic Surgeons in the United States" Journal of Bone & Joint Surgery, American Volume;Jan2010, Vol. 92-A Issue 1, p240 [l] Matsukawa K. et al., Accuracy of cortical bone trajectory screw placement using patient-specific template guide system, Neurosurgical Review, July 2019

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PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS

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MySpine

UNIQUE ANATOMIES PATIENT-MATCHED SOLUTIONS

MySpine is a tailor made patient specific spine vertebrae guide, created to lead the surgeon through the critical steps of accurate pedicle screw placement whilst reducing the surgical time and intra-operative X-ray radiation.

REAL PATIENT MATCHED INSTRUMENTATION

MySpine Pedicle Screw Placement guides are developed specifically for each patient.

COMPREHENSIVE

- Standard MySpine guides are suitable for challenging deformities and long constructs.
- Low Profile MySpine guides are ideal for degenerative cases.

AT THE SURGEON'S HAND

The surgeon determines the entry points for the pedicle screws, and sets their trajectory along with the main geometrical parameters.

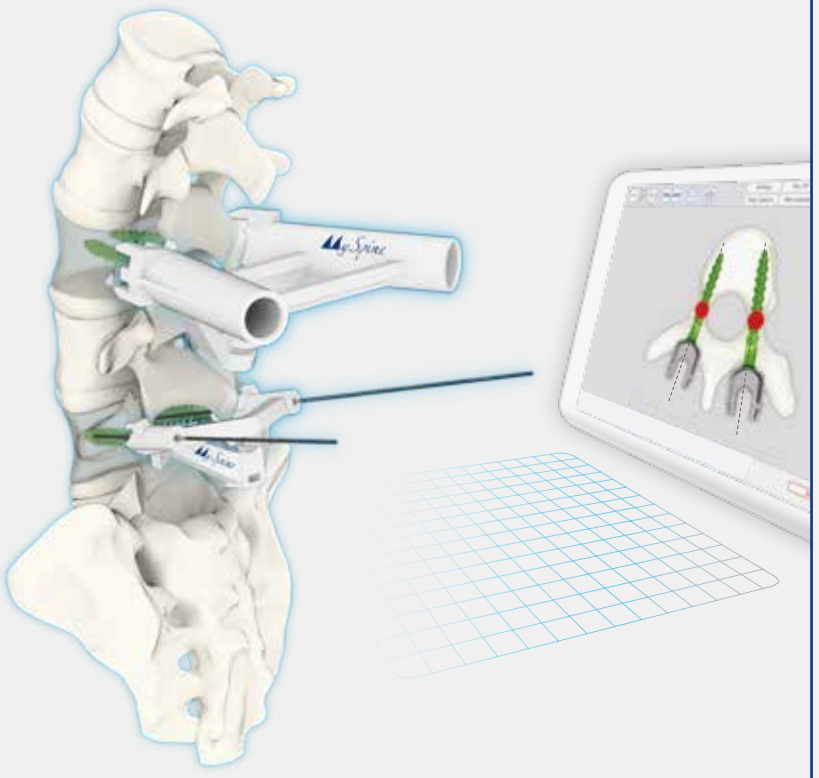
STANDARD VERSION

LOW PROFILE VERSION
K-WIRE BASED

MYSPINE CASE MANAGEMENT

Online interactive 3D planning tool for reliable pedicle targeting and screw trajectory identification.

- **ONLINE CASE MANAGEMENT**
  MySpine cases are managed entirely online with no need to install additional software. The case database is available to the surgeon anytime and anywhere. The information on the website is always kept up-to-date.
- **COMPLETE IN-HOUSE TECHNOLOGY**
  The MySpine process is kept entirely in-house from the 3D anatomical reconstruction to the manufacturing of the guides, allowing a direct contact between the surgeon and the MySpine team.
- **ONLY 3 WEEKS LEAD TIME**
  The shortest delivery time in today's market for this technology.
- **A PERSONAL MYSPINE TECHNICIAN JUST FOR YOU**
  Each surgeon is assigned a personal MySpine technician to assist with any questions or concerns.

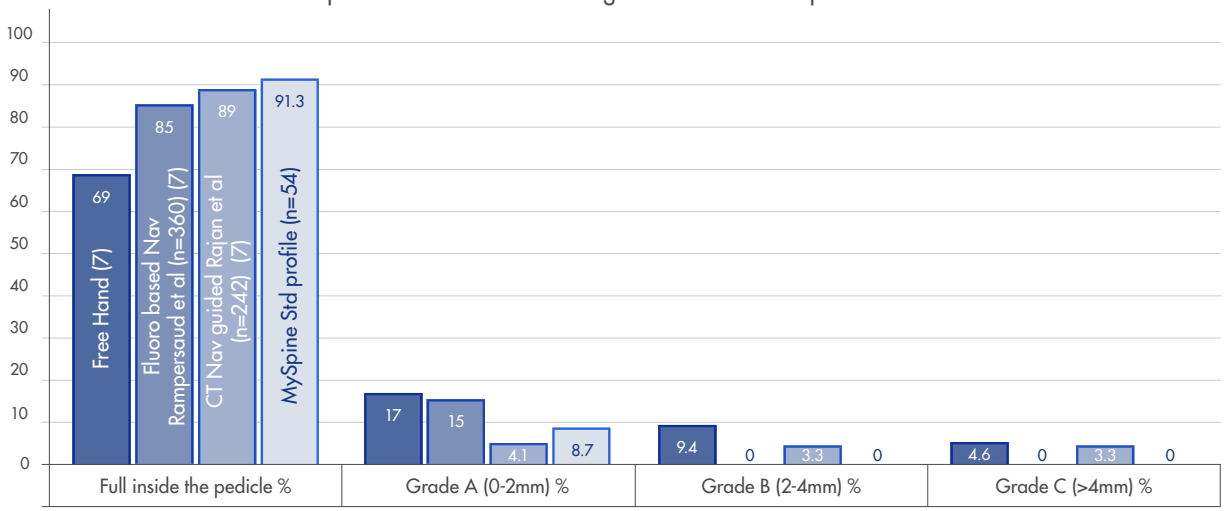


UNIQUE ANATOMIES PATIENT-MATCHED

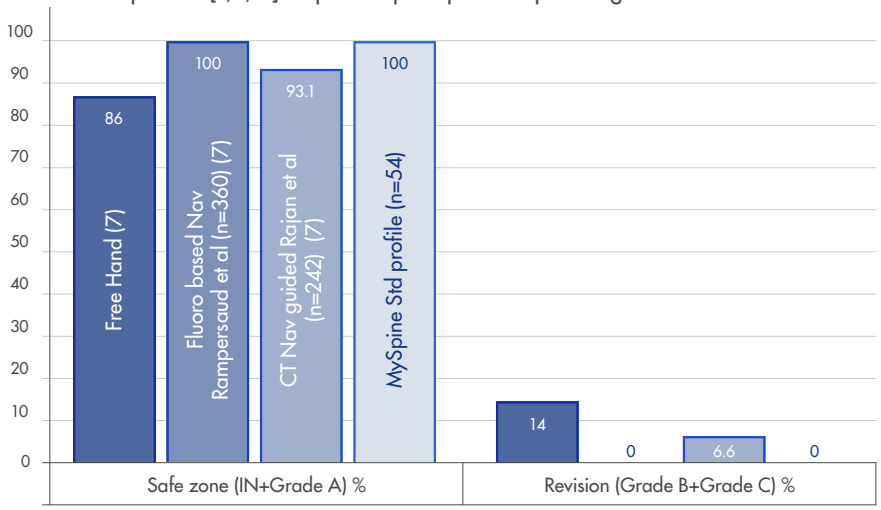
ACCURATE SCREW POSITIONING

The MySpine guides are made to match the surgeon's pre-operative planning.

Greater accuracy than traditional freehand approaches and comparable performance to that of navigation-based techniques [2,4,5]



Up to 100% of pedicle screws correctly placed within the 2mm breach zone within the pedicle [1,2, 3] as per the pre-operative planning instructions.



OUTSTANDING PERFORMANCE

REPRODUCIBLE SURGICAL TECHNIQUE

The MySpine technology, along with the M.U.S.T. Pedicle Screw System, leads to a more accurate screw positioning for both junior and expert surgeons[6].

SIGNIFICANT REDUCTION IN THE SURGERY TIME

Substantial results in terms of screw positioning mean time have been achieved with the MySpine technique; the overall time is reduced about 30% vs free hand technique[6].

SIGNIFICANT REDUCTION IN THE HOSPITAL STAY

From the patient side, potential reduction in the post-operative morbidity and shortened length of hospital stay[4] is a direct advantage of the MySpine technology.

COST SAVING

Reducing treatment costs is crucial for all Hospitals. To this end, the MySpine system is a good tool to act on the following:

- Improving screw positioning may result in reducing the number of revision surgeries.
  Literature data show that misplaced screws range from 1 to 5% of the total number[8]. A revision surgery has been calculated to cost between $18,000 and $28,000[8].

- Reducing surgery time.
  In a cadaver experiment, template-guided pedicle screw placement was measured to be faster[6]. According to the above-mentioned study, the cost of an active Operative Room was measured to be worth $93 per minute. Higher accuracy can therefore be coupled with lower expenditure.

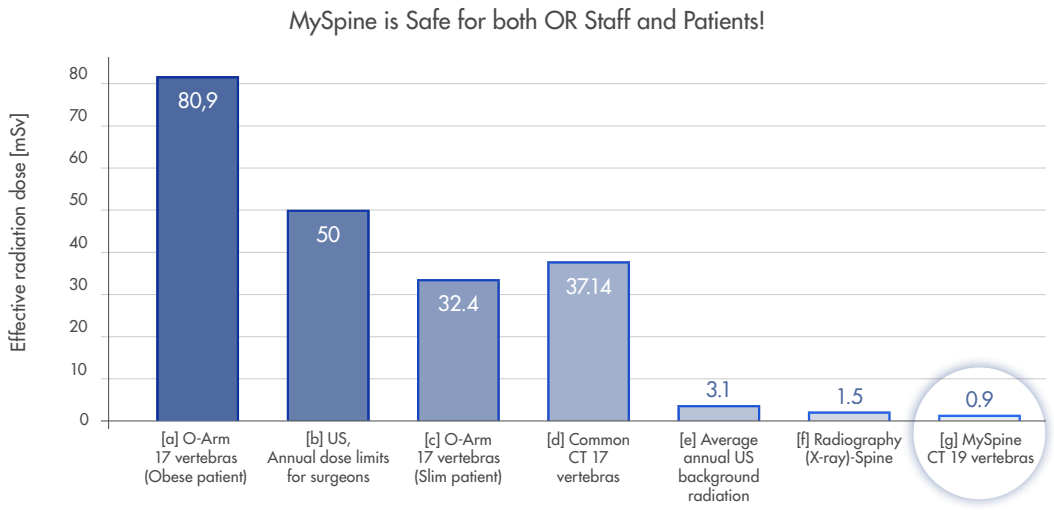
- No capital investment.
  Unlike navigation systems, MySpine technology does not require any capital investment.

REDUCED X-RAY DOSE

A dedicated MySpine Low Dose CT protocol has been developed in order to minimize the X-ray exposure for the patient, moreover MySpine pedicle screw placement potentially allows a reduction of intraoperative fluoroscopy without sacrificing accuracy[6].

- Low dose radiation protocol allows for dramatic dose reduction to patients than using C-Arm or O-Arm technologies: more than 30 times less irradiation! (c).

- Overall radiation dose per surgery is up to 50 full spine X-rays less than the free-hand technique (data on internal files)



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

TECHNICAL FEATURES

The MySpine Pedicle Screw Placement guides are made to match the individual patient's anatomy.

MAXIMIZED STABILITY

MySpine guides are positioned on the vertebra using distinct references, such as the spinous and transverse processes, in order to achieve the maximum stability.

MINIMIZED INVASIVENESS

The MySpine guides are designed to preserve the patient's anatomy.

MAXIMIZED VISIBILITY

Distal windows enhance the field of view during all surgical steps.

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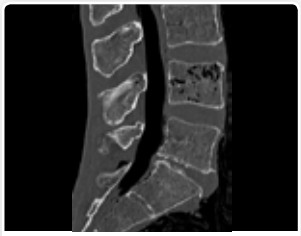
THE MYSPINE JOURNEY



1. Medacta receives the CT scan of the patient's spine.

2. MySpine pre-operative planning commences with the 3D reconstruction of the spine.

3. Following the surgeon's preferences, virtual positioning of the implants is proposed. This planning can be modified if required.

4. Once the planning has been validated by the surgeon, the in-house manufacturing process starts.

MYSPINE EDUCATION PROGRAM

The M.O.R.E. Institute has created a comprehensive Education Program which supports the surgeon in the application of the MySpine system through:

- **Reference Center**
  You will have the opportunity to visit a Reference Center and attend live MySpine surgeries.

- **Learning Center**
  The Learning Center offers the opportunity to attend a MySpine workshop, meet experienced surgeons and discuss the clinical and economic benefits of the MySpine technology.

- **Support**
  Upon request, you will receive the assistance of an experienced Reference Surgeon to attend your first surgery in your own hospital.

- **Continuous Education**
  You can continue your education through MySpine user meetings, M.O.R.E. International events, Reference Center visits and other educational tools.

Designed for you by you!

Simply contact Medacta and we will create an Education Program for you!

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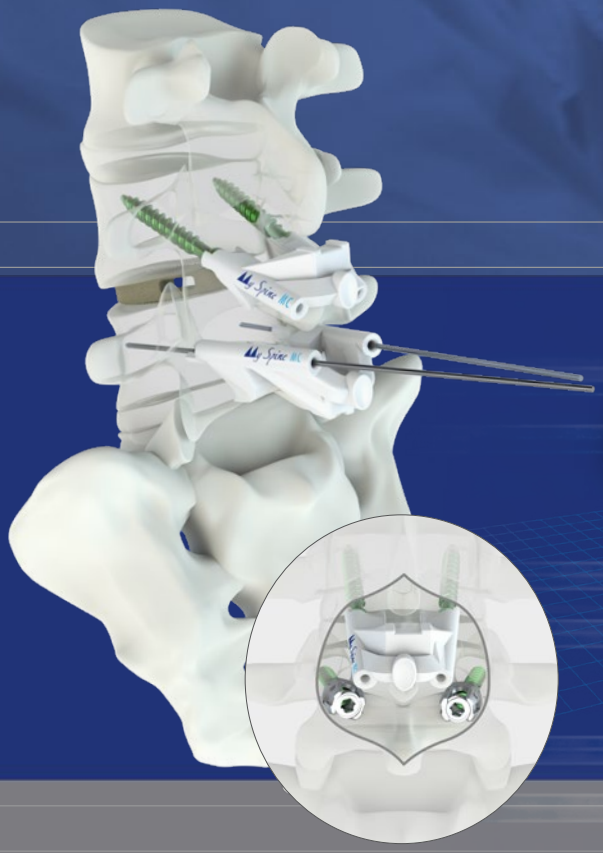
swiss made

mySpine® MC

PERSONALIZED MIS SOLUTION

MINIMALLY INVASIVE PATIENT-MATCHED SOLUTIONS



MEDTECH BREAKTHROUGH AWARDS

BEST HEALTHCARE
NAVIGATION/ROBOTICS SOLUTION
2019

Brochure

Joint | **Spine** | Sports Med

Medacta International

MINIMALLY INVASIVE PATIENT-MATCHED SOLUTIONS

MySpine MC is a **3D printed** patient-matched solution in the **midline cortical** approach. Posterior lumbar fusion is performed in a **minimally invasive,** muscle sparing way, allowing for shorter operating times and a substantial reduction of both radiation exposure and costs.

- **MINIMALLY INVASIVE**
- **EXCELLENT CLINICAL OUTCOMES**
- **HIGH EFFICIENCY**
- **LOW RADIATION DOSE**

The goal of MySpine MC is to combine an **excellent fusion rate** with **greater predictability** of the clinical outcomes.

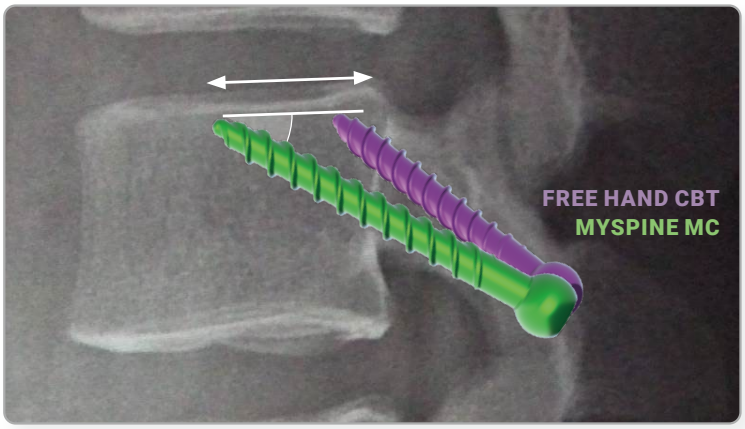
MySpine **MC** - **M**idline **C**ortical

EXCELLENT CLINICAL OUTCOMES

MySpine MC provides **highly precise implant positioning** which:

- allow **accurate positioning** of entry points in the the pars interarticularis with **favourable cortical bone purchase** [4]
- may enable the use of **longer screws** and **larger diameters** than CBT free hand [5]
- may lead to **uncompromised fusion rate** [6]

Moreover, the pre-operative trajectory management may **reduce the risk of nerve root injury** [7]



99.5%
SAFE PEDICLE SCREW POSITIONING [14]

-69%
REDUCED SCREW LOOSENING RATE [9]

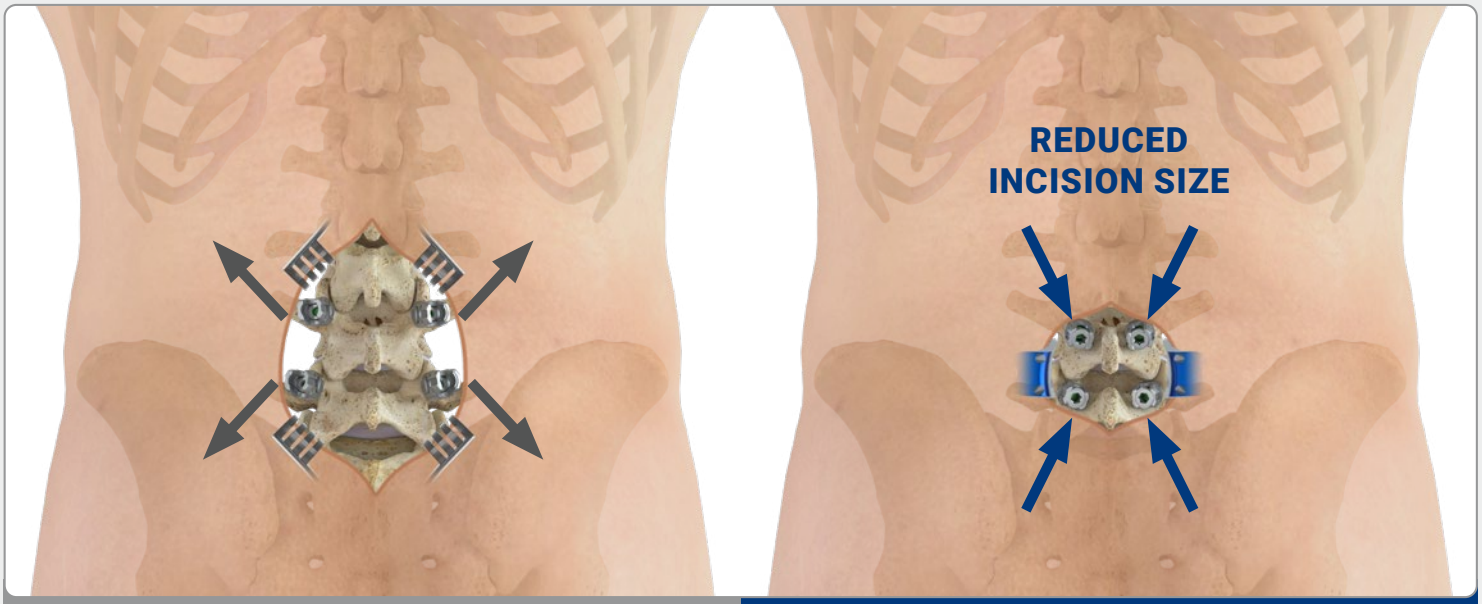
+35%
SIGNIFICANT INCREASE IN PULL-OUT RESISTANCE [14]

-83%
ANTEROPOSTERIOR SPONDYLOLISTHESIS CORRECTION SLIP [10]

PERSONALIZED MIS SOLUTION

WHY A MYSPINE MC MINIMALLY INVASIVE SURGERY?

Thanks to its muscle sparing technique, the erector spinae muscles are gently manipulated and a **small skin incision** of 4-5cm is performed.
For this reason, MySpine MC delivers a **minimally disruptive surgery**, which is fundamental to drive a **fast patient recovery**. MySpine MC will **improve the patients' quality of life** and **hasten their recovery** after a spinal fusion surgery.



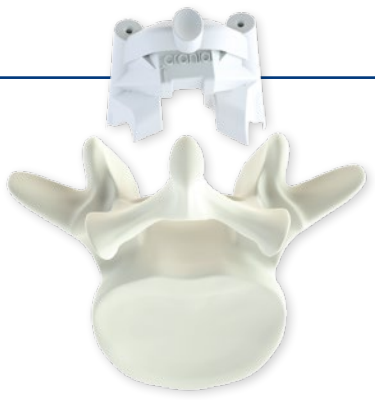
CONVENTIONAL APPROACH | **MIS MYSPINE MC APPROACH**

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

HIGH EFFICIENCY

ECONOMIC EFFICIENCY

- **No expensive** capital investment is required
- **No recurrent service cost**
- **Rapid Learning Curve** for effective accuracy
- **Outpatient Surgery:** hospital can potentially capitalize on resources and increase volumes as patients return home the same day of the surgery [12]



DECREASED POST-OPERATIVE PAIN

In comparison with "conventional" open surgical techniques, the MySpine MC approach may **reduce the postoperative pain** thanks to a l**ess invasive technique**. [16,17] **ODI** index at 12 months is **reduced by 18% more** than conventional technique, leading to a **better patient clinical score**.

-18%
POST-OP PAIN [16,17]

SHORTER REHABILITATION

While **not violating the neuro-muscular structures**, the MySpine MC technique may **decrease the muscular atrophy** leading to a **shorter rehabilitation**. [16,17]

*"My patients can **walk autonomously** the day after the surgery."* MD N. Marengo, Italy

SHORTER HOSPITAL STAY

The MySpine MC technique usually **significantly reduces the duration of the hospital stay by 37%**. [13]

*"MySpine MC is a **Minimally Invasive** technique proven to be successful in **Outpatient Setting**."* MD I. LaMotta, USA

-37%
HOSPITAL STAY [13]

SMALL SKIN INCISION

With MySpine MC, the skin incision is often shorter than with "conventional" open surgery and therefore **scar tissue is reduced**, guaranteeing an **easier soft tissue handling** and a **more "cosmetic" procedure**. [16,17]

FASTER RETURN TO DAILY ACTIVITIES

The MySpine MC 3D Printed Patient-Specific Solution may provide **better biomechanical performance**, allowing for an **improved long-term outcome**. [15,16,17]

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

LESS BLOOD LOSS

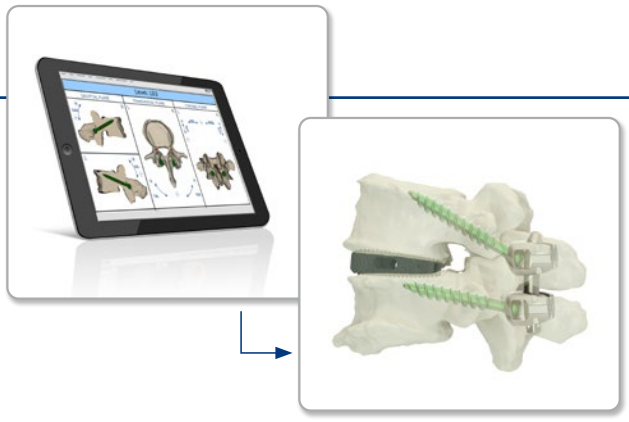
Preservation of muscles and vessels may **reduce blood loss**, -16% compared to conventional open access surgery, for **more conservative treatments**. [16,17]

-16%
BLOOD LOSS [16,17]

REDUCED COMPLICATIONS

The MySpine MC technique **significantly reduces the incidence of complications,** when compared to free-hand techniques, because of the **highly accurate implant positioning**. [13,14]

*"In our specific setting, the same surgical team **reduced complications** from 16% using the free-hand technique to **0% with MySpine MC**."* MD S. Petrone, MD N. Marengo et al., Italy



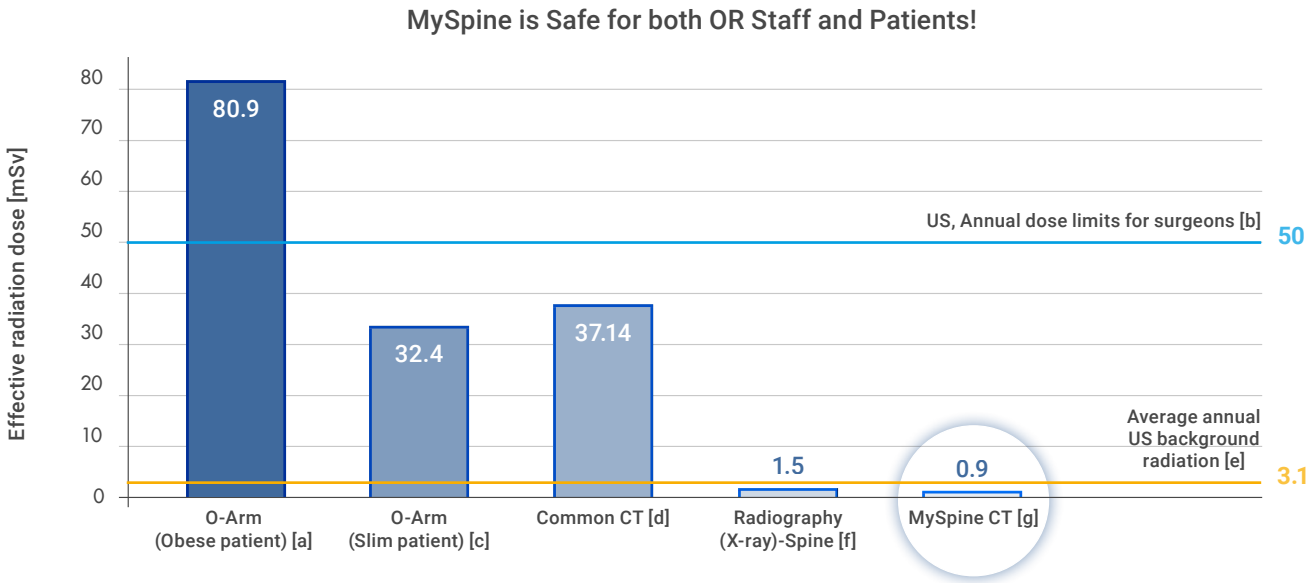
TIME EFFICIENCY

- **No peri-operative image acquisition,** thanks to the accurate pre-op planning [11]
- Compared to free-hand CBT, the MIS MySpine MC technique leads to a significant **34% reduction** of **procedural time** [13]

-34%
PROCEDURAL TIME [13]

LOW RADIATION DOSE

- Patients are exposed to a **low dose** pre-op **CT scan**, resulting in a lower radiation exposure than a single full spine x-ray
- Pre-operative planning potentially **eliminates the need of intra-operative checks**, with a dramatic reduction of irradiation **-33%** compared to the free-hand technique [11,13]
- The **cumulative dose is potentially reduced** with respect to navigation-assisted technique



Comparison of irradiation between conventional and competitors' techniques and MySpine

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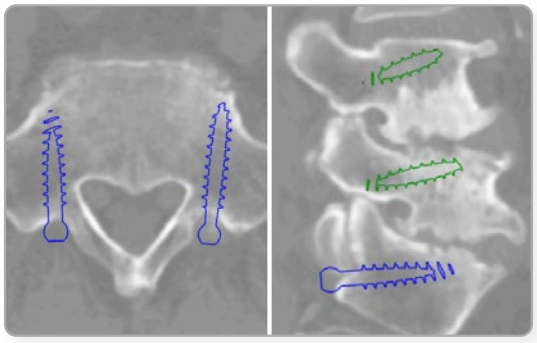
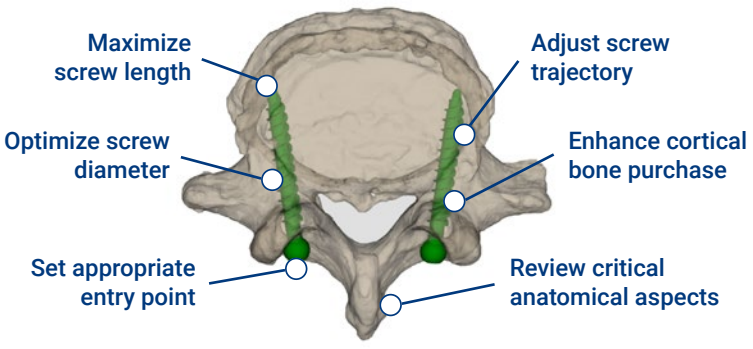
ACCURATE PRE-OP PLANNING

The MySpine Web Platform allows for a **simple** and **accurate 3D pre-operative planning**. The surgeon can simulate the final screw position in the patient's medical images and **preview any potential surgical critical aspects**.



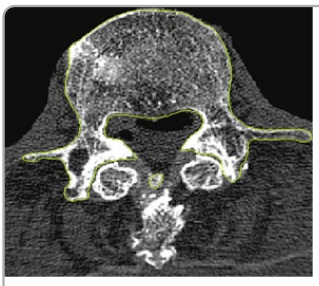
2D CT VIEW

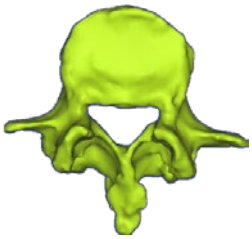


3D VIEW

An **effective** tool for a **personalized surgical planning**.

MYSPINE CASE MANAGEMENT





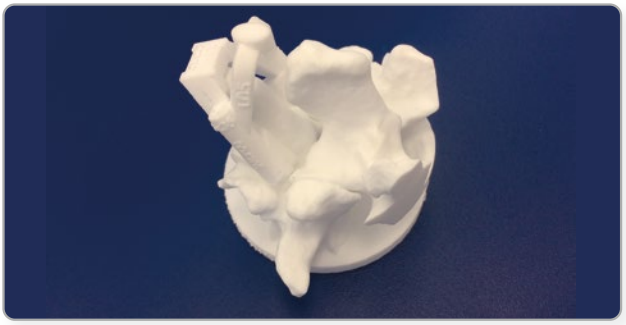
CT BASED SEGMENTATION 3D ANATOMY

1. IMAGE ACQUISITION

Low Dose CT scan to deliver 3D reconstruction of **each patient's** 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

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