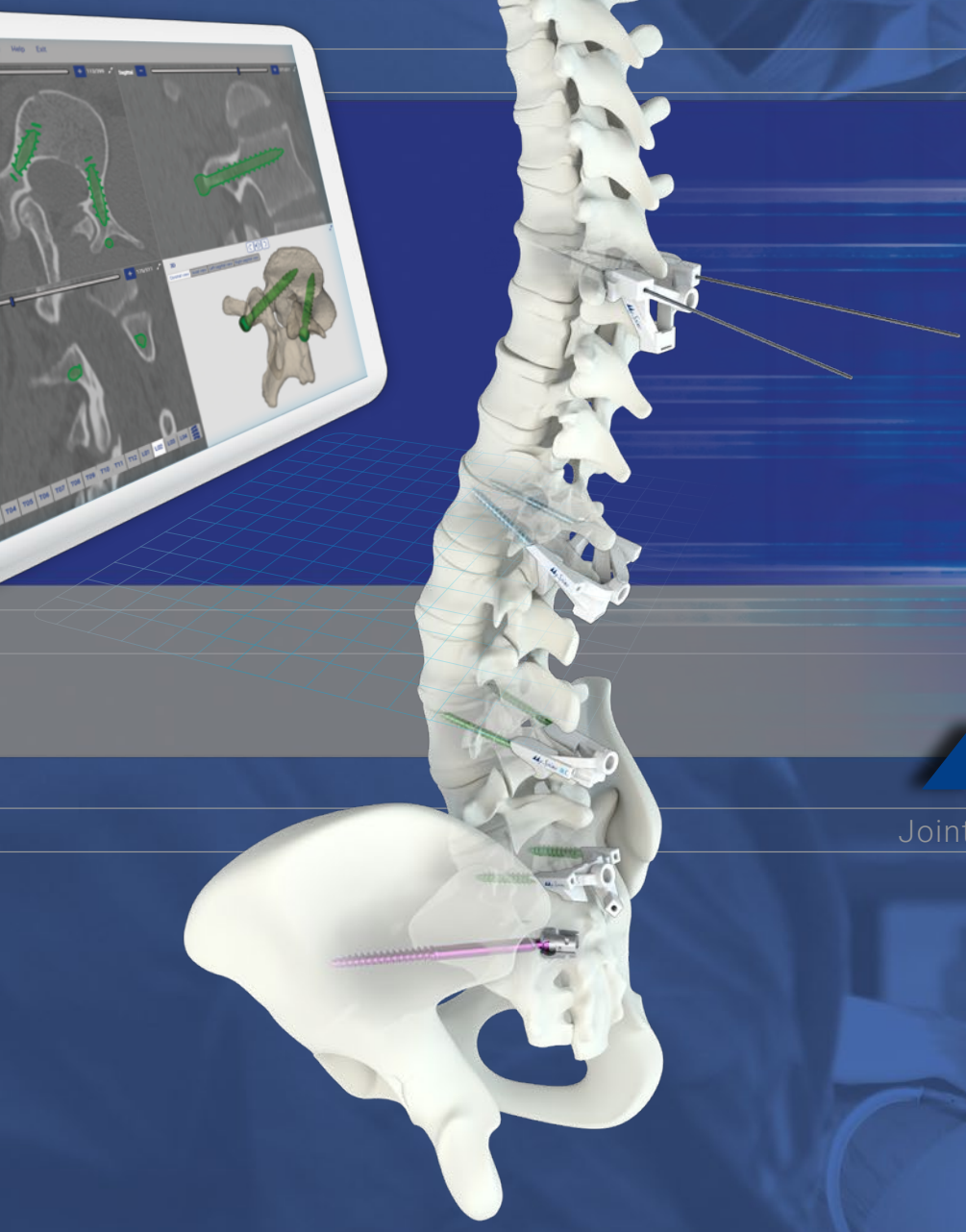
mySpine®

PATIENT MATCHED TECHNOLOGY
IN SPINE SURGERY

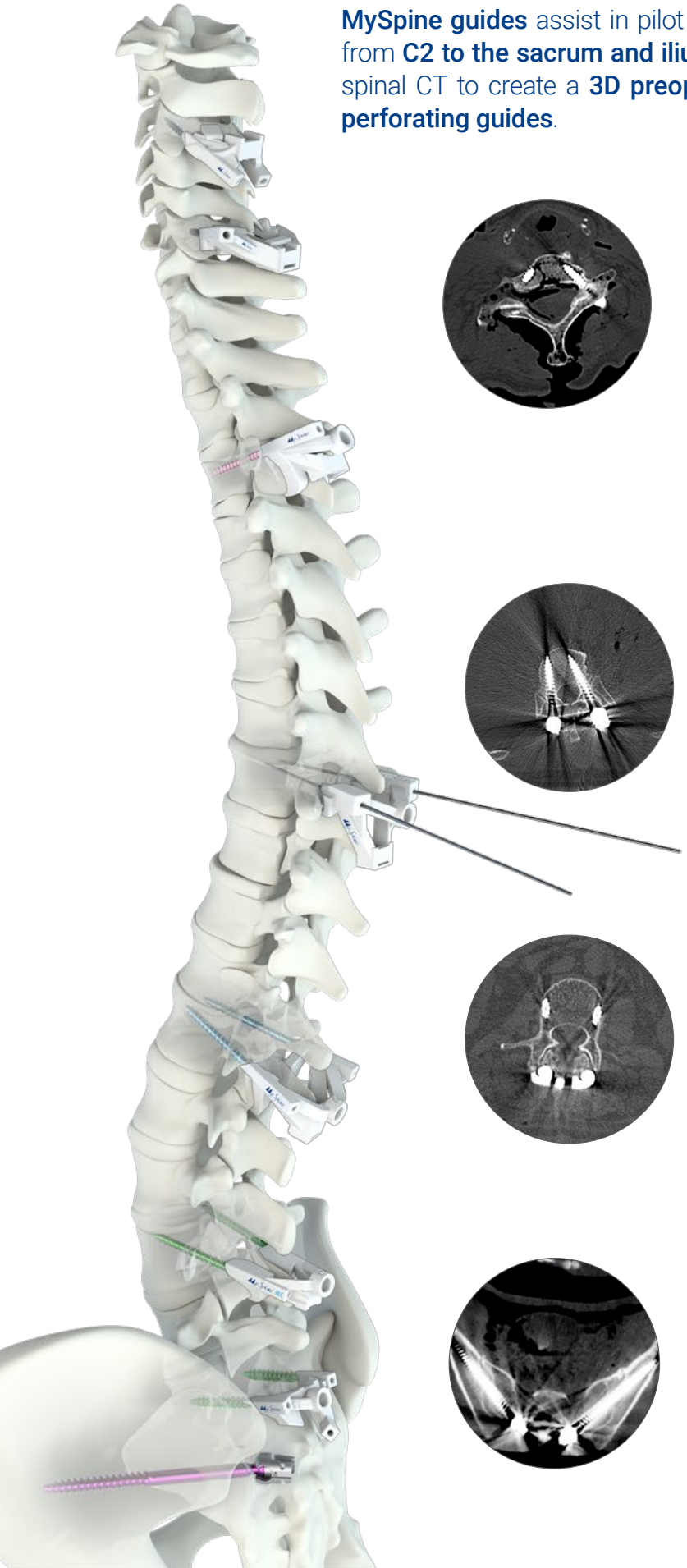
UNIQUE ANATOMIES, PATIENT-MATCHED SOLUTIONS



Brochure

Joint | **Spine** | Sports Med

Medacta International



MySpine guides assist in pilot hole preparation for **posterior fixation screws** from **C2 to the sacrum and ilium**. The MySpine technology uses the patient's spinal CT to create a **3D preoperative plan** and **patient-specific anatomical perforating guides**.

MySpine® CERVICAL

MySpine Cervical guides are patient-specific devices intended for use as anatomical perforating guides to assist with the intraoperative positioning of screws during posterior cervical fixation surgery between the C2 to C7 levels. MySpine Cervical guides accommodate both lateral mass and pedicle planning trajectories.

MySpine®

MySpine guides are individually developed for each patient, with different configurations (K-wire- or drill-based) available for screw placement using a conventional trajectory, in both bilateral and unilateral configurations. They are intended as thoracic and lumbar guides for patients requiring spinal fusion between the levels of T1 to L5.

MySpine® MC

MySpine MC is a minimally invasive, muscle sparing, midline cortical solution designed for patients requiring spinal fusion between the levels of L1 to S1.[1,2]

MySpine® S2AI

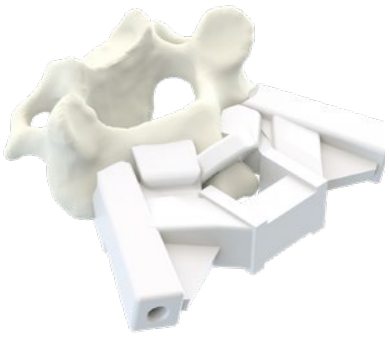
MySpine S2AI is the solution for posterior sacroiliac fusions. These guides can be used, for example, in long constructs to potentially overcome insufficient lower spine fixation.

NATOMIES, PATIENT-MATCHED SOLUTIONS

MySpine offers a complete portfolio to support posterior cervical, thoracic, lumbar, and sacral procedures.

CERVICAL

BILATERAL PEDICLE

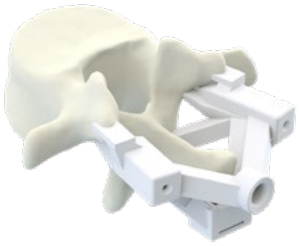


UNILATERAL PEDICLE

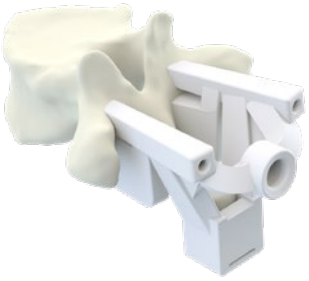
LATERAL MASS

THORACOLUMBAR

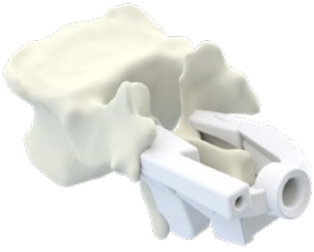
LOW PROFILE K-WIRE



LOW PROFILE DRILL PILOT



UNILATERAL

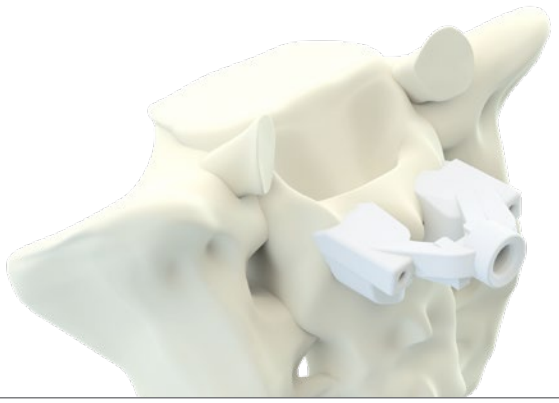


LUMBAR

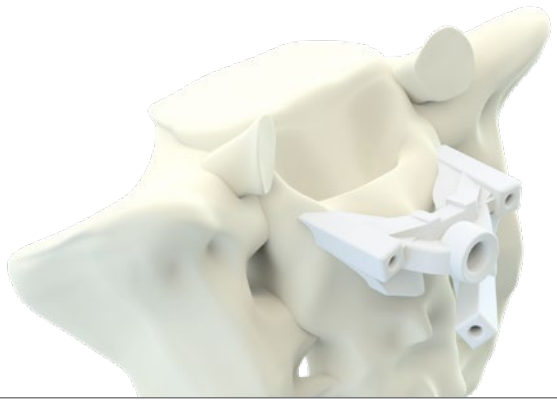
MIDLINE CORTICAL (MC)

SACRAL

S1



S2AI

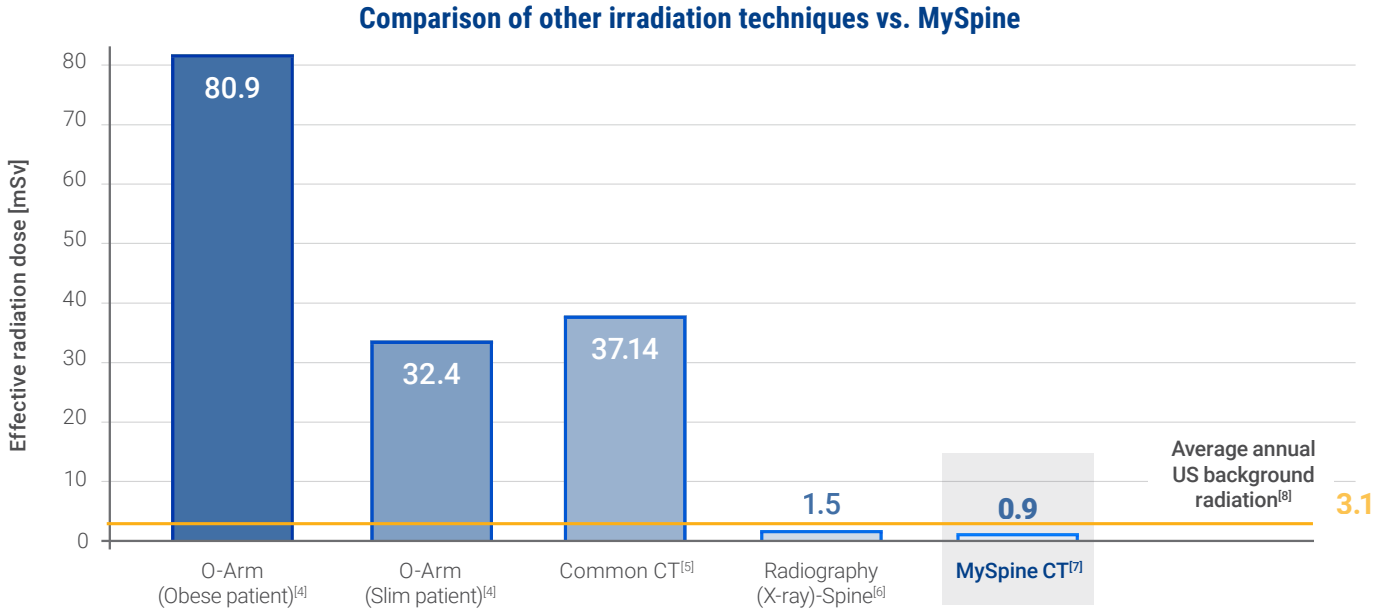


MYSPINE CASE MANAGEMENT

The MySpine process is managed entirely in-house, with **zero capital investment**. A 3D reconstruction of the patient's anatomy is obtained from **low dose CT scan**. Then, an **accurate 3D preoperative planning** is prepare to design patient-matched guides.

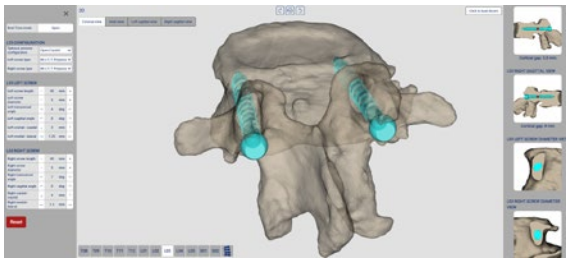
IMAGE ACQUISITION

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 fluoro scans, with a **reduction of intraoperative radiation for both OR staff and patients**.[3] The cumulative dose is potentially reduced compared to a navigation-assisted technique.



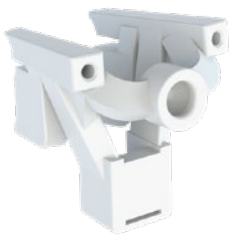
MYSPINE WEBPLANNER

MySpine cases are managed **entirely online** with no need to install additional software. The case **database** is available to the surgeon **anytime and anywhere**, and the information on the website is always kept up-to-date.



3D PRINTING

The MySpine guide is designed to **match the vertebral anatomy of the patient and provide maximum stability** on the vertebra as well as correct pilot hole preparation for the screw placement. Guides and vertebral models are produced with **3D printing technology**. Prior to the surgery, surgeons will receive the MySpine instruments and the plastic 3D bone model, anatomically reproducing the patient's vertebra. This model is provided to simulate the proper positioning of the MySpine guide in the operating room.



PROCTORED SURGERY

Medacta's mission is to **support surgeons through the M.O.R.E. Education Program**. Upon request, the surgeon can receive the assistance of an experienced Medacta Proctoring Surgeon to assist with the first surgeries in the local hospital or surgery center. **With Medacta, the surgeon is never alone**.

NATOMIES, PATIENT-MATCHED SOLUTIONS

VALUE PROPOSITION

97.9% screw accuracy

MySpine is a **highly accurate** guiding option for **precise screw placement**, compared to the free-hand technique.[9] Additionally, a superimposed CT analysis showed a 100% accuracy of pedicle screw placement without any violation of the pedicle wall or other relevant structures.[10]

100% safety

The MySpine 3D-printed guide technology is a **safe and accurate** tool for precise pedicle screw insertion.[10] This suggests that average spine surgeons can provide **patient safety through the use of this technology**, which may be applicable to a wide range of spinal conditions.[11]

Shortened hospital stay

From the patient's perspective, a **potential reduction in postoperative morbidity** and a **shortened hospital stay** are advantages of MySpine technology.[12]

35% reduction in screw placement time

MySpine pedicle screw placement is **faster than the free-hand technique** considering intraoperative instrumentation time.[9]

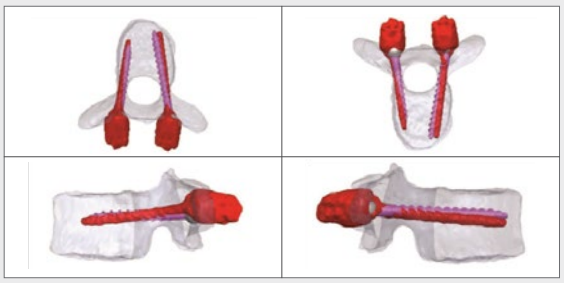
Suitable for revision surgeries

MySpine technology is **effective and safe** for pedicle screw placement **in spine revision surgery**. It can reduce the incidence of malpositioning compared to the standard freehand techniques, without requiring the cost, training, or radiation exposure associated with navigation and robotics.[13]

Precise planning execution

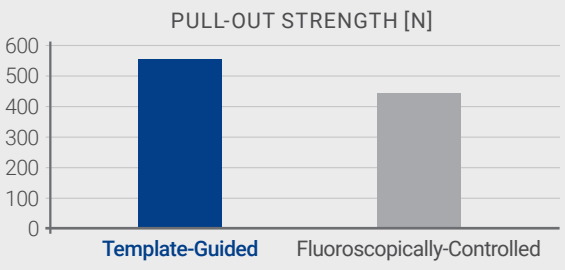
Superimposed CT analysis of the preoperative images with the planned pedicle screw trajectories provided as a part of the MySpine planning process demonstrates the following:[10]

- Mean linear deviation = 0.92 mm
- Mean angular deviation = 2.92°



25% increase in pull-out strength

There is a significantly **higher pull-out strength** of thoracolumbar pedicle screws when inserted via MySpine patient-specific template-guided technique versus conventional free-hand fluoroscopically controlled technique.[14]



SYNERGY

The **M.U.S.T. MINI** posterior cervical screw system, the **M.U.S.T.** pedicle screw system, and the **M.U.S.T. SI** implant system provide comprehensive solutions for the fixation of the cervical, thoracolumbar, and sacral spine regions. The wide range of screw types, rod shapes, connectors, and hooks offers surgeons the **flexibility needed to tailor the construct to the patient's anatomy** and pathology that is to be treated.

CERVICAL

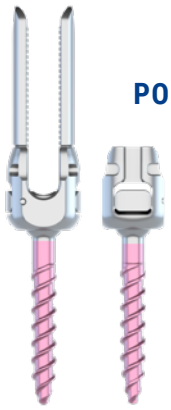
M.U.S.T. MINI

SINGLE LEAD
Solid or Cannulated
Full or Partial thread

DUAL LEAD
Solid or Cannulated

THORACOLUMBAR

M.U.S.T.



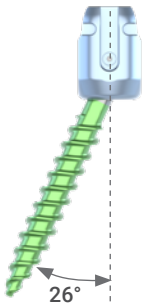
POLYAXIAL

Used in combination with the locking tower

New M.U.S.T. polyaxial screw that can accommodate a Ø5.5 or Ø6.0 rod

M.U.S.T. MC

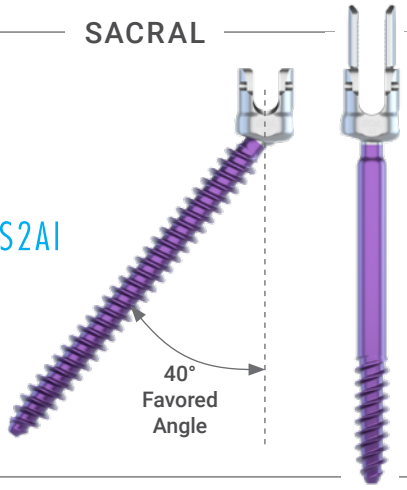
M.U.S.T. UNIPLANAR



Uniplanar Angle

SACRAL

M.U.S.T. S2AI



Medacta International

NATOMIES, PATIENT-MATCHED SOLUTIONS

MYSOLUTIONS PERSONALIZED ECOSYSTEM

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

Medacta's 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. Medacta has created a pathway to improve patients' surgical experience and support them during the continuum of care.

Why choose Medacta personalized enabling technologies?

PERSONALIZED 3D PLANNING

Leverage Medacta's surgeon experience with our personalized **3D planning tool**. The preoperative planning software offers solutions to accurately plan even the most challenging case.

PRECISE EXECUTION

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

STREAMLINED WORKFLOW

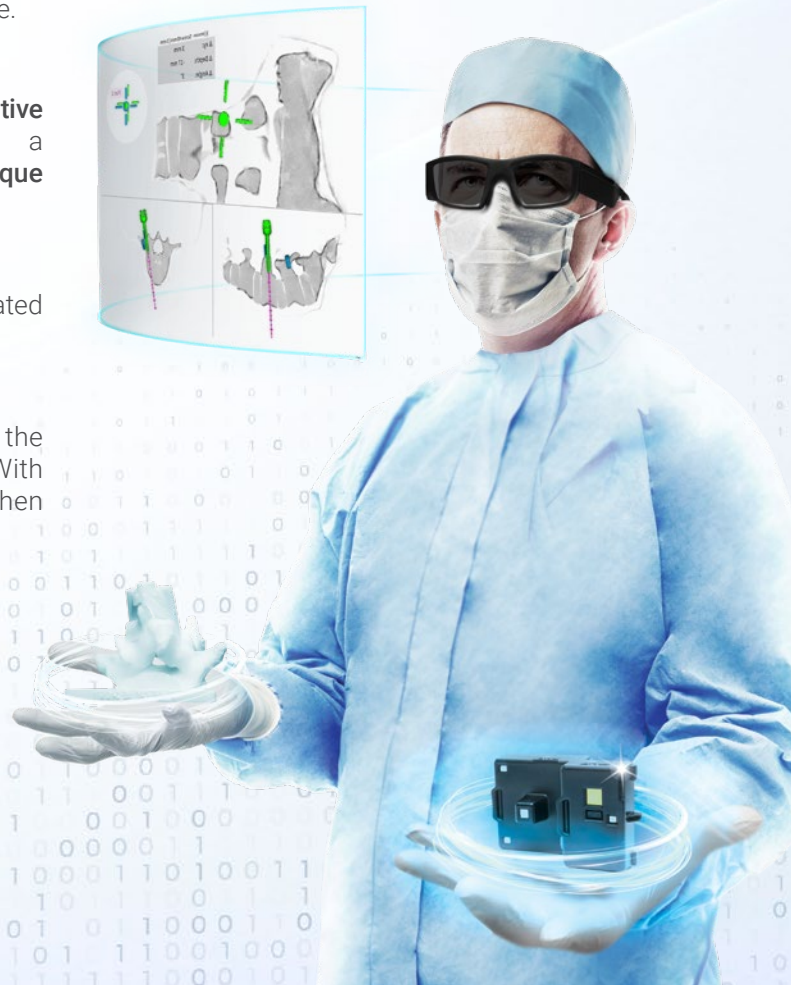
Surgeon's procedural workflow can be seamlessly integrated with Medacta's personalized enabling technology.

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.



NEXTAR AUGMENTED REALITY SURGICAL PLATFORM

MySpine® PATIENT MATCHED TECHNOLOGY IN SPINE SURGERY

REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY

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This document is intended only for the Japanese market.
For all indications, contraindications, warnings, precautions, and potential adverse effects of the product presented, see the instructions for use or contact your local representative.
For additional product information, visit www.medacta.com.

MySpine®
Brochure

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rev. 00

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References: *[1] Marengo N. et al., Cortical bone trajectory screws in posterior lumbar interbody fusion: minimally I invasive surgery for maximal muscle sparing – A prospective comparative study with the traditional open technique. Clinical Study 2018. [2] Matsukawa K., MySpine cortical Bone Trajectory. 2nd MORE Japan 2017. [3] Matsukawa K. et al., Comparison of safety and perioperative outcomes between patient-specific template-guided and fluoroscopic-assisted freehand lumbar screw placement using cortical bone trajectory technique, Global Spine Journal, 2022. [4] Lange et.al, Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery, Spine 2013. [5] Biswas et.al., Radiation Exposure from Musculoskeletal Computerized Tomographic Scans, JBJS Am. 2009. [6] Radiation Dose in X-Ray and CT Exams; 2013 Radiological Society of North America, Inc. [7] MySpine, Charité University Hospital, Berlin, Germany. [8] Health Physics Society Specialists in Radiation Safety, Lawrence Berkeley National Laboratory: Fact Sheet 2010. [9] Farshad M. 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. European Spine Journal 2016. [10] Van Royen B. et al., Accuracy assessment of pedicle screw insertion with patient specific 3D-printed guides through superimpose CT-analysis in thoracolumbar spinal deformity surgery. European Spine Journal 2021. [11] Cecchinato R. et al., Pedicle screw insertion with patient-specific 3D-printed guides based on low-dose CT scan is more accurate than free-hand technique in spine deformity patients: a prospective, randomized clinical trial, European Spine Journal 2019. [12] Landi A. 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? Journal of Spine 2015. [13] Faldini C. et al., Accuracy of patient-specific 3D-printed guides for pedicle screw insertion in spine revision surgery: results of a retrospective study. Surgical Technology International 2022. [14] Farshad M. et al., Pull-out strength of patient-specific template-guided vs. free-hand fluoroscopically controlled thoracolumbar pedicle screws: a biomechanical analysis of a randomized cadaveric study. European Spine Journal 2017.*