Medacta International

Improve your quality of life

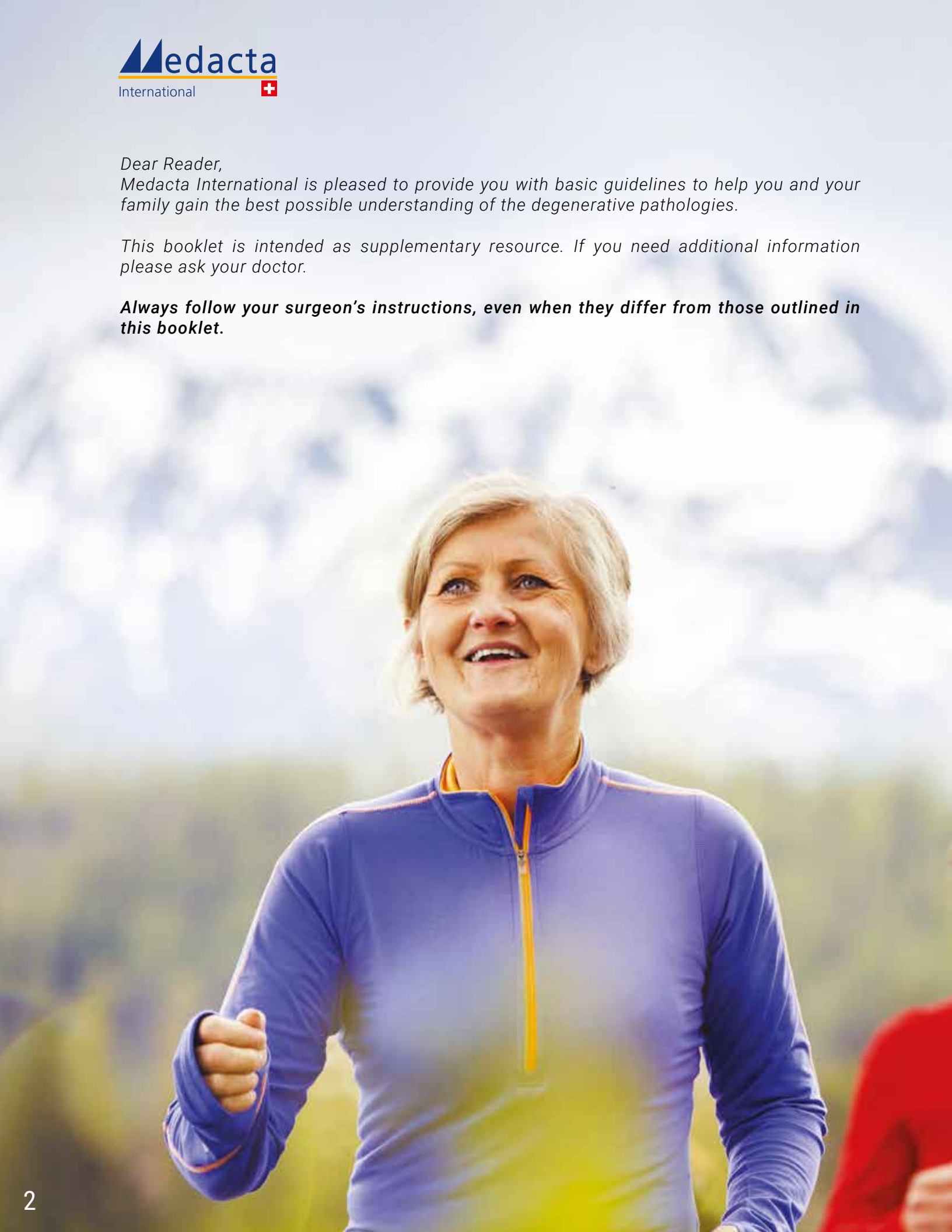
with the

MYSPINE PATIENT-SPECIFIC SPINAL FUSION

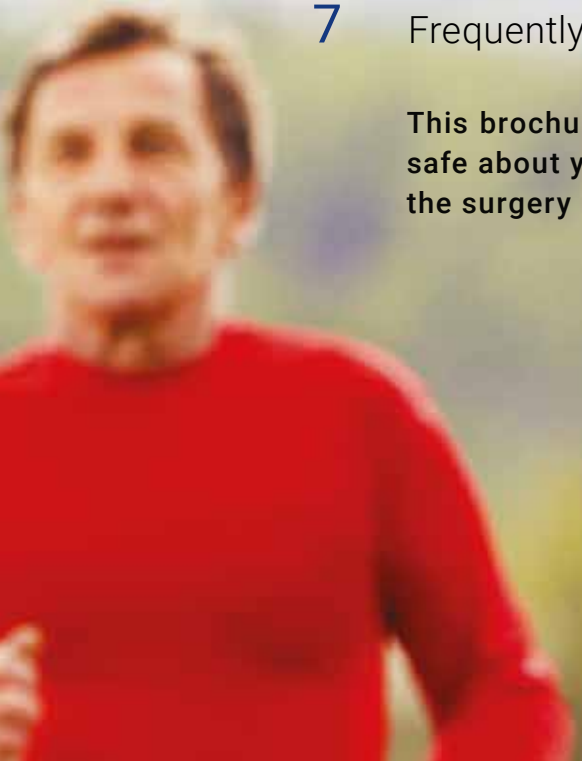
Dear Reader,
Medacta International is pleased to provide you with basic guidelines to help you and your family gain the best possible understanding of the degenerative pathologies.

This booklet is intended as supplementary resource. If you need additional information please ask your doctor.

Always follow your surgeon's instructions, even when they differ from those outlined in this booklet.



This brochure has been produced to help you to feel comfortable and safe about your operation. It addresses questions you may have about the surgery and post-operative recovery.



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INTRODUCTION

The Spine, also known as the backbone or vertebral column, consists of 33 interlocking bones positioned on top of each other. It is made up of 24 separate bones interspaced with the “intervertebral discs”, with the sacrum (5 fused bones) and the coccyx (4 fused bones) at the base.

The spine is a complex combination of interconnected bones, tendons, muscles, ligaments and nerves, any of which can become injured, misaligned or damaged leading to dysfunction.

The spine provides the main structural support of the body allowing mobility, the ability to walk upright, and it gives protection to the neurological elements (spinal cord and nerve roots) underlying and surrounding the bony structures.

Dysfunction specifically affecting the neurological elements (spinal cord or nerve roots) can result in sensitivity changes, muscle weakness or pain in the regions of the body supplied by the nerves. This can have far-reaching effects on a person’s activity levels and general well-being.

Surgery may not be the only course of action as there are also a number of non-surgical treatments available. Discuss your options with your doctor to determine the best course of action for you.

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1. ANATOMY OF THE SPINE

The spine is one of the most important structures in the human body. It supports much of the body weight, provides points of attachment for muscles and ligaments, and protects the spinal cord, which carries information from the brain to the rest of the body.
A healthy spine is strong yet flexible, allowing a wide range of movements. It appears straight if viewed from behind and curved from the side. To understand scoliosis, you must first understand what a healthy spine looks like.

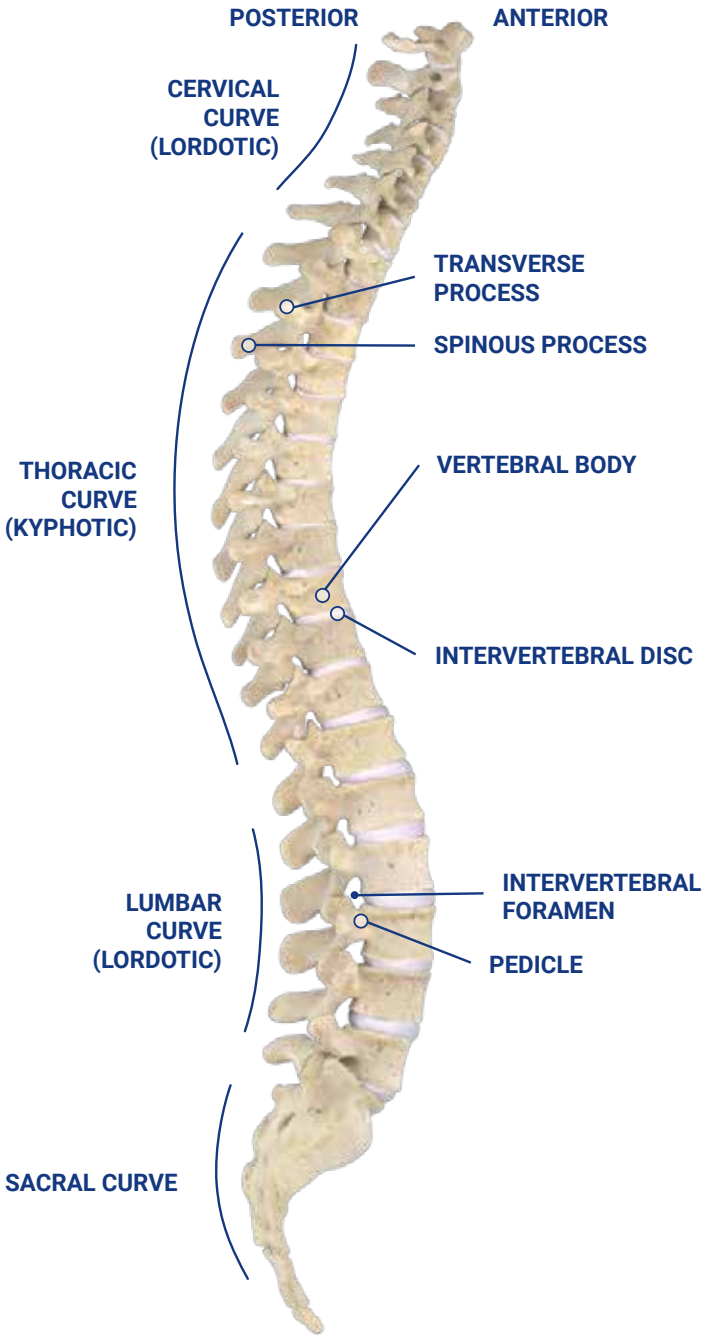
The spine is made up of vertebrae and is divided into five distinct regions:

- The **cervical spine** is your neck. It is composed of 7 vertebrae (C1-C7) and gives you the most motion.
- The **thoracic spine** is your mid-back. It is very stiff and composed of 12 vertebrae (T1-T12) larger than the cervical vertebrae and smaller than the lumbar vertebrae.
- The **lumbar spine** is your lower back. It contains 5 of the vertebrae, is the largest and strongest, and carries most of the body weight. It allows motion, especially bending and rotation.
- The **sacrum** consists of 5 fused vertebrae, it connects with the pelvis.
- The **coccyx** is made of 4 fused bones.

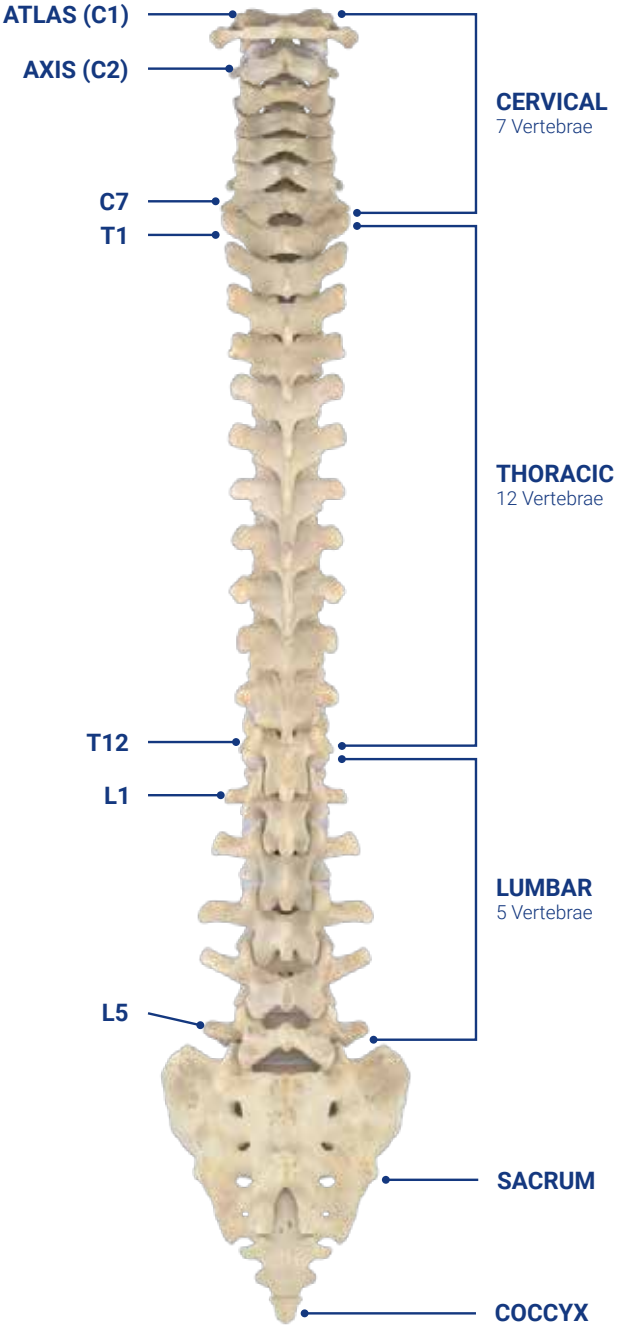
The vertebrae are separated by intervertebral discs, which act as shock absorbers to protect the vertebrae and allow spinal rotation and bending. Each disc consists of two parts:

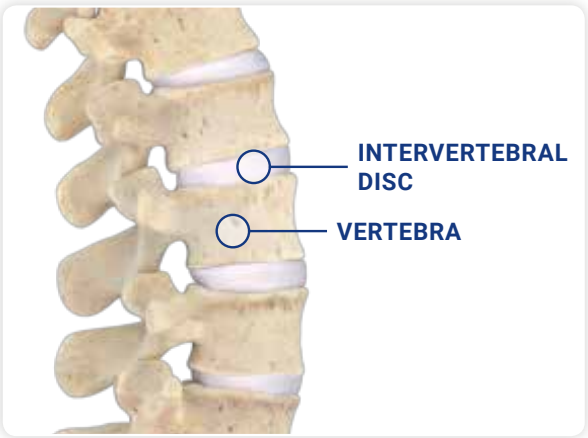
- Annulus fibrosis, a tough outer fibrous ring
- Nucleus pulposus, a soft gelatinous center

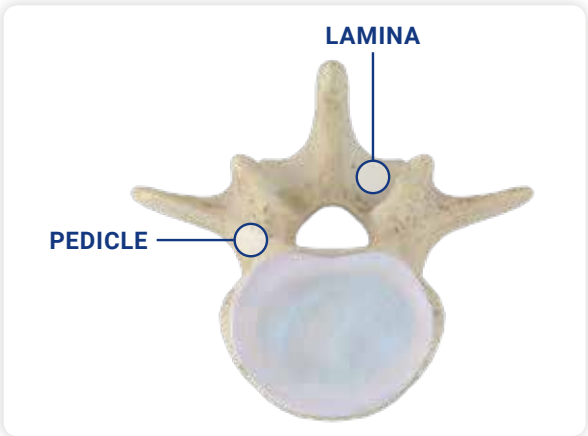
LATERAL VIEW (SIDE)



POSTERIOR VIEW (BACK)





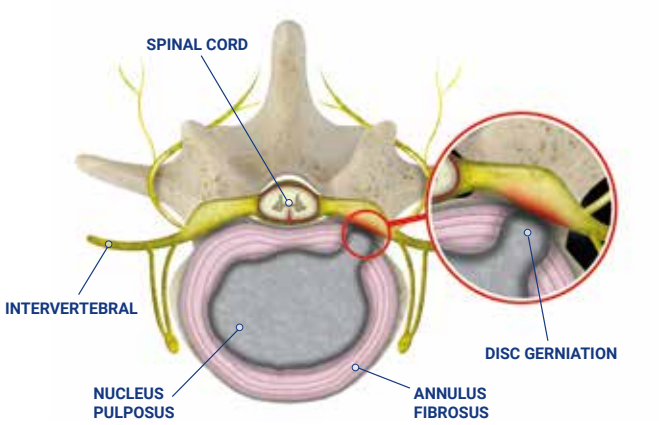


2. DEGENERATIVE DISEASES

There are several causes of lower back pain and spine problems. The root cause of these symptoms is your discs, bones, or ligaments pressing onto the nerve roots or spinal cord.

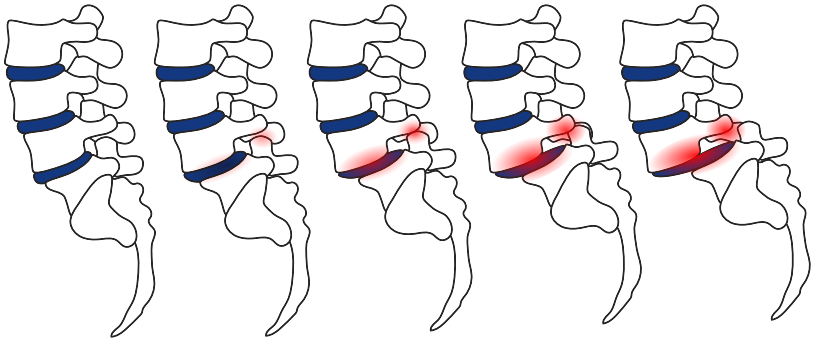
2.1 Degenerative disc disease (DDD)

When one or more of the discs are damaged over time due to injury, trauma, or natural aging of the spine, part of the gel-like center of the disc leaks ("herniates") into the gap between the vertebrae where the nerves and spinal cord are located. A herniation, loss of disc height, or slippage of one vertebra over another can reduce the amount of room for nerves and the spinal cord to pass ("stenosis"). For some people, there are no symptoms associated with this condition, but others feel pain, numbness, or a tingling sensation in their neck and/or extremities.



2.2 Spondylolisthesis

Spondylolisthesis is a spinal condition where one of your vertebrae slips with respect to the vertebrae below. This displaced vertebrae can apply pressure to the nerve, causing lower back or leg pain. This type of instability in your spine can occur from degenerative changes, stress fractures, congenital abnormalities, and in rare cases from a tumor or trauma.

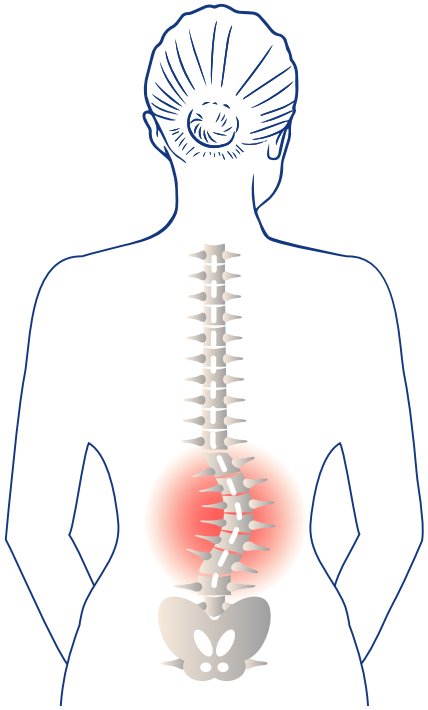


THE SPONDYLOLISTHESIS IS GRADED BY MEASURING HOW MUCH OF A VERTEBRAL BODY HAS SLIPPED FORWARD OVER THE BODY BENEATH IT (I.E. GRADE 1: 25% OF VERTEBRAL BODY HAS SLIPPED FORWARD)

2.3 Degenerative adult scoliosis

In the elderly, the incidence of the adult scoliosis can be as high as 70%. This type of scoliosis begins in the adult patient due to degeneration of the discs, arthritis of the facet joints and collapse and wedging of the disc spaces.

It is typically seen in the lumbar spine (lower back), and usually accompanied by straightening of the spine from the side view (loss of lumbar lordosis).



2.4 Spinal stenosis

Degenerative spinal stenosis is a spinal condition in which the space where nerves pass through the spine gradually narrows. This narrowing may be the result of natural ageing and “wear and tear” on the spine from everyday activities.

Pressure on the nerves may cause pain and damage. Symptoms may include numbness and a “prickly” feeling in your legs, calves, or buttocks; aching, dull back pain spreading to your legs; decreased endurance when standing or walking. Symptoms may improve when sitting, leaning forward, lying on your back or sitting with raised feet.

3. TREATMENT OPTIONS

If your surgeon has determined that your spine condition requires a surgical treatment you may benefit from a fusion surgery. Your surgeon will operate on your spine removing the diseased disc(s) (discectomy) and replace it with an implant called a “cage” to restore the disc height and allow bone to grow between your vertebrae. This is called fusion. Your surgeon may also insert screws and rods in the back of your spine to stabilize the vertebrae.

3.1 Midline cortical approach

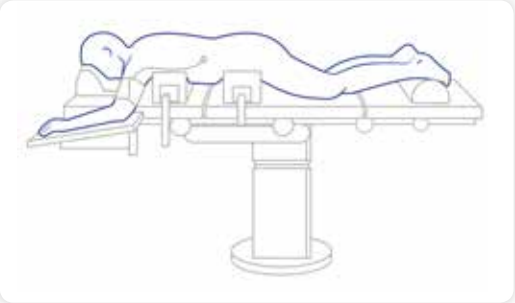
The Midline Cortical approach is a Minimally Invasive Surgery (MIS) that attempts to eliminate instability in your lower back. The major difference with a traditional “open” spinal fusion is that the Midline Cortical procedure reduces the need to retract muscle further laterally, therefore requiring a smaller incision than an “open” spinal fusion.

Both open and Midline Cortical surgeries aim to decompress nerve roots and fuse vertebrae together.

Thanks to a minimized amount of muscle disruption, the Midline Cortical procedure is intended to reduce post-operative morbidity, such as muscle pain with a faster recovery for the patient.

3.2 What happens during the surgery?

APPROACH
The patient is comfortably positioned in prone position over the operating table. A midline incision is performed and the soft tissue is gently moved laterally to expose the bony structures that need to be treated.



IMPLANT
The pedicle screws are implanted into the vertebrae and the cage is implanted into the disc space after discectomy. The rods are securely locked over the screws to fix the final construct.

DECOMPRESSION
With dedicated instruments the surgeon decompresses the nerve roots and restores the physiological disc height.

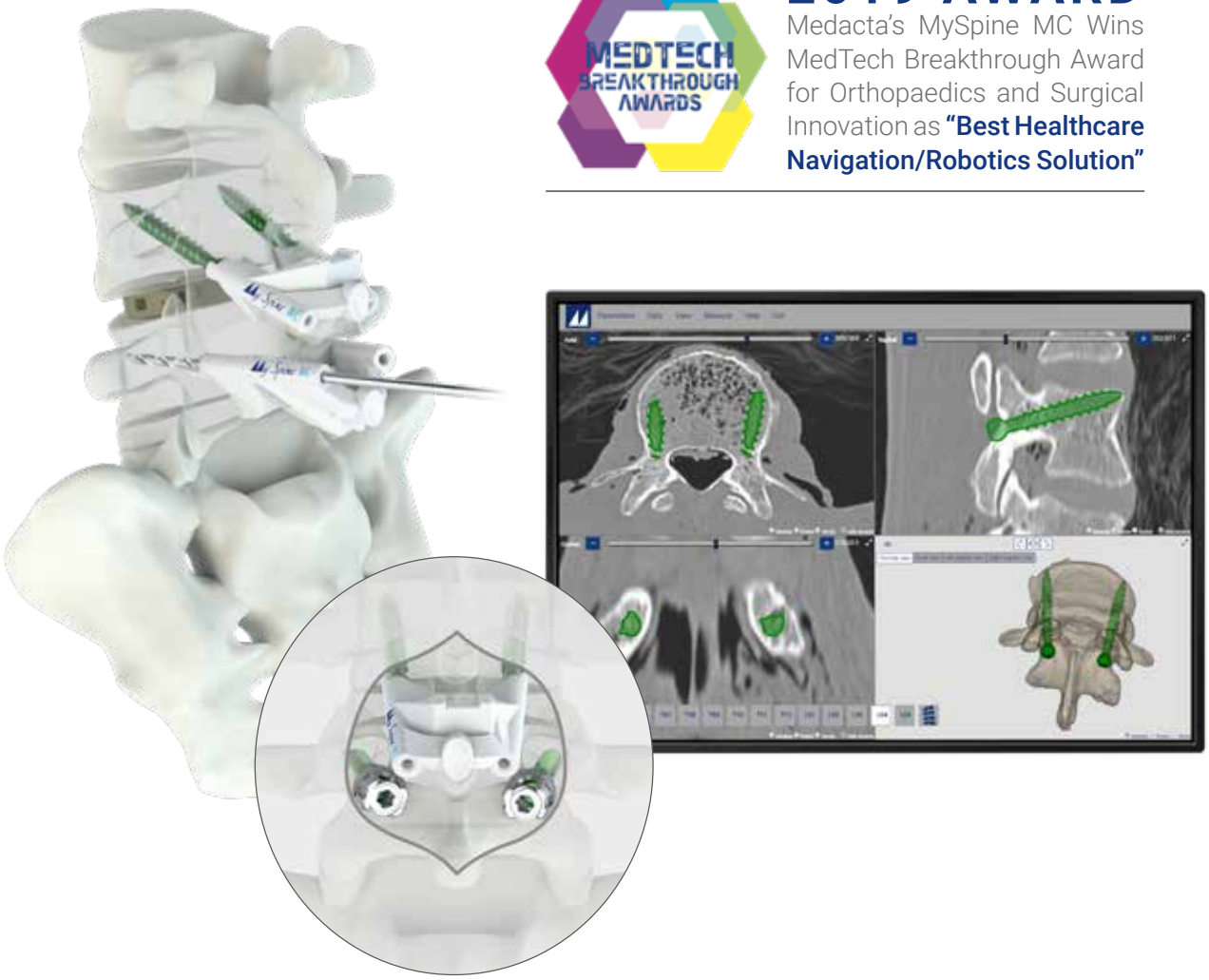
3.3 Why would my doctor choose a MySpine MC surgery?

MySpine MC is a patient-matched, 3D printed technology tailored to the patient's anatomy allowing to simplify pedicle screw placement. MySpine MC is a validated technology supported by scientific data. The potential patient benefits of MySpine MC are:

- **Accuracy** of pedicle screw position[1]
- **Patient-matched technology** allowing for device customisation
- **Low dose X-ray radiation** protocol in comparison to C-Arm or O-Arm navigational technologies[2]
- Potential **reduction** in the post-operative morbidity and **shortening** of the length of hospital stay[2,3]

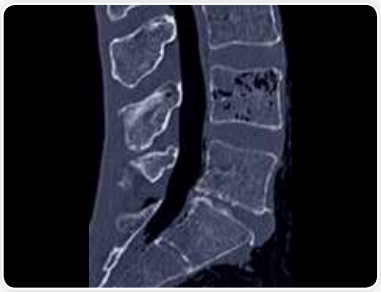
2019 AWARD

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



3.4 The MySpine MC journey

MySpine is a surgical instrument designed to accurately fit your vertebrae. How does it work?



OBTAIN AN IMAGE OF YOUR SPINE

The surgeon will ask you to have a CT scan of your vertebral column. Medacta developed a specific Low Dose CT protocol to ensure a safe image acquisition. In fact you will receive a very similar amount of irradiation to only a single spine X-ray!

REPLICATION OF YOUR SPINE

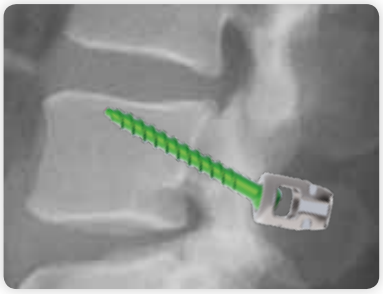
Using images of your spine, Medacta will create a plastic 3D model for each of the vertebra to be treated, in order to allow the Surgeon to select the best implant position and size for you.

CREATION OF MYSPINE

Using the model of your vertebrae and a dedicated planning software, your surgeon tailors your personalized surgical guides around the unique anatomy.

PREPARATION OF SURGERY

Prior to the surgery, your surgeon will receive the MySpine instruments and the plastic replica of your vertebrae. The bone model and the screw placement guides will be analyzed to accurately prepare for your spine operation.



THE DAY OF SURGERY

The surgeon will benefit of the MySpine guides that will help positioning the pedicle screws very accurately according to pre-operative plan.

3.5 Why MySpine MC would be beneficial for me?

MySpine MC can potentially provide you with the following benefits:

DECREASED POST-OPERATIVE PAIN

In comparison with "conventional" surgical techniques, the MySpine MC approach can reduce the postoperative pain thanks to a less invasive technique. [2,3]

BETTER MUSCULAR PRESERVATION

The MySpine MC technique can decrease the muscular atrophy leading to a potential shorter rehabilitation subject to your doctor's approval, based on your post-operative conditions. [2,3]

"On the first postoperative day, she was able to walk autonomously"

SHORTER HOSPITAL STAY

The MySpine MC technique usually significantly reduces the duration of hospital stay. Your surgeon may still recommend a longer stay, depending on your post-operative condition. [2,3]

"All patients were discharged from the hospital on the 2nd postoperative day"

SMALL SKIN SCAR

With MySpine MC the skin incision is often shorter than with "conventional" surgery and therefore scar tissue is reduced. [2,3]

LESS BLOOD LOSS

Preservation of muscles and vessels potentially reduces blood loss during the surgery. [2,3]

SAFE PEDICLE SCREW POSITIONING

The accuracy of the MySpine MC technique leads to a safer implant positioning, potentially reducing the risk of a revision surgery. [1]

BIOMECHANICAL PERFORMANCES

The MySpine MC 3D Printed Patient Specific Solution can potentially provide you with better biomechanical performance allowing for improved long-term patient condition. [1,2,3]

"The patients showed an important clinical improvement, without new neurologic deficits or radiologic pathologic findings, at 6-month follow-up."

99,5%

SAFE PEDICLE SCREW POSITIONING [1]

-24%

DURATION OF THE HOSPITAL STAY [2,3]

4. PREPARATION

Depending on your condition, your recovery will be tailored to meet your needs. Your physician will determine the appropriate length of your hospital stay. Your recovery will continue at home or in a rehabilitation center.

It is important for you to make a commitment to follow your doctor's instructions so you can benefit the most from surgery. Plan for assistance in your home after surgery. Consider your need for assistance in meal preparation, cleaning and other domestic activities.

4.1 What To Do Before Surgery

Four weeks before surgery
Quitting smoking is the single best thing you can do to have your wound heal, bone fuse and reduce risks of infection.

Ten days before surgery
According to your conditions, you might be asked to discontinue arthritis medication. Aspirin, aspirin-containing medications and antiplatelet drugs should be discussed with your physician since many of these drugs can cause interactions with others in preparation for surgery.

The night before surgery
Unless otherwise directed by your doctor DO NOT eat or drink anything after midnight. This includes no water, gum, candies and do not smoke. Brush your teeth. Be sure to have a bowel movement prior to the surgery, using a suppository or laxative if necessary.

The morning of surgery
Clean your body. Do not apply lotions or powders to your surgical area or legs. Take only the medications directed by your physician. Take them with the smallest amount of water needed to swallow the medication (only a sip).

4.2 Prepare Your Home

Arrange for help

- You will not be able to drive for a certain amount of time after your surgery.
- Make arrangements to have someone stay with you, if needed.
- Have family or friends available to assist you once you're home.

Reduce your risk for a fall

- Remove any throw rugs.
- Tack down any loose carpeting so walking will be safer.
- Look around the room for other hazards and remove them.
- Wear shoes with non-skid soles (not house slippers).
- Make sure you have a supportive, comfortable chair in your home.

4.3 What to bring to the hospital

- List of medications that you are taking, amount you take, and how frequently you take them (do not bring all your medications)
- DO BRING migraine medications if you are prone to migraines
- DO BRING inhalers if you use them
- Glasses, hearing aides, dentures, toiletries and slippers
- Orthoses
- Insurance information and an emergency telephone number
- Wear comfortable clothes to the hospital - you will wear these home

5. IN THE HOSPITAL

The following staff members may be involved in your care:

Neurosurgeon or orthopedic surgeon

- Performs surgery and directs your care
- Visits you on rounds in the hospital
- Evaluates you at follow-up appointments at the office

Nursing staff

- Coordinates and provides patient care in the hospital
- Shares information about your condition to the healthcare team
- Helps you plan for the move to your home or extended care facility
- Is available to answer your questions during your hospital stay

Physical therapist

- Evaluates your physical capabilities
- Instructs and assists you with a rehabilitation program
- Provides instructions for home activity
- Identifies possible home needs

Your responsibility as a patient

- Ask questions about anything you do not understand
- Let the staff know about any problems
- Come with an up-to-date and correct list of your home medications
- Carefully follow the directions given by the medical team both before and after discharge from the hospital
- Plan for help at home after surgery

6. AFTER THE SURGERY

Recovery

You will wake up after your procedure in the post-operative recovery room. This is the area of the hospital where your condition is monitored and your vital signs are observed. Generally, a patient will only remain in the post-operative recovery room for a few hours. From there, according to your conditions, you will be transferred to your hospital room on the ward.

Some pain around the incision site is normal, but discuss how you are feeling with your medical team.

Release from hospital

The hospital discharge depends on the extent of your operation and how your recovery is progressing. Your doctor will decide on the best post-operative course of action for you.

Rehabilitation

During your recovery phase in the hospital you may be asked to carefully sit, stand or walk under supervision. You may also be required to use a brace to assist your spine with the fusion process. Once you have been released from the hospital, it is important to adhere to the instructions given by your medical team. You may need to limit certain activities or undergo some prescribed physical therapy. Your doctor will discuss any required medications you require as well as give you instructions on wound care, activities and exercise.

Don't Forget

- A healthy diet and regular exercise are important.
- Schedule regular check-ups.
- Contact your surgeon if you have any concerns about your Spine.

7. FREQUENTLY ASKED QUESTIONS

Will I have a scar?
Your physician will discuss the incisions that will be made during your Midline MIS procedure. Small scars of approximately two inches are common.

When can I drive?
For a period of time after your surgery, determined by your physician, you may be cautioned about activities such as driving. Your physician will tell you when you may drive again.

Are there any risks for this kind of operation?
Any surgical procedure comes with risks. Serious complications are rare and your surgical team will do everything possible to avoid issues arising. However, the most serious potential risks include

- Paraplegia (Very rare – 1 in 1,000 to 1 in 10,000 chance)
- Excessive blood loss
- Continued progression of the curve after surgery
- Failure of the spine to fuse
- Infection

Please consult your doctor for a complete list of indications, warnings, precautions, adverse effects, clinical results, and other important medical information that pertains to spinal fusion surgery.

Is the procedure covered by insurance?
It is always best to check and confirm with your insurance plan provider in advance.

Do the Spine implants activate the metal detectors at airports?
Sometimes this can happen but it depends on the sensitivity of the detectors at the points of control of the airport. All of Medacta's Spine implants are identified by a card called Implant Passport, provided by your surgeon after the operation. Always carry it with you and present it if necessary!

Should you have any questions or concerns regarding your condition, do not hesitate to contact your doctor and, finally...

...enjoy your active life!

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PHARMACOTHERAPY

References:

[1] *Matsukawa K. et al., Accuracy of cortical bone trajectory screw placement using patient-specific template guide system, Neurosurgical Review, July 2019*

[2] *Marengo N. et al., Cortical Bone Trajectory Screw Placement Accuracy with a Patient-Matched 3-Dimensional Printed Guide in Lumbar Spinal Surgery: A Clinical Study, WORLD NEUROSURGERY, June 2019*

[3] *Marengo N. et al., Cortical Bone Trajectory Screws in Posterior Lumbar Interbody Fusion: Minimally Invasive Surgery for Maximal Muscle Sparing—A Prospective Comparative Study with the Traditional Open Technique, Clinical Study, February 2018*

PHYSIOTHERAPY

Contraindications, Complications, Warnings and Precautions

All Spinal procedures come with a small risk of complications. Please speak with your doctor about the potential risks of your surgery as well as the common post-operative side-effects such as pain and discomfort.

Redefining Better in
Orthopaedics and Spine surgery

For further information visit our website:

patientspine.medacta.com

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