



SPINAL IMPLANTS & INSTRUMENTATION



CONTENTS

02

About Us
Quality Management
Certificates
Customer Satisfaction
Distributorship
Raw Materials

14

Anterior Cervical
Posterior Cervical

20

Posterior Fixation Systems

24

Lumbar Fusion

27

Spinal Surgery Instrumentation
Contact



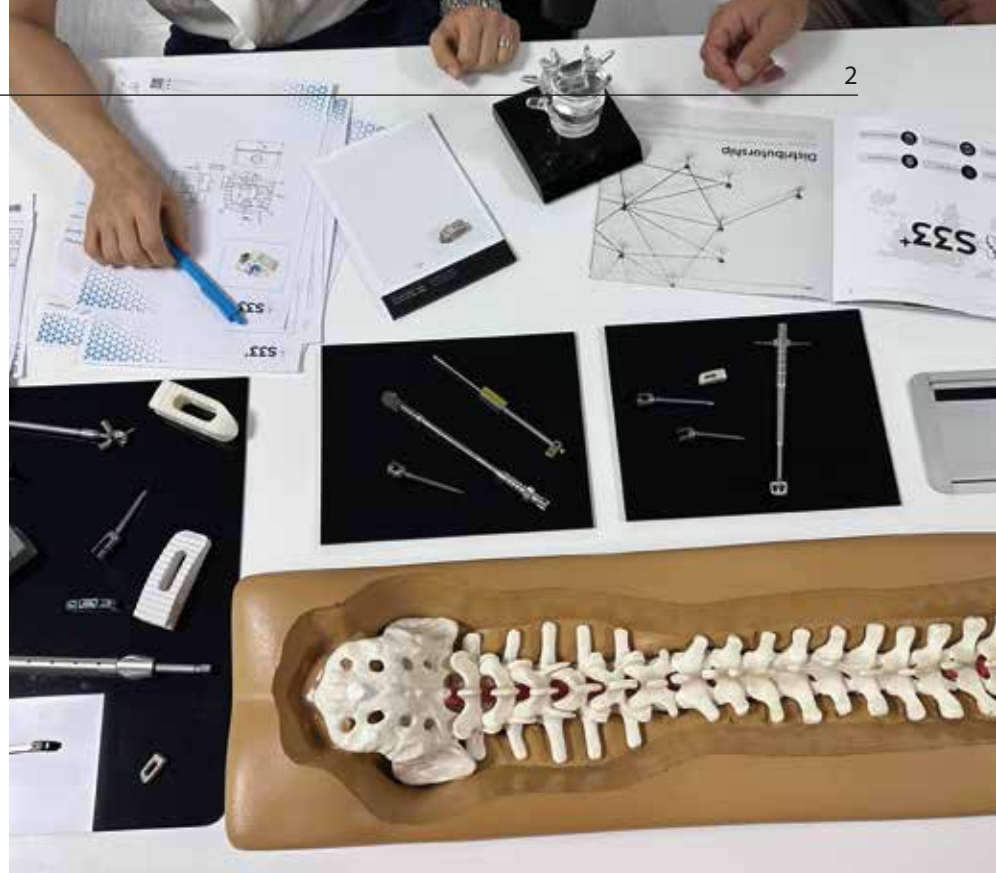
About Us

S33 Spine which has been developed based on our spinal implants manufacturing and brand-management background with a years of experience is a sub brand under Prodorth umbrella. The products of S33 Spine are manufactured with perfection to match our high quality standards. We developed alternative solutions to offer affordable prices by data transfers from Prodorth's infrastructure such as technical files, technical drawings, established workmanship organization, ads design etc. Teamwork, enthusiasm and dedication are crucial for the sustainable success of S33 Spine. We guarantee added value for our users and clear competitive benefits for our distributors.

RD Medikal is the name of the company where commercial brand names Prodorth and S33 Spine products are produced. It was founded in 2013 by Mechanical & Materials Engineers, as well as the contribution of the healthcare professionals.

Within our journey, we always tried to follow up the latest technologies by combining them with the user-friendly approaches which are the accepted and well-known methods by surgeons.

We always try to provide the most simple instrumentation not only to carry out the surgical procedures simply but also to obtain the most efficient solutions and to provide patients and surgeons with our progressive spinal medical devices with RD Medikal's high tech production lines.



Mission

Aiming to provide innovative solutions which match customer demand. We are continuously monitoring research and development advancements in our field while expanding into a new market

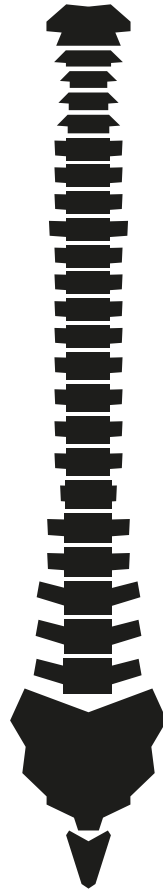


Vision

Creating a better life for patients and providing preferred products and services for surgeons through our distributors.



**Spinal Implants &
Spinal Surgery Instrumentation**



Quality Management

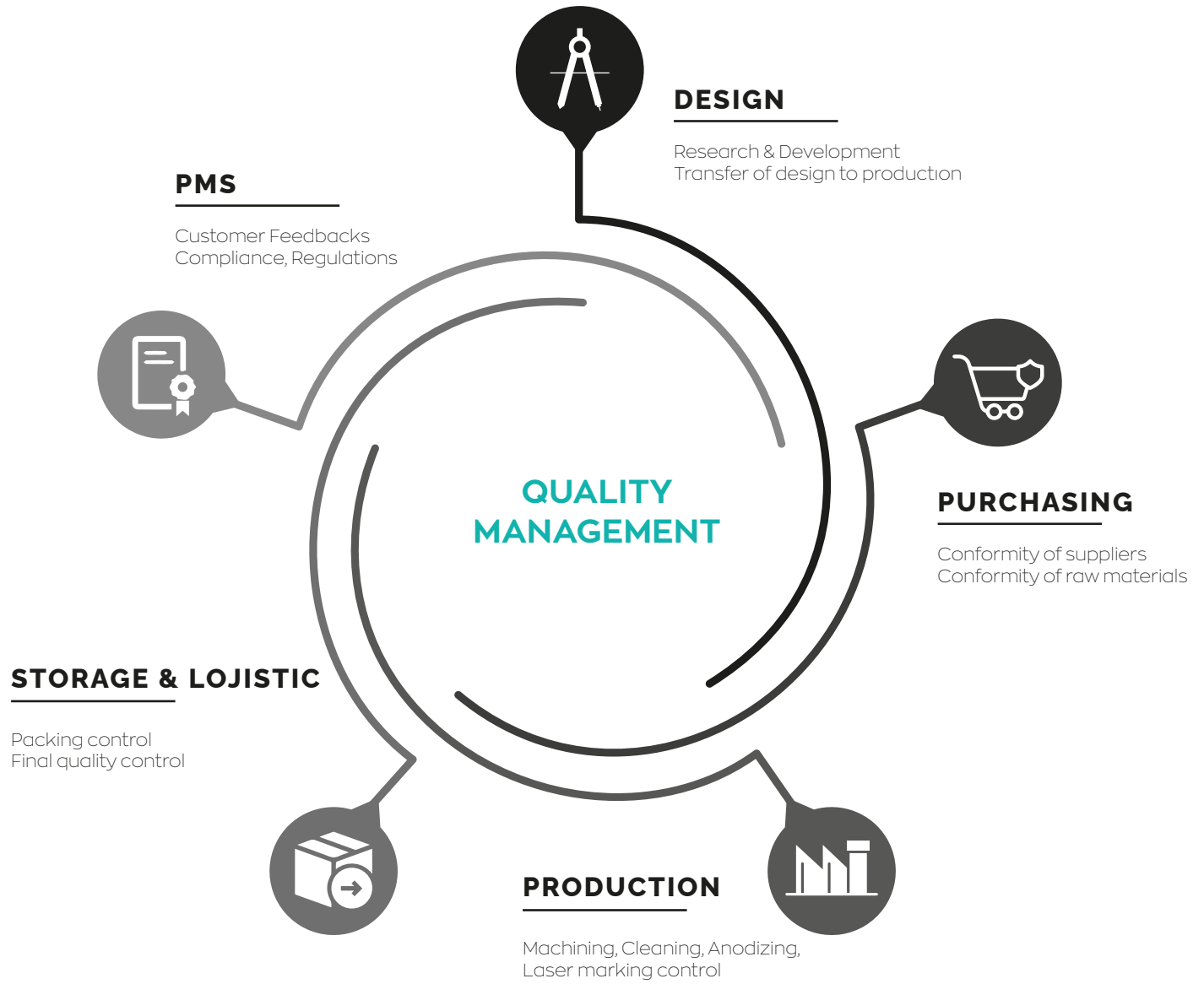
ISO 13485:2016 Quality Management System is efficiently adapted on the organization of S33 Spine and provides a 100% traceability from raw material to final product.

Our main task with respect to Quality Management is ensuring a complete control in a reliable and continuous production quality with machining, polishing, ultrasonic washing, color anodizing and laser marking units within our organization. Biomechanical and biocompatibility tests were performed in accordance with ASTM and ISO standards which are required to launch our products to the market reliably.

Our claim is to consistently develop our products, to keep our quality at the highest level, to ensure requirements of quality management procedures considering countries' regulatory systems.

We also strive to provide requirements of the MDR (2017/745/ EU) which is the new regulation for medical device companies to sell their products in Europe as well as other countries.







Customer Satisfaction

The company takes part in the biomedical industry with its innovative and high quality products. S33 Spine products are designed, manufactured and developed in our organization, and the results are always met with the approval of well-known surgeons.



S33 Spine began its journey with the principle of “Human First” and always proceed in this way.

Knowledge combined with technology and innovator approach...

“Customer Satisfaction” is not just a catchphrase for us as we aim at maintaining long-term relationships with our customers. Therefore, we are highly aware that we have to provide perfect after-sale services.

In our opinion high quality should not be a privilege, but rather a standard in the medical industry, hence we are always keen on following up on the latest technologies and keep on investing in our technical staff in order to keep the level of our products' quality intact.

We reflect the value of our brand to our products and we would like to see the doctors feel our effort of understanding and solving their problems.

High Quality and innovation are the first details you will notice about S33 Spine products.







High Quality Production



ISO 13485:2016



+10 Years Experience



Customer Satisfaction



Wide Product Range



Certification & Regulatory



**EXCELLENCE
BEGINS
HERE.
GROW WITH US.**

Distributorship

For expanding or improving our sales force, we reach patients and surgeons with our gained experiences all around the world through our distributors since 2013.

RD MEDIKAL is a company located in Izmir, Turkey, manufactures Spinal Implants & Instruments under our registered brand "S33 Spine" with competitive prices without compromising of the quality of our products. Our primary goal is reaching innovative solutions by simple approaches which earned us a reputation within the spinal implants field.

Products & Spinal Implants & Raw Materials

Product Specifications

Material selection is one of the most important point for implants.

Titanium Alloy (Ti6Al4V-ELI Grade 23 / ISO 5832-3 / ASTM F136) and PEEK (Polyether-ether-ketone / ASTM F2026) are used as raw materials for all S33 Spine products and these are all originated from EU and USA. Both material are biocompatible and adequate for long term use (C = Permanent (> 30 days)).

PEEK material is a remarkable raw material with its unique properties;

- Biocompatible
- It does not cause any lesional problems
- Has elastical and hardness features near to bone tissue
- Titanium alloy materials give an opaque image under X-Ray, besides PEEK materials is able to be viewed transparently. This provides a more efficient follow-up for the bone fusion through the implant material at post-operative period



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Anterior Cervical PEEK Cages & Bladed

S33 Spine Cervical PEEK Cages provide a great hold on to the endplates with its blade, which allows it to be used without a plate.

One of the best advantage of S33 Spine Cervical Peek Cages is offering a very simple application which is found user-friendly by surgeons.

S33 Spine Cervical Peek Cages with mono / double blade options and regular cervical peek cages are available on request.

- Toothed surface is designed to prevent migration
- As for the bladed options, blades provides a more reliable hold on to the endplates
- Anatomical geometry
- Enhanced cage-inserter connection, designed to withstand rotational forces and user-friendly instrumentation to facilitate the procedure
- X-ray marker pins for the visibility
- Made of PEEK material (ASTM F2026), originated from EVONIK Industries Germany. While titanium alloy materials give opaque image under X-Ray, PEEK materials is able to be seen transparently. This provides efficient follow up of the bone fusion through the implant at the targeted periods
- Maximized Strong Construction / Large Fusion Space ratio
- Various sizes and footprints are available



FOOTPRINTS :

12x14 mm, 14x14 mm, 14x16 mm

HEIGHTS :

4-8 mm (by 1 mm increments)



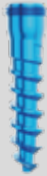
Anterior Cervical PEEK Cage with Screws

S33 Spine Stand-Alone Cervical PEEK Cage System provides an improved stability with the screws on it.

The system offers an interbody fusion device with screw fixation and is intended to be used in ACDF procedures. S33 Spine PEEK cage with titanium screws and locking mechanism provides a stable fixation without the need of an anterior plate.

S33 Spine Stand-Alone Cervical PEEK Cage System keeps the cervical spine's natural sagittal anatomic profile while providing anterior column support and contribution to the fusion.

- Zero profile
- Self-locking screws
- Optimized screw angulation
- S33 Spine Cervical Stand Alone System offers a simple application which is found user-friendly by surgeons. Therefore, the instrumentation of this system has been simplified as possible to meet the general requirements.
- X-ray marker pins for the visibility
- Maximized Strong Construction / Large Fusion Space ratio
- Titanium internal structure for top-notch strength
- Three footprints and four height options are available
- S33 Spine Cervical PEEK cage with screws is available in different footprints and heights and made of a combination of PEEK (ASTM F2026) which is a polymer based composite material and Ti6Al4V-ELI (Grade 23) (ASTM F 136). PEEK material's modulus of elasticity is similar to vertebral bodies and it gives radiolucent imaging



FOOTPRINTS :

12x14 mm, 14x14 mm, 14x16 mm

HEIGHTS :

5-8 mm (by 1 mm increments)

SCREWS :

Ø3-3,5 mm

HEIGHTS :

10-16 mm (by 2 mm increments)



Anterior Cervical Disc Prosthesis

It is an alternative to the commonly performed anterior cervical discectomy and fusion (ACDF), a surgical procedure that is designed to address the pathology by eliminating motion at the diseased disc level.

Artificial disc replacement (ADR) surgery—also known as a total disc arthroplasty or total disc replacement (TDR)—is typically performed for a patient with a cervical disc herniation that is causing significant neck pain and/or arm pain that has not responded to nonsurgical treatment options and is significantly affecting the individual's quality of life and ability to function.



- Completely made of titanium and PEEK
- PEEK material at the internal mechanism provides a super-smooth surface for a perfect motion capability
- PEEK cover which is shaped as a ring, placed around the internal mechanism in order to prevent the bone-fusion into the disc prosthesis
- One-piece and anatomical design
- Motion preservation
- Dark anodized and rough surface options are available
- Wide range of motion for flexion, extension, lateral bending and rotation
- Minimizing the scratching by the coating
- Smart design for the most effective movement capability
- Spikes for the enhanced hold on to vertebral bodies
- Reliable and stable connection with the instrument designed to withstand rotational forces and streamlined instrumentation
- Appropriate for Smith-Robinson approach
- Ti6Al4V-ELI (Grade 23) is used as raw materials for S33 Spine Cervical Disc Prosthesis and these are originated only from our reliable partners in USA and Italy. PEEK material (ASTM F2026) is supplied from EVONIK INDUSTRIES Germany. All certificates are available on request



FOOTPRINTS :

12x14 mm, 14x14 mm, 14x16 mm

HEIGHTS :

5-8,5 mm (by 0,5 mm increments)





Anterior Cervical Plate System

S33 Spine Cervical Plate System is designed to meet the clinical expectations of anterior cervical surgery and it offers a wide range of plates and screw sizes. Fixation is provided by screws inserted into the vertebral body of the cervical spine using an anterior approach.

- Low profile (2,0 mm) pre-bended plates
- Variety in plate sizes which provides a convenience for implant selection for surgeons
- User-friendly instrumentation
- Single driver to place screws and secure the locking mechanism
- Different bone screws can be identified by their unique color coding
- High degree of screw angulations
- Simplified locking mechanism of the screws
- Self-tapping screws
- Deep screw threads for high pull-out strength
- Wide graft spaces
- S33 Spine Cervical Plate System consists of cervical plates, locking caps, bone screws, and the instruments required for implanting this specific system. All implant components are made from a titanium alloy Ti6Al4V-ELI (Grade 23) (ASTM F136 / ISO 5832-3)

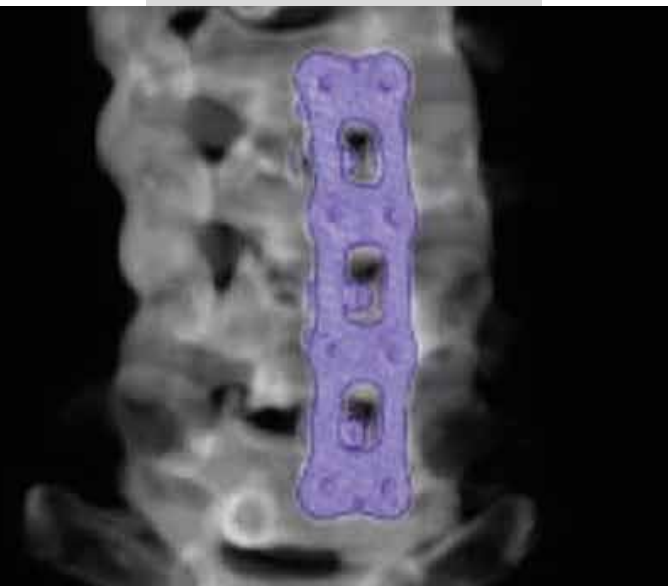


PLATE LEVELS :

- 1 Level (20-32 mm)
- 2 Level (34-48 mm)
- 3 Level (50-74 mm)
- 4 Level (77-100 mm)

SCREWS :

Ø3,5-4 mm

HEIGHTS :

12-26 mm (by 2 mm increments)





Posterior Cervical Pedicular Screws

S33 Spine Posterior Cervical Fixation System offers multiple screws, hooks, rods with hexagonal tips, transition rods, occipital plates and different type of connectors for a better match to patient anatomy.

- Friction head screw feature
- Offers wide range of angulation
- Five points of fixation on the occipital plate
- Colour-coded implants for easy identification and user-friendly instrumentation to facilitate the procedure
- Self-tapping Screws for a proper and safe placement and are available in 3.5 mm & 4.0 mm diameters
- Titanium / Ti6Al4V-ELI Grade 23 (ASTM F136 / ISO 5832-3) is used as raw materials for S33 Spine pedicle screws and these are originated only from our reliable partners in USA and Italy



SCREWS :
Ø3,5 - 4 mm

HEIGHTS :
10-34 mm (by 2 mm increments)



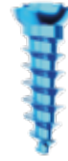


Posterior Cervical

Occipital Plate

FOOTPRINTS :

- Small (28 mm)
- Medium (35 mm)
- Large (42 mm)



SCREWS :

Ø3,5-4 mm

HEIGHTS :

8-16 mm (by 2 mm increments)



Posterior Cervical

Spinal Connectors

Multiaxial Connector

SIZES : 20-30 mm, 30-40 mm, 40-50 mm



Linear Connector

SIZES : 30-60 mm (by 10 mm increments)



Bar Type Connector

SIZES : 20-30 mm, 30-40 mm, 40-50 mm



Hooks

SIZES : *Small, Medium, Large

Posterior Cervical

Spinal Rods

SIZES :

Ø3,5x100 - Ø5,5x250 mm

SIZES :

Ø3,5 // 30-200 mm



Transition Rod



Titanium Rod



Posterior Fixation Systems

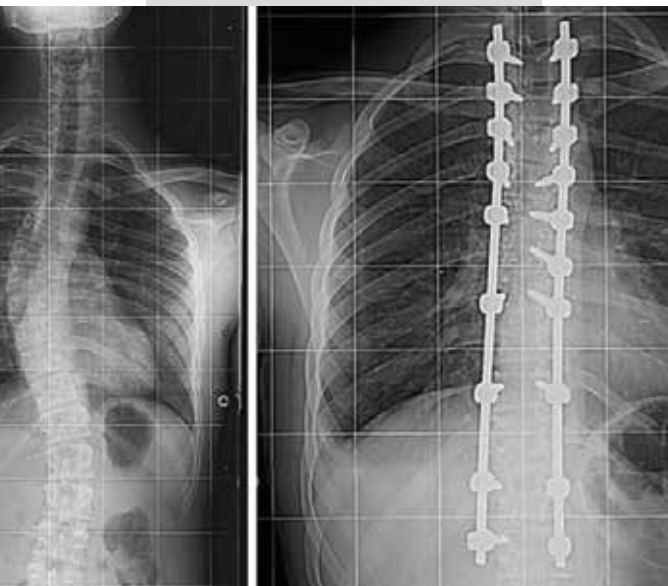
Pedicular Screws

S33 Spine Pedicular Screws have a unique design with V-Shaped highly sharp threads, as well as a polished surface which results in successful clinical outcomes with long-term stability.

As it's proven so far, there is a direct relationship between the profile of the pedicle screws and the pull-out strength, hence a strict quality control process is performed on the threads during the production.



- Stronger connection with friction head screw feature
- More reliable tightening with the torx design of setscrew. Reverse angled thread design of setscrew
- Offers wide range of angulation
- Cutting flute design for facilitating initial insertion to bone
- Mono threaded and double threaded options are available on request. In addition, double threaded Pedicle Screws have been designed for decreasing the number of rotations of the screw to reduce the operation time of the entire surgery
- Integratable with posterior cervical systems
- Improved features for use in deformity cases
- Conventional and commonly preferred application
- Strong tulip design to prevent head splay
- Wide range of Polyaxial & Monoaxial screws, connectors and hooks to meet a multitude of patient pathologies
- Colour-coded implants for easy identification and user-friendly instrumentation to streamline the procedure
- Titanium / Ti6Al4V-ELI Grade 23 (ASTM F136 / ISO 5832-3) is used as raw materials for S33 Spine pedicle screws and these are originated only from our reliable partners in USA and Italy



Polyaxial Screw

Ø3,5-8 mm (by 0,5 mm increments)

LENGTHS: 25-120 mm (by 5 mm increments)

L. Polyaxial Screw

Ø4,5-7,5 mm (by 0,5 mm increments)

LENGTHS: 25-80 mm (by 5 mm increments)

Monoaxial Screw

Ø3,5-8 mm (by 0,5 mm increments)

LENGTHS: 25-120 mm (by 5 mm increments)

L. Monoaxial Screw

Ø4,5-7,5 mm (by 0,5 mm increments)

LENGTHS: 25-80 mm (by 5 mm increments)



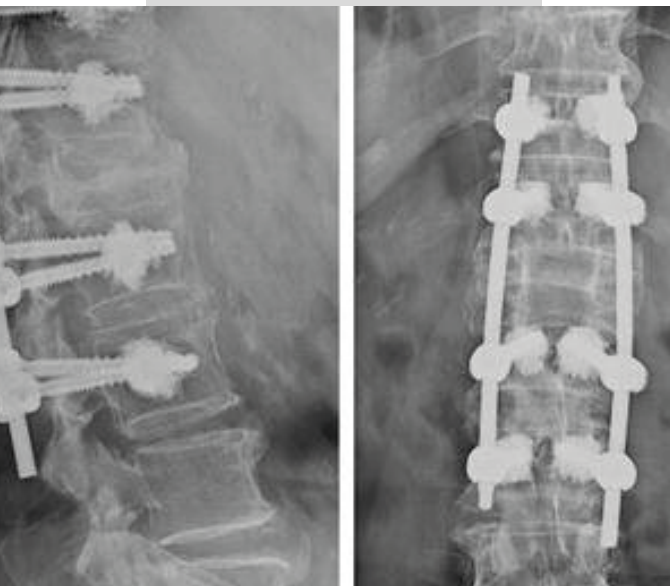


Posterior Fixation Systems

Cannulated Pedicular Screws

S33 Spine Fenestrated Screw System which is also known as Cannulated Screw System is intended to be used for osteoporotic pathologies, fractures, and osteotomies.

- Cement injectable design
- Offered along with practical instrument for a smooth cement injection
- Titanium / Ti6Al4V-ELI Grade 23 (ASTM F136 / ISO 5832-3) is used as raw materials for S33 Spine pedicle screws and these are originated only from our reliable partners in USA and Italy



SCREWS :

Ø5-7,5 mm (by 0,5 mm increments)

LENGTHS:

30-80 mm (by 5 mm increments)



Posterior Fixation Systems

Spinal Connectors



Multi-axial Connector

SIZES : 30-45 mm, 38-53 mm, 45-60 mm, 53-68 mm, 60-75 mm



Linear Connector

SIZES : 40-100 mm (by 10 mm increments)



Bar Type Connector

SIZES : 30-40 mm, 40-50 mm, 50-60 mm



Hooks

SIZES : *Small, Medium, Large



Single



Quadruple



Double



Double-II

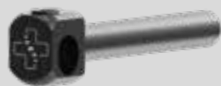


T-30

Domino Connectors

CONVENIENT with Ø3,5 - 5,5 mm RODS





Long Closed



Long Open



Short Closed



Short Open

Posterior Fixation Systems

Spinal Connectors

Lateral Connectors

CONVENIENT with $\varnothing 3,5 - 5,5$ mm RODS

Posterior Fixation Systems

Spinal Rods

(Ti6Al4V-ELI Grade 23 (ASTM F 136))

SIZES :

$\varnothing 3,5 \times 100 - \varnothing 5,5 \times 250$ mm

SIZES :

$\varnothing 5,5 // 40-600$ mm

SIZES :

$\varnothing 5,5 // 40-120$ mm



Transition Rod



Titanium Rod



Curved Rod



Lumbar Fusion

TLIF PEEK Cage

S33 Spine TLIF Cage has a unique placement procedure and it's intended to restore the degenerative disc pathologies.

- S33 Spine TLIF Cage is made of a combination of PEEK (ASTM F2026) which is a polymer based composite material and Ti6Al4V-ELI Grade 23 (ASTM F136 / ISO 5832-3). PEEK material's modulus of elasticity is similar to vertebral bodies and it gives radiolucent imaging
- Circular toothed surface design to minimize the risk of migration
- Multiple footprint options for various surgical solutions
- Anatomical design
- The implantation process is performed by a single instrument
- Enhanced cage-inserter connection, designed to withstand rotational forces
- S33 Spine TLIF Cages provides an uninterrupted guidance during operation. It has a capability of movement to both directions
- It can be fixed by rotating the wheel behind the inserter, and it is easily released by loosening it. This provides an easy positioning as required
- After discectomy, the wheel is rotated clockwise while the TLIF cage is at upright position and it's introduced into intervertebral area so on. After that the wheel is loosened and the TLIF cage is released at the required position



LENGTHS : 25 & 28 mm
HEIGHTS : 7-15 mm
(by 1 mm increments)





Lumbar Fusion

PLIF PEEK Cage

- Enhanced cage-inserter connection, designed to withstand rotational forces
- X-Ray markers for efficient visualization during implantation
- Toothed surface design to minimize the risk of migration
- Easy to introduce with sharp ended design
- Large fusion space
- Anatomical geometry
- Made of a combination of PEEK (ASTM F2026) which is a polymer based composite material and Ti6Al4V-ELI Grade 23 (ASTM F136 / ISO 5832-3). PEEK material's modulus of elasticity is similar to vertebral bodies and it gives radiolucent imaging



LENGTHS : 25 & 28 mm
HEIGHTS : 7-15 mm
(by 1 mm increments)

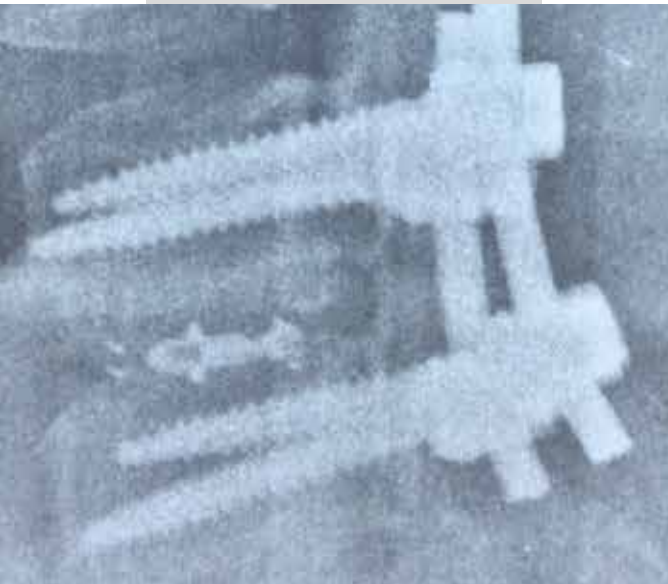




Lumbar Fusion

Expandable PLIF PEEK Cage

- Holding on to inferior and superior endplates strongly with unique surface design
- Enhanced cage-inserter connection, designed to withstand rotational forces
- X-Ray markers for efficient visualization during implantation
- Toothed surface design to minimize the risk of migration
- Easy to introduce with sharp ended design
- Large fusion space
- Anatomical geometry
- As for the expandable PLIF cages, stopping system is integrated during expansion to prevent over expansion
- Made of a combination of PEEK (ASTM F2026) which is a polymer based composite material and Ti6Al4V-ELI Grade 23 (ASTM F136 / ISO 5832-3). PEEK material's modulus of elasticity is similar to vertebral bodies and it gives radiolucent imaging



LENGTHS : 25 & 28 mm
HEIGHTS : 7-15 mm
(by 1 mm increments)



Spinal Surgery Instrumentation

S33 SPINE SURGERY KIT



INSTRUMENTATION SET - I
Posterior Fixation System Instrumentation



INSTRUMENTATION SET - II
Lumbar Fusion System Instrumentation



INSTRUMENTATION SET - III
Derotation Systems for Deformity Instrumentation



INSTRUMENTATION SET - IV
Posterior Cervical Fixation System Instrumentation



INSTRUMENTATION SET - V
Hook System Instrumentation

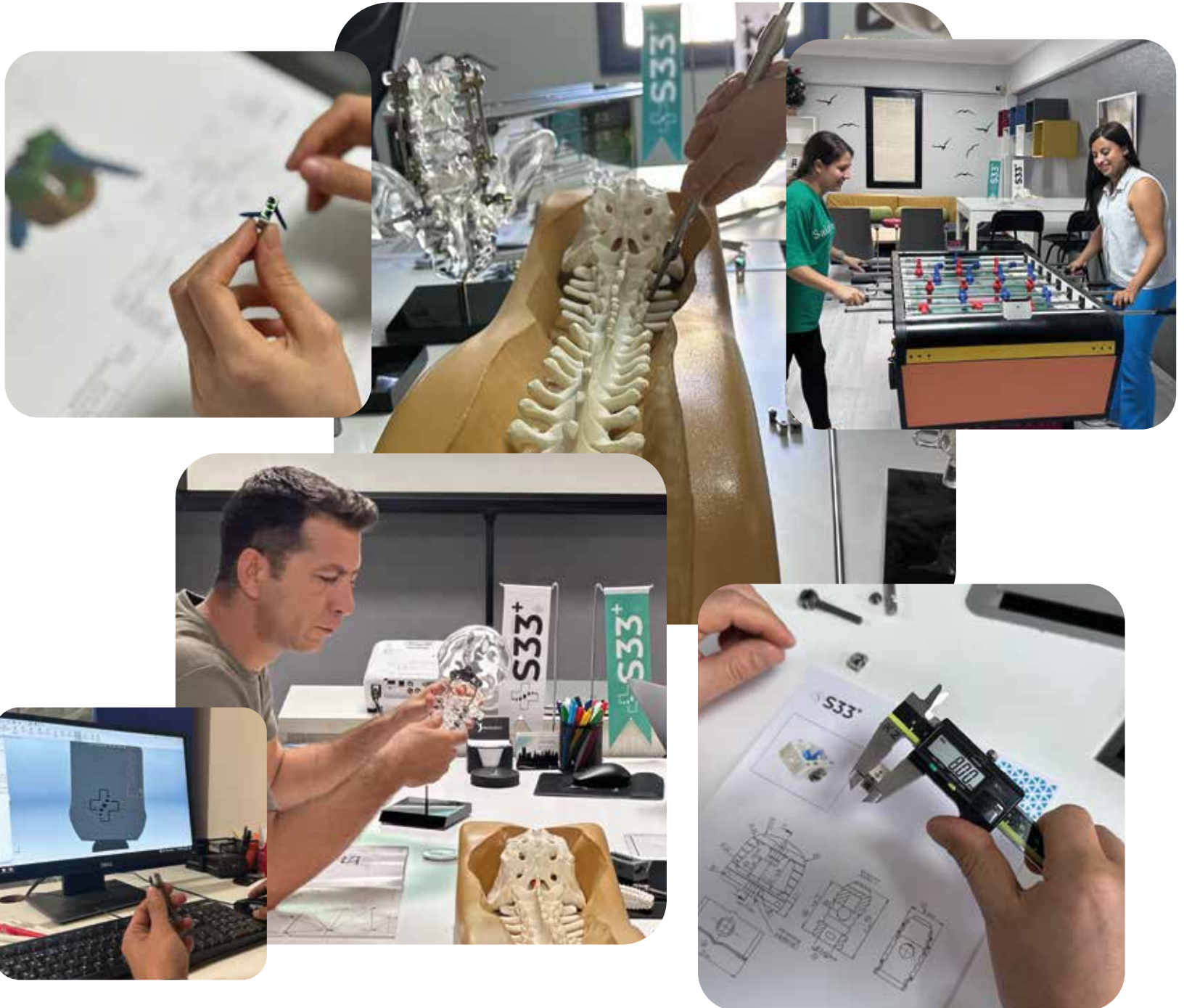


INSTRUMENTATION SET - VI
Anterior Cervical Combined Instrumentation



INSTRUMENTATION SET - VII
Anterior Cervical Plate System Instrumentation









Turkey



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