SMAIO GLOBAL PRESENTATION

FEBRUARY 2021

CONFIDENTIAL

KHEIRON-PRS-001-CE-EN-09-2020-V01

INDEX

01 ABOUT SMAIO

1 ABOUT SMAIO

- **SMAIO (S**oftware **M**achines & **A**daptative **I**mplants in **O**rthopaedics**)** is a spine medical device manufacturer.
- French company .
- Founded in 2009 by surgeons.
- Experts in personalized medicine with a focus on patient sagittal restoration.
- **Main objective: efficiently** and **safely** treat spinal pathologies requiring surgery.
- 600+ patients treated with KHEIRON spinal fixation system since CE mark (May 2019).

OUR 4 IN 1 SOLUTION

1. EDUCATION : Sagittal balance academy and Konnect program.

2. SURGICAL PLANNING SERVICE : Balance Analyzer 3D and case simulation provided by our *Krew team.*

3. IMPLANTS & INSTRUMENTS : Kheiron spinal fixation system.

4. DATA MANAGEMENT : Keops patient registry.

Our vision and philosophy

SMAIO aims to become a leader in the supply of medical devices and associated services, our main objective being to efficiently and safely treat spinal pathologies requiring surgery.

The philosophy of SMAIO is based on the conviction that a successful spinal surgery must achieve two objectives:

1

Efficiency

Provide the patient a measurable improvement in his quality of life, his functional capacities and his abilities for social integration at all ages.

2

Safety / Sustainability

Restore or preserve the biomechanical spino-pelvic balance in order to guarantee the sustainability of the clinical results obtained over time and limit the need of surgical revisions.

To achieve these objectives, SMAIO develops and markets a range of products and services that aim at making surgery less dependent on the operator who performs it, improving the repeatability of surgical procedures.

Strategy

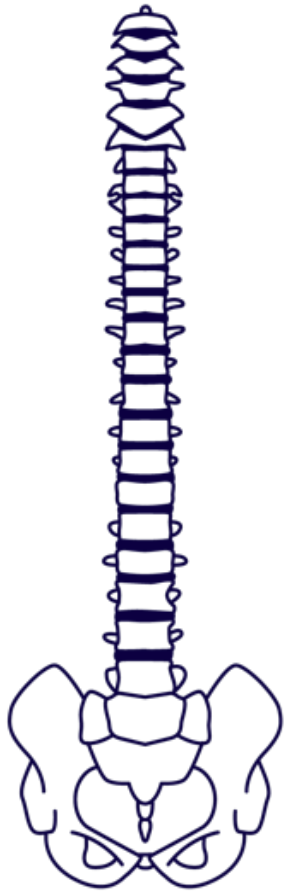
MARKET TODAY

400+ suppliers :

(6 are holding 80% of the current market) representing roughly $9B.

Material provided :

Tulip screws which don't have 100% power of correction (even with a pre-op planning and customized rods).



SMAIO OFFER

Immediate addressing :

Sagittal Balance + Per-op planning.

Focus on thoraco-lumbar.

2-3 years addressing :

Robotics & connected objects.

2-3 years addressing :

Percutaneous & mini open.

SMAIO

Highlights 2019-2020

May2019

CE marking of the KHEIRON spinal fixation system®.

June2019

1st participation in a national congress: SFCR (France).

September 2019

1st participation in an international congress: Eurospine.

October 2019

100ème Surgery.

December 2019

150 Surgeries Made.

Now

+ 650 surgeries performed in countries (FR/BL/ES/PT/DK).

Business coverage

Europe is a KEY territory

ACTIVE PRESENCE
IN 12 COUNTRIES

UNDER
DEVELOPMENT

PLANNED

Prevision

2020

50 - 60 KHEIRON® instruments / implants sets.
Manage Europe key countries + USA.
Obtain CE Marking for all extensions + FDA Marking of KHEIRON® range.

2021

100-120 KHEIRON® instruments / implants sets.
Manage Europe key countries + USA + Australia + Latin America.
Offer sterile package.

2022

200 KHEIRON® instruments / implants sets.
Manage Europe key countries + USA + Australia + Latin America + Japan.

A '4 in 1' solution

For vertebral realignment, integrating: Implants – Technologies.

EDUCATION : Sagittal Balance Academy.

SURGICAL PLANNING: Krew team + Keops Balance Analyzer 3D.

IMPLANTS - INSTRUMENTS : Spinal fixation system.

DATABASE: Patient registry.

02 KHEIRON: IMPLANTS & INSTRUMENTS

About KHEIRON

1 p.d. atitikimas: "Užpakalinė..."

KHEIRON is a posterior spine fixation system.

1 unique system for correcting various spinal pathologies
(degenerative, trauma, tumor or deformity).

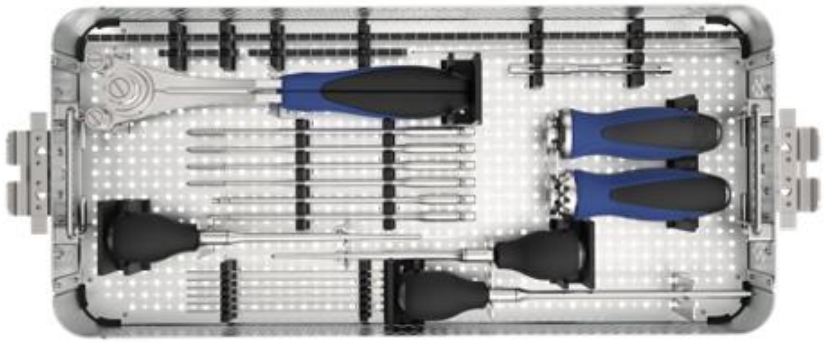
3 instrumentation boxes and 1 modular implant box.	Pre-curved rods with different angulations available.	Screws with extension for a progressive correction.
Extensions of canulated screws used as a working tunnel.	Full range of screws dia. 4.5 mm - 8.5 mm.	Open connector, makes it easier to connect to the rod.

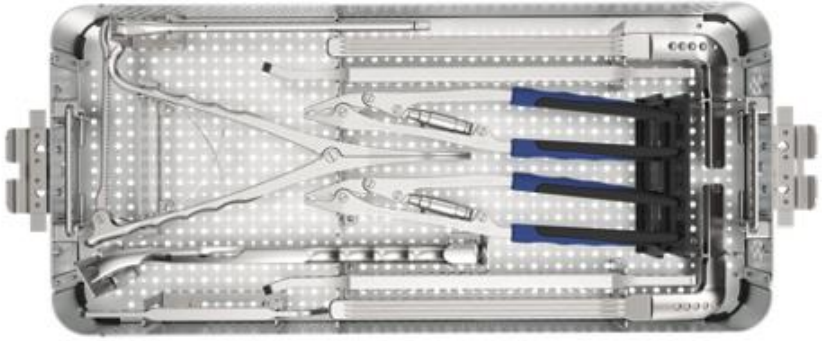
Implants

The material used for the implants is titanium alloy TI-6A1-4V ELI.

Instruments

- The instruments are composed of different alloys of steel and silicone for surgical use, mainly:
- -Stainless steel X20Cr13 / 1.4021.
- -Stainless steel X2CrNiMo18-15-3.
- -Stainless steel X2CrNiMo18-15-3/1.4441.





Implants

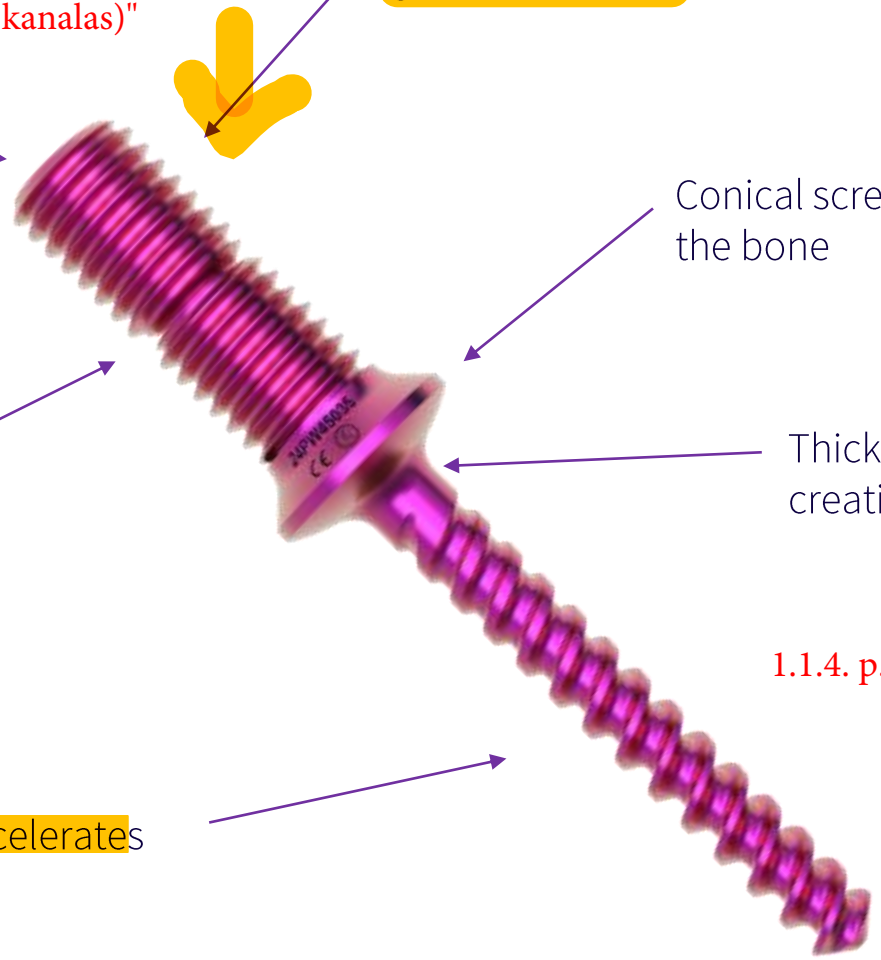
A “fixation unit” consists of screw, connector, nut and rod.

Implants: screw

1.1.4. p.d. atitikimas:"Polis yra su sriegiu, nulaužiamas bei kanuliuotas (naudojamas kaip darbinis kanalas)"

Breakeable extension for a gradual reduction

Canulated extension used as a working canal



Conical screw head to flush with the bone

Thick neck below the screw head creating an area of high resistance

Breakage of the extension over the connector

1.1.4. p.d. atitikimas:"Sraigto spalvinis žymėjimas pagal diametrą"

Color code corresponding to diameter

1.1.4. p.d. atitikimas:"Dvigubo sriegio"

Double-threading screws, accelerates penetration into the bone

1.1.4. p.d. atitikimas:"Atraumatinis įsukimas"

Rounded tip for atraumatic insertion

Implants: screw

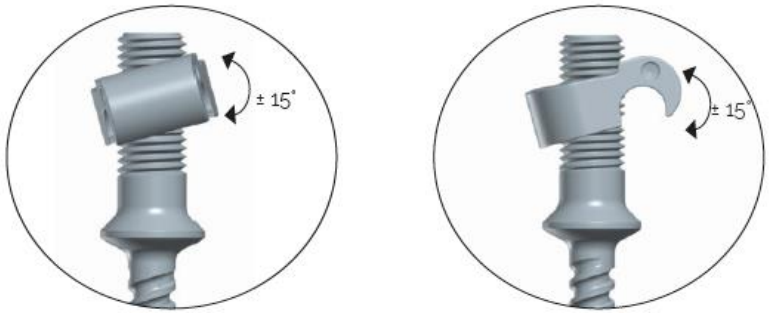
Screw length **25mm to 60mm.**

Implants: connector

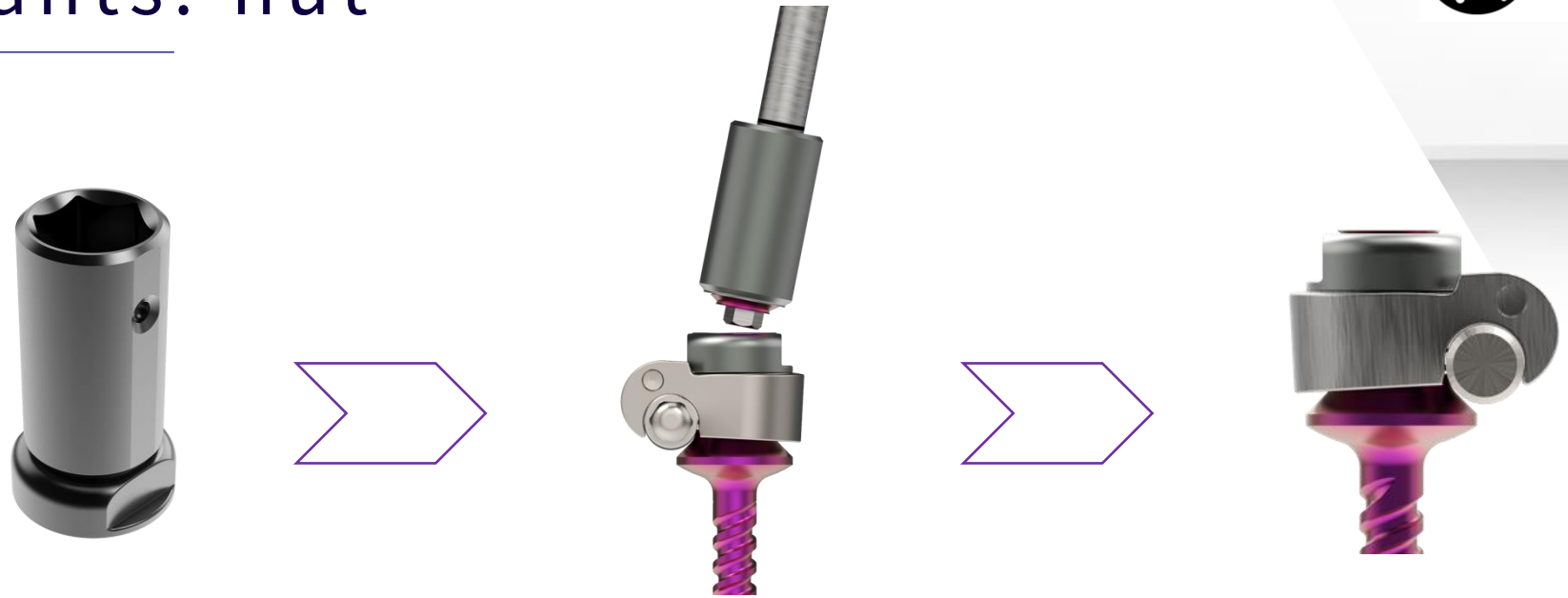
- Open conector.
- Clip to the rod in a "click“.
- A 5.5mm rod connector and a 6mm rod connector.
- It is possible to click and unclick the connector in a single gesture.
-
- +/- 15° of freedom around the screw to make it easier to connect to the rod.

1.1.5. p.d. atitikimas: "Užtikrina strypo fiksavimą prie sraigto"

1.1.5. p.d. atitikimas: "Konektorius ant strypo uždedamas (atviras montavimo būdas)"



Implants: nut



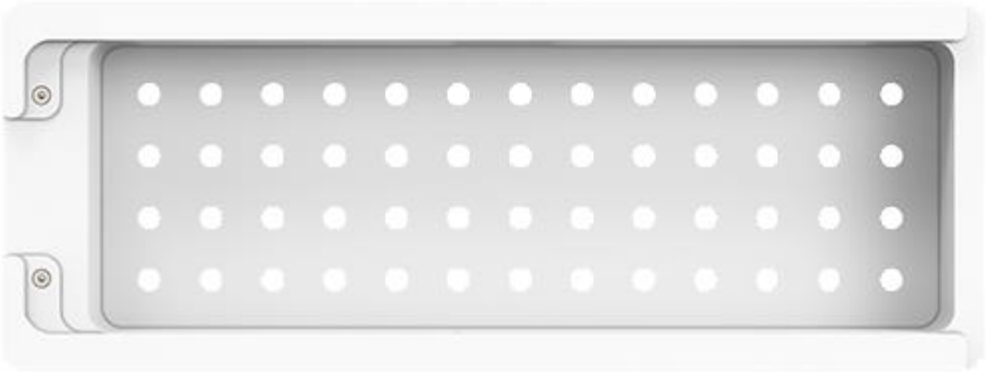
- Hexagonal footprint.
- “Cross-threading” impossible.
- Breaking point at 12 Nm.
- Once broken, the footprint remains intact for a possible revision.
- Used with all diameter pedicle screws

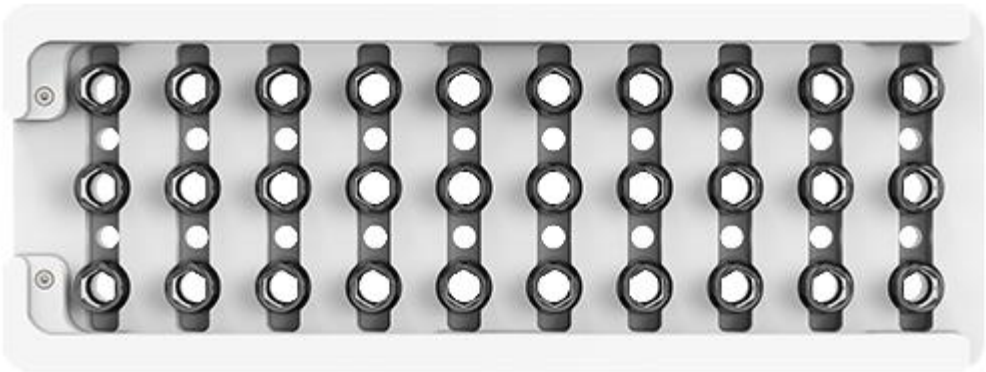
1.1.6. p.d. atitikimas:"Tinkama naudoti su visų diametrų pedikuliniais sraigtais"

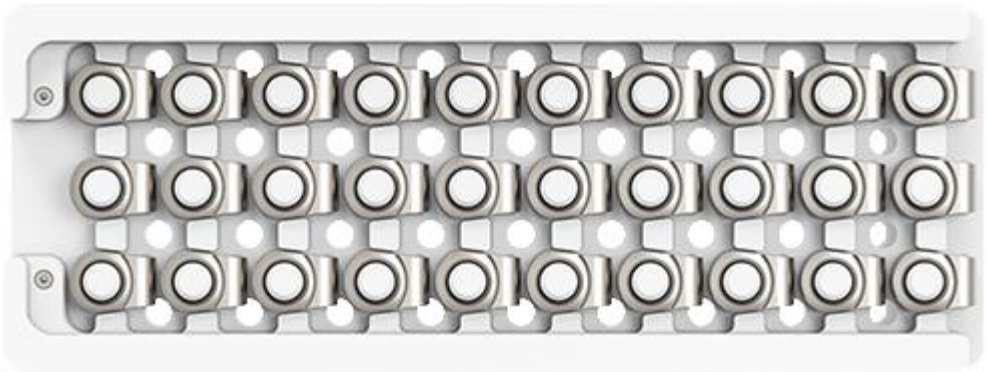
Implants: transverse systems

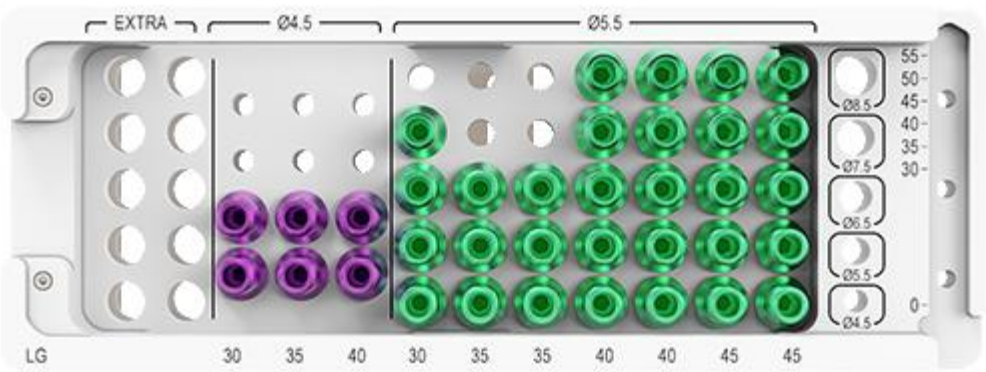
- Adjustable width.
- 3 pivot points for perfect fit.
- Lengths:
  - 29-31 mm
  - 31-35 mm
  - 35-43 mm
  - 43-59 mm
  - 59-91 mm

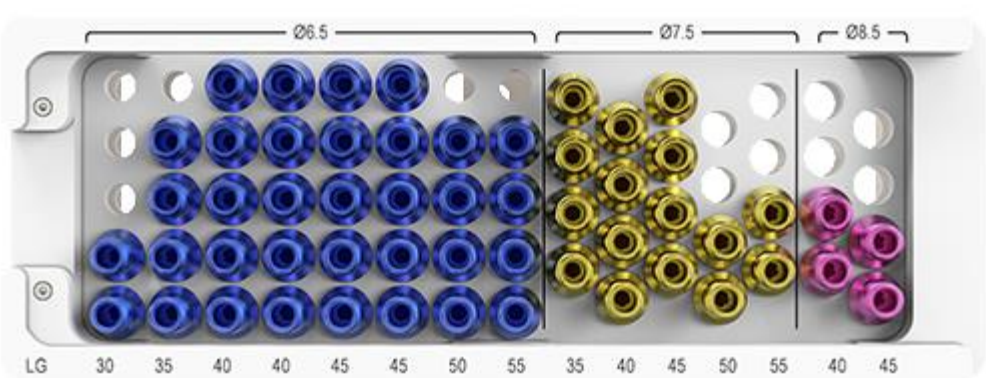
KHEIRON








EXTRA
Ø4.5
Ø5.5
Ø8.5
Ø7.5
Ø6.5
Ø5.5
Ø4.5
55
50
45
40
35
30
0
LG
30 35 40 30 35 35 40 40 45 45


Ø6.5
Ø7.5
Ø8.5
LG
30 35 40 40 45 45 50 55 35 40 45 50 55 40 45

Implants: rods

- Titanium.

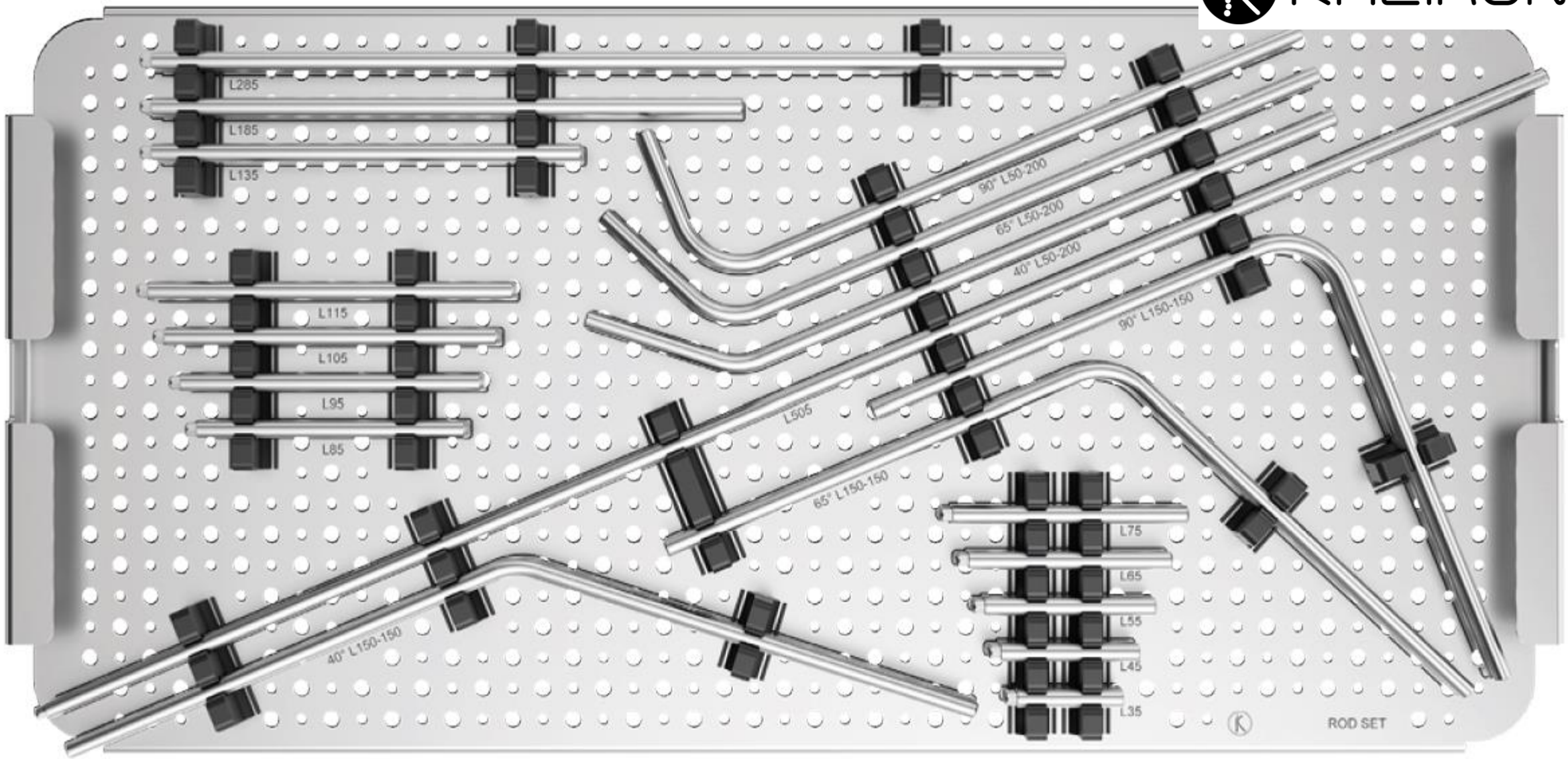
- **Straight**
  - 35mm to 115mm by increments of 10mm.
  - 135mm, 185mm, 285mm, 505mm.

1.1.1. p.d. atitikimas: "Gilimybė rinktis trumpesnius strypus (<500 mm)"

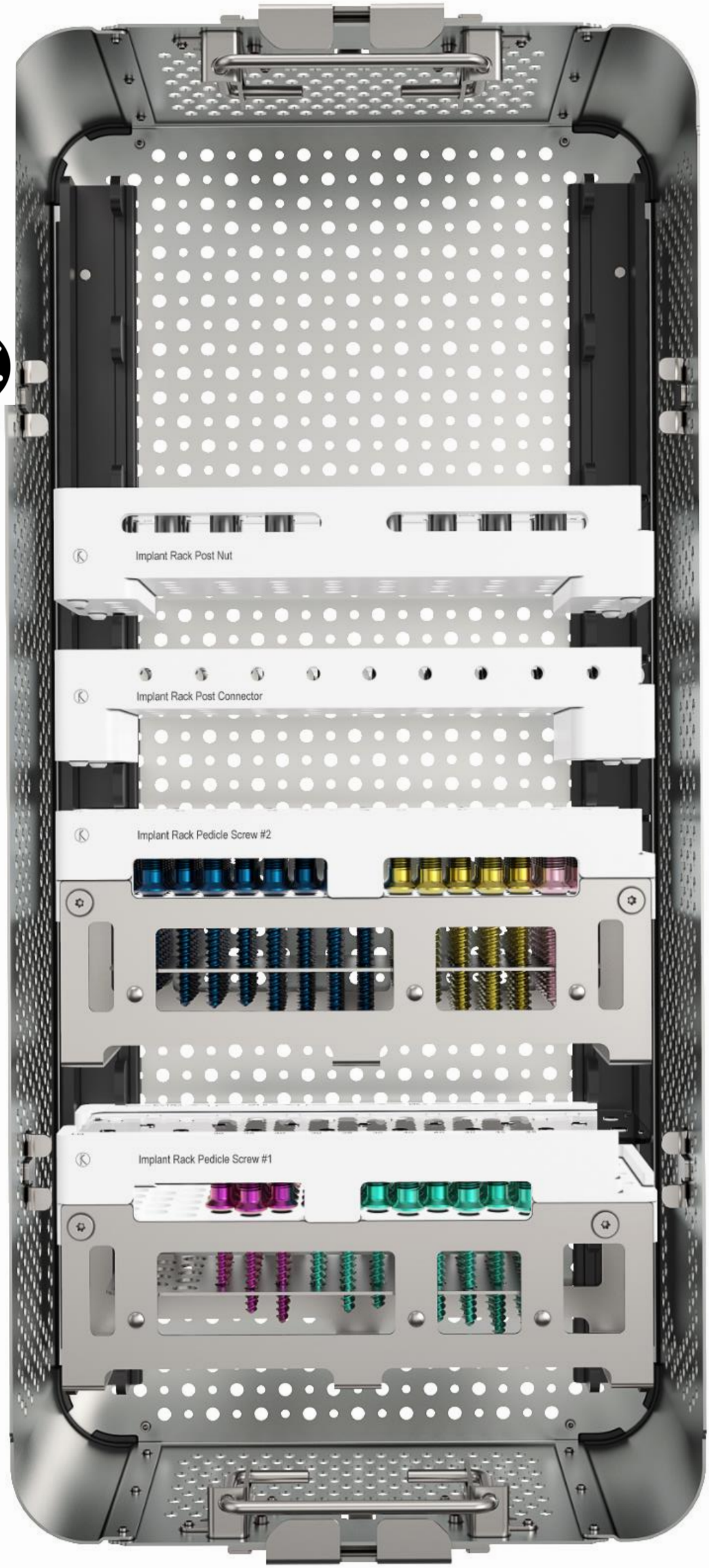
- **Pre-curved** in different angulations.
  - 40° L50-200mm
  - 40° L150-150mm
  - 65° L50-200mm
  - 65° L150-150mm
  - 90° L50-200mm
  - 90° L 150-150mm

- Ø 5.5mm and 6 mm.

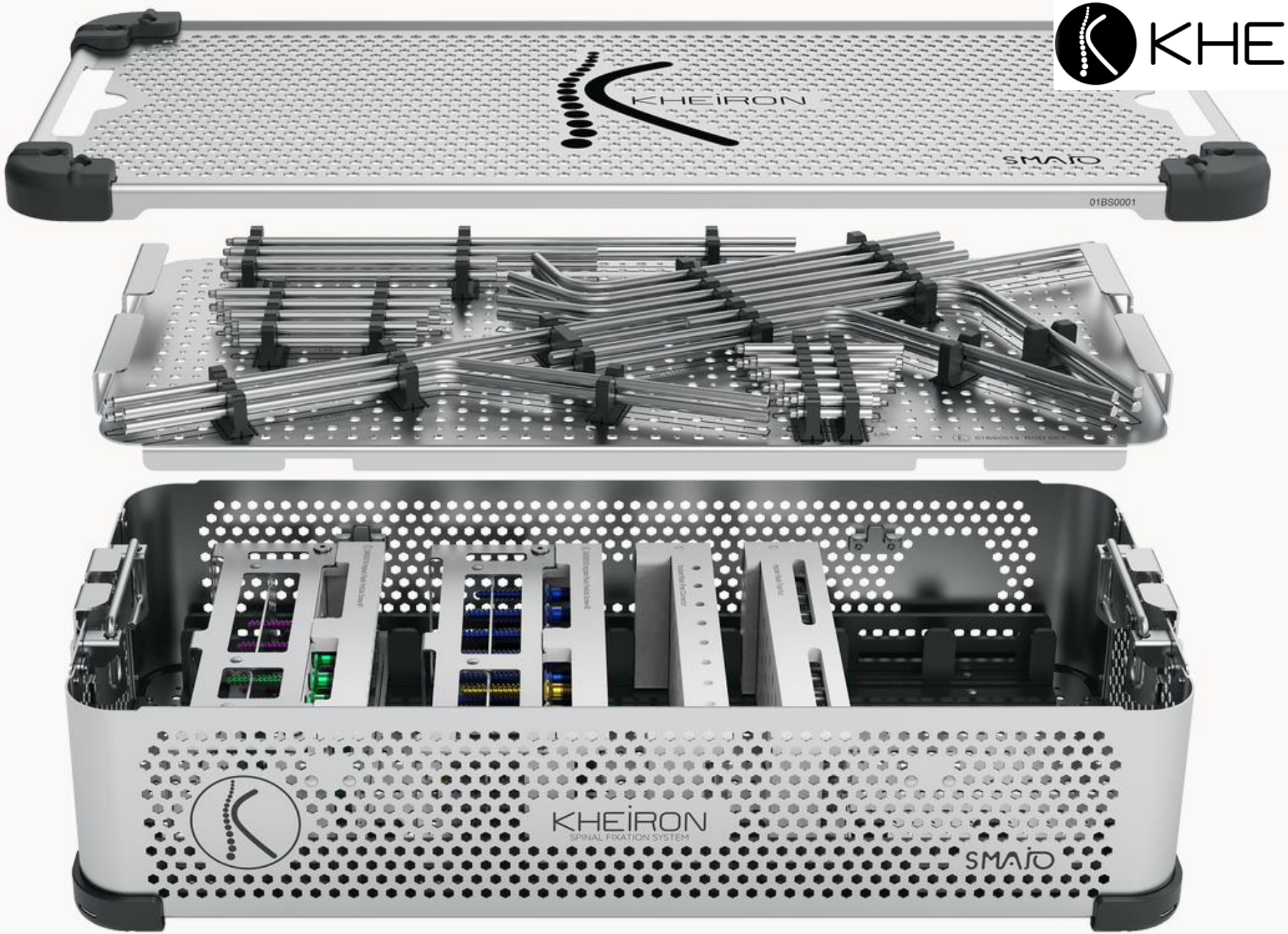
KHEİRON


L285
L185
L135
L115
L105
L95
L85
90° L50-200
65° L50-200
40° L50-200
90° L150-150
L505
65° L150-150
40° L150-150
L75
L65
L55
L45
L35
ROD SET

KHEIRON


Implant Rack Post Nut
Implant Rack Post Connector
Implant Rack Pedicle Screw #2
Implant Rack Pedicle Screw #1

KHEİRON

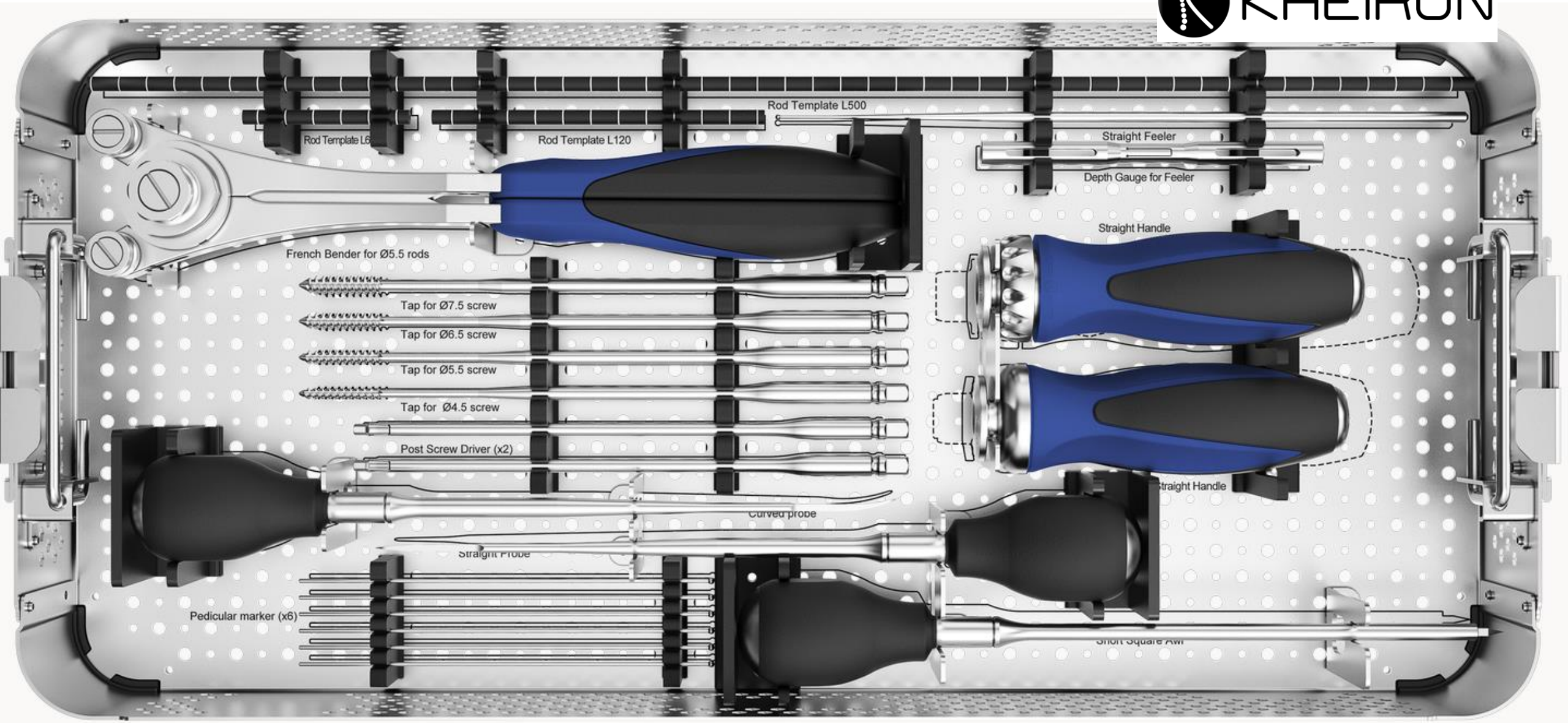

KHEİRON
SMAİO
01BS0001
KHEİRON
SPINAL FIXATION SYSTEM
SMAİO

KHEIRON

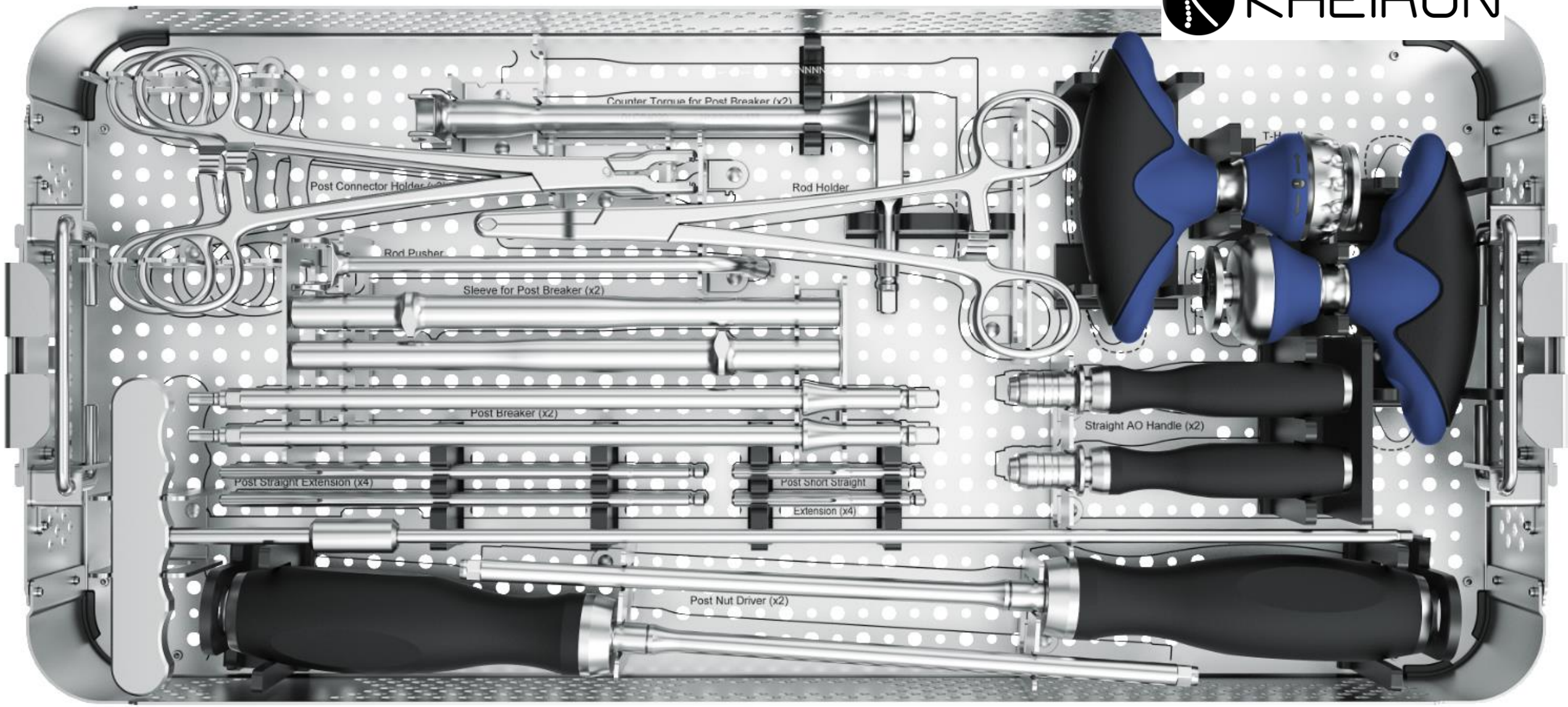
KHEİRON


Tap for Ø7,5 screw
Post Screw Driver (x2)
KHEİRON
SPINAL FIXATION SYSTEM
SMAIO

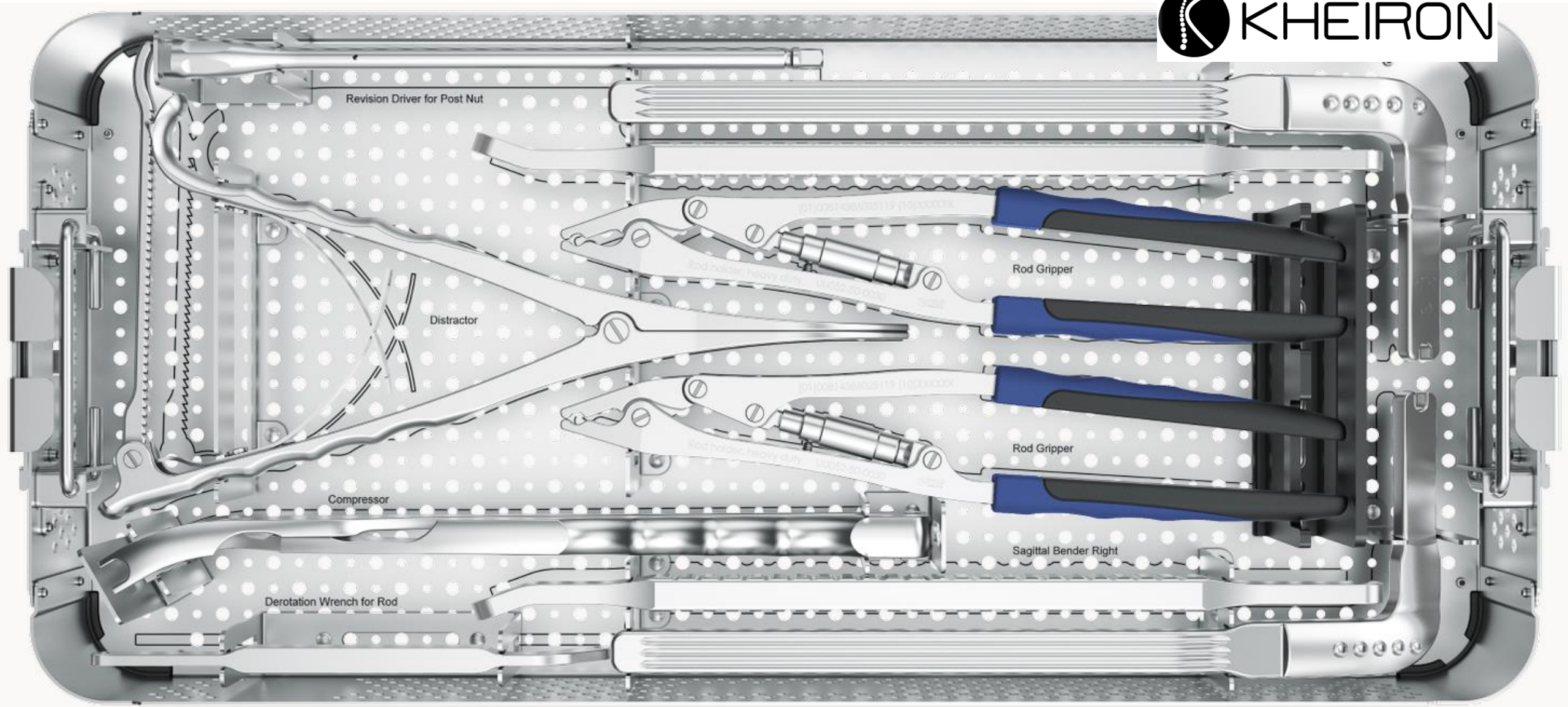
KHEIRON


Rod Template L500
Rod Template L120
Straight Feeler
Depth Gauge for Feeler
Straight Handle
French Bender for Ø5.5 rods
Tap for Ø7.5 screw
Tap for Ø6.5 screw
Tap for Ø5.5 screw
Tap for Ø4.5 screw
Post Screw Driver (x2)
Curved probe
Straight Probe
Pedicular marker (x6)

KHEİRON


Counter Torque for Post Breaker (x2)
Post Connector Holder
Rod Holder
Rod Pusher
Sleeve for Post Breaker (x2)
Post Breaker (x2)
Straight AO Handle (x2)
Post Straight Extension (x4)
Post Short Straight
Extension (x4)
Post Nut Driver (x2)

KHEİRON


Revision Driver for Post Nut
Distractor
Rod Gripper
Rod Gripper
Compressor
Sagittal Bender Right
Derotation Wrench for Rod

Other implants

Wide range of implants for the spine and pelvis.

Hooks

Iliac extensions

Dominos

Sacral plates

Implants: sacral plates

1.2.5. p.d. atitikimas:"Dvigubo sriegio"

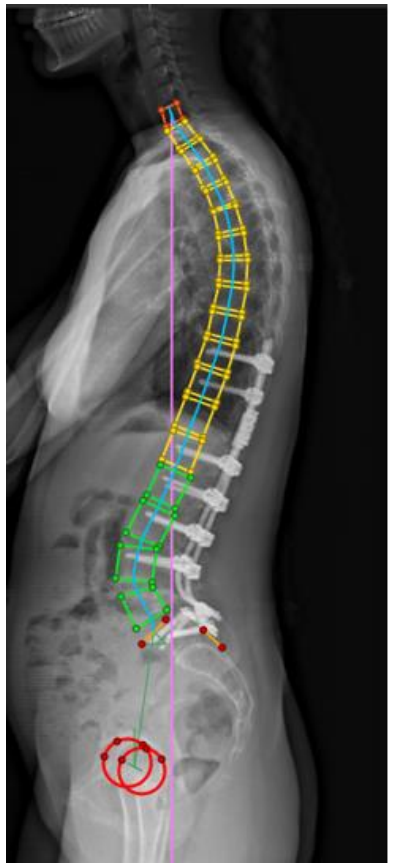
- Plates with angulations 60 or 90 ° °
- Double lead thread screws of 6.5 and 7.5 mm diameters, lengths from 30 to 70 mm
- 5.5mm and 6mm rod connectors.
- Anti-migration security plug.

Implants: sacral plates

Sacral plate to achieve acute distal lordosis L4-L5-S1

Lumbar lordosis L4-L5-S1 is not a constant angle, it is a bent with two radius, one acute usually L4-S1 and other more flattened.

Once understood this particularity, sacral plate helps the surgeon to achieve this acute angulation due to its further placement.



60°

90°

KHEIRON


LG
30
35
40
45
50
55
60
65
70
EXTRA SCREWS
Ø6.5
Ø7.5
70 65 60 55 50 45 40 35 30


SACRAL PLATES
SACRAL NUTS
ALAR NUTS

Implants: dominos

1 – Connector closed/closed (7.5 – 9 – 11 – 13 – 15 – 17mm).
2 – Open/open connector (7.5 – 9 – 11 – 13 – 15 – 17mm).
3 – Connector open/closed (7.5 – 9 – 11 – 13 – 15 – 17mm).
4 – Axial connector (one size).
5 – Parallel tulip connector (11 – 13 – 15 – 17mm).

Compatible rods 5.5mm / 6mm.

1

2

3

4

5

KHEIRON

Implants: hooks

Transversa/laminar hooks

Height [2]	Length (internal part) [2]	Width of the blade[4]	Angulation [2] (rear angle)
5mm	8mm	4.3mm	45°
7.5mm	8.5mm	4.3mm	45°
10mm	9mm	4.3mm	45°

Pedicular Hooks

Height	Length (internal part)	Largeur [4]
4mm	13mm	8mm
6mm	13mm	8mm
4mm	10mm	8mm
6mm	10mm	8mm

Implants: iliac extensions

Range of screws: Ø 6.5mm to 10.5mm.

Screw lengths de 55mm to 110mm.

Length of extensions: 15 / 20 / 25 / 30 / 35 mm.

Iliac screw heads offer 15 ° of freedom.

Compatible with Ø 5.5mm and 6mm rods.

To remember

KHEIRON® posterior fixation system

- Complete system dedicated to correct spinal deformities.
- Thought and designed to achieve the planned result in pre-operative.
- Orthogonal relationship between screw and rod.
- Gradual reduction system. No persuader needed.
- In case of revision: a screw can be revised on its own without the need to disassemble the entire system.

1 p. d. atitikimas: "Instrumentai telpa į 5 dėžes. Implantai telpa į 3 dėžes."

- 3 boxes of instruments and 1 box of implants.
- Light instruments and boxes.

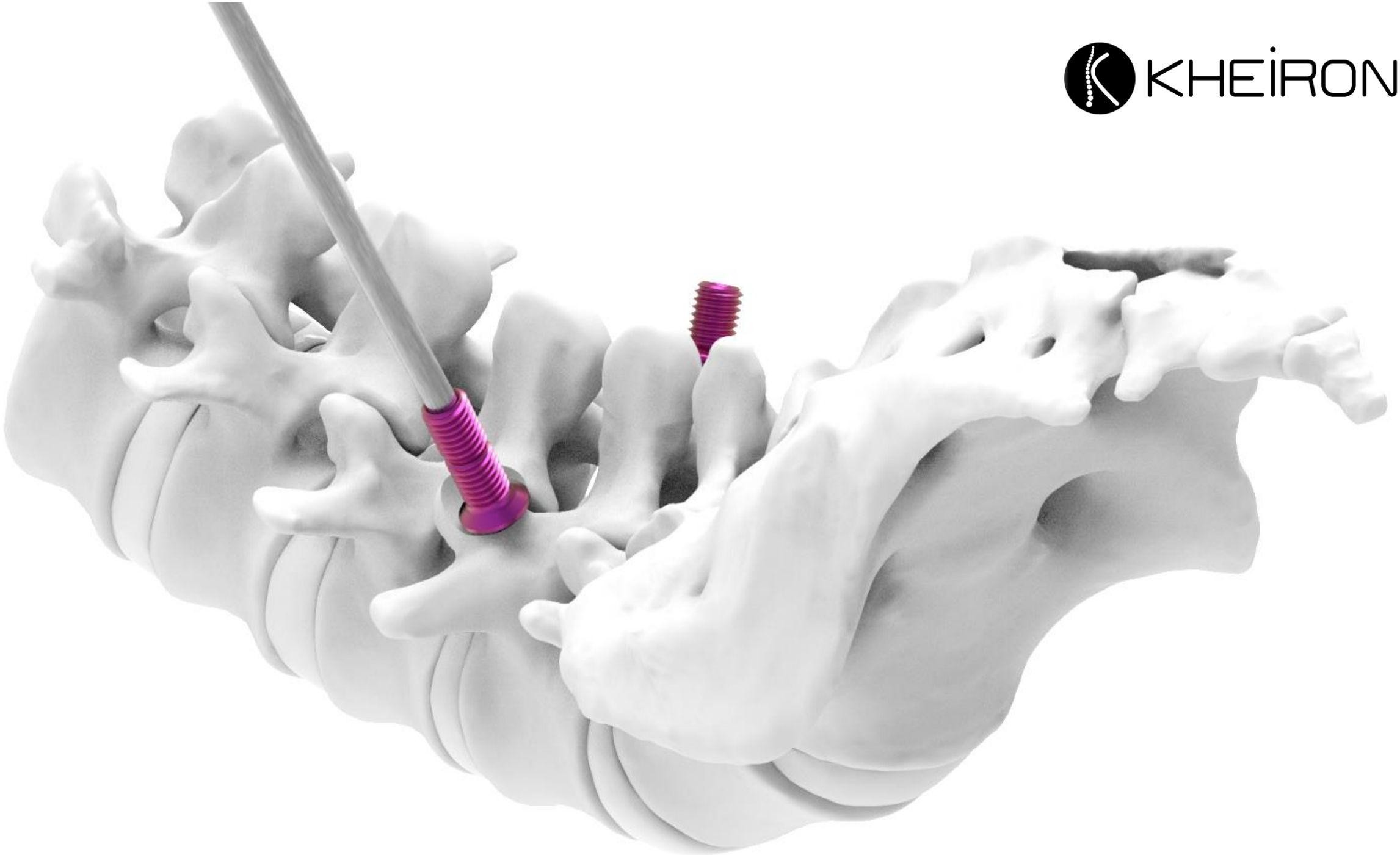
KHEIRON: differential characteristics

Screws with canulated post

- Allows derotation maneuvers to be carried out.
- Increased control and feeling during maneuvers. “Joystick movements” .
- Lighter instruments.
- Better visualization of the surgical field.

KHEIRON: differential characteristics

- Adjusting the height of the screw possible even after the system is ensambled.
- Improves anatomy adaptation.
- The footprint remains intact for a possible revision.


KHEIRON

KHEIRON: differential characteristics

Placing the connector

- **Fig 1**: grab the connector with the connector holder.
- **Fig 2:** slide the connector along the extension, and by applying light pressure, clip onto the stem.
- **Fig 3:** play with angulation of the connector to fit it perfectly on the rod.
- Once clipped, disengage the connector holder.

Fig.1

Fig.2

Fig.3

KHEIRON: differential characteristics

Placing the connector

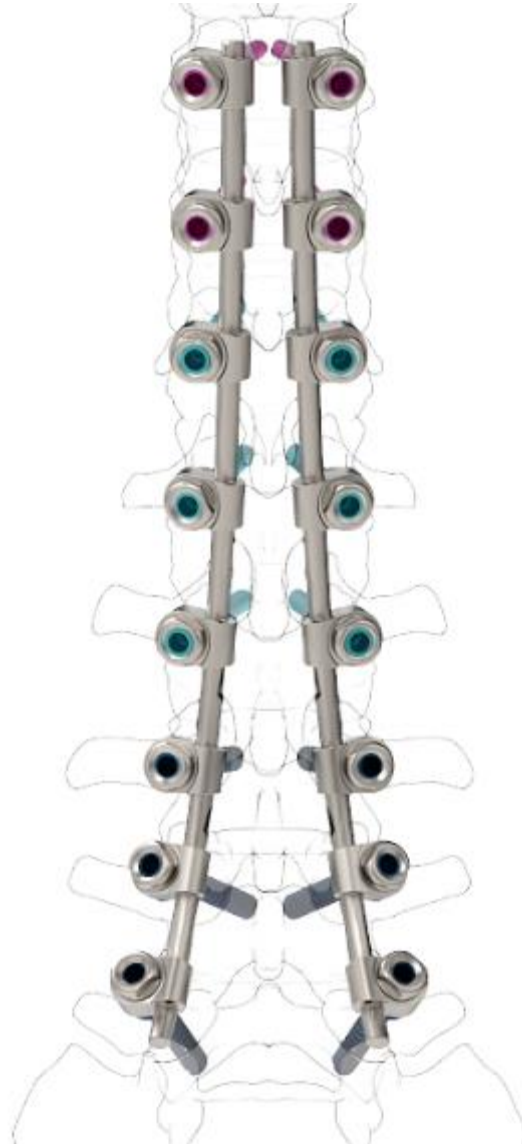
- Implementation is made easier by long or short extensions.
- Extensions can also be used to transmit movement to the vertebra, e.g. derotation, compression, distraction…

KHEIRON: differential characteristics

Breaking the threaded extension and nut

- No need for a dynamometric instrument.
- The breakage occurs at 12Nm.
- The breakage does not damage the implant and leaves an intact footprint for revision.

KHEİRON



KHEIRON: differential characteristics

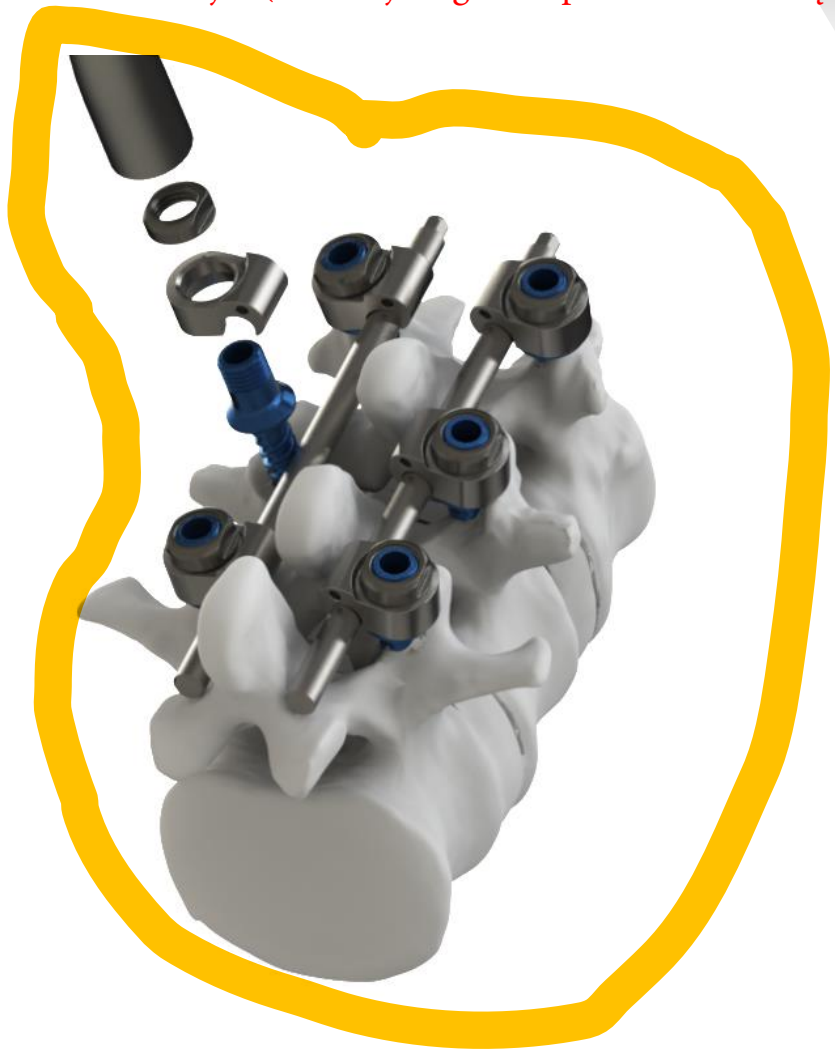
1.1.4. p.d. atitikimas: Sraigto revizijai nereikia numontuoti visos konstrukcijos (revizuojant galima pašalinti tik vieną sraigtą).

Revision

With the Kheiron system, it is possible to remove a single screw without having to disassemble the entire construction.

The nut and connectors are removed. Using the screwdriver, the screw is holded through the canal and unscrewed.

A new screw can be inserted, the connector repositioned on the rod and locked with a nut.

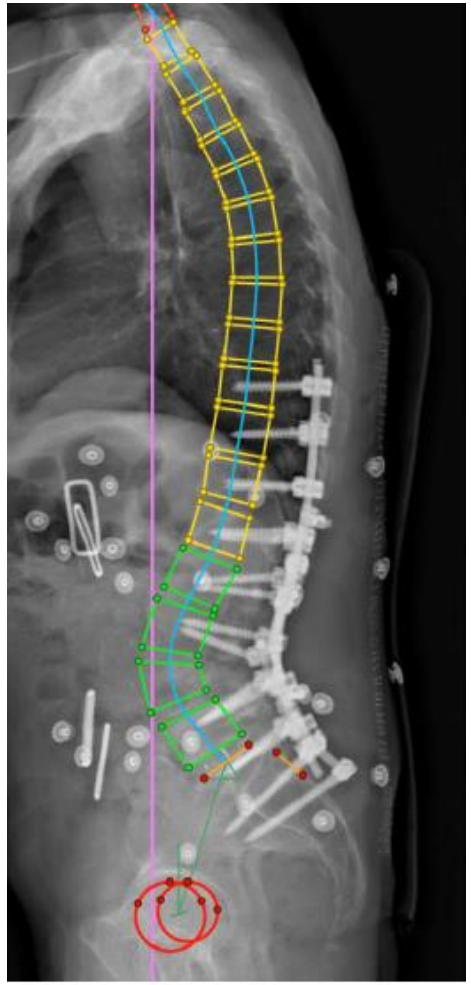


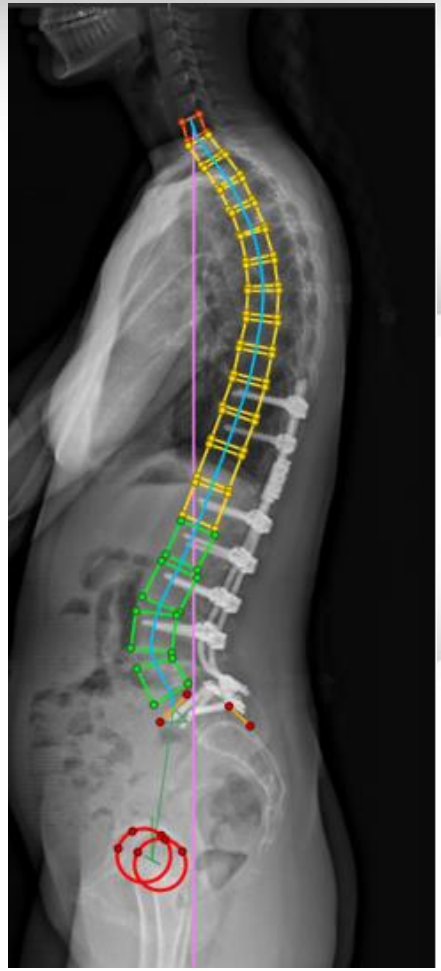
KHEIRON: differential characteristics

Maximum adaptation to anatomy and planning

- When the lumbar lordosis is very acute, the polyaxiality of the tulip does not always allow an adjusted correction to the anatomy.
- The orthogonal relationship between the screw and the rod allows this setting to be more accurate.
- Sacral plate helps to increase distal lordosis (L4-S1).

Polyaxial Tulip screw

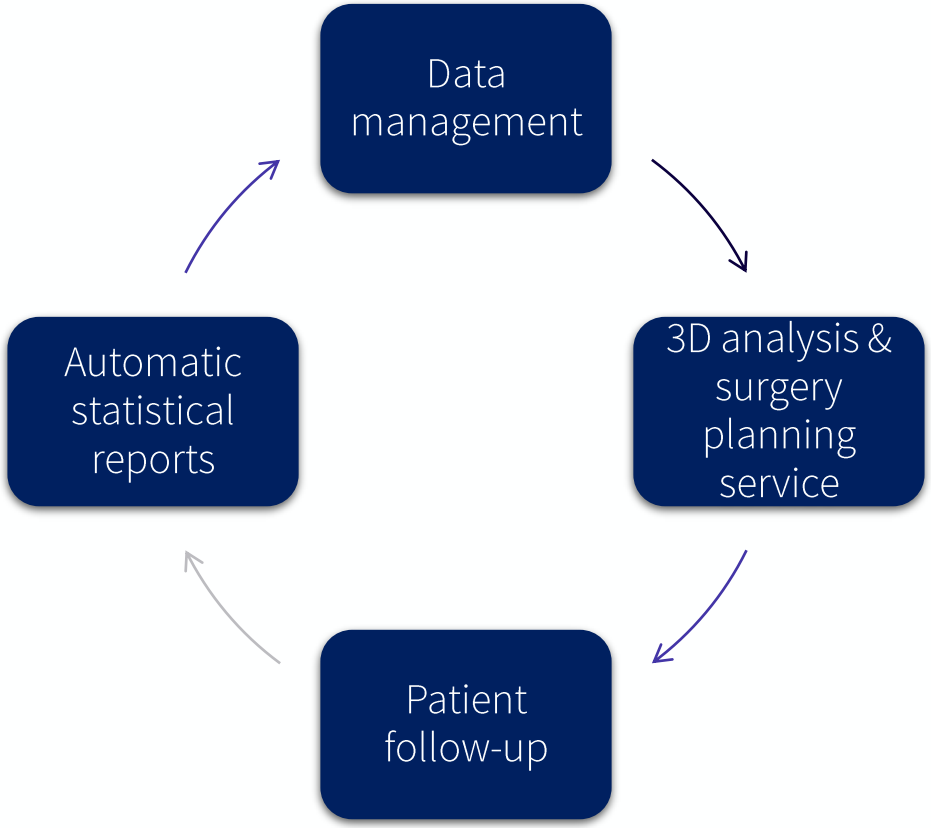




03 KEOPS

What KEOPS is?

KEOPS is a customizable patient online database to record clinical data, images, QoL questionnaires, complications… and to track and evaluate the surgical results.



What KEOPS is?

Data management:

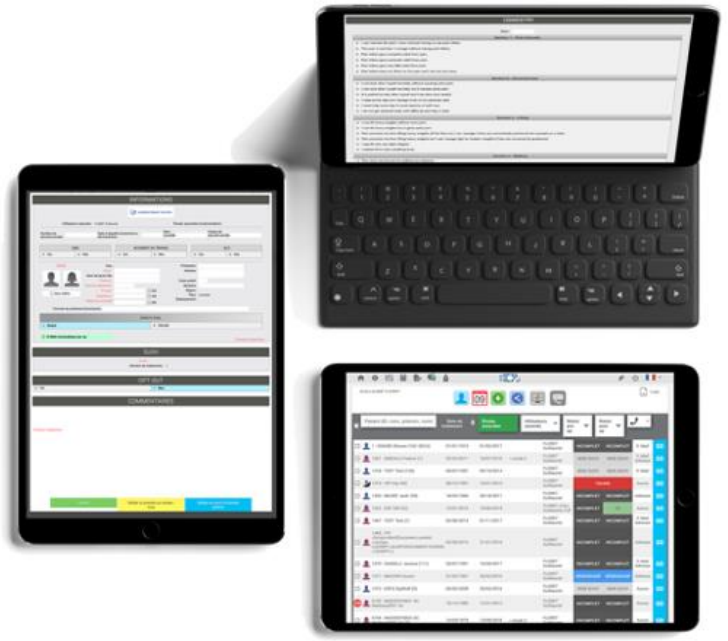
The use of the patient registry allows to preserve the patient's history since the first consultation/operation and thus to measure quantitatively and qualitatively the evolution of the pathology. Provides the possibility of a remote patient relation customizable.

Surgery Planning Service :

KEOPS Balance Analyzer 3D allows the measurement and advanced analysis of spino-pelvic parameters.

Our **KREW team** is proposing surgical strategies based on surgeon's specifications, literature, proprietary algorithms…

Surgeon decides which strategy to follow.

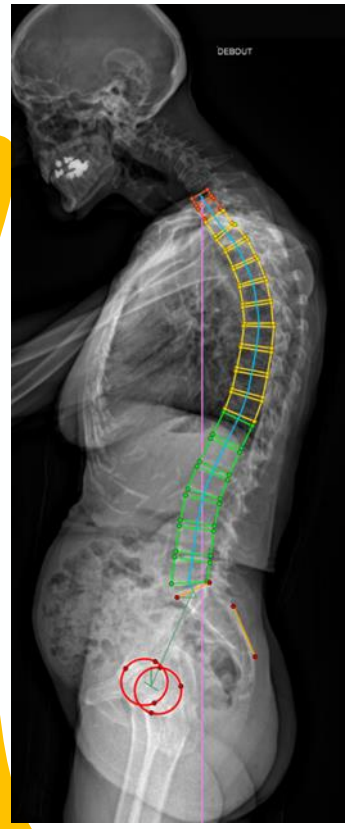


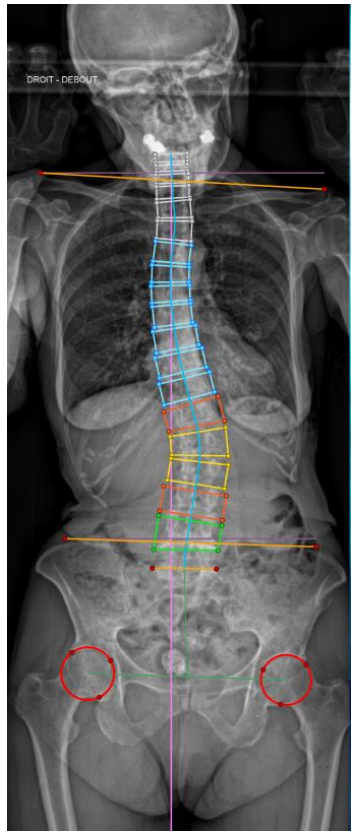
KEOPS: Planning the surgery

1 p. d. atitikimas: "Chirurginio planavimo programa sudaro stuburo 3D vaizdą pagal rentgenogramas"

3D X-rays Analysis

- Global image acquisition performed in less than 2 minutes and automatically export measures into the database.
- Hundreds of measurements provided along with key spino-pelvic parameters to analyze , with automatic comparison to normal population.
- Global image acquisition generating local vertebra/disk settings.





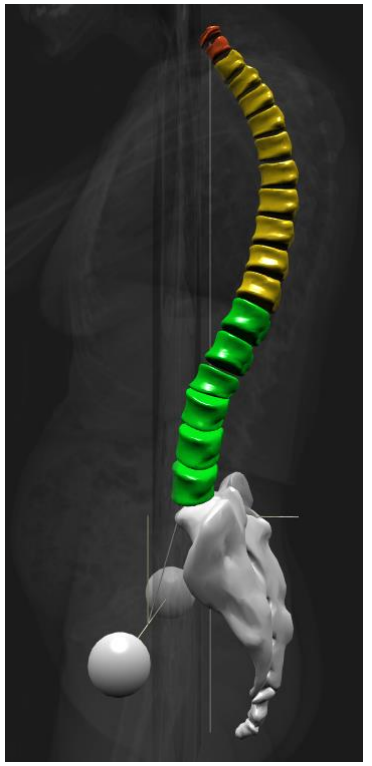
KEOPS: Planning the surgery

1 p. d. atitikimas: "Chirurginio planavimo programa sudaro stuburo 3D vaizdą pagal rentgenogramas"

3D X-rays Analysis

- 3D model to better understand the anatomy and plan your correction.
- The ability to insert new settings based on search needs.

Request our **Krew team** support to perform the measurements and coming to the surgeon with surgery simulation proposal: krew@smaio.com



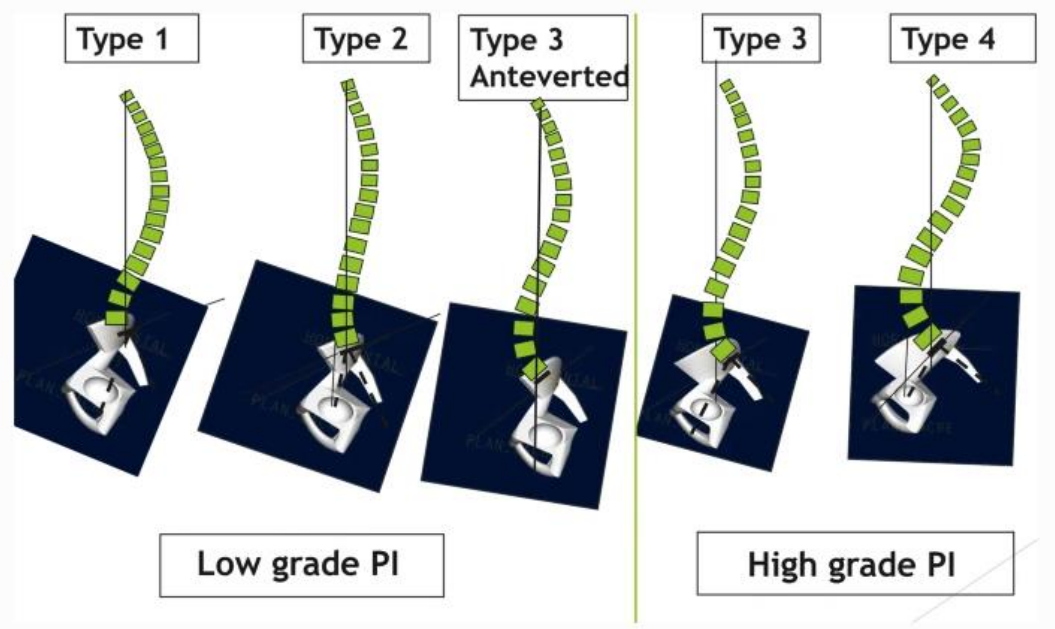
KEOPS: Planning the surgery

Surgery planning service

How our Krew Team do it?

1. Measuring for the surgeon the spino/pelvic parameters
2. Simulating a correction following the Dr.'s strategy and specifications
3. Sending him the detailed plan and strategy for approval

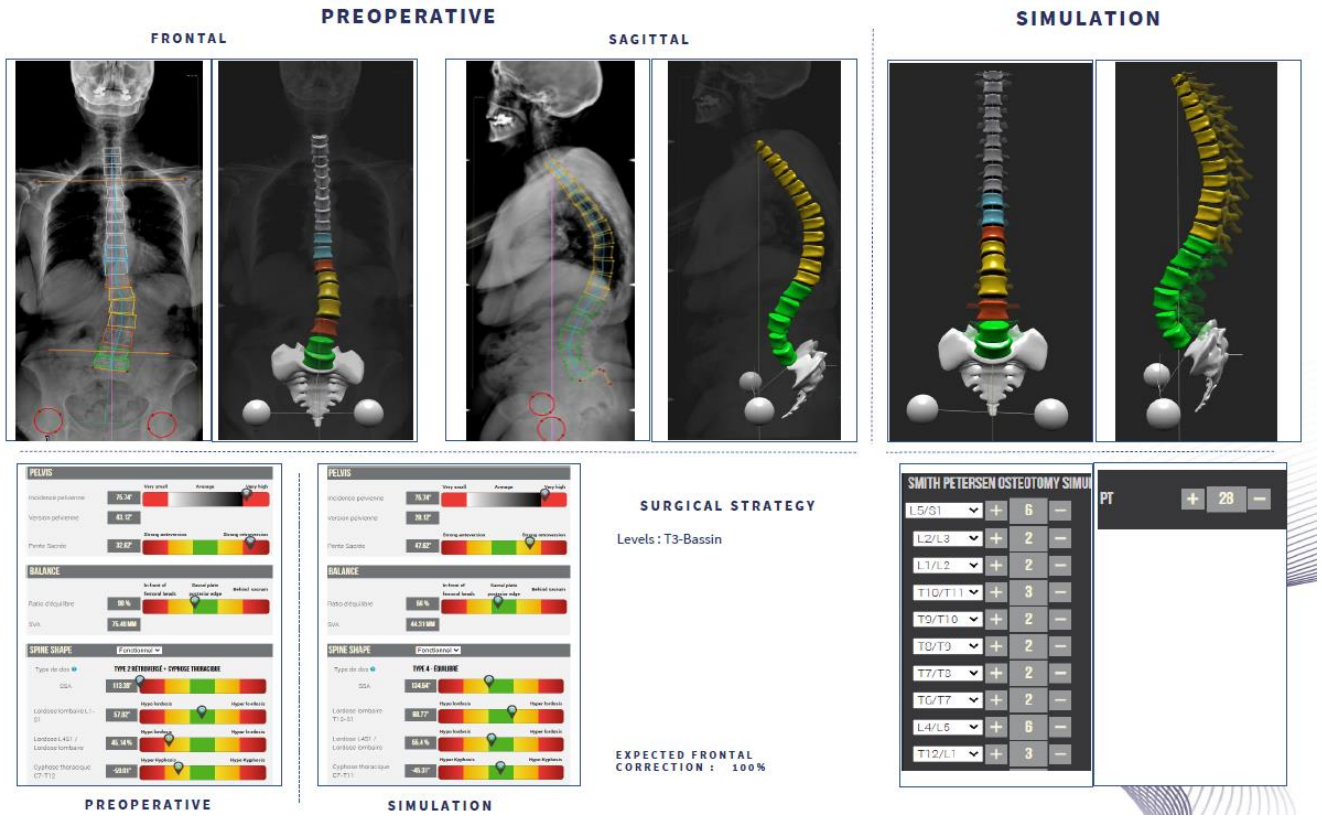
Optional: as an alternative or an add-on, the team can propose a strategy based on Roussouly types of back to optimize the result.

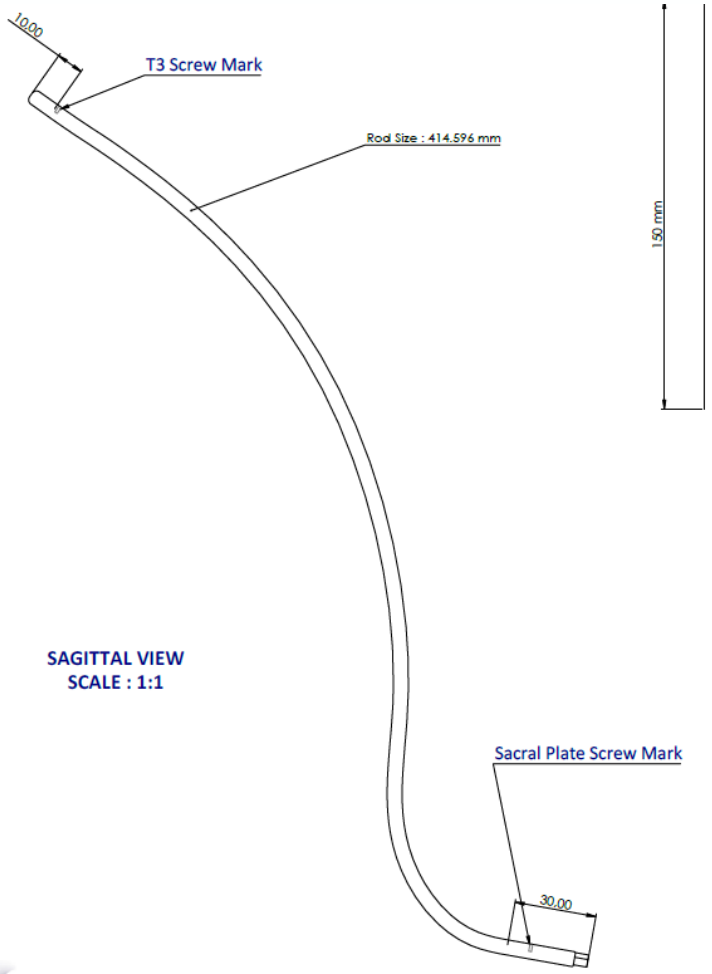


Whatever strategy or alternative proposal, the doctor remains the only one to validate the simulation.

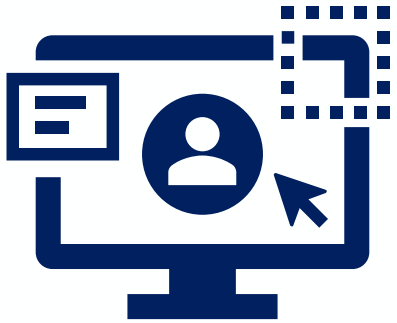
KEOPS: Planning the surgery

Surgery planning service





KEOPS: Patient follow-up

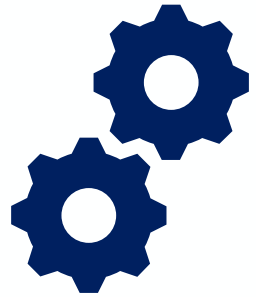


Patient interface to enable online questionnaires to be filled out.

Automatic email follow-up with invitation link to patient interface.

Large selection of patient quality of life questionnaires available.

Online monitoring.

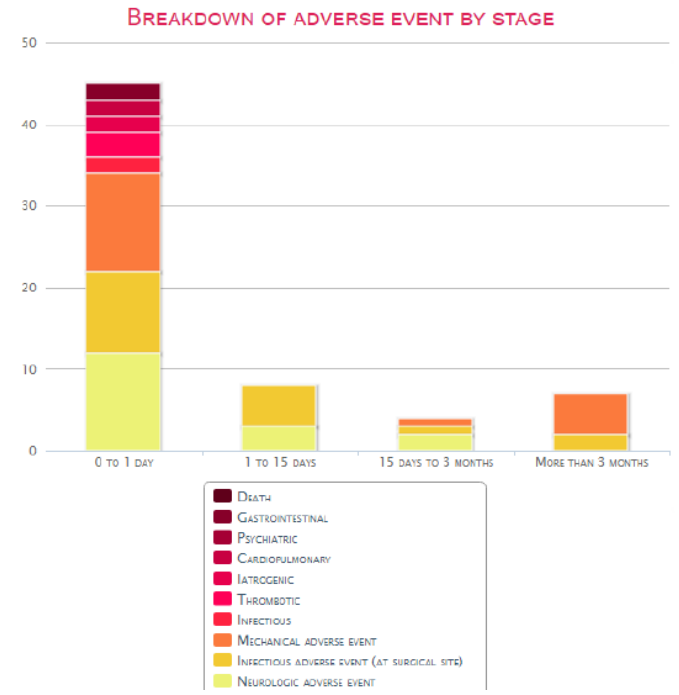


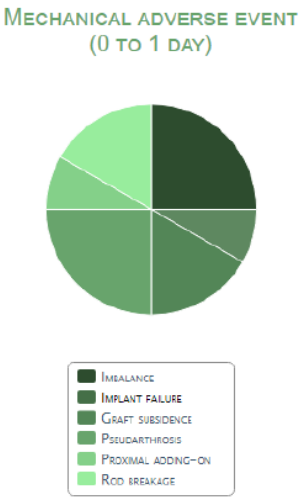
100% Customizable per protocol, per study.

KEOPS: Automatic statistical reports

1	The ability to sort, filter, extract patient populations by selecting multi-criterion queries.
2	Export the entire database to Excel in two clicks.
3	View statistics that include score, complication rate, surgeries performed.
4	Obtaining advanced custom extraction models and specific statistical dashboards.

Complication report for a given study with focus on mechanical complications from 0 to 1 day





KEOPS: Why using it?

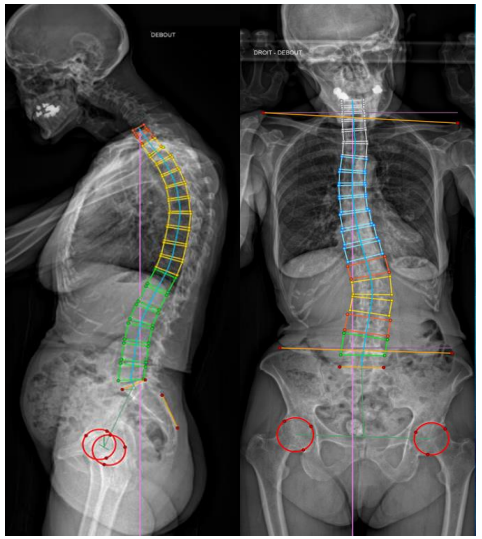
6 reasons why

#1

Standardizing the day-to-day practice of data collection.

#2

Deep patient spino-pelvic diagnosis and surgery follow-up.



#3

An all-in-one platform for data management, 3D analysis, planning and statistics monitoring.

KEOPS: Why using it?

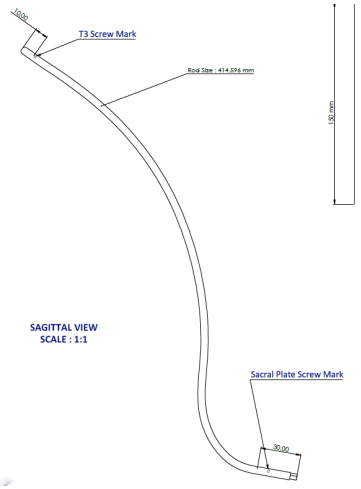
6 reasons why

#4

A dedicated expert team supporting your case: the **Krew team.**

#5

The materialization of your plan with a rod template and patient-specific rod (available early 2021).



#6

A database accessible from anywhere.

To conclude, next steps

Keep **moving forward** in our relationship

Know your documentary **requirements**

Introduce the material in detail (**workshop**)

When do we start?