SALES PITCH

10 features that make the difference

KHEIRON-PRS-003-CE-EN-09-2020-V01

Introduction

- SMAIO is a French Company based in Lyon which started supplying surgeons software to plan and to follow up their patients since 2009, with KEOPS solution.
  The company shifted to manufacture and distribute medical devices as of May 2019 in Europe with the EC marking and October 2020 in the USA with the 510K FDA marking.

- Software KEOPS Balance analyzer 3D measures needed spinopelvic parameters supporting the surgeon to plan his surgical strategy, focusing particularly on sagittal balance restoration.

- Despite a precise measurement and case planning, the accuracy of the correction is often deviated from the initial plan, since the gold standard fixation system remains the “polyaxial tulip” and polyaxility increases the loss of correction over the construct.

- SMAIO ambition is to go further in the accuracy and planning match. In that purpose, based on in his large experience and following the KOL’s experience, SMAIO designed a monoaxial fixation system to mimic the shape of the spine with the shape of the rod.

- Our solution range consists in:

Posterior monoaxial fixation system + 3D planning & data management
+ personalized Implants (early 2021)

SMAIO

KHEIRON

1. The screw
2. Working through the canal
3. Light instrumentation
4. Low profile
5. Breakable implants
6. Full range of implants
7. Revision

KEOPS

1. Data management
2. Surgery planning service & 3D analyzer
3. Patient specific rods

SMAIO

Objective:

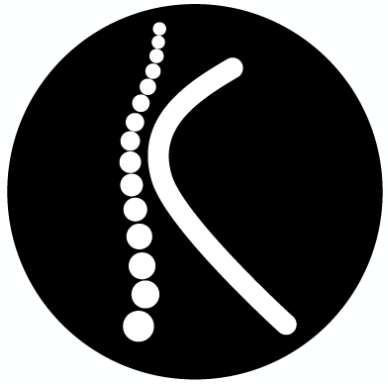
Translate as much accurate as possible the plan to the surgery.
Re-establish anatomical balances in all the plans (especially sagittal).
Move forward to a more standard surgeries VS artisanal ones.

We don’t just supply implants, but a full offer:

Planning software 3D analyser KEOPS
Data management.
Implants KHEIRON
Tailor made implants.

Generate knowledge, tools and scenarios to share it and evolve it.

“The school of Athens” was painted by Raphael 1510-12

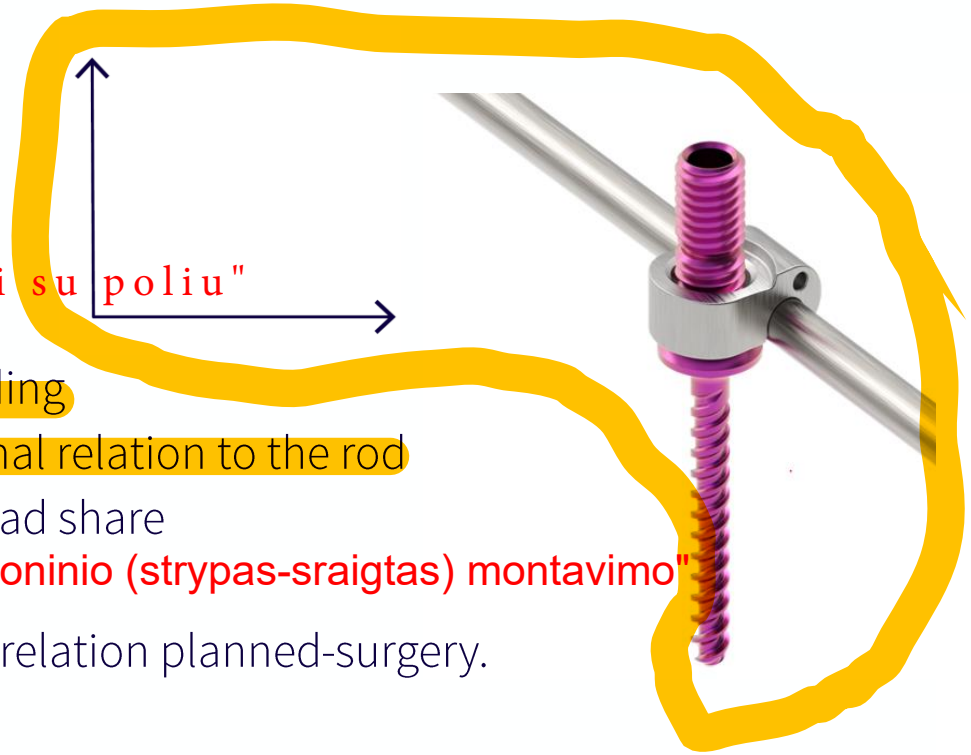


KHEIRON

SPINAL FIXATION SYSTEM

KHEIRON SYSTEM

1.1.4. p.d. atitikimas:"Monoaksialiniai su poliu"



- Monoaxial posted screw: - Side loading
  - Orthogonal relation to the rod
  - Gentle load share

1 p.d. atitikimas: "Stuburo fiksavimo sistema yra šoninio (strypas-sraigtas) montavimo"

- Most accurate corrections. Optimal relation planned-surgery.
- Designed by spine surgery experts.
- Deformity historical success.

KHEIRON

1.The screw

1.The screw

1.1.5. p.d. atitikimas: "Neužveržtas konektorius sraigtui suteikia ±15° poliaksiškumą"

No need of different kind of implants like: polyaxial, monoaxial, uniplanar or reduction.

1.1.4. p.d. atitikimas:"Sraigto ± 15° poliaksiškumas išgaunamas per konektorių"

Polyaxiality is on the connector (+/- 15°).

KHEIRON screw can behave as a:

- Curve reduction screw
- Trauma screw
- Reduction screw for spondylolisthesis

Reduces the amount of implants over the table.

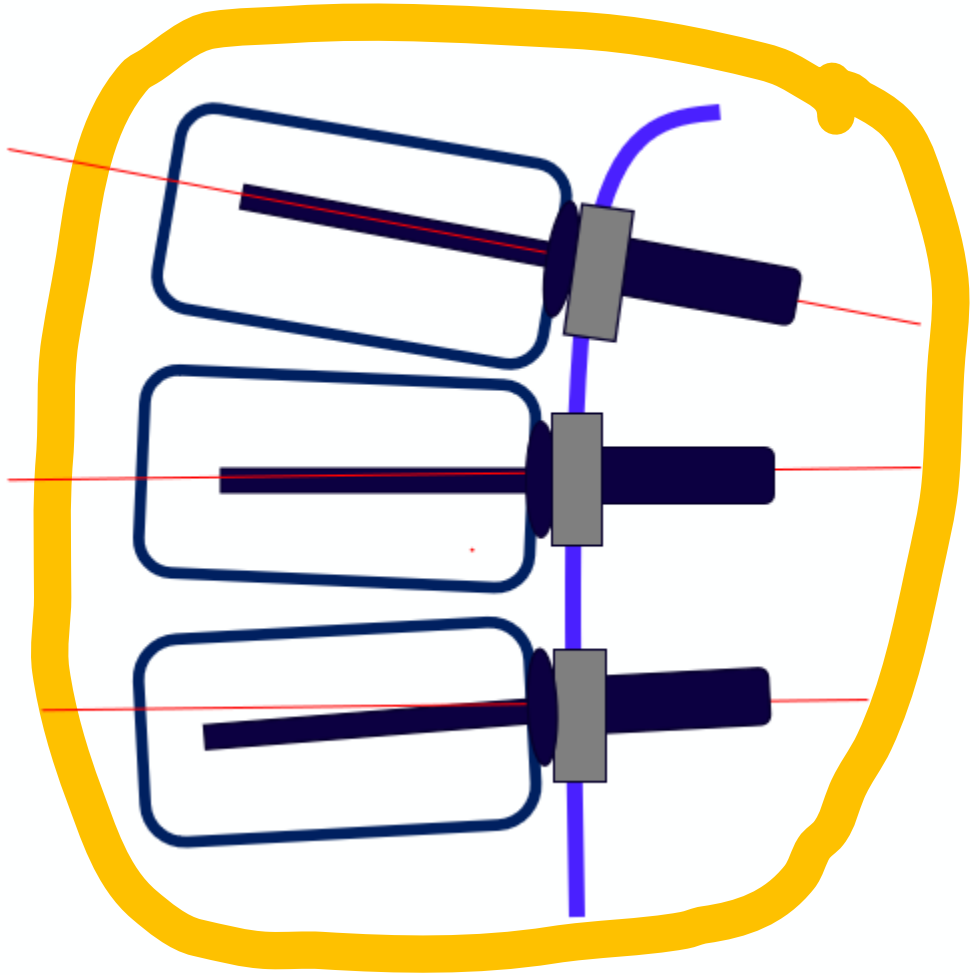
1.The screw

1 p.d. atitikimas: "Stuburo fiksavimo sistema yra šoninio (strypas-sraigtas) montavimo"

Orthogonal relation “rod-screw”.

The movement is translated straight linearly to the vertebra

In addition, its post eases the **rod implantation** sharing loads and without needing strong tools.



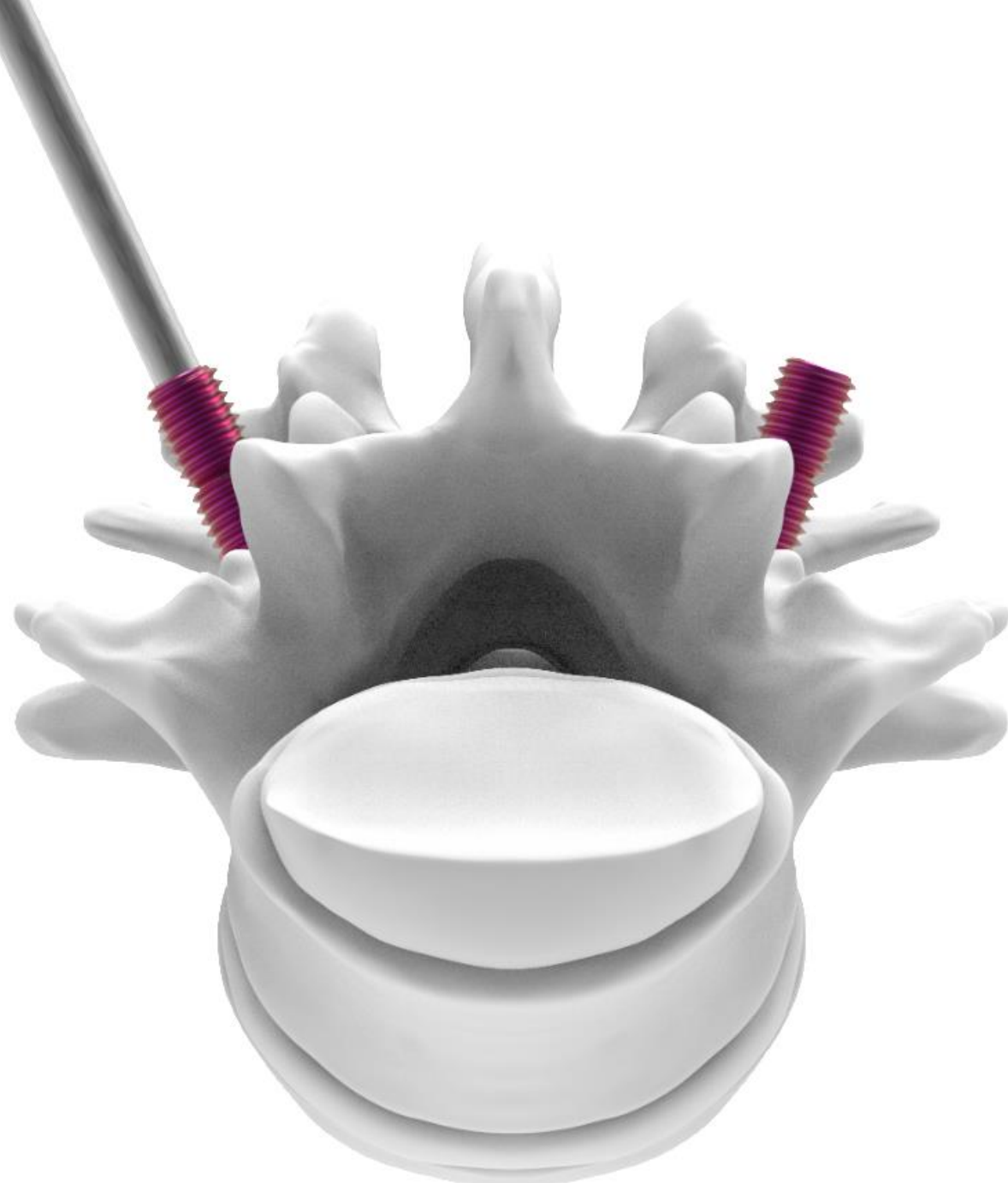
2.Working through the channel

2. Working through the channel

Screws with cannulated post.

Through the working canal the surgeons can:

- “Feel” the bone.
- Translate movement to the vertebra.
- Have a better surgery area view.

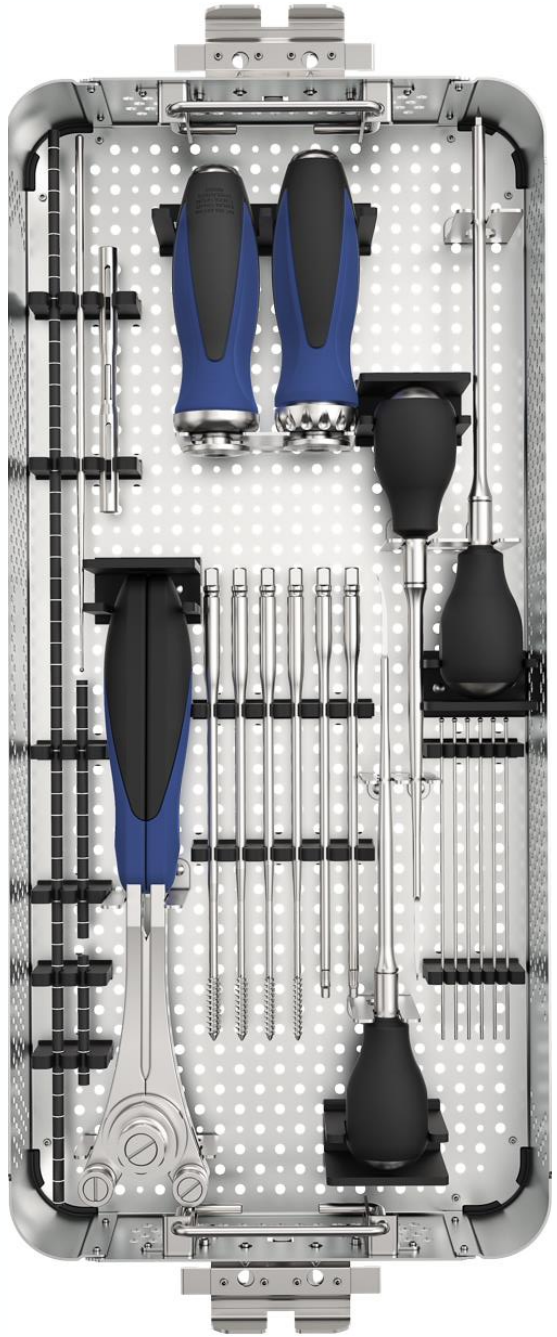


KHEIRON

3.Light instrumentation

3.Light instrumentation

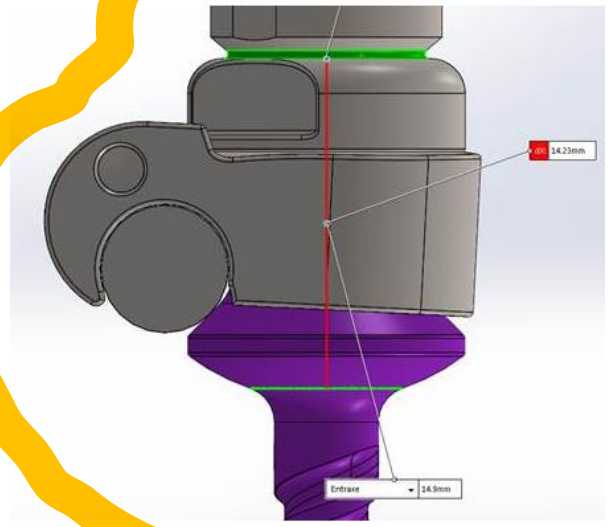
- All instruments are thin because they work through the post canal.
- Implants act as instruments – no persuaders.
- Minimalist instrument range.
- Easy to learn.
- 3 instruments boxes.



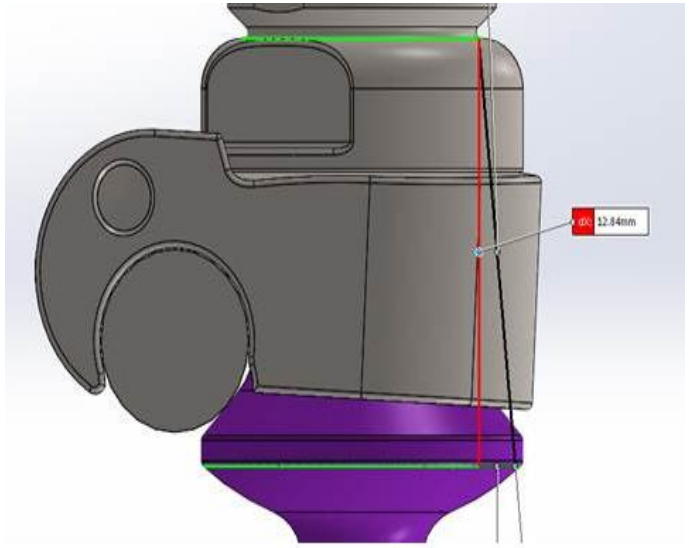
4.Low-profile

4.Low profile

14,21mm



12,44mm



As the load is lateralized, the rod is really close to the bone.

5.Full range of implants

5.Full range of implants

Wide range for fixating the thoracic part to the pelvic part.

Hooks

Dominos

Sacral plates

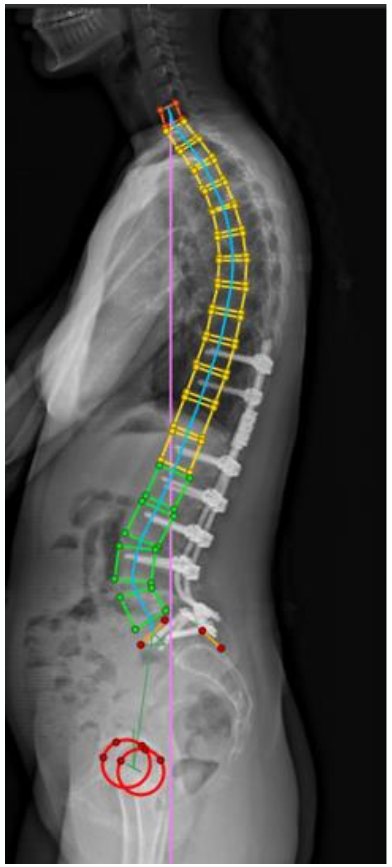
Iliac extensions

5.Full range of implants

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.



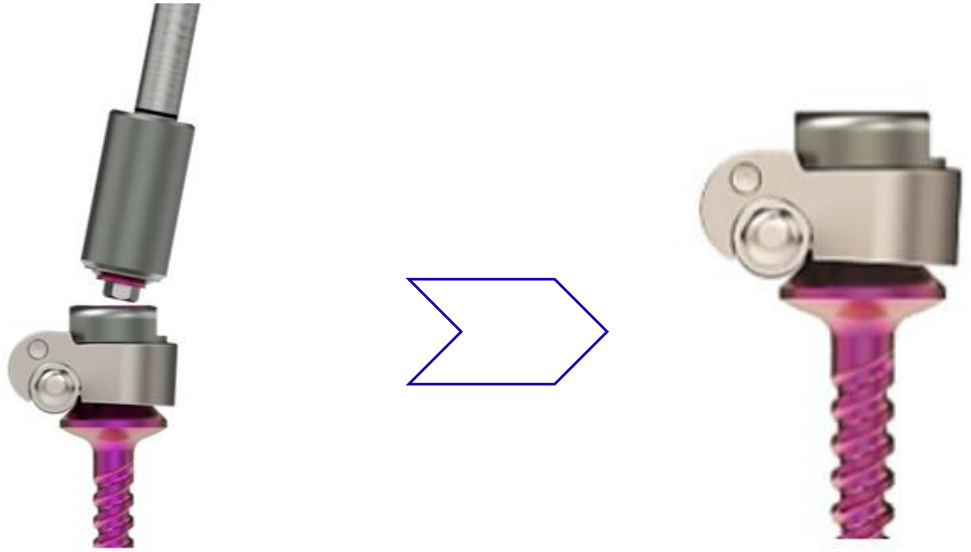
90°

60°

6. Breakable implants

6.Breakable implants

- **Post and nut breakage.**
- No dynamometric needed.
- Breakage occurs at 12Nm.
- The breakage does not damage the implant, leaving new marks to ensure its revision.



7.Revision

7.Revision

Removing one screw once the system is closed is a tough job regarding all the construct must be removed to have access to the misplaced one.

KHEIRON provides a simple maneuver to remove one screw without removing all the system, less than 5 minutes.


KEOPS

KEOPS

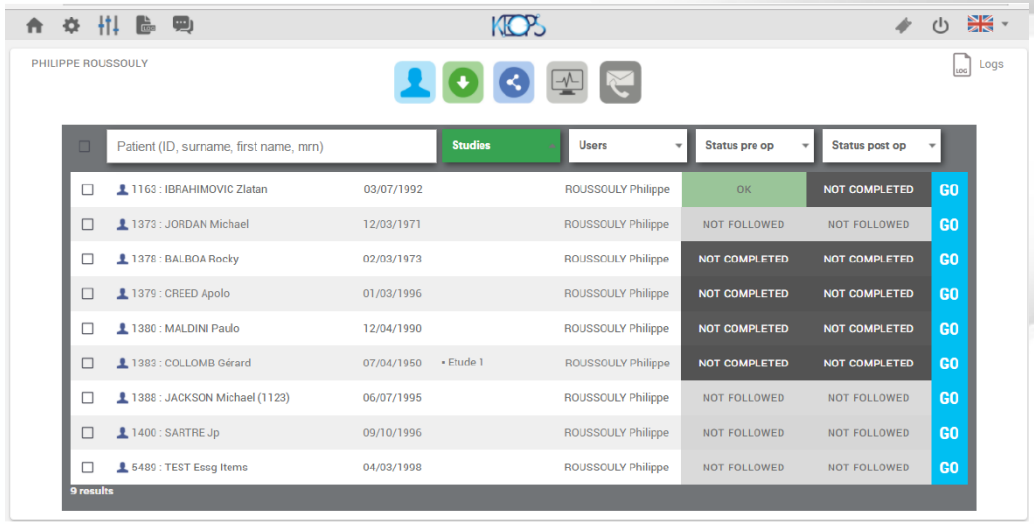
KEOPS is a customizable patient online database to record clinical data, images, QoL questionnaires, complications… and to track and evaluate the surgical results.

Data management

3D Analysis & Surgery Planning Service

Follow up

Automatic statistical reports



1.Data management

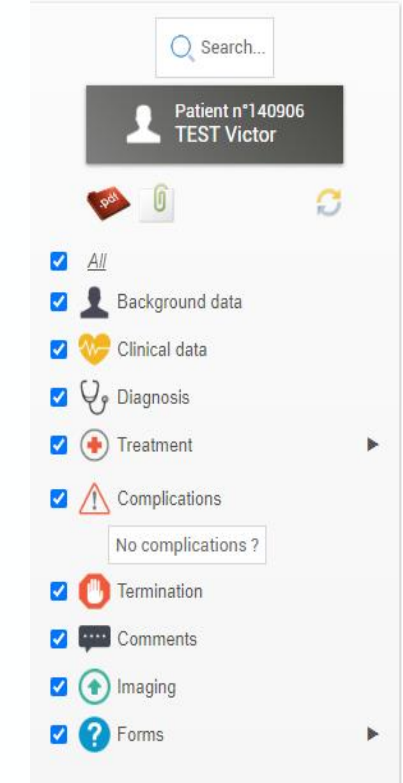
1. Data management

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.

Customizable forms with detailed menus to set and define your patients' timeline, including but not limited to:

- Background data
- Clinical data
- Diagnosis
- Treatment
- Images
- …



2.Surgery Planning Service

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

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

Surgeon decides which strategy to follow.

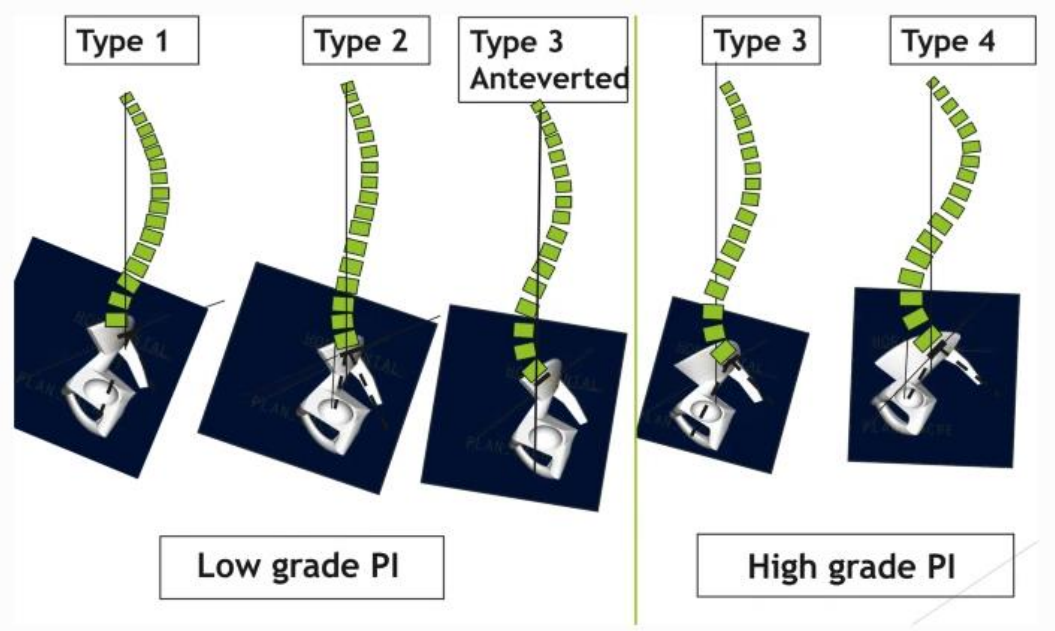
2.Surgery Planning Service

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.

3. Patient-specific rods

3. Patient-specific rods

Using our **3D planning software** we can supply a patient **specific rod** based in patients back needs, our clinical data base, our biomedical engineers experience and artificial intelligence.

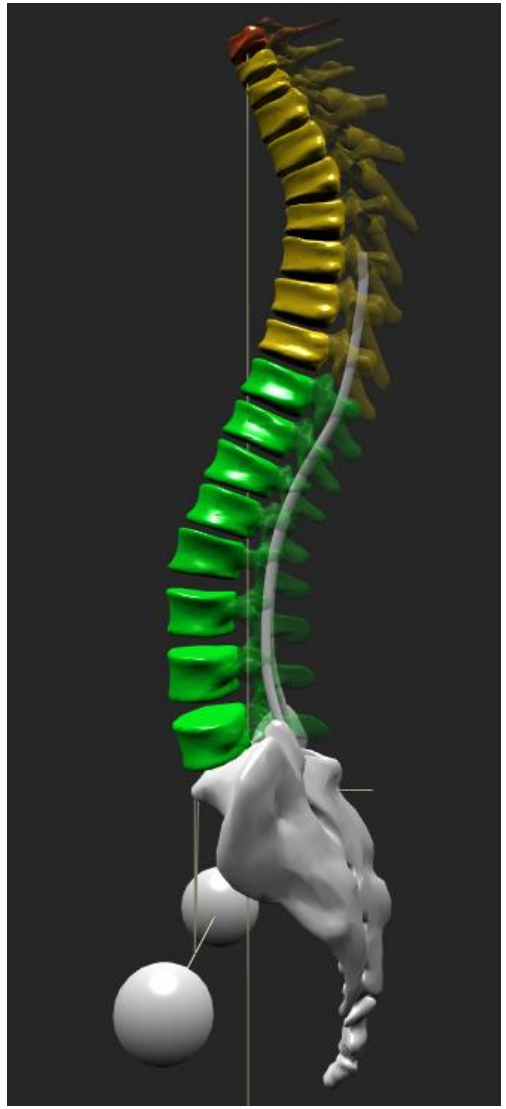
It helps to:

Ideal restoration of the patient's back.

Reducing:

- risks of reintervention (rod breakage, bad correction…).
- surgery time.
- secondary effects due to inaccurate corrections.

KREW team: specialized department dedicated to manage doubts, training and surgery plans.



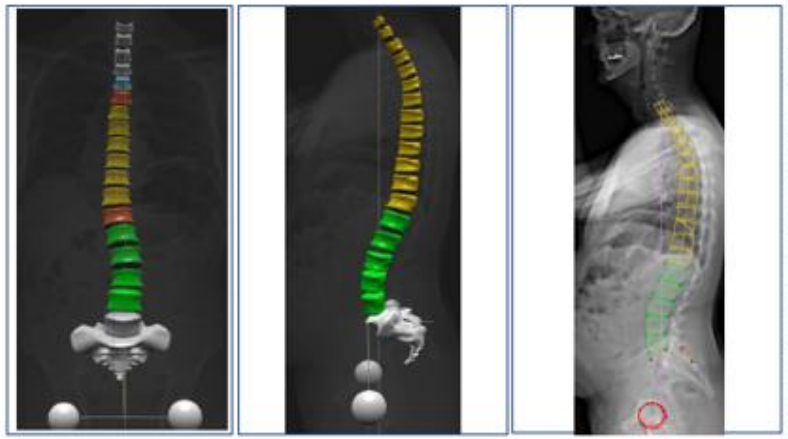
* We can also provide the rod bending plan when the specific rod could not be supplied due to different issues. It will help the surgeon to adjust the hand-bending process to the optimal rod shape.

Post-Op Memo

Patient ID :
Patient Initials :
Surgery Date:

Age : 57
Gender : M

PREOP PARAMETERS



FRONTAL SAGITTAL

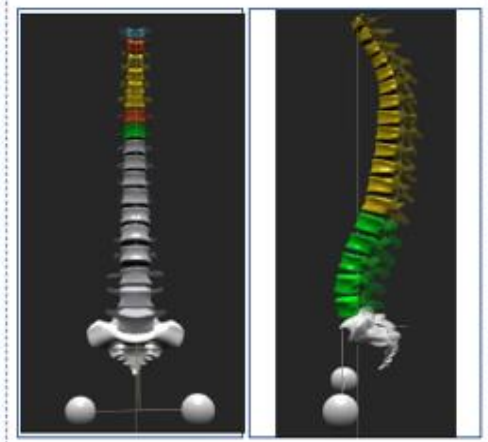
EXPECTED CORRECTION : 100%

SURGICAL STRATEGY

T11-S2

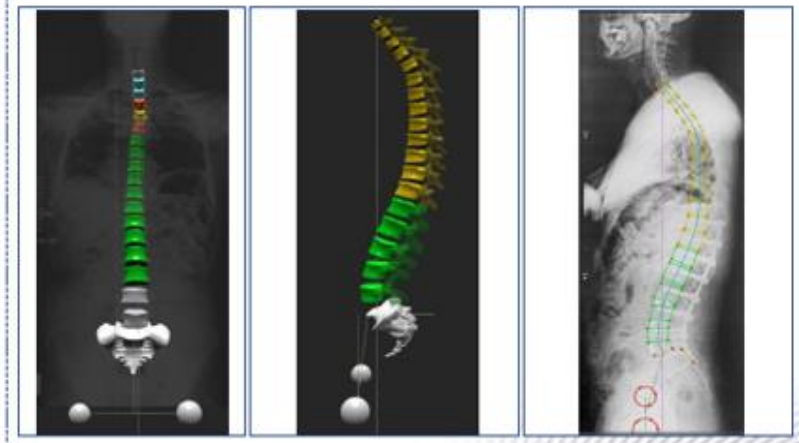
Cages L5-S1; L4-L5; L3-L4

SIMULATION



FRONTAL SAGITTAL

POST-OP PARAMETERS



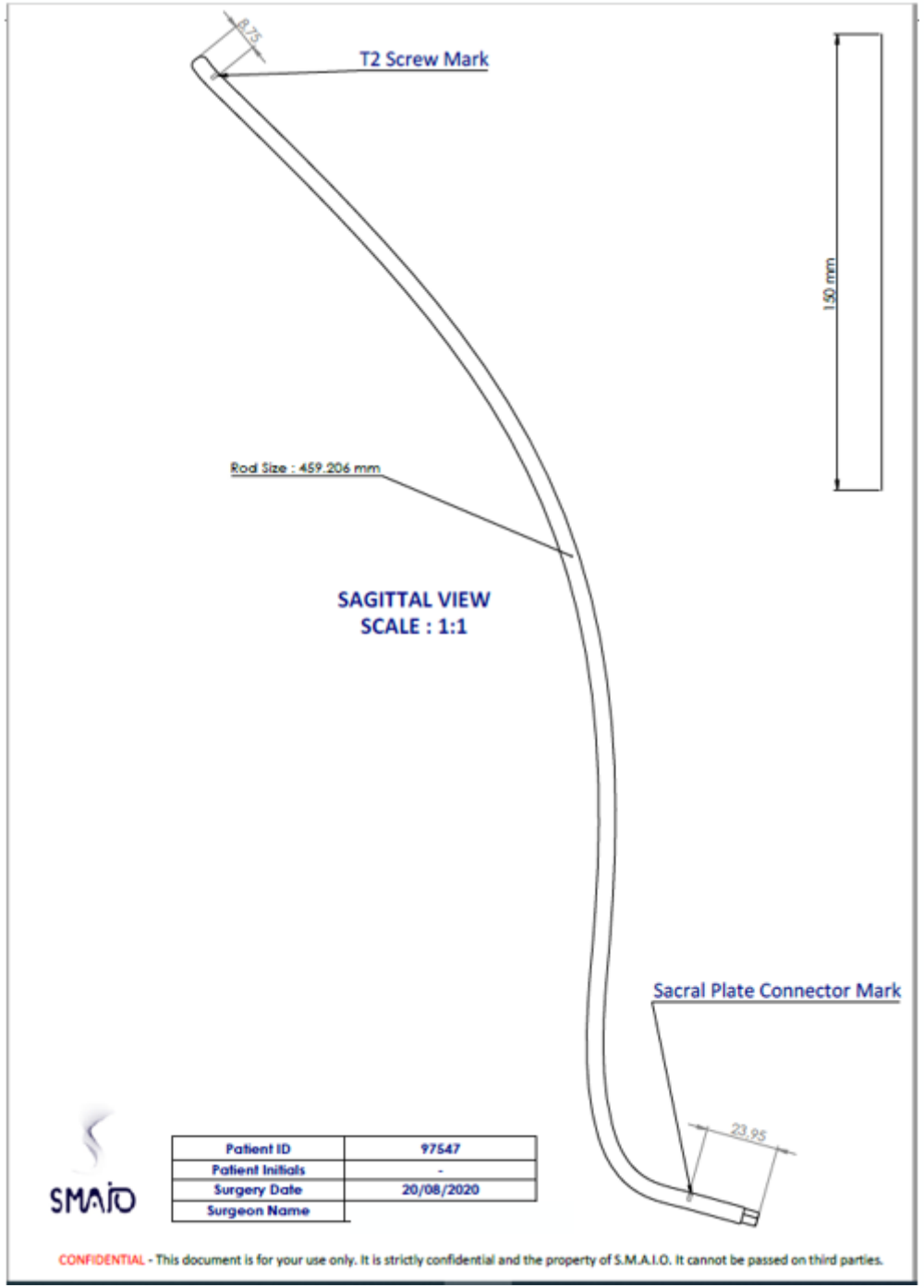
FRONTAL SAGITTAL

CORRECTION OBTAINED : 100%

SURGICAL STRATEGY

T11-S2

Cages L5-S1; L4-L5; L3-L4


8.75
T2 Screw Mark
150 mm
Rod Size : 459.206 mm
SAGITTAL VIEW
SCALE : 1:1
Sacral Plate Connector Mark
23.95
SMAIO
Patient ID 97547
Patient Initials -
Surgery Date 20/08/2020
Surgeon Name
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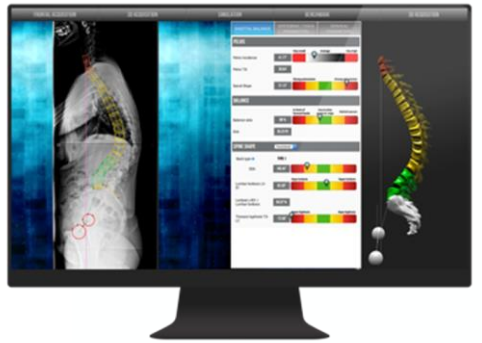
Reduces surgery time

Reduces surgery time

Surgery plan:
A good planning is the best way to succeed. Keops helps the surgeon to be one step forward the surgery.



Instrumentation:
Due to the simplicity of its instruments it’s easier to perform the maneuvers.
No difficult footage neither tricky coupling.

If something does not go straight:
One screw revision <5min despite the system is closed.
Revision fingerprints brand new once broken.
Wide domino range to adapt whatever previous construction.

SUMMARY

- Those 10 features are important but are not the only ones.
- A workshop will help to fully understand this sales pitch. Get a date!
- KHEİRON is not only a deformity fixation system, it covers most of the surgeon needs (trauma, degenerative, tumor and deformity).
- “Time is gold” in the OR, highlight how KHEİRON helps to save time.
- Our goal: patient-specific and standardized surgery.

WE ARE EXPERTS IN SPINE SURGERY