Surgical Technique

SAXXO™

Spine fixation system

orthopaedic & spine development

Table of contents

I. PRESENTATION OF THE PRODUCT

a. Implants (Class IIb)

SAXXO is an Osteosynthesis system for thoraco-lumbar arthrodesis via posterior approach.
All the implants are made in titanium alloy TA6V4 Eli (ISO 5832-3) and some rods are made cobalt-chrome alloy CoCr28Mo (ISO 5832-12).

References	Description
SEO1VP4.30	Polyaxial screw Ø 4.5 mm L 30 mm
SEO1VP4.35	Polyaxial screw Ø 4.5 mm L 35 mm
SEO1VP4.40	Polyaxial screw Ø 4.5 mm L 40 mm
SEO1VP5.35	Polyaxial screw Ø 5 mm L 35 mm
SEO1VP5.40	Polyaxial screw Ø 5 mm L 40 mm
SEO1VP5.45	Polyaxial screw Ø 5 mm L 45 mm
SEO1VP5.50	Polyaxial screw Ø 5 mm L 50 mm
SEO1VP5.55	Polyaxial screw Ø 5 mm L 55 mm
SEO1VP6.35	Polyaxial screw Ø 6 mm L 35 mm
SEO1VP6.40	Polyaxial screw Ø 6 mm L 40 mm
SEO1VP6.45	Polyaxial screw Ø 6 mm L 45 mm
SEO1VP6.50	Polyaxial screw Ø 6 mm L 50 mm
SEO1VP6.55	Polyaxial screw Ø 6 mm L 55 mm
SEO1VP7.35	Polyaxial screw Ø 7 mm L 35 mm
SEO1VP7.40	Polyaxial screw Ø 7 mm L 40 mm
SEO1VP7.45	Polyaxial screw Ø 7 mm L 45 mm
SEO1VP7.50	Polyaxial screw Ø 7 mm L 50 mm
SEO1VP7.55	Polyaxial screw Ø 7 mm L 55 mm
SEO1VR5.35	Reduction screw Ø 5 mm L 35 mm
SEO1VR5.40	Reduction screw Ø 5 mm L 40 mm
SEO1VR6.40	Reduction screw Ø 6 mm L 40 mm
SEO1VR6.45	Reduction screw Ø 6 mm L 45 mm
NUT 9.1	Tightening Nut for Screw

References	Description
CRL100	Hook for crosslink
SLT010	Rod for crosslink 75 mm
CNL001	Lateral connector
SRS1TT400	Rod Ø 5 mm L 400 mm (TA6V4 Eli)
SRS1TT280	Rod Ø 5 mm L 280 mm (TA6V4 Eli)
SRS1TT140	Rod Ø 5 mm L 140 mm (TA6V4 Eli)
SRS1TT120	Rod Ø 5 mm L 120 mm (TA6V4 Eli)
SRS1TT110	Rod Ø 5 mm L 110 mm (TA6V4 Eli)
SRS1TT100	Rod Ø 5 mm L 100 mm (TA6V4 Eli)
SRS1TT90	Rod Ø 5 mm L 90 mm (TA6V4 Eli)
SRS1TT80	Rod Ø 5 mm L 80 mm (TA6V4 Eli)
SRS1TT70	Rod Ø 5 mm L 70 mm (TA6V4 Eli)
SRS1TT60	Rod Ø 5 mm L 60 mm (TA6V4 Eli)
SRS1TT50	Rod Ø 5 mm L 50 mm (TA6V4 Eli)
SRS1TT40	Rod Ø 5 mm L 40 mm (TA6V4 Eli)
SRS1TT35	Rod Ø 5 mm L 35 mm (TA6V4 Eli)
TCC400	Rod Ø 5 mm L 400 mm (CoCr28Mo)
TCC280	Rod Ø 5 mm L 280 mm (CoCr28Mo)
TCC140	Rod Ø 5 mm L 140 mm (CoCr28Mo)
TCC120	Rod Ø 5 mm L 120 mm (CoCr28Mo)
TCC110	Rod Ø 5 mm L 110 mm (CoCr28Mo)
TCC100	Rod Ø 5 mm L 100mm (CoCr28Mo)
TCC90	Rod Ø 5 mm L 90 mm (CoCr28Mo)
TCC80	Rod Ø 5 mm L 80 mm (CoCr28Mo)

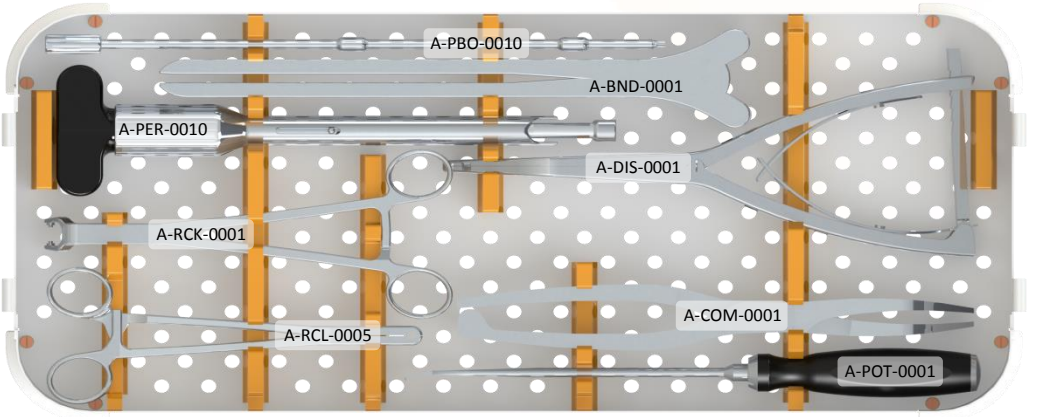
CE 0459

b. Instrumentation set (Class I)

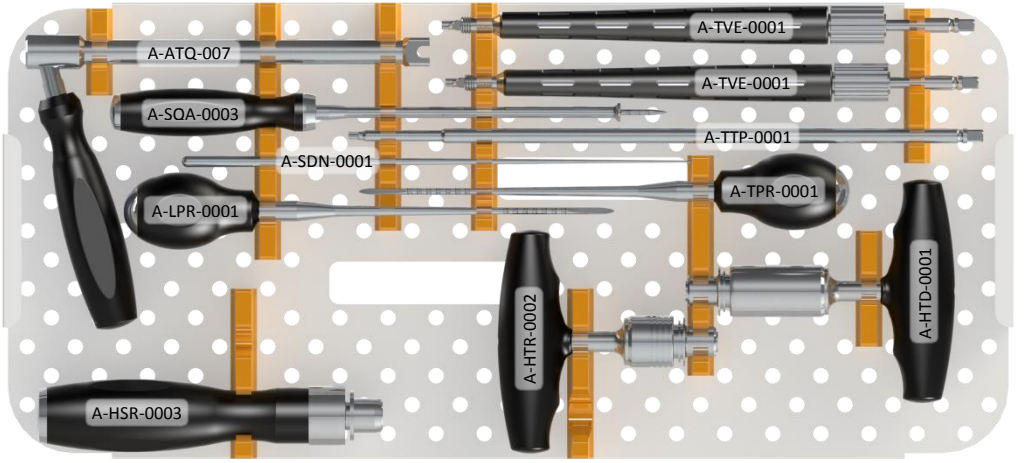
References	Description	Qty per set
BO-SAX	Instrumentation box - Base	1
INS-SAX	Instrumentation box – Upper tray	1
SAX-BO-2	Implant box	1
A-SQA-0003	Square Awl	1
A-SDN-0001	Straight Sounder	1
A-LPR-0001	Straight Lumbar Probe	1
A-TPR-0001	Curved Thoracic Probe	1
A-RCL-0005	Rod Clamp	1
A-BND-0001	French Bender	1
A-POT-0001	Rod Pusher	1
A-RCK-0001	Rocker	1
A-PER-0010	Persuader	1
A-PBO-0010	Nut Holder	1
A-COM-0001	Compressor	1
A-DIS-0001	Distractor	1
A-ATQ-007	Counter -Torque	1
A-TTP-0001	Torx Driver 1/4 simple	1
A-HTD-0001	Dynamometric Silicon Handle T23 1/4	1
A-TVE-0001	Polyaxial Screwdriver	1
A-HSR-0003	Cannulated Ratchet Silicon Handle D28 1/4	1
A-HTR-0002	Ratchet Silicon Handle T23 1/4	optional
A-TTM-0001	Torx Driver T	optional
A-BMV-0001	Holding ring for reduction screw	optional

c. Instrumentation box

BO-SAX : Instrumentation box - Base



INS-SAX: Instrumentation box – Upper tray



d. Recovery kit

References	Description	Qty per set
SEO1VP8.40	Polyaxial screw Ø 8 mm L 40 mm	6
SEO1VP8.45	Polyaxial screw Ø 8 mm L 45 mm	6
SEO1VP8.50	Polyaxial screw Ø 8 mm L 45 mm	6
NUT9.8	Tightening nut for screw Ø 8 mm	20

References	Description	Qty per set
A-TVE-0004	Revision screwdriver in one piece for polyaxial screw	1
A-ATQ-007	Counter-Torque	1
A-HSR-0003	Ratchet cannulated straight handle	1
A-HTR-0002	Ratchet cannulated T handle	1

e. Monoaxial screw

References	Description
SVM5.35	Monoaxial screw Ø 5mm L 35mm
SVM5.40	Monoaxial screw Ø 5mm L 40mm
SVM5.45	Monoaxial screw Ø 5mm L 45mm
SVM5.50	Monoaxial screw Ø 5mm L 50mm
SVM5.55	Monoaxial screw Ø 5mm L 55mm
SVM6.35	Monoaxial screw Ø 6mm L 35mm
SVM6.40	Monoaxial screw Ø 6mm L 40mm
SVM6.45	Monoaxial screw Ø 6mm L 45mm
SVM6.50	Monoaxial screw Ø 6mm L 50mm
SVM6.55	Monoaxial screw Ø 6mm L 55mm
SVM7.35	Monoaxial screw Ø 7mm L 35mm
SVM7.40	Monoaxial screw Ø 7mm L 40mm
SVM7.45	Monoaxial screw Ø 7mm L 45mm
SVM7.50	Monoaxial screw Ø 7mm L 50mm
SVM7.55	Monoaxial screw Ø 7mm L 55mm

IMPORTANT:

Use monoaxial screwdriver *A-TVE-0003* during the utilisation of monoaxial screw.

II. RECOMMENDATIONS

Before reading this document, it is important to note that this surgical technique as well as quoted and recommended sources cannot and must not be taken as a lecture on spine Osteosynthesis.

This document shall be only regarded as technical instructions on how to use the instruments.

In our concern towards constant improvement of our products, we keep the right to alter this documents as well the implant, without notice in order to match them up to the needs of our users.

a. Indications and contraindications

INDICATIONS
1) Thoraco-lumbar degenerative disc disease 2) Thoraco-lumbar stenosis 3) Recurring lombar discal hernia 4) Deformities (scoliosis, kyphosis) 5) Spondylolisthesis 6) Thoraco-lumbar fracture 7) Pseudarthrosis due to fusion failure 8) Intervertebral instability 9) Degeneration of the distal segment after anterior surgery
CONTRAINDICATIONS
Contraindications brought to the attention of OSD : 1) Is contraindicated any patient who may not be able to follow post-operative instructions including some cases of senility and mental illness 2) Acute or chronic, local or systemic infection 3) Allergy, hypersensitivity or intolerance (suspected or known) to one or more materials constituting the device 4) Addiction and / or a tendency to drug abuse, alcohol or tobacco 5) Morbid obesity 6) Sign of local inflammation 7) Pregnancy 8) Tumours 9) Any disease that treatment does not require the use of a posterior fixation system 10) Neuromuscular deficit putting weight during the convalescence 11) Osteoporosis 12) Osteopenia 13) Vascular pathology

14) Metabolic pathology
15) Major fractures on other sites
16) Major comorbidity

b. Factors that may compromise the life of the implant

Factors brought to the attention of OSD.

1) All cases of poor bone quality which may cause fusion failure including among other cases of severe osteoporosis, osteomalacia or rapid joint disease or osteopenia
2) Intense and/or repetitive loads
3) Professional or sportive physical inappropriate activities
4) Tobacco consumption
5) Unsuitability of the overall size of the implant relative to the size of the site instrumented

c. Potential adverse events

Potential adverse events brought to the attention of OSD

1) Infection or inflammation
2) Allergic reaction to materials or debris materials
3) Loosening of implant
4) Wrong screws positioning
5) Dislodgment of the screws
6) Dislodgement of the hooks
7) Breaking or dismantling of one or several of the components
8) Pseudarthrosis
9) Stop of growth at the consolidated part of the spine
10) Bleeding, hematoma
11) Pulmonary embolism
12) Gout
13) Uncomfortable pressure on the skin
14) Dural leak
15) Loss of a correct curve of the spine , loss of correction and/or reduction
16) Delayed consolidation or no consolidation
17) Decreased bone density
18) Crack, fracture or perforation of the spine
19) Bursitis
20) Discopathy at instrumented level
21) Loss or increase in spinal mobility
22) Deterioration of adjacent segments
23) Pseudarthrosis

24) Muscle necrosis
25) Pneumonia
26) Pulmonary edema
27) Cholelithiasis
28) Retroperitoneal hematoma
29) Retrograde ejaculation
30) Loss of neurological function
31) Neuronal and vascular complications
32) Complications at the bone graft donor site
33) Deficit of the urinary system
34) Gastrointestinal complications
35) Complications in the reproductive system
36) Mental status change
37) Pain
38) Ileus
39) Deep vein thrombosis
40) Osteolysis
41) Death
42) Bed sore
43) Pleural effusion
44) Seroma
45) Synovial facet cyst

These potential adverse events may sometimes cause a reoperation.

d. Precautions and warnings

SAXXO IMPLANTS ARE SINGLE USE ONLY.
DO NOT RE-USE.

e. Preoperative precautions

1) Before considering implanting a device, the surgeon must take into account the patient's general condition and the effectiveness or the impossibility of using another operative or non-operative treatment.
2) The surgeon must take into account any previous surgeries performed on the patient.
3) Any patient with a contraindication should be refused
4) The patient should be informed of the potential risk of failure and its consequences
5) The patient should also be warned of the risk of non-union related to tobacco

f. Intraoperative and postoperative precautions

1) The surgeon must warn the patient about the post-operative precautions
2) Clean and decontaminate implants and instruments prior to sterilization
3) Not combine SAXXO devices with devices from another manufacturer that may modify the physical integrity of the device
4) The surgical technique must be identical to that presented by the manufacturer and the surgeon must be familiar with it
5) Choose the correct size and position the implant properly (if the implant cannot be placed correctly, it is recommended to consider other treatment).
6) The surgeon must know the mechanical properties and limits of the device and the material used.
7) Protection against radiation: the surgeon will take all necessary measures to protect against radiation caused by intraoperative fluoroscopic control of the correct positioning of bone fragments and implants.
8) The implants are single use only.
9) Do not bend the rods excessively and/or repetitively.
10) Do not apply a excessively strong tightening the screw.
11) Master the surgical approach of pedicle screws.
12) Use the largest screw diameter as much as possible.
13) The rod should rest on the bottom of the ring groove before locking (check if a bone does not interfere with the insertion of the rod).
14) An external support can be proposed.
15) It is not recommended to do intense physical activities before consolidation
16) Smoking before consolidation is not recommended

g. Packaging

Implants are delivered NON-STERILE in individual packaging or in the implant box.
The instruments are filed in a container.

h. Cleaning

Devices concerned: all the medical devices non-sterilized.

Process	The person who does the cleaning must wear glove, mask and safety glasses. Use a disposable cloth so as to remove any soil.
<u>Manual pre-cleaning</u>	
	• **Disassembly is absolutely required, in particular the persuader A-PER-010.** • Disassemble the handle and the instruments snapped. • Immerse all the elements, in lukewarm tap water during 5 minutes at least. • Brush with a soft nylon brush under lukewarm tap water until no residuals visible, in particular the extremities threaded or torx instruments. • Brush the lumens (hollow and tight cavity) of the counter torque *A-ATQ-007*, the persuader *A-PER-0010 and the A-TVE-0001* with the appropriate swab. • Slide under water the handle mechanism and French bender *A-BND-0001* (10 time at least). • Activate under water the pliers opening system 10 time at least (*A-DIS-0001*, *A-COM-0001*, *A-RCK-0001*, *A-RCL-0005, A-BND-0001*). • Rinse all surfaces and lumens of the elements, with cold water, 20 minutes at least, at minimum static pression 4 bar. • **<u>Check all the elements,</u>** in particular, extremities, the thread and lumens.
<u>Automated cleaning</u> (For *example equipment: Miele G 7735 CD (Program:Vario TD)*).	
Description of the cycle cleaning	• 2 minutes pre-cleaning in cold water. • Drain. • 5 minutes cleaning in deionized water at 55°C and 0,5% of soft alkalin detergent (*For example : NeodisherMediClean - Dr.Weigert*). • Drain. • 3 minutes rinsing and neutralization with deionized water • Drain. • 2 minutes final rinse in deionized water • Drain.
Inspection and function tasting	• Check instruments and lumens for complete removal of visible soil. • If necessary, repeat cycle cleaning. • After cleaning/disinfection, the disassembled instruments must be reassembled and visually inspected.

i. Sterilization

Devices concerned: the entire non-sterile medical device.

<table>
<tr><th colspan="2">Autoclave sterilization</th></tr>
<tr><td>Packaging</td><td>

Always put interior and exterior sterilization marks on the container, like physico-chemical indicator to check the efficiency of the sterilization.
Put implants and instruments into them concerned box.
Pack the box under double sterilization paper.

</td></tr>
<tr><td>Sterilization of the instruments</td><td>

The instruments must be sterilized by the clinics or hospitals before each intervention according to the current legislation.
Sterilize the box in the vapor sterilizer (for example equipment: Selectomat HP MMM) according to the following parameters :

Air elimination,
sterilization at 134°C during 5 minutes at 3 bar maximum,
Drying during 10 minutes at least.

In France, sterilization must be between 134° and 138°C during 18 minutes at least (according to the instruction DGS/RI3/2011/449 of 1st December 2011).
Do not stack boxes in sterilizer.

</td></tr>
<tr><td>Sterilization of the implants</td><td>

The implants must be sterilized by clinics and hospitals before each intervention according the current legislation.
Sterilize the box in a vapor sterilizer (for example equipment: BBC/Technic Labo) according to the following parameters :

<table>
<tr><th>Cycle</th><th>Conditions</th><th>T (°C)</th><th>Time</th><th>Drying</th></tr>
<tr><td>FR</td><td>Air elimination</td><td>134-138°C</td><td>18 min</td><td>30 min</td></tr>
<tr><td>UK</td><td>Air elimination</td><td>134-138°C</td><td>3 min</td><td>30 min</td></tr>
<tr><td>US</td><td>Air elimination</td><td>132-135°C</td><td>4 min</td><td>30 min</td></tr>
</table>

In France, sterilization must be between 134° an 138°C during 18 minutes at least (according to instruction DGS/RI3/2011/449 of 1st December 2011).
Do not stack boxes in sterilizer.

</td></tr>
<tr><td>Storage</td><td>

Store in a clean and dry place.

</td></tr>
</table>

Addicional information	• Manufacturer and distributor assume no responsibility for the cleaning and re-sterilization of implants, components or re-usable instruments, performed by the hospital. • Re-usable instruments must be cleaned, decontaminated and sterilized before and after use according to the following detailed method and the current legislation (in France, instruction DGS/RI3/2011/449 of 1st December 2011).
Manufacturer contact	ORTHOPAEDIC & SPINE DEVELOPMENT Chemin de Fontanille - BP 11211, 84911 Avignon Cedex 9 - FRANCE Tel : + 33 (0)4 32 74 01 10 / Fax : + 33 (0)4 90 80 02 39 info@osdevelopment.fr / www.osdevelopment.fr

j. Disassembling of the persuader A-PER-0010

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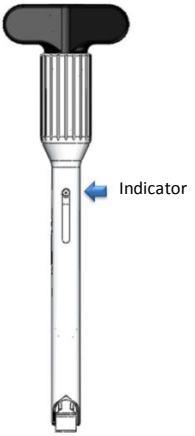
<td> 
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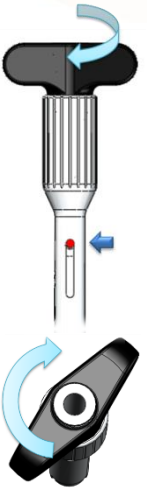
<td>  </td>
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</tr>
<tr>
<td>1) Before beginning to disassemble, check if the indicator is at its highest position..</td>
<td colspan="2">2) Press strongly on the indicator (red circle on the picture) with the thumb while turning the black handle (rotate clockwise).</td>
<td colspan="2">3) Continue to turn it until that it is turning in the space. The indicator will disappear progressively inside the Persuader.</td>
</tr>
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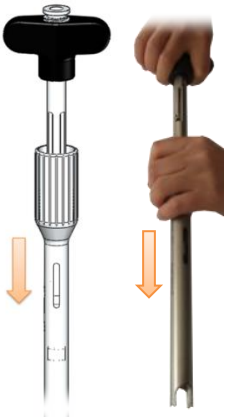
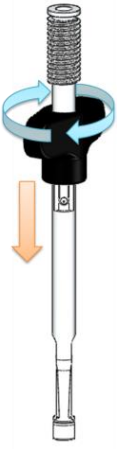
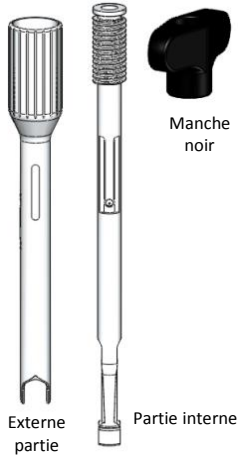
<td>  </td>
<td>  </td>
<td colspan="2"> 
</td>
</tr>
<tr>
<td>4) Push the external part of the Persuader downward.</td>
<td>5) Turn the black handle to remove it.</td>
<td colspan="2">6) Persuader is now disassembled in three parts.</td>
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k. Assemblage du Persuader A-PER-0010

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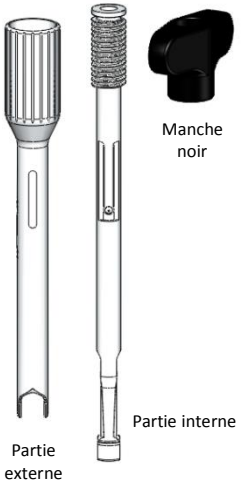
<td> 
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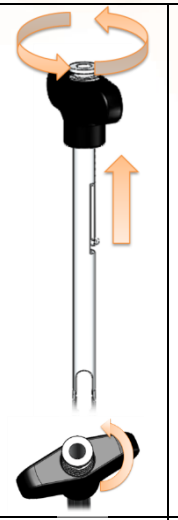
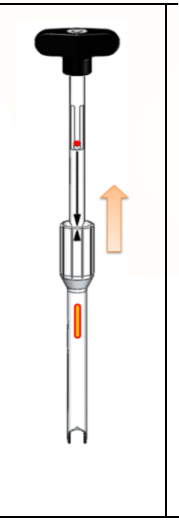
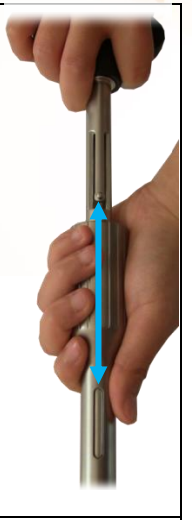
<td>  </td>
<td>  </td>
<td>  </td>
</tr>
<tr>
<td>1) Begin the assembly with the internal part and the handle.</td>
<td colspan="2">2) Insert the handle through the bottom. Once it reaches the thread, turn the handle (rotate counter clockwise) to make it.</td>
<td colspan="2">3) Insert the external into the internal part. Check if the indicator is correctly aligned with the window (in yellow on the picture).</td>
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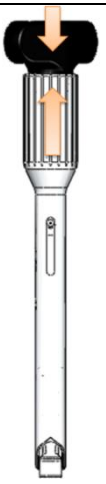
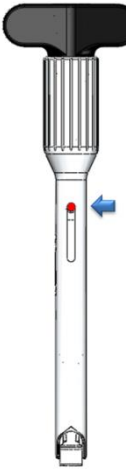
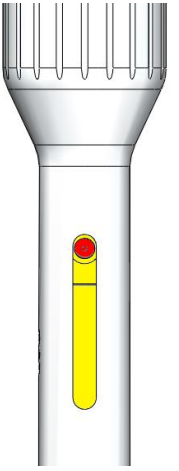
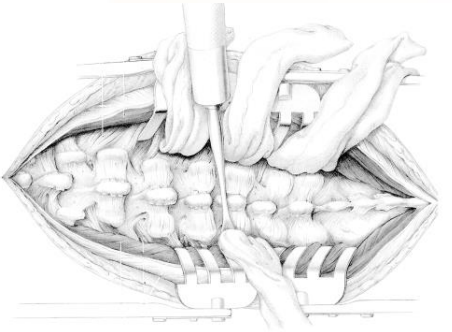
<td>  </td>
<td colspan="2">  </td>
<td colspan="2">  </td>
</tr>
<tr>
<td>4) Pull the Persuader towards the black handle.</td>
<td colspan="4">5) The indicator must reappear in its window. The Persuader is now ready to use.</td>
</tr>
</table>

III. SURGICAL TECHNIQUE

a. Pacient facility

The patient is placed in a ventral decubitus position, on block iliac and thoracic, abdomen bared.

Control the lack of vascular compression pelvic-abdominal, compressive support at the elbow (ulnar nerves), of the eyeballs.



Per-operative radiographic control of pedicle trip before implantation and screw positioning.

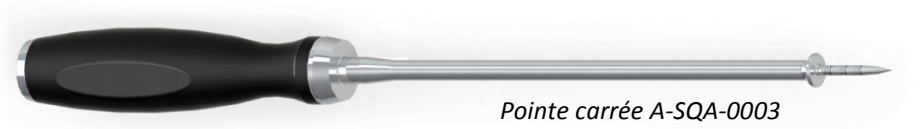
Posterior median approach and exposure of the paravertebral grooves.

Lateral releasing up to the base of the transversal apophysis on levels which arthrodesis is to be performed.

b. Preparation of the pedicle

Preparations of the pedicle polyaxial screw path as usual mark, using the approach the square awl *A-SQA-0003*.

Start to make a hole using the square point in making it turn according to the position of the chosen path for the vertebra.



Pointe carrée A-SQA-0003

c. Checking

The position and orientation of screw path can be controled,in order to get an alignment which eases the rod positioning.

Place the sounder *A-SDN-0001* in the pedicular holes and control its position and path with a radiograph, ideally face and profile.

Sonde A-SDN-0001

One has to avoid, as much as possible, to bend and rebend the sounder *A-SDN-0001* too many times, risking to break the axis.

Use sounder (thoracic and lumbar) or tap if necessary.

d. Screw driving

Insert the polyaxial screwdriver *A-TVE-0001* in the ratchet cannulated T handle *A-HTR-0002* or in ratchet cannulated straight handle *A-HSR-0003*.

Ratchet cannulated T handle A-HTR-0002

Polyaxial screwdriver A-TVE-0001

Ratchet cannulated straight handle A-HSR-0003

The polyaxial screw is inserted **with fully engaging the torx tip** of the polyaxial screwdriver *A-TVE-0001* into the head of the screw.

e. Handle using A-HTR-0002 and A-HSR-0003

L ⟵ ●

Set the handle to « L » :
To unscrew.

● ⟶ R

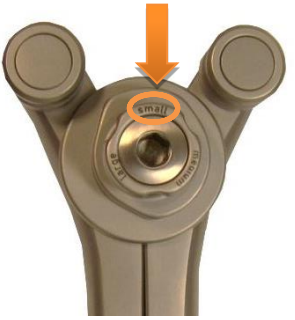
Set the handle to « P » :
To screw without needing to make a whole turn.

f. Bending and insertion of the rod

Bend the rod with a French bender *A-BND-0001* according the desired spinal contours, considering the screw alignment.

Bending previously, check the position instrument, it must be “SMALL”.

SMALL



French bender A-BND-0001

The rod holder is positioned in the head of screw with rod clamp *A-RCL-0005*.

Rod clamp A-RCL-0005

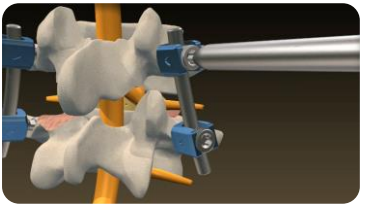
If necessary, use the rod pusher *A-POT-0001* to place the rod on the screw.

Rod pusher A-POT-0001

The asembly screw-rod must be bilateral and same lenght.

g. Screw closing

Once the rod is laid on the bottom of the screw head, the nut may be seated on the top of the screw head using the nut holder *A-PBO-0010*, and **screw without be closed**. this procedure is applied for all the nut.



Nut holder A-PBO-0001

If necessary, use the rocker *A-RCK-0001* or the persuader *A-PER-0010* to lower the rod inside the screw head. Please see for use the persuader *A-PER-0010.*

h. Reducing maneuvers

Reducing maneuvers are realized with compressor *A-COM-0001* and distractor *A-DIS-0001*.

Distractor A-DIS-0001

Compressor A-COM-0001

i. Screw locking

Assemble torx screwdriver *A-TTP-0001* with dynamo T handle *A-HTD-0001* to obtain a dynamo screwdriver.

Once all the reduction maneuvers finished, all the nut are tightened with dynamo screwdriver *A-HTD-0001* and counter torque *A-ATQ-007*.

The counter torque is placed on the screw head and dynamo screwdriver is inserted in the counter torque so as to press the nut of screw.

Turn the handle until hear one "*clic*". The torque tightening is at 10 Nm.

j. Transverse link insertion

If desired an assembly more rigid, use one or more transverse link.

Once the transverse link stranded flat on longitudinal rod, this one can be spreaded unscrewing the nut.

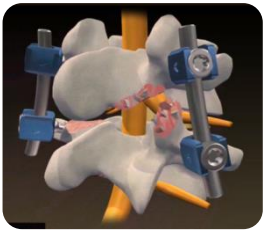
When the correct size is found, screw the nut of connector with the screwdriver.

k. Bone grafting

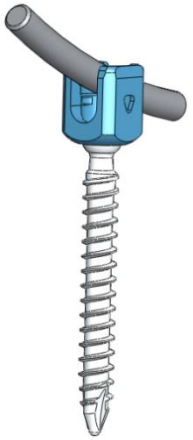
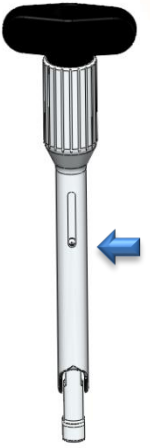
If necessary complete the graft on both side of the system

Eventual radiologic control.

Closing, one after the other, according the usual technique.



I. How to use the Persuader A-PER-0010

<table>
<tr>
<td>  </td>
<td>Position A
  </td>
<td>Position B
  </td>
<td>  </td>
</tr>
<tr>
<td>Persuader A-PER-0010 is used to lower the rod into correct position.</td>
<td colspan="2">1) If you begin with the position A, please follow the steps 2 and 3. If you begin with the position B, please skip to the step 4.</td>
<td>2) Turn the black handle until the maximum so as to unscrew it.</td>
</tr>
<tr>
<td>  </td>
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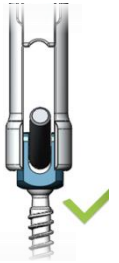
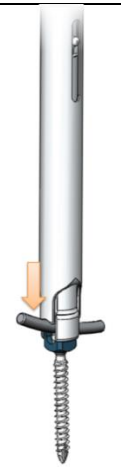
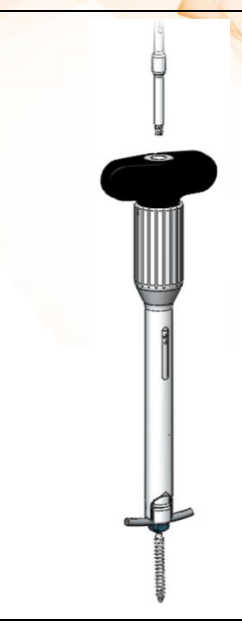
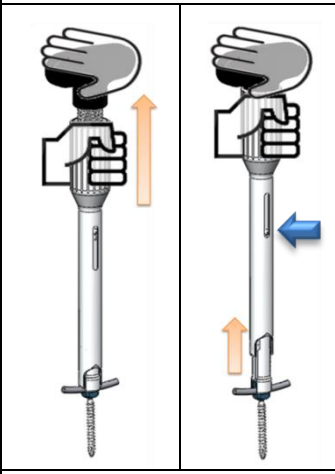
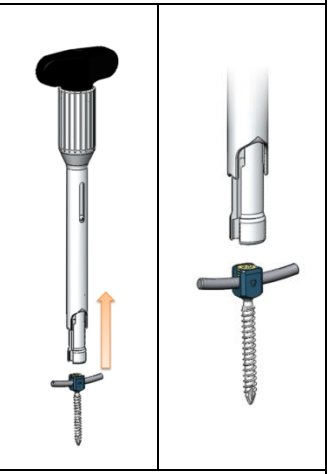
<td> 
Incorrect</td>
<td> 
Correct</td>
<td>  </td>
<td>  </td>
</tr>
<tr>
<td>3) Push the black handle as the persuader slides down.</td>
<td colspan="3">4) Check if the indicator is at the lowest position. Then, place the persuader on the head of the screw.</td>
<td colspan="2">5) While holding the black handle with the other hand, push the persuader slowly downward until it comes in contact with the rod.</td>
</tr>
</table>

		
6) Turn the black handle until the indicator reaches the highest position..	7) Place the nut on the head of the screw with the nut holder *A-PBO-0010* and turn it..	8) Remove the nut holder.
		
9) Turn the black handle to the maximum to unscrew the handle.	10) Pull the persuader upward while blocking the handle with the other hand “opened”. Before trying to remove the Persuader, check if the indicator is at the lowest position.	11) Remove the persuader from the head of the screw.

IV. ABLATION

Unscrew the nuts with a torx screwdriver A-TTM-0001. Remove the rods. Screws are removed using the same torx screwdriver.

V. PRECAUTIONS TO TAKE REGARDING THE INSTRUMENTS USING

Re-usable instruments must be cleaned, decontaminated and sterilized before and after use according to the detailed method and the current la legislation (in France instruction DGS/RI3/2011/449 of 1st December 2011 concerning the hazards of Creutzfeldt-Jakob disease).

ORTHOPAEDIC & SPINE DEVELOPMENT recommended a number of cycles of 150 sterilization maximum for its instruments. ORTHOPAEDIC & SPINE DEVELOPMENT instruments must be repaired and should be cleaned, decontaminated, sterilized and before being sent to the address shown on this document. At your return must enclose the traceability sheet.

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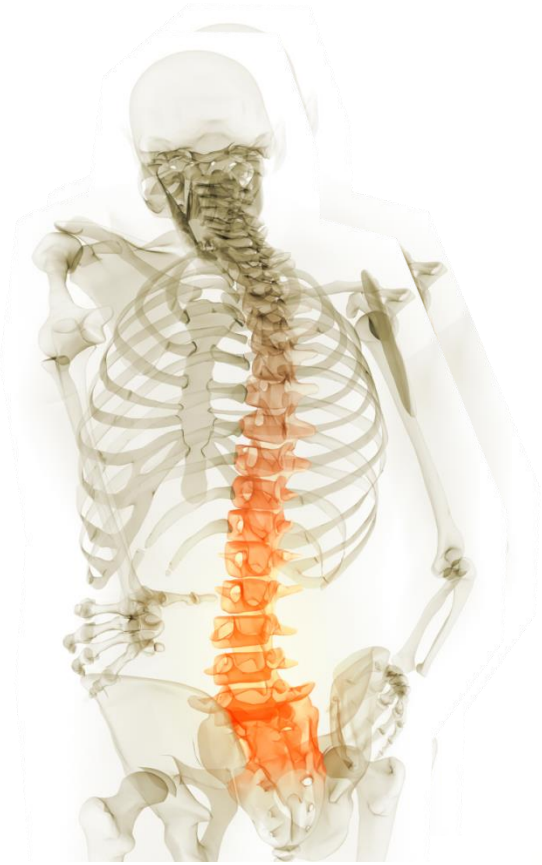
www.osdevelopment.fr



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