ROMEO®2 PAD

BY SPINEART

POSTERIOR AXIAL DEVICE

CONTENT

CONCEPT AND DESIGN

Spineart has a proven track record in Minimally Invasive Surgery having designed the world's first K-wireless screw system and the world's first « screw based » and fully radiolucent carbon-fiber retractor. Spineart is now pushing back the boundaries of Minimally Invasive Surgery with the ROMEO®2 PAD, a unique P-Screwless technology, delivered sterile packed, with an ultra-compact set of intuitive instruments.
Just as Steve Jobs said, "Design is not just what it looks like and feels like. Design is how it works", ROMEO®2 PAD has been designed to combine effectiveness and elegance in line with Spineart's philosophy which guarantees Quality, Innovation, and Simplicity of use.

AT A GLANCE

POLYAXIAL PLATE

ONE STEP LOCKING MECHANISM

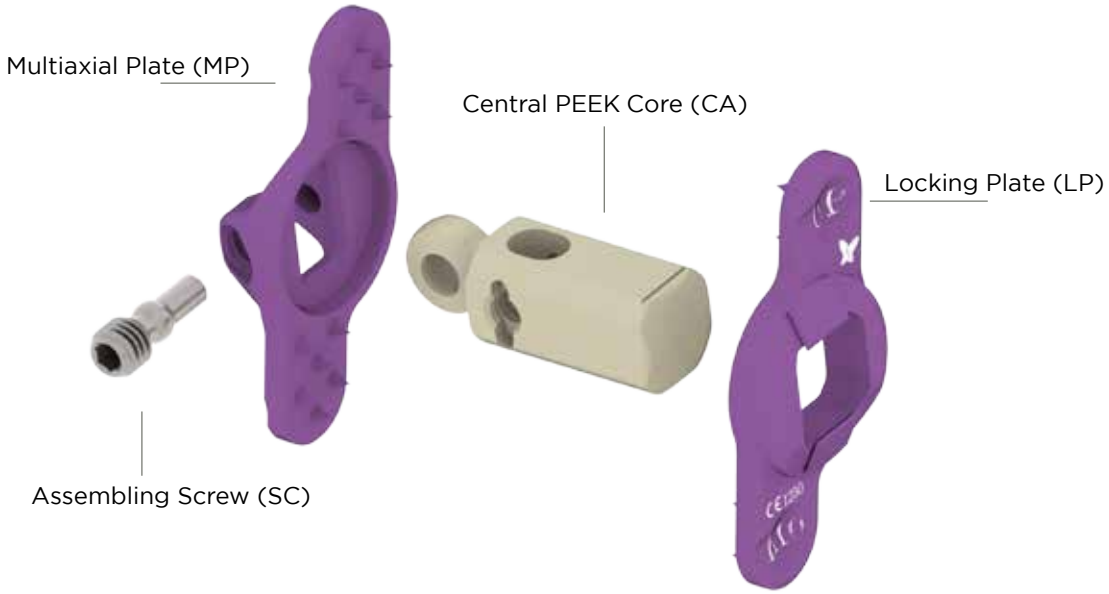
P-SCREWLESS TECHNOLOGY

CENTRAL PEEK CORE

INDICATIONS

The ROMEO®2 PAD implant is intended to be used as a fixation, completed by an intersomatic device, to achieve fusion in lumbar spine. It's indicated for patients presenting with the following pathologies between L1 and S1: degenerative disc disease (DDD), degenerative spondylolisthesis grade 1, spinal stenosis, stabilization after decompression for spinal stenosis, failed of previous fusion and pseudoarthrosis.

IMPLANTS



DESCRIPTION	REFERENCE
POSTERIOR AXIAL DEVICE - H08	**PAD-IM WT 08-S**
MP	PAD-FU MP 08-S
SC	PAD-FU SC 08-S
CA	PAD-FU CA 08-S
LP	PAD-FU LP 08-S

DESCRIPTION	REFERENCE
POSTERIOR AXIAL DEVICE - H10	**PAD-IM WT 10-S**
MP	PAD-FU MP 10-S
SC	PAD-FU SC 08-S
CA	PAD-FU CA 10-S
LP	PAD-FU LP 10-S

DESCRIPTION	REFERENCE
POSTERIOR AXIAL DEVICE - H12	**PAD-IM WT 12-S**
MP	PAD-FU MP 12-S
SC	PAD-FU SC 08-S
CA	PAD-FU CA 12-S
LP	PAD-FU LP 12-S

DESCRIPTION	REFERENCE
POSTERIOR AXIAL DEVICE - H14	**PAD-IM WT 14-S**
MP	PAD-FU MP 14-S
SC	PAD-FU SC 08-S
CA	PAD-FU CA 14-S
LP	PAD-FU LP 14-S

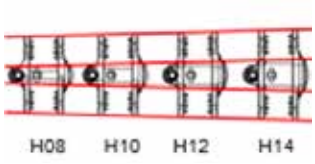
TECHNICAL FEATURES

SPIKES

- 24 pyramidal spikes to achieve stabilization
- The height of the spikes is 2 mm for purchase in the cortical bone

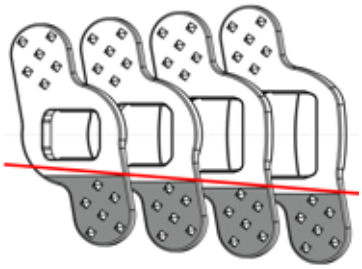
PEEK CORE SIZES

- 4 heights available from 8 to 14 mm
- Graft window volume increases with core size



PLATE

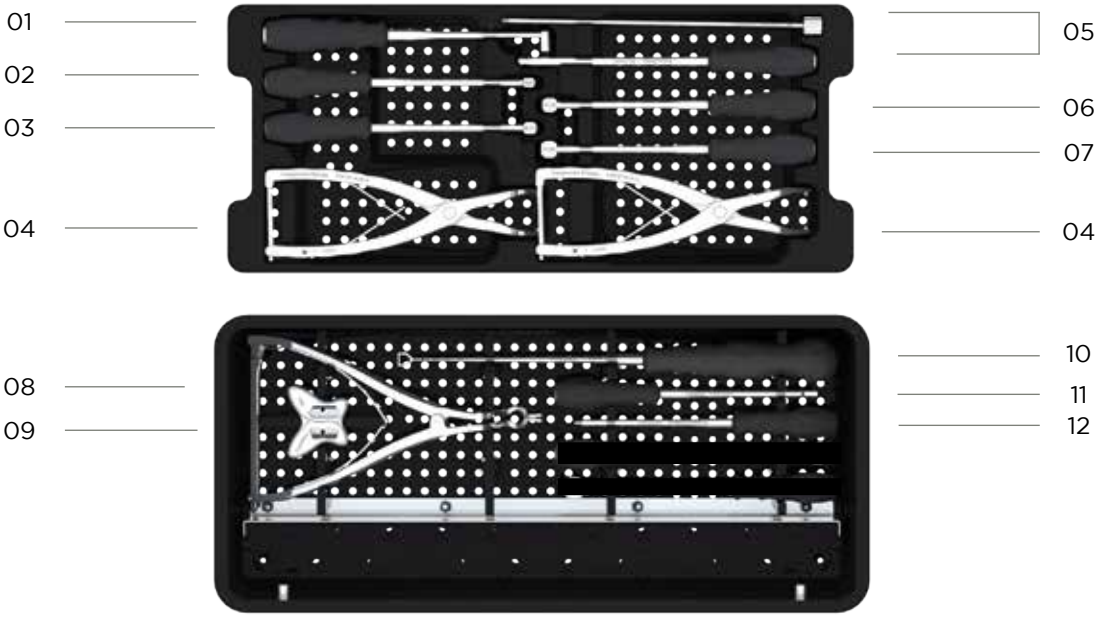
- The size of the plate increases with the height of the implant
- The plate surface in contact with the spinous processes remains constant



SMART LOCKING MECHANISM

- The locking mechanism operates like a smooth ratcheting system
- The locking plate has 2 flexible blades for strong grip on the central PEEK core preventing any separation of the plates once compressed against the spinous processes

INSTRUMENT SET



#	DESCRIPTION	REFERENCE
	INSTRUMENT CONTAINER	**PAD-BX 10 01-N**
01	SPINOUS PROCESS PREPARER	PAD-IN 01 00-N
02	TRIAL H08	PAD-IN 02 08-N
03	TRIAL H10	PAD-IN 02 10-N
06	TRIAL H12	PAD-IN 02 12-N
07	TRIAL H14	PAD-IN 02 14-N

#	DESCRIPTION	REFERENCE
05	IMPLANT HOLDER	PAD-IN 03 00-N
04	COMPRESSION FORCEPS	PAD-IN 06 00-N
10	CURETTE	PAD-IN 08 00-N
11	COMPACTOR	PAD-IN 05 00-N
09	COMPACTION BASE	PAD-IN 04 00-N
12	REVISION SCREWDRIVER	PAD-IN 07 00-N
08	SPREADER (OPTIONAL)	PAD-IN 09 00-N

INSTRUMENTS

SPINOUS PROCESS PREPARER	PAD-IN 01 00-N

CURETTE	PAD-IN 08 00-N

TRIAL H08	PAD-IN 02 08-N
TRIAL H10	PAD-IN 02 10-N
TRIAL H12	PAD-IN 02 12-N
TRIAL H14	PAD-IN 02 14-N

COMPACTION BASE	PAD-IN 04 00-N

COMPACTOR	PAD-IN 05 00-N

IMPLANT HOLDER	PAD-IN 03 00-N

COMPRESSION FORCEPS	PAD-IN 06 00-N

SPREADER (optional)	PAD-IN 09 00-N

REVISION SCREWDRIVER	PAD-IN 07 00-N

SURGICAL TECHNIQUE

STEP **1**

PATIENT POSITIONING

Position the patient in a prone position.

Perform a midline approach, resecting the supra-spinous and interspinous ligaments. Use the SPINOUS PROCESS PREPARER and the CURETTE to clean the contact surface between implant and bone on both sides of the spinous processes and between the spinous processes.

The contact surface between the bone and the implant must be free of tissue, muscles and ligaments.

INSTRUMENT	REFERENCE
SPINOUS PROCESS PREPARER	PAD-IN 01 00-N
CURETTE	PAD-IN 08 00-N

STEP **2**

TRIAL FOR IMPLANT SIZE

Insert the TRIALS in order to determine the correct size of the device.

The SPREADER can be used to distract and to facilitate the insertion.

INSTRUMENT	REFERENCE
TRIAL H08	PAD-IN 02 08-N
TRIAL H10	PAD-IN 02 10-N
TRIAL H12	PAD-IN 02 12-N
TRIAL H14	PAD-IN 02 14-N
SPREADER (optional)	PAD-IN 09 00-N

SURGICAL TECHNIQUE

STEP **3**

IMPLANT PREPARATION

Use the COMPACTION BASE to clip the plate onto the PEEK core of the implant.

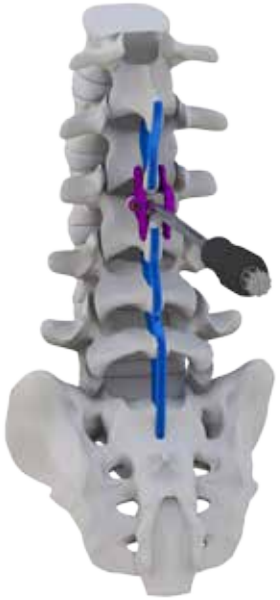
Connect the implant to the IMPLANT HOLDER by screwing the threaded shaft into the PEEK core.

If you want to add graft, reverse the COMPACTION BASE put the implant inside and fill in the graft window with the help of the COMPACTOR.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	PAD-IN 03 00-N
COMPACTOR	PAD-IN 05 00-N
COMPACTION BASE	PAD-IN 04 00-N

SURGICAL TECHNIQUE

STEP **4**



IMPLANT INSERTION

Insert the implant and place it in the desired position between the spinous processes.

Make sure that the « up » marking is pointing cephalad and the head of the assembling screw is visible.

The SPREADER can be used to facilitate the insertion.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	PAD-IN 03 00-N
SPREADER (option)	PAD-IN 09 00-N

STEP **5**

FINAL COMPRESSION

Use the COMPRESSION FORCEPS to compress the implant and fix it on the spinous processes.

The implant has two hollows on each side to receive the tips of the COMPRESSION FORCEPS used to secure fixation and locking.

It's recommended to use both COMPRESSION FORCEPSES simultaneously.

INSTRUMENT	REFERENCE
COMPRESSION FORCEPS	PAD-IN 06 00-N

SURGICAL TECHNIQUE

FINAL CONSTRUCT

REVISION

In case of revision, use the REVISION SCREWDRIVER to take out the screw and remove the implant.

If the implant is disassembled, a new implant has to be inserted.

INSTRUMENT	REFERENCE
REVISION SCREWDRIVER	PAD-IN 07 00-N

NOTE

NOTE

spineart.com

SPINEART SA
20 route de Pré-Bois
1215 Geneva 15
Switzerland

SPINEART USA
227 East 58th St. 2nd Floor
New York, NY 10022
United States of America

9200 Irvine Center Drive, Suite 150
Irvine, CA 92618
United States of America

SWISS MADE

0115-V2 ref.PAD-BR LU 31-E CE 1250