ROMEO®2 PAD

INTERSPINOUS FUSION DEVICE

C O N T E N T

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 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.

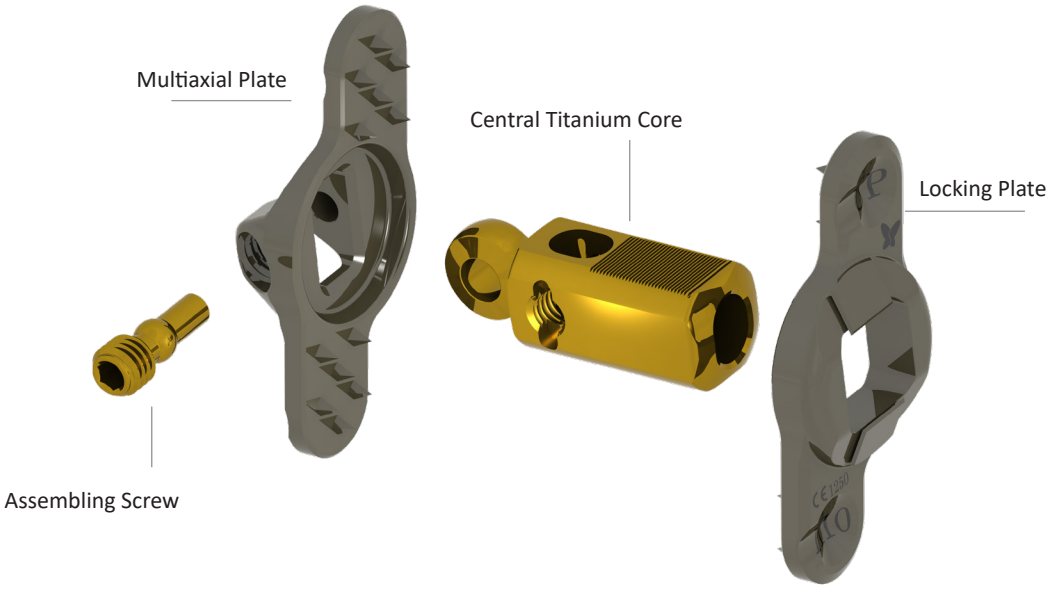
AT A GLANCE

Polyaxial Plate
One Step Locking Mechanism
P-Screwless Technology
Titanium Central Core

INDICATIONS

The ROMEO®2 PAD Posterior Axial Device is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e.,fracture or dislocation) and /or tumor. The ROMEO®2 PAD Posterior Axial Device is not intended for standalone use.

IMPLANTS



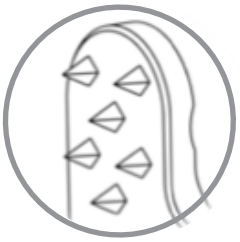
POSTERIOR AXIAL DEVICE TI

	HEIGHT	REFERENCE
	08	PAD-IM TI 08-S
	10	PAD-IM TI 10-S
	12	PAD-IM TI 12-S
	14	PAD-IM TI 14-S
•	16	PAD-IM TI 16-S
•	18	PAD-IM TI 18-S

• : OPTIONAL

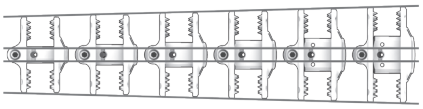
TECHNICAL FEATURES

SPIKES



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

CORE SIZES

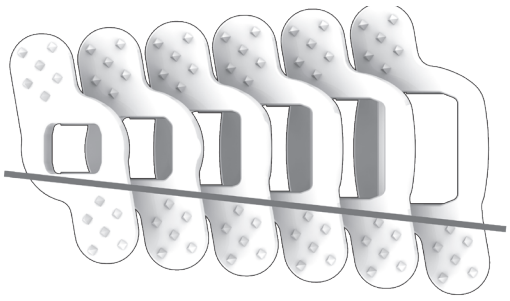


H08 H10 H12 H14 H16 H18

6 heights available from 8 to 18 mm
Graft window volume increases with core size

TECHNICAL FEATURES

PLATE

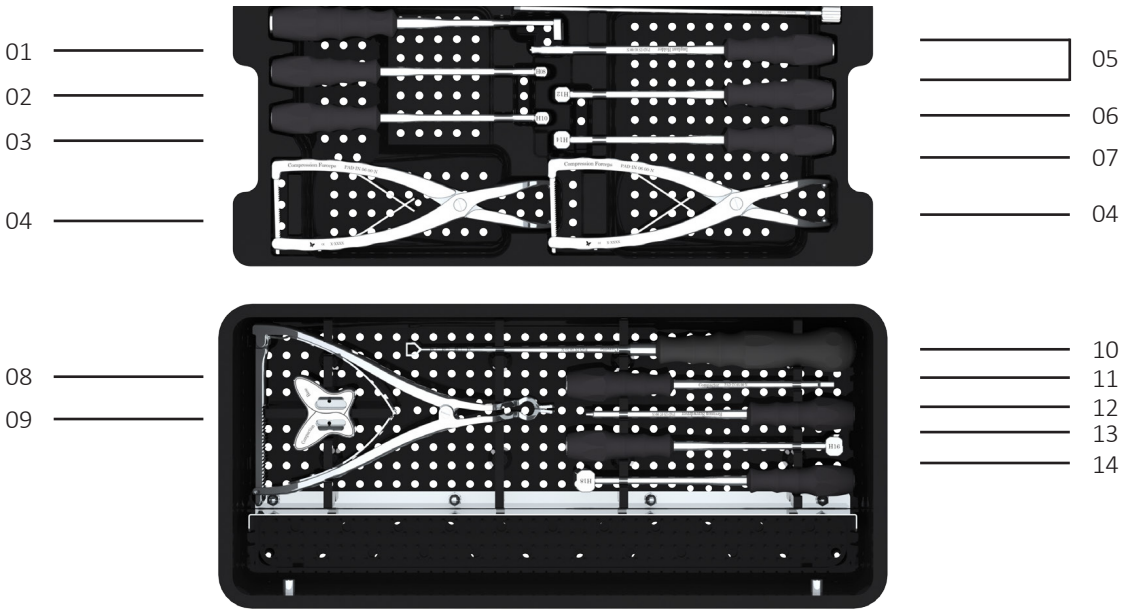


The size of the plate increases with the height of the implant
The plate surface in contact with the spinous processes remains constant

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 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
04	COMPRESSION FORCEPS	PAD-IN 06 00-N
05	IMPLANT HOLDER	PAD-IN 03 00-N
06	TRIAL H12	PAD-IN 02 12-N
07	TRIAL H14	PAD-IN 02 14-N
• 08	SPREADER	PAD-IN 09 00-N
09	COMPACTION BASE	PAD-IN 04 00-N
10	CURETTE	PAD-IN 08 00-N
11	COMPACTOR	PAD-IN 05 00-N
12	REVISION SCREWDRIVER	PAD-IN 07 00-N
• 13	TRIAL H16	PAD-IN 02 16-N
• 14	TRIAL H18	PAD-IN 02 18-N
•	SPINOUS PROCESS COMPRESSION FORCEPS	PAD-IN 12 00-N

• : OPTIONAL

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
TRIAL H16 (OPTIONAL)	PAD-IN 02 16-N
TRIAL H18 (OPTIONAL)	PAD-IN 02 18-N

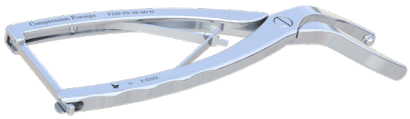
COMPACTION BASE	PAD-IN 04 00-N

SPINOUS PROCESS COMPRESSION FORCEPS (OPTIONAL)	PAD-IN 12 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

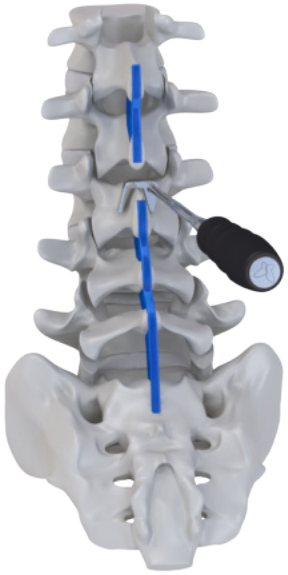
Position the patient in a prone position.

Perform a midline approach, resecting the supraspinous 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 soft tissue, muscle and ligament.

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.

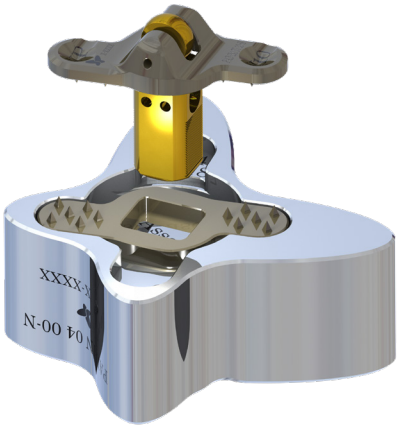
The **Spreader** can be used to distract and to facilitate the insertion.

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
TRIAL H16 (OPTIONAL)	PAD-IN 02 16-N
TRIAL H18 (OPTIONAL)	PAD-IN 02 18-N
SPREADER (OPTIONAL)	PAD-IN 09 00-N

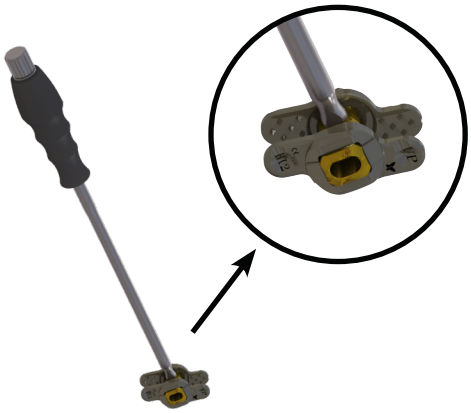
SURGICAL TECHNIQUE

_STEP 3

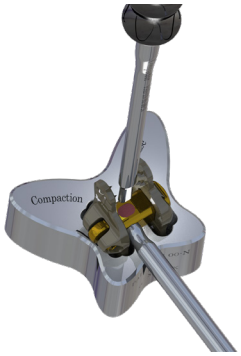
IMPLANT PREPARATION



Use the **Compaction Base** to clip the plate onto the core of the implant.



Connect the implant to the **Implant Holder** by screwing the threaded shaft into the 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

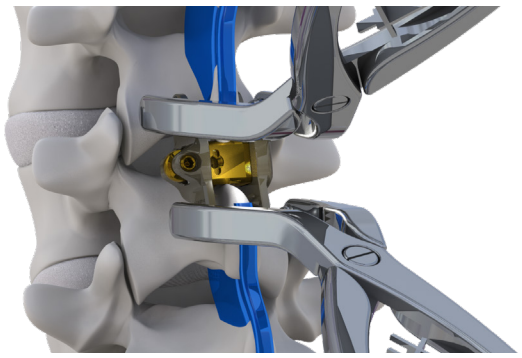
Insert the implant and place it in the desired position between the spinous processes.

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 (OPTIONAL)	PAD-IN 09 00-N

_STEP 5



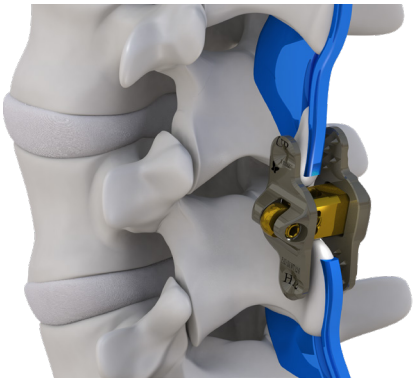
FINAL COMPRESSION

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.
The **Spinous Process Compression Forceps** could help compressing the spinous processes against the central core of the implant.

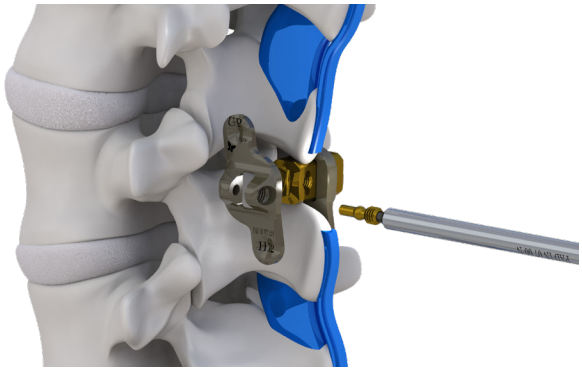
INSTRUMENT	REFERENCE
COMPRESSION FORCEPS	PAD-IN 06 00-N
SPINOUS PROCESS COMPRESSION FORCEPS (OPTIONAL)	PAD-IN 12 00-N

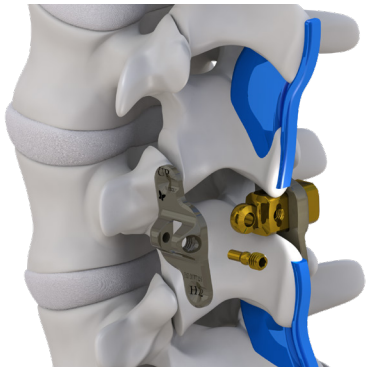
SURGICAL TECHNIQUE

_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

GENERAL INFORMATION

REFERENCE OF THE IFU	ROM-IF PD 00-US	REVISION OF THE FINAL IFU	V1-2017

_STERILITY

The implant is provided sterile.

Implants are packaged in a first polyethylene pouch, included in a second PETG blister.

Each packaging is labeled and an IFU is included.

_CAUTION

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the implant must not be used. The re-sterilization of the gamma sterilized implant is forbidden. The ROMEO®2 PAD Implant must only be used with the ROMEO®2 PAD instruments. Based on the testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the Posterior Axial Device.

US Caution Federal law restricts these devices to sale by or on the order of a physician.

_DESCRIPTION

ROMEO®2 PAD Posterior Axial Device is a spinous process fixation, designed to ensure the best possible adaptation to patient's anatomic variations.

ROMEO®2 PAD Posterior Axial Device range is composed of various sizes.

ROMEO®2 PAD implants are made of Titanium alloy.

_INDICATIONS

The ROMEO®2 PAD Posterior Axial Device is a posterior, non-pedicle supplemental fixation device, intended for use as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization as an adjunction to fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e.,fracture or dislocation) and /or tumor.

The ROMEO®2 PAD Posterior Axial Device is not intended for standalone use.

_CONTRAINDICATIONS

Include but not limited to:

- Allergy to titanium or foreign body sensitivity
- Known or suspected infection/immune system incompetence
- Any abnormality present which affects the normal process of bone remodeling, including but not limited to severe osteoporosis, bone absorption, osteopenia or active infection at the site
- Morbid obesity
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Open wounds
- Pregnancy
- Any medical or surgical condition which could preclude the potential benefit of spinal surgery
- Any case requiring the mixing of two different component systems
- Fever or leukocytosis (elevated white blood cell count)
- Signs of local infection or previous inflammation
- Previous history of infection
- Alcoholism or heavy smoking
- Senility, mental illness or substance abuse of such severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications
- Inability to follow post-operative instructions
- Inadequate tissue coverage over the operative site
- Incompetent or missing posterior arch

_WARNINGS

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

GENERAL INFORMATION

_SIDE EFFECTS

Per operative:

Haemostatic problems, injuries to the nervous system resulting in temporary or permanent weaknesses, pain or functional handicap, fractures.

Post operative:

Venous thrombosis and pulmonary embolism, infection, cardio-vascular disorders, hematoma and late wound healing.

Specific to implant:

Implant migration, adhesion and fibrosis, limited range of movement, secondary fractures.

Potential risk identified with the use of this Posterior Axial Device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

_CAUTION - PRECAUTIONS FOR USE

- The ROMEO®2 PAD Posterior Axial Device has not been evaluated for safety and compatibility in the MR environment. The ROMEO®2 PAD Posterior Axial Device has not been tested for heating or migration in the MR environment.
- Every surgeon who uses these implants must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case.
- Implants are technical devices that can be worn, damaged or broken. An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of inadequate size, and patient hyperactivity or a misuse will increase the risk of complications, including wear and tear or rupture.
- The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support the implant, thus causing instability and/or malformation. The benefits of this posterior osteosynthesis procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures. Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient. It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.

_HANDLING

When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device. Sharp-edged, serrated or toothed instruments should not be used.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful reconstruction. Surgeons are advised not to remove the device from its sterile packaging until after the implant site has been properly prepared and precise measurements have been taken.

_SURGERY METHODS

Precaution: The implantation of ROMEO®2 PAD Posterior Axial Device should be performed only by experienced surgeons with specific training in the use of such device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The surgeon is responsible for familiarizing himself/herself with the surgical technique used for implanting these devices, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used. We strongly recommend that excessive force should not be applied when installing any of the ROMEO®2 PAD implants.

A handbook on surgical techniques, describing the standard implant procedure, is available.

_PATIENT CARE FOLLOWING TREATMENT

Detailed instructions on the use and limitations of the device should be given to the patient. Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician. The patient should be

instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient.

_STORAGE CONDITION

It is mandatory that the implants are stored in their original packaging, in a clean, dry location where atmospheric pressure is moderate.

_INSTRUMENTATION

The instruments were specifically designed for use when installing the ROMEO®2 PAD Posterior Axial Device.

They are delivered non-sterile.

Trial implants have specific markings to facilitate identification of the adequate implant size.

_DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below.

Prior to starting the surgical procedure, all non sterile reusable instruments must be properly cleaned, decontaminated and sterilized.

The ROMEO®2 PAD instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments and not sterile implants.

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled will be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and thoroughly clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minutes. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and thoroughly clean for 2 minutes using soft-bristled brush at room temperature (+15/+25°C).
- Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Water	<45°	2 minutes
Cleaning	Water + Neutral enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Water	<45°	2 minutes
Rinsing	Tap water	<45°	2 minutes
Thermal disinfection	Reversed osmosis water	90°C	5 minutes

- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts will be activated during rinsing.
- Visually inspect devices.
- Dry using a soft, lint-free cloth.

Automatic disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 30 seconds, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled will be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and thoroughly clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 30 seconds. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts will be activated during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint-free cloth.

Sterilization trays cleaning and disinfection

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

• Subsequent sterilization in containers is then recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10-6.The validation for sterilization have been done according to overkill/half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report.

Sterilization parameters:

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave)

Cycle 1 (EU):

Minimum exposure time: 18 minutes

Minimum temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Minimum exposure time: 4 minutes

Minimum temperature: 132°C

Drying time: 30 minutes

GENERAL INFORMATION

This 134°C – 18 minutes sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

"Do not stack trays during sterilization"

• In order to assemble the implant holder, insert the shaft into the tube and turn the shaft until the end tip of the inner shaft comes out of the instrument. At the end of the surgery, reverse the procedure to disassemble the instrument for the cleaning and sterilization steps.

_MAINTENANCE AND REPAIR

Spineart® instruments are guaranteed for at least 150 steam sterilization runs.

Spineart® instruments that need to be repaired must be decontaminated and cleaned, then sent to the address mentioned in this document.

_FURTHER INFORMATION

If further directions for use of this system are needed, please check with the Spineart® Customer Service. If further information is needed or required, please see the addresses on this document.

N O T E

N O T E

N O T E

SPINEART

SPINEART US
23332 MILL CREEK DR. SUITE
150 LAGUNA HILLS,
CA 92653 USA

SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

MAY-2020-REF-PAD-TI-ST-US