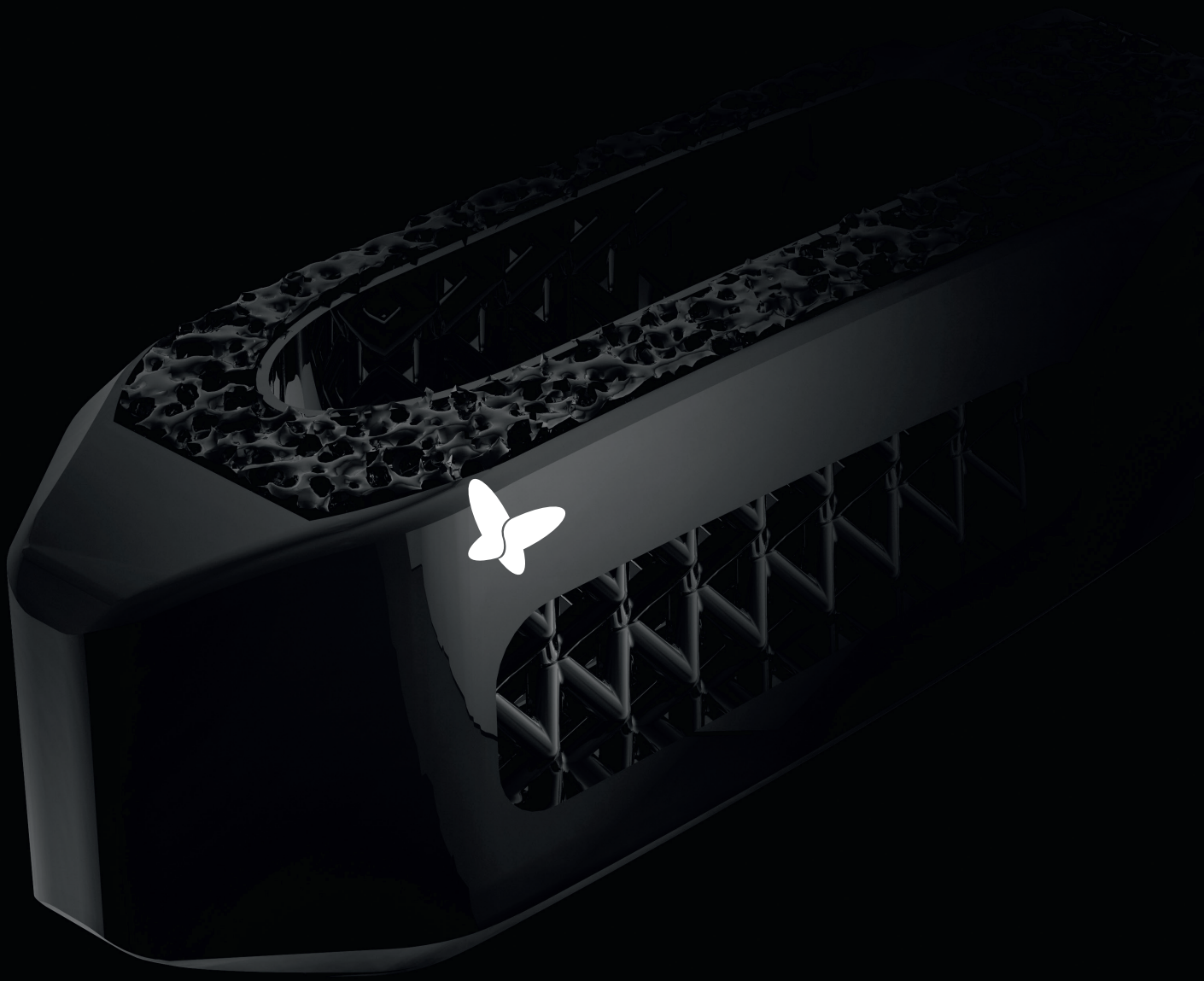


JULIET®Ti OL I/R

INSERT/ROTATE Ti CAGE

C O N T E N T

CONCEPT AND DESIGN

In 2006, to accompany the ROMEO® posterior fusion system, Spineart developed a range of interbody devices to achieve 360° fusion: the JULIET® interbody system. Named after William Shakespeare's characters Romeo and Juliet, the two systems complement each other perfectly.

The JULIET® PO, JULIET® OL, JULIET® AN and JULIET® TL are designed to be used with the ROMEO®2 system for a reliable, efficient and easy-to-use platform to achieve fusion.
Building on the success and experience acquired with our PEEK range, Spineart developed a new Titanium range, featuring the Ti-LIFE Technology, a state-of-the-art porous, interconnected structure replicating the trabecular bone geometry.

With each product development, Spineart is relentlessly driven by the same motto: Quality, Innovation and Simplicity.

AT A GLANCE

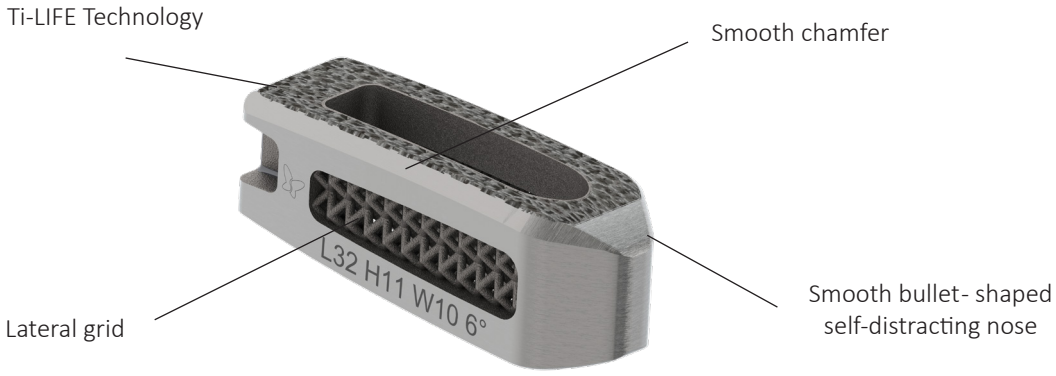
Ti-LIFE Technology
Insert/Rotate Technique
Anatomical Shape
Optimal Visualization

INDICATIONS

JULIET®Ti OL Insert/Rotate posterior lumbar cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1.
DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. JULIET®Ti OL Insert/Rotate posterior lumbar cages are to be used with supplemental fixation that has been cleared for use in the lumbosacral spine. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

IMPLANTS

JULIET®Ti OL INSERT/ROTATE



LORDOSIS 6°

HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L28	08	JIR-O6 28 09-S
H10	L28	09	JIR-O6 28 10-S
H11	L28	10	JIR-O6 28 11-S
H12	L28	10.5	JIR-O6 28 12-S
H13	L28	10.5	JIR-O6 28 13-S
H14	L28	10.5	JIR-O6 28 14-S

HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L32	08	JIR-O6 32 09-S
H10	L32	09	JIR-O6 32 10-S
H11	L32	10	JIR-O6 32 11-S
H12	L32	10.5	JIR-O6 32 12-S
H13	L32	10.5	JIR-O6 32 13-S
H14	L32	10.5	JIR-O6 32 14-S

LORDOSIS 12°

HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L28	08	JIR-OX 28 09-S
H10	L28	09	JIR-OX 28 10-S
H11	L28	10	JIR-OX 28 11-S
H12	L28	10.5	JIR-OX 28 12-S
H13	L28	10.5	JIR-OX 28 13-S
H14	L28	10.5	JIR-OX 28 14-S

HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L32	08	JIR-OX 32 09-S
H10	L32	09	JIR-OX 32 10-S
H11	L32	10	JIR-OX 32 11-S
H12	L32	10.5	JIR-OX 32 12-S
H13	L32	10.5	JIR-OX 32 13-S
H14	L32	10.5	JIR-OX 32 14-S

IMPLANTS

OPTIONAL

LORDOSIS 6°

HEIGHT	LENGTH	WIDTH	REFERENCE
H15	L28	10.5	JIR-O6 28 15-S
H16	L28	10.5	JIR-O6 28 16-S

HEIGHT	LENGTH	WIDTH	REFERENCE
H15	L32	10.5	JIR-O6 32 15-S
H16	L32	10.5	JIR-O6 32 16-S

HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L36	08	JIR-O6 36 09-S
H10	L36	09	JIR-O6 36 10-S
H11	L36	10	JIR-O6 36 11-S
H12	L36	10.5	JIR-O6 36 12-S
H13	L36	10.5	JIR-O6 36 13-S
H14	L36	10.5	JIR-O6 36 14-S
H15	L36	10.5	JIR-O6 36 15-S
H16	L36	10.5	JIR-O6 36 16-S

LORDOSIS 12°

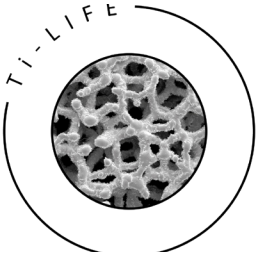
HEIGHT	LENGTH	WIDTH	REFERENCE
H15	L28	10.5	JIR-OX 28 15-S
H16	L28	10.5	JIR-OX 28 16-S

HEIGHT	LENGTH	WIDTH	REFERENCE
H15	L32	10.5	JIR-OX 32 15-S
H16	L32	10.5	JIR-OX 32 16-S

HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L36	08	JIR-OX 36 09-S
H10	L36	09	JIR-OX 36 10-S
H11	L36	10	JIR-OX 36 11-S
H12	L36	10.5	JIR-OX 36 12-S
H13	L36	10.5	JIR-OX 36 13-S
H14	L36	10.5	JIR-OX 36 14-S
H15	L36	10.5	JIR-OX 36 15-S
H16	L36	10.5	JIR-OX 36 16-S

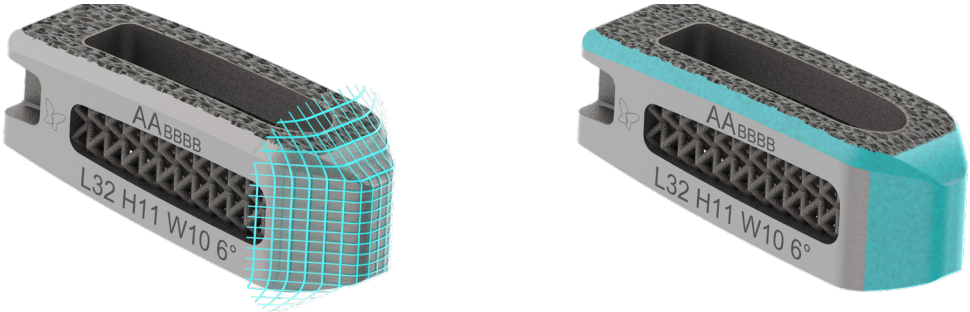
TECHNICAL FEATURES

Ti-LIFE Technology



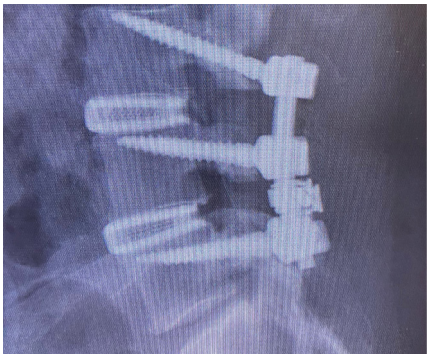
The structure replicates trabecular bone to support cell adhesion and bone ingrowth. This patented technology is based on a revolutionary algorithm associated with a state-of-the-art additive manufacturing process.

SMOOTH BULLET NOSE



The cages feature a smooth bullet selfdistracting nose and polished chamfer. This design is aimed for easy insertion, enabling distraction of the intervertebral space while mitigating the risk of damage to the endplates, nerve roots and soft tissue.

OPTIMAL VISUALIZATION



X-RAY image courtesy of: Connor J. Telles, M.D. | Sierra Pacific Orthopedics | California

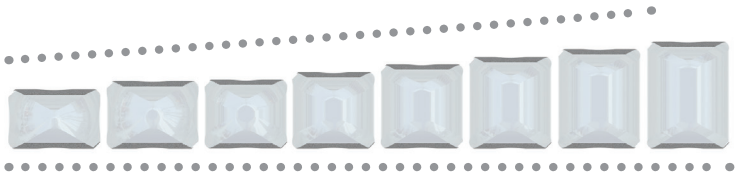
The JULIET®Ti OL I/R features an overall reduced density, optimizing medical imaging and postoperative evaluations.

TECHNICAL FEATURES

BONE GRAFT

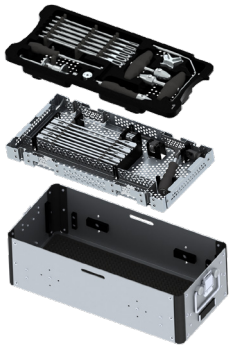
In addition to the properties of the Ti-Life Technology, the large windows allow for an extensive bone graft area.
Therefore 100 % of the cage surface is dedicated to bone fusion without compromising the mechanical properties of the cage.

COMPLETE RANGE



JULIET®Ti OL Insert/Rotate cages are available in a wide range of options, to address different patient anatomies, and various surgical approach techniques. For a detailed list of cages please refer to page 6 of this guide.

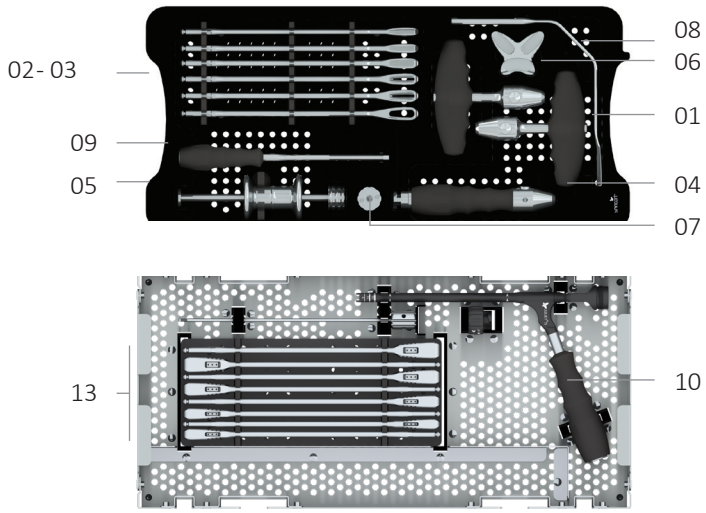
STREAMLINED AND COMPACT INSTRUMENTATION



The Combo instrument set provides a complete, modular and compact solution.

INSTRUMENT SET

JULIET®TI OL INSERT/ROTATE



UNIVERSAL CONTAINER

#	DESCRIPTION	REFERENCE
	BASE	JUL-BX 10 01-N

PREPARATION TRAY

#	DESCRIPTION	REFERENCE
	UNIVERSAL INSERT	JUL-BX 10 02-N
	UNIVERSAL RACK	JUL-BX 10 05-N
01	T-HANDLE	HAN-SI MD TE-N
02	PADDLE DISTRACTOR	JUL-IN 00 05-N JUL-IN 00 06-N JUL-IN 00 07-N
03	DISC SHAVER	JUL-IN 01 07-N JUL-IN 00 08-N JUL-IN 00 09-N JUL-IN 00 10-N JUL-IN 00 11-N JUL-IN 00 12-N JUL-IN 00 13-N JUL-IN 00 14-N
04	MODULAR STRAIGHT HANDLE	HAN-SI SH ST-N
05	SLAP HAMMER	HAN-SS SH 01-N
06	COMPACTION BASE	JUT-IN 00 01-N
07	IMPACTOR CAP	HAN-SS SH 02-N
08	NERVE ROOT RETRACTOR	DYN-IP 00 05-N
09	COMPACTOR	JUL-IN 14 00-N

PO/OL TRAY

	#	DESCRIPTION	REFERENCE
		JULIET® COMBO SET TRAY INSERT/ROTATE	JUL-BX 10 13-N
		JULIET® COMBO SET RACK INSERT/ROTATE	JUL-BX 10 14-N
	10	INSERT/ROTATE IMPLANT HOLDER	JIR-IN 00 02-N
●		CURETTE	JUL-IN 15 00-N
●		INTERLAMINA DISTRACTOR	DYN-IT 00 04-N
	13	TRIAL IMPLANT Ti PO/OL SMALL WIDTH	JUT-IN 02 09-N
		TRIAL JULIET®Ti PO/OL	JIR-IN 02 10-N JIR-IN 02 11-N
		TRIAL IMPLANT Ti PO/OL	JUT-IN 01 12-N JUT-IN 01 13-N JUT-IN 01 14-N JUT-IN 01 15-N JUT-IN 01 16-N
		TRIAL JULIET®Ti PO/OL	JIR-IN 07 09-N JIR-IN 07 10-N JIR-IN 07 11-N
		RASP PO/OL TRIAL IMPLANT	JUT-IN 07 12-N JUT-IN 07 13-N JUT-IN 07 14-N JUT-IN 07 15-N JUT-IN 07 16-N

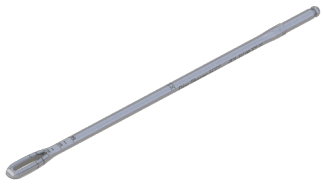
● : OPTIONAL

INSTRUMENTS

T-HANDLE	HAN-SI MD TE-N

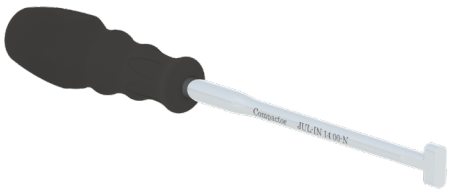
PADDLE DISTRACTOR	JUL-IN 00 XX-N

DISC SHAVER	JUL-IN 0X XX-N



MODULAR STRAIGHT HANDLE	HAN-SI SH ST-N

COMPACTOR	JUL-IN 14 00-N



SLAP HAMMER	HAN-SS SH 01-N

CURETTE	JUL-IN 15 00-N

COMPACTION BASE	JUT-IN 00 01-N

INSTRUMENTS

IMPACTOR CAP	HAN-SS SH 02-N

NERVE ROOT RETRACTOR	DYN-IP 00 05-N

TRIAL IMPLANT Ti PO/OL SMALL WIDTH	JUT-IN 02 09-N
TRIAL JULIET®Ti PO/OL	JIR-IN 02 10-N JIR-IN 02 11-N
TRIAL IMPLANT Ti PO/OL	JUT-IN 01 12-N JUT-IN 01 13-N JUT-IN 01 14-N JUT-IN 01 15-N JUT-IN 01 16-N
TRIAL JULIET®Ti PO/OL	JIR-IN 07 09-N JIR-IN 07 10-N JIR-IN 07 11-N
RASP PO/OL TRIAL IMPLANT	JUT-IN 07 12-N JUT-IN 07 13-N JUT-IN 07 14-N JUT-IN 07 15-N JUT-IN 07 16-N

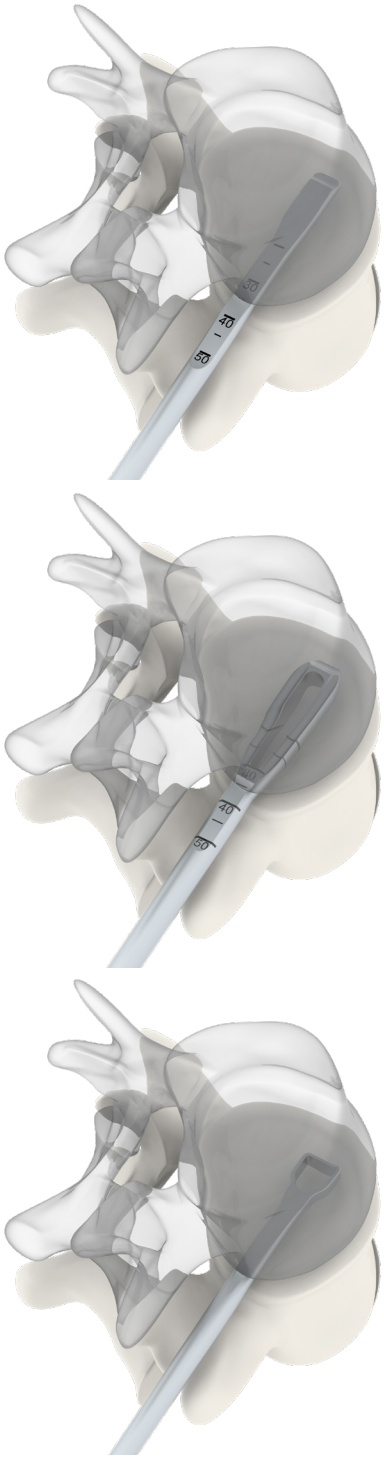
INSERT ROTATE IMPLANT HOLDER	JIR-IN 00 02-N

INTERLAMINAR DISTRACTOR	DYN-IT 00 04-N

SURGICAL TECHNIQUE

JULIET®TI OL INSERT/ROTATE

_STEP 1



DISCECTOMY AND PREPARATION OF THE ENDPLATES

Partially remove the facet joints. Once the approach is done, distract the disc space with the **Paddle Distractors**, previously assembled with the **Modular Straight Handle**, or the **T-Handle**, for a better rotation.

Proceed to the discectomy.

Prepare and freshen the endplates using the 1mm increment **Disc Shavers**. A **Curette** can also be used.

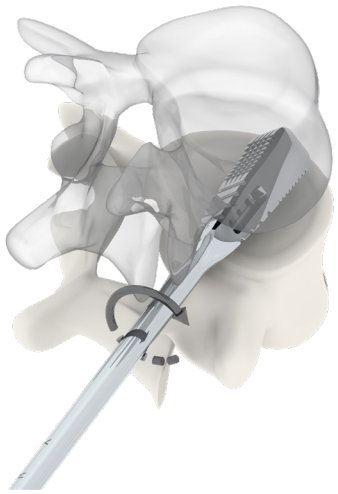
For an optimal protection of the dura, a **Nerve Root Retractor** is available.

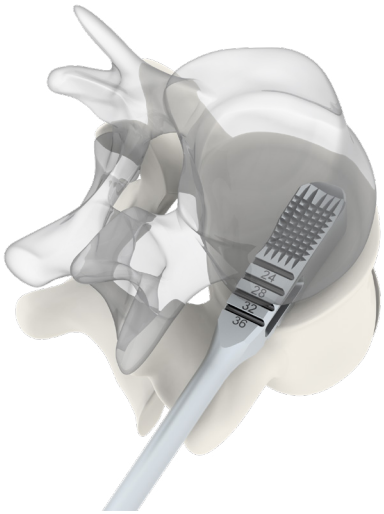
INSTRUMENT	REFERENCE
NERVE ROOT RETRACTOR	DYN-IP 00 05-N
CURETTE	JUL-IN 15 00-N
DISC SHAVER	JUL-IN 0X XX-N
PADDLE DISTRACTOR	JUL-IN 00 XX-N
T-HANDLE	HAN-SI MD TE-N
MODULAR STRAIGHT HANDLE	HAN-SI SH ST-N

SURGICAL TECHNIQUE

JULIET®TI OL INSERT/ROTATE

_STEP 2





SELECTION OF THE IMPLANT SIZE

To determine the right cage to implant, it is mandatory to use dedicated JULIET®Ti OL Insert/Rotate **Implant Trials**.

Each **Implant Trial** represents the 3 different lengths.

To insert the **Trial Implants**, the **Impactor Cap** can be connected to the **Modular Straight Handle** prior to gently hammering on the assembly.

The trial is inserted by the side - the rasp is not visible in this position.

Once the **Trial** is fully inserted, rotate the **Trial** at 90°.

Once satisfied with the selected trial size, proceed to fluoroscopic controls to confirm the correct sizing.

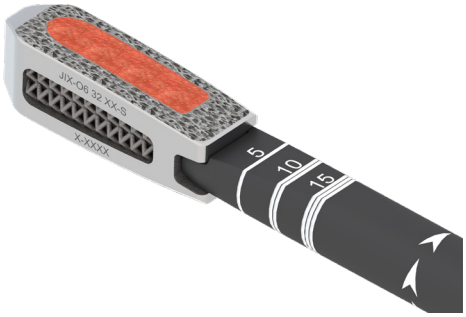
You can use the **Slap Hammer** to remove the **Implant Trial**.

NOTE: These **Implant Trials** can also be used to further rasp the endplates.

INSTRUMENT	REFERENCE
TRIAL IMPLANT Ti PO/OL SMALL WIDTH	JUT-IN 02 09-N
TRIAL JULIET®Ti PO/OL	JIR-IN 02 10-N JIR-IN 02 11-N
TRIAL IMPLANT Ti PO/OL	JUT-IN 01 12-N JUT-IN 01 13-N JUT-IN 01 14-N JUT-IN 01 15-N JUT-IN 01 16-N
TRIAL JULIET®Ti PO/OL	JIR-IN 07 09-N JIR-IN 07 10-N JIR-IN 07 11-N
RASP PO/OL TRIAL IMPLANT	JUT-IN 07 12-N JUT-IN 07 13-N JUT-IN 07 14-N JUT-IN 07 15-N JUT-IN 07 16-N
NERVE ROOT RETRACTOR	DYN-IP 00 05-N
MODULAR STRAIGHT HANDLE	HAN-SI SH ST-N
SLAP HAMMER	HAN-SS SH 01-N
IMPACTOR CAP	HAN-SS SH 02-N

_STEP 3

CAGE PREPARATION



Select the corresponding cage.

Connect it with the **Insert/Rotate Implant Holder**.

These spinal implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

INSTRUMENT	REFERENCE
INSERT/ROTATE IMPLANT HOLDER	JIR-IN 00 02-N
COMPACTION BASE	JUT-IN 00 01-N
COMPACTOR	JUL-IN 14 00-N

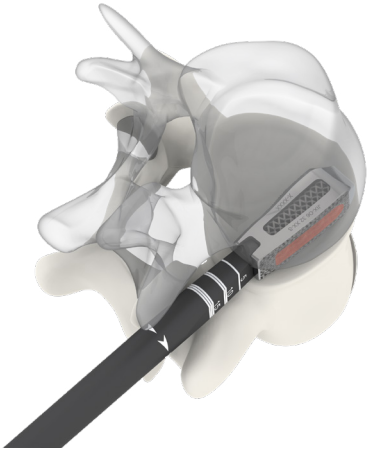
Insert the Inner Shaft of the Inserter into the Outer Shaft.

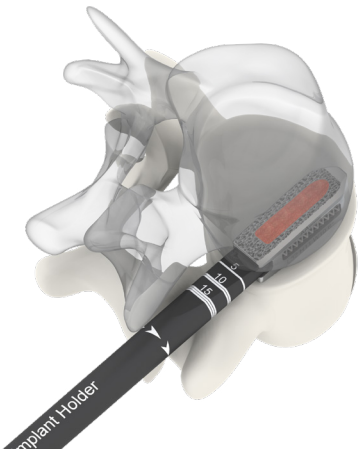
Screw counter clockwise the cap onto the Outer Shaft.

Align the inserter tip tabs with the recess on the implant.

Advance and rotate the Inserter knob clockwise to engage and secure the cage.

_STEP 4





INSERTION OF THE INSERT/ ROTATE CAGE

Insert the cage into the disc space while protecting the dura with the **Nerve Root Retractor**.

The cage is inserted by the side - the graft window is not visible in this position.

It is possible to gently hammer on the implant holder handle to ease the insertion of the implant.

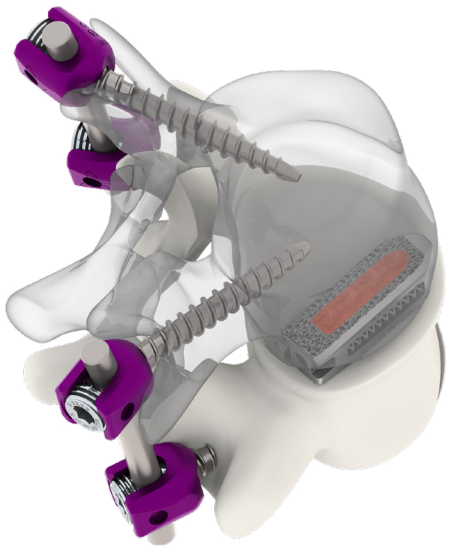
Once the cage is fully inserted, rotate the cage clockwise at 90°.

⚠ **WARNING:** Use fluoroscopy to confirm cage positioning before to proceed to the rotation.

NOTE: Placement angle of the JULIET®Ti OL Insert/Rotate is 40 degrees from the median plane.

INSTRUMENT	REFERENCE
NERVE ROOT RETRACTOR	DYN-IP 00 05-N
INSERT/ROTATE IMPLANT HOLDER	JIR-IN 00 02-N

_FINAL CONSTRUCT



Compression forceps should be used for final compression of the construct.

⚠ **WARNING:** The JULIET®Ti OL Insert/Rotate Interbody Devices are to be used with supplemental fixation, such as ROMEO® 2, ROMEO® 2 MIS and ROMEO®2 PAD.

_REVISION

Attach the Insert/Rotate implant holder to the JULIET®Ti OL Insert /Rotate cage.

If needed, the slap hammer can be used to remove the cage.

Attach the slap hammer to the insert/rotate implant holder and slide the slap hammer upward.

Repeat this motion until the implant is removed.

INSTRUMENT	REFERENCE
INSERT/ROTATE IMPLANT HOLDER	JIR-IN 00 02-N
SLAP HAMMER	HAN-SS SH 01-N

GENERAL INFORMATION

REFERENCE OF THE IFU	JUT-IR-IF-WW	REVISION OF THE FINAL IFU	DEC-2019

_STERILITY

The implant is provided sterile.

Implants are double packaged in a polyethylene pouch and a PETG blister.

Each package 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. Re-sterilization of the gamma sterilized implant is forbidden. The JULIET®Ti OL Insert/Rotate implant must only be used with JULIET® instruments.

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

Based on the dynamic testing result, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.

Do not use titanium and stainless steel components together.

Components of JULIET®Ti OL Insert/Rotate cage system should not be used withcomponents of any other system or manufacturer.

_DESCRIPTION

The JULIET®Ti OL Insert/Rotate implant range was designed to ensure the best possible adaptation to patient's anatomic variations.

JULIET®Ti OL Insert/Rotate posterior lumbar cages: lumbar implant used to perform fusion between lumbar vertebras after discectomy: Transforaminal approach.

The JULIET®Ti OL Insert/Rotate posterior lumbar cages are made of TA6V4 ELI Titanium alloy.

_INDICATIONS

JULIET®Ti OL Insert/Rotate posterior lumbar cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. JULIET®Ti OL Insert/Rotate posterior lumbar cages are to be used with supplemental fixation that has been cleared for use in the lumbosacral spine. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

_CONTRAINDICATIONS

- Mental illness.
- Infection.
- Severely damaged bone structures that could prevent stable implantation of the cage.
- Neuromuscular or vascular disorders or illness.
- Inadequate activity.
- Pregnancy
- Bone tumour in the region of implant
- Fractures

_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 cicatrisation

Specific to implant:

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

Potential risk identified with the use of this intervertebral body fusion 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 – PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with lumbar interbody fusion is beyond the scope of these instructions. 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 mechanical 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 lumbar interbody fusion 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.

_MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that SpineArt's Lumbar Interbody Cages are MR Conditional. A patient with a SpineArt Lumbar Interbody Cage can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 3,160 G/cm (31.6 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg at 1.5 T and 3 T.

RF Heating

Under the scan conditions defined above, SpineArt's Lumbar Interbody Cages are expected to produce a maximum temperature rise of less than 1.0 ºC after 15 minutes of continuous scanning at 1.5 T and less than or equal to 1.2 ºC after 15 minutes of continuous scanning at 3 T.

Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In non-clinical testing, the image artifact caused by SpineArt Lumbar Interbody Cages extends approximately 5.3 cm from the devices when imaged in a 3 T MRI system.

_HANDLING

Spineart® ensures that only the highest-quality materials and expertise have been deployed in producing each implant. 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. Metallic trial implants provided can be used to assess disc space and help in making this selection. 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 lumbar interbody cage should be performed only by experienced surgeons

with specific training in the use of this lumbar interbody cage because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The surgeon is responsible for familiarizing him/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 JULIET®Ti OL Insert/Rotate 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 CONDITIONS

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 JULIET®Ti OL Insert/Rotate implants.

They are delivered non-sterile.

Specific markings are engraved on each instrument to facilitate identification of the corresponding implant size.

Spineart® instruments are validated for 150 steam sterilization runs.

Prior to use all components should be checked for functionality and the absence of defects such as wear, tear, corrosion, pitting and discoloration to ensure that there is no damage.

Damaged components must not be used and should be returned to Spineart®.

_DECONTAMINATION, CLEANING, AND 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.

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 JULIET®Ti OL Insert/Rotate instruments have been designed in order to avoid disassembly manipulation prior

WASHER-DISINFECTOR PARAMETERS

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

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. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually 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 must be manipulated through their full range of motion during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually 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).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts must be manipulated through their full range of motion 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. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually 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 must be manipulated through their full range of motion 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 must be manipulated through their full range of motion 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.

GENERAL INFORMATION

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):

Exposure time: 18 minutes

Temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

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"

• The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described above, particularly before they are returned to Spineart®.

_MAINTENANCE AND REPAIR

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.

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