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

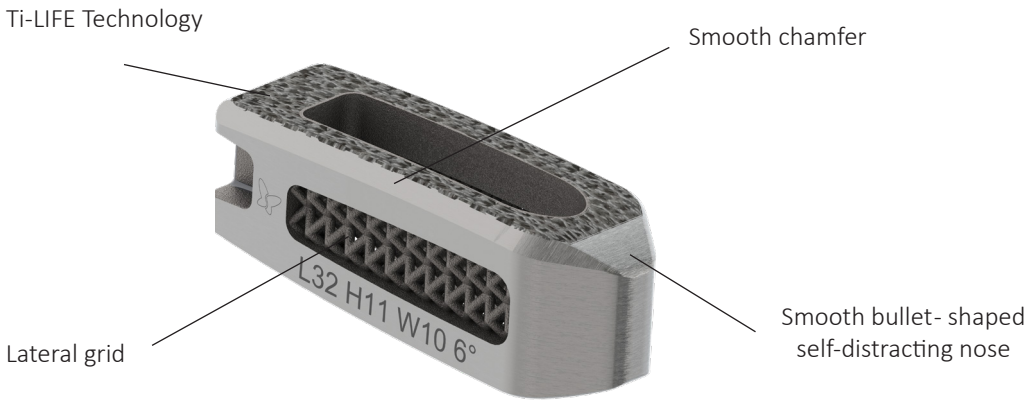
The JULIET®Ti OL Insert/Rotate range is indicated for arthrodesis of the lumbar spine at one level or two contiguous levels from L2 to S1 in patients with:

- Degenerative pathology, including symptomatic disc degeneration, recurrent hernia, degenerative spondylolisthesis;
- Isthmic spondylolisthesis;

These patients should be skeletally mature and have had six months of non-operative therapy. Supplemental fixation/stabilization as well as additional bone grafting material are required.

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
H15	L28	10.5	JIR-O6 28 15-S
H16	L28	10.5	JIR-O6 28 16-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
H15	L32	10.5	JIR-O6 32 15-S
H16	L32	10.5	JIR-O6 32 16-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
H15	L28	10.5	JIR-OX 28 15-S
H16	L28	10.5	JIR-OX 28 16-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
H15	L32	10.5	JIR-OX 32 15-S
H16	L32	10.5	JIR-OX 32 16-S

IMPLANTS

OPTIONAL

LORDOSIS 6°

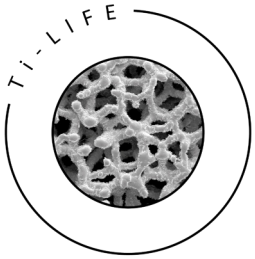
HEIGHT	LENGTH	WIDTH	REFERENCE
H09	L36	08	JIR-O6 36 09-S
H10	L36	09	JIR-O6 36 10-S
H11	L36	10	JIR-O6 36 11-S
H12	L36	10.5	JIR-O6 36 12-S
H13	L36	10.5	JIR-O6 36 13-S
H14	L36	10.5	JIR-O6 36 14-S
H15	L36	10.5	JIR-O6 36 15-S
H16	L36	10.5	JIR-O6 36 16-S

LORDOSIS 12°

HEIGHT	LENGTH	WIDTH	REFERENCE
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

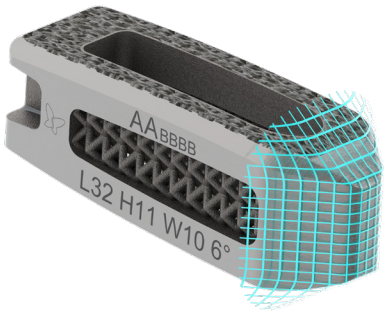
TECHNICAL FEATURES

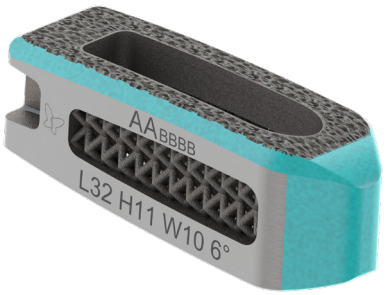
Ti-LIFE Technology



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.

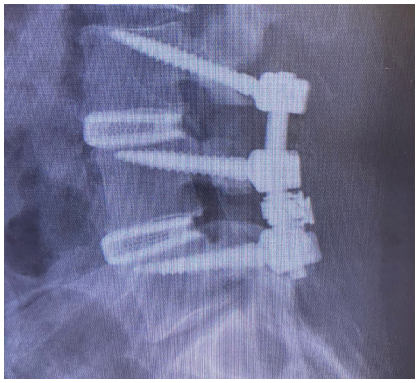
SMOOTH BULLET NOSE





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

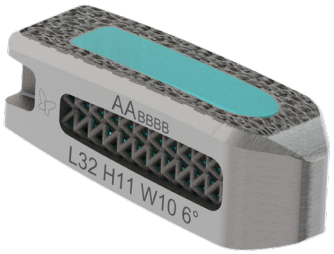


X-RAY image courtesy of: Connor J. Telles, M.D. | Sierra Pacific Orthopedics | California

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

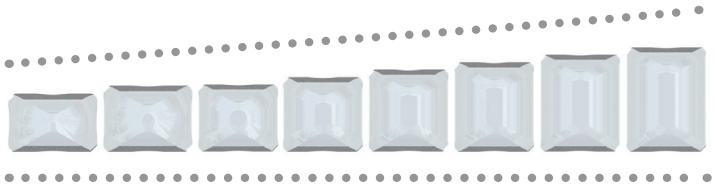
TECHNICAL FEATURES

BONE GRAFT



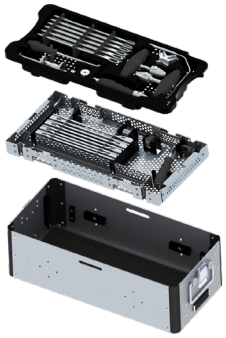
In addition to the properties of the Ti-Life Technology, the large windows allow for an extensive bone graft area.
Therefore 100 % of the cage surface is dedicated to bone fusion without compromising the mechanical properties of the cage.

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.

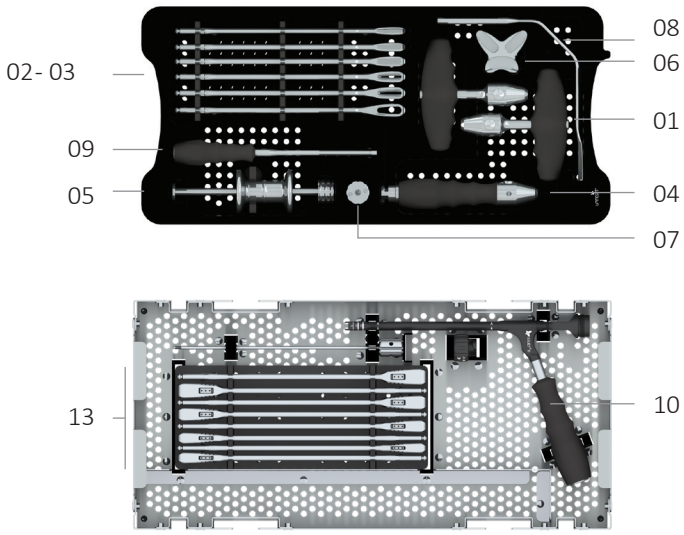
STREAMLINED AND COMPACT INSTRUMENTATION



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	DISC PADDLE	JUL-IN 00 05-N JUL-IN 00 06-N JUL-IN 00 07-N
03	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
	TRIAL IMPLANT Ti PO/OL SMALL WIDTH L36 W08 H09	JUT-IN 02 09-N
	TRIAL JULIET®Ti PO/OL W09 H10 6°	JIR-IN 02 10-N
	TRIAL JULIET®Ti PO/OL W10 H11 6°	JIR-IN 02 11-N
	TRIAL IMPLANT Ti PO/OL L36 W10.5 H12	JUT-IN 01 12-N
	TRIAL IMPLANT Ti PO/OL L36 W10.5 H13	JUT-IN 01 13-N
	TRIAL IMPLANT Ti PO/OL L36 W10.5 H14	JUT-IN 01 14-N
13	TRIAL IMPLANT Ti PO/OL L36 W10.5 H15	JUT-IN 01 15-N
	TRIAL IMPLANT Ti PO/OL L36 W10.5 H16	JUT-IN 01 16-N
	TRIAL JULIET®Ti PO/OL W08 H09 12°	JIR-IN 07 09-N
	TRIAL JULIET®Ti PO/OL W09 H10 12°	JIR-IN 07 10-N
	TRIAL JULIET®Ti PO/OL W10 H11 12°	JIR-IN 07 11-N
	RASP PO/OL TRIAL IMPLANT H12 12°	JUT-IN 07 12-N
	RASP PO/OL TRIAL IMPLANT H13 12°	JUT-IN 07 13-N
	RASP PO/OL TRIAL IMPLANT H14 12°	JUT-IN 07 14-N
	RASP PO/OL TRIAL IMPLANT H15 12°	JUT-IN 07 15-N
	RASP PO/OL TRIAL IMPLANT H16 12°	JUT-IN 07 16-N

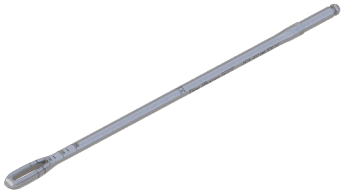
● : OPTIONAL

INSTRUMENTS

T-HANDLE	HAN-SI MD TE-N

DISC PADDLE	JUL-IN 00 XX-N

DISC SHAVERS	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 L36 W08 H09	JUT-IN 02 09-N
TRIAL JULIET®Ti PO/OL W09 H10 6°	JIR-IN 02 10-N
TRIAL JULIET®Ti PO/OL W10 H11 6°	JIR-IN 02 11-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H12	JUT-IN 01 12-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H13	JUT-IN 01 13-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H14	JUT-IN 01 14-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H15	JUT-IN 01 15-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H16	JUT-IN 01 16-N
TRIAL JULIET®Ti PO/OL W08 H09 12°	JIR-IN 07 09-N
TRIAL JULIET®Ti PO/OL W09 H10 12°	JIR-IN 07 10-N
TRIAL JULIET®Ti PO/OL W10 H11 12°	JIR-IN 07 11-N
RASP PO/OL TRIAL IMPLANT H12 12°	JUT-IN 07 12-N
RASP PO/OL TRIAL IMPLANT H13 12°	JUT-IN 07 13-N
RASP PO/OL TRIAL IMPLANT H14 12°	JUT-IN 07 14-N
RASP PO/OL TRIAL IMPLANT H15 12°	JUT-IN 07 15-N
RASP PO/OL TRIAL IMPLANT H16 12°	JUT-IN 07 16-N

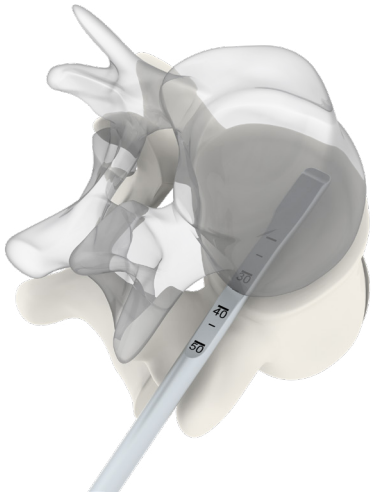
INSERT ROTATE IMPLANT HOLDER	JIR-IN 00 02-N

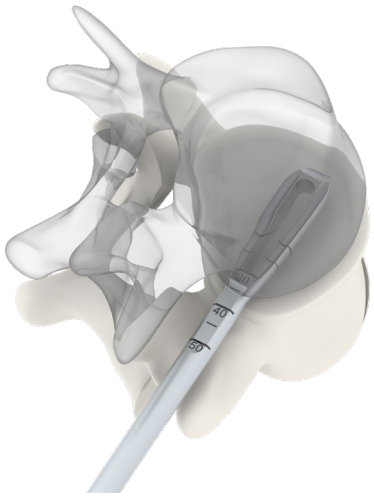
INTERLAMINAR DISTRACTOR	DYN-IT 00 04-N

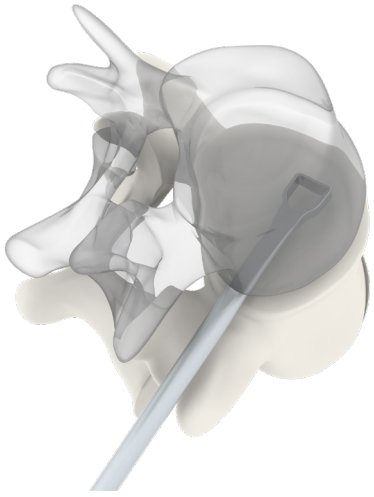
SURGICAL TECHNIQUE

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 Modular Paddle Distractor, 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.

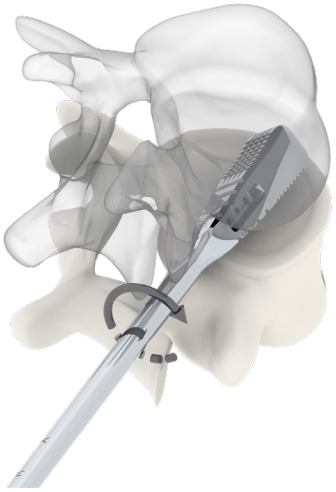
For an optimal protection of the dura, a **Nerve Root Retractor** is available.

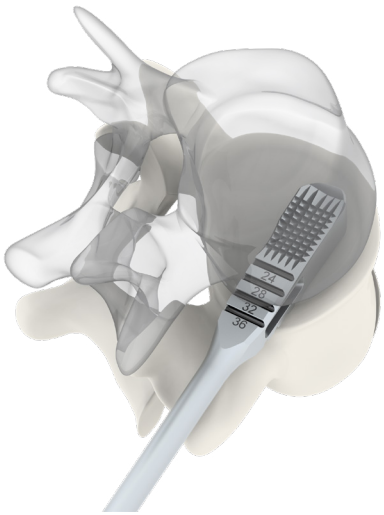
INSTRUMENT	REFERENCE
NERVE ROOT RETRACTOR	DYN-IP 00 05-N
CURETTE	JUL-IN 15 00-N
DISC SHAVER	JUL-IN 0X XX-N
PADDLE DISTRACTOR	JUL-IN 00 XX-N
T-HANDLE	HAN-SI MD TE-N
MODULAR STRAIGHT HANDLE	HAN-SI SH ST-N

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 **Implant Trials**, physicians can connect the Impactor Cap to the **Modular Straight Handle** to gently hammer 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 L36 W08 H09	JUT-IN 02 09-N
TRIAL JULIET®Ti PO/OL W09 H10 6°	JIR-IN 02 10-N
TRIAL JULIET®Ti PO/OL W10 H11 6°	JIR-IN 02 11-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H12	JUT-IN 01 12-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H13	JUT-IN 01 13-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H14	JUT-IN 01 14-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H15	JUT-IN 01 15-N
TRIAL IMPLANT Ti PO/OL L36 W10.5 H16	JUT-IN 01 16-N
TRIAL JULIET®Ti PO/OL W08 H09 12°	JIR-IN 07 09-N
TRIAL JULIET®Ti PO/OL W09 H10 12°	JIR-IN 07 10-N
TRIAL JULIET®Ti PO/OL W10 H11 12°	JIR-IN 07 11-N
RASP PO/OL TRIAL IMPLANT H12 12°	JUT-IN 07 12-N
RASP PO/OL TRIAL IMPLANT H13 12°	JUT-IN 07 13-N
RASP PO/OL TRIAL IMPLANT H14 12°	JUT-IN 07 14-N
RASP PO/OL TRIAL IMPLANT H15 12°	JUT-IN 07 15-N
RASP PO/OL TRIAL IMPLANT H16 12°	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

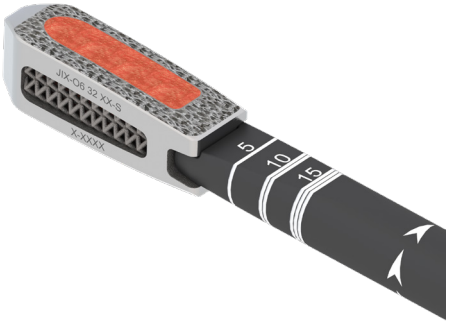
CAGE PREPARATION

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



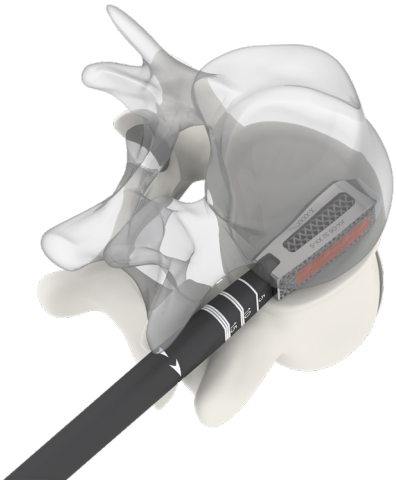
Insert the Inner Shaft of the Inserter into the Outer Shaft.

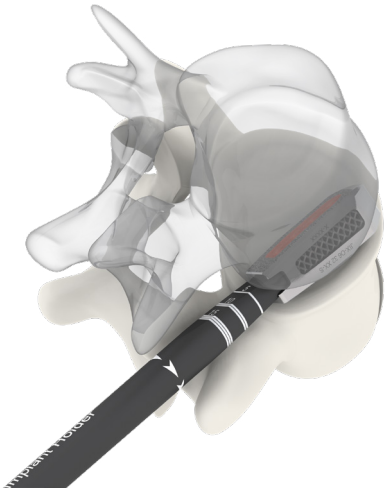
Screw counter clockwise the cap onto the Outer Shaft.

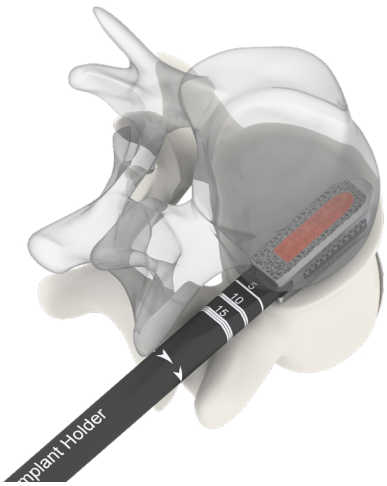
Align the inserter tip tabs with the recess on the implant.

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.

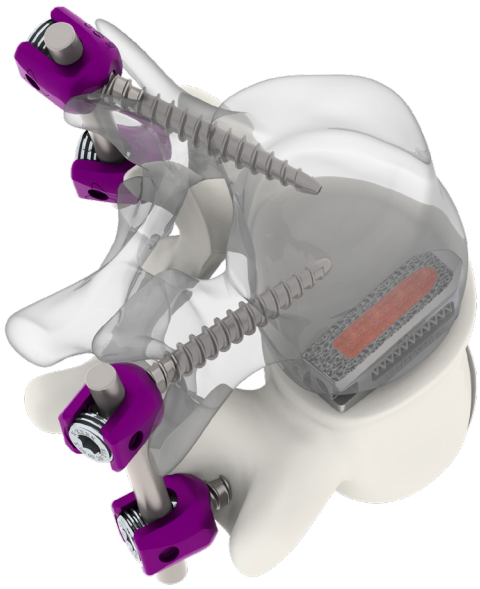
Once the cage is fully inserted, rotate the cage clockwise at 90°.

⚠ **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 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 Pedicle screw system.

_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.

GENERAL INFORMATION

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

_STERILITY

JULIET®Ti OL Insert/Rotate posterior lumbar cages are single-use devices delivered sterile. Reprocessing of the implant is strictly forbidden and would expose the patient to risks of serious health deterioration. If the implant or its packaging seems to be damaged, if the expiry date is exceeded or in the event that sterility cannot be guaranteed, the device shall not be implanted. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The implant must be discarded. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. Such re-use may also result in infection in the patient.

JULIET® instruments are reusable devices and delivered non-sterile. Prior to usage, JULIET® instrumentation shall be processed according to the procedure detailed in the section “Decontamination, cleaning and sterilization”.

Please refer to the individual package labeling.

_DESCRIPTION

JULIET®Ti OL Insert/Rotate posterior lumbar cages are designed for lumbar spinal arthrodesis. It comprises a medical grade titanium alloy (Ti-6Al-4V) bullet-shaped body and a central cavity to accommodate bone-filling material. In addition, in view to accommodate to anatomic variability, JULIET®Ti OL Insert/Rotate posterior lumbar cages are available in several height, length, width and lordosis angulation.

JULIET®Ti OL Insert/Rotate posterior lumbar cages shall exclusively be implanted using JULIET® instrumentation. Specific marking is engraved on each instrument to facilitate identification of the corresponding implant size.

_INDICATIONS

The JULIET®Ti OL Insert/Rotate range is indicated for arthrodesis of the lumbar spine at one level or two contiguous levels from L2 to S1 in patients with:

- Degenerative pathology, including symptomatic disc degeneration, recurrent hernia, degenerative spondylolisthesis;
- Isthmic spondylolisthesis;

These patients should be skeletally mature and have had six months of non-operative therapy. Supplemental fixation/stabilization as well as additional bone grafting material are required.

_CONTRAINDICATIONS

JULIET®Ti OL Insert/Rotate interbody devices are contraindicated as follows:

- Spondylolisthesis Grade II or higher;
- Burst fracture and/or comminuted vertebral body and/or endplate fracture;
- Metal sensitivity/allergies to the implant materials;
- Osteoporosis, insufficient vertebral bone quality and/or bone tumor;
- Mental illness or patient hyperactivity;
- Neuromuscular and/or vascular disorders or illness;
- Pregnancy;

_SIDE EFFECTS

Perioperative:

Hemostatic problems, nervous injury resulting into temporary or permanent neurological disorders, fractures, and dural tear.

Postoperative:

Venous thrombosis, pulmonary embolism, cardio-vascular disorders, superficial infection, hematoma and wound complications.

Serious adverse device effects:

Foreseeable clinical risks that may require additional surgery: implant migration, subsidence, pseudarthrosis (i.e. non-union), deep infection, hematoma, neurological disorder, and persistent pain.

GENERAL INFORMATION

_WARNINGS

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should implant lumbar interbody cages. 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. Abnormal use of the device may lead to risks of serious injury and/or health deterioration of the patient.

The safety and effectiveness of oblique (posterolateral) interbody devices have only been established with supplemental posterior fixation and in combination with additional bone grafting material.

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 arthrodesis procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures. Patients undergoing lumbar spinal arthrodesis shall, therefore, be informed.

Significant weight on the implant, patient hyperactivity or abnormal behavior may increase clinical risks and require secondary surgery. Patient who underwent this type of procedure shall, therefore, be informed of the residual clinical risks.

In rare cases, the patient may have or develop hypersensitivity to medical grade titanium alloy.

_MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that SpineArt's Cervical and Lumbar Interbody Cages are MR Conditional. A patient with a SpineArt Cervical or 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 Cervical and 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 Cervical and Lumbar Interbody Cages extends approximately 5.3 cm from the devices when imaged in a 3 T MRI system.

_SURGERY METHODS

The implantation of an implant should be performed only by experienced surgeons with specific training in the use of this implant because this is a technically demanding procedure presenting 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.

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.

The surgical procedure is standard for experienced surgeons. Your local representative should have communicated the handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly Spineart®.

_HANDLING PRECAUTIONS

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing each implant.

GENERAL INFORMATION

Implants are mechanical devices that can be worn, damaged or broken. 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.

Surgeons are advised not to remove the device from its sterile packaging until the implant site has been properly prepared and precise measurements have been taken.

We strongly recommend that excessive force should not be applied when installing any of the implants.

_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.

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

_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.

These 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 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 minute. 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 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 will be activated during rinsing.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

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

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 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 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 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

“Do not stack trays during sterilization”

_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

S P I N E A R T

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

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