TRYPTIK® Ti

CERVICAL Ti CAGE

CONTENT

CONCEPT AND DESIGN

The TRYPTIK® CA cervical cage was the first-ever Spineart device implanted in 2005.

Building on the success and experience of this PEEK cervical cage, Spineart developed a titanium cervical cage featuring Ti-LIFE Technology, an enhanced algorithm for additive manufacturing of titanium cages with a bone-like matrix.

As with each Spineart product developed, TRYPTIK®Ti Cervical Cages have been designed with surgeons in accordance with same Spineart's philosophy:
Quality, Innovation, Simplicity.

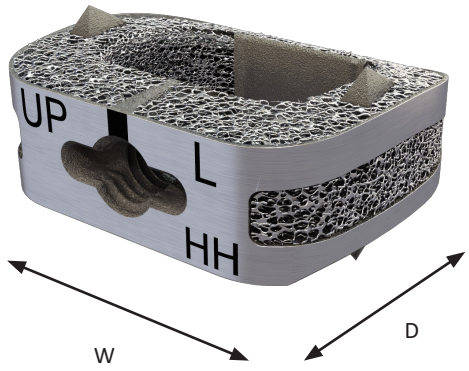
AT A GLANCE

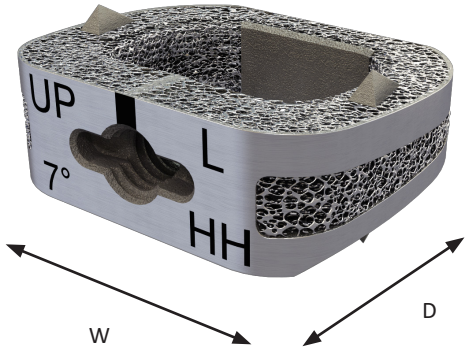
Ti-LIFE Technology
Anatomic or Lordotic Shape
Optimal Visualization
Stabilizing & Securing Fins

INDICATIONS

TRYPTIK®Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous disc levels from C2 to T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK®Ti is used to facilitate intervertebral body fusion in the cervical spine using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. TRYPTIK®Ti is to be used with supplemental fixation that has been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

IMPLANTS





ANATOMIC CAGE - SMALL D12 MM X W15 MM

	HEIGHT (MM)	REFERENCE
•	4.5	TRY-TC SM 45-S
	5	TRY-TC SM 50-S
	6	TRY-TC SM 60-S
	7	TRY-TC SM 70-S
	8	TRY-TC SM 80-S
•	9	TRY-TC SM 90-S
•	10	TRY-TC SM 10-S

LORDOTIC CAGE - SMALL D12 MM X W15 MM

	HEIGHT (MM)	REFERENCE
•	4.5	TRY-TL SM 45-S
	5	TRY-TL SM 50-S
	6	TRY-TL SM 60-S
	7	TRY-TL SM 70-S
	8	TRY-TL SM 80-S
•	9	TRY-TL SM 90-S
•	10	TRY-TL SM 10-S

ANATOMIC CAGE - LARGE D14 MM X W17MM

	HEIGHT (MM)	REFERENCE
•	4.5	TRY-TC LA 45-S
	5	TRY-TC LA 50-S
	6	TRY-TC LA 60-S
	7	TRY-TC LA 70-S
	8	TRY-TC LA 80-S
•	9	TRY-TC LA 90-S
•	10	TRY-TC LA 10-S

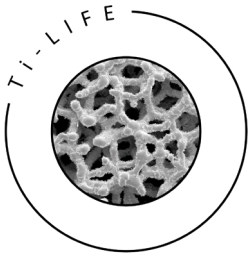
LORDOTIC CAGE - LARGE D14 MM X W17MM

	HEIGHT (MM)	REFERENCE
•	4.5	TRY-TL LA 45-S
	5	TRY-TL LA 50-S
	6	TRY-TL LA 60-S
	7	TRY-TL LA 70-S
	8	TRY-TL LA 80-S
•	9	TRY-TL LA 90-S
•	10	TRY-TL LA 10-S

• : OPTIONAL

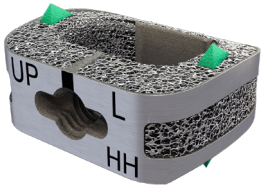
TECHNICAL FEATURES

Ti-LIFE TECHNOLOGY



Ti-Life structures have an average pore diameter and overall porosity similar to trabecular bone, which may enable cell colonization and promote bone ingrowth[123],
This technology is based on an enhanced algorithm for additive manufacturing commonly known as 3D printing.

STABILIZING AND SECURING FINS



Upper and lower fins improve primary stability.

OPTIMAL VISUALIZATION

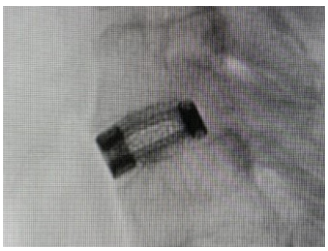


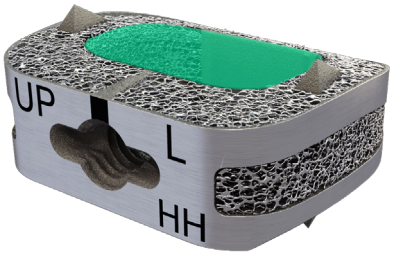
Image on specimen

Decreased cage density allows optimal visualization.

1. In Vivo performance of selective electron beam-melted Ti-&Al-4V structures Ponader, S et al.,2010
2. Evaluation of biological properties of electron beam melted Ti6al4V implant with biomimetic coating in vitro and in vivo. Li, X et al., 2012
3. Porous titanium-6 aluminium-4 vandium cage has better osseointegration and less micromotion than a poly-ether-etherketone cage in sheep vertebral fusion. Wu, S.-H.,et al., 2013

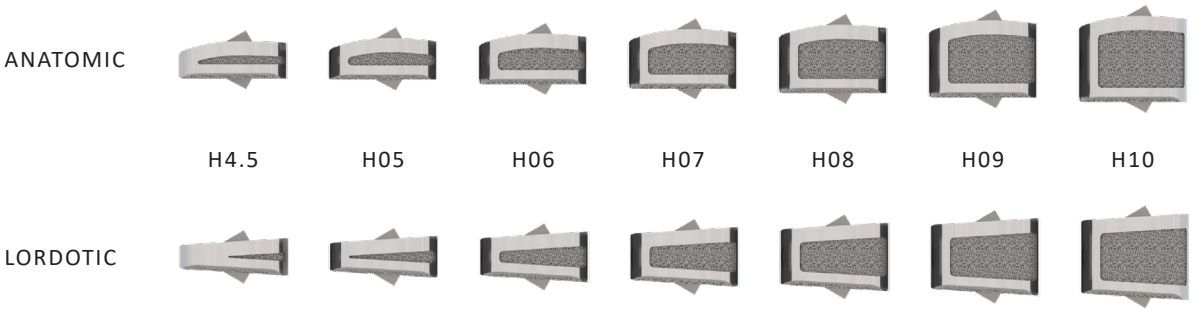
TECHNICAL FEATURES

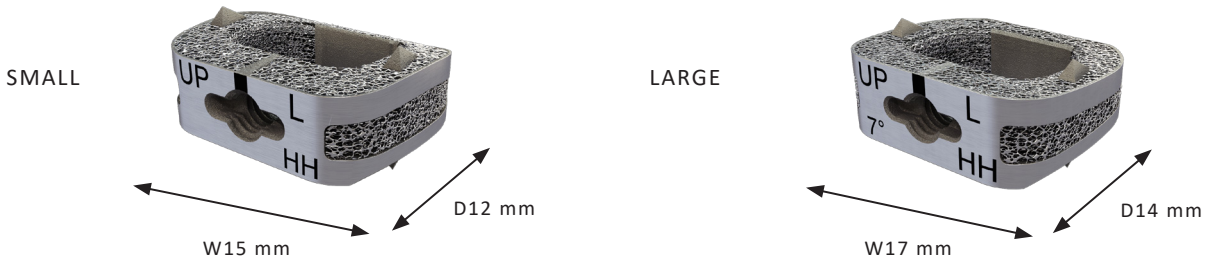
BONE GRAFT WINDOW



The central opening provides a large bone graft area for bone fusion without compromising structural integrity of the cage

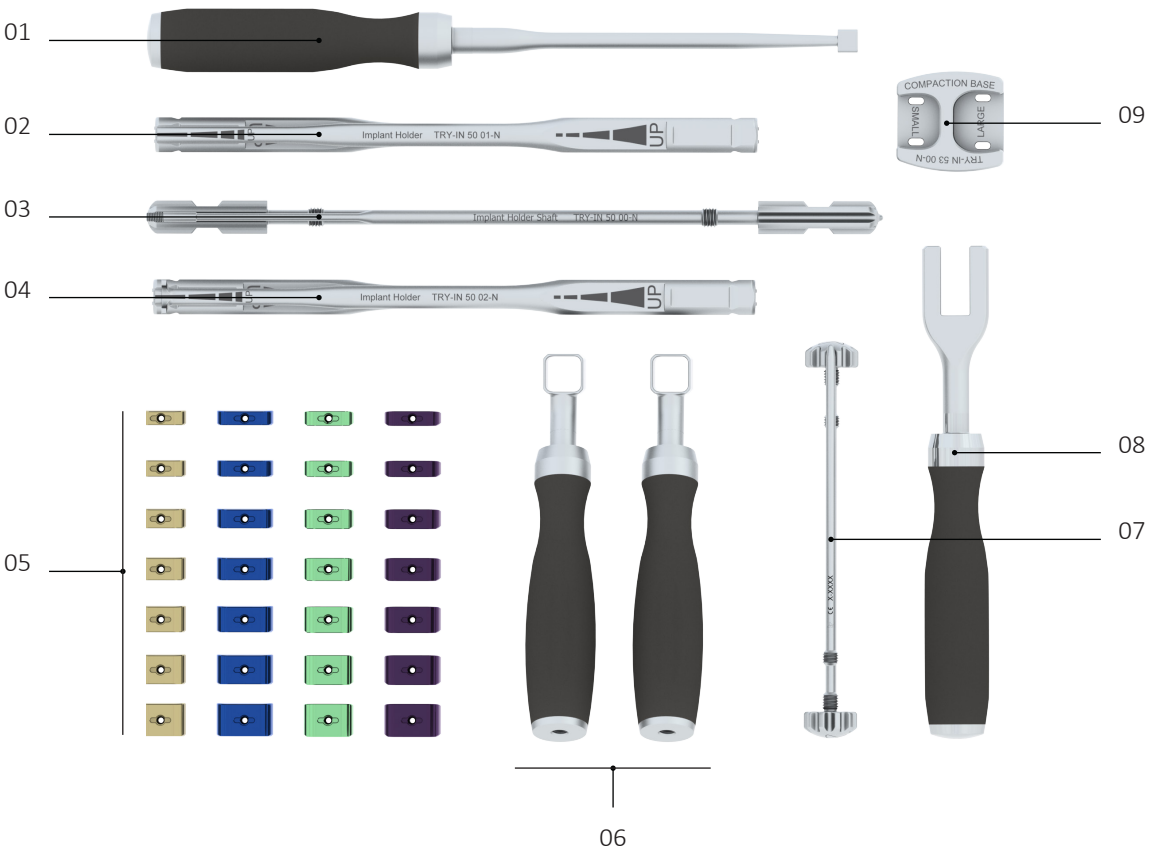
COMPREHENSIVE IMPLANT RANGE





TRYPTIK®Ti cages are available in a wide range of options to better address variable patient anatomy and surgeon preferences. For a detailed list of cages please refer to page 6 of this guide.

INSTRUMENT SET



#	DESCRIPTION	REFERENCE
	TRYPTIK Ti-LIFE INSTRUMENT BOX	TRY-BX 10 01-N
01	COMPACTOR	TRY-IN 52 00-N
02	IMPLANT HOLDER	TRY-IN 50 01-N
03	IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
04	IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N
05	ANATOMIC RASP TRIAL SMALL H4.5-H08 (GOLD)	TRY-00 RS XX-N
05	ANATOMIC RASP TRIAL LARGE H4.5-H08 (BLUE)	TRY-00 RL XX-N
• 05	ANATOMIC RASP TRIAL SMALL H09-H10 (GOLD)	TRY-00 RS XX-N
• 05	ANATOMIC RASP TRIAL LARGE H09-H10 (BLUE)	TRY-00 RL XX-N
05	LORDOTIC SMOOTH TRIAL SMALL H4.5-H08 (GREEN)	TRY-07 SS XX-N
05	LORDOTIC SMOOTH TRIAL LARGE H4.5-H08 (PURPLE)	TRY-07 SL XX-N
• 05	LORDOTIC SMOOTH TRIAL SMALL H09-H10 (GREEN)	TRY-07 SS XX-N
• 05	LORDOTIC SMOOTH TRIAL LARGE H09-H10 (PURPLE)	TRY-07 SL XX-N
• 05	ANATOMIC SMOOTH TRIAL SMALL H4.5-H10 (GOLD)	TRY-00 SS XX-N
• 05	ANATOMIC SMOOTH TRIAL LARGE H4.5-H10 (BLUE)	TRY-00 SL XX-N
06	SILICONE HANDLE	TRY-IN 51 02-N
07	HANDLE SHAFT	TRY-IN 51 00-N
08	EXTRACTION MALLET	TRY-IN 54 00-N
09	COMPACTION BASE	TRY-IN 53 00-N
•	3D PRINTED HANDLE	TRY-IN 51 01-N

• : OPTIONAL

INSTRUMENTS

IMPLANT HOLDER SHAFT	TRY-IN 50 00-N

IMPLANT HOLDER	TRY-IN 50 01-N

IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N

HANDLE SHAFT	TRY-IN 51 00-N

3D PRINTED HANDLE	TRY-IN 51 01-N

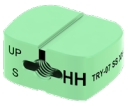
SILICONE HANDLE	TRY-IN 51 02-N

COMPACTOR	TRY-IN 52 00-N

COMPACTION BASE	TRY-IN 53 00-N

EXTRACTION MALLET	TRY-IN 54 00-N

LORDOTIC SMOOTH TRIAL SMALL/ LARGE H4.5-H10	TRY-07 SS XX-N TRY-07 SL XX-N



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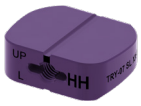
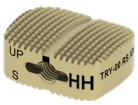


LARGE

ANATOMIC RASP TRIAL SMALL/LARGE H4.5-H10	TRY-00 RS XX-N TRY-00 RL XX-N



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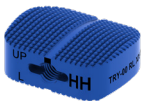
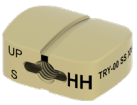


LARGE

ANATOMIC SMOOTH TRIAL SMALL/ LARGE H4.5-H10	TRY-00 SS XX-N TRY-00 SL XX-N



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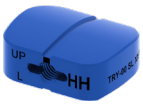
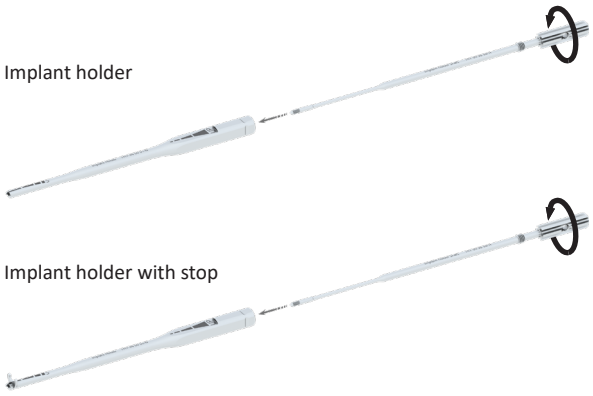


LARGE

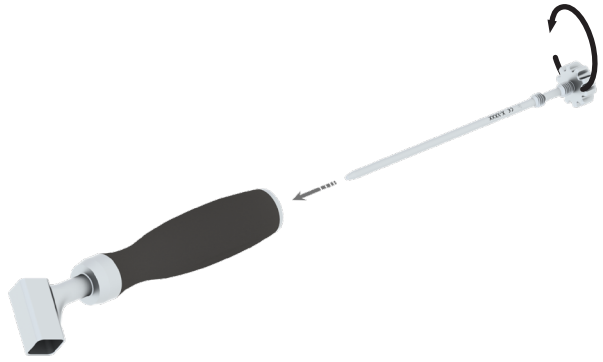
INSTRUMENT ASSEMBLY



IMPLANT HOLDER ASSEMBLY

Slide the implant holder shaft into the implant holder or implant holder with stop and rotate the knob clockwise.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N



HANDLE ASSEMBLY

Insert the handle shaft into the handle and rotate the knob clockwise to secure.

INSTRUMENT	REFERENCE
HANDLE SHAFT	TRY-IN 51 00-N
SILICONE HANDLE	TRY-IN 51 02-N
3D PRINTED HANDLE	TRY-IN 51 01-N

Figure A

HANDLE ATTACHMENT

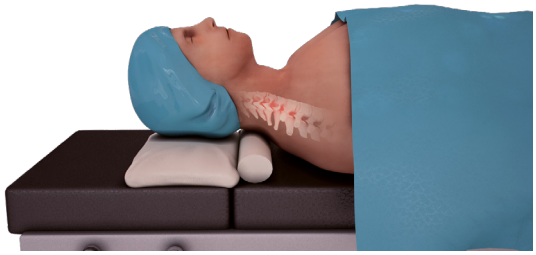
Align and insert the handle into the selected implant holder. Rotate the knurl clockwise to secure the handle.
The handle can be connected in various positions (Figure A).
Orient the Handle, per surgeon preference, onto the Implant Holder. Rotate the knob clockwise to secure the handle.

PRECAUTIONS: Confirm that the connection is secured.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N
HANDLE SHAFT	TRY-IN 51 00-N
SILICONE HANDLE	TRY-IN 51 02-N
3D PRINTED HANDLE	TRY-IN 51 01-N

SURGICAL TECHNIQUE

_STEP 1



PATIENT POSITIONING

The patient is positioned on the operating table in the supine position.

A pillow can be positioned under the neck to preserve lordosis.

_STEP 2

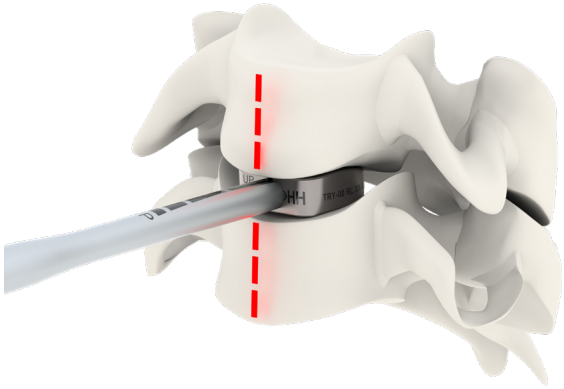


Figure A
Implant holder

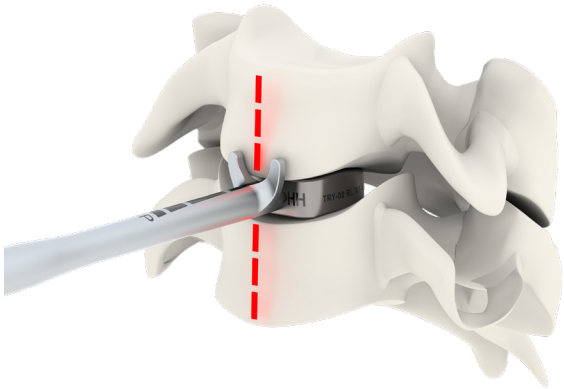


Figure B
Implant holder with stop

PREPARATION OF THE ENDPLATES AND SELECTION OF CAGE SIZE

Disc material is removed and endplates are prepared using various instruments: curettes, burrs, or rasps.

Attach the trial to the implant holder by rotating the implant holder shaft clockwise. The implant holder is available with and without a stop.

NOTE: The handle can be attached to the implant holder for ease of handling (see Instrument Assembly, page 11).

Use the trials to help determine the appropriate cage width, depth and height. The shortest trial height should be inserted first.

Lines on the implant holder help center the trial within the vertebral body (see Figures A & B).

Under AP fluoroscopy, the trial is gently impacted into the disc space. Trial heights are progressively increased until a snug fit within the disc space.

Proper implant position and fit are verified using AP and lateral fluoroscopic images.

Implant height will correspond to the last trial size used.

PRECAUTIONS: Avoid excessive impaction to prevent over-insertion of the trial.

The extraction mallet can be used to remove trials.

SURGICAL TECHNIQUE

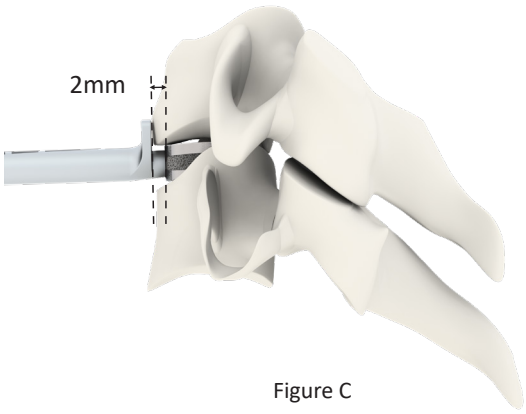
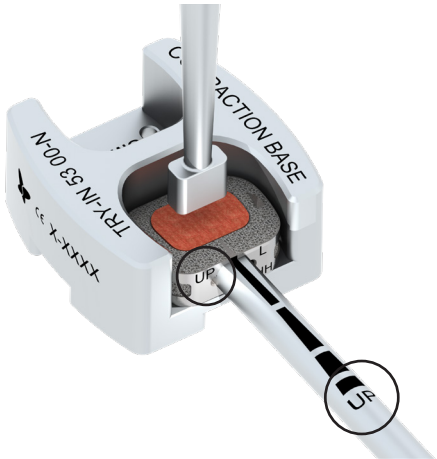


Figure C

NOTE: When using the implant holder with stop, there is a 2mm gap between the stop and the trial/implant (see figure C).

INSTRUMENT	REFERENCE
ANATOMIC RASP TRIAL SMALL H4.5-H10	TRY-00 RS XX-N
ANATOMIC RASP TRIAL LARGE H4.5-H10	TRY-00 RL XX-N
LORDOTIC SMOOTH TRIAL SMALL H4.5-H10	TRY-07 SS XX-N
LORDOTIC SMOOTH TRIAL LARGE H4.5-H10	TRY-07 SL XX-N
ANATOMIC SMOOTH TRIAL SMALL H4.5-H10	TRY-00 SS XX-N
ANATOMIC SMOOTH TRIAL LARGE H4.5-H10	TRY-00 SL XX-N
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N
HANDLE SHAFT	TRY-IN 51 00-N
SILICONE HANDLE	TRY-IN 51 02-N
EXTRACTION MALLET	TRY-IN 54 00-N
3D PRINTED HANDLE	TRY-IN 51 01-N

_STEP 3



CAGE PREPARATION

Attach the cage to the implant holder by rotating the implant holder shaft clockwise.

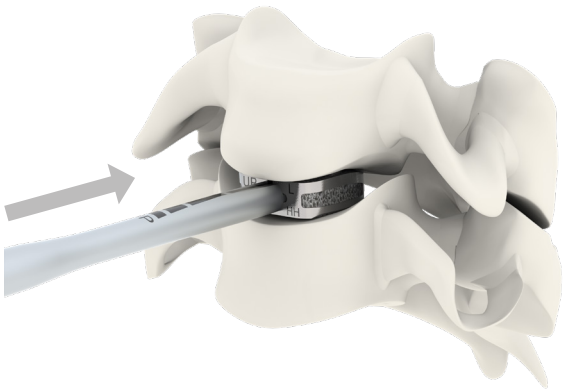
PRECAUTIONS: Ensure the “UP” marking on the implant holder is aligned with the “UP” marking on the implant.

Place the cage into the respective slot on the compaction base. Introduce graft material into the window and compress using the compactor.

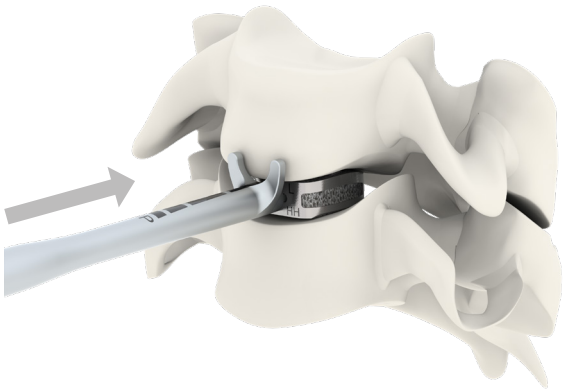
INSTRUMENT	REFERENCE
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N
HANDLE SHAFT	TRY-IN 51 00-N
SILICONE HANDLE	TRY-IN 51 02-N
3D PRINTED HANDLE	TRY-IN 51 01-N
COMPACTOR	TRY-IN 52 00-N
COMPACTION BASE	TRY-IN 53 00-N

SURGICAL TECHNIQUE

_STEP 4



Implant holder



Implant holder with stop

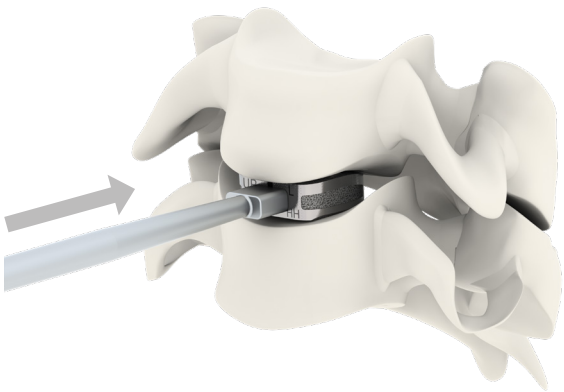


Figure A

INSERTION

Insert the cage into the intervertebral space. If necessary, advance the cage with a mallet.

Lines on the implant holder help center the cage within the vertebral body.

Ensure correct orientation and monitor position using fluoroscopic images.

To separate the implant holder from the cage, rotate the implant holder shaft counterclockwise.

The compactor can be used for slight advancements in cage position (Figure A).

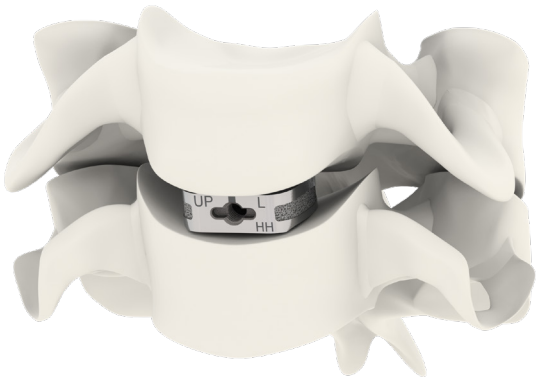
PRECAUTION: Avoid excessive impaction to prevent over-insertion of the cage.

Use fluoroscopic images to confirm correct final cage position.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N
HANDLE SHAFT	TRY-IN 51 00-N
SILICONE HANDLE	TRY-IN 51 02-N
3D PRINTED HANDLE	TRY-IN 51 01-N
COMPACTOR	TRY-IN 52 00-N

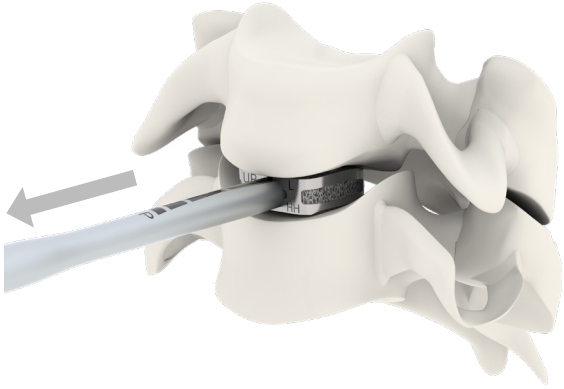
SURGICAL TECHNIQUE

_FINAL CONSTRUCT



⚠ **WARNING:** The TRYPTIK®Ti cages are to be used with a supplemental fixation, such as TRYPTIK®2 C-PLATE (Anterior Cervical Plate system) or PERLA® (Posterior Cervical Fixation System)

_REVISION



In case of revision, connect the implant holder to the cage. Gently extract the cage from the intervertebral space.

In addition, gentle impaction from the Extraction Mallet can be used to remove the cage.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
HANDLE SHAFT	TRY-IN 51 00-N
SILICONE HANDLE	TRY-IN 51 02-N
EXTRACTION MALLET	TRY-IN 54 00-N
3D PRINTED HANDLE	TRY-IN 51 01-N

GENERAL INFORMATION

REFERENCE OF THE IFU	TRY-TI-IF-US	REVISION OF THE FINAL IFU	DEC-2019

_STERILITY

The implant is provided sterile. Under sterile condition, implants are packaged in a first polyethylene pouch, included in a second PETG blister. Each of these 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 mustn't be used. The re-sterilization of the gamma sterilized implant is forbidden. The TRYPTIK®Ti implant must not be used with implant other than TRYPTIK®Ti range. The TRYPTIK®Ti Implant must only be used with the TRYPTIK®Ti instruments.

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

Based on the dynamic testing results, 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.

_DESCRIPTION

The TRYPTIK®Ti implant was designed to ensure the best possible adaptation to the patient's anatomic variations. TRYPTIK®Ti is cervical implant used to perform fusion between cervical vertebras after discectomy.

The TRYPTIK® Titanium cages are made of TA6V4 ELI Titanium alloy.

_INDICATIONS

TRYPTIK®Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous disc levels from C2 to T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK®Ti is used to facilitate intervertebral body fusion in the cervical spine using autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. TRYPTIK®Ti is to be used with supplemental fixation that has been cleared for use in the cervical spine. Patients should have at least six (6) weeks 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 tumor in the region of implant.

_SIDE EFFECTS

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

Post operative:
Venous thrombosis and pulmonary embolism, infection, cardio-vascular desorders, 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 cervical interbody fusion with cage 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.

GENERAL INFORMATION

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 cervical 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 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 °C after 15 minutes of continuous scanning at 1.5 T and less than or equal to 1.2 °C 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.

_HANDLING

No effort has been spared to ensure 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.

_SURGERY METHODS

Precaution: the implantation of cervical interbody cage should be performed only by experienced surgeons with specific training in the use of this cervical interbody cage 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. We strongly recommend that excessive force should not be applied when installing any of the TRYPTIK®Ti implants.

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

_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 TRYPTIK®Ti implants.

They are delivered non-sterile.

Specific markings are engraved on each instrument to facilitate identification of the corresponding 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 TRYPTIK®Ti 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.

GENERAL INFORMATION

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.
- 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.

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.
- 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.

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

GENERAL INFORMATION

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 proto- col 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"

_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.

NOTE

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