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

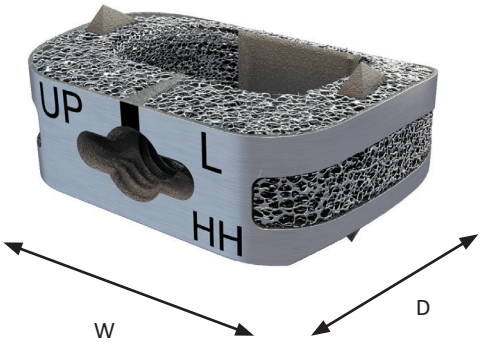
TRYPTIK®Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous disc levels from C2 to T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed 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.

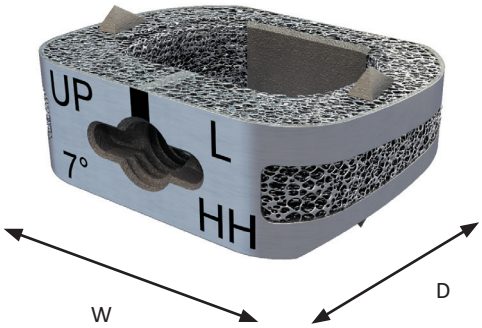
CONTRAINDICATIONS

- 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.

Please refer to the TRYPTIK®Ti Instructions for Use for complete device description, indications, contraindications, precautions and warnings.

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

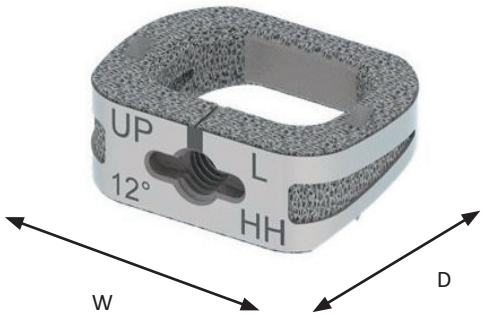
LORDOTIC CAGE – EXTRA LARGE D16 MM X W18 MM

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

• : OPTIONAL

IMPLANTS

HYPERLORDOTIC



HYPERLORDOTIC CAGE – SMALL D12 MM X W15MM

	HEIGHT (MM)	REFERENCE
•	6	TRY-TH SM 60-S
•	7	TRY-TH SM 70-S
•	8	TRY-TH SM 80-S
•	9	TRY-TH SM 90-S
•	10	TRY-TH SM 10-S
•	11	TRY-TH SM 11-S

HYPERLORDOTIC CAGE -LARGE D14 MM X W 17MM

	HEIGHT (MM)	REFERENCE
•	6	TRY-TH LA 60-S
•	7	TRY-TH LA 70-S
•	8	TRY-TH LA 80-S
•	9	TRY-TH LA 90-S
•	10	TRY-TH LA 10-S
•	11	TRY-TH LA 11-S

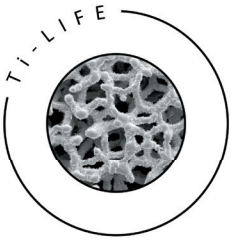
HYPERLORDOTIC CAGE – EXTRA LARGE D16 MM X W18 MM

	HEIGHT (MM)	REFERENCE
•	6	TRY-TH XL 60-S
•	7	TRY-TH XL 70-S
•	8	TRY-TH XL 80-S
•	9	TRY-TH XL 90-S
•	10	TRY-TH XL 10-S
•	11	TRY-TH XL 11-S

• : OPTIONAL

TECHNICAL FEATURES

Ti-LIFE TECHNOLOGY

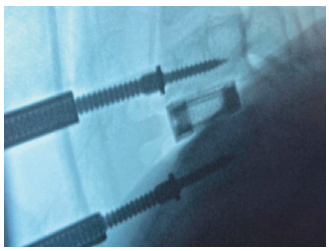


Ti-Life structures have an average pore diameter and overall porosity similar to trabecular bone, which may enable cell colonization and promote bone ingrowth[1][2][3],
This technology is based on an enhanced algorithm for additive manufacturing commonly known as 3D printing.

STABILIZING AND SECURING FINS

Upper and lower fins improve primary stability.

OPTIMAL VISUALIZATION

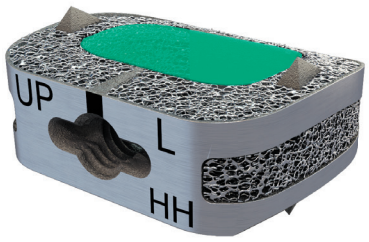


X-ray image[4]
Decreased cage density allows optimal visualization.

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
4. X-RAY image courtesy of: Rishi K. Wadhwa, MD, FAANS | Spine Institute of Louisiana | USA

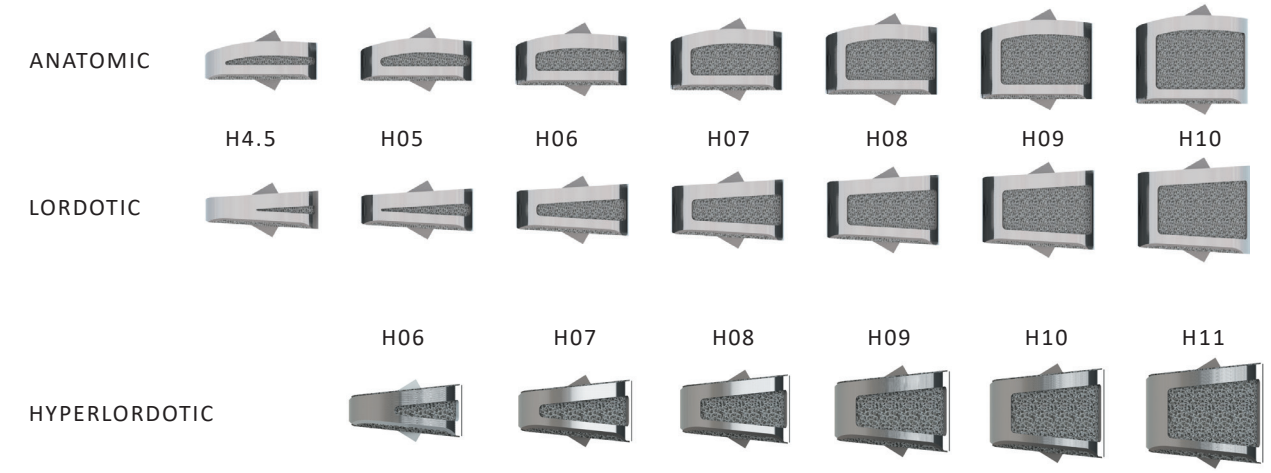
TECHNICAL FEATURES

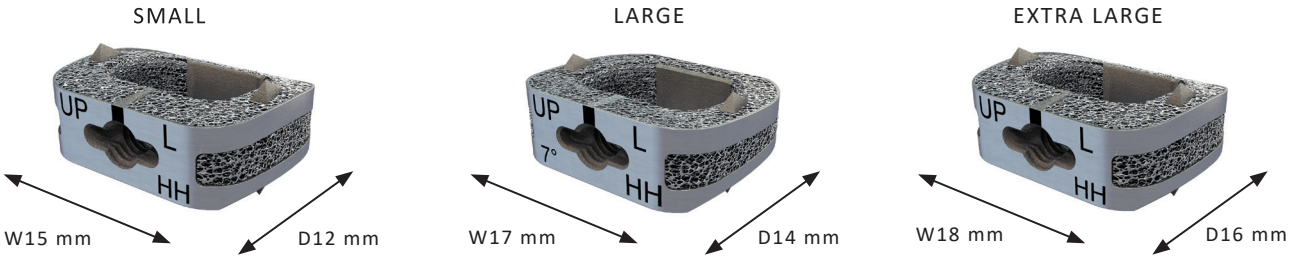
BONE GRAFT WINDOW



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

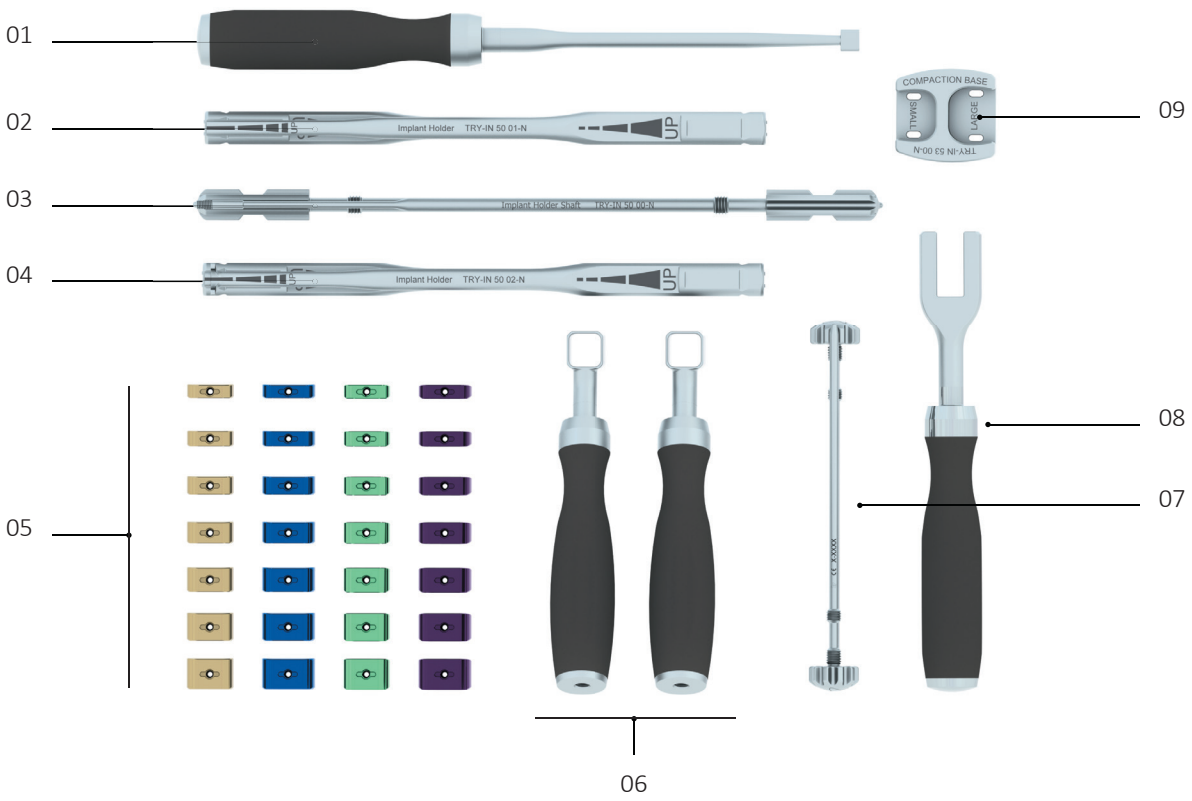
COMPREHENSIVE IMPLANT RANGE





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 and 7 of this guide.

INSTRUMENT SET



INSTRUMENT SET

	#	DESCRIPTION	REFERENCE
		TRYPTIK Ti-LIFE INSTRUMENT BOX	TRY-BX 10 01-N
		TRYPTIK Ti - ANATOMIC RASP TRIAL RACK	TRY-BX 10 02-N
		TRYPTIK Ti - LORDOTIC TRIAL RACK	TRY-BX 10 03-N
•		TRYPTIK Ti - ANATOMICAL SMOOTH TRIAL RACK	TRY-BX 10 04-N
		LID	LID-BX 13 00-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
		ANATOMIC RASP TRIAL LARGE H4.5-H08 (BLUE)	TRY-00 RL XX-N
•		ANATOMIC RASP TRIAL SMALL H09-H10 (GOLD)	TRY-00 RS XX-N
•		ANATOMIC RASP TRIAL LARGE H09-H10 (BLUE)	TRY-00 RL XX-N
		LORDOTIC SMOOTH TRIAL SMALL H4.5-H08 (GREEN)	TRY-07 SS XX-N
		LORDOTIC SMOOTH TRIAL LARGE H4.5-H08 (PURPLE)	TRY-07 SL XX-N
•		LORDOTIC SMOOTH TRIAL SMALL H09-H10 (GREEN)	TRY-07 SS XX-N
•		LORDOTIC SMOOTH TRIAL LARGE H09-H10 (PURPLE)	TRY-07 SL XX-N
•		ANATOMIC SMOOTH TRIAL SMALL H4.5-H10 (GOLD)	TRY-00 SS XX-N
•		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
•		TRYPTIK Ti - HYPERLORDOTIC SMOOTH TRIAL RACK	TRY-BX 10 05-N
•		HYPERLORDOTIC SMOOTH TRIAL SMALL H06-H11 (GREEN)	TRY-12 SS XX-N
•		HYPERLORDOTIC SMOOTH TRIAL LARGE H06-H11 (PURPLE)	TRY-12 SL XX-N
•		TRYPTIK Ti - EXTRA LARGE SMOOTH TRIAL RACK	TRY-BX 10 06-N
•		LORDOTIC SMOOTH TRIAL EXTRA LARGE H05-H10 (PINK)	TRY-07 SX XX-N
•		HYPERLORDOTIC SMOOTH TRIAL EXTRA LARGE H06-H11 (PINK)	TRY-12 SX XX-N

• : OPTIONAL

INSTRUMENTS

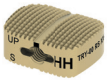
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N

IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N

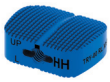
COMPACTOR	TRY-IN 52 00-N

EXTRACTION MALLET	TRY-IN 54 00-N

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

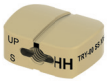


SMALL



LARGE

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



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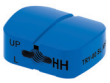


LARGE

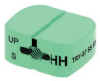
IMPLANT HOLDER	TRY-IN 50 01-N

HANDLE SHAFT	TRY-IN 51 00-N

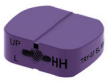
SILICONE HANDLE	TRY-IN 51 02-N

COMPACTION BASE	TRY-IN 53 00-N

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

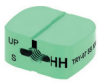


SMALL



LARGE

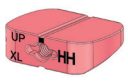
HYPERLORDOTIC SMOOTH TRIAL SMALL / LARGE H06-H11	TRY-12 SS XX-N TRY-12 SL XX-N



SMALL

LARGE

HYPERLORDOTIC / LORDOTIC SMOOTH TRIAL EXTRA LARGE H05-H10	TRY-07 SX XX-N TRY-12 SX XX-N



EXTRA LARGE

INSTRUMENT ASSEMBLY

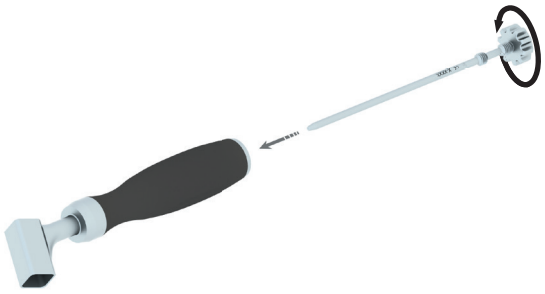
Implant holder

Implant holder with stop

IMPLANT HOLDER ASSEMBLY

Slide the **Implant Holder Shaft** into the **Implant Holder** or **Implant Holder With Stop** and rotate the knob clockwise.

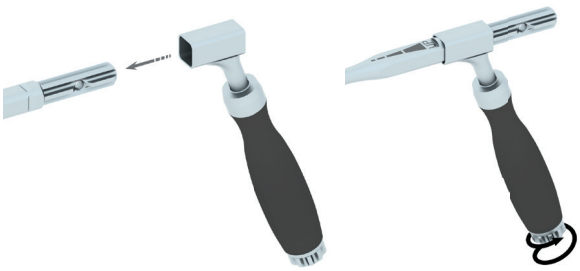
INSTRUMENT	REFERENCE
IMPLANT HOLDER SHAFT	TRY-IN 50 00-N
IMPLANT HOLDER	TRY-IN 50 01-N
IMPLANT HOLDER WITH STOP	TRY-IN 50 02-N



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



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.

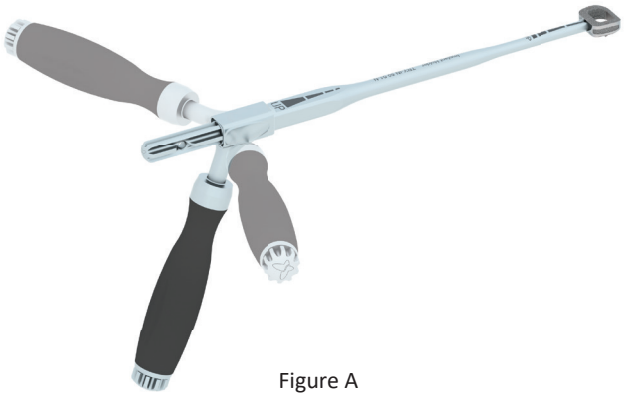


Figure A

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

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

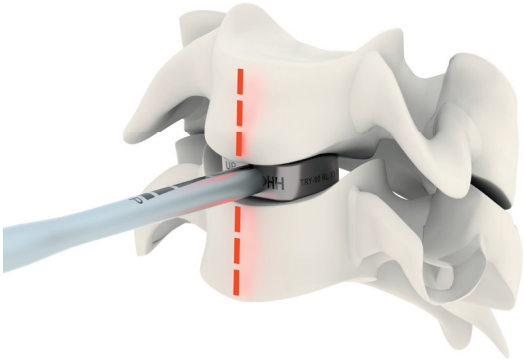


Figure A
Implant holder

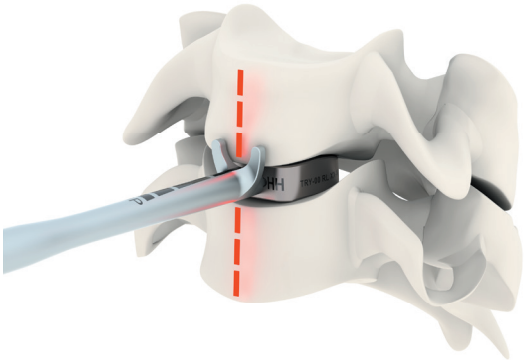


Figure B
Implant holder with stop

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

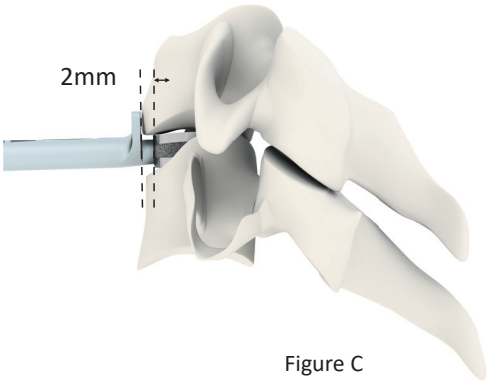


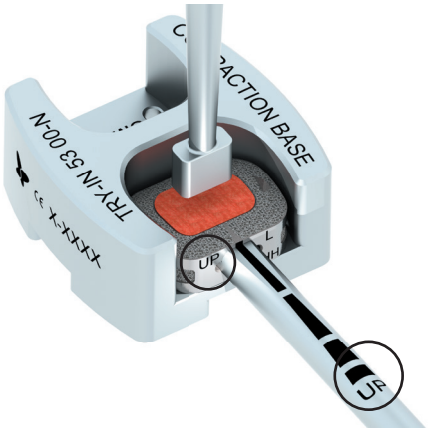
Figure C

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
HYPERLORDOTIC SMOOTH TRIAL SMALL H06-H11	TRY-12 SS XX-N
HYPERLORDOTIC SMOOTH TRIAL LARGE H06-H11	TRY-12 SL XX-N
LORDOTIC SMOOTH TRIAL EXTRA LARGE H05-H10	TRY-07 SX XX-N
HYPERLORDOTIC SMOOTH TRIAL EXTRA LARGE H06-H11	TRY-12 SX 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

SURGICAL TECHNIQUE

_STEP 3



CAGE PREPARATION

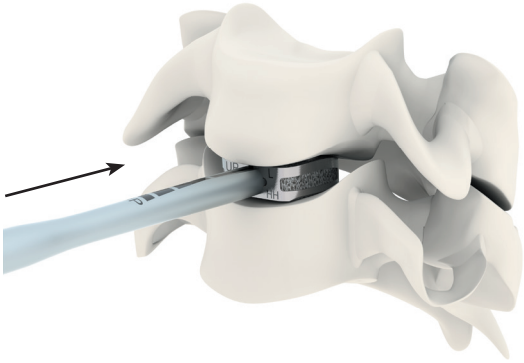
Attach the cage to the **Implant Holder** by rotating the **Implant Holder Shaft** clockwise.

PRECAUTIONS: Ensure the “UP” marking on the **Implant Holder** is aligned with the “UP” marking on the implant.

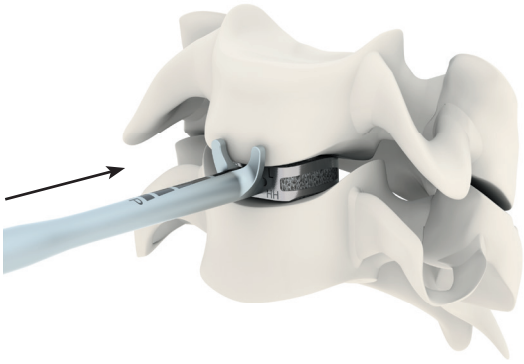
Place the cage into the respective slot on the **Compaction Base**. Introduce graft material into the window and compress using the **Compactor**.

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
COMPACTOR	TRY-IN 52 00-N
COMPACTION BASE	TRY-IN 53 00-N

_STEP 4



Implant holder



Implant holder with stop

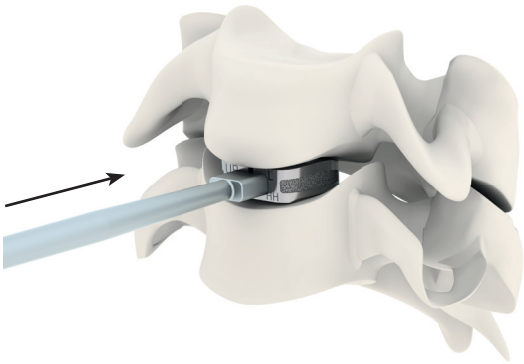


Figure A

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).

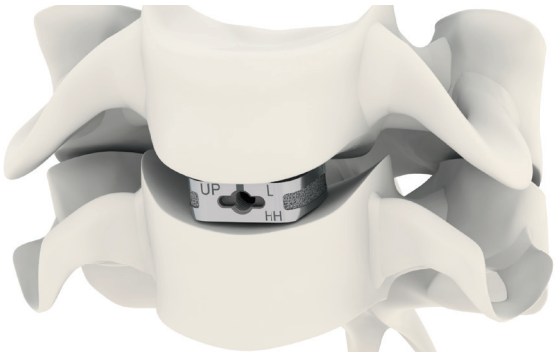
PRECAUTION: Avoid excessive impaction to prevent over-insertion of the cage.

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
COMPACTOR	TRY-IN 52 00-N

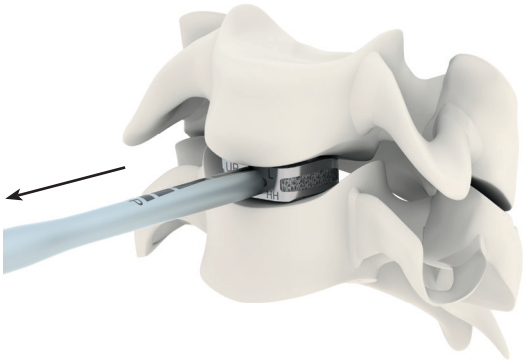
SURGICAL TECHNIQUE

_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

S P I N E A R T

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

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

FEB-2023-REF-TRY-TI-ST-US