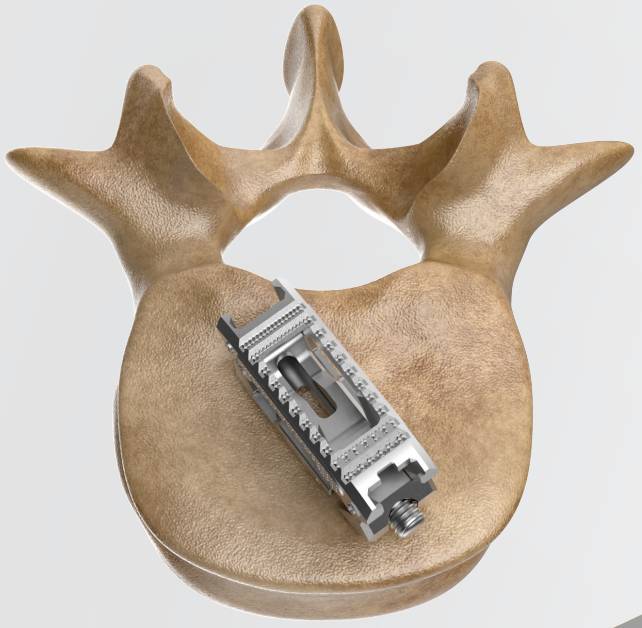
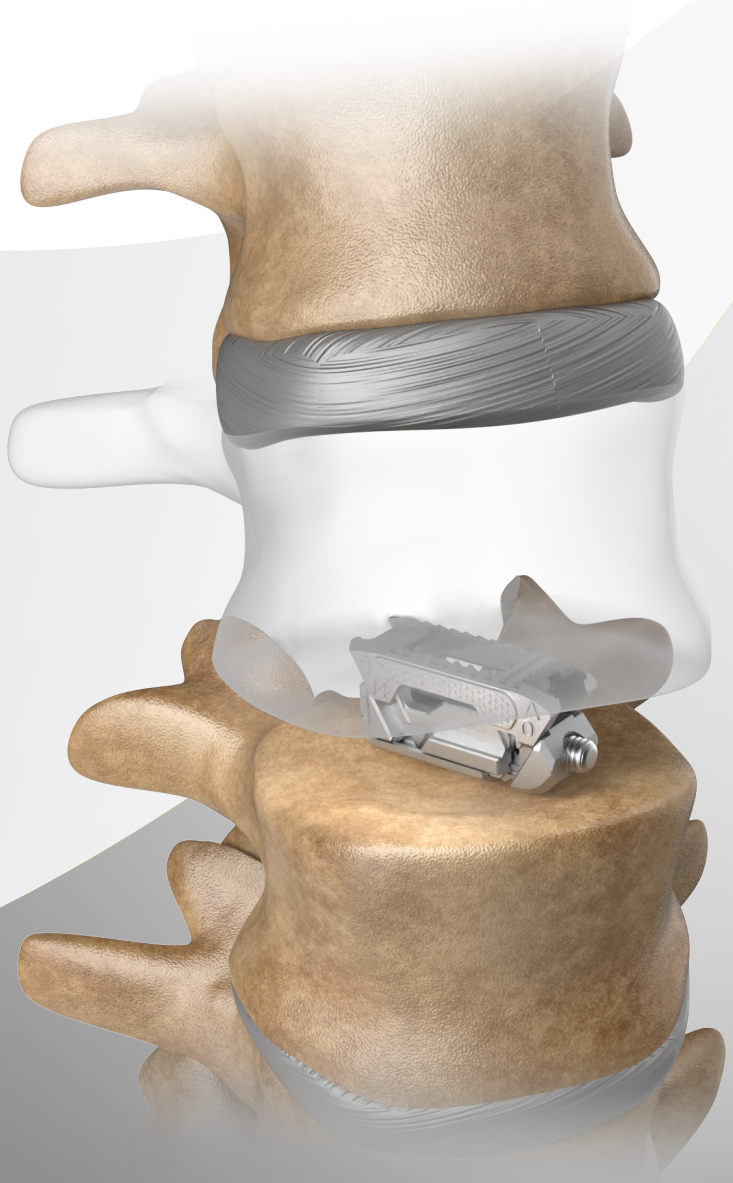
KLIMT™

Expandable Lumbar Interbody Fusion Cage System





SURGICAL TECHNIQUE GUIDE

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PRODUCT OVERVIEW

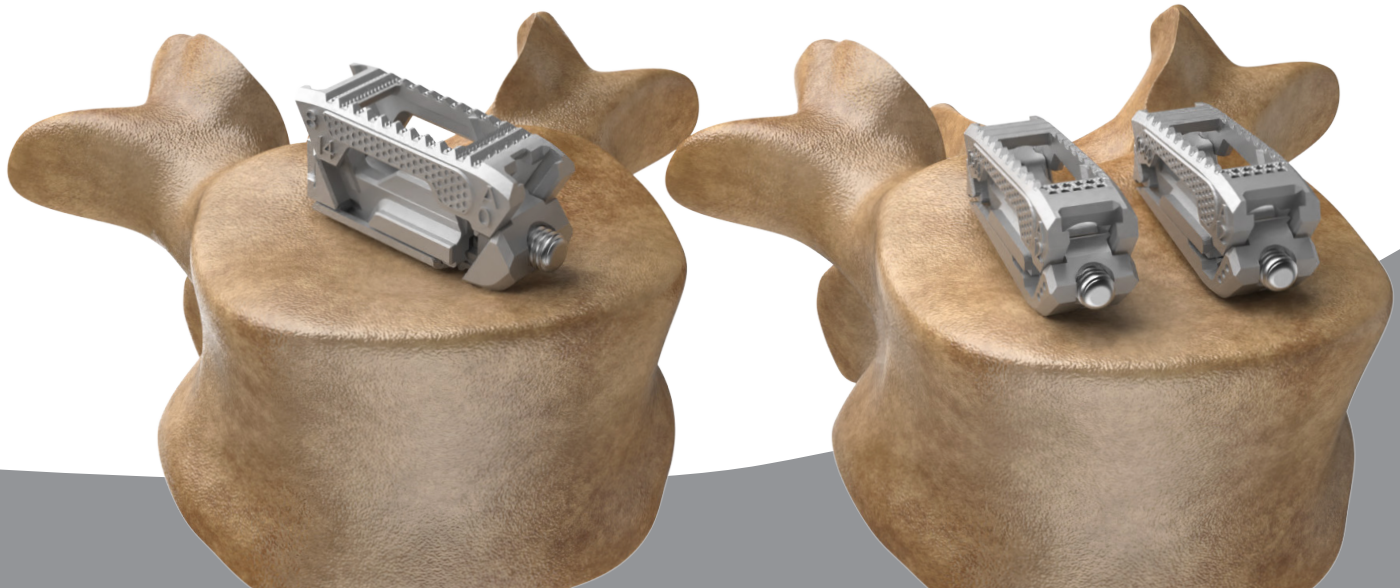
KLIMT™ Expandable LIF Cage System are 3D-printed titanium lumbar interbody fusion implants for posterior and transforaminal approach to thoracolumbar disease. The implant is designed to accommodate a wide range of patient anatomies and surgical preferences.

SYSTEM FEATURES AND BENEFITS

- MINIMIZED INSERTION HEIGHT provides lower impaction and less nerve retraction
- GRADUAL VERTICAL EXPANSION adjusts between (0 to 4mm) -or- (0 to 6mm) based on the minimized insertion height and leads to less endplate disruption
- MICRO "3D POROUS" TEXTURE enhances bone inter-digitation
- MACRO "SERRATED" SURFACE prevents cage migration
- LARGE BONE GRAFT WINDOW provides maximum volume for bone graft packing
- MANY SIZE OPTIONS accommodates a wide range of patient anatomies

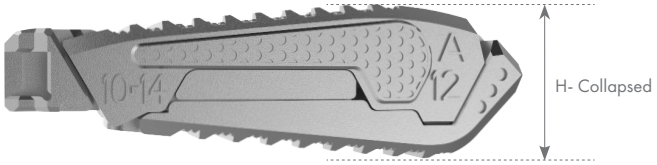
Standard (TLIF)

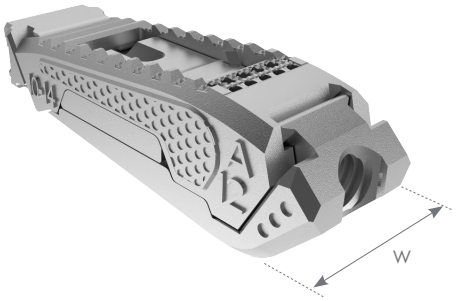
Lordotic (PLIF)



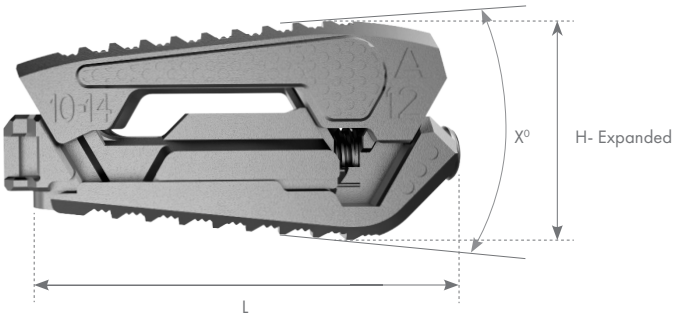
SYSTEM SPECIFICATIONS
IMPLANT

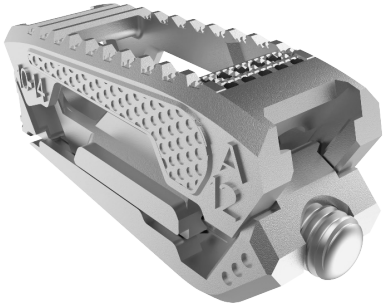
Collapsed Implant



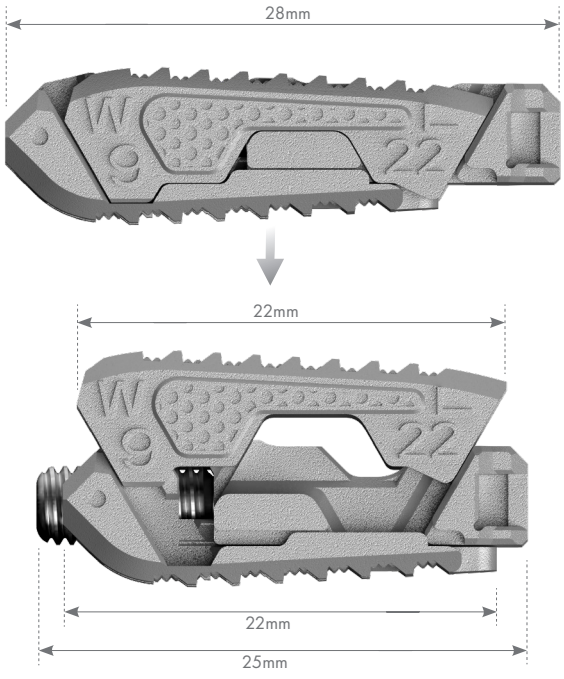


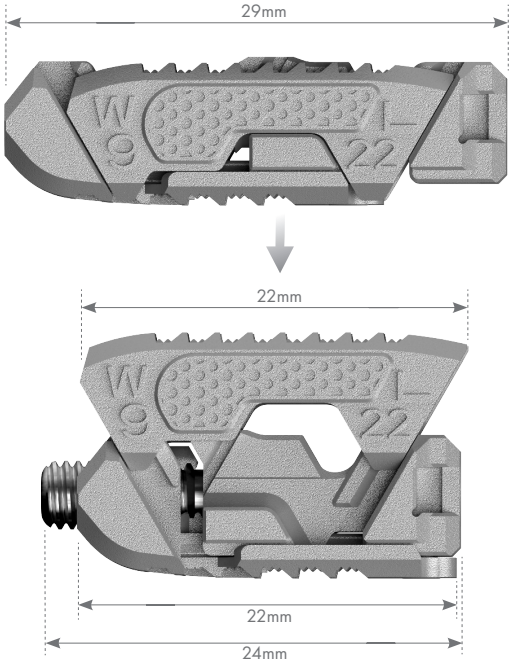
Deployed Implant





	9x22mm/ 4mm Height Expansion	9x22mm/ 6mm Height Expansion
Fully collapsed length (mm)	28	29
Fully expanded length (mm)	25	24
Endplate length (mm)	22	22
Expansion range (mm)	8-12	8-14





W9mm KLIMT™ 3D PRINTED EXPANDABLE STERILE CAGE

0° Lordosis	Part Number	Length(mm)	Height(mm)
	S.367.4003	22	8-14
	S.367.4013	24	8-14
	S.367.4023	26	8-14
	S.367.4033	28	8-14
	S.367.4043	30	8-14
	S.367.4053	32	8-14

6° Lordosis			
	S.367.1103	22	8-12
	S.367.4105	22	10-16
	S.367.1113	24	8-12
	S.367.4115	24	10-16
	S.367.1123	26	8-12
	S.367.4125	26	10-16
	S.367.1133	28	8-12
	S.367.4135	28	10-16
	S.367.1144	30	9-13
	S.367.4146	30	11-17
	S.367.1154	32	9-13
	S.367.4156	32	11-17

9° Lordosis			
	S.367.1204	22	9-13
	S.367.4206	22	11-17
	S.367.1214	24	9-13
	S.367.4216	24	11-17
	S.367.1224	26	9-13
	S.367.4226	26	11-17
	S.367.1235	28	10-14
	S.367.4237	28	12-18
	S.367.1245	30	10-14
	S.367.4247	30	12-18
	S.367.1255	32	10-14
	S.367.4257	32	12-18

12° Lordosis	Part Number	Length(mm)	Height(mm)
	S.367.1304	22	9-13
	S.367.4306	22	11-17
	S.367.1315	24	10-14
	S.367.4317	24	12-18
	S.367.1325	26	10-14
	S.367.4327	26	12-18
	S.367.1335	28	10-14
	S.367.4337	28	12-18
	S.367.1346	30	11-15
	S.367.1356	32	11-15

15° Lordosis			
	S.367.1405	22	10-14
	S.367.4407	22	12-18
	S.367.1416	24	11-15
	S.367.1426	26	11-15
	S.367.1436	28	11-15
	S.367.1447	30	12-16
	S.367.1457	32	12-16

18° Lordosis			
	S.367.1506	22	11-15
	S.367.1516	24	11-15
	S.367.1527	26	12-16
	S.367.1537	28	12-16
	S.367.1548	30	13-17
	S.367.1558	32	13-17

W11mm KLIMT™ 3D PRINTED EXPANDABLE STERILE CAGE

0° Lordosis	Part Number	Length(mm)	Height(mm)
	S.367.5003	22	8-14
	S.367.5013	24	8-14
	S.367.5023	26	8-14
	S.367.5033	28	8-14
	S.367.5043	30	8-14
	S.367.5053	32	8-14

6° Lordosis			
	S.367.2103	22	8-12
	S.367.5105	22	10-16
	S.367.2113	24	8-12
	S.367.5115	24	10-16
	S.367.2123	26	8-12
	S.367.5125	26	10-16
	S.367.2133	28	8-12
	S.367.5135	28	10-16
	S.367.2144	30	9-13
	S.367.5146	30	11-17
	S.367.2154	32	9-13
	S.367.5156	32	11-17

9° Lordosis			
	S.367.2204	22	9-13
	S.367.5206	22	11-17
	S.367.2214	24	9-13
	S.367.5216	24	11-17
	S.367.2224	26	9-13
	S.367.5226	26	11-17
	S.367.2235	28	10-14
	S.367.5237	28	12-18
	S.367.2245	30	10-14
	S.367.5247	30	12-18
	S.367.2255	32	10-14
	S.367.5257	32	12-18

12° Lordosis	Part Number	Length(mm)	Height(mm)
	S.367.2304	22	9-13
	S.367.5306	22	11-17
	S.367.2315	24	10-14
	S.367.5317	24	12-18
	S.367.2325	26	10-14
	S.367.5327	26	12-18
	S.367.2335	28	10-14
	S.367.5337	28	12-18
	S.367.2346	30	11-15
	S.367.2356	32	11-15

15° Lordosis			
	S.367.2405	22	10-14
	S.367.5407	22	12-18
	S.367.2416	24	11-15
	S.367.2426	26	11-15
	S.367.2436	28	11-15
	S.367.2447	30	12-16
	S.367.2457	32	12-16

18° Lordosis			
	S.367.2506	22	11-15
	S.367.2516	24	11-15
	S.367.2527	26	12-16
	S.367.2537	28	12-16
	S.367.2548	30	13-17
	S.367.2558	32	13-17

DISC PREP

DISC SCRAPER

	Height
367.7106	6mm
367.7107	7mm
367.7108	8mm
367.7109	9mm
367.7110	10mm
367.7111	11mm
367.7112	12mm
367.7113	13mm
367.7114	14mm
367.7115	15mm

PADDLE DISTRACTOR

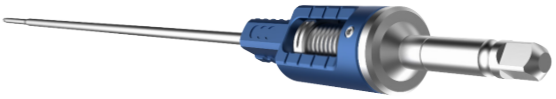
	Height
367.7007	7mm
367.7008	8mm
367.7009	9mm
367.7010	10mm
367.7011	11mm
367.7012	12mm
367.7013	13mm
367.7014	14mm
367.7015	15mm

HEIGHT ADJUSTABLE TRIAL

	Lordosis	Height
367.7200	0°	8-14mm

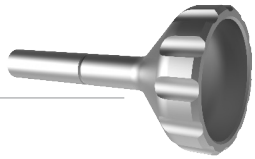
INSERTING & GRAFTING

367.7500 CAGE INSERTER

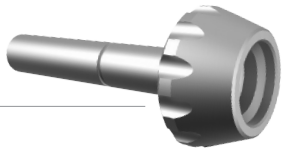


367.7505 EXPANSION DRIVER

367.7520 IMPACTION CAP ADAPTER



367.7550 INSERTER FUNNEL

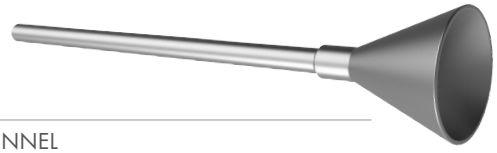


367.7551 INJECTION FUNNEL

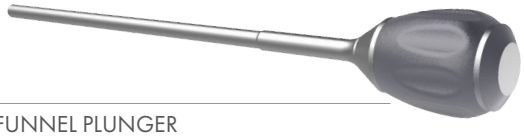
367.7555 INSERTER FUNNEL PLUNGER

MISCELLANEOUS

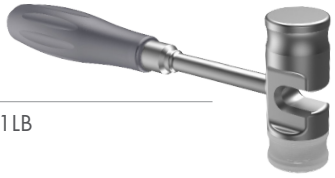
367.7600 STRAIGHT CAGE IMPACTER



100.7056 FUNNEL



100.7058 FUNNEL PLUNGER



100.7075 MALLET, LUMBAR, 1LB

HANDLES

100.2021 T-HANDLE, 1/4" SQUARE QC

100.3000 TORQ LMT, MINI, SLIM STD, 1/4" SQ, 2N-m

SURGICAL TECHNIQUE
POSITIONING AND PREPARATION

I. SURGICAL APPROACH AND PREPARATION

The patient is positioned in the prone position, and the appropriate surgical site is identified. Preoperative planning is critical in the preparation for spinal surgery and lateral fluoroscopy should be utilized to determine the precise implant size and intraoperative positioning

*Note: **Fig. 1** illustrates patient orientation using the paramedian, muscle splitting approach. The amount of bony dissection is dependent on the specific insertion technique selected by the surgeon. Standard soft tissue dissection techniques allow the surgeon to reach the pertinent bone anatomy.*

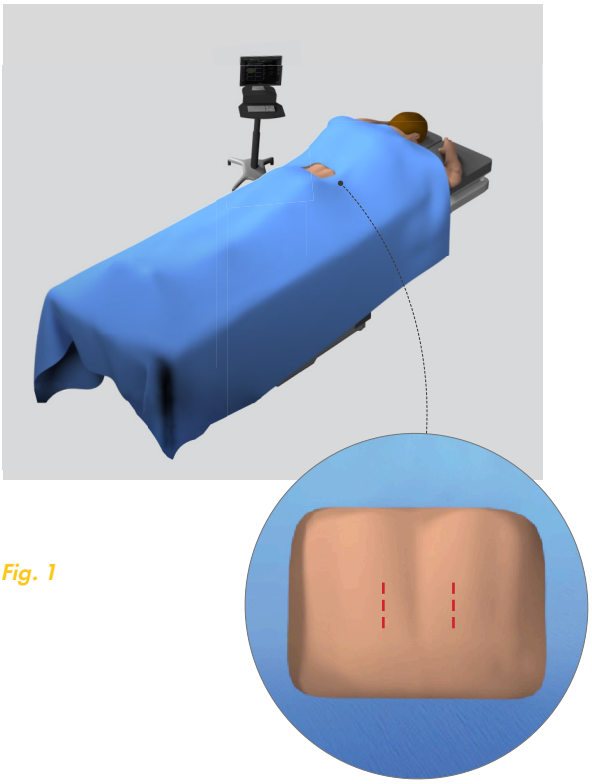


Fig. 1

II. TRANSFORAMINAL WINDOW PREPARATION FOR TLIF APPROACH

(SHOWN FOR REF.)

Step 1

Identify the cephalad and caudad transforaminal transverse processes.

Step 2

Remove the facet capsule using a cautery tool or rongeur. The facet joint's articular cartilage is then removed with a burr, rongeur, or any suitable instrument, in preparation for fusion. The superior and inferior articular facets on the side where the TLIF is to be inserted are taken out. The removal of the entire facet on the opposite side may lead to an improvement in segmental lordosis. ***(Fig. 2)***

Caution: *Care should be taken to prevent penetration of the pedicle cortex if using a high speed burr.*

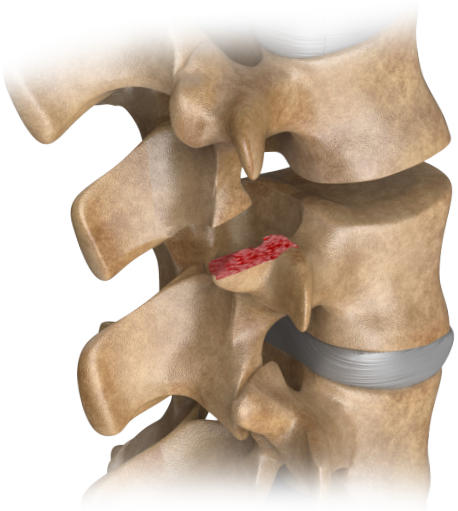


Fig. 2

Step 3

Clear any epidural veins or other soft tissue debris to clearly identify the margins of the disc and both the inferior endplate of the suprajacent vertebra and the superior end plate of the subjacent vertebra.

Note: *Protect the existing nerve root with nerve root retractor.*

Tips and Pearls: *The local bone may be saved, decorticated and used as bone graft material.*

III. ACCESS AND DISC SPACE PREPARATION

Step 1

Access and create a working window to the disc utilizing various generic surgical tools as necessary, such as Scalpel, Osteotome, and so on.

Step 2

Distract the disc space sequentially using the distractors such as the Paddle Distractor (367.7007 through 367.7015) provided in the KLIMT™ case.

Step 2

Place the Paddle Distractor so that its sides are in contact with the endplates, then rotate it to distract. If needed, continue to insert distractors of different sizes until the desired height of the disc space and size of the foramen is achieved. *(Fig. 3)*

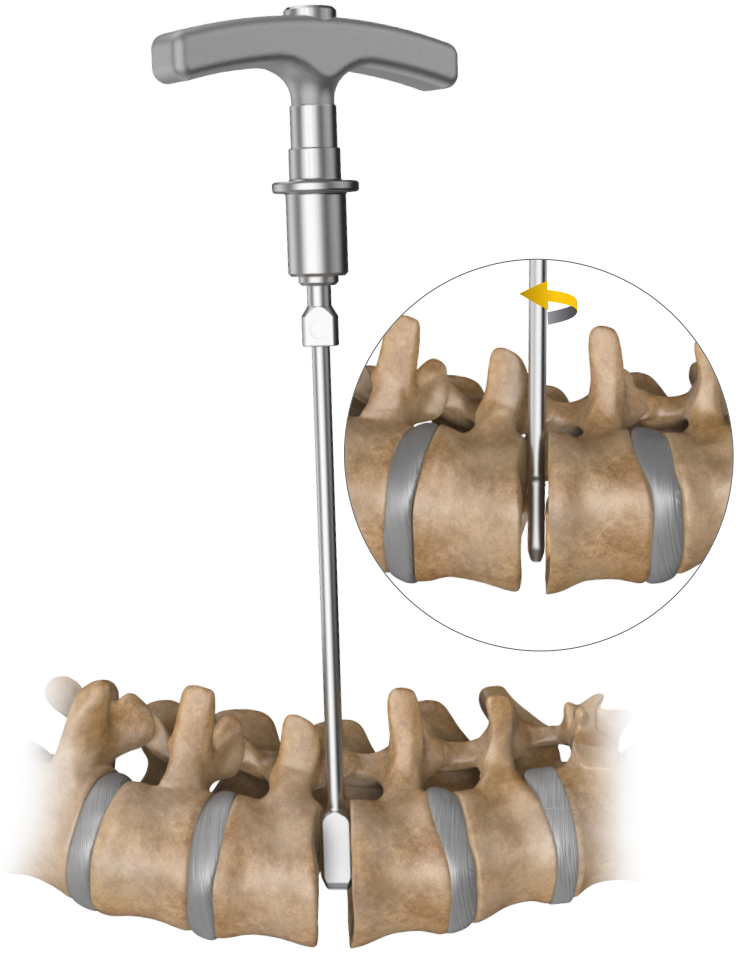


Fig. 3

IV. DISCECTOMY AND ENDPLATE PREPARATION

Roughen endplates to achieve cancellous bone bleeding using disc prep tools. Remove the superficial layers of the endplates and expose bleeding bone. Disc Scrapers (367.7106 through 367.7115) may be used to assist with preparation of the vertebral endplates. Appropriate endplate preparation on each vertebral body will optimize surface contact with the selected interbody implant. ***(Fig. 4)***

Note: Care should be taken not to remove excessive bone as this may weaken the endplates, possibly resulting in subsidence and segmental instability.

Tip: To remove cartilaginous endplates prior to implant placement, use a paddle shaver one size smaller than measured trial.

Caution: Ensuring the disc space is properly cleaned will assist with proper trialling and deployment of the implant.

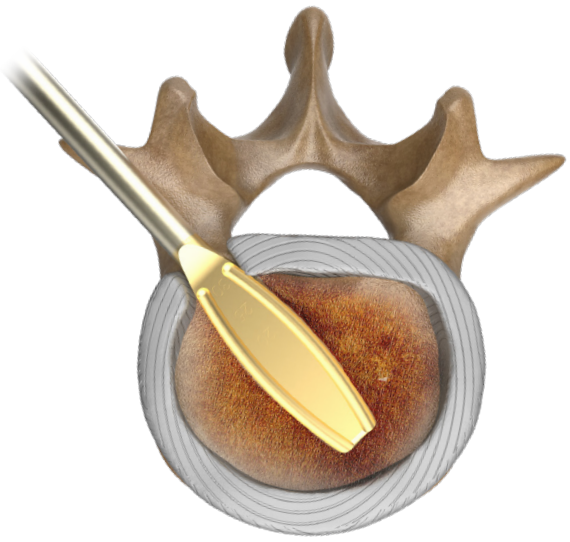


Fig. 4

V. TRIAL & IMPLANT SELECTION

Trial

Step 1

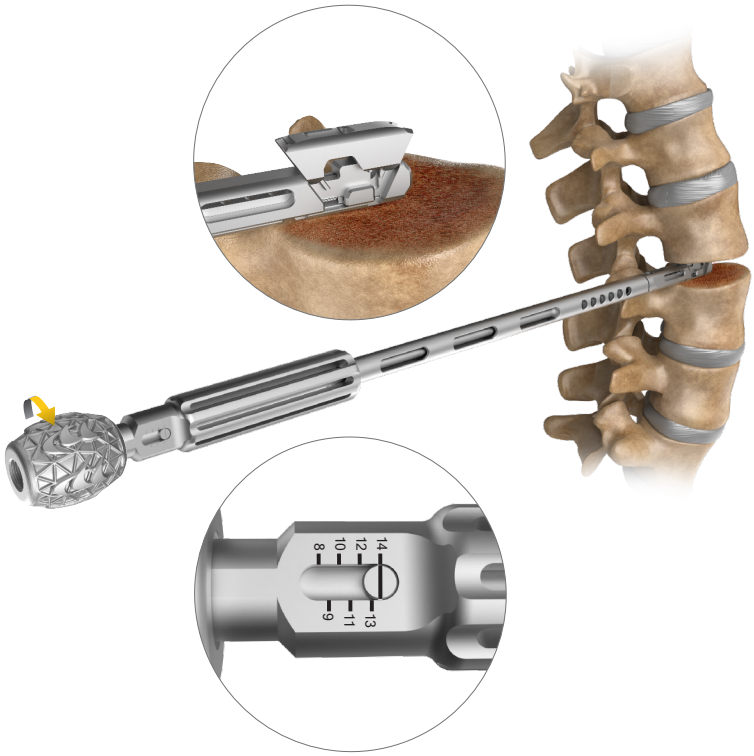
To insert the Height Adjustable Trial (367.7200) into the disc space, a Lumbar Mallet (100.7075) can be utilized to ease placement. It is preferred to place the Height Adjustable Trial on the apophyseal ring.

367.7200 Height Adjustable Trial

Step 2

Once the Height Adjustable Trial is properly positioned in the intervertebral disc space, turn the handle clockwise to extend the tip of the Height Adjustable Trial. The window on the Height Adjustable Trial will display the amount of intradiscal expansion. Consult the chart on page 5 & 6 to select the appropriate implant size and respective expansion range. *(Fig. 5)*

Caution: Trials are not meant for rotation within the disc space. Fluoroscopy may be used to confirm correct trial size.



Expansion Range (8-14mm)

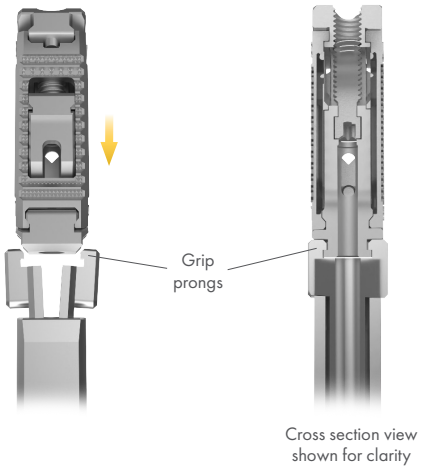
Fig. 5

Loading Implant onto Inserter

Step 3

Select the implant that corresponds to the previously selected trial size and securely attach the implant to the Cage Inserter (367.7500). Ensure locking mechanism is in its Open(OP) state. To secure the implant to the Cage Inserter, insert the grip prongs on the distal end of the Cage Inserter onto the implant. *(Fig. 6)*

*Note: The selected implant length "L" as this value will be displayed in the Expansion Driver length display window. See **Fig. 9** for reference.*



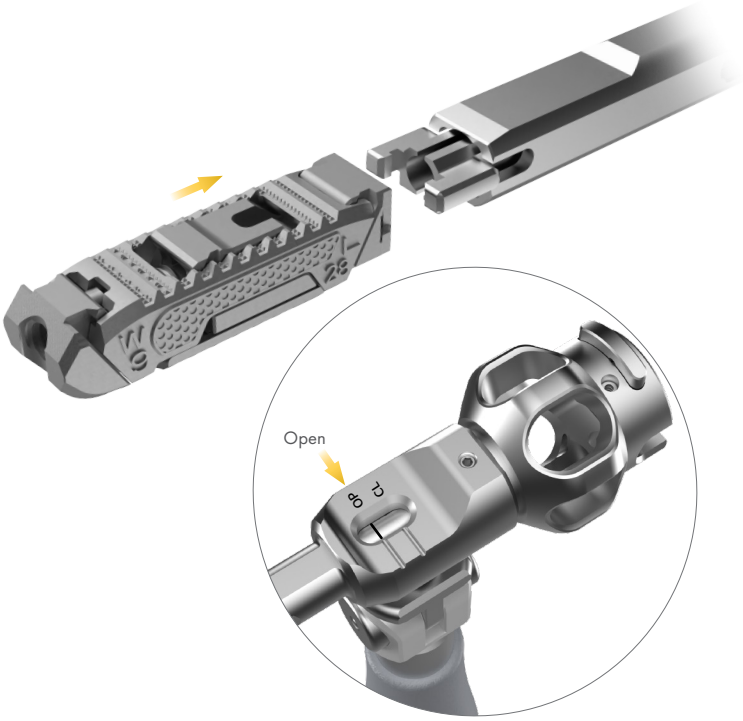


Fig. 6

Step 4

While holding the implant in place, turn Cage Inserter knob clockwise to secure the implant. Turn the knob until it won't turn anymore. Make sure the locking mechanism is in its Closed (CL) state at this point. *(Fig. 7)*

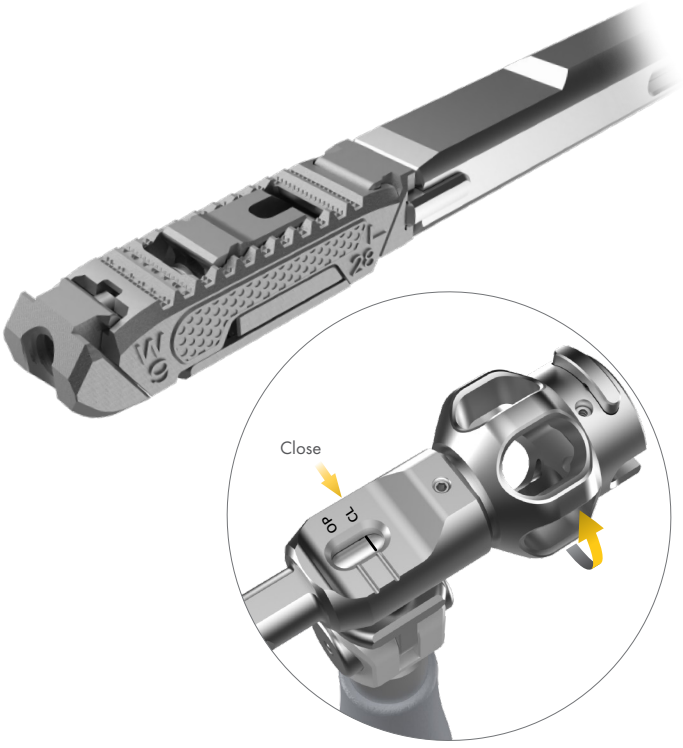


Fig. 7

VI. IMPLANT INSERTION

Assembling the Inserter

Step 1

Insert the Expansion Driver (367.7505) into the Cage Inserter (367.7500) until engaged with the implant. *(Fig. 8)*

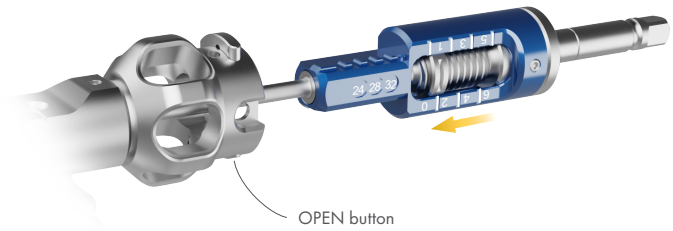
Fig. 8

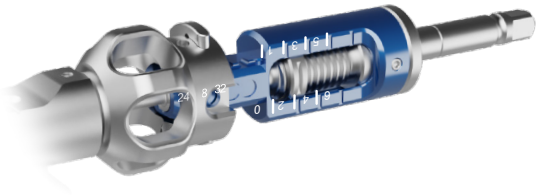
Step 2

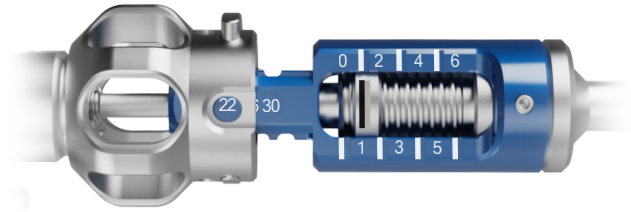
Press and hold the OPEN button until the Length number shows through the Expansion Driver circle window and then release. The selected implant length will provide the hard stop seen by the Expansion Driver. (i.e. When L24mm cage is assembled to the Cage Inserter, the Expansion Driver will advance until Length number "24" is shown through the circle window of the Cage Inserter. ***(Fig. 9)***

Note: *Verify the driver is fully engaged in the expansion bolt in the cage by checking the side marking. The side marking number indicates the implant length.*

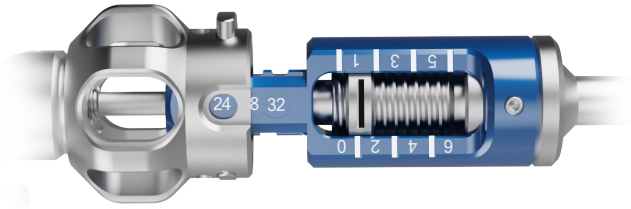
Note: *Confirm the driver is fully engaged in the expansion bolt via lateral fluoroscopy.*







Near Side: 22,26,30



Far Side: 24,28,32

Fig. 9

Step 3

Attach the Impaction Cap Adapter (367.7520) securely to the Expansion Driver. *(Fig. 10)*

Fig. 10

Step 4

Lightly impact the implant in the disc space. *(Fig. 11)(1)* Then attach the Torque Limiting Handle (100.3000) securely to the Expansion Driver *(Fig. 11)(2)* after detaching the Impaction Cap Adapter.

Note: Confirm proper fit and position of the implant via lateral fluoroscopy.

Note: Only Mallet, Lumbar, 1LB (100.7075) in the set is allowed for impacting the Impaction Cap Adapter

Note: Only 2N-m Torque Limiting Handle in the set is allowed for implant expansion. Do not use any other handle for this.

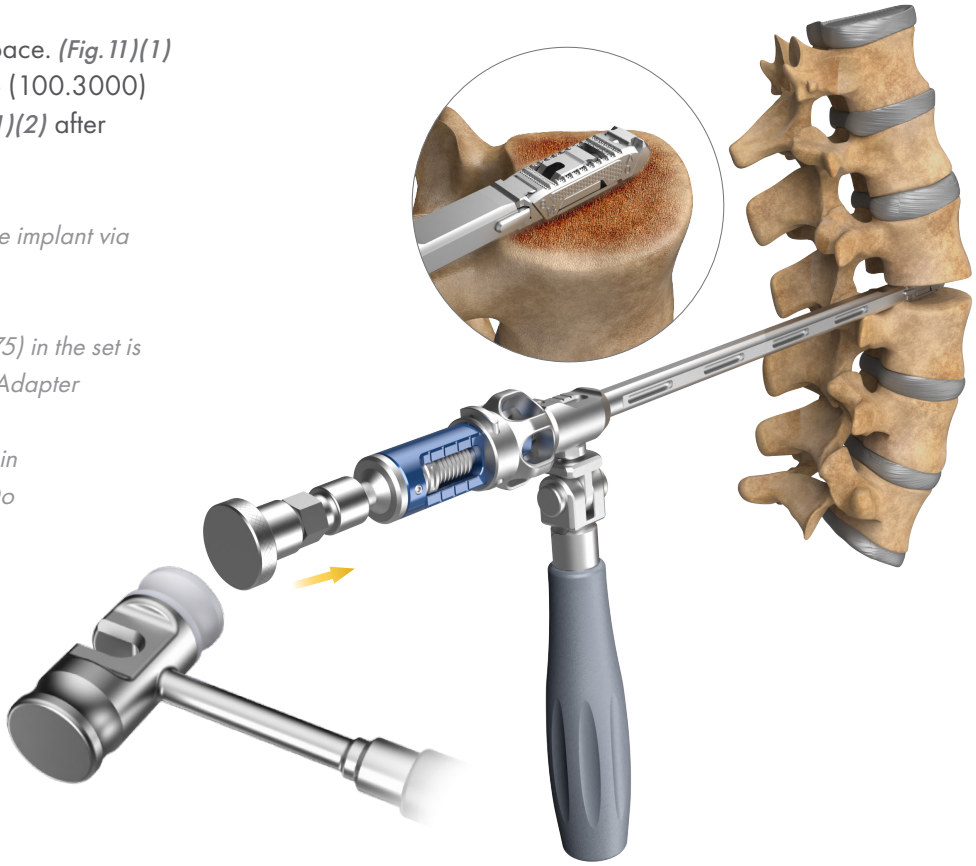


Fig. 11 (1)

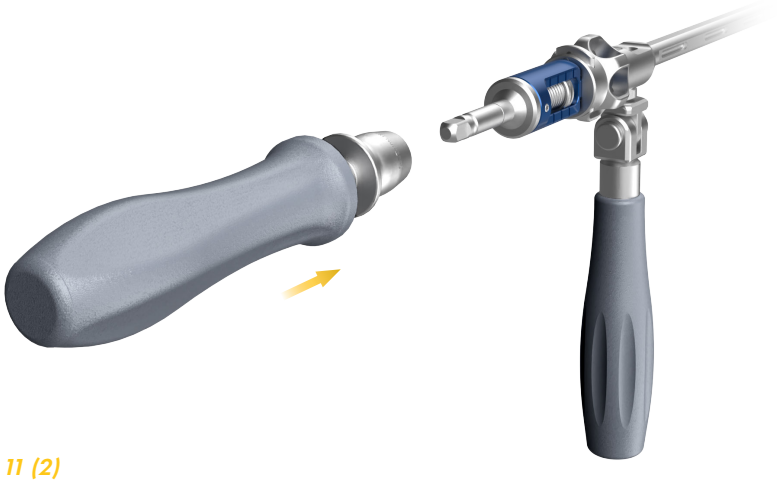


Fig. 11 (2)

Step 5

Verify the expansion gauge is at 0mm height when the implant is in collapsed state. *(Fig. 12(1))* Then expand the implant as needed by rotating the Torque Limiting Handle clockwise. *(Fig. 12(2))*

Note: Confirm implant position and endplate contact via lateral fluoroscopy.

Caution: To ensure proper functioning, the Expansion Driver must be fully inserted into the Cage Inserter assembly so that the driver midline shaft can engage with both the implant and the expansion gauge. If the Expansion Driver is not fully inserted, there is a risk of engaging only with the expansion gauge, which can cause the expansion gauge's indicator to move without expanding the implant and potentially lead to device disassembly. Avoid impacting the Torque Limiting Handle during insertion. Always use the Torque Limiting Handle to limit expansion force, and be careful not to over-expand the implant as it could lead to broken vertebral endplates. The expansion gauge indicates the approximate implant expansion. Once the implant is expanded to the desired height and in its final position, verification must be performed using fluoroscopy or similar to ensure desired expansion.

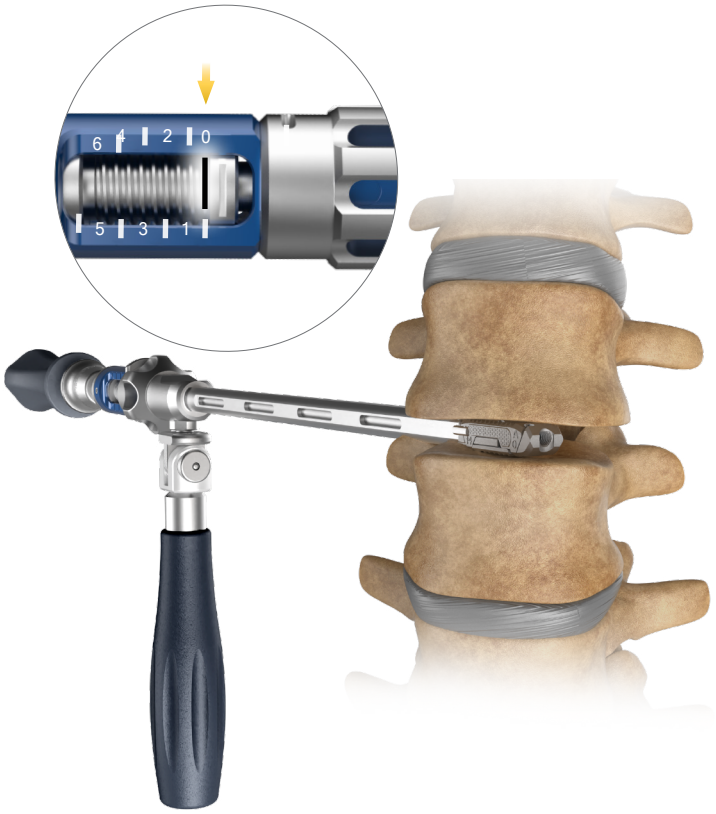


Fig. 12 (1)

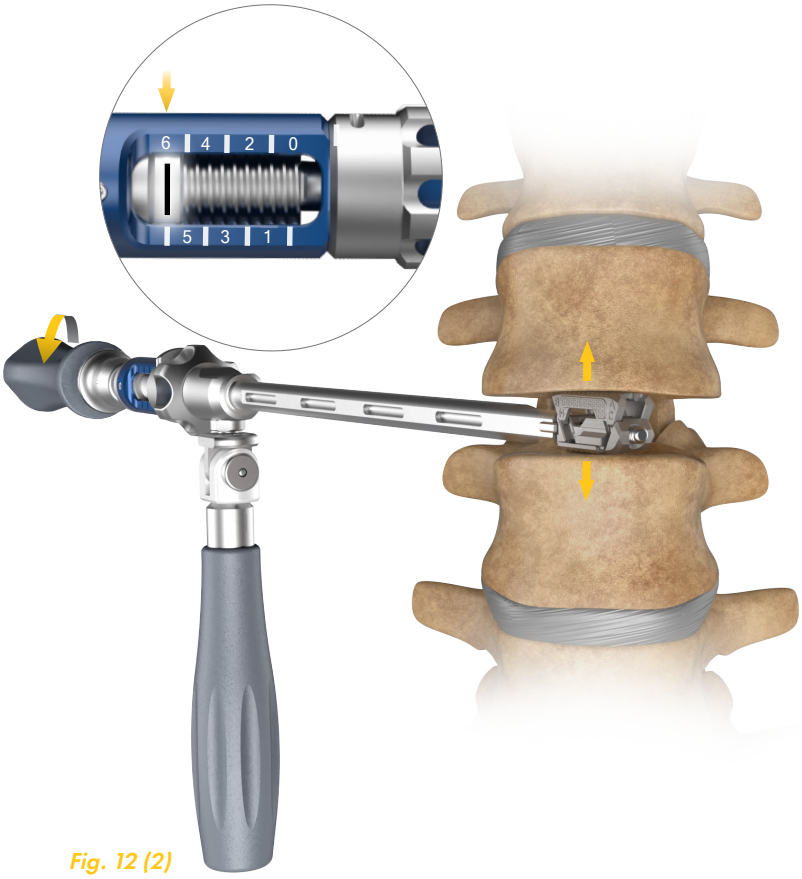


Fig. 12 (2)

Step 6

After final expansion of the implant, and verification of placement, remove the Expansion Driver from the inserter. To remove, gently pull it away from the implant while pushing and holding the button on the Cage Inserter while keeping the Cage Inserter in place. *(Fig. 13)*

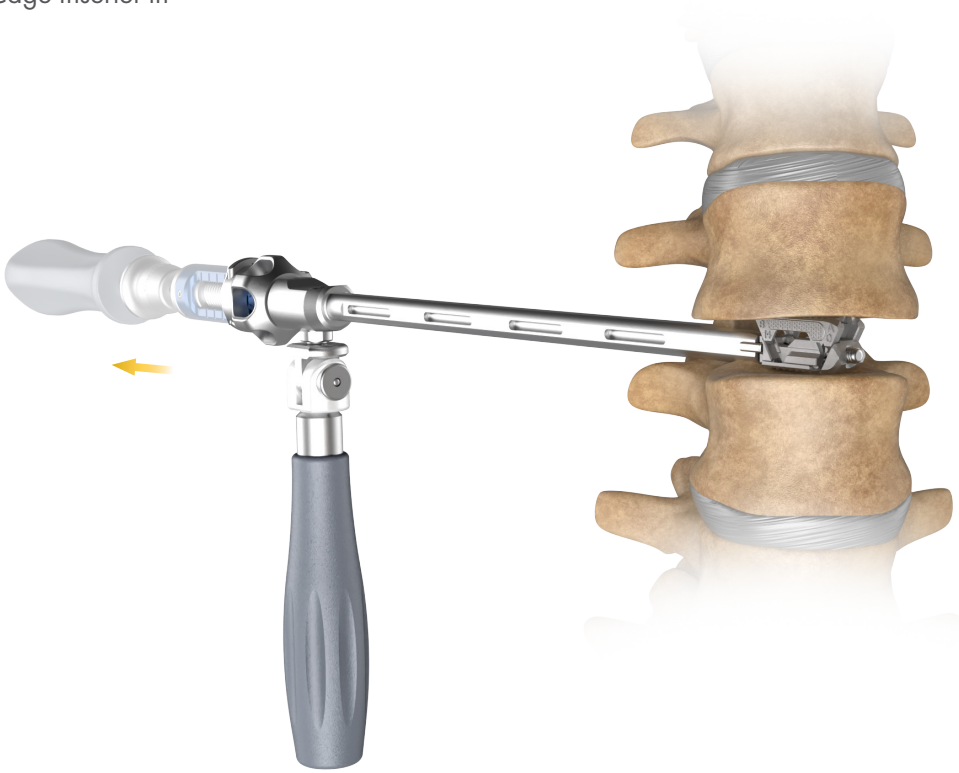


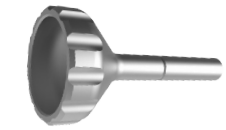
Fig. 13

VII. BONE GRAFT APPLICATION

Option 1: Using Inserter Funnel

Step 1

Assemble the Inserter Funnel (367.7550) into the back end of the Cage Inserter. *(Fig. 14)*



367.7550 Inserter Funnel

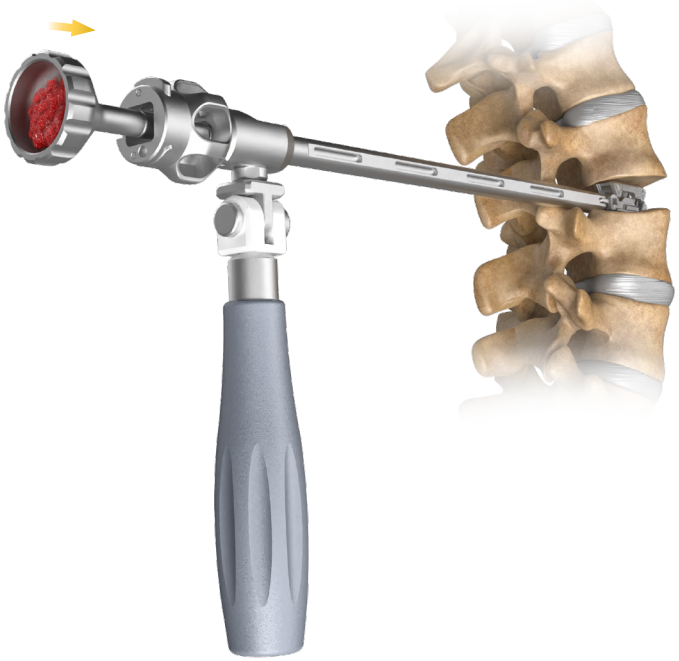


Fig. 14

Step 2

Push the bone graft down the Inserter Funnel using Inserter Funnel Plunger. *(Fig. 15)*

367.7555 Inserter Funnel Plunger

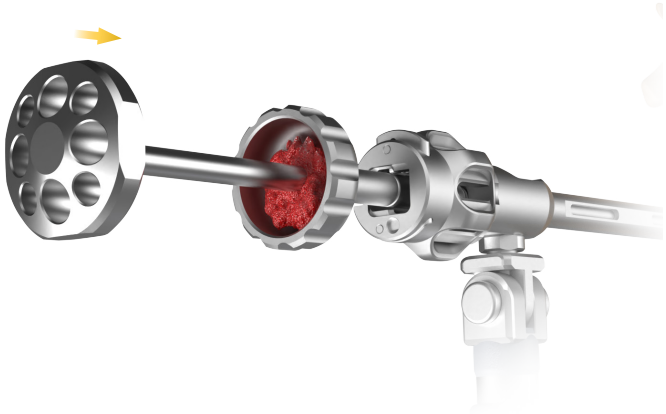
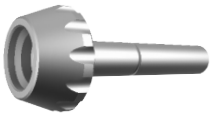


Fig. 15

Option 2: Using Injection Funnel

Step 1

Insert Injection Funnel (367.7551) into the inserter. *(Fig. 16)*



367.7551 Injection Funnel

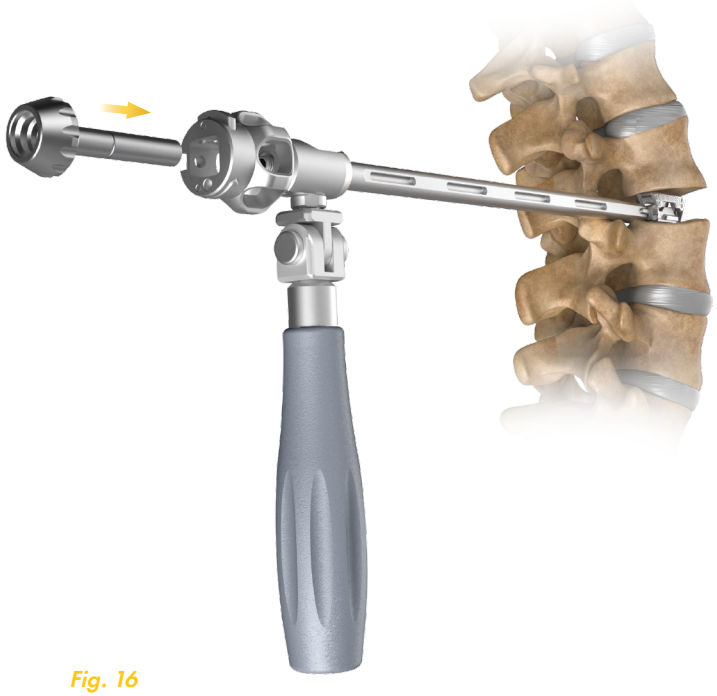


Fig. 16

Step 2

Engage bone putty syringe filled with graft material directly into the Injection Funnel. *(Fig. 17)*

Fig. 17

Step 3

Push the bone graft down the Injection Funnel using Inserter Funnel Plunger. *(Fig. 18)*

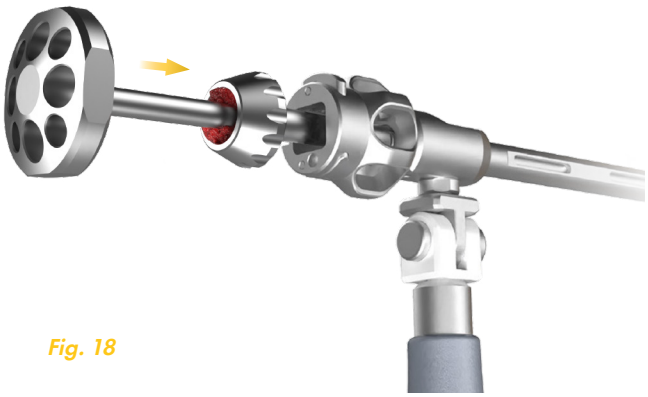


Fig. 18

Final Bone Graft Delivery *(Optional)*

After implanting, more bone graft should be added to the disc space. Fill the Funnel (100.7056) with autogenous bone graft and use the Funnel Plunger (100.7058) to push it into the Funnel's distal end, making sure to fill both sides of the implant. Check that enough bone graft has been added with an x-ray. *(Fig. 19)*

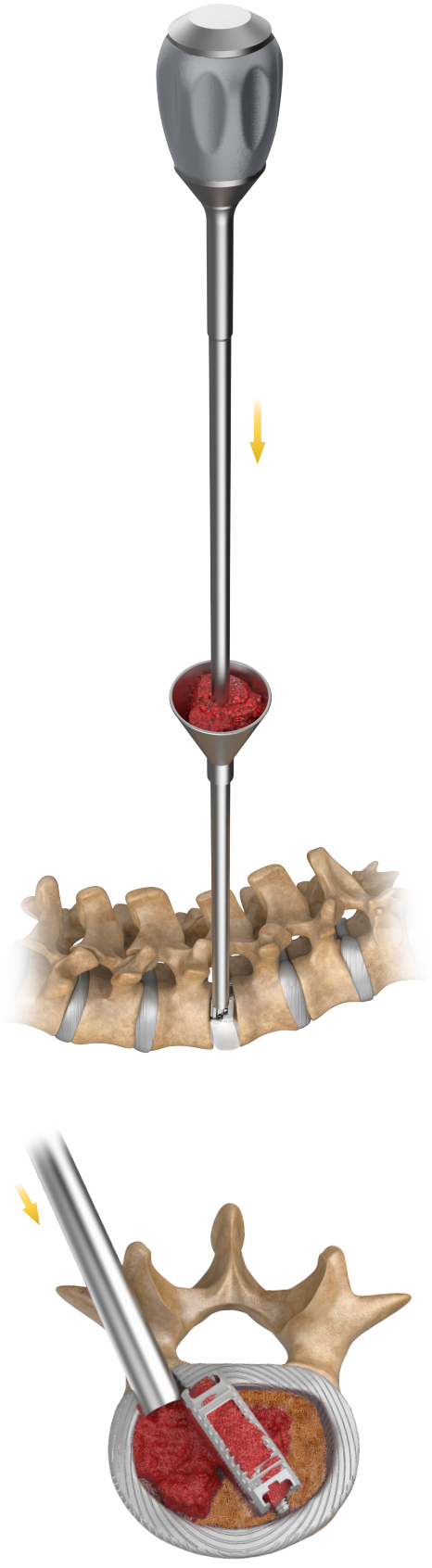


Fig. 19

Implant Impaction *(Optional)*

The provided Cage Straight Impacter (367.7600) may be utilized to adjust the deployed placement of the implant. Tap as necessary to adjust. *(Fig.20)*

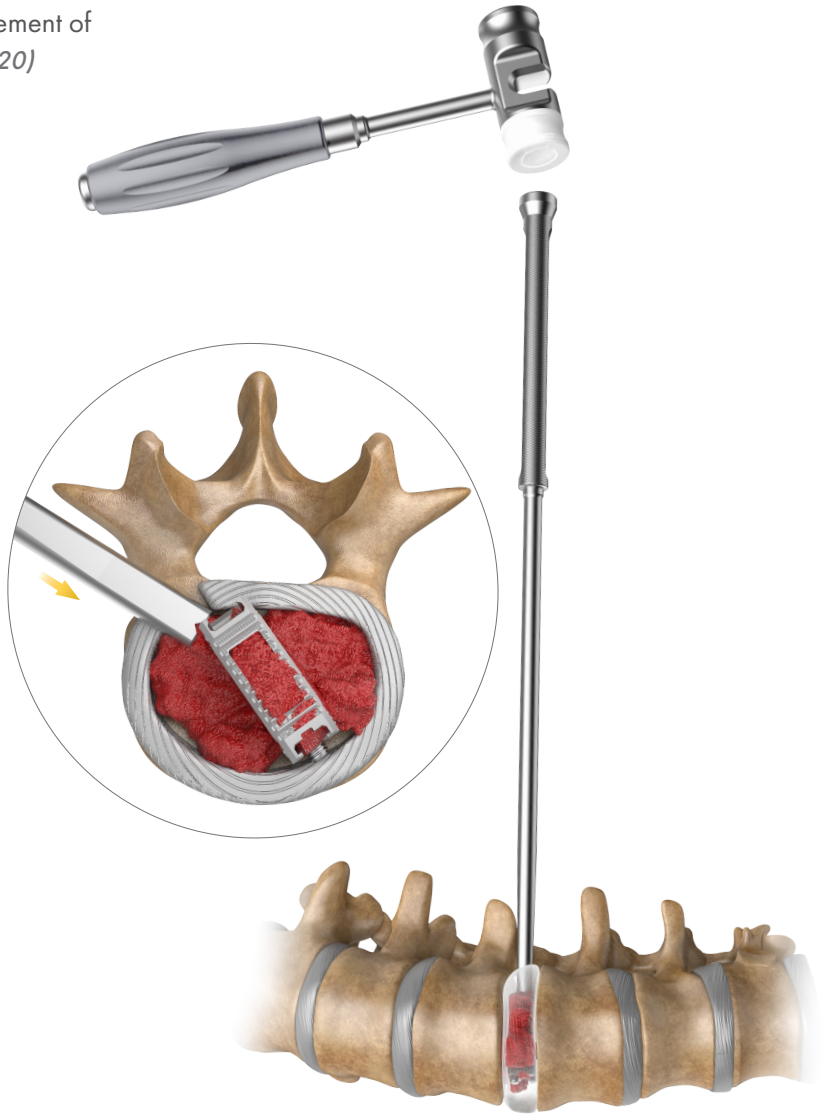


Fig. 20

VIII. INSERTER REMOVAL

After the implant is successfully placed and confirmed to need no further adjustments, turn the Cage Inserter knob counterclockwise until it is detached from the implant. Gently pull the Cage Inserter away from the implant to remove it. *(Fig.21)*

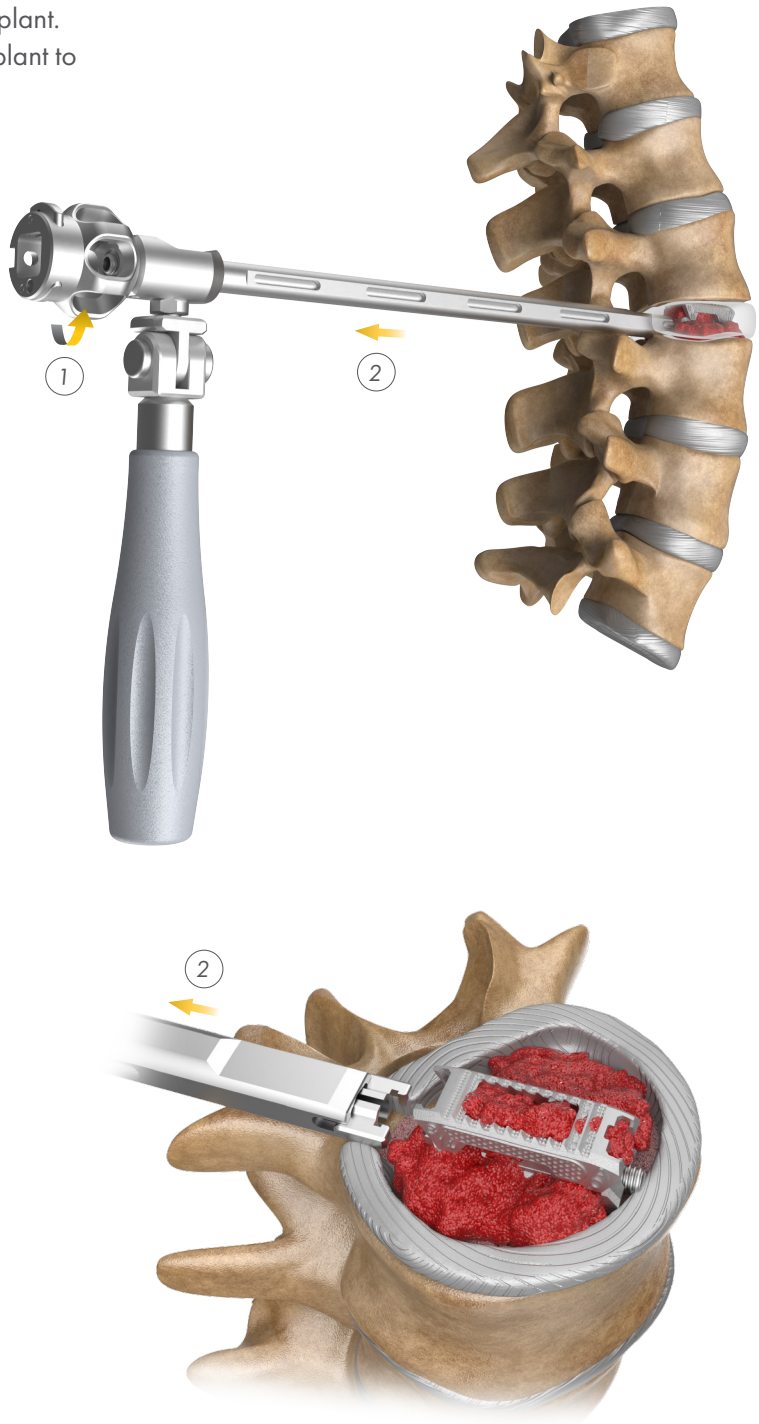


Fig. 21

IX. IMPLANT REMOVAL

Step 1

If removal or revision is required, securely attach the Cage Inserter to the implant by turning the knob clockwise. *(Fig.22)-1*

Step 2

Once the Expansion Driver is securely attached and engaged to the implant, collapse the implant by rotating the Torque Limiting Handle counterclockwise. *(Fig.22)-2*

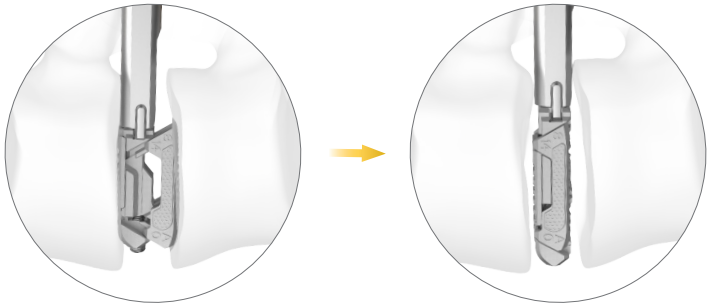


Fig. 22

Step 3

Once the implant is fully collapsed, pull it out using the Cage Inserter. *(Fig.23)*

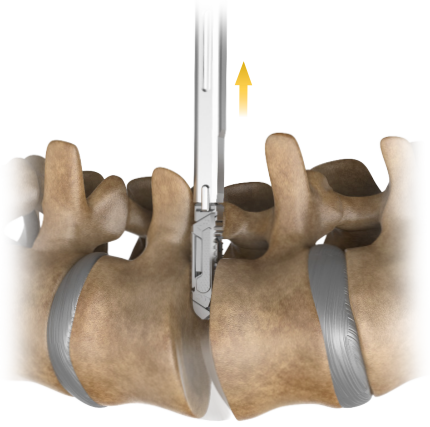


Fig. 23

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