



Idys[®]-**ALIF 3DTi**

ANTERIOR INTERBODY



3DTi

Surgical Technique - USA



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Idys-**ALIF 3DTi**

ANTERIOR INTERBODY



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Surgical Technique

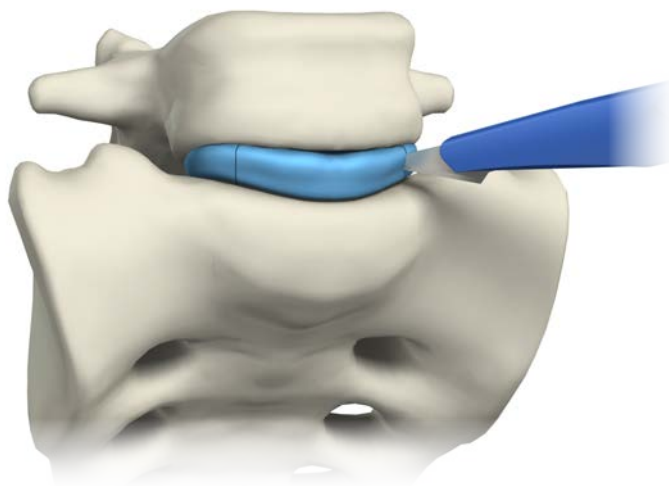


To become the architects of spine, Clariance has developed its products in collaboration with expert surgeons in their practice from all backgrounds including from France and the US. Because of this diversity, Clariance offers solutions that meet all practices. This surgical technique guide is the result of the proximity between the surgeons and Clariance.

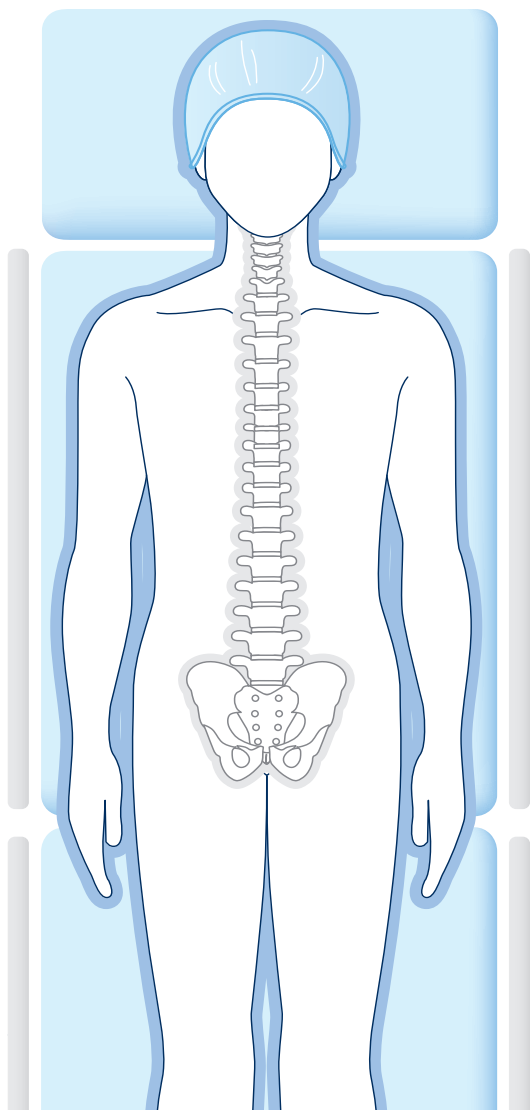
Prior to using any Clariance device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

1 | DISCECTOMY

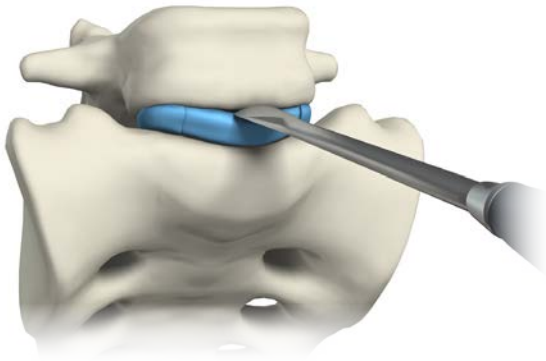
- Using a scalpel, cut a rectangular window with equivalent width of the Clariance Idys-ALIF 3DTi Cage into the intervertebral disc.



*In accordance with safety procedures, the patient is placed in the **supine position** on the operating table. The surgical approach is based on the usual techniques used by the surgeon.*

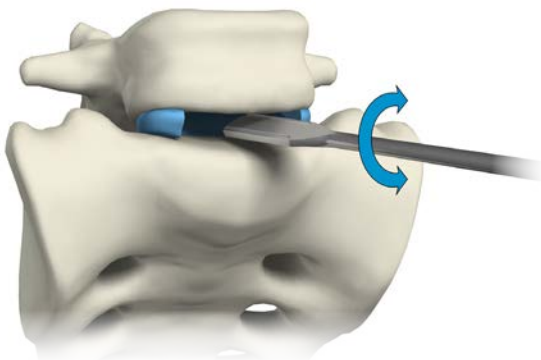


- Separate the disc from the superior and inferior endplates with the **Cobb Elevator**.

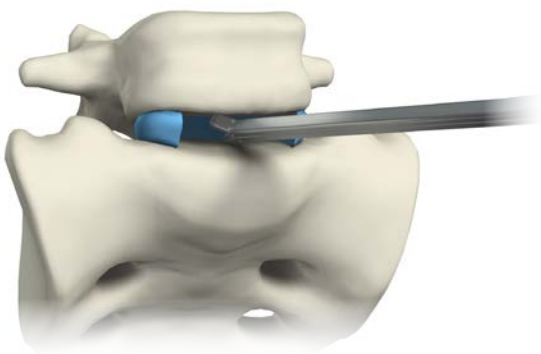


- Connect the **Shaver** to the **T-Handle**.
- Rotate the Shaver to begin the discectomy.

Shavers are available in heights ranging from 8 - 18mm in 2mm increments.



- Use the **Disc Rongeur** to remove the disc fragments.



RECOMMENDATION:

It is recommended to retain as much of the anterolateral posterior walls of the annulus as possible.



COBB ELEVATOR

24703001



SHAVER

247070xx



CANNULATED T-HANDLE

99781001



DISC RONGEUR STRAIGHT

24708xxx



ANGLED 30° DISC RONGEUR

24708132



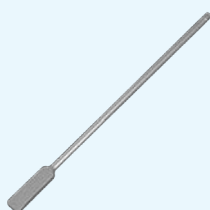
CANNULATED T-HANDLE

99781001



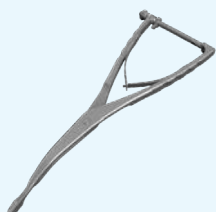
ROUNDED DISTRACTOR

247090xx



DISTRACTOR FORCEPS

24741000



CURETTE

24704109

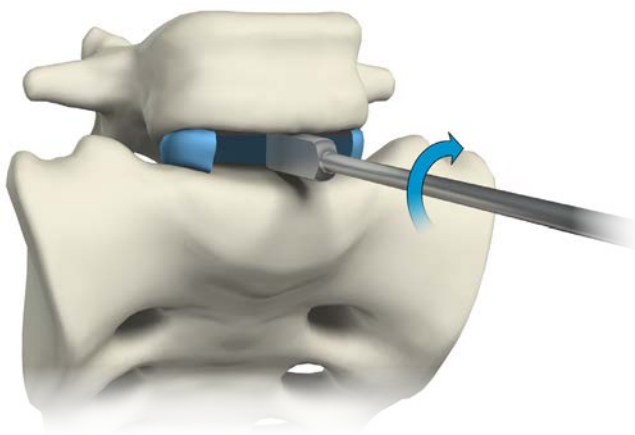


2 | SEGMENT DISTRACTION

Use the **Distraction Forceps** or **Rounded Distractor** to open the disc space and gradually restore the disc height.

- Connect the **Rounded Distractor** to the **T-Handle**.

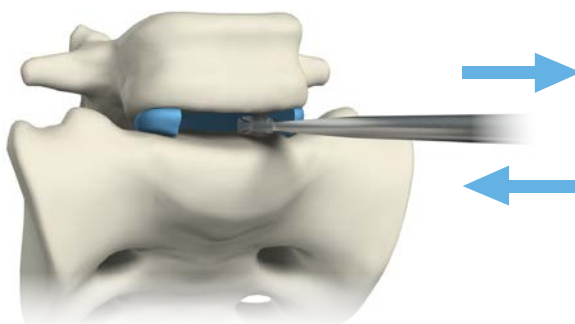
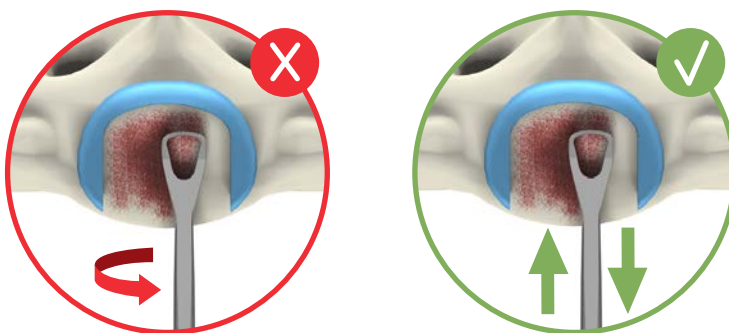
Rounded Distractors are available in heights ranging from 10 - 18mm in 2mm increments.



3 | ENDPLATE PREPARATION

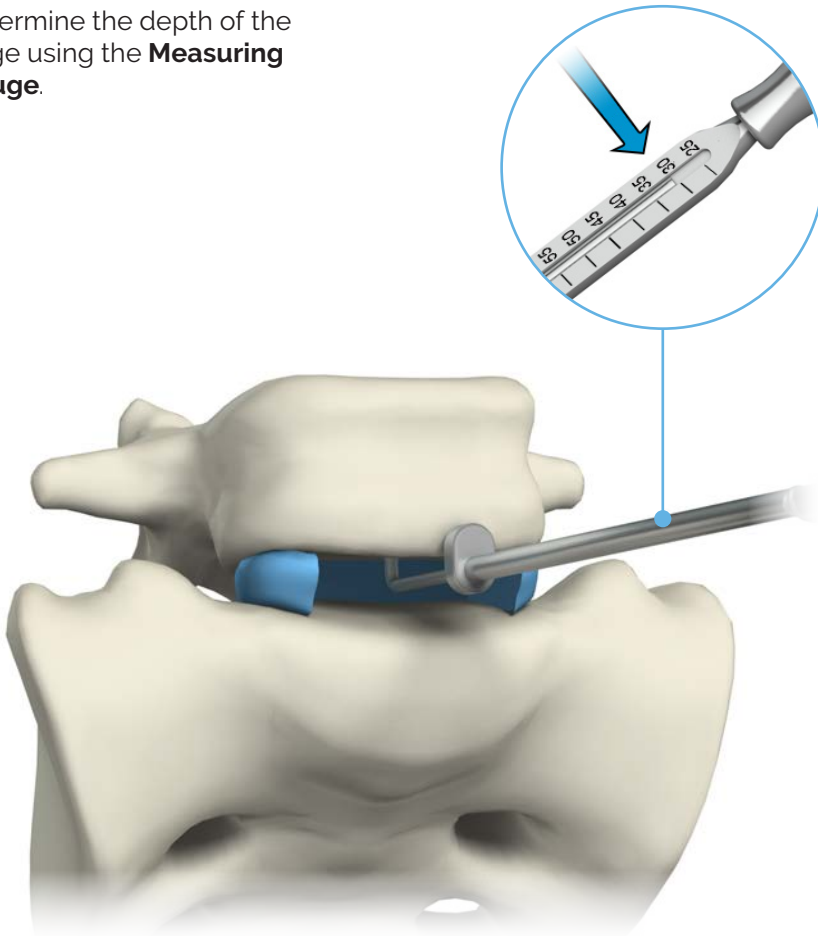
Use the **Curette** to prepare the endplates, further excising the disc material and removing the cartilaginous layer from the endplates.

This is to improve vascularization of the implanted bone graft.



4 | CAGE DEPTH MEASUREMENT (OPTIONAL)

Determine the depth of the Cage using the **Measuring Gauge**.



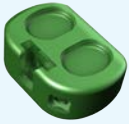
MEASURING GAUGE

24732001



TRIAL

2471xxxx



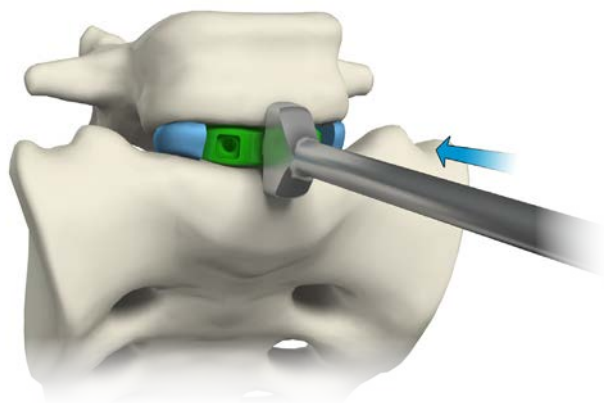
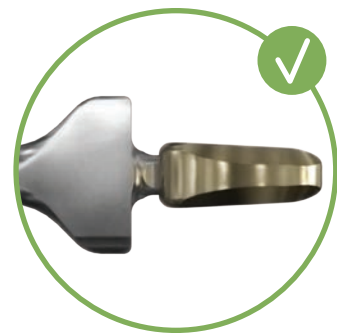
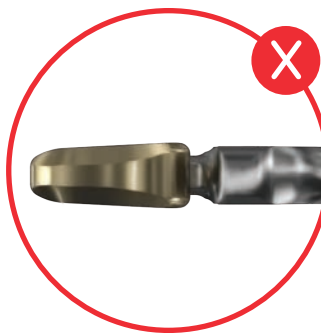
TRIAL INSERTER

24715001



5 | CAGE HEIGHT MEASUREMENT

- Connect the **Trial** to the tip of the **Trial Inserter**, rotating the knob of the Trial Inserter clockwise until the Trial is flush.
- Insert the Trial into the intervertebral disc space.
- The **Trial** Inserter has a depth stop.



Verify the position of the Trial and confirm the appropriate lordotic angle and disc height via X-Ray.



6 | PREPARATION OF ANTERIOR ADJACENT VERTEBRAE (OPTIONAL)

- After selecting the Trial, snap it onto the corresponding **Hollow Chisel Template**.

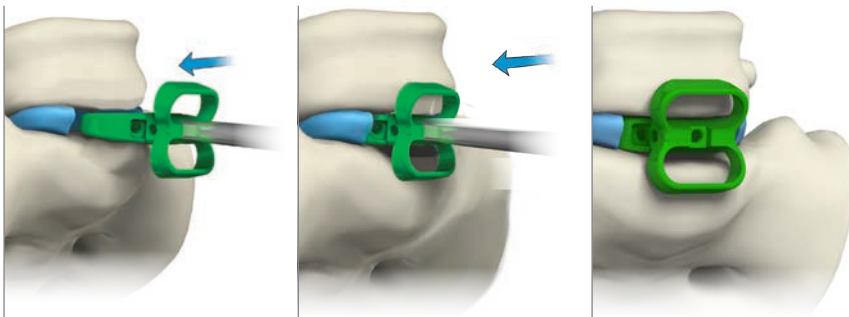


- Connect the Trial/Template assembly to the **Cage Inserter** by inserting the tip of the Cage Inserter into the Hollow Chisel Template and rotating the knob of the Cage Inserter clockwise.



- Using the **Slap Hammer**, insert the Trial/Template assembly into the intervertebral disc space until the Hollow Chisel Template lies flush against the anterior surface of the adjacent vertebral bodies.

Pay special attention to keep the Trial/Template assembly centered in the intervertebral disc space.



- Detach the **Cage Inserter** from the **Hollow Chisel Template**.

HOLLOW CHISEL TEMPLATE

247060xx



CAGE INSERTER

24912009 Body
24911005 Tube



SLAP HAMMER

99762000



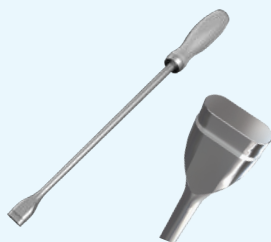
HOLLOW CHISEL

24705003



BONE IMPACTOR

24716000



SLAP HAMMER

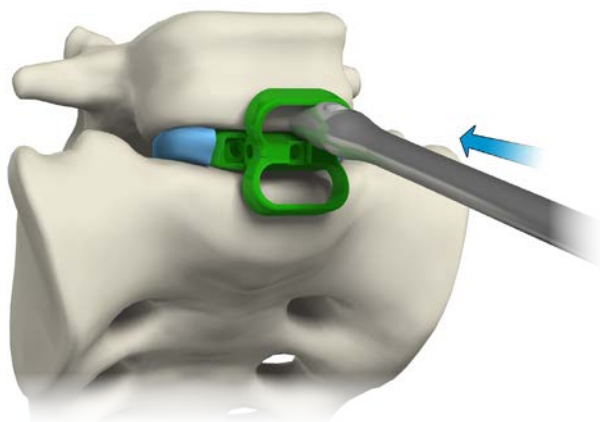
99762000



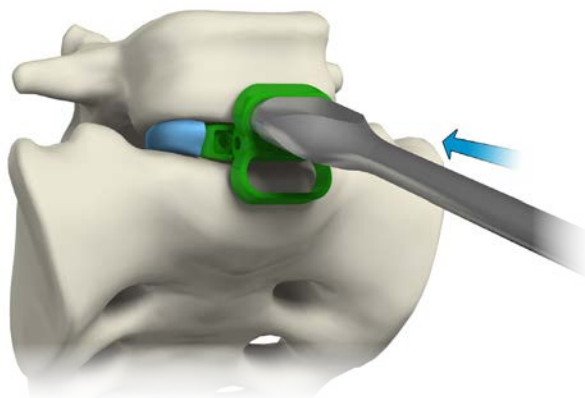
- Use the **Hollow Chisel** to impact the anterior edge of the adjacent vertebral bodies in a minimum of four different locations.
- Use the Hollow Chisel Template as a guide.

RECOMMENDATION:

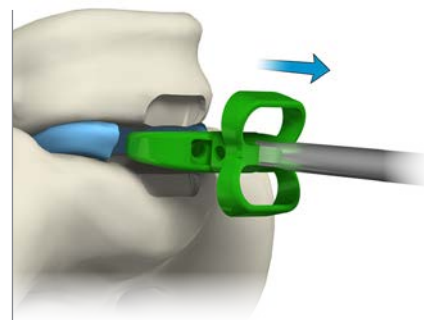
Do not remove the impacted bone.



- Use the **Bone Impactor** to compact the punctured anterior edges of the adjacent vertebral bodies.



- Reattach the Cage Insertor onto the Hollow Chisel Template.
- Use the **Slap Hammer** to remove the **Trial/Template assembly** from the intervertebral space.



7 | IMPLANT PREPARATION

- Snap the **Plate** of appropriate height onto the Cage.
- The height of the Plate should not exceed the height of the vertebrae.



- Attach the Cage/Plate assembly onto the Cage Inserter.



8 | CAGE PACKING

- Place the Cage into the corresponding **Filling Block**.



- Use the corresponding **Graft Impactor** to firmly pack graft material into the cavities of the implant.

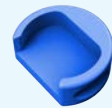
CAGE INSERTER

24715002



FILLING BLOCK

247170xx



GRAFT IMPACTOR

46761000 24x26 / 26x32
46761001 30x35 / 30x40



SLAP HAMMER

99762000

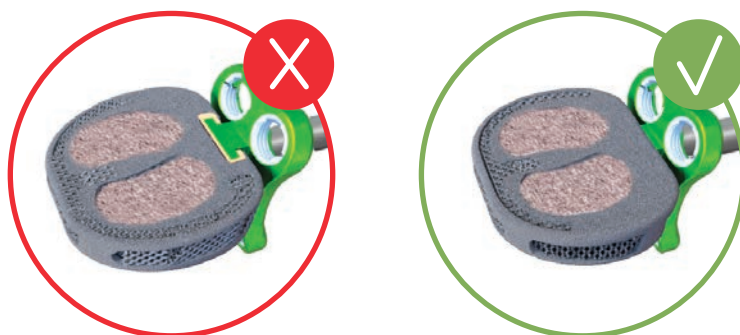


9 | IMPLANT INSERTION

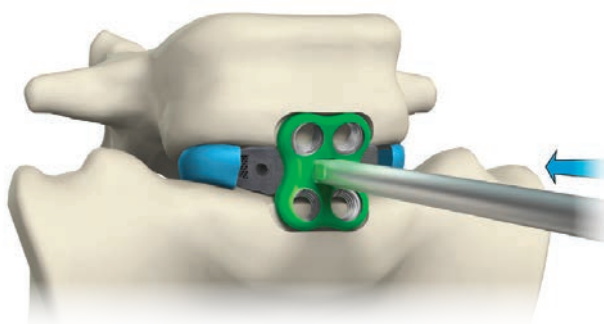
- Insert the **Cage/Plate assembly** into the intervertebral space with the snap connection oriented caudally as seen below.

RECOMMENDATION:

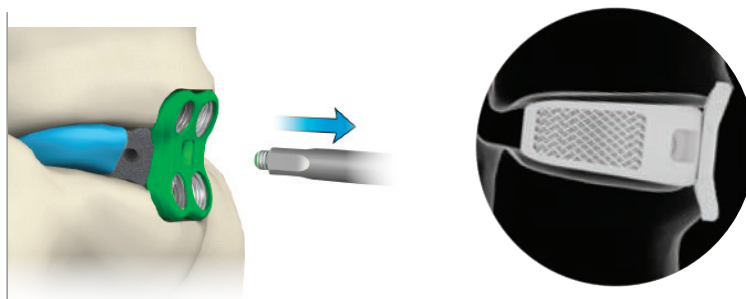
This position is recommended for optimal Cage/Plate assembly in the presence of a large sacral slope.



- Lightly impact with the Slap Hammer. The Plate should lie flush against the prepared anterior edges of the adjacent vertebral bodies.
- Pay special attention to keep the Cage centered in the intervertebral disc space.



- Detach the **Cage Inserter** from the **Plate** by rotating the knob counterclockwise.
- Verify the proper position of the implant via X-Ray.



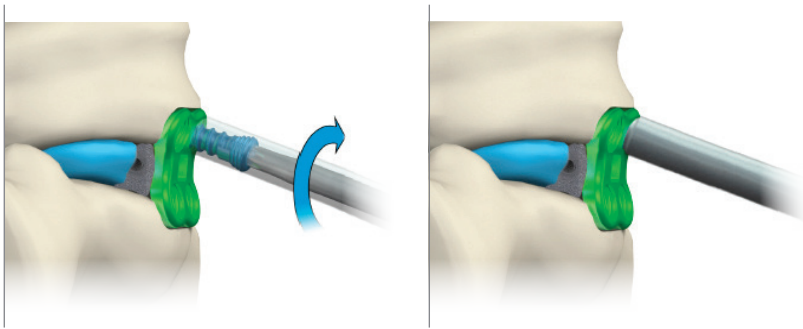
10 | SCREW INSERTION

Idys-ALIF Screws are :

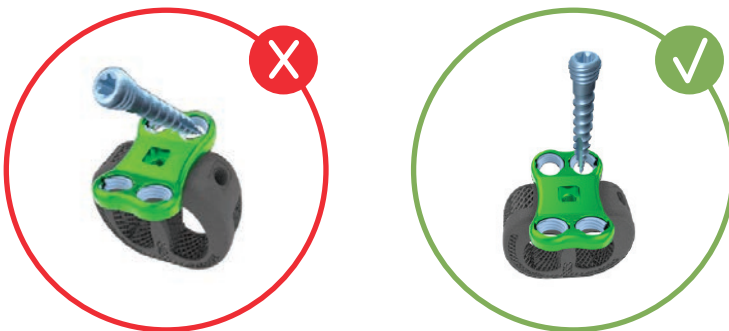
- Self-tapping
- Self-drilling



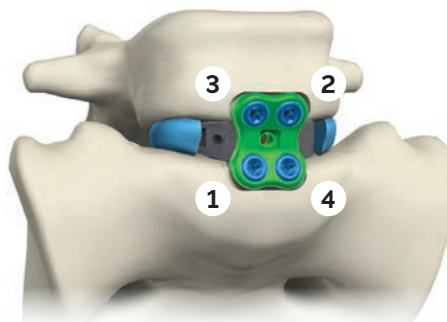
- The selected screw is inserted into the plate using the **Tightening Wrench** assembled with the **Ratcheting Cylindrical Handle**, until the screw head enters the plate.



The tip of the Screw must not be applied against the sleeve of the Plate when screwing.



- Repeat this pre-tightening step for all **4 screws**.



RATCHETING CYLINDRICAL HANDLE

99782001



TIGHTENING WRENCH

45720000



RECOMMENDATION:

It is recommended to insert the Screws in a staggered position to ensure the Plate is placed on the anterior surface of adjacent vertebral bodies.

TIGHTENING WRENCH

45720000



COUNTER TORQUE

24721001



CAGE INSERTER

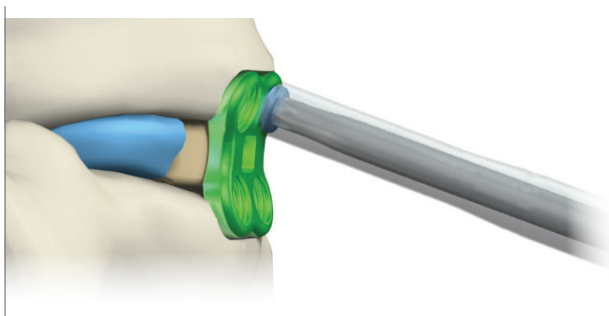
24912009 Body
24911005 Tube



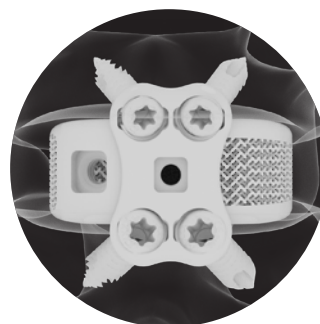
- Once the pre-tightening has been performed on the 4 screws, the final tightening of each screw must be performed using the **Tightening Wrench** assembled with the **Ratcheting Cylindrical Handle**.
- Screw-locking is obtained when the head of the Screw is completely inserted into the **Plate**.

RECOMMENDATION:

In order to perform the final tightening, it is recommended to use the counter-torque, positioning it beforehand on the sleeve, prior to perform the final tightening using the Tightening Wrench.



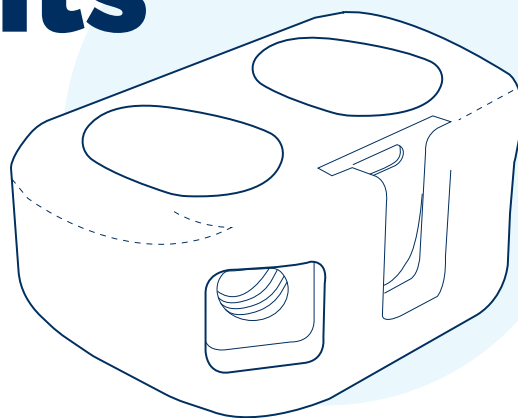
- Perform a final X-Ray check to verify the final positioning of the Cage/Plate and four Screws.



11 | REMOVAL

- Remove the four Screws using the **Tightening Wrench** and the **Counter Torque**.
- Attach the **Cage Inserter** to the **Plate**.
- Remove the **Cage/Plate** assembly using the **Slap Hammer**.

Instruments



Instruments IDYS-ALIF Tray #1



**IDYS-ALIF
INSTRUMENT BASE #1**

24992006 Base
24991005 Instruments Tray



**CANNULATED
T-HANDLE**

99781001



CURETTE

24704109



COBB ELEVATOR

24703001



RETRACTOR PIN

J44123



SHAVER

24707008 H08mm
24707010 H10mm
24707012 H12mm
24707014 H14mm
24707016 H16mm
24707018 H18mm



**DISC RONGEUR
STRAIGHT**

24708432 04mm
24708832 08mm



**ANGLED 30° DISC
RONGEUR**

24708132 08mm

Instruments IDYS-ALIF Tray #2



**IDYS-ALIF
INSTRUMENT BASE #2**

24992007 **Base**
24991005 **Instruments Tray**



**ROUNDED
DISTRACTOR**

24709010 **H10mm**
24709012 **H12mm**
24709014 **H14mm**
24709016 **H16mm**
24709018 **H18mm**



SLAP HAMMER

99762000



**CANNULATED
T-HANDLE**

99781001



BONE RONGEUR

24709232 **02mm**
24709432 **04mm**



HOLLOW CHISEL

24705003



BONE IMPACTOR

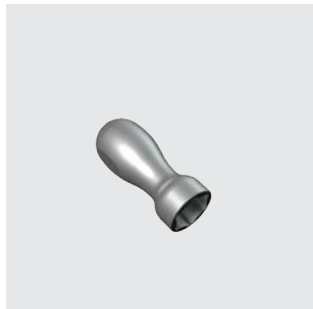
24716000

Instruments IDYS-ALIF Tray #3



IDYS-ALIF INSTRUMENT BASE #3

24992008 Base
24991005 Instruments Tray



UNLOCKING WRENCH

24762001



MEASURING GAUGE

24732001



CAGE INSERTER

24912009 Body
24911005 Tube



TRIAL INSERTER

24715001

Instruments IDYS-ALIF Tray #4



**IDYS-ALIF
INSTRUMENT BASE #4**

24992009 Base
24991005 Instruments Tray



**RATCHETING
CYLINDRICAL HANDLE**

99782001



DISTRACTOR FORCEPS

24741000



GRAFT IMPACTOR

46761000 24x26 / 26x32
46761001 30x35 / 30x40



FILLING BLOCK

24717032 26x32mm
24717035 30x35mm
24717040 30x40mm



COUNTER TORQUE

2472001



TIGHTENING WRENCH

45720000

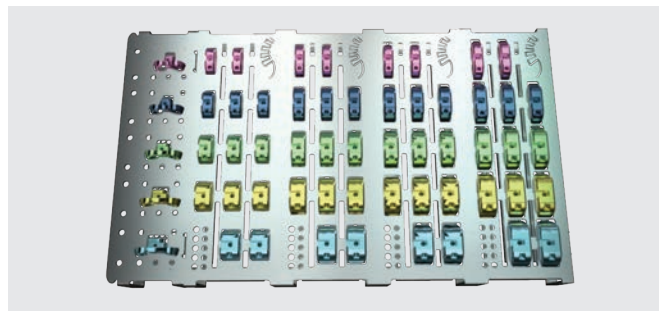
Instruments IDYS-ALIF Tray #5



IDYS-ALIF INSTRUMENT BASE #5

24992010
24991005

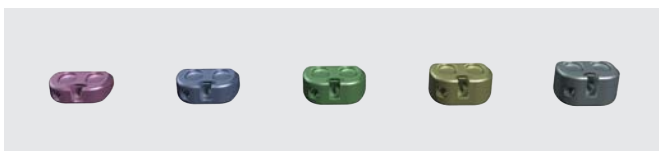
Base
Instruments Tray



TRIALS RACK

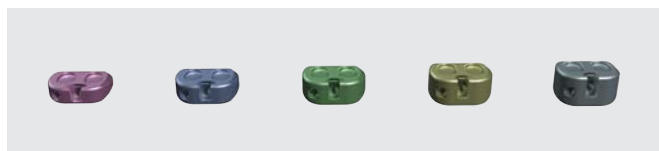
24992107
24992108
24992109

Trials 26x32mm
Trials 30x35 mm
Trials 30x40mm



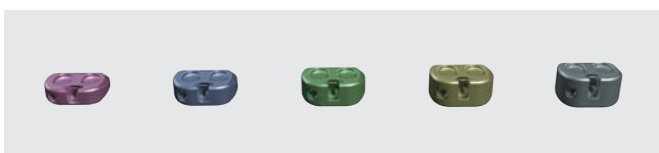
IDYS-ALIF TRIAL - 26x32MM

	06°	10°	14°	18°
H10mm	24710006	24710010	-	-
H12mm	24710206	24710210	24710214	-
H14mm	-	24710410	24710414	-
H16mm	-	24710610	24710614	24710618
H18mm	-	-	-	-



IDYS-ALIF TRIAL - 30x35MM

	06°	10°	14°	18°
H10mm	-	-	-	-
H12mm	24711206	24711210	24711214	-
H14mm	-	24711410	24711414	24711418
H16mm	-	24711610	24711614	24711618
H18mm	-	-	24711814	24711818



IDYS-ALIF TRIAL - 30x40MM

	06°	10°	14°	18°
H10mm	-	-	-	-
H12mm	-	24713210	-	-
H14mm	-	24713410	24713414	-
H16mm	-	24713610	24713614	24713618
H18mm	-	-	24713814	24713818



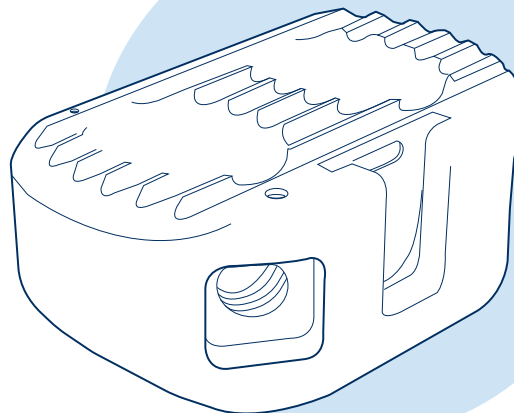
HOLLOW CHISEL TEMPLATE

H10mm	H12mm	H14mm	H16mm	H18mm
24706010	24706012	24706014	24706016	24706018

Implants

Sterile

Product availability may vary upon markets. Please check with your Clariance representative.



IDYS-ALIF CAGES - 26x32MM

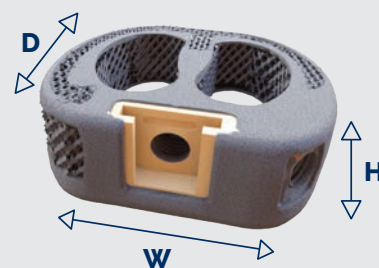
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H12mm	46570206-S	46570210-S	46570214-S	-
H14mm	-	46570410-S	46570414-S	-
H16mm	-	46570610-S	46570614-S	46570618-S
H18mm	-	-	-	-

IDYS-ALIF CAGES - 30x35MM

	06°	10°	14°	18°
H10mm	-	-	-	-
H12mm	46571206-S	46571210-S	46571214-S	-
H14mm	-	46571410-S	46571414-S	46571418-S
H16mm	-	46571610-S	46571614-S	46571618-S
H18mm	-	-	46571814-S	46571818-S

IDYS-ALIF TIVAC CAGES - 30x40MM

	06°	10°	14°	18°
H10mm	-	-	-	-
H12mm	-	46573210-S	-	-
H14mm	-	46573410-S	46573414-S	-
H16mm	-	46573610-S	46573614-S	46573618-S
H18mm	-	-	46573814-S	4657 3818-S



IDYS-ALIF PLATES

H10mm	H12mm	H14mm	H16mm	H18mm	
24430010-S	24430012-S	24430014-S	24430016-S	24430018-S	

VERTEBRAL SCREWS Ø5MM

L20mm	L25mm	L30mm	L35mm	-	
24020520-S	24020525-S	24020530-S	24020535-S	-	



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Notified Body N°2460 - As some references are not covered by the 
marking, refer to the product label which bears the  marking