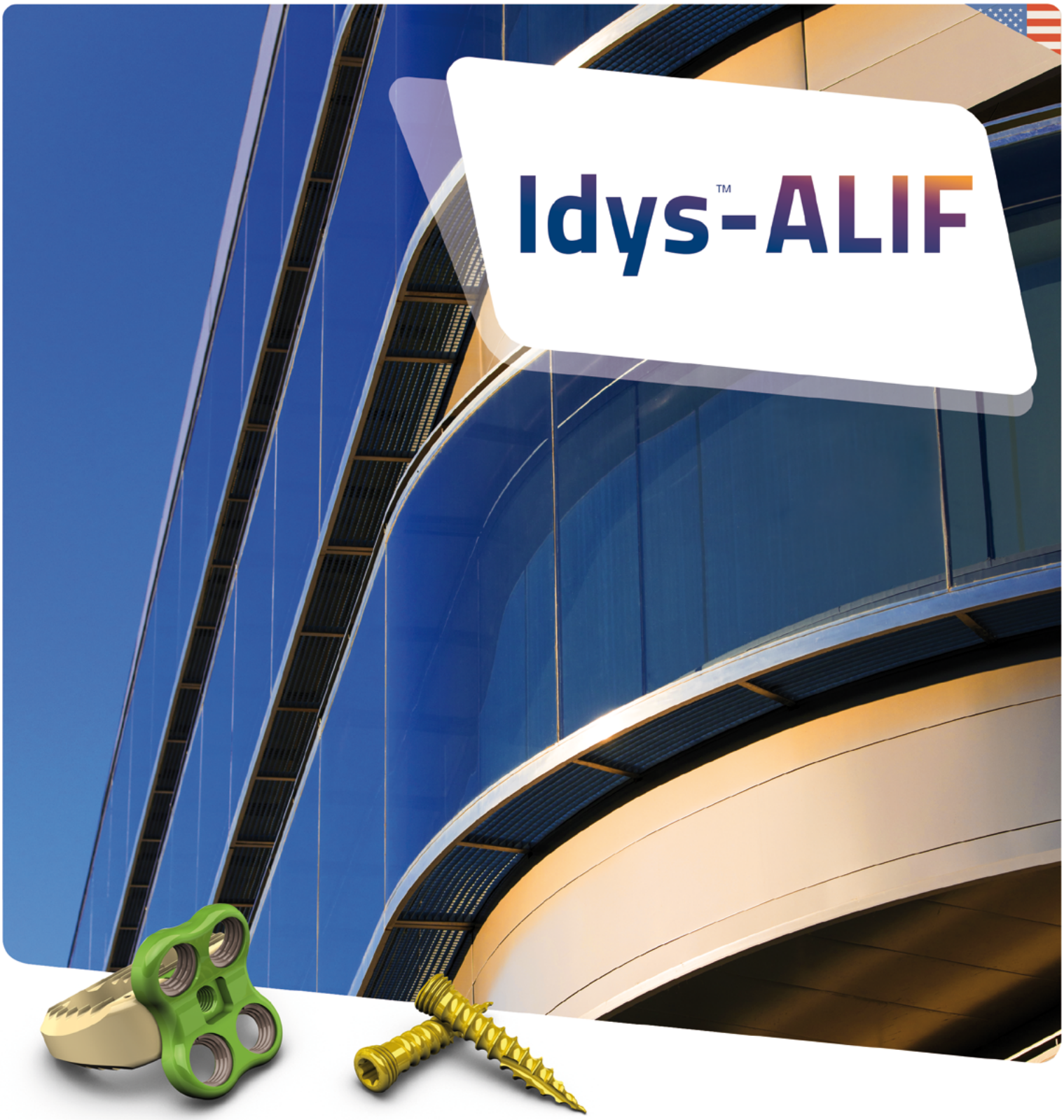
Idys™-ALIF



FUSION TECHNOLOGIES

CLARIANCE
innovation for spine surgery

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CE 2460

Contents

Introduction

Idys™-ALIF is an implant developed to perform interbody fusions of the lumbar spine using an anterior approach.

Idys™-ALIF cages and plates were designed in collaboration with surgeons, by an experienced development team in the field of spinal implants. The design team has worked to create a cage made of PEEK, as well as an anatomical ALIF plate to restore disc height and lumbar lordosis whilst providing immediate stability in terms of treatment. The goal is to create optimal conditions to promote bone fusion. Ergonomic instrumentation of the Idys ™ -ALIF cage meets the needs of surgeons in regards to reliability, safety, and installation convenience.

This surgical technique is for illustrative purposes only. The technique performed in each case will be determined by the medical judgement of the surgeon evaluated before and during the surgery as the best mode of treatment for each patient.

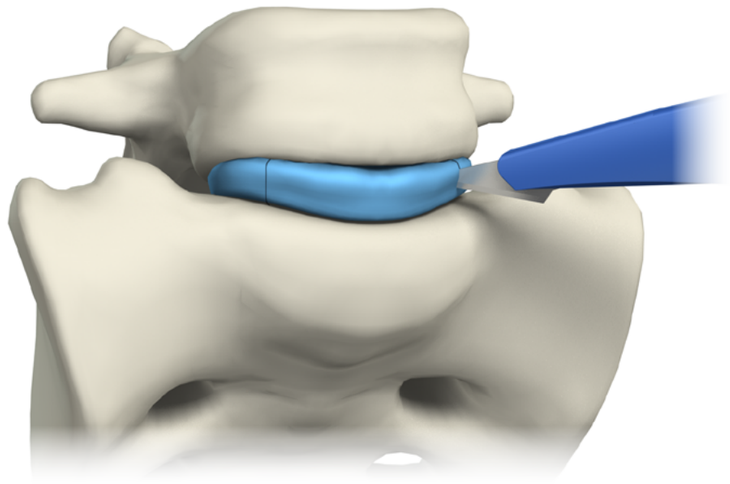
Surgical Technique

1 Discectomy
2 Segment distraction
3 Endplate preparation
4 Cage depth measurement
5 Cage height measurement
6 Preparation of anterior aspects of adjacent vertebrae
7 Implant preparation
8 Cage packing
9 Implant insertion
10 Implant fixation
11 Removal

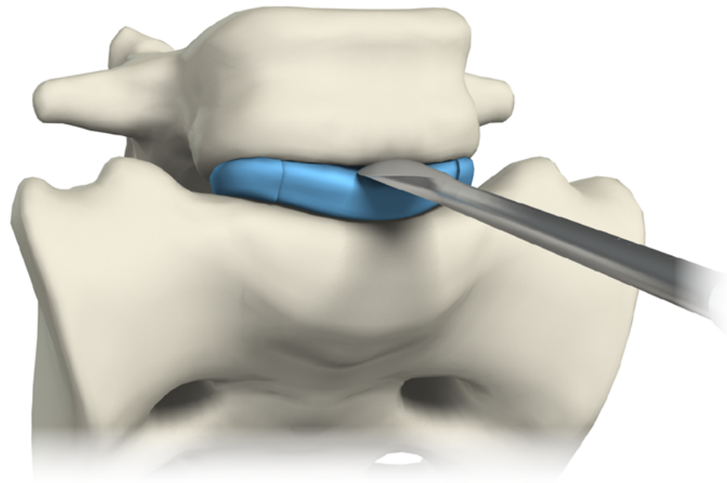
Following all necessary safety protocols, place the patient on the operating table in the supine position. Final positioning of the patient and surgical approach are based on known techniques routinely used by surgeons.

Discectomy 1

Using a scalpel, cut a rectangular window the width of the Clariance Idys™-ALIF cage into the intervertebral disc.



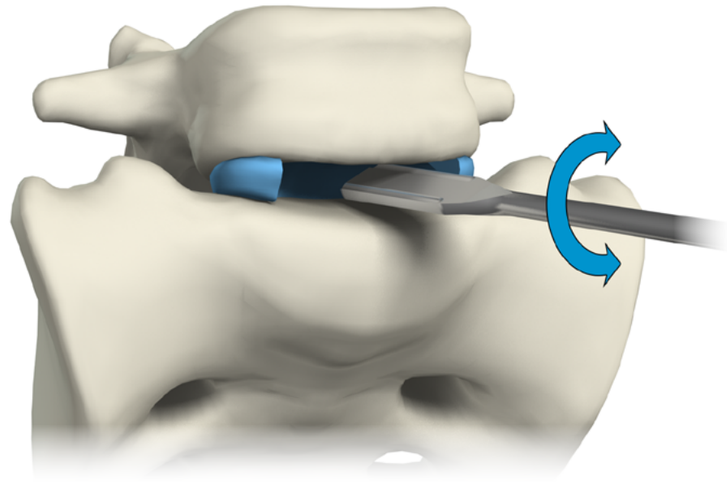
Separate the disc from the superior and inferior endplates with the Cobb's elevator.



24703001
COBB'S ELEVATOR

Rotate the distractor blades to begin the discectomy.

Distractor blades are available in heights ranging from 8 - 18 mm, in 2 mm increments.

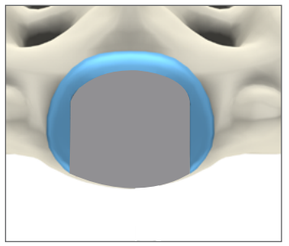


99781001
T-HANDLE

247070XX
SHAVERS
8-10-12-14-16-18 MM

Recommandations

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



24708XXX
STRAIGHT DISC RONGEUR

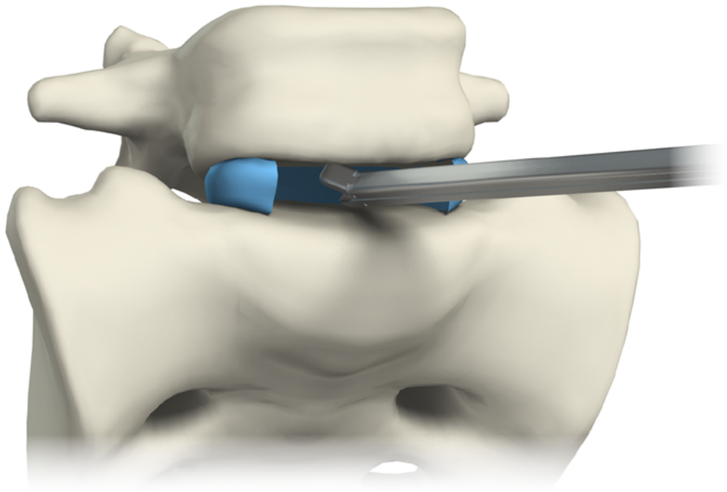
24708XXX
INCLINED 30 DISC
RONGEOUR

24741000
DISTRACTION FORCEPS

99781001
CANNULATED T-HANDLE

247090XX
ROUNDED DISTRACTOR
10-12-14-16-18 MM

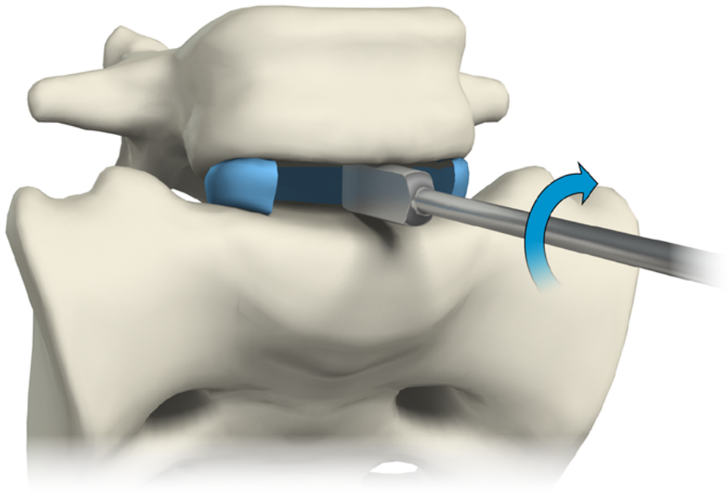
Use a straight disc rongeur to remove the disc fragments.



Segment distraction 2

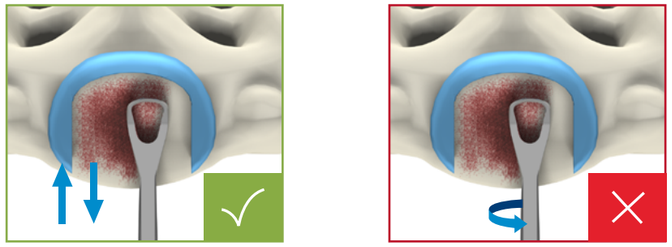
Use the distraction forceps or rounded distractor to open the disc space and gradually restore disc height.

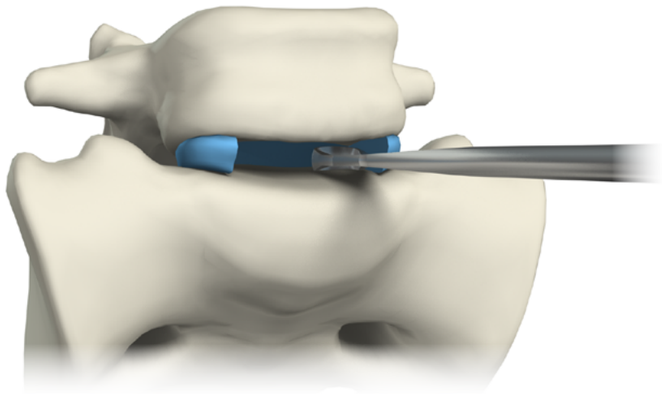
Spreaders are available in heights ranging from 10 - 18 mm, in 2 mm increments.



Endplate preparation 3

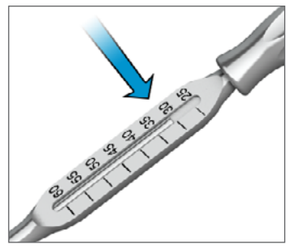
Use the curette to prepare the endplates, further excising the disc material and removing the cartilaginous layer from the endplates. This is to improve vascularization of the implanted bone graft.

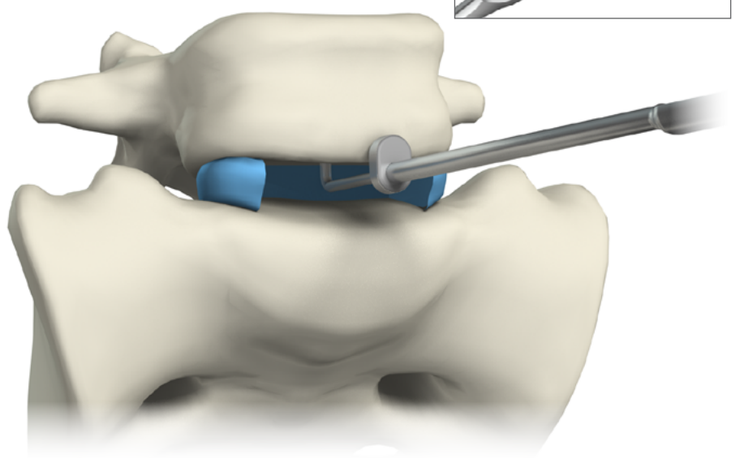




Cage depth measurement (Optional) 4

Determine the depth of the cage (P 24, P 26 or P 30 mm) using the measuring gauge.





24704109
CURETTE

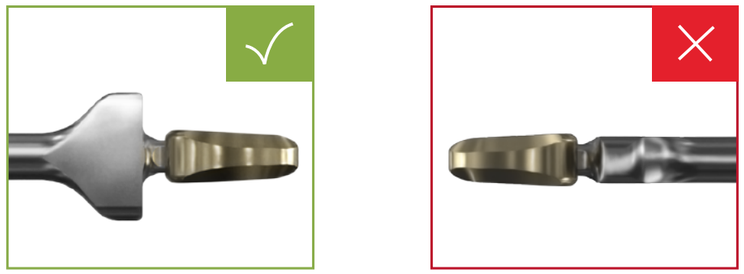
24732001
MEASURING GAUGE

2471XXXX
TRIAL

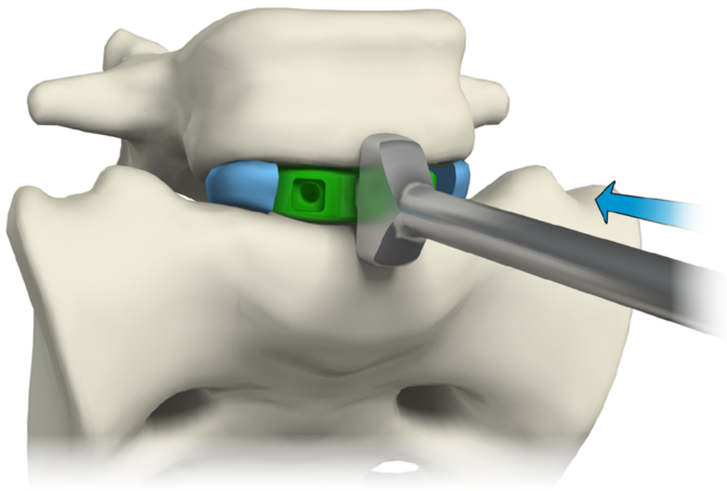
24715001
TRIAL INSERTER

Cage height measurement 5

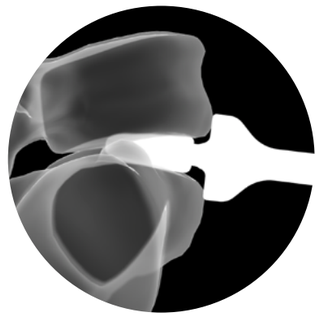
Mount the trial as far as it will go onto the Trial Inserter.



Insert the trial into the intervertebral disc space.

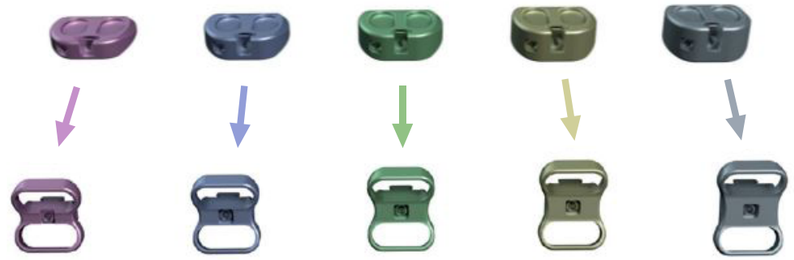


Verify the position of the trial and confirm the appropriate lordotic angle and disc height via x-ray.

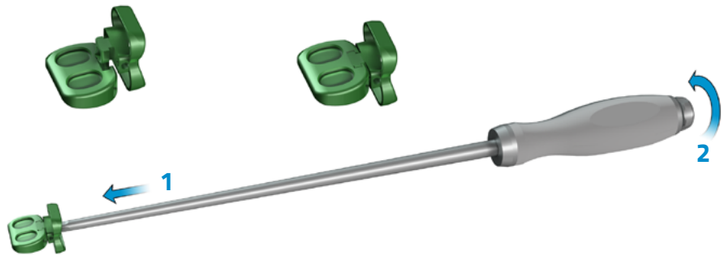


Preparation of anterior aspects of adjacent vertebrae (Optional) 6

After selecting the trial, snap it onto the corresponding hollow chisel template.

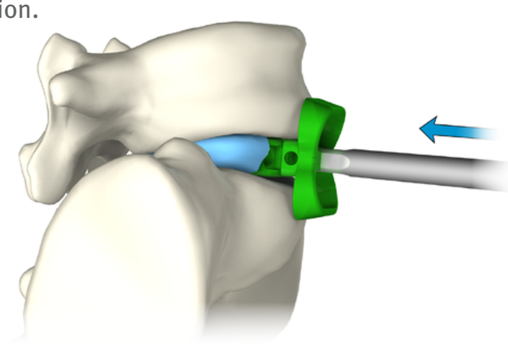


Attach the assembly onto the cage inserter.

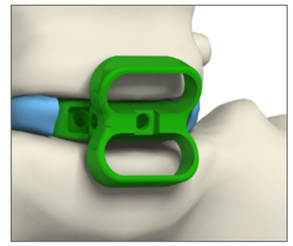


Using the slap hammer, insert the trial/template assembly into the intervertebral disc space until the cut-out template lies flush against the anterior surface of the adjacent vertebral bodies.

Special attention to center the cage and plate is required during this operation.



Detach the cage inserter from the hollow chisel template.



247060XX
HOLLOW CHISEL
TEMPLATE

24715002
CAGE INSERTER

24762000
SLAP HAMMER

24705003
HOLLOW CHIESEL

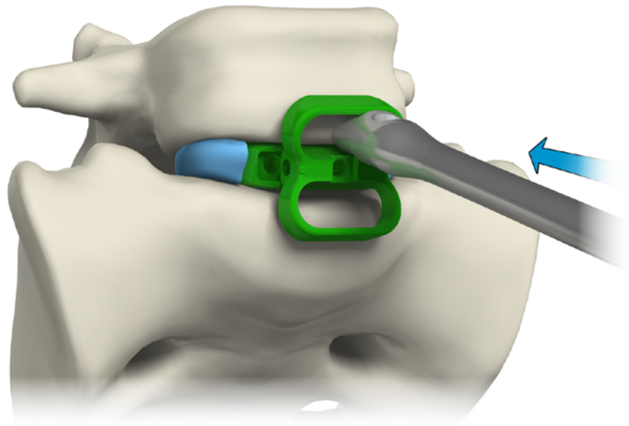
24716000
BONE IMPACTOR

24762000
SLAP HAMMER

Use the bone hollow chiesel to puncture the anterior edge of the adjacent vertebral bodies in at least 4 spots. Use the cut-out template as a guide.

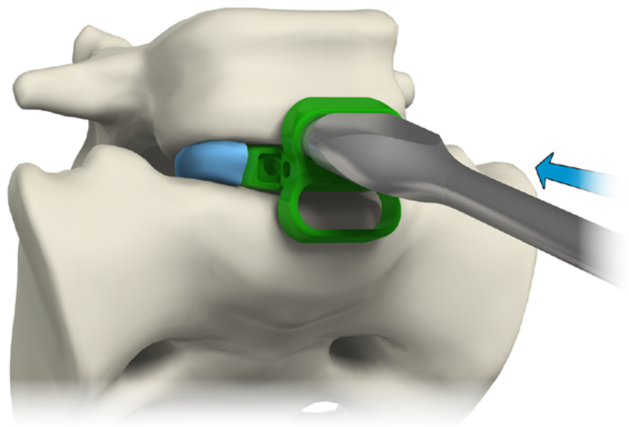
Recommandation

Leave the punctured bone. It will be impacted on the next step.

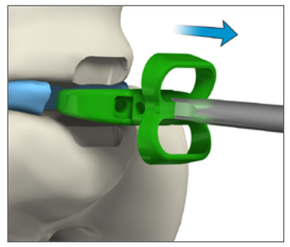


Use the bone impactor to compact the punctured anterior edges of the adjacent vertebral bodies.

It push the anterior edges in order to reduce the relief of the plate on the anterior wall.



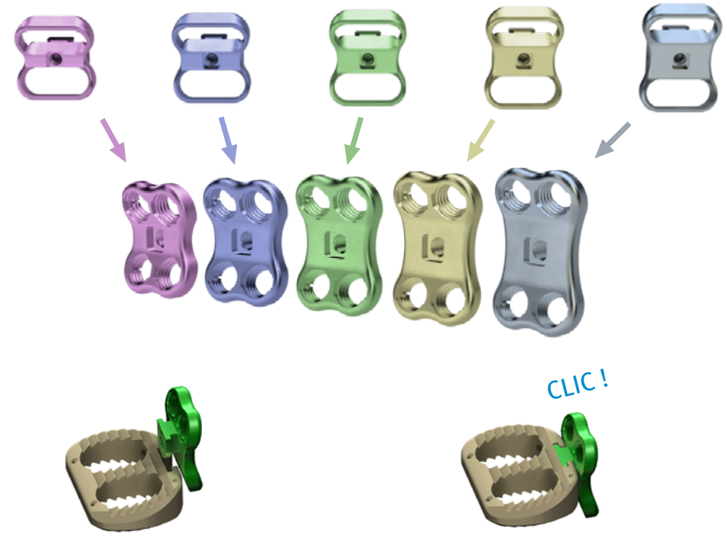
Reattach the cage holder onto the cut-out template using the slap hammer in order to remove the template/trial assembly from the intervertebral space.



Implant preparation 7

Snap the plate for the selected cage height by hand onto the selected cage.

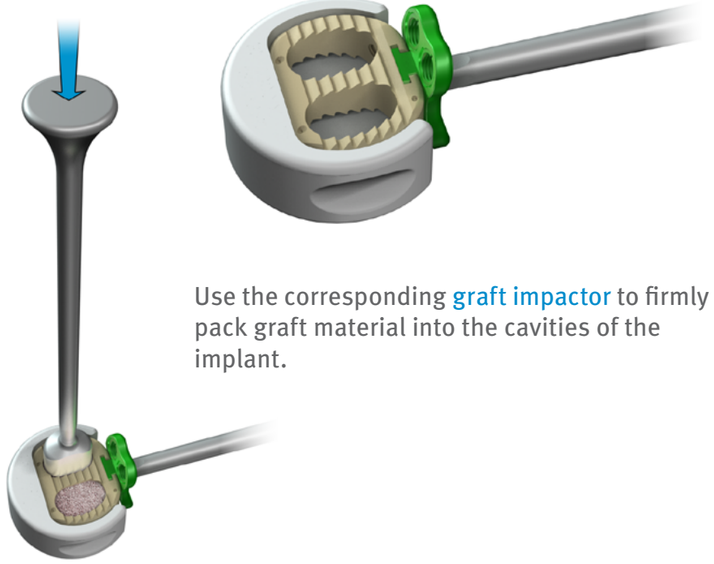
The height of the plate can't exceed the height of the vertebra.



Attach the cage/plate assembly onto the cage inserter.

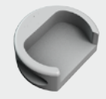
Cage packing 8

Place the cage into the corresponding filling block.



Use the corresponding graft impactor to firmly pack graft material into the cavities of the implant.

24715002
CAGE INSERTER



247170XX
FILLING BLOCK
24X26 | 26X32 | 30X35
30X40

247610XX
GRAFT IMPACTOR
24X26 | 26X32 | 30X35
30X40

24762000
SLAP HAMMER

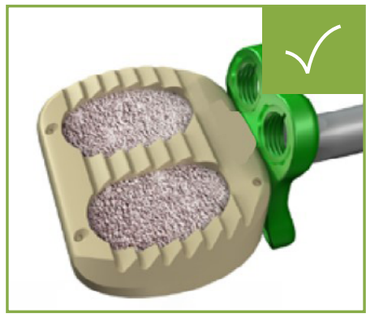
Implant insertion 9

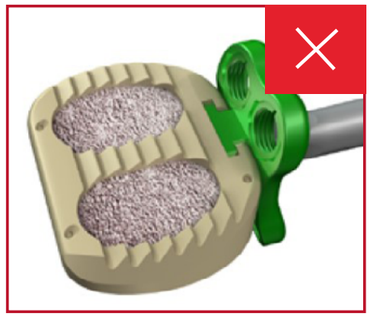
Insert the cage/plate assembly into the intervertebral space and lightly impact with the slap hammer. The plate should lie flush against the prepared anterior edges of the adjacent vertebral bodies.

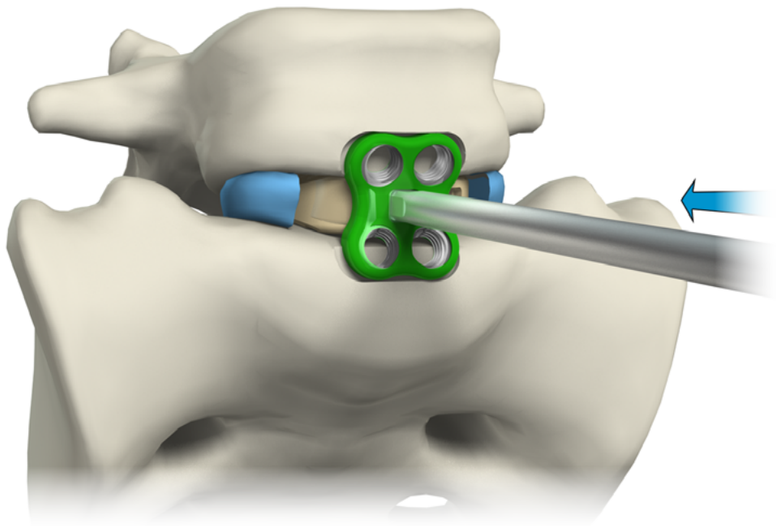
Special attention is needed to respect the centering obtained during the preparation of the implantation site.

Recommandation

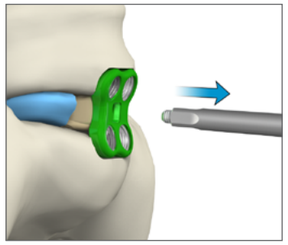
It is recommended to insert the cage with the face containing the notch downward.



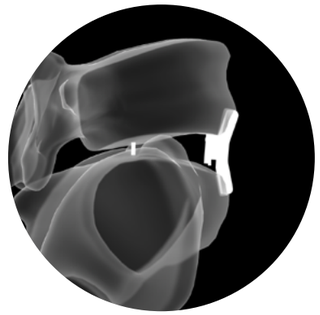




Detach the cage holder from the plate by turning the mallet.



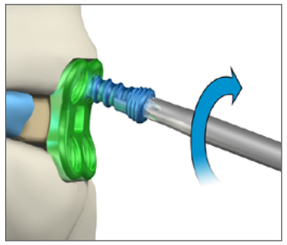
Verify the proper position of the implant via x-ray.

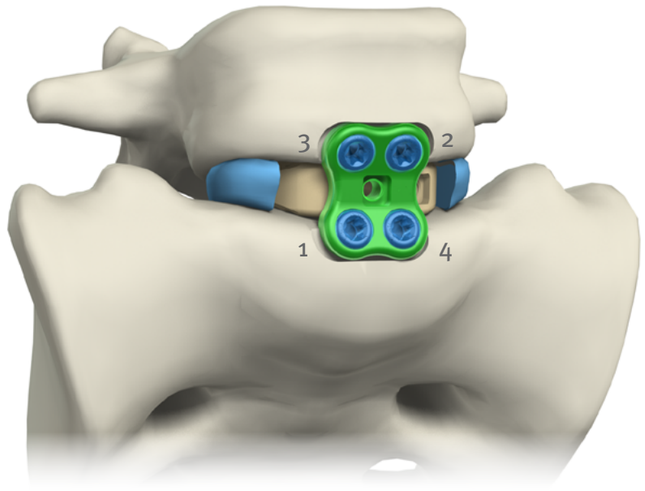


Implant fixation 10

Use the screw-holding tightening wrench to insert the screws into the plate.

Screw locking is obtained when the head of the screw is completely inserted into the plate.





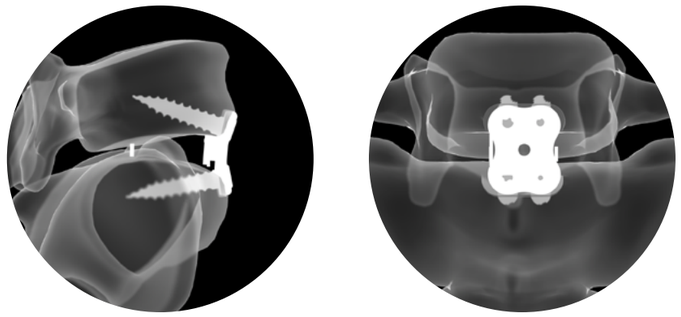
99782001
RATCHETING CYLINDRICAL HANDLE

99720002
TIGHTENING WRENCH

24715002
CAGE INSERTER

24721001
COUNTER-TORQUE

Perform a final x-ray check to verify the final positioning of the cage/plate and 4 screws via x-ray.



Removal

11

1. Remove the 4 screws using the tightening wrench and the counter-torque.
2. Attached the cage inserter to the plate.
3. Remove the cage-plate assembly using the slap hammer.

Instruments Idys ALIF

ROUNDED DISTRACTOR
H. 10 MM 24709010
H. 12 MM 24709012
H. 14 MM 24709014
H. 16 MM 24709016
H. 18 MM 24709018

SLAP HAMMER 24762000

BONE IMPACTOR 24716000

HOLLOW CHIESEL 24705003

BONE RONGEUR
02 MM 24709232
04 MM 24709432

T-HANDLE 99781001

COBB'S ELEVATOR 24703001

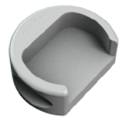
CURETTE 24704109

SHAVER
Ø 08 MM 24707008
Ø 10 MM 24707010
Ø 12 MM 24707012
Ø 14 MM 24707014
Ø 16 MM 24707016
Ø 18 MM 24707018

STRAIGHT DISC RONGEUR
04 MM ····· 24708432
08 MM ····· 24708832

INCLINED 30 DISC RONGEUR
08 MM ····· 24708132

WEITHEIMER'S CANNULA CA02718



FILLING BLOCK
26/32 ····· 24717032
30/35 ····· 24717035
24/26 ····· 24717026
30/40 ····· 24717040

COUNTER-TORQUE 24721001

GRAFT IMPACTOR
26/32 ····· 24761032
30/35 ····· 24761035
24/26 ····· 24761026
30/40 ····· 24761040

POINTE CARRÉE
DE ROCHER PO 395 16

SET SCREW FINAL TIGHTENER
24762001

CAGE INSERTER 24715002

DISTRACTOR FORCEPS 24741000

TIGHTENING WRENCH 24720001

MEASURING GAUGE 24732001

TRIAL INSERTER 24715001

RATCHETING CYLINDRICAL HANDLE
99782001

ALIF TRIAL 24 X 26 MM

	H10	H12	H14	H16	H18
6°	24710006	24710206	-	-	-
10°	24710010	24710210	24710410	24710610	-
14°	-	24710214	24710414	24710614	24710814
18°	-	-	24710418	24710618	24710818

ALIF TRIAL 26 X 32 MM

	H10	H12	H14	H16	H18
6°	24710006	24710206	-	-	-
10°	24710010	24710210	24710410	24710610	-
14°	-	24710214	24710414	24710614	24710814
18°	-	-	24710418	24710618	24710818

ALIF TRIAL 30 X 35 MM

	H10	H12	H14	H16	H18
6°	24711006	24711206	-	-	-
10°	24711010	24711210	24711410	24711610	-
14°	-	24711214	24711414	24711614	24711814
18°	-	-	24711418	24711618	24711818

ALIF TRIAL 30 X 40 MM

	H10	H12	H14	H16	H18
6°	24710006	24710206	-	-	-
10°	24710010	24710210	24710410	24710610	-
14°	-	24710214	24710414	24710614	24710814
18°	-	-	24710418	24710618	24710818

HOLLOW CHISEL TEMPLATE

H10	H12	H14	H16	H18
24706010	24706012	24706014	24706016	24706018

INSTRUCTIONS FOR USE

1 | PURPOSE

The Idys™-ALIF cages are PEEK (POLYETHERETHERKETONE) fusion devices intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is knowledgeable in the implant's material and surgical aspects and who has been trained as to its mechanical and material applications and limitations.

2 | DESCRIPTION

The Idys™-ALIF System is designed for use as a lumbar intervertebral body fusion device. The device is manufactured from medical grade polyetheretherketone (INVIBIO PEEK OPTIMA LT1) and is to be used with autograft. The device has a shape which restores the intervertebral height and lordosis. The device contains two slots to receive the autologous bone graft to promote the fusion process between the endplates. The superior and inferior surfaces of the implant are designed with teeth which interact with the surface of the vertebral endplates and helps in resisting back out. The Idys™ ALIF System is a standalone system intended to be used with plate and four bone screws, autogenous bone graft and requires no additional supplementary fixation. The Idys™-ALIF System cages are made of ASTM F2026 compliant polyetheretherketone (PEEK) and, markers made of Tantalum according to ASTM F560, the plate and screws are made of ASTM F136 titanium alloy. It is essential to insert implants with instrumentation specifically designed for this purpose. For more description of the instrumentation it is necessary to read the technical documentation associated to the Idys™-ALIF System. Detailed information concerning the surgical technique of the Idys™-ALIF System are available upon request, please contact CLARIANCE or its local representative.

3 | INDICATIONS

The Idys™ ALIF (Anterior Lumbar Interbody Fusion) System is intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The Idys™ ALIF System should be used with the integrated fixation screws provided.
The Idys™ ALIF System is intended to be used with autograft.

4 | CONTRA-INDICATIONS

The Idys™-ALIF Lumbar Interbody device is not intended for posterior surgical implantation. Contraindications include, but are not limited to:

- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any patient having inadequate bone stock quality or poor bone quality.
- Fever or leukocytosis, Infection, local to the operative site, Signs of local inflammation.
- Any patient unwilling to co-operate with postoperative instructions, having mental illness, morbid obesity, pregnancy.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication because this condition may limit the degree of correction and/or or the possibility of mechanical fixation.
- Suspected or documented allergy or intolerance to the constitutive materials.
- These devices must not be used for pediatric cases, or where the patient still has general skeletal growth.

IMPORTANT NOTE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption and osteoporosis, osteomalacia.

5 | SECONDARY AND POSSIBLE SIDE EFFECTS

Secondary and possible side effects may occur when the device is used either with or without associated instrumentation. The potential risk of side effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential secondary and possible side effects include but are not limited to:

- Infection, Non-union (or pseudarthrosis).
- Implant migration, loss of correction height, and/or reduction of the spinal curvature, breakage of the device(s), foreign body reaction to the implants.
- Bone fracture or stress shielding at, above, or below the level of surgery, bone graft donor site complication.
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain, neurovascular compromise including temporary paralysis , or other types of serious injury.
- Cerebral spinal fluid leakage, hemorrhage of blood vessels and/or hematomas, deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Discitis, and/or other types of inflammation.
- Inability to resume activities of normal daily living. Early or late loosening or movement of the device(s). Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, micro fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery, graft expulsion.
- Herniated nucleus pulposus, disc disruption or degeneration at above, or below the level of surgery.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, Change in mental status, Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

6 | WARNINGS

- Do not use if package is opened or damaged or if expiration date has passed
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, which may impact on the performance of the device. In addition, the surgeon should properly size the device such that the length of the plate does not exceed the adjacent vertebral bodies.
- These devices are provided as single use only implants and are not to be reused or re-implanted regardless of an apparent undamaged condition. This is indicated on the labeling of the implant package by the next symbol.W.
- The reuse of single-use devices can have irreversible consequences on the security and the health of the patients (risk of contamination, risk of failure of the device, etc.). It is therefore strongly prohibited to reuse single use devices.
- The Idys™-ALIF system is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support.
- Supplemental internal fixation must be used. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
- Because different manufacturers employ different materials, varying tolerances, manufacturing specifications, and differing design parameters, components of the Idys™-ALIF System should not be used in conjunction with components from any other manufacturer's implant systems. Any such use shall negate the responsibility of CLARIANCE for the performance of the resulting mixed component implant.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

7 | CAUTION OF USE

> Preoperative

- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient,
- Only patients that meet the criteria described in the indications should be selected, correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery. The size of device for the case should be determined prior to beginning the surgery.
- Proper function of the surgical instruments should be verified prior to every surgical procedure. All instruments must be cleaned and sterilized before use.

> Intraoperative

- The instructions in Idys™-ALIF System surgical technique manual should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To ensure good fusion of the treated spinal segment, bone autograft should be used.

> Postoperative

- Detailed instructions on the use and limitations of the device should be given to the patient. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion. It is important that immobilization of union is established and confirmed by x-rays, CT scans examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

FOR US AUDIENCE ONLY
CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

8 | PACKAGING HANDLING AND STORAGE

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all instruments sets should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to CLARIANCE.
The handling of the Idys™-ALIF System components must be done as seldom as possible and always with the utmost care. The Idys™-ALIF system components (in their original packaging) must be stored with care in a clean and dry place. Do not expose the Idys™-ALIF system components to radiations or extreme temperatures.
Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

9 | CLEANING – DECONTAMINATION – STERILISATION

All instruments must be cleaned using neutral cleaners followed by a deionized water rinse before sterilization. Note that a good cleaning must make necessary the disassembly of some instruments. Refer to document 99REPINS "Manual instruments for Spinal Surgery Instructions for care, Cleaning Maintenance, and Sterilization" to obtain detailed instructions. All products must be sterile prior the introduction into a sterile surgical field, or (if applicable) return of the product to CLARIANCE.

Method	Cycle	Temperature	Exposure Time	Drying time
Steam	Dynamic Air R] Removal	132°C (270°F)	4 minutes	20 minutes
Steam	Gravity	132°C (270°F)	15 minutes	30 minutes
Steam *	Dynamic Air Removal*	134°C (273°F)	18 minutes	30 minutes

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system. However we advise the users not following the recommended method to validate their methods by means of appropriate laboratory.

10 | MRI SAFETY INFORMATION

The Idys™-ALIF system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Idys™-ALIF system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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