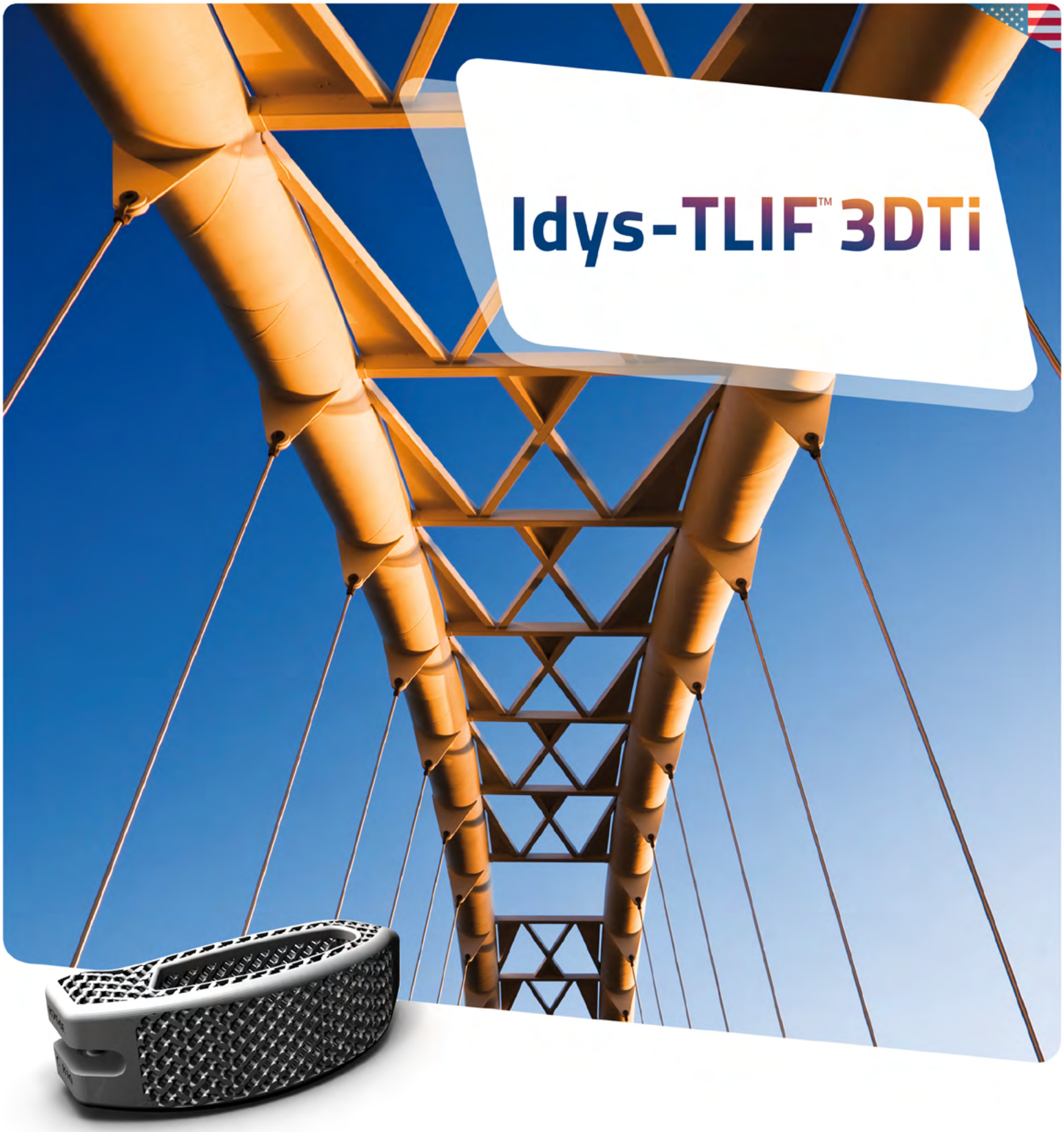
Idys-TLIF™ 3DTi



Surgical Technique

CLARIANCE
innovation for spine surgery

Introduction

Made of titanium, the Idys™-TLIF 3DTi cage is specially designed for lumbar and lumbo-sacral interbody fusion via the transforaminal approach.
The design team focused on creating a TLIF cage suited to the anterior vertebral anatomy that would maintain disc height, restore lumbar lordosis and stabilize the treated segment. Thus, Idys™-TLIF 3DTi creates favorable conditions to optimize bone fusion.
Its complete and ergonomic instrumentation meets the spine surgeon's need for reliability, safety and ease of use during surgical practice.

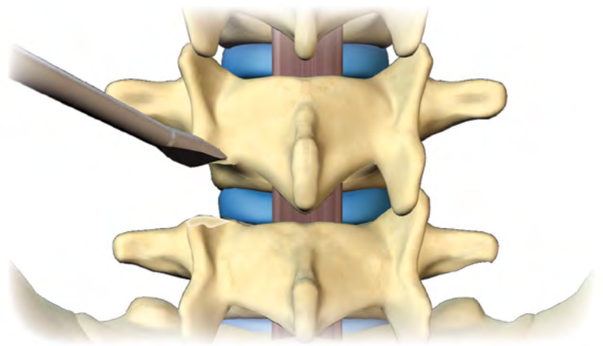
The surgical technique shown is for illustrative purposes only. The technique actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. It is recommended to see the package insert for the complete list of indications, warnings, precautions and other medical information.

Surgical Technique

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

Disc Exposure 1

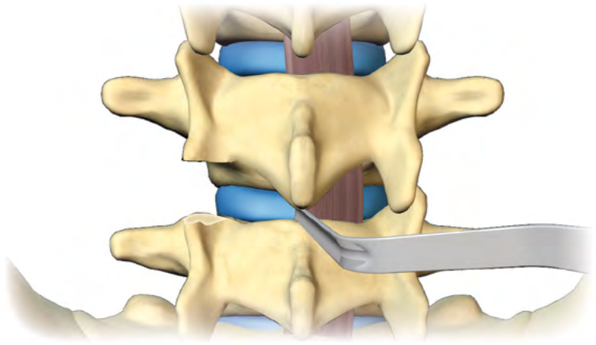
Transforaminal access to the disc space is obtained by performing a unilateral facetectomy on the cage insertion side using the osteotome.
Resection must be sufficient to allow access of the instruments and insertion of the cage into the disc space.



04705010 OSTEOTOME

0478100X
NERVE ROOT RETRACTOR

The nerve root retractor is used to protect the surrounding nerve structures throughout the surgical procedure.



Distraction

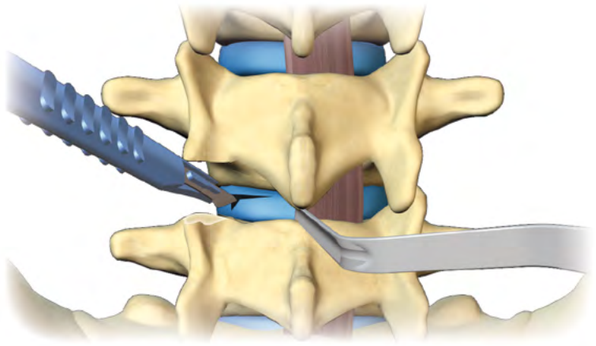
2

Progressive distraction tension is applied in accordance with the surgeon's habits and preferences. This maneuver temporarily opens the posterior disc space and promotes increased exposure for discectomy, decompression and delivery of the implant.

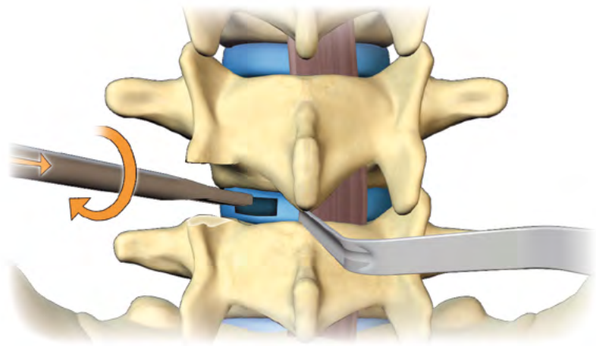
Discectomy

3

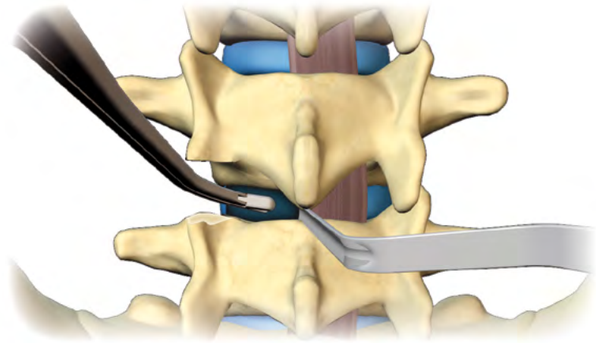
A window is created in the intervertebral disc using a scalpel.



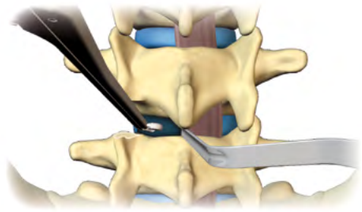
Shavers are used in rotation to start the discectomy and gradually restore the disc height. Shavers come in sequential heights from 6mm to 14mm, increasing in 1 mm increments.

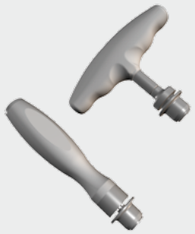


The disc material is removed using the disc rongeur 45° or the straight rongeur. The curved disc rongeur is used to extend the discectomy on opposite side of the disc.



When possible, the anterior and lateral walls of the annulus are preserved in order to provide additional stability for the Idys™-TLIF 3DTi cage.



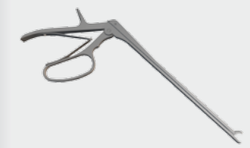


99781001 T-HANDLE
99782003
CYLINDRICAL HANDLE - LARGE

047070XX SHAVER

06708002
CURVED DISC RONGEUR

06708003 DISC RONGEUR 45°



06708001
STRAIGHT DISC RONGEUR

04704015 CURETTE

04704005 STRAIGHT CURETTE

06704015 CURVED CURETTE

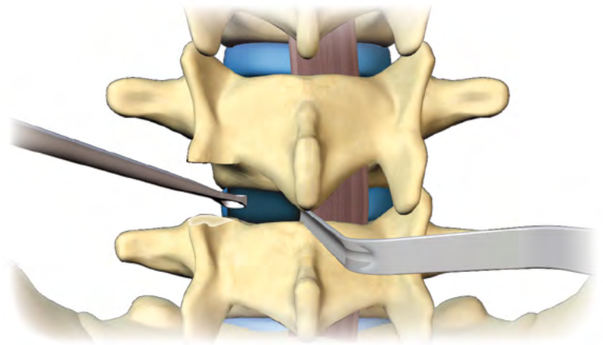
06704105
RIGHT CUP CURETTE

06704205
LEFT CUP CURETTE

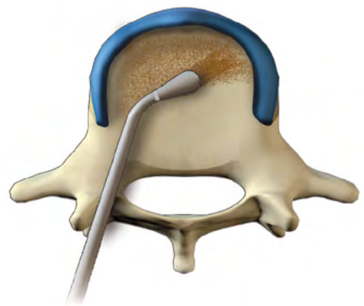
Endplate Preparation

4

The endplates are prepared using the curette and the straight curette to remove the remaining layers of the entire cartilaginous endplates and expose bleeding bone. The curved curette, the right cup curette and the left cup curette are used to facilitate removal of material in the distant lateral disc area.



Optimizing endplate preparation
To promote fusion of the intervertebral space, careful scraping of the vertebral endplate is crucial. Specific straight and curved curettes contribute to making this step as efficient as possible.



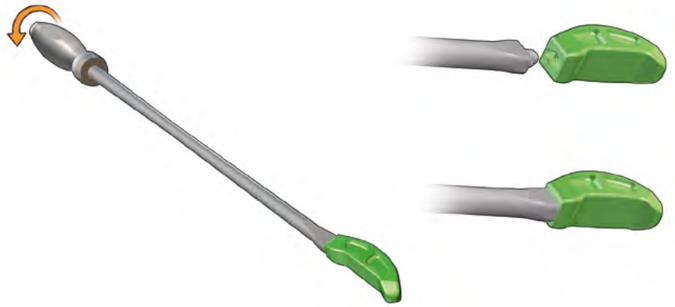
Thorough cleaning of the endplates is important for the vascular supply of the bone graft. The structural integrity of the endplates must be preserved to allow for structural support of the cage.

Implant Sizing

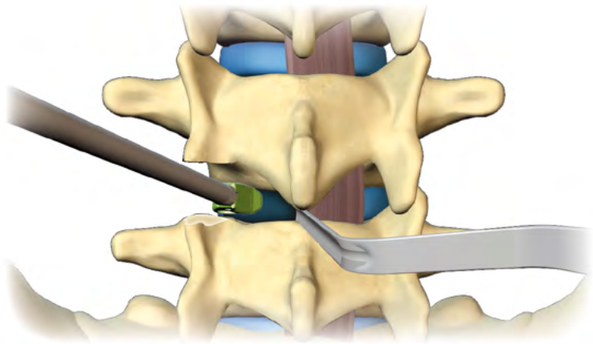
5

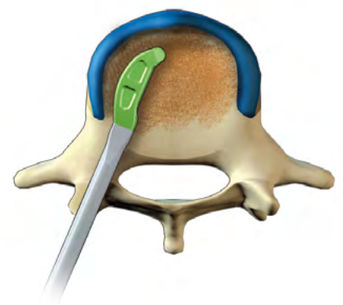
The height of the final implant is determined by selecting the trial that restores the desired disc height and lumbar lordosis of the treated segment.

The TLIF trial is connected and secured to the TLIF trial inserter by turning the locking knob clockwise.



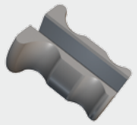
The trial is then inserted in the intervertebral space, and placed as close as possible to the final position. The trial is not dissociated from the TLIF trial inserter.





067144XX TLIF TRIAL

06715003 TLIF TRIAL INSERTER



04762000 SLAP HAMMER

06715002 TLIF CAGE HOLDER

06717003
TLIF FILLING SUPPORT

31761000
BONE GRAFT IMPACTOR

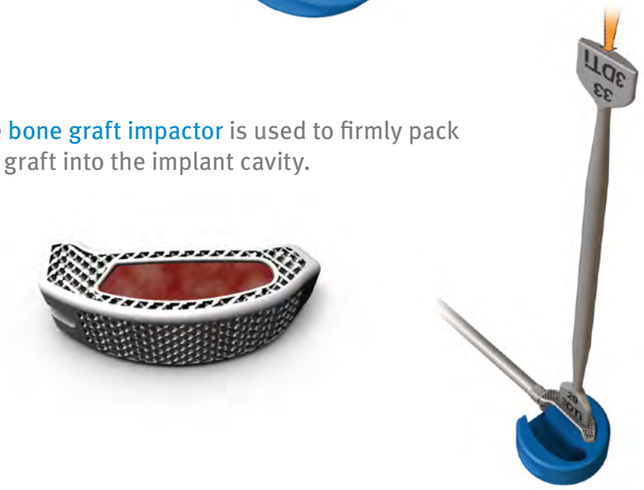
Distraction is momentarily released and an X-ray check is performed to verify the trial position and validate the height of the final implant.
Distraction is re-established and the trial is removed using the slap hammer.

Implant preparation 6

It is important to completely fill the implant cavity in order to ensure optimal contact between the graft material and the vertebral endplates.

The selected cage is connected to the TLIF cage holder and placed into the TLIF filling support.

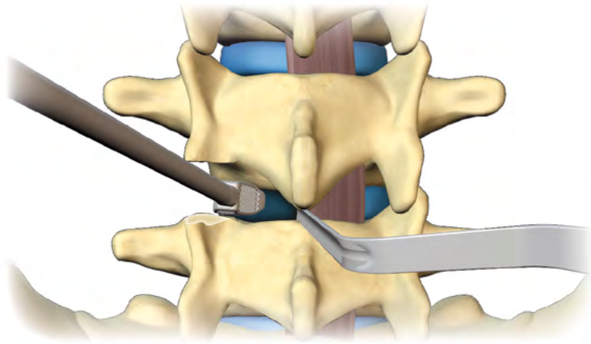
The bone graft impactor is used to firmly pack the graft into the implant cavity.

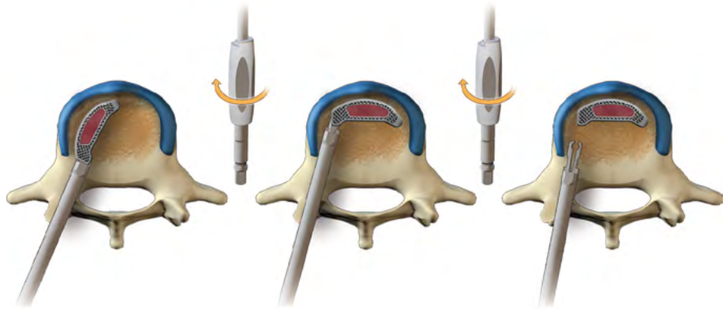


Implant Insertion 7

The cage is first inserted straight into the intervertebral space. Then, the locking knob located on the TLIF cage holder is turned anticlockwise to release the cage in rotation. Light impactions allow oblique orientation of the cage. The cage can also be pushed sideways to be centered.

An X-ray check is performed and the cage is disconnected.





06715002 TLIF CAGE HOLDER

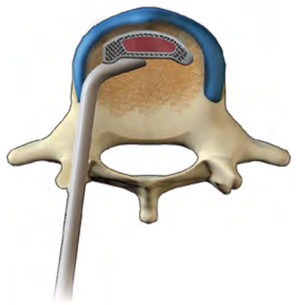
06716003
CURVED TLIF CAGE PUSHER

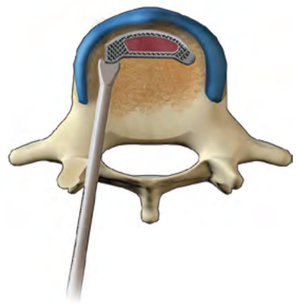
06716002
STRAIGHT TLIF CAGE PUSHER

Final Positioning

8

The cage can be pushed into its final position using the straight TLIF cage pusher and the curved TLIF cage pusher.



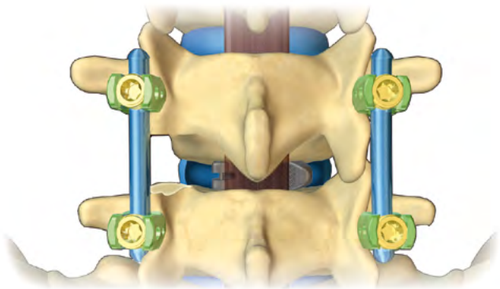


Additional graft can be inserted at the back of the cage.
Distraction is released and a final X-ray check is performed.

Supplementary Posterior Fixation

9

Posterior fixation is required to place the treated segment under compression and to enhance the stability of the Idys™-TLIF 3DTi cage.



Product Catalogue

OSTEOTOME 04705010

NERVE ROOT RETRACTOR 04781006

SHAVER

Ø 6mm	04707006
Ø 8mm	04707008
Ø 9mm	04707009
Ø 10mm	04707010
Ø 11Mm	04707011
Ø 12mm	04707012
Ø 13mm	04707013
Ø 14mm	04707014

DISC RONGEUR

Straight	06708001
45°	06708003
Curved	06708002

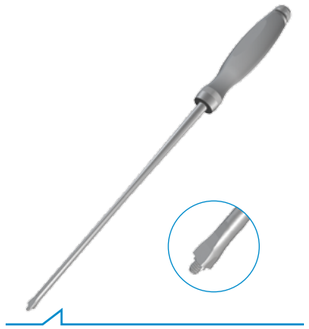
CURETTE 04704015

STRAIGHT CURETTE 04704005

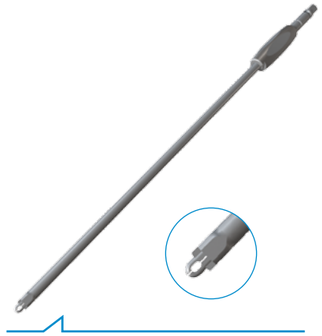
CURVED CURETTE 06704015

RIGHT CUP CURETTE 06704105

LEFT CUP CURETTE 06704205

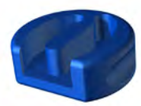


TLIF TRIAL INSERTER 06715003



TLIF CAGE HOLDER 06715002

SLAP HAMMER 04762000



TLIF FILLING SUPPORT 06717003

BONE GRAFT IMPACTOR 31761000

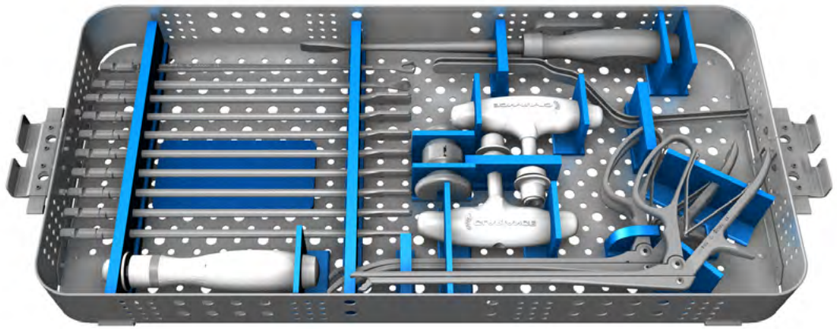
TLIF CAGE PUSHER

Straight	06716002
Curved	06716003

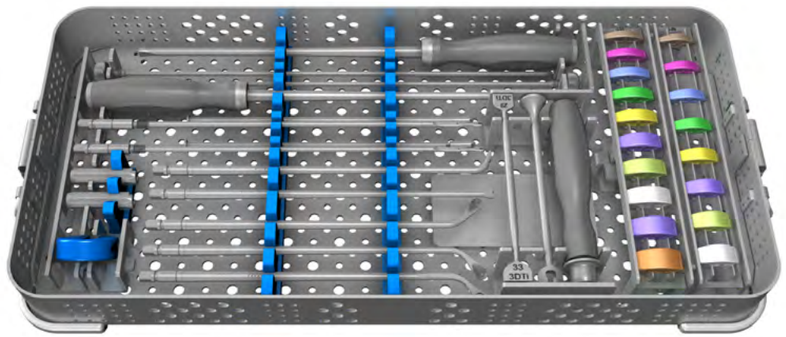
CYLINDRICAL HANDLE - LARGE 99782003

T-HANDLE 99781001

Product Catalogue

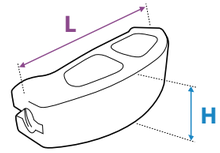


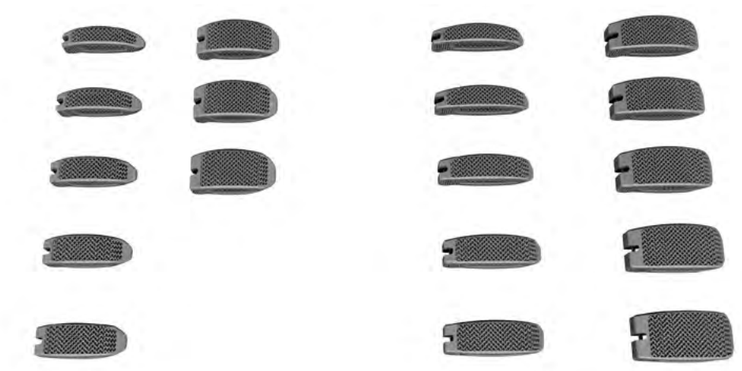
IDYS-LIF COMMON INSTRUMENTS TRAY 04990010



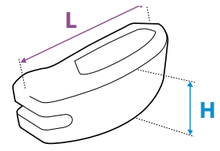
IDYS-TLIF INSTRUMENTS TRAY 04990012

TLIF TRIALS	L 29 MM	L 33 MM
H 07 mm	06714407	06714507
H 08 mm	06714408	06714508
H 09 mm	06714409	06714509
H 10 mm	06714410	06714510
H 11 mm	06714411	06714511
H 12 mm	06714412	06714512
H 13 mm	06714413	06714513
H 14 mm	06714414	06714514
H 15 mm		06714515
H 16 mm		06714516





TLIF CAGE	L 29 MM	L 33 MM
H 07 mm	31572907-S	31573307-S
H 08 mm	31572908-S	31573308-S
H 09 mm	31572909-S	31573309-S
H 10 mm	31572910-S	31573310-S
H 11 mm	31572911-S	31573311-S
H 12 mm	31572912-S	31573312-S
H 13 mm	31572913-S	31573313-S
H 14 mm	31572914-S	31573314-S
H 15 mm		31573315-S
H 16 mm		31573316-S



Important product information

1 | PURPOSE

The Idys™-LIF product includes the Idys™-PLIF, Idys™-PTLIF, Idys™-TLIF and Idys™-TLIF 3DTi cages. These cages are interbody 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™-LIF cages, which have various widths and heights, are designed for use as a lumbar intervertebral body fusion device. The device has to be used with autograft. The device has a shape which restores the intervertebral height and lordosis. The device can contain one or more 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 a rough surface which interact with the surface of the vertebral endplates and help in resisting back out. The Idys™-LIF cages can be made of compliant ASTM F2026 polyetheretherketone (PEEK) with markers made of compliant ASTM F560 Tantalum or can be made of compliant ASTM F136 Titanium alloy. It is essential to insert implants with instrumentation specifically designed for this purpose. Detailed information concerning the surgical technique of the Idys™-LIF are available upon request, please contact CLARIANCE or its local representative.

3 | INDICATIONS

The Idys™ LIF cages are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a posterior and/or transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

4 | CONTRA-INDICATIONS

Idys™-LIF 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 of poor bone quality
- Any patient having a prior fusion at the level(s) to be treated.
- 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 | WARNING

- 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.
- 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 Idys™-LIF device 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™-LIF device 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
- The Idys™ LIF Cages have not been evaluated for safety and compatibility in the MR environment. The Idys™ LIF Cages have not been tested for heating or migration in the MR environment.

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 begin 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™-LIF 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.
- Idys™-LIF Cages are interbody devices and are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

!USA
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™-LIF Cages must be done as seldom as possible and always with the utmost care. The Idys™-LIF Cages (in their original packaging) must be stored with care in a clean and dry place. Do not expose the Idys™-LIF Cages 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-Removal	270°F (132°C)	4 minutes	20 minutes
Steam	Gravity	270°F (132°C)	15 minutes	30 minutes
Steam *	Dynamic Air-Removal	273°F (134°C)	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 technique.

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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.