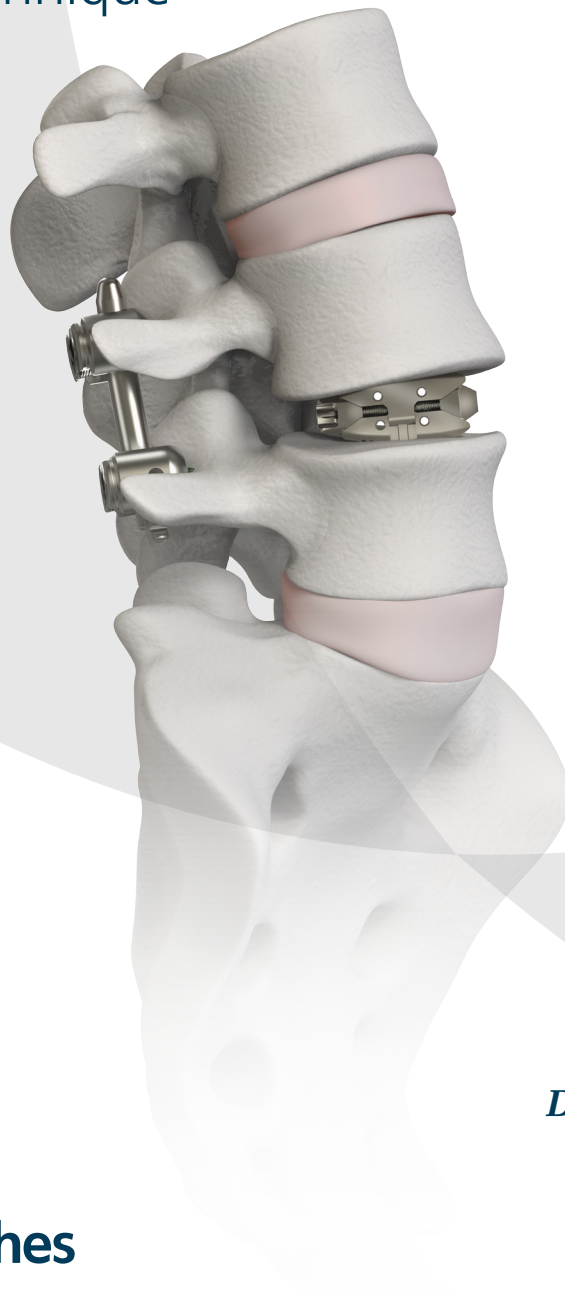


CONCORDE LIFT™

Expandable Interbody Device

Surgical Technique



Utilizing technology developed by
Dr. Rudolf Morgenstern

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MR Information

This device has not been evaluated for safety and compatibility in the MR environment.
This device has not been tested for heating or migration in the MR environment.

Product Overview

CONCORDE LIFT™ Expandable Interbody Device

The CONCORDE LIFT™ Expandable Interbody Device must be used with supplemental internal spinal fixation (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems) that has been cleared for use in the lumbar spine.

This surgical technique guide presents the steps suggested for a Transforaminal Lumbar Interbody Fusion (TLIF) approach. However, the CONCORDE LIFT Expandable Interbody Device may also be used in Posterior Lumbar Interbody Fusion (PLIF) procedures utilizing open or minimally invasive techniques.

This document is intended to demonstrate general surgical technique using the CONCORDE LIFT Expandable Interbody Device.

The surgeon who performs the implant procedure is responsible for determining and utilizing the appropriate technique for implanting the device in each individual patient.

DePuy Synthes is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

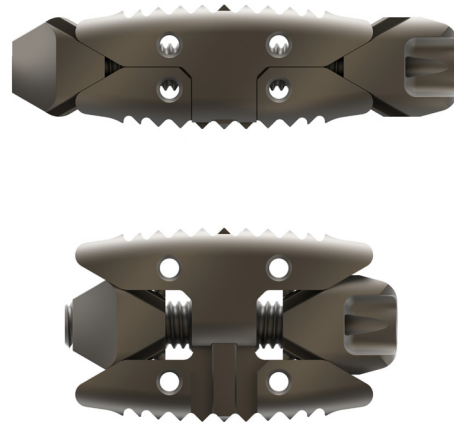
Value Proposition

The CONCORDE LIFT Expandable Devices platform will provide a robust expandable titanium interbody device with instrumentation that delivers control and performance to clinicians through tactile feedback and reliable graft delivery producing a true procedural solution for the TLIF approach.

Convex Configuration

Part Number	Description	Expansion Range
US-1978-09-021C	CONCORDE LIFT, Convex 9x21 mm	8-13mm
US-1978-09-026C	CONCORDE LIFT, Convex 9x26 mm	8-13mm

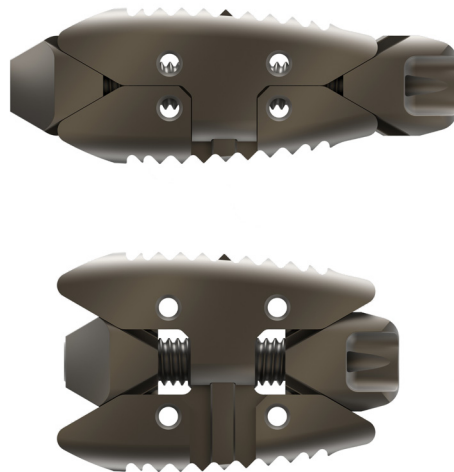
Convex Configuration



Lordotic Configuration

Part Number	Description	Expansion Range
US-1978-09-023L	CONCORDE LIFT, Lordotic 9x23 mm	10-15mm
US-1978-09-027L	CONCORDE LIFT, Lordotic 9x27 mm	10-15mm

Lordotic Configuration



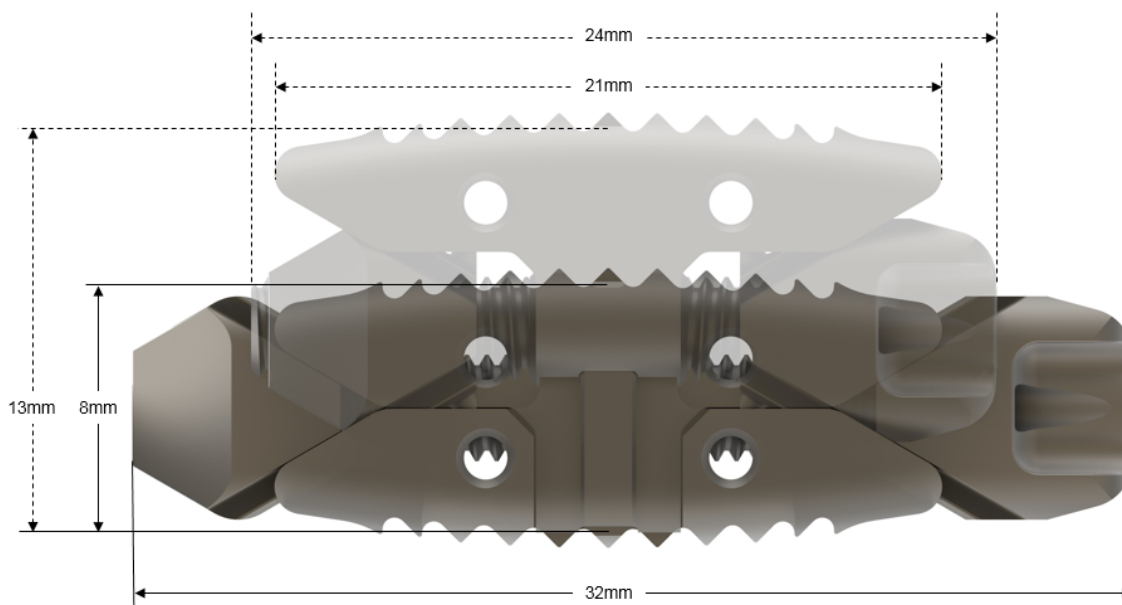
Dimensions for Convex Configuration

	9x21 mm	9x26 mm
Fully collapsed length (mm)	32	36
Fully expanded length (mm)	24	28
Endplate length (mm)	21	26
Expansion range (mm)	8-13	

Dimensions for Lordotic Configuration

	9x23 mm	9x27 mm
Fully collapsed length (mm)	32	36
Fully expanded length (mm)	24	28
Endplate length (mm)	23	27
Expansion range (mm)	10-15	

Image below shows 9x21 mm Convex Configuration



CONCORDE LIFT Expandable Interbody Device

The CONCORDE LIFT Expandable Interbody Device expands by utilization of a threaded actuator shaft that when rotated clockwise, forces the wedges of the CONCORDE LIFT Expandable Interbody Device to move inward thereby expanding the upper and lower plates. The actuator shaft has a drive feature that mates with the Driver Shaft to assist in implantation.

The surgeon should use their discretion on whether or not the CONCORDE LIFT Expandable Interbody Device needs to be expanded to its limit. In many cases the CONCORDE LIFT Expandable Interbody Device does not need to be expanded to its maximum limit, to reduce the likelihood of endplate fracture and/or subsidence. It is mandatory to always utilize the Torque-Limiting Handle, which limits the expansion force.

The following signals may alert the surgeon that the CONCORDE LIFT Expandable Interbody Device is reaching its expansion limit:

- First, there is a noticeable tactile feedback of tightening in the Cage Inserter. As the expansion force becomes greater, it becomes more difficult to rotate the Torque Limiting Handle.
- Second, there may be an audible squeal when the expansion forces become high.

Precautions:

Some patients' anatomy may not accommodate such high expansion forces and, in these cases, the surgeon should halt the expansion of the CONCORDE LIFT Expandable Interbody Device prior to reaching the expansion limit of the device and / or prior to reaching the limit of the Torque Limiting Handle.

For the expansion procedure, the Driver Shaft must always be used in conjunction with the Torque Limiting Handle. Any other Handles used for this procedure may potentially cause a fracture of the endplates and / or cause damage to the Driver Shaft tip.

In summary, it is important to use care during the procedure to not over-expand the CONCORDE LIFT Expandable Interbody Device due to the variation in individual patient anatomy and potential for vertebral endplate fracture and/or subsidence. Expand the CONCORDE LIFT Expandable Interbody Device slowly, in small increments, to better react to the tactile and audible feedback prior to reaching the expansion limit.

Precautions:

Conditions when the height expansion needs to be stopped:

- 1. Torque Limiting Handle reaches its limit.**
- 2. Implant is fully expanded (check expansion gauge).**
- 3. As a result of appropriate expansion allowed by the patient's anatomy, surgeon feels sufficient tactile feedback and decides to stop.**
- 4. Based on both AP and lateral fluoroscopy, surgeon feels that appropriate expansion has been reached despite not reaching limits of the instrument expansion stop.**

Surgical Technique

Preparation

Step 1

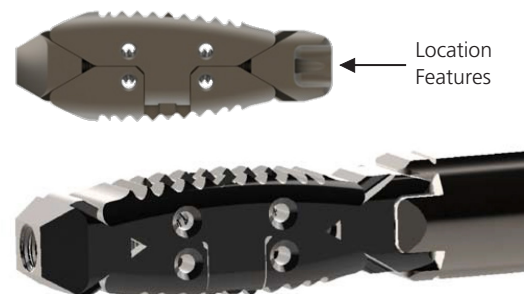
Ensure the Cage Inserter (2878-04-100) expansion gauge is set to zero. To accomplish this, insert the Driver Shaft into the Cage Inserter and rotate counterclockwise until the expansion gauge reads zero. Confirm the implant is fully collapsed.

Precautions: After opening the sterile packaging, it must be confirmed that the implant is fully collapsed (both endplates should touch each other). To prevent Expandable Interbody Device disassembly, do not collapse the implant after the upper and lower plates initially contact each other.

Step 2

To attach the CONCORDE LIFT Expandable Interbody Device to the Cage Inserter, position the CONCORDE LIFT Expandable Interbody Device so that the flat surfaces and markings on the Outer Sleeve align with the teeth of the implant. Insert the Tether into the Outer Sleeve and turn the Tether knob clockwise until snug to securely anchor the Cage Inserter to the CONCORDE LIFT Expandable Interbody Device (finger tight is acceptable and it should not be tightened any further).

Cage Inserter Assembly



Preparation

Step 3

In order to achieve a solid interbody fusion, the disc space should be filled with as much bone graft as possible. Fill the anterior third and contralateral side of the disc space with bone graft using graft delivery instruments provided in the CONCORDE LIFT Instrument Set.

Prepack the implant with autogenous bone graft through the graft windows.

Precaution: Ensure that the drive feature of the implant is free of any graft material prior to attaching the implant to the Cage Inserter assembly and prior to inserting it into the intervertebral disc space.



Insertion

Step 4

With the CONCORDE LIFT Expandable Interbody Device implant securely tethered to the Cage Inserter, place it into the disc space so that the implant crosses mid line in both the sagittal and coronal planes.

Light tapping can be used at the back of the Tether to advance the implant in tight disc spaces.

Warnings:

Tapping too hard can damage the device and render it useless.

During insertion, do not rotate the implant: the flat surfaces of the Cage Inserter must always align with the vertebral endplates.

Do not insert the Driver Shaft with Torque Limiting Handle attached to the Cage Inserter during the insertion procedure. Initial placement of the implant must be performed without the Driver Shaft and Torque Limiting Handle in place. This provides a better surface for persuading the implant into the desired position within the disc space. The Driver Shaft in conjunction with the Torque Limiting Handle attached should be used only after the device is in the appropriate position in the disc space when it is time to expand it.

Insertion

Step 5

Once the implant is confirmed to be in the appropriate position in the intervertebral disc space, insert the Driver Shaft in conjunction with the Torque Limiting Handle until engaged with the implant. Expand the implant as needed by rotating the Torque Limiting Handle clockwise.

Precautions:

Ensure that the Driver Shaft is fully inserted into the Cage Inserter assembly to ensure that the Driver Shaft is engaging the implant as well as the expansion gauge. If it is not fully inserted, there is a risk of engaging with the expansion gauge alone but not with the implant. Turning the Driver Shaft in that position will only move the indicator of the expansion gauge without expanding the implant which may lead to device disassembly.

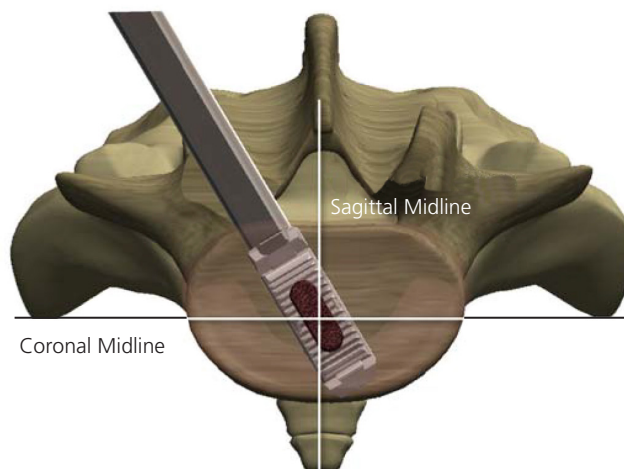
Do not impact on Driver Shaft and / or Torque Limiting Handle. When inserting and locating the device within the disc space the angle between the device and the attached Cage Inserter should never be more than 10° to avoid damaging the expansion mechanism.

It is always mandatory to utilize the Torque Limiting Handle which limits the expansion force. Care should be taken not to over expand the implant for the patient anatomy which could lead to broken vertebral endplates. The expansion gauge on the Tether will indicate approximate implant expansion.

Once the implant is expanded to the desired height and is in its final placement, verification has to be performed. Verify desired expansion radiographically using fluoroscopy or similar.

If repositioning is necessary intraoperatively, the Torque Limiting Handle can simply be rotated counterclockwise to lower the CONCORDE LIFT Expandable Interbody Device to allow for repositioning.

Once the desired position is achieved again, the CONCORDE LIFT Expandable Interbody Device should be expanded to the desired height.



Insertion

Step 6

Once the CONCORDE LIFT Expandable Interbody Device is implanted successfully and reconfirmed that no further adjustment or graft placement is required, remove the Driver Shaft / Torque Limiting Handle from the Cage Inserter.

The Tether must then be removed to detach the Cage Inserter assembly from the implant. To disconnect, rotate the Tether counterclockwise while holding the Outer Sleeve until it has become loosened from the implant. The Tether and Outer Sleeve are then removed by gently pulling them away from the implant.

Precaution: If it is desired to place graft in and around the device after final positioning, please refer to the Multiple Options for Bone Graft Delivery section.

The Torque Limiting Handle has an indicator which will change from green to yellow after 100 actuations of the torque limiting feature, indicating that the end of life of the instrument is nearing. At 120 actuations of the torque limiting feature, the indicator will change color from yellow to red, at which point the handle can no longer be used and should be disposed of properly. After the indicator turns red, the torque-limiting feature is no longer functional. Reference eFU-0902-90-140 for more specific Torque Limiting Handle instructions.

Precautions:

The Torque Limiting Handle is indicated for multiple uses and must be cleaned and sterilized between uses; however, the Handle can not be used once the indicator changes color to red.



Indicator →
shows green =
good to use



Indicator →
shows red =
no longer
functional and
needs to be
replaced



Multiple Options for Bone Graft Delivery

Additional bone graft can be placed into the intervertebral disc space after the CONCORDE LIFT Expandable Interbody Device is implanted. With the Outer Sleeve of the Cage Inserter attached to the CONCORDE LIFT Expandable Interbody Device, autogenous bone graft may be packed into the funnel feature of the Outer Sleeve.

Precaution: After removing the Tether from the Cage Inserter assembly, keep forward pressure onto the Outer Sleeve to ensure that the implant stays engaged to the Outer Sleeve.

Using the Graft Plunger, bone graft is pushed through the Outer Sleeve and into the CONCORDE LIFT Expandable Interbody Device through the graft ports, helping to further fill the implant with bone graft. The Small and/or Large Graft Delivery System may also be used to place additional bone graft around the implant.



Graft Ports

Large Graft Delivery System



Small Graft Delivery System



Removal or Revision

Although much care and attention has been taken to minimize the risks, as with any spinal implant designed to promote intervertebral fusion, risks do exist for pseudoarthrosis, non-fusion, and/or continued symptoms (as explained in the cautions/indications/warnings section). In these cases the operating surgeon may elect to remove, replace, or otherwise revise the implant.

The following procedures should be utilized to safely remove the device:

Step 1a: Inserter attached

Acutely, or intraoperatively, the Cage Inserter (2878-04-100) should be used to facilitate removal of the CONCORDE LIFT Expandable Interbody Device implant. The CONCORDE LIFT Expandable Interbody Device can be collapsed by rotating the Torque Limiting Handle counterclockwise when attached to the Driver Shaft and engaged to the implant. The implant can then be removed.

Step 1b: Inserter detached

Prior to re-attaching to the implant, properly assemble and set up the Cage Inserter assembly (Outer Sleeve, Tether and Driver Shaft) and rotate the Torque Limiting Handle clockwise until it stops (the corresponding reference gauge should read 5), taking care not to over-tighten or over-rotate. Turn the Torque Limiting Handle counterclockwise one-half turn (the corresponding reference gauge should read between 4 and 5). Disassemble the Cage Inserter assembly and follow steps 2-7.



Removal or revision

Step 2

Guide only the Outer Sleeve of the Cage Inserter to the location features of the implant such that the instrument fully engages onto the implant location features. It may be helpful to use x-ray/fluoroscopy, a surgical microscope, and/or an endoscope for this process. The markings and the flat surfaces on the Outer Sleeve must align with the teeth of the implant / the vertebral endplates.

Step 3

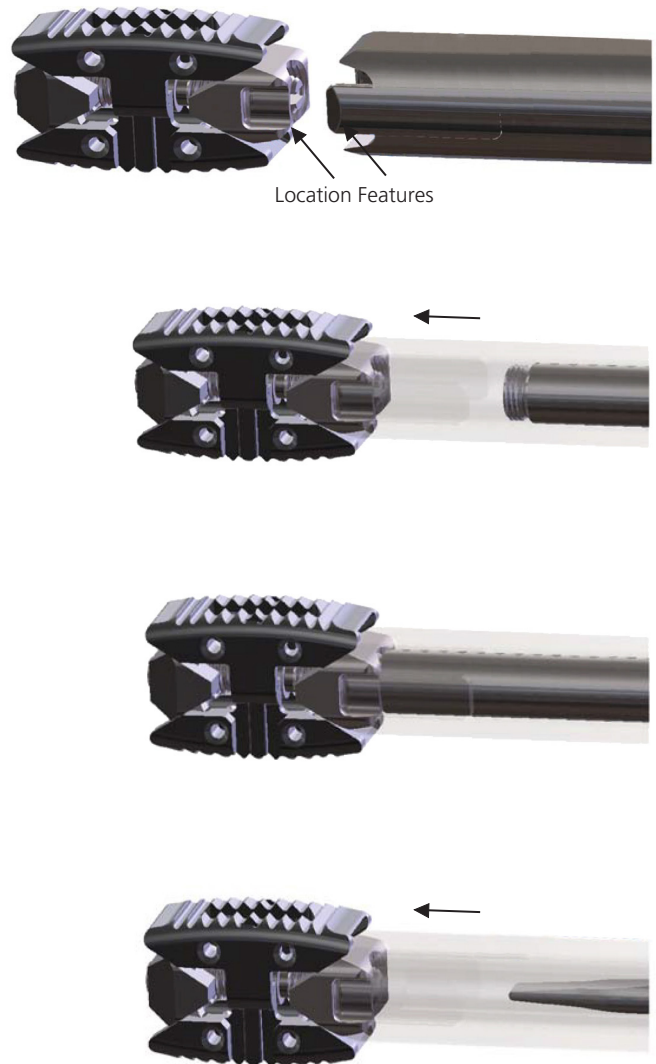
Once the Outer Sleeve of the Cage Inserter is fully seated onto the device, introduce the Tether through the Outer Sleeve and rotate the Tether clockwise until it is snugly attached to the implant. Take care not to over-tighten the Tether to the device (finger tight is acceptable and it should not be tightened any further).

Step 4

Introduce the Driver Shaft until it engages with the drive feature of the implant.

Step 5

Attach the Torque Limiting Handle.

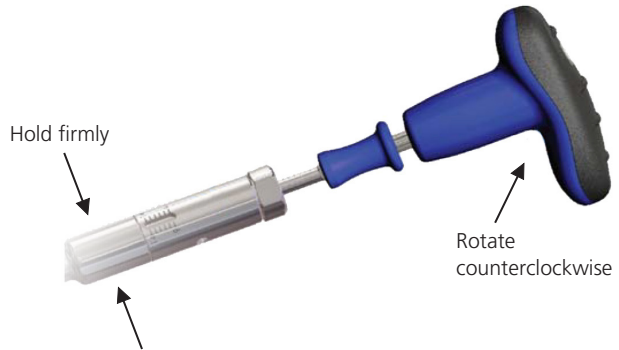


Removal or Revision

Step 6

While firmly holding the Outer Sleeve of the Cage Inserter, rotate the Torque Limiting Handle counterclockwise to collapse the height of the CONCORDE LIFT Expandable Interbody Device. The Handle should be turned counterclockwise until the device is collapsed, as confirmed either visually or with fluoroscopy, or until the instrument reaches the intended stop (or limit).

Precaution: Do not rely on the expansion gauge alone for the decision to stop collapsing the implant. If the implant was not fully expanded, then it will be fully collapsed prior to the expansion gauge reaching 0. Please use fluoroscopy to confirm height of the implant.



Step 7

The Cage Inserter is pulled away from the surgical site with the attached CONCORDE LIFT Expandable Interbody Device, removing it from the patient.

Precaution: If, for any reason the CONCORDE LIFT Expandable Interbody Device does not stay attached to the Cage Inserter, other surgical instruments may be used to grasp the CONCORDE LIFT Expandable Interbody Device and remove it from the surgical site.

Product Catalog

Implants (Expresscare Code: CONLIA)

US-1978-09-021C CONCORDE LIFT, Convex 9x21 mm, 8-13mm



US-1978-09-026C CONCORDE LIFT, Convex 9x26 mm, 8-13mm

US-1978-09-023L CONCORDE LIFT, Lordotic 9x23 mm, 10-15mm



US-1978-09-027L CONCORDE LIFT, Lordotic 9x27 mm, 10-15mm

Instruments (Expresscare Code: CONLIB)

2878-04-100 CONCORDE LIFT™ Cage Inserter



2878-04-101G CONCORDE LIFT™ Driver-Shaft-AO



2878-04-112 CONCORDE LIFT™ Graft Plunger



2878-04-102 CONCORDE LIFT™ Torque Limiting Handle



2878-04-113 CONCORDE LIFT™ Small Graft Delivery



2878-04-119G CONCORDE LIFT™ Flex Graft Plunger



2878-04-114 CONCORDE LIFT™ Large Graft Delivery



Instruments (Expresscare Code: CONLIB)

2878-04-107G CONCORDE LIFT™ Distractor/Shaver 5X7-AO



2878-04-108G CONCORDE LIFT™ Distractor/Shaver 5X8-AO



2878-04-109G CONCORDE LIFT™ Distractor/Shaver 5X9-AO



2878-04-110G CONCORDE LIFT™ Distractor/Shaver 5X10-AO



2878-04-111G CONCORDE LIFT™ Distractor/Shaver 5X11-AO



2878-04-106G CONCORDE LIFT™ T-Handle-AO

2875-70-006 CONCORDE LIFT™ Case Lid

2878-04-115G CONCORDE LIFT™ Instrument Case-US

2878-04-116G CONCORDE LIFT™ Implant Case-US

Indications and Contraindications

CONCORDE LIFT™ Expandable Interbody Device

Indications For Use

The CONCORDE LIFT Expandable Interbody Device is a posterior lumbar intervertebral body fusion device, and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine, L2 to S1, who have had a six-month course of conservative treatment. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The CONCORDE LIFT Expandable Interbody Device can be implanted via posterior or transforaminal approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had a six-month course of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels. The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems.)

Contraindications

The DePuy Synthes Spine, CONCORDE LIFT Expandable Interbody Device is contraindicated for use in patients with any conditions in which the use of a device could preclude adequate and appropriate treatment of their conditions. Additionally, it is contraindicated for:

1. Active sepsis
2. Prior fusion at the level(s) to be treated
3. Pregnancy
4. Muscular, neurological or vascular deficiencies, which compromise the affected extremity
5. Conditions that place excessive demand on the device (i.e. Charcot's joints, muscle deficiencies, refusal to modify postoperative physical activities, skeletal immaturity)
6. Known metal allergy (i.e. jewelry)
7. Active infection in the area of proposed surgery
8. Recurrent disc herniation
9. Severe osteoporosis
10. Paget's disease
11. Renal osteodystrophy
12. Cancer of the spine
13. Advanced diabetes
14. Rheumatoid arthritis
15. Immunological suppression
16. Sustained trauma with instability
17. Fracture of the vertebra
18. Degenerative spondylolysis
19. Conditions requiring steroids in excess of usual doses
20. Obesity

Materials

The DePuy Synthes Spine, CONCORDE LIFT Expandable Interbody Device is fabricated from a medical grade Titanium 6AL-4V Alloy, conforming to ASTM F136.

Warnings

The DePuy Synthes Spine CONCORDE LIFT Expandable Interbody Device should only be used by surgeons experienced in spinal fusion procedures who have undergone adequate training with this device. The following specific warnings, precautions, and adverse effects should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to metallic internal fixation devices. General surgical risks should also be explained to the patient prior to surgery.

1. Correct device selection - While proper selection of the device is important in minimizing risks, the size and shape of the patient's bones must also be considered.
2. Failed Fusion – Metallic implant devices cannot withstand the same activity levels or loads equal to those placed on normal healthy spines. These devices are not designed to withstand the full weight bearing load. If fusion is delayed, or a pseudarthrosis occurs, the device may break. The patient should understand that stress on a device may in some cases result in failure of that device.
3. Infection – This device is contraindicated in the presence of an active infection.
4. Osteoporotic bone – Extremely osteoporotic bone may not be suitable for traditional forms of posterior spinal fixation and may increase the risk of device failure. Should extremely osteoporotic bone be determined intraoperatively, the device may be removed and an alternative approach should be considered.
5. Conservative treatment – This device is contraindicated when conservative treatment is appropriate.
6. Corrosion – Metal devices in the human body are subjected to a chemical environment consisting of salts, acids and proteins that may cause corrosion due to galvanic corrosion effects. Dissimilar metals in contact with each other can accelerate the corrosion process; mixing of device components from different manufacturers is never recommended for metallurgical, mechanical and functional reasons.
7. Histological conditions – Certain degenerative diseases or physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, and risk device failure.
8. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed non-union of bone will result in excessive and repeated stresses on the device. Mechanical fatigue testing shows that these stresses can cause eventual bending, loosening, or breakage of the device(s).
9. This device is meant to be used with posterior supplemental fixation (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems) – confirm fusion before removing such fixation systems.
10. The CONCORDE LIFT Expandable Interbody Device has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. The CONCORDE LIFT Expandable Interbody

Device has not been tested for heating or migration in the MR environment.

11. Any case that requires the mixing of metals from two different components or systems, e.g., titanium and stainless steel can result in galvanic effects leading to corrosion.
12. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Precautions

The operating surgeon should be trained to the appropriate Surgical Technique, in order to produce a successful outcome.

1. Device performance – Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
2. Device Insertion – when inserting and locating the device within the disc space the angle between the device and the attached Cage Inserter should never be more than 10° to avoid damaging the expansion mechanism.
3. To prevent Expandable Interbody Device disassembly, do not collapse the implant after the upper and lower plates initially contact each other.
4. Ensure implant is fully collapsed and Cage Inserter expansion gauge is set to zero prior to assembly of implant to Cage Inserter.
5. Always use the Cage Inserter assembly in conjunction with the Driver Shaft and Torque Limiting Handle for expanding and / or collapsing the implant, and ensure the Driver Shaft is engaged with the Expandable Interbody Device when turning the Torque-Limiting Handle.
6. Do not impact on Driver Shaft or any Handle attached to Driver Shaft.
7. Devices should never be reused. An explanted metal device must never be re-implanted.
8. Handling of devices – Extreme care should be taken in the handling of the device. No bending or changing of the device's shape should be attempted. These may produce internal stresses, which may cause eventual breakage.
9. Instructions to patient – Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fusion management. The patient must be made aware of the limitations of the device. The patient should understand that a metallic device is not as strong as a normal, healthy bone and with time will fracture under normal weight bearing or load bearing in the absence of a fusion. Mental or physical impairment, which compromises or prevents a patient's ability to comply with the necessary limitations or precautions, may place that patient at a particular risk during postoperative rehabilitation.
- components.
4. Foreign body (allergic) reaction to devices.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, persistent cerebrospinal fluid (CSF) leakage, meningitis.
8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
10. Loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (pseudarthrosis), delayed union, mal-union.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.

Possible Adverse Events

1. Failure of the device to provide adequate mechanical stability.
2. Early or late loosening of any or all of the components.
3. Disassembly, bending, and/or breakage of any or all of the

CONCORDE LIFT™ Torque Limiting Handle NON-STERILE

Product Description

The DePuy Synthes Spine Torque Limiting Handle part number 2878-04-102 is set to 10 in-lbs \pm 10%. It is manufactured from medical grade polymers and stainless steel and includes a standard AO quick-connect adapter.

REF 2878-04-102 CONCORDE LIFT™ Torque Limiting Handle

Instruction For Use

Any Torque Limiting Instrument **MUST** be restricted to use by a physician or qualified health care professional and used in accordance with manufacturer's instruction. The surgeon or qualified health care professional is responsible for the prescribed use of the Torque Limiting Instrument. The Torque Limiting function may drift out of calibration if used beyond the prescribed useful life. Do not use the Torque Limiting device beyond manufacturers' recommendations. After any autoclave cycle, allow 1 Hour (60 minutes) for device to equilibrate with surrounding temperature and humidity. Before using device in situ, actuate the device one to two times to confirm audible actuation. The Torque Limiting Handle should not be used for any other function than the intended manufacturers' recommendations and design. Exceeding, disregarding and **NOT** following these instructions may cause the device to break and or not perform correctly. Efficient screw tightening requires a delicate calibration. Be careful not to allow the device to be mishandled. If the torque increases over the maximum set limit, the coupling will slip to protect against risk of breakage. At this point, an audible Torque Limiting actuation has occurred.

Warnings

DePuy Synthes Spine Torque Limiting Devices should only be used by qualified personnel trained in the use of surgical instruments and the relevant surgical procedures. The surgeon should thoroughly understand all aspects of the surgical procedures and the limitations of the instrumentation. It is strictly prohibited to carry out any modifications on the DePuy Synthes Spine Torque Limiting Handle device. DePuy Synthes Spine disclaims any and all liability resulting from use of such modified devices.

DO NOT USE Limiting Instrumentation in **EXCESS** of the following guidelines:

- No more than 120 actuations of the torque functions set point.
- No more than 20 autoclave cycles per the manufacturer reprocessing recommendations.
- No more than 31 procedures of recorded surgical instrument usage.
- Do not use if there are any indications of damage, excessive wear or performance failure.
- Do not expose to corrosive detergents, enzymatic soaking solution or any other corrosive type solution.
- Do not use device after expiration date.
- Do not impact Torque Limiting Handle.

IMPORTANT: any one of the above conditions is an absolute indication to dispose of the instrument and to discontinue use.

Precautions

All health care workers should apply Universal Precautions when handling sharp instruments and instruments using torque limiting set points of any force.

Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



For recognized manufacturer, refer to product label.

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