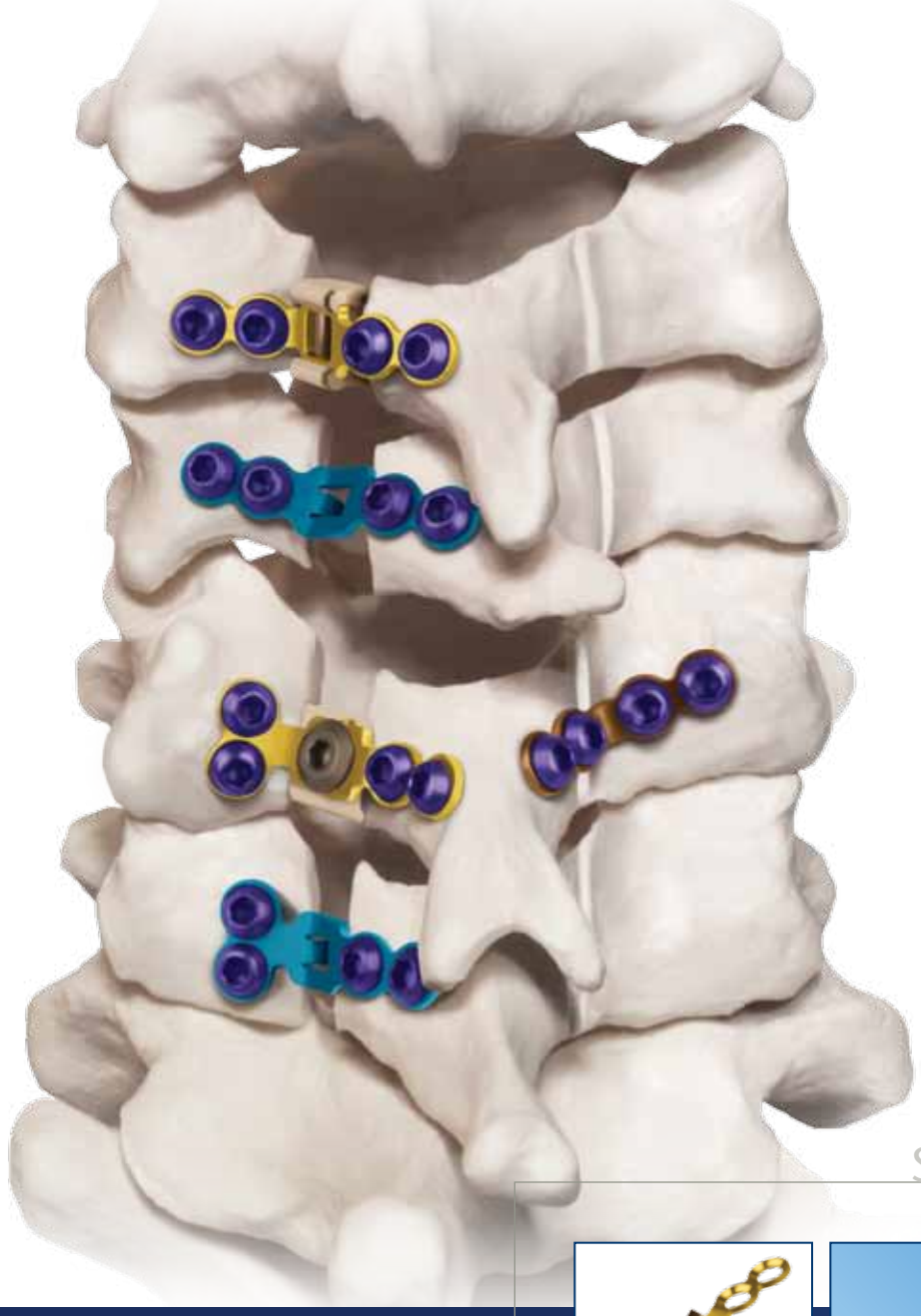


Life moves us

SURGICAL TECHNIQUE

CANOPY™

Laminoplasty System

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

CANOPY™

Laminoplasty System

CANOPY™ is a complete Open Door Laminoplasty System offering a controlled approach consisting of streamlined instrumentation and a variety of plate and spacer options for optimal intraoperative adaptability.

CANOPY™
LAMINOPLASTY SYSTEM

Most Comprehensive Implant Set

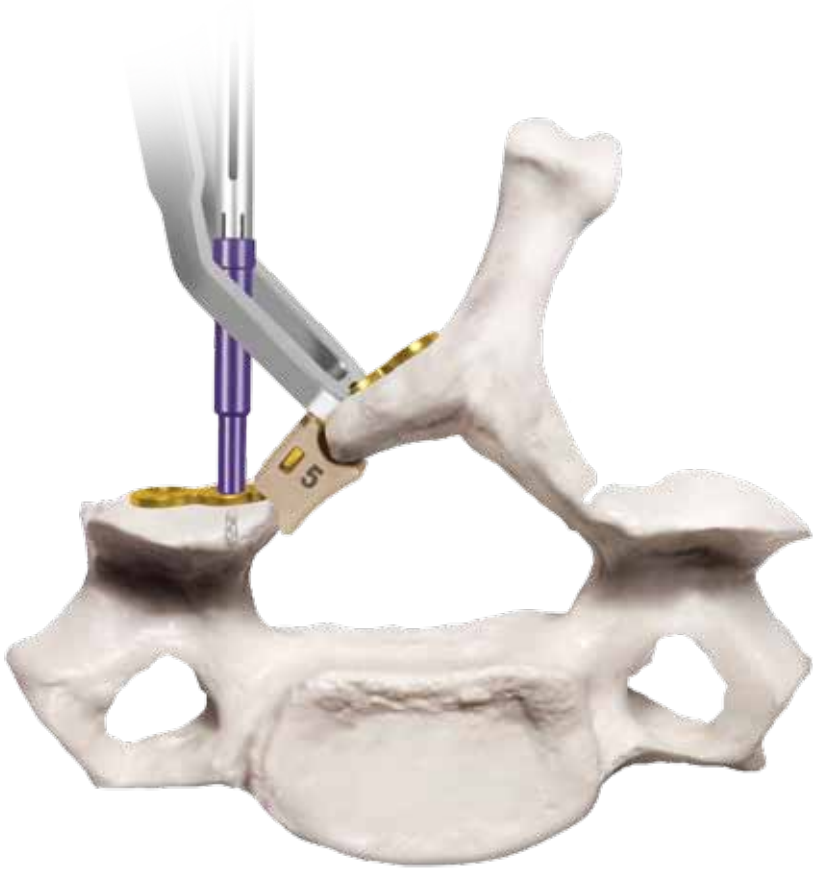
A variety of plate designs provide intraoperative adaptability and accommodate various patient anatomies.

No Hassle Approach

Easy-release screwdriver, drill-through plate holder, and versatile self-centering drill bits are provided for precision implantation.

Controlled Decompression

A novel laminar distraction device is designed for controlled decompression.



CONTENTS

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW

Graft Plates

- Double bend plate design
- In-line and adjacent screw hole configurations
- Available in 5–13mm sizes in 2mm increments
- Can be used with allograft or PEEK spacer

Radiolucent Spacer

- Slide-on PEEK spacer/graft plate assembly
- Corresponding spacer and plate sizes
- Graft packing chamber
- Composed of radiolucent PEEK material with tantalum markers for postoperative radiographic and CT/MRI visualization

Shelf Plates

- Double bend plate design
- In-line and adjacent screw hole configurations
- Shelf design maintains intralaminar opening and provides laminar support
- Available in 5–13mm sizes in 2mm increments

Hinge Plates

- Designed to accommodate an unstable hinge
- In-line and adjacent screw hole options

IMPLANT OVERVIEW

Bone Screws

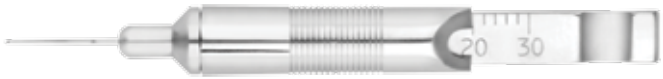
- 2.2mm and 2.6mm diameter self-drilling or self-tapping
- 3.0mm diameter self-tapping rescue screw
- Lengths from 4–12mm in 2mm increments
- Color-coded lengths match drill sleeves

CANOPY™ Graft Screw

- 2.6x5mm graft screw secures allograft to graft plate
- Large screw head diameter secures allograft to plate through graft window

INSTRUMENT OVERVIEW

Preparation Instruments



Depth Gauge 6102.1040

Awl, 1.3mm 636.460

Quick Connect Handle 636.451

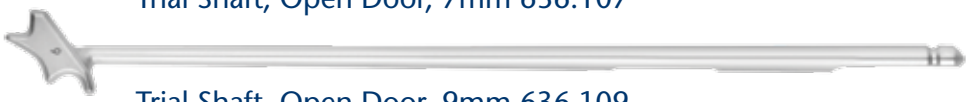
Quick Connect Handle, Swivel 636.450

Cutter 6102.1003

Trials

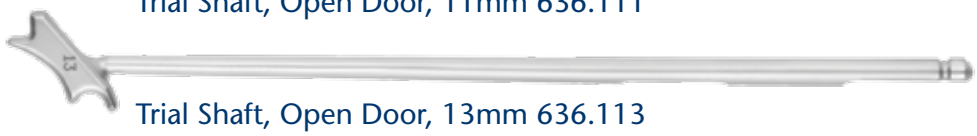
Trial Shaft, Open Door, 5mm 636.105

Trial Shaft, Open Door, 7mm 636.107



Trial Shaft, Open Door, 9mm 636.109

Trial Shaft, Open Door, 11mm 636.111



Trial Shaft, Open Door, 13mm 636.113

Drill Bits and Drill Sleeves

Drill Bit and Depth Sleeve Assembly for Laminoplasty Bone Screws

Drill Bit, 1.4mm 6102.5000

Depth Sleeve, 4mm 6102.5004
Depth Sleeve, 6mm 6102.5006
Depth Sleeve, 8mm 6102.5008
Depth Sleeve, 10mm 6102.5010
Depth Sleeve, 12mm 6102.5012

Drill Bit, Small and Drill Bit Sleeve Assembly

Drill Bit, Small, for 3.5mm Screws 615.504
Drill Bit, Small, for 4.0mm Screws 615.505

Drill Bit Sleeve, 10mm 6102.3010
Drill Bit Sleeve, 12mm 6102.3012
Drill Bit Sleeve, 14mm 6102.3014
Drill Bit Sleeve, 16mm 6102.3016

Plate Holders

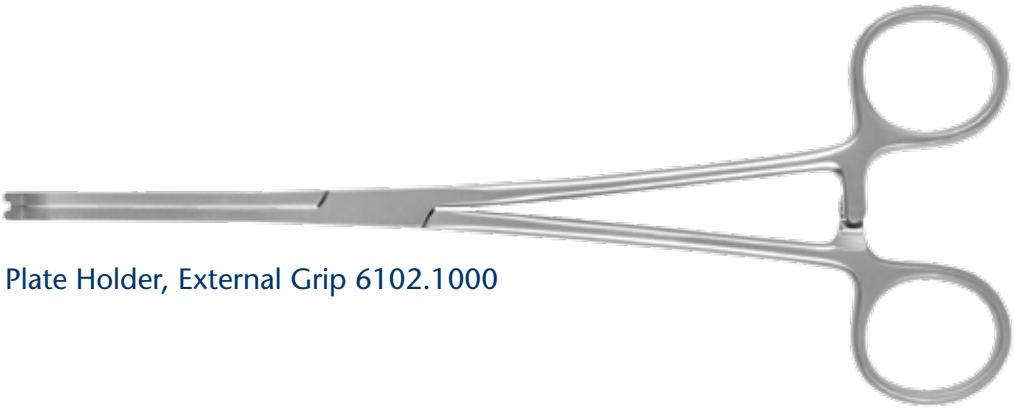


Plate Holder, External Grip 6102.1000

Drill-Through Plate Holder 6102.1001

Plate Holder, Internal Grip 6102.1004

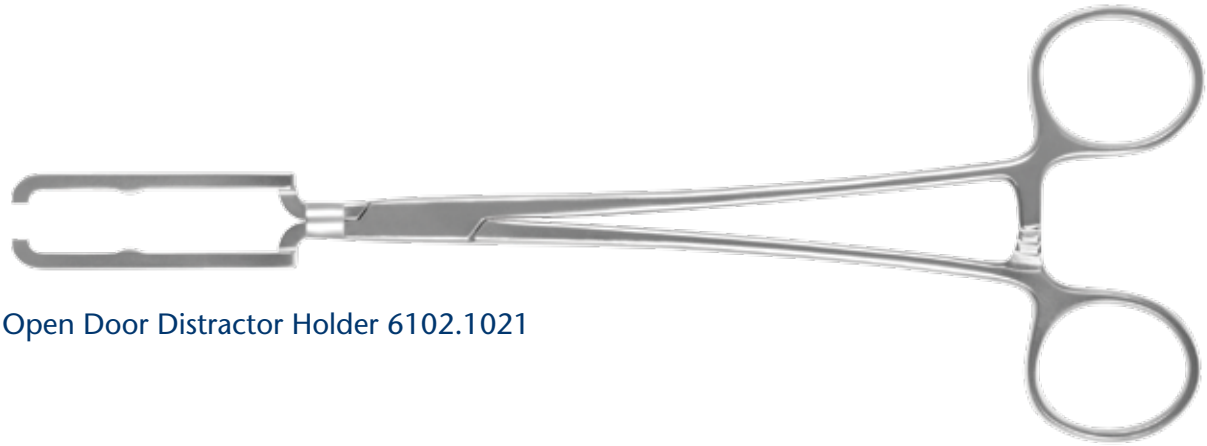
Articulating Plate Holder, External Grip 6102.1006

Screw Insertion

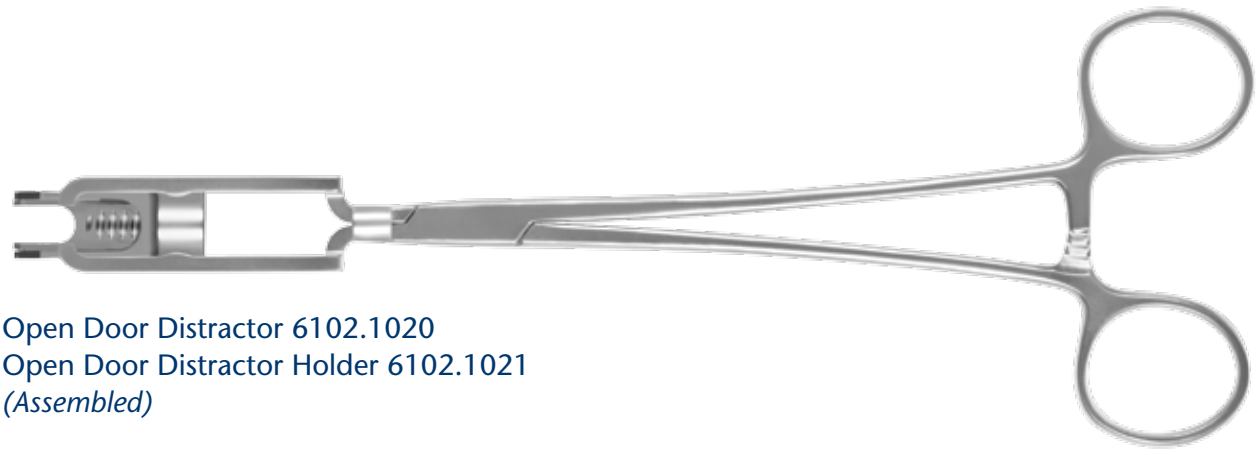
Pushbutton Hex Driver, 2.0mm 636.471

Distractor and Distractor Holder

Open Door Distractor 6102.1020



Open Door Distractor Holder 6102.1021



Open Door Distractor 6102.1020
Open Door Distractor Holder 6102.1021
(Assembled)

CANOPY™ Laminoplasty System
SURGICAL TECHNIQUE

Step 1 Approach

The patient is positioned prone with the neck in slight flexion, such that cervical lordosis is maintained. A standard posterior midline incision is created down to the tips of the spinous processes. The paraspinal muscles are dissected laterally, exposing the lamina out to the mid-portion of the lateral masses. The muscle origins and insertions over the lateral half of the lateral masses are preserved.

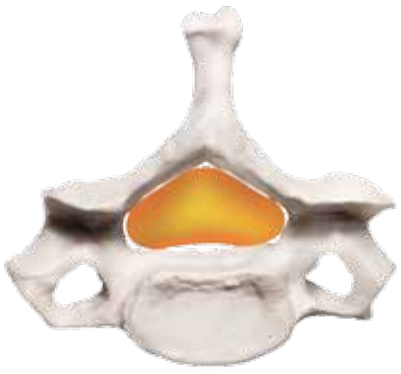
Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout surgery to ensure correct implant placement.

Please refer to the product insert printed at the back of this technique guide for complete description, indications, contraindications, warnings and precautions.

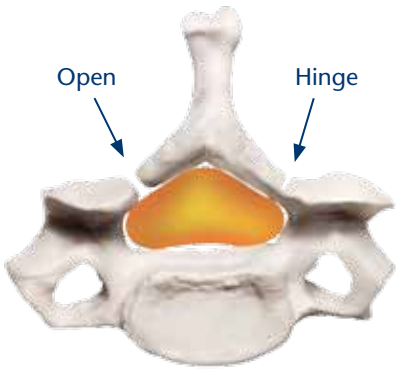
Step 2 Site Preparation

The open side trough is prepared along the junction of the lamina and lateral mass. The side with the most apparent compression is often chosen as the open side allowing foraminal decompression if required. Remove the bone through the ventral cortex. On the hinge side of the laminoplasty, another trough should be made, leaving the ventral cortex intact and releasing the ligamentum flavum.

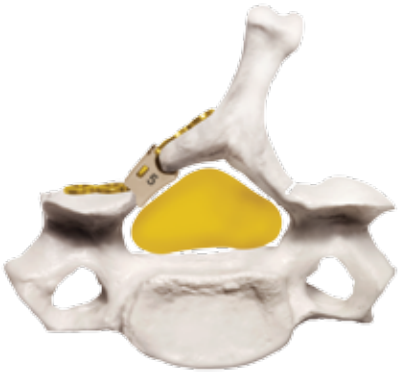
To open the lamina, soft tissue may need to be excised at the caudal and cranial endpoints of the involved section.



Spinal cord compressed



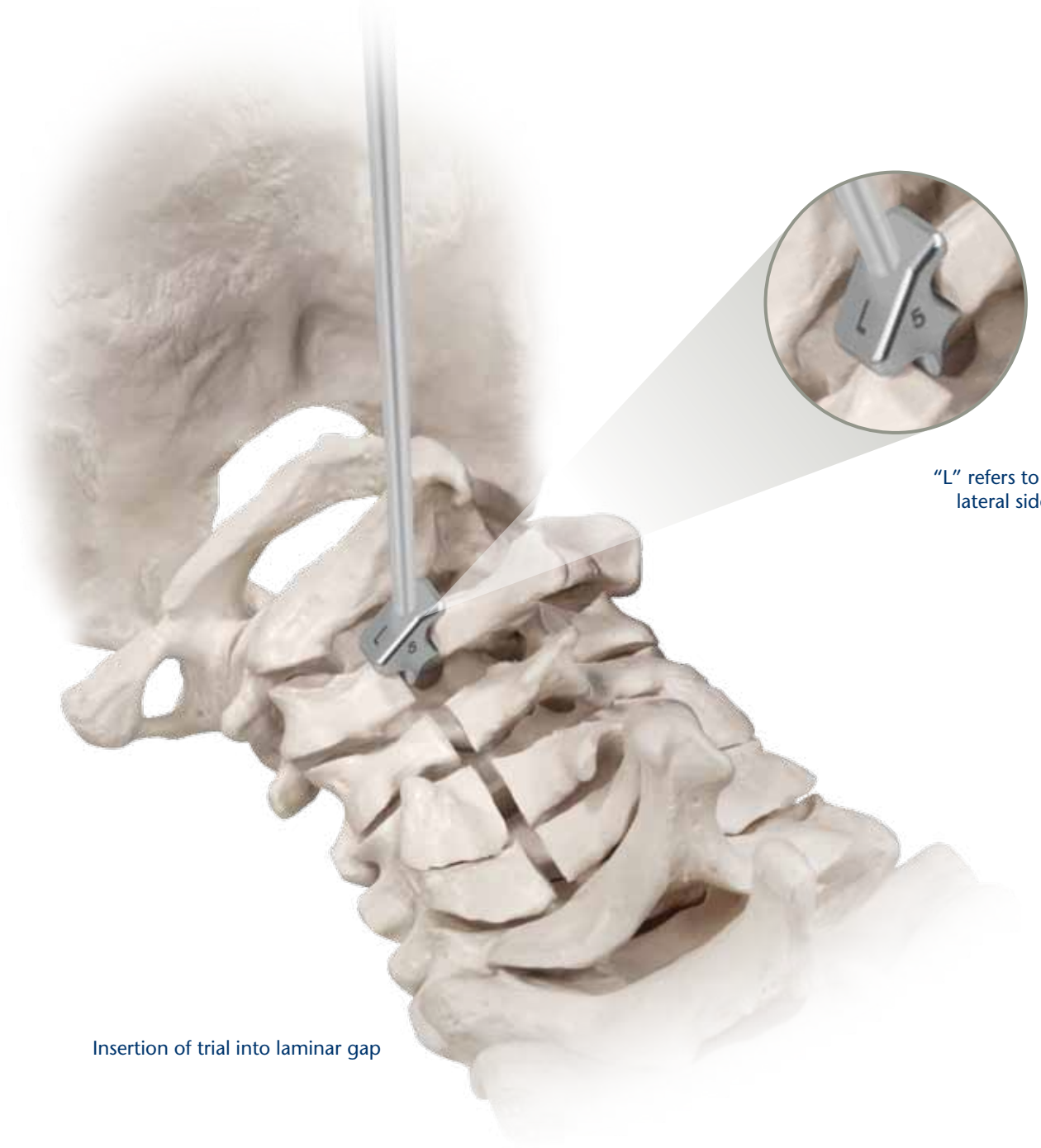
Laminoplasty



CANOPY™ inserted

Step 3 Implant Selection

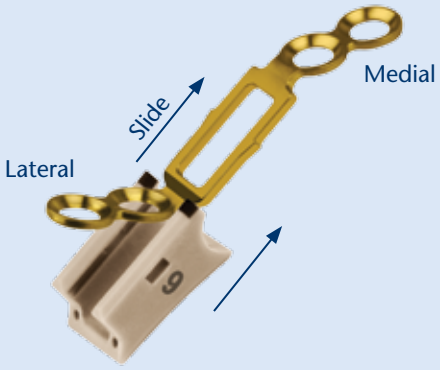
Insert the **Trial Shaft, Open Door** of the approximate size into the space between the lamina and lateral mass. One side of the trial should rest on the lamina and the other side of the trial should be placed on the lateral mass, as shown below. Determine the trial that best fits this space.



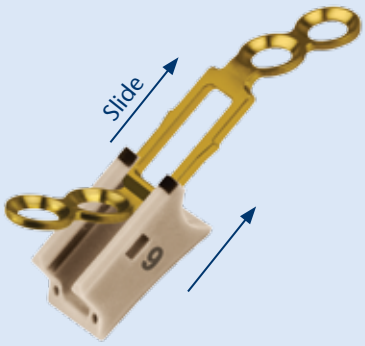
"L" refers to the lateral side

Insertion of trial into laminar gap

Assembling the Graft Plate and Radiolucent Spacer



Align the etched lines on the plate with the spacer



Slide the spacer forward until the grooves on the outside of the plate snap into the open grooves of the spacer

The spacer is LOCKED into place when the grooves of the plate align with the grooves in the spacer

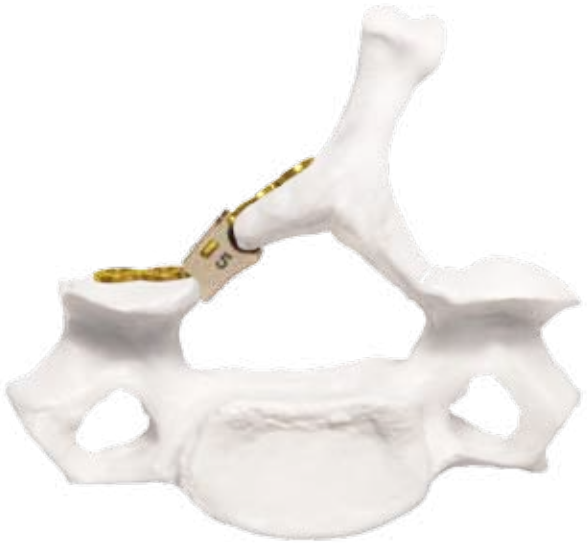
Note: Once the spacer is assembled to the plate, it cannot be disassembled.

Plate Options

Option A: CANOPY™ Graft Plate and Radiolucent Spacer

The Graft Plate, In-Line or Graft Plate, Adjacent may be assembled intraoperatively with a radiolucent spacer.

Choose the appropriate plate size and the corresponding spacer size. Assemble the spacer to the graft plate by sliding the plate and spacer together. The spacer may be packed with allograft or autogeneous bone graft.



Graft plate with radiolucent spacer assembly (vertebral body shown for visualization purposes)

Option B: CANOPY™ Graft Plate and Allograft

The graft plate may be used with an allograft spacer. Load the Graft Screw onto the **Pushbutton Hex Driver, 2.0mm**.

Align the spacer with the plate and insert the screw through the window of the plate into the spacer.

Graft plate with allograft assembly
(vertebral body shown for visualization purposes)

Option C: CANOPY™ Shelf Plate

The Shelf Plate, In-Line and the Shelf Plate, Adjacent may be used only if a plate without a radiolucent spacer or allograft spacer is desired. The shelf plate design incorporates two kickstands that rest on the lateral mass and support the lamina maintaining the intralaminar opening without the use of a spacer as, shown below.

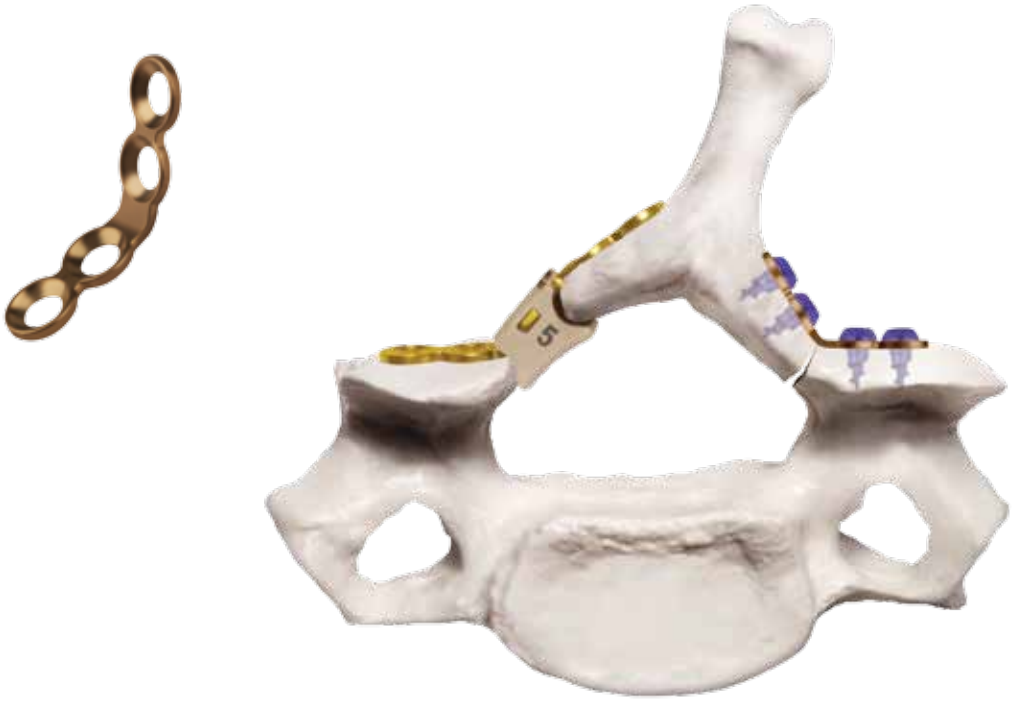
Additional contouring of the plates may be required. If desired, the plate may be cut between the screw holes using the **Cutter** to best fit patient anatomy.

Shelf plate
(vertebral body shown for visualization purposes)

Plate Options (cont'd)

Option D: CANOPY™ Hinge Plate

The Hinge Plate, In-line and Hinge Plate, Adjacent are provided for increased stability on the contralateral side.

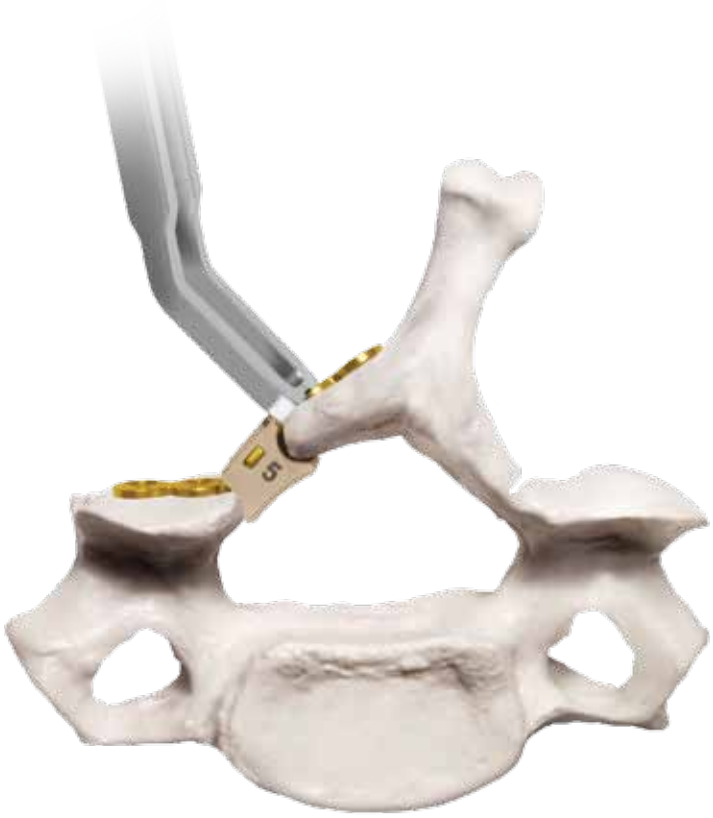


Hinge plate, In-line
(vertebral body shown for visualization purposes)

Step 4 Plate Placement

When placing the plate into the intralaminar space, one of four plate holders may be used, as shown at right.

The **Drill-Through Plate Holder** stabilizes the implant and allows simultaneous drilling and screw insertion. Grip the plate from the outside edge, as shown below. The curved arms of the plate holder allow access to the lamina and lateral mass screw holes when drilling or placing screws.



Using the Drill-Through Plate Holder

Plate Holder Options

The **Drill-Through Plate Holder** stabilizes the implant and allows simultaneous drilling or screw insertion.

The **Plate Holder, External Grip** attaches to the outside edges of the graft plates and shelf plates.

The **Articulating Plate Holder, External Grip** attaches to the outside edge of the plates and articulates to the desired angle.

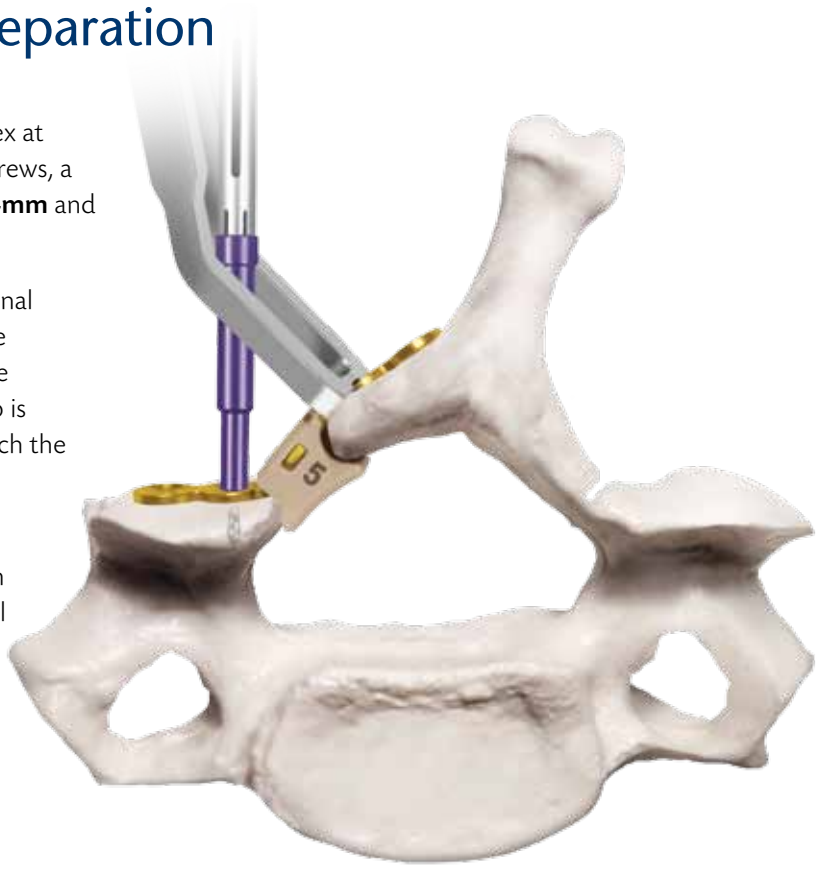
The **Plate Holder, Internal Grip** grips the central opening in the shelf plates.

Step 5 Screw Hole Preparation

The **Awl, 1.3mm** is used to perforate the cortex at the site of screw placement. For self-tapping screws, a pilot hole may be drilled using the **Drill Bit, 1.4mm** and **Depth Sleeve**.

Assemble the **Quick Connect Handle** or optional swivel handle to the selected drill bit. Select the appropriate depth sleeve. Slide the depth sleeve over the tip of the drill bit, until an audible snap is heard. Each depth sleeve is color-coded to match the corresponding screw length.

Place the tip of the drill bit and depth sleeve assembly into the desired plate hole. The depth sleeve centers the drill bit in the plate hole. Drill to the stop. The **Depth Gauge** may be used to verify depth.



Assembling the Drill Bit and Depth Sleeve

Slide the depth sleeve over the tip of the drill bit

Push the depth sleeve forward to snap onto the drill bit

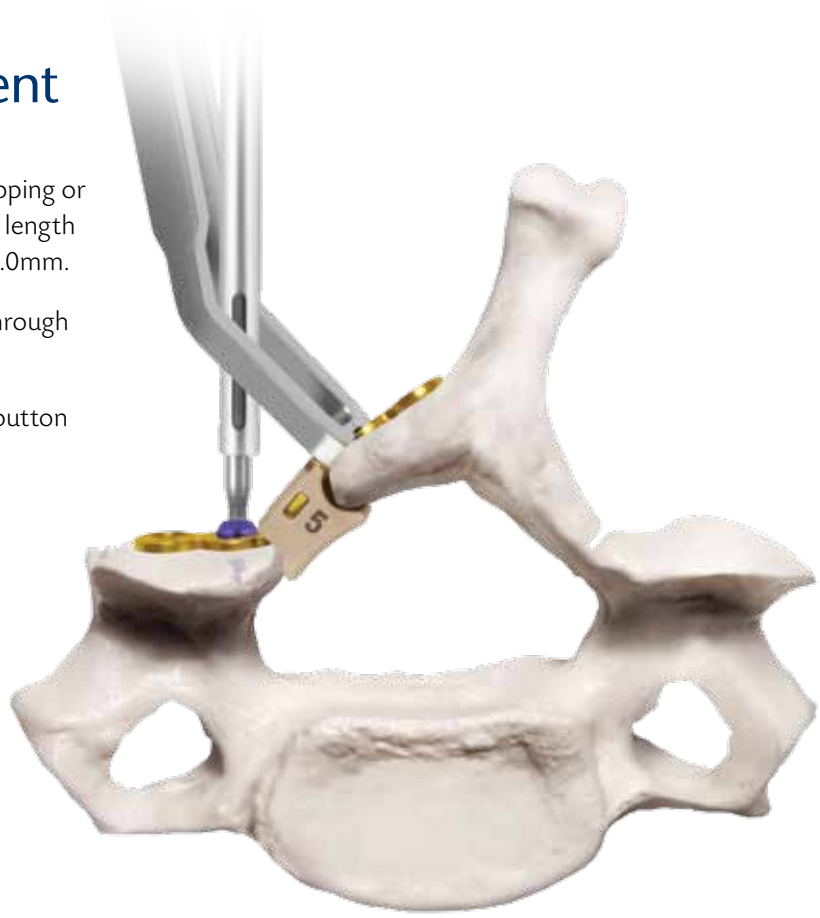
The depth sleeve is spring loaded to cover the tip of the drill bit and retracts only as it is advanced through the screw hole

Step 6 Screw Placement

Once the screw hole has been prepared, self-tapping or self-drilling screws of the selected diameter and length are inserted using the Pushbutton Hex Driver, 2.0mm.

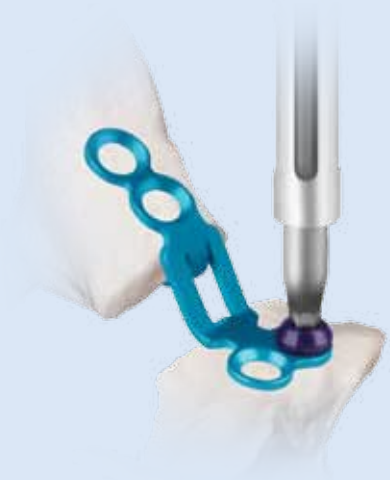
Load the screw from the module and insert it through the plate and into the bone.

To release the driver from the screw, press the button at the distal end of the driver, as shown below.

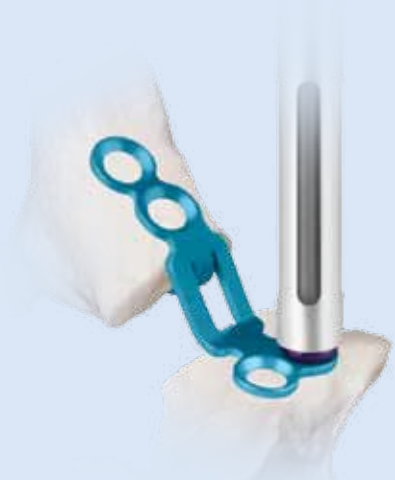


Using the Pushbutton Hex Driver, 2.0mm

Releasing the screw

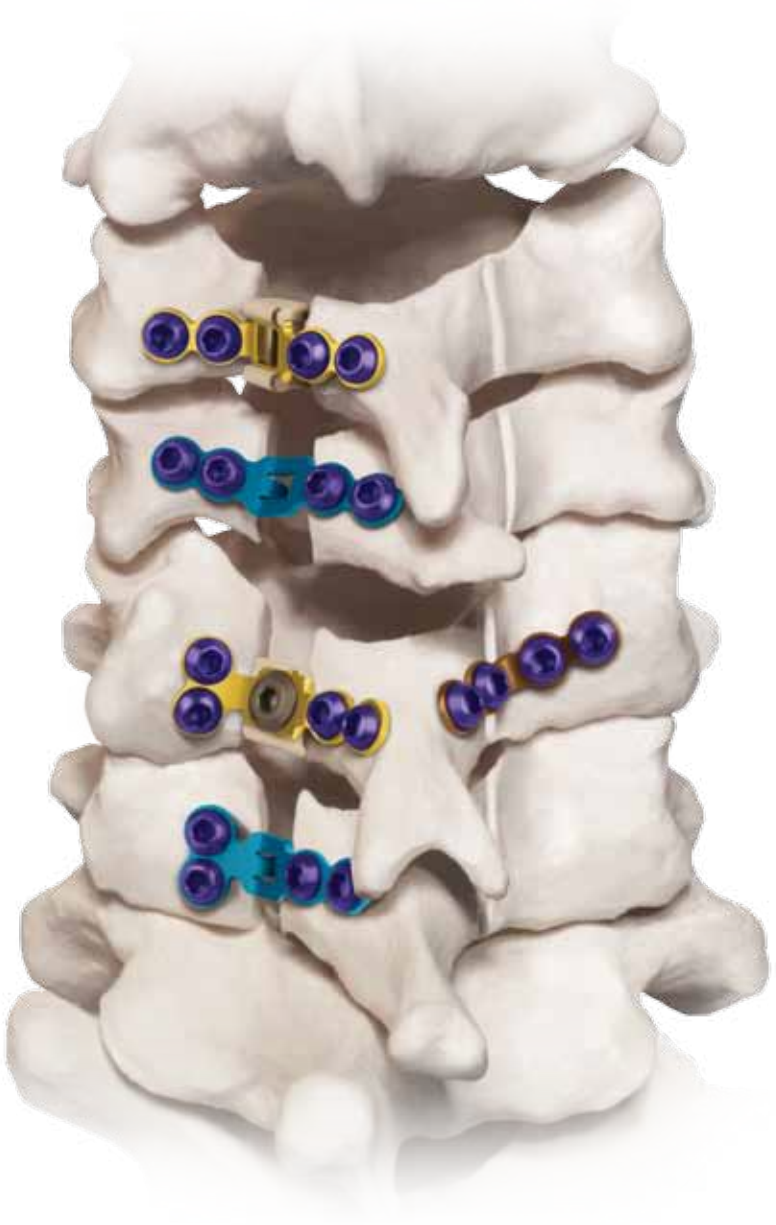


Hex engaged in screw



Button compressed, lowering driver shaft and releasing the hex

Final Construct



Optional: Implant Removal

For removal of CANOPY™ implants, select a plate holder to grip the plate during screw removal. Insert the Pushbutton Hex Driver, 2.0mm into the hex of the screw head and rotate counterclockwise to remove the bone screws. Once the screws are removed, the plate can be removed.

Optional Technique: Using the Open Door Distractor

The **Open Door Distractor** is used to lift the lamina to decompress the spinal canal. It also maintains the intralaminar opening during the insertion of a shelf plate.

Assemble the distractor and **Open Door Distractor Holder**, by aligning the tabs of the holder with the laser markings on the distractor for a rigid connection.

Securely place the assembly between the intralaminar space. Insert the Pushbutton Hex Driver, 2.0mm into the hex of the distractor.

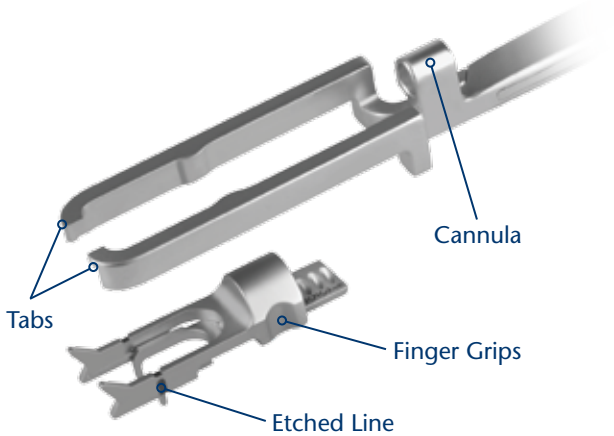
Rotate the driver clockwise to lift the lamina to achieve decompression of the spinal cord. Each rotation equals 2mm of distraction.

The laser markings indicate the appropriate size plate required to maintain the decompressed intralaminar opening, as shown at right.

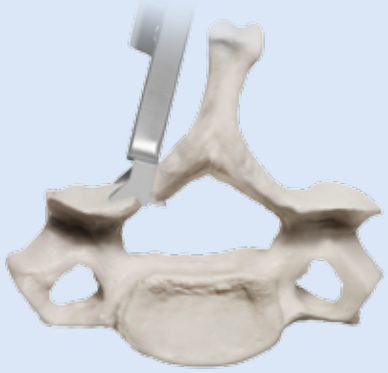
The Plate Holder, Internal Grip may be used to insert the shelf plate through the distractor, as shown at right.

Note: Care should be taken not to over distract the lamina which could potentially damage the hinge. The distractor will not distract more than 13mm.

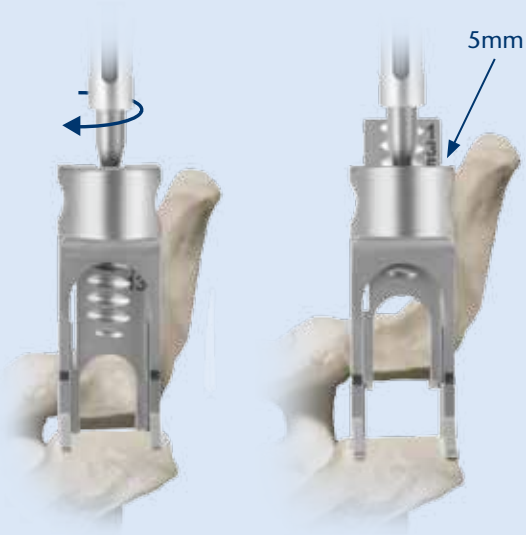
Detail of Distractor Holder



Placing the Shelf Plate



Distractor placement



Insert driver and rotate to distract

Plate size determined

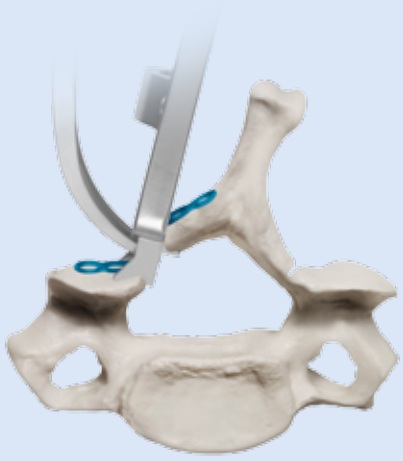
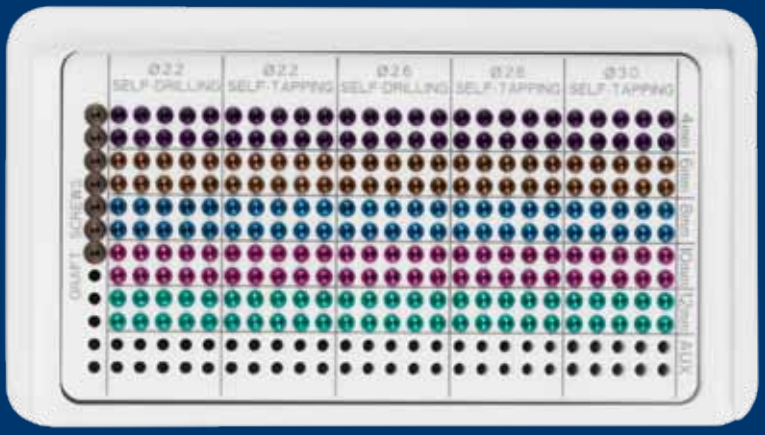
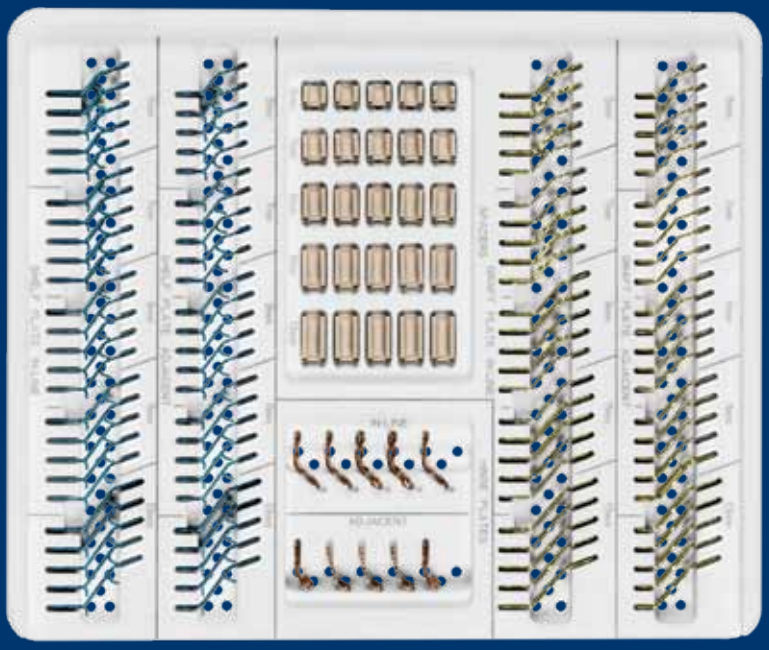
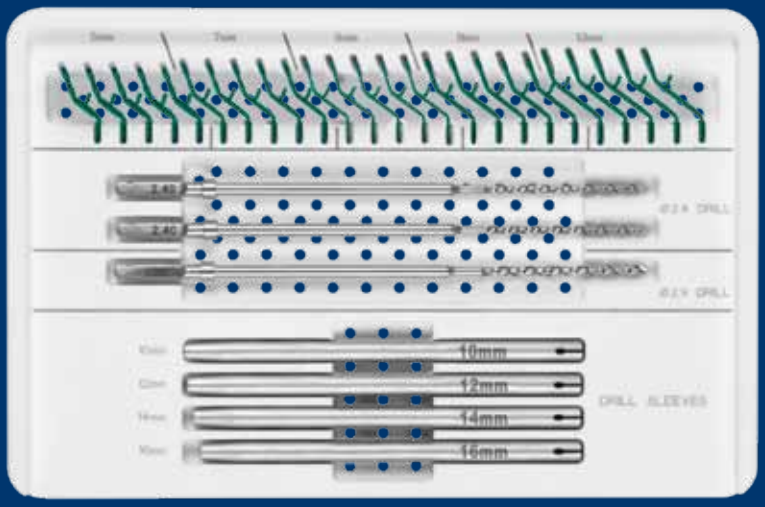


Plate Holder, Internal Grip inserting shelf plate

CANOPY™ IMPLANTS







CANOPY™ Implant Sets

CANOPY™ Screw Set 9102.9002

Description		Qty
2.2mm Screw, Self-Drilling		
136.404	RELIEVE® 2.2mm Screw, Self-Drilling, 4mm	10
136.406	RELIEVE® 2.2mm Screw, Self-Drilling, 6mm	10
136.408	RELIEVE® 2.2mm Screw, Self-Drilling, 8mm	10
136.410	RELIEVE® 2.2mm Screw, Self-Drilling, 10mm	10
136.412	RELIEVE® 2.2mm Screw, Self-Drilling, 12mm	10
2.2mm Screw, Self-Tapping		
136.504	RELIEVE® 2.2mm Screw, Self-Tapping, 4mm	10
136.506	RELIEVE® 2.2mm Screw, Self-Tapping, 6mm	10
136.508	RELIEVE® 2.2mm Screw, Self-Tapping, 8mm	10
136.510	RELIEVE® 2.2mm Screw, Self-Tapping, 10mm	10
136.512	RELIEVE® 2.2mm Screw, Self-Tapping, 12mm	10
2.6mm Screw, Self-Drilling		
1102.6004	CANOPY™ 2.6mm Screw, Self-Drilling, 4mm	10
1102.6006	CANOPY™ 2.6mm Screw, Self-Drilling, 6mm	10
1102.6008	CANOPY™ 2.6mm Screw, Self-Drilling, 8mm	10
1102.6010	CANOPY™ 2.6mm Screw, Self-Drilling, 10mm	10
1102.6012	CANOPY™ 2.6mm Screw, Self-Drilling, 12mm	10
2.6mm Screw, Self-Tapping		
136.704	RELIEVE® 2.6mm Screw, Self-Tapping, 4mm	10
136.706	RELIEVE® 2.6mm Screw, Self-Tapping, 6mm	10
136.708	RELIEVE® 2.6mm Screw, Self-Tapping, 8mm	10
136.710	RELIEVE® 2.6mm Screw, Self-Tapping, 10mm	10
136.712	RELIEVE® 2.6mm Screw, Self-Tapping, 12mm	10
3.0mm Screw, Self-Tapping		
1102.8004	CANOPY™ 3.0mm Screw, Self-Tapping, 4mm	10
1102.8006	CANOPY™ 3.0mm Screw, Self-Tapping, 6mm	10
1102.8008	CANOPY™ 3.0mm Screw, Self-Tapping, 8mm	10
1102.8010	CANOPY™ 3.0mm Screw, Self-Tapping, 10mm	10
1102.8012	CANOPY™ 3.0mm Screw, Self-Tapping, 12mm	10
Graft Screw		
1102.9000	CANOPY™ Graft Screw	7
9102.0002	CANOPY™ Screw Module	1

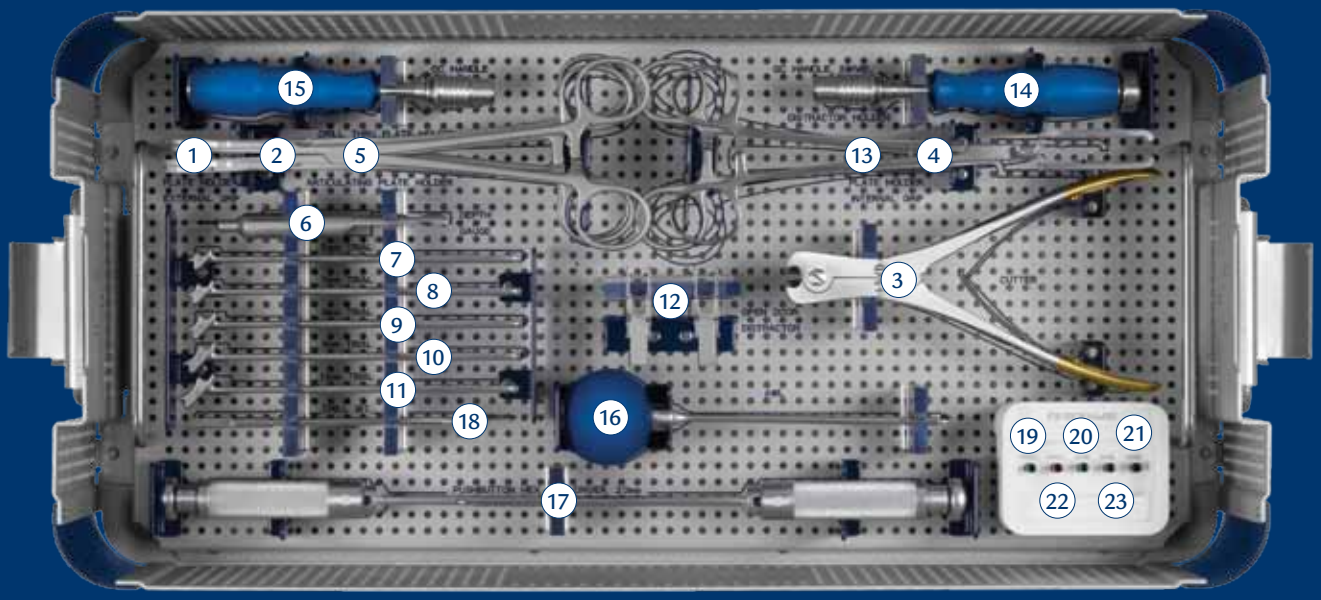
CANOPY™ Plate and Spacer Set 9102.9003

Description		Qty
Graft Plate, In-Line		
1102.1005	CANOPY™ Graft Plate, In-line, 5mm	5
1102.1007	CANOPY™ Graft Plate, In-line, 7mm	5
1102.1009	CANOPY™ Graft Plate, In-line, 9mm	5
1102.1011	CANOPY™ Graft Plate, In-line, 11mm	5
1102.1013	CANOPY™ Graft Plate, In-line, 13mm	5
Description		**Qty**
Graft Plate, Adjacent		
1102.2005	CANOPY™ Graft Plate, Adjacent, 5mm	5
1102.2007	CANOPY™ Graft Plate, Adjacent, 7mm	5
1102.2009	CANOPY™ Graft Plate, Adjacent, 9mm	5
1102.2011	CANOPY™ Graft Plate, Adjacent, 11mm	5
1102.2013	CANOPY™ Graft Plate, Adjacent, 13mm	5
Shelf Plate, In-Line		
1102.3005	CANOPY™ Shelf Plate, In-line, 5mm	5
1102.3007	CANOPY™ Shelf Plate, In-line, 7mm	5
1102.3009	CANOPY™ Shelf Plate, In-line, 9mm	5
1102.3011	CANOPY™ Shelf Plate, In-line, 11mm	5
1102.3013	CANOPY™ Shelf Plate, In-line, 13mm	5
Shelf Plate, Adjacent		
1102.4005	CANOPY™ Shelf Plate, Adjacent, 5mm	5
1102.4007	CANOPY™ Shelf Plate, Adjacent, 7mm	5
1102.4009	CANOPY™ Shelf Plate, Adjacent, 9mm	5
1102.4011	CANOPY™ Shelf Plate, Adjacent, 11mm	5
1102.4013	CANOPY™ Shelf Plate, Adjacent, 13mm	5
Hinge Plates		
1102.7000	CANOPY™ Hinge Plate, In-line	5
1102.7001	CANOPY™ Hinge Plate, Adjacent	5
Spacers		
3102.6005	CANOPY™ Radiolucent Spacer, 5mm	5
3102.6007	CANOPY™ Radiolucent Spacer, 7mm	5
3102.6009	CANOPY™ Radiolucent Spacer, 9mm	5
3102.6011	CANOPY™ Radiolucent Spacer, 11mm	5
3102.6013	CANOPY™ Radiolucent Spacer, 13mm	5
9102.0003	CANOPY™ Plate Module	1

CANOPY™ Polyaxial Plate Implant and Instrument Set 9102.9004

Description		Qty
1102.5005	CANOPY™ Polyaxial Screw Hole Plate, 5mm	5
1102.5007	CANOPY™ Polyaxial Screw Hole Plate, 7mm	5
1102.5009	CANOPY™ Polyaxial Screw Hole Plate, 9mm	5
1102.5011	CANOPY™ Polyaxial Screw Hole Plate, 11mm	5
1102.5013	CANOPY™ Polyaxial Screw Hole Plate, 13mm	5
615.504	Drill Bit, Small, for 3.5mm Screws	1
615.505	Drill Bit, Small, for 4.0mm Screws	1
6102.3010	Drill Bit Sleeve, 10mm	1
6102.3012	Drill Bit Sleeve, 12mm	1
6102.3014	Drill Bit Sleeve, 14mm	1
6102.3016	Drill Bit Sleeve, 16mm	1
9102.0004	CANOPY™ Polyaxial Plate Module	1

CANOPY™ INSTRUMENT SET



CANOPY™ Instrument Set 9102.9001

	Instruments		Qty
1	6102.1000	Plate Holder, External Grip	1
2	6102.1001	Drill-Through Plate Holder	1
3	6102.1003	Cutter	1
4	6102.1004	Plate Holder, Internal Grip	1
5	6102.1006	Articulating Plate Holder, External Grip	1
6	6102.1040	Depth Gauge	1
7	636.105	Trial Shaft, Open Door, 5mm	1
8	636.107	Trial Shaft, Open Door, 7mm	1
9	636.109	Trial Shaft, Open Door, 9mm	1
10	636.111	Trial Shaft, Open Door, 11mm	1
11	636.113	Trial Shaft, Open Door, 13mm	1
12	6102.1020	Open Door Distractor	2
13	6102.1021	Open Door Distractor Holder	1
14	636.450	Quick Connect Handle, Swivel	1
15	636.451	Quick Connect Handle	1
16	636.460	Awl, 1.3mm	1
17	636.471	Pushbutton Hex Driver, 2.0mm	1
18	6102.5000	Drill Bit, 1.4mm	2
19	6102.5004	Depth Sleeve, 4mm	1
20	6102.5006	Depth Sleeve, 6mm	1
21	6102.5008	Depth Sleeve, 8mm	1
22	6102.5010	Depth Sleeve, 10mm	1
23	6102.5012	Depth Sleeve, 12mm	1
	9102.0001	CANOPY™ Graphic Case	

Additionally Available Instruments

636.490	Tap Bit, 2.2mm Screw

IMPORTANT INFORMATION ON CANOPY™ LAMINOPLASTY FIXATION SYSTEM

DESCRIPTION

The CANOPY™ Laminoplasty Fixation System consists of spinal fixation plates and screws for use in laminoplasty procedures. CANOPY™ implants are inserted through a posterior cervical or thoracic approach, and are available in various sizes and geometric options to fit individual patient anatomy. Fixation plates may be used with bone graft material. Hinge plates may be used to stabilize a weakened or displaced lamina. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy.

CANOPY™ plates and screws are manufactured from titanium or titanium alloy, as specified in ASTM F67, F136, F1295 and F1472. Optional graft chambers are manufactured from radiolucent PEEK as specified in ASTM F2026 and contain tantalum or titanium alloy markers to permit radiographic visualization, per ASTM F67, F136, F560, F1295 or F1472.

INDICATIONS

The CANOPY™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The CANOPY™ Laminoplasty Fixation System is used to hold bone allograft material in place in order to prevent the allograft from expulsion or impinging the spinal cord.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium or titanium alloy and radiolucent polymer. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

PRECAUTIONS

The implantation of laminoplasty fixation devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

The CANOPY™ polyaxial screw hole plate is only to be used with ELLIPSE® polyaxial screws (3.5-4.0mm diameter, 8-12mm length), and only at the T1-T3 levels. When using this plate, the ELLIPSE® screw head must be fully seated to provide plate fixation.

The CANOPY™ Laminoplasty Fixation System has not been evaluated for safety and compatibility in the MR environment. The CANOPY™ System has not been tested for heating or migration in the MR environment.

When using the CANOPY™ Laminoplasty Fixation System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

1. Use of the CANOPY™ Laminoplasty System is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.

IMPORTANT INFORMATION ON CANOPY™ LAMINOPLASTY FIXATION SYSTEM

10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

CANOPY™ implants and instruments are provided non-sterile.

CANOPY™ implants and instruments have been validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*

Implants:

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 Minutes	30 Minutes

Instruments:

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	15 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law restricts this Device to Sale by or on the order of a Physician.

REV A

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