



HAVENTM

Dual Plate Laminoplasty System



Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life Moves Us

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.

SURGICAL TECHNIQUE GUIDE

HAVEN™

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HAVEN™

Dual Plate Laminoplasty System

HAVEN™ is a dual plate laminoplasty system that offers bilateral lamina support following an open door laminoplasty in the cervico-thoracic spine (C3-T3). HAVEN™ bridges the posterior arch to provide structural support and to help protect the spinal cord. The plates come in a variety of configurations that may be used with or without posterior cervico-thoracic fusion systems.

Bilateral Advantage

Bilateral fixation to the lateral masses provides a rigid supporting structure to bridge the posterior arch with one continuous implant.

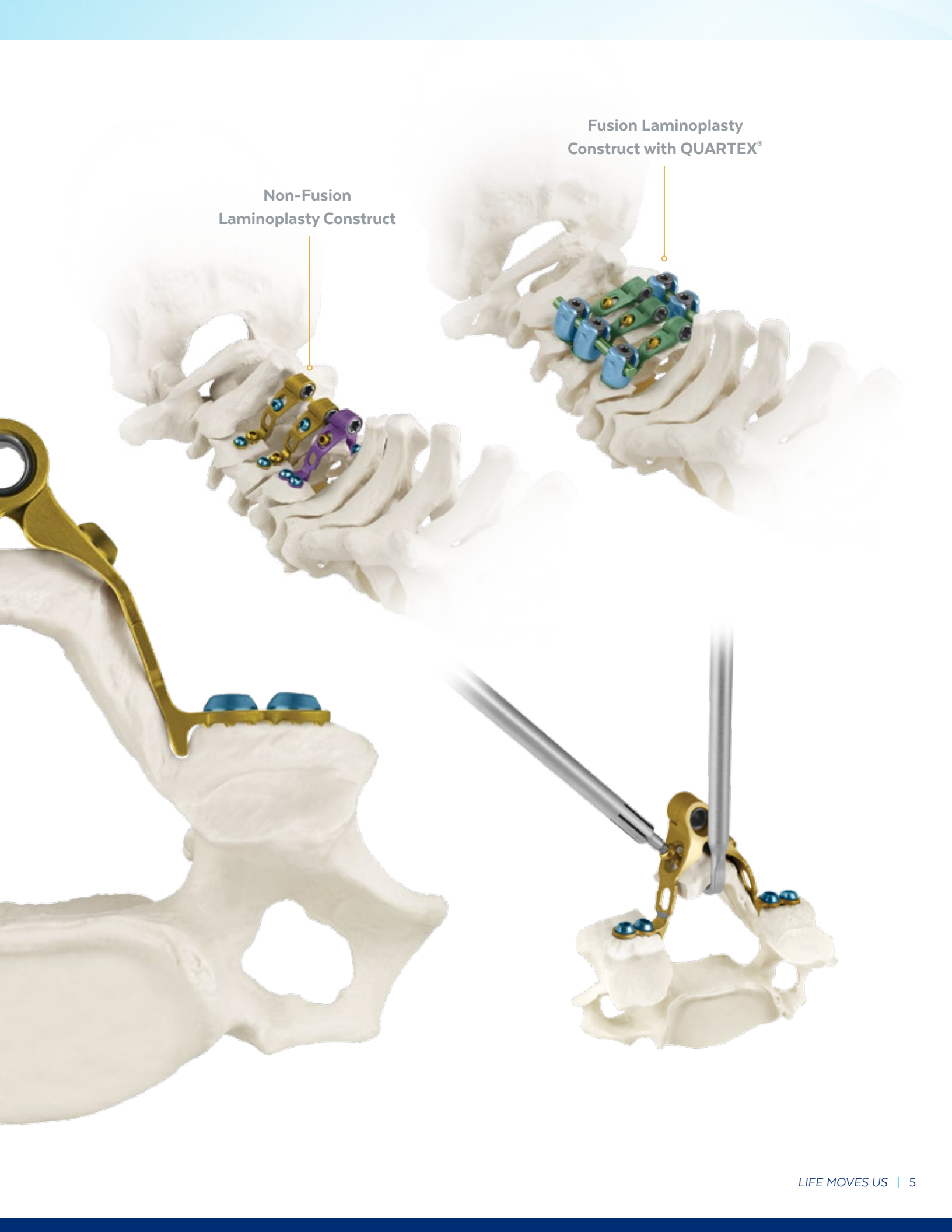
Restore Natural Anatomy

Anatomical implant design mimics intact anatomy.

Fusion and Non-Fusion Plate Configurations

HAVEN™ is offered in a variety of plate configurations that may be used in a traditional non-fusion laminoplasty procedure or may be coupled with cervico-thoracic fusion systems such as QUARTEX® or ELLIPSE®.





Non-Fusion
Laminoplasty Construct

Fusion Laminoplasty
Construct with QUARTEX®

IMPLANT OVERVIEW

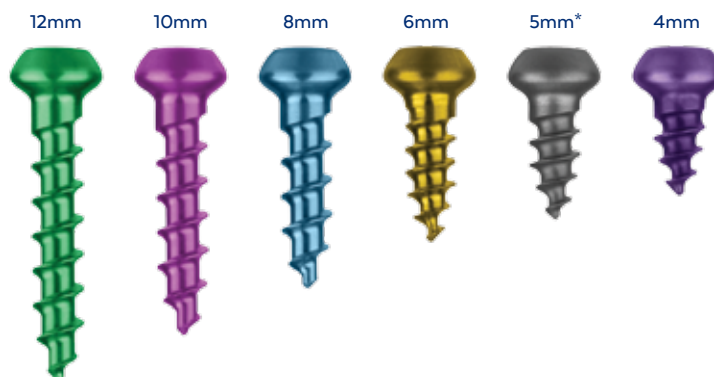
HAVEN™ Dual Plates

- Hinged design accommodates varying patient anatomy
- Inline, adjacent, and polyaxial screw hole configurations allow versatile application
 - Inline and adjacent plates for non-fusion (non-segmental fixation) constructs
 - Polyaxial screw hole plates as an adjunct to cervico-thoracic fusion



Laminoplasty Screws

- 2.2mm and 2.6mm diameter self-drilling or self-tapping
- 3.0mm diameter self-tapping rescue screw option
- Lengths from 4-12mm in 2mm increments



INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS



Depth Gauge 6102.1040



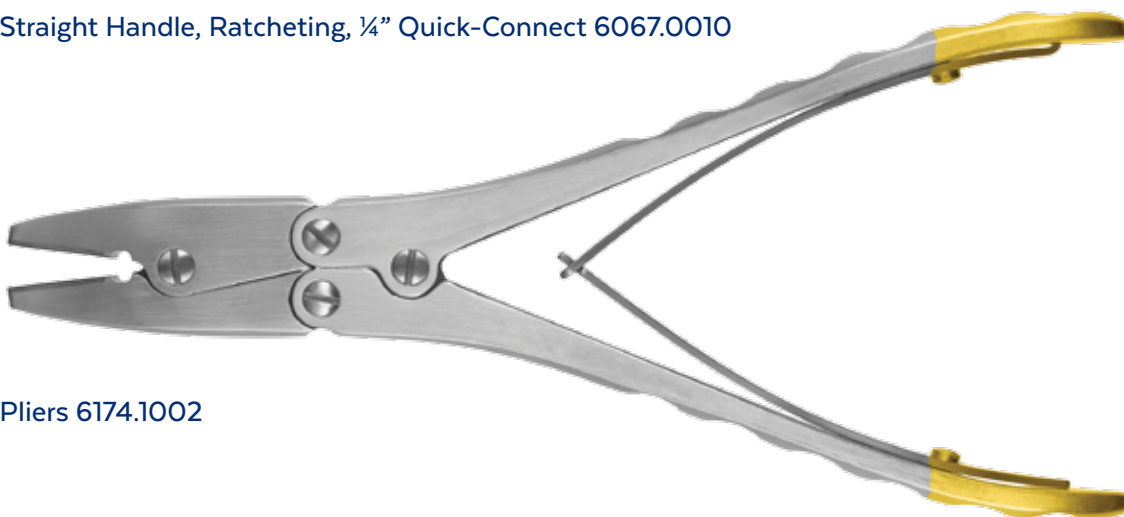
Awl, 1.3mm 636.460



Easy Connect Handle, Small 697.705

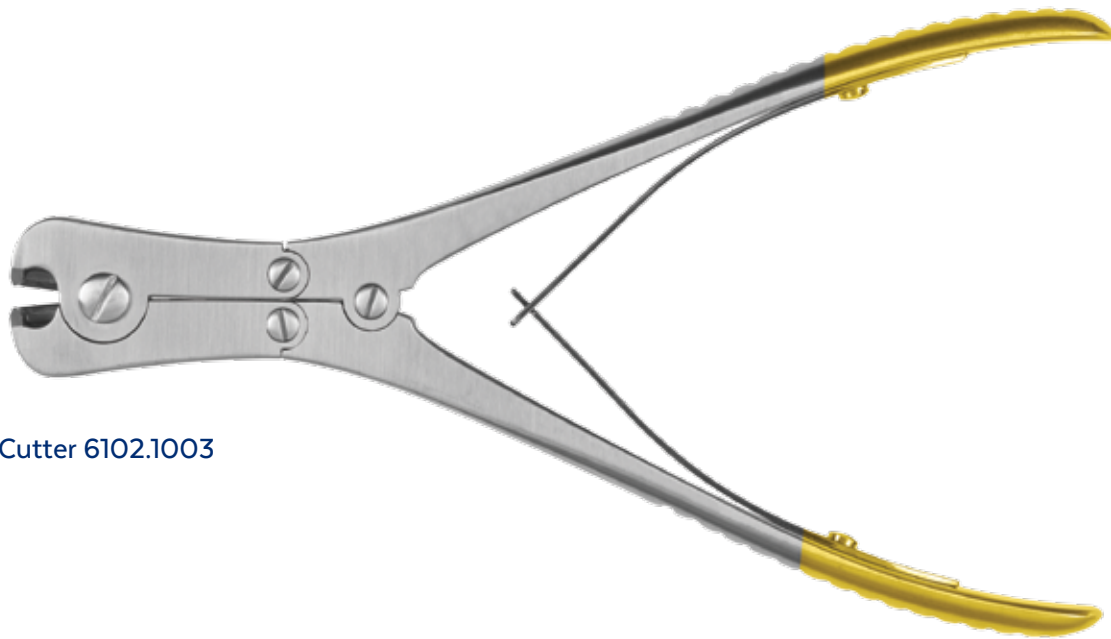


Straight Handle, Ratcheting, 1/4" Quick-Connect 6067.0010



Pliers 6174.1002

PREPARATION INSTRUMENTS (CONT'D)



Cutter 6102.1003

DRILL BITS AND DRILL SLEEVES FOR LAMINOPLASTY SCREWS



Drill Bit, for 2.2mm Screw (1.4mm diameter) 6174.5014



Drill Bit, for 2.6mm Screw (1.6mm diameter) 6174.5016



Depth Sleeve, 4mm 6174.5004



Depth Sleeve, 5mm 6174.5005



Depth Sleeve, 6mm 6174.5006



Depth Sleeve, 8mm 6174.5008



Depth Sleeve, 10mm 6174.5010



Depth Sleeve, 12mm 6174.5012



Drill Bit and Depth Sleeve Assembly for Laminoplasty Screws

Items highlighted in gray are additionally available.

DRILL BITS AND DRILL SLEEVES FOR POLYAXIAL SCREWS



Drill Bit, for 3.5mm Screw (2.4mm diameter) 6174.1035



Drill Bit, for 4.0mm Screw (2.9mm diameter) 6174.1040



Drill Bit, for 4.5mm Screw (3.4mm diameter) 6174.1045



Adjustable Drill Sleeve, for Small Diameter Drill Bit 6174.3000



Drill Bit and Drill Sleeve Assembly for Polyaxial Screws

DRILL BITS AND DRILL SLEEVES FOR LARGE DIAMETER POLYAXIAL SCREWS



Drill Bit, for 5.0mm Screw (3.9mm diameter) 6174.1050



Drill Bit, for 5.5mm Screw (4.4mm diameter) 6174.1055

DRILL BITS AND DRILL SLEEVES FOR LARGE DIAMETER POLYAXIAL SCREWS (CONT'D)



Adjustable Drill Sleeve, for Large Diameter Drill Bit 6174.4000



Drill Bit and Drill Sleeve Assembly for Large Diameter Polyaxial Screws

PLATE HOLDERS

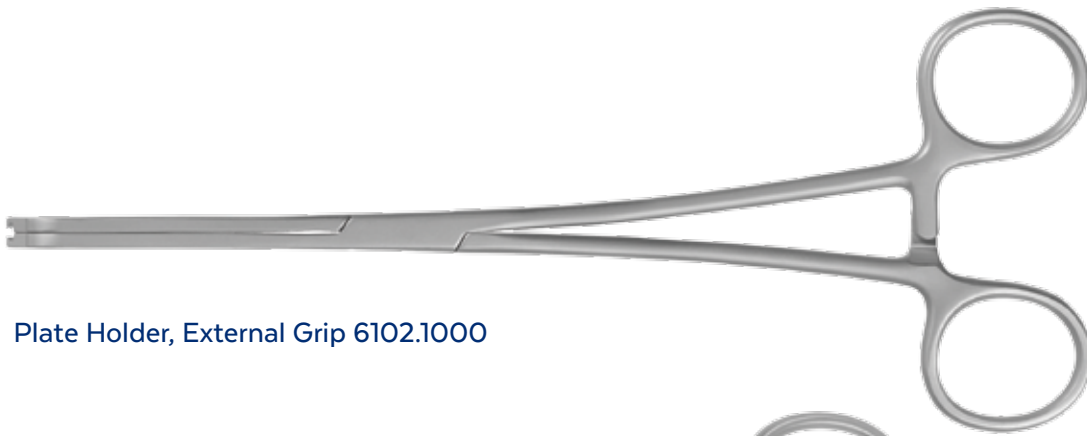


Plate Holder, External Grip 6102.1000



Plate Holder, Internal Grip 6102.1004



Forceps Plate Holder 6174.1005

SCREW INSERTION



Push-Button Driver, 2.0mm Hex 6174.2000



2.0mm Hex, Self-Retaining Shaft 6174.2001

DECOMPRESSION INSTRUMENT



Lamina Hook 6174.7000

LOCKING INSTRUMENTS



Pin Counter Torque 6174.8001



Torque Limiting Wrench, #25 Hexalobe (0.5Nm) 6174.9000

SURGICAL TECHNIQUE

HAVEN™

STEP 1 APPROACH

The patient is positioned prone with the neck in slight flexion to maintain cervical lordosis. A standard posterior midline incision is created down to the tips of the spinous processes at the appropriate level(s). 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 may be used throughout surgery to ensure correct implant placement.

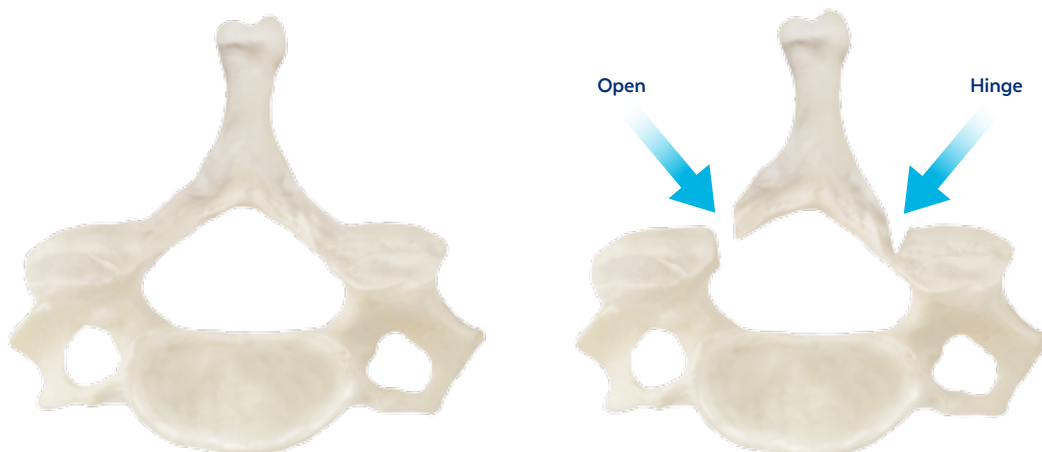
Please refer to the package insert printed at the back of this technique guide for complete description, contraindications, warnings, and precautions.

STEP 2 SITE PREPARATION

Perform an open door laminoplasty procedure following proper surgical technique.

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

Choose the appropriate plate for the procedure type, lateral screw hole placement, and patient anatomy. Adjacent and Inline plate placement is described from pages 14 to 15 for a non-fusion, non-segmental construct. If desired, the Adjacent and Inline plates may be cut between the screw holes using the **Cutter** to best fit patient anatomy. Polyaxial Screw Hole plate and Large Diameter Polyaxial Screw Hole plate placement is described from pages 16 to 17 for a fusion construct. **Pliers** may be used to further contour the plates.

A radiolucent spacer may be assembled to the plate intraoperatively. Refer to CANOPY® Laminoplasty System Technique Guide GMTGD75 for trialing, spacer selection, and assembly.

Non-Segmental Fixation



Inline Plate
2.2-3.0mm screws



Adjacent Plate
2.2-3.0mm screws

Fusion Constructs



Polyaxial Screw Hole Plate
3.5-4.5mm ELLIPSE® or
QUARTEX® polyaxial screws



Large Diameter Polyaxial Screw Hole Plate
3.5- 6.5mm QUARTEX® polyaxial screws

STEP 4 PLATE PLACEMENT

Once the desired plate is selected, one of the three plate holders may be used, as shown on page 15.

Insert the plate by first anchoring the kickstand in the trough of the hinge cut of the laminoplasty. Adjust the width of the plate so the kickstand on the contralateral side anchors into the lateral mass.



Anchoring kickstand in trough of hinge cut



Width adjusted so that plate fits anatomy

PLATE HOLDER OPTIONS

The **Plate Holder, External Grip** grasps to the outside edges of the HAVEN™ plates.



The **Plate Holder, Internal Grip** fits inside the windows of the HAVEN™ plates.



The **Forceps Plate Holder** grasps the hinge joint of the HAVEN™ plates.



LATERAL MASS SCREW PREPARATION AND PLACEMENT

Screw Preparation and Placement of Inline and Adjacent Plates

With the plate in place, use the **Awl, 1.3mm** to perforate the cortex at the site of screw placement. A pilot hole may be drilled using a **Drill Bit** and **Depth Sleeve** of appropriate length and diameter.

Determine the appropriate screw diameter and length. Choose the Drill Bit for the selected screw diameter and the Depth Sleeve for the selected length. Slide the Depth Sleeve onto the tip of the Drill Bit until an audible snap is heard. Attach the Drill Bit to the **Easy Connect Handle, Small** and drill through the lateral screw hole in the plate until it reaches the stop. The **Depth Gauge** may be used to verify depth.

To load the **Push-Button Driver, 2.0mm Hex**, insert the hex tip into the screw until fully engaged. The same process may be followed to load the screw onto the **2.0mm Hex, Self-Retaining Shaft**.

Prior to inserting, screw size may be verified by checking the length and diameter using the gauges provided in the screw module.

Insert the screw through the plate into the prepared hole until the screw is fully seated in the plate. To release the driver from the screw, push the button at the distal end of the driver. Repeat these steps on the contralateral side to secure the plate to the lateral masses or pedicles.



Drilling lateral screw holes



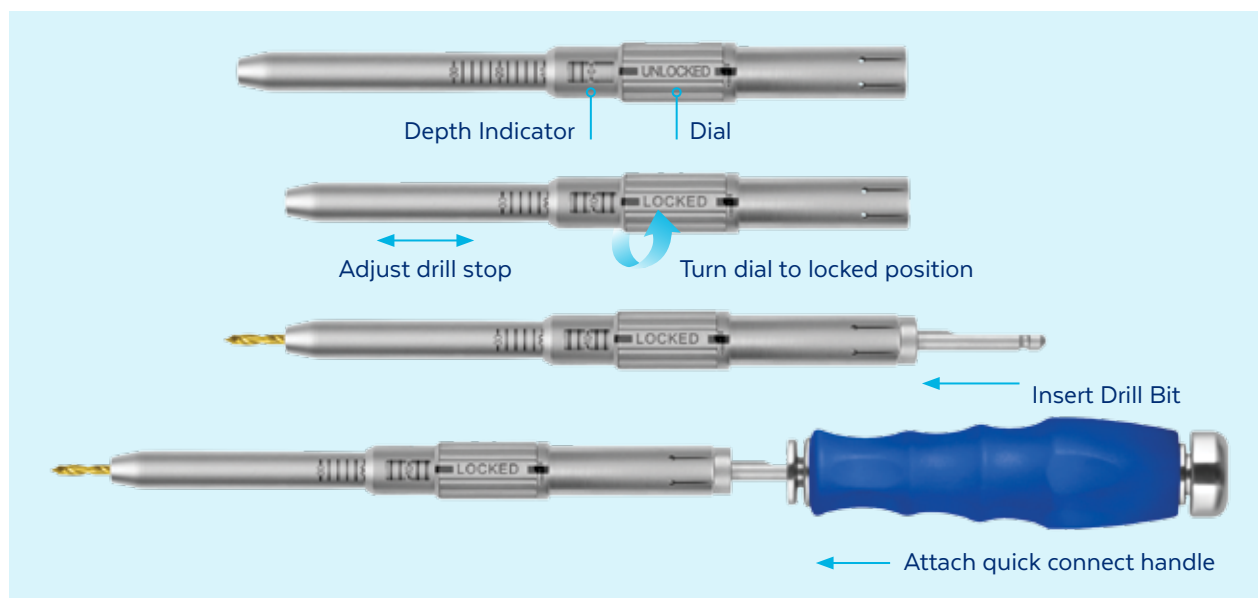
Inserting screws into lateral mass

Screw Preparation and Placement of Polyaxial Plates

Align the **Awl, 2.4mm** from the ELLIPSE® or QUARTEX® Instrument Set in the trajectory for the screw and perforate the cortex to create a pilot hole through the polyaxial screw hole of the plate. The **Pedicle Probe, Straight** or **Pedicle Probe, Curved** from the ELLIPSE® or QUARTEX® Instrument Set may be used to open the pedicle pathway. The **Ball Tip Probe** may be used to verify that the walls of the prepared pathway are not violated.

Determine the appropriate screw diameter and length. Choose the drill bit and **Adjustable Drill Sleeve** for the selected screw diameter. The **Adjustable Drill Sleeve, for Small Diameter Drill Bit** accepts drill bits for 3.5 to 4.5mm diameter screws. The **Adjustable Drill Sleeve, for Large Diameter Drill Bit** accepts drill bits for 5.0 to 6.5mm diameter screws. The drill sleeves allow drill depths from 0–30mm, in 2mm increments.

To prepare the drill sleeve, align the laser marking on the sleeve with the laser markings on the side marked “UNLOCKED.” Adjust the drill stop until the appropriate depth is indicated in the window and rotate the dial 180° degrees to the “LOCKED” position. Insert the drill bit through the drill sleeve until the drill bit is bottomed out onto the sleeve, as shown below. Attach the **Easy Connect Handle, Small** to drill bits used for 3.5–4.5mm screws. Attach the **Straight Handle, Ratcheting, ¼” Quick-Connect** to the drill bits used for 5.0–6.5mm screws.



Drill through the lateral screw hole in the plate until it reaches the stop. The depth gauge from the ELLIPSE® or QUARTEX® Instrument Set may be used to verify hole depth.



Drilling lateral screw holes

LATERAL MASS SCREW PREPARATION AND PLACEMENT (Cont'd)

Use a driver to insert the desired screw. For polyaxial screw insertion, rod insertion, locking cap insertion, and final tightening, refer to the ELLIPSE® or QUARTEX® Surgical Technique Guide (GMTGD45 or GMTGD172).



Inserting polyaxial screws into the lateral mass

The polyaxial screw should be fully seated against the plate before rod insertion. Repeat these steps on the contralateral side to secure the plate to the pedicles or lateral masses.



Polyaxial screws fully seated

STEP

6

LAMINAR SCREW PREPARATION
AND PLACEMENT

Once the lateral mass or pedicle screws are in place, laminar screws may be inserted to hold the lamina open. Using the **Lamina Hook**, pull the lamina toward the plate to decompress the spinal cord.



Lamina Hook pulling lamina toward the plate

With the lamina held in a decompressed state, repeat Step 4 to prepare the screw hole and insert a laminar screw.



Inserting screws into lamina

OPTIONAL: PLATE LOCKING

The hinge joint may be locked once the plate and screw construct is complete. Engage the tips of the **Pin Counter Torque** with the plate at the hinge. Insert the **Torque Limiting Wrench, #25 Hexalobe** into the set screw on the plate. While holding the counter torque, rotate the wrench clockwise until it reaches its torque limit of 0.5Nm.



Engaging Pin Counter Torque on plate



Locking hinge joint on plate

FINAL CONSTRUCT



OPTIONAL: IMPLANT REMOVAL

For revision or removal of HAVEN™ implants, reverse the insertion steps until the desired implants are removed. Remove all laminar screws using a 2.0mm hex screwdriver. For polyaxial screws, reverse the insertion steps based on the system that was used. Unscrew the locking caps and remove the rods from the construct. Remove the polyaxial screws using the corresponding driver from the ELLIPSE® or QUARTEX® Instrument Set. For lateral mass screws, insert a 2.0mm hex screwdriver into the hex of the screw head and remove all screws. Once the screws are removed, the plate can move freely.

HAVEN™

IMPLANT SET 9174.9002

PART NO.	DESCRIPTION	QTY
1174.1001	HAVEN™ Laminoplasty Dual Plate, Inline, 39mm	5
1174.2001	HAVEN™ Laminoplasty Dual Plate, Adjacent, 33mm	5
1174.3001	HAVEN™ Laminoplasty Dual Plate, Polyaxial, 32mm	5
1174.4001	HAVEN™ Laminoplasty Dual Plate, Large Polyaxial, 34mm	5
9174.0002	HAVEN™ Laminoplasty Dual Plate Module	1

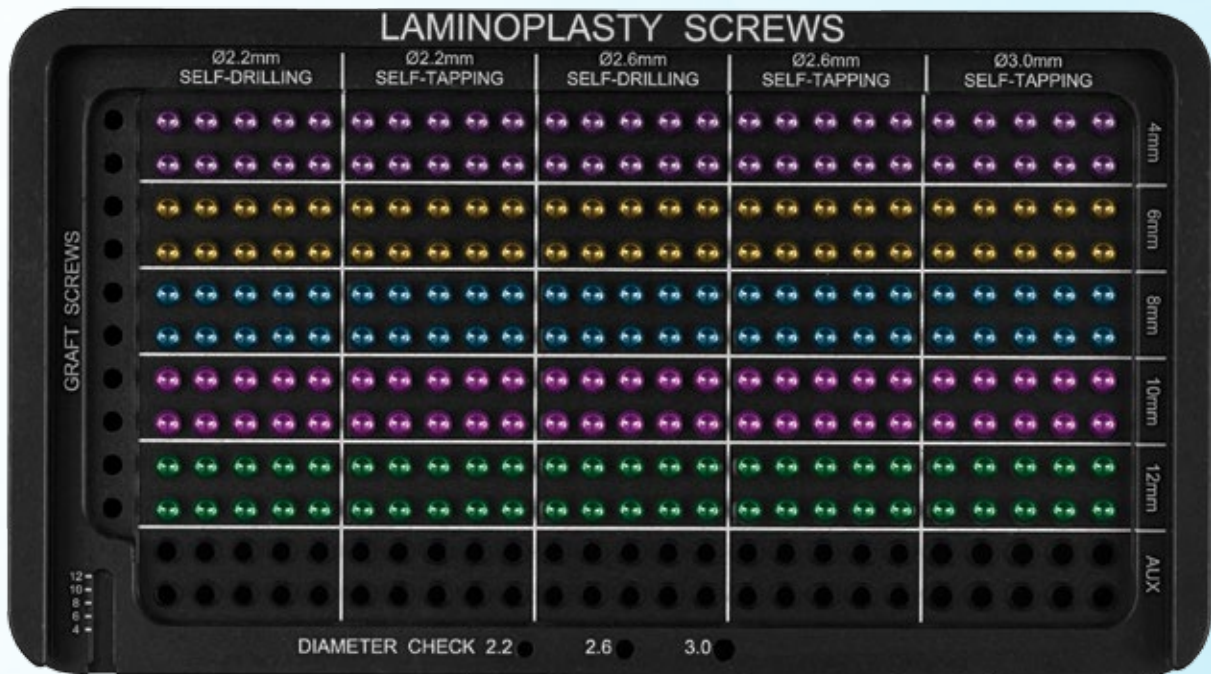


HAVEN™

SCREW SET 9174.9003

PART NO.	DESCRIPTION	QTY
136.404	RELIEVE® 2.2mm Screw, Self-Drilling, 4mm	10
136.405	RELIEVE® 2.2mm Screw, Self-Drilling, 5mm	
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
136.504	RELIEVE® 2.2mm Screw, Self-Tapping, 4mm	10
136.505	RELIEVE® 2.2mm Screw, Self-Tapping, 5mm	
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
136.704	RELIEVE® 2.6mm Screw, Self-Tapping, 4mm	10
136.705	RELIEVE® 2.6mm Screw, Self-Tapping, 5mm	
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
1102.6004	CANOPY® 2.6mm Screw, Self-Drilling, 4mm	10
1102.6005	CANOPY® 2.6mm Screw, Self-Drilling, 5mm	
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
1102.8004	CANOPY® 3.0mm Screw, Self-Tapping, 4mm	10
1102.8005	CANOPY® 3.0mm Screw, Self-Tapping, 5mm	
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
1102.9000	CANOPY® Graft Screw	
9102.0003	CANOPY® Screw Module	1

Items highlighted in gray are additionally available.

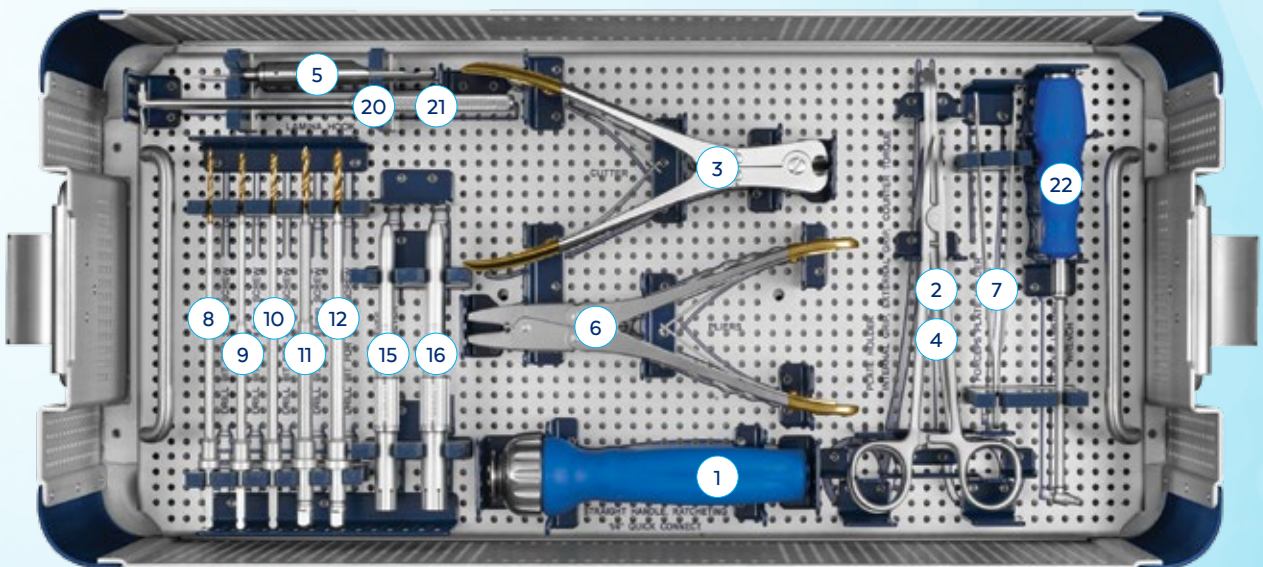
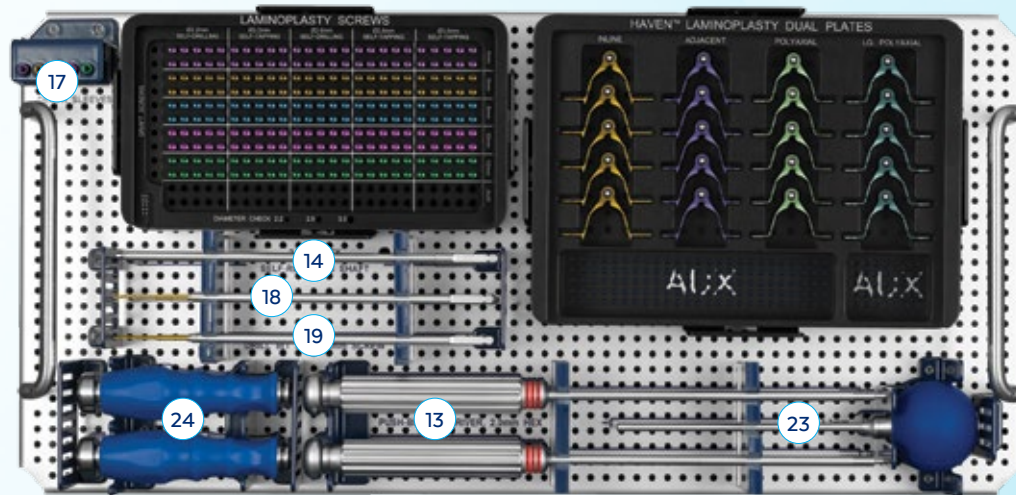


HAVEN™

INSTRUMENT SET 9174.9001

	PART NO.	DESCRIPTION	QTY
1	6067.0010	Straight Handle, Ratcheting, 1/4" Quick-Connect	1
2	6102.1000	Plate Holder, External Grip	1
	6102.1001	Drill Through Plate Holder	
3	6102.1003	Cutter	1
4	6102.1004	Plate Holder, Internal Grip	1
	6102.1006	Articulating Plate Holder, External Grip	
5	6102.1040	Depth Gauge	1
6	6174.1002	Pliers	1
7	6174.1005	Forceps Plate Holder	1
8	6174.1035	Drill Bit, For 3.5mm Screw	1
9	6174.1040	Drill Bit, For 4.0mm Screw	1
10	6174.1045	Drill Bit, For 4.5mm Screw	1
11	6174.1050	Drill Bit, For 5.0mm Screw	1
12	6174.1055	Drill Bit, For 5.5mm Screw	1
13	6174.2000	Push-Button Driver, 2.0mm Hex	2
14	6174.2001	2.0mm Hex, Self-Retaining Shaft	2
15	6174.3000	Adjustable Drill Sleeve for Polyaxial Drill Bits	1
16	6174.4000	Adjustable Drill Sleeve for Large Diameter Drill Bits	1
17	6174.5004	Depth Sleeve, 4mm	1
	6174.5005	Depth Sleeve, 5mm	
	6174.5006	Depth Sleeve, 6mm	1
	6174.5008	Depth Sleeve, 8mm	1
	6174.5010	Depth Sleeve, 10mm	1
	6174.5012	Depth Sleeve, 12mm	1
18	6174.5014	Drill Bit, For 2.2mm Screw	2
19	6174.5016	Drill Bit, For 2.6mm Screw	2
20	6174.7000	Lamina Hook	1
	6174.8000	Counter Torque	
21	6174.8001	Pin Counter Torque	1
22	6174.9000	Torque Limiting Wrench, #25 Hexalobe	1
23	636.460	Awl, 1.3mm	1
	636.490	Tap Bit, 2.2mm Standard Screw	
	636.491	Tap Bit, 2.2mm Cortical Screw	
	636.492	Tap Bit, 2.6mm Standard Screw	
	636.493	Tap Bit, 2.6mm Cortical Screw	
24	697.705	Easy Connect Handle, Small	2
	9174.0001	HAVEN™ Implants and Instruments Graphic Case	1

Items highlighted in gray are additionally available.



IMPORTANT INFORMATION ON HAVEN™ LAMINOPLASTY FIXATION SYSTEM

DESCRIPTION

The HAVEN™ Laminoplasty Fixation System consists of spinal fixation plates for use in laminoplasty. These implants are composed of titanium or titanium alloy (per ASTM F67, F136, F1295, and F1472). HAVEN™ implants may be used with previously cleared CANOPY®, RELIEVE®, QUARTEX®, ELLIPSE®, PROTEX CT® screws and CANOPY® Spacer.

INDICATIONS

The HAVEN™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The HAVEN™ Laminoplasty Fixation System is used to hold bone allograft or autograft material in place in order to prevent the graft 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. 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 HAVEN™ polyaxial screw hole plate is only to be used with ELLIPSE® polyaxial screws, PROTEX CT®, or QUARTEX® polyaxial screws. The HAVEN™ large polyaxial screw hole plate is only to be used with QUARTEX® polyaxial screws. When using this plate, the polyaxial screw head must be fully seated to provide plate fixation.

When using the HAVEN™ 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 HAVEN™ 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.

MRI SAFETY INFORMATION

The HAVEN™ Laminoplasty Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of HAVEN™

Laminoplasty Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging 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 Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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 Enzo® (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 Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
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

HAVEN™ implants may be available sterile or nonsterile. Instruments are available nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile products are packaged in a heat sealed, Tyvek pouch. The expiration date is provided in the package label.

IMPORTANT INFORMATION ON HAVEN™ LAMINOPLASTY FIXATION SYSTEM

These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated following ANSI/AAMI/ISO 17665-1:2006 Guidelines for Steam Sterility Validation to assure 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*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

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

Do not stack trays during sterilization. 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 sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	QUANTITY		MANUFACTURER
	USE BY (YYYY-MM-DD)		

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This image shows a full page of blank, lined paper. It features approximately 20 evenly spaced horizontal grey lines across its entire width, providing a guide for handwriting or typing. The background is a clean, solid white color.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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