RELIEVE® Laminoplasty System

Surgical Technique

RELIEVE

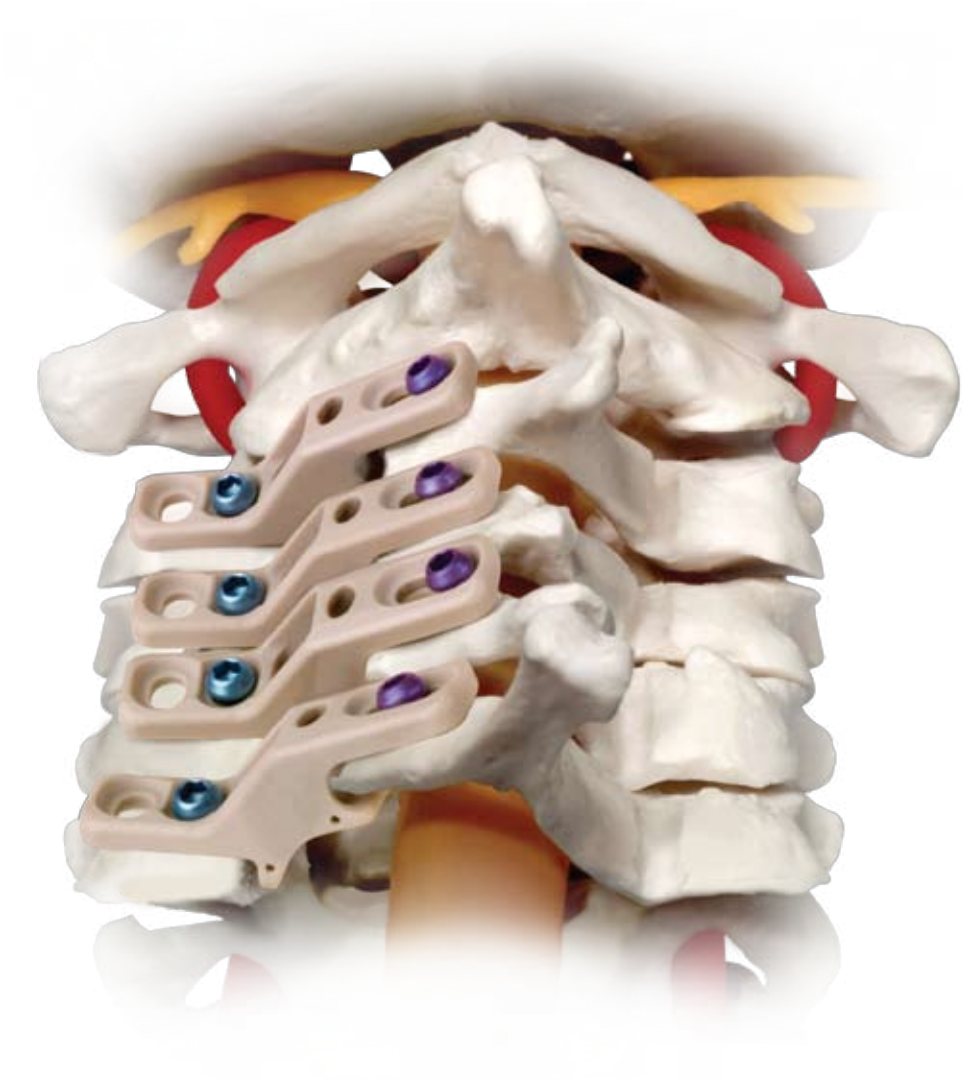
GLOBUS MEDICAL

Contents

Indications for Use: The RELIEVE® Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The RELIEVE® Laminoplasty Fixation System is used to hold the bone graft material in place in order to prevent the bone graft material from expulsion, or impinging the spinal cord. Please refer to product insert for complete description, indications and warnings.

RELIEVE® Laminoplasty System

Unitary Design Simplifies Technique



Opens the Posterior Arch

Built-in Graft Packing Chamber

PEEK Construction Aids Visualization

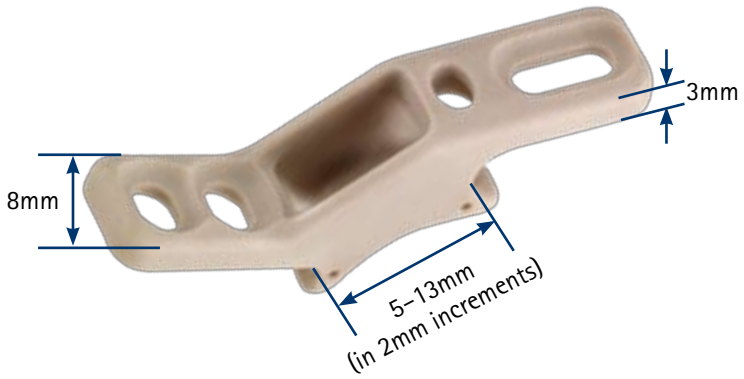
Implant Overview

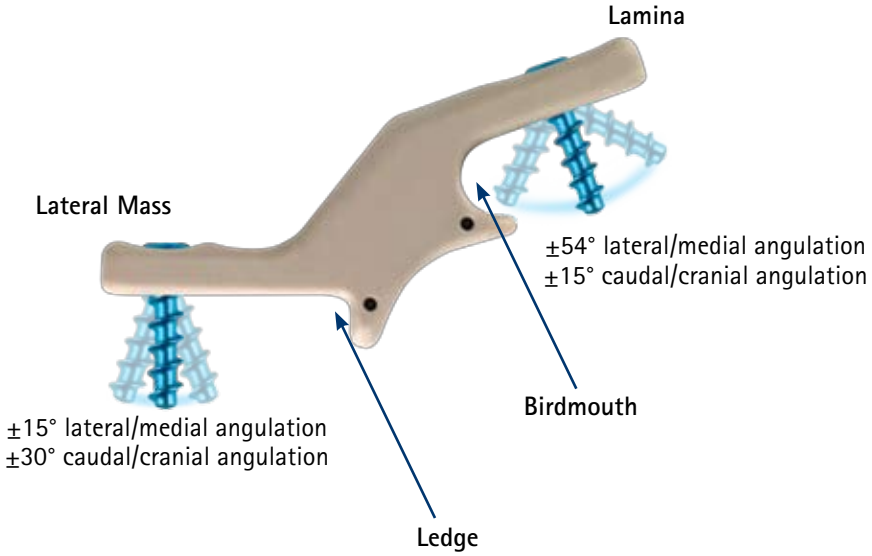
Open Door Plate

- Structural channel allows for addition of bone graft within implant
- Composed of radiolucent PEEK material with tantalum markers for post-operative radiographic and CT/MRI visualization
- Unitary plate-spacer for open door laminoplasty

Screws

- Spherical screw head interfaces with the implant to allow for variable screw angulation
- Variety of screw sizes
  - Lengths from 4mm to 12mm in 2mm increments
  - 2.2mm diameter self-tapping and self-drilling screws
  - 2.6mm diameter self-tapping screws
- Color-coded lengths





Instrument Overview

Lamina Elevator 636.010

Micro Depth Gauge 636.020

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

Implant Holder, Open Door 636.410

Implant Holder, Open Door, Forceps 636.411

Instrument Overview (cont'd)

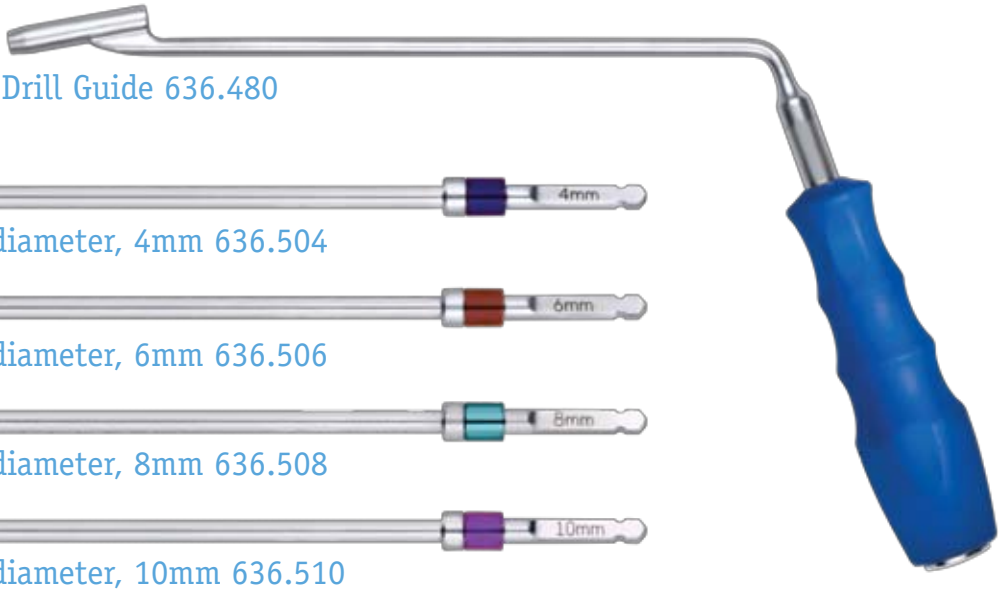
Quick Connect Handle, Swivel 636.450

Quick Connect Handle 636.451

Awl 636.460

Screwdriver Shaft, Self-Retaining 636.470

Assembly:
Screwdriver Shaft, Self-Retaining 636.470 + Quick Connect Handle, Swivel 636.451



Drill Guide 636.480

Drill Bit, 1.3mm diameter, 4mm 636.504

Drill Bit, 1.3mm diameter, 6mm 636.506

Drill Bit, 1.3mm diameter, 8mm 636.508

Drill Bit, 1.3mm diameter, 10mm 636.510

Drill Bit, 1.3mm diameter, 12mm 636.512

RELIEVE® Surgical Technique

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.

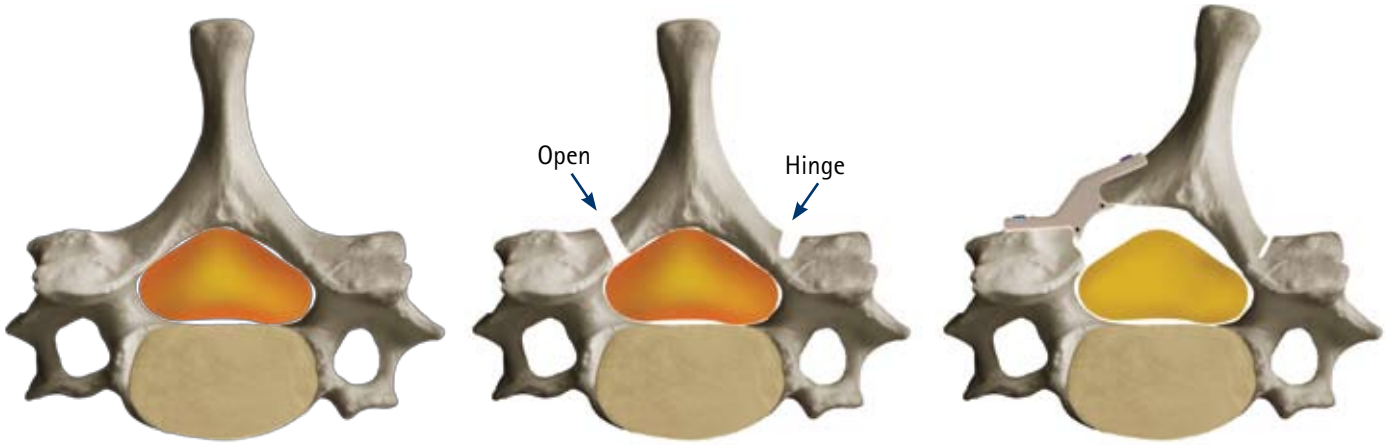
Please refer to the product insert for complete description, indications, and warnings.

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. Using a high speed burr, remove the bone through the ventral cortex. On the hinge side of the laminoplasty, another trough should be made with the burr, 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. Once these soft tissues are removed, the **Lamina Elevator** may be used to lift the lamina away from the spinal canal. Securely grasp the hinged lamina or spinous process to create an opening. Care should be taken not to disturb the dura.

Lifting away from spinal canal



Spinal cord compressed | Bone removed | Implant inserted

3 Trial and Implant Insertion

Insert the **Trial Shaft, Open Door** of the approximate size into the space between the lamina and lateral mass. The open door trials are available in 5, 7, 9, 11, and 13mm. One side of the Trial should rest on the lamina and the other side should rest on the lateral mass. The side of the Trial with a lip should be placed on the lamina (see below for example). Determine the trial that best fits this space.

Once the implant size is determined, one of two implant holders can be used. The **Implant Holder, Open Door** is used for lamina stabilization during implant attachment and the **Implant Holder, Open Door, Forceps** simply grasps the implant for insertion. The Open Door Implant Holder is used throughout this technique for demonstration purposes.

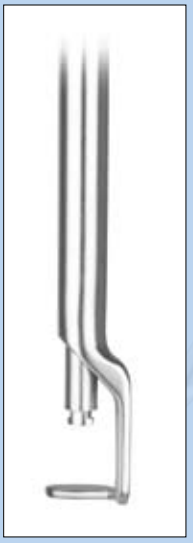
Note: When implanting on the patient's left side, start at the most cranial level first and work in the caudal direction. When implanting on the patient's right side, start at the most caudal level first and work in the cranial direction. This will avoid interference with the holder.

Trial Shaft, Open Door

Insertion of Trial into laminar gap

To remove the RELIEVE® Open Door Implant from the module, first ensure that the handle is released and the thumb lock is in the "UNLOCKED" position. Slide the paddle of the Implant Holder under the implant. Line up the locking rod of the Implant Holder with the oval implant attachment hole.

Removing implant from module



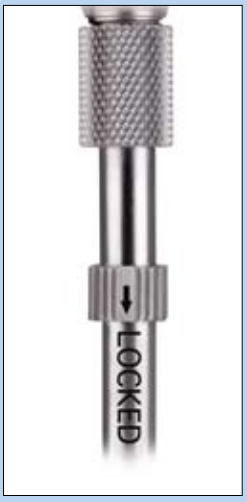
Tip of Implant Holder

Implant Holder,
Open Door
636.410

Insert the end of the locking rod into the oval hole on the top of the implant. After inserting the rod end into the implant, turn the thumb lock 90° to the "LOCKED" position (see illustration below).

Unlocked Position

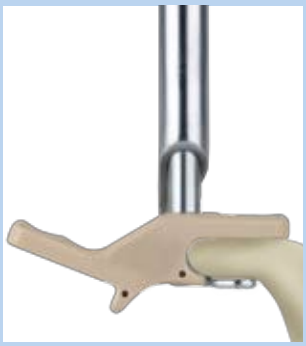
Rotate one quarter
turn clockwise
to engage implant



Locked Position

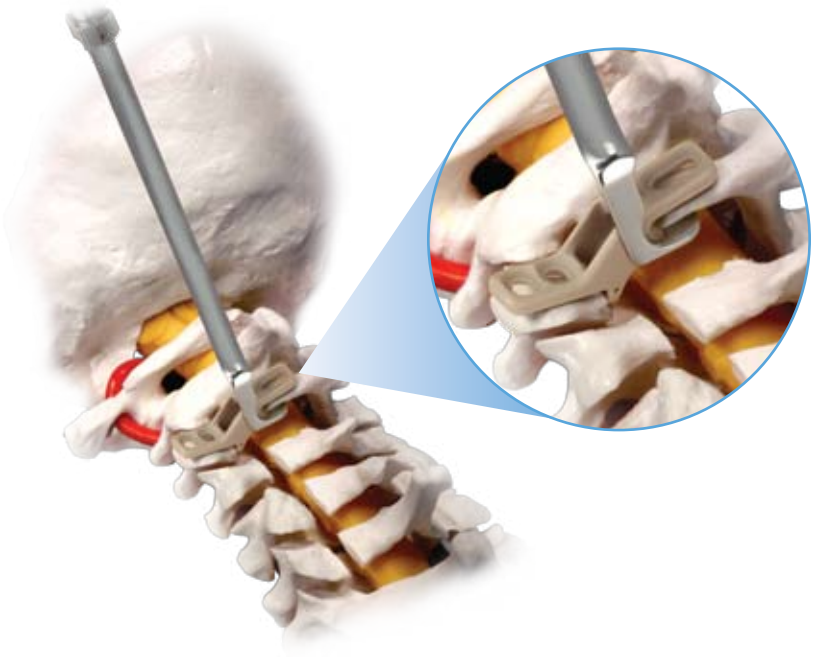
Implant Engaged

Place the birdmouth of the implant on the lamina



Compress the handles of the holder to stabilize the lamina to the implant

For implant insertion into the intralaminar space, use the **Implant Holder, Open Door**. Introduce the paddle of the implant holder under the lamina and compress the handles to stabilize the segment. Adjust the implant so that the lateral ledge rests on the lateral mass.

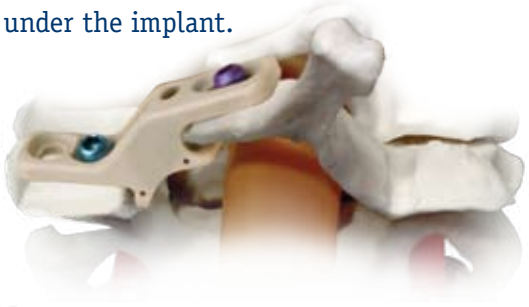


4 Attachment

The **Awl** is used to perforate the cortex at the site of screw placement. For self-tapping screws, a pilot hole may be drilled using a drill bit of appropriate length and diameter. **Drill Bits** are available with a 1.3mm diameter (used for 2.2mm diameter screws) and lengths of 4mm, 6mm, 8mm, 10mm, and 12mm. The Drill Bits have color indicators that correlate to screw length. If using a Drill Bit, the **Micro Depth Gauge** can be used to verify depth. The implant is used as a drill stop.

Once the screw hole has been prepared, either a **Self-Tapping** or **Self-Drilling Screw** of appropriate diameter and length are inserted, using the **Self-Retaining Hex Driver** and **Quick Connect Handle, Swivel**. At least one screw must be used to fasten the lamina and one screw for the lateral mass at each affected level.

To disengage the holder from implant, first rotate thumb lock to the "UNLOCKED" position. Release the handle and verify that the rod end of the holder is withdrawn from the oval hole in the implant, keeping the paddle against the lamina. After the rod end is completely disengaged from the holder, remove the holder paddle from under the implant.

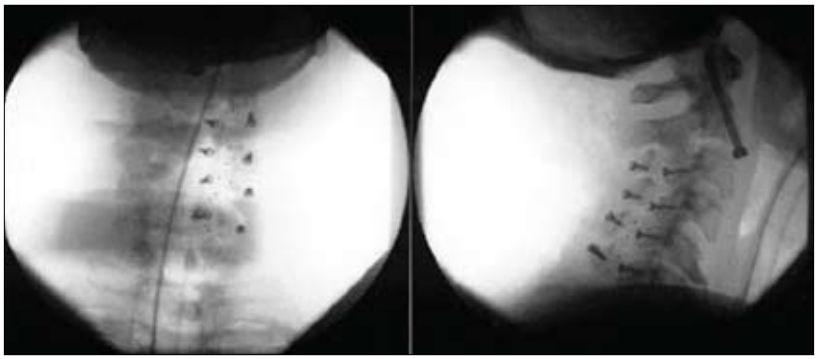


Screwdriver Shaft, Self-Retaining 636.470 + Quick Connect Handle, Swivel 636.451

5 Final Position

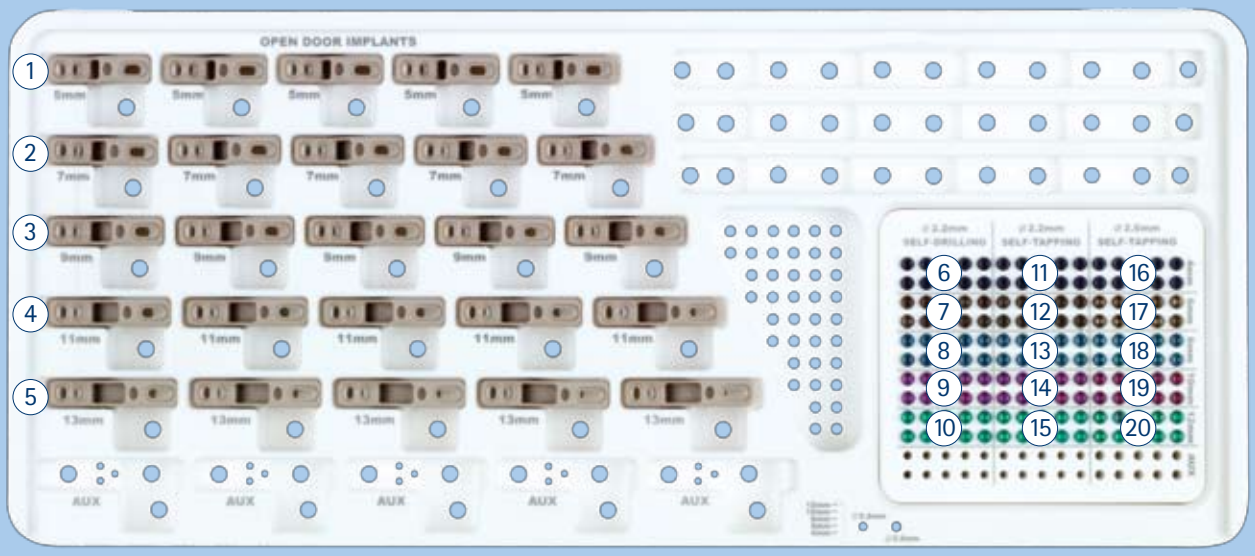
Insert one RELIEVE® Laminoplasty Open Door Plate at each affected level. A four level RELIEVE® implant configuration is shown below.

Note: The chambers of the plates may be filled with bone graft material.



AP View Lateral View

RELIEVE® Implant Set



RELIEVE® Implant Set List 936.902

Open Door Plates			Set Qty
1	336.105	RELIEVE® Radiolucent Plate, Open Door, 5mm	5
2	336.107	RELIEVE® Radiolucent Plate, Open Door, 7mm	5
3	336.109	RELIEVE® Radiolucent Plate, Open Door, 9mm	5
4	336.111	RELIEVE® Radiolucent Plate, Open Door, 11mm	5
5	336.113	RELIEVE® Radiolucent Plate, Open Door, 13mm	5

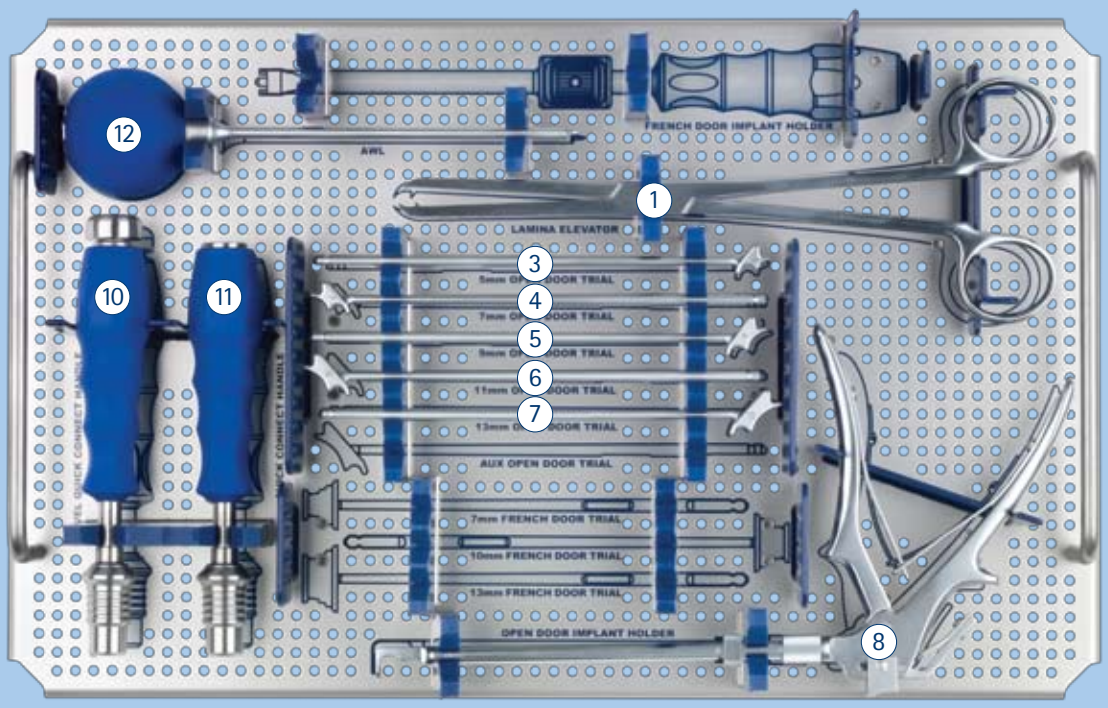
Self-Drilling Screws			Set Qty
6	136.404	2.2mm Screw, Self-Drilling, 4mm	10
7	136.406	2.2mm Screw, Self-Drilling, 6mm	10
8	136.408	2.2mm Screw, Self-Drilling, 8mm	10
9	136.410	2.2mm Screw, Self-Drilling, 10mm	10
10	136.412	2.2mm Screw, Self-Drilling, 12mm	10

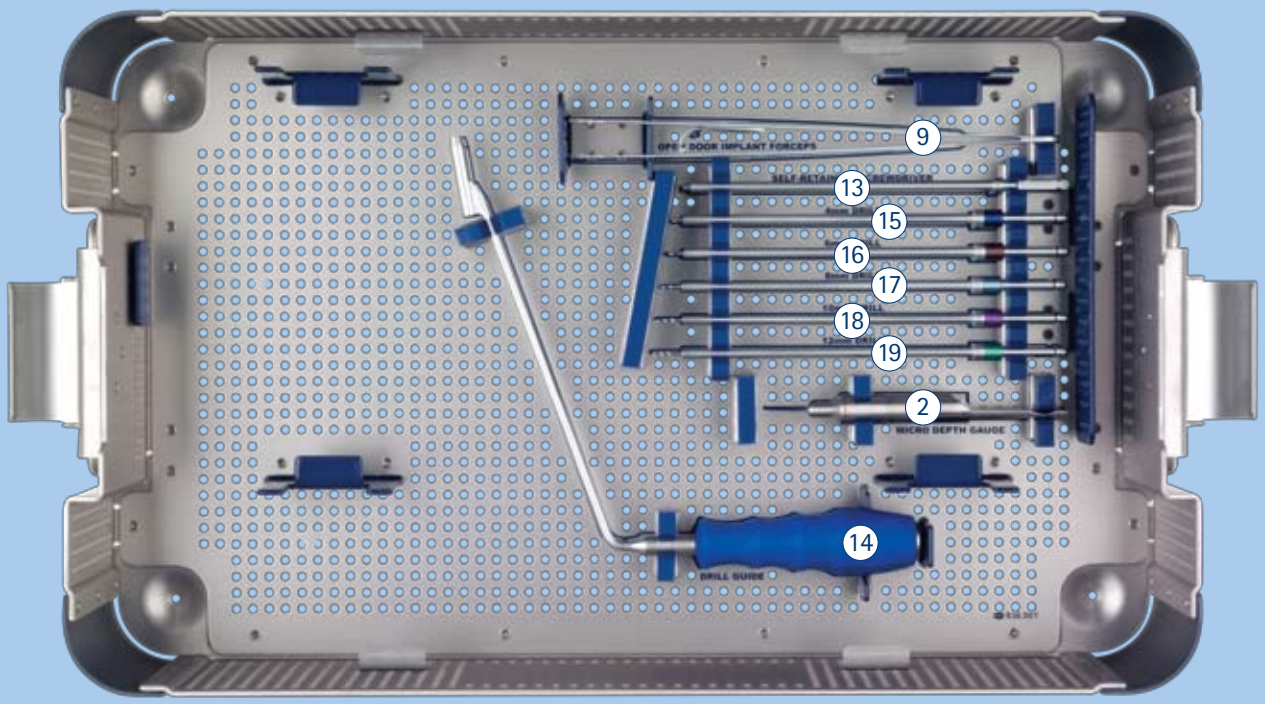
Self-Tapping Screws			Set Qty
11	136.504	2.2mm Screw, Self-Tapping, 4mm	10
12	136.506	2.2mm Screw, Self-Tapping, 6mm	10
13	136.508	2.2mm Screw, Self-Tapping, 8mm	10
14	136.510	2.2mm Screw, Self-Tapping, 10mm	10
15	136.512	2.2mm Screw, Self-Tapping, 12mm	10

Auxiliary Screws			Set Qty
16	136.704	2.6mm Screw, Self-Tapping, 4mm	10
17	136.706	2.6mm Screw, Self-Tapping, 6mm	10
18	136.708	2.6mm Screw, Self-Tapping, 8mm	10
19	136.710	2.6mm Screw, Self-Tapping, 10mm	10
20	136.712	2.6mm Screw, Self-Tapping, 12mm	10

936.002 RELIEVE® Implant Module, Plates & Screws 1

RELIEVE® Instrument Set





RELIEVE® Instrument Set 936.901

Preparation Instruments			Set Qty
1	636.010	Lamina Elevator	1
2	636.020	Micro Depth Gauge	1

Trials			Set Qty
3	636.105	Trial Shaft, Open Door, 5mm	1
4	636.107	Trial Shaft, Open Door, 7mm	1
5	636.109	Trial Shaft, Open Door, 9mm	1
6	636.111	Trial Shaft, Open Door, 11mm	1
7	636.113	Trial Shaft, Open Door, 13mm	1

Implant Instruments			Set Qty
8	636.410	Implant Holder, Open Door	1
9	636.411	Implant Holder, Open Door, Forceps	1

Quick Connect Handles			Set Qty
10	636.450	Quick Connect Handle, Swivel	1
11	636.451	Quick Connect Handle	1

Attachment Instruments			Set Qty
12	636.460	Awl	1
13	636.470	Screwdriver Shaft, Self-Retaining	1
14	636.480	Drill Guide	1

Drill Bits			Set Qty
15	636.504	Drill Bit, 1.3mm diameter, 4mm	1
16	636.506	Drill Bit, 1.3mm diameter, 6mm	1
17	636.508	Drill Bit, 1.3mm diameter, 8mm	1
18	636.510	Drill Bit, 1.3mm diameter, 10mm	1
19	636.512	Drill Bit, 1.3mm diameter, 12mm	1

	936.001	RELIEVE® Laminoplasty System Graphic Case	1

Additionally Availabale

636.490 Tap Bit, 2.2mm Screw

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