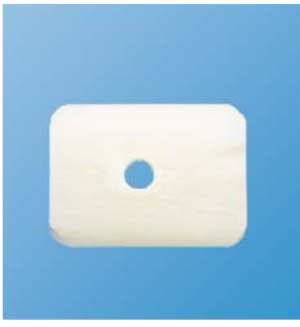
ARCH Fixation System. Implants and instruments for open door laminoplasty procedures.

Technique Guide



SYNTHES® Spine

Instruments and implants approved by the AO Foundation

Table of Contents

ARCH Fixation System

The aims of the ARCH Fixation System are to:

– Maintain an expanded spinal canal
– Secure spinal stability
– Preserve the protective function of the spine after a laminoplasty has been performed

Miniplates

The ARCH Fixation System miniplates are:

– Pre-bent (single bend and double bend) to fit the anatomy of the dorsally elevated lamina
– Low profile to prevent tissue irritation
– Available in 5 sizes corresponding to the ARCH ODL allograft spacers
– Made from commercially pure titanium

Single bend

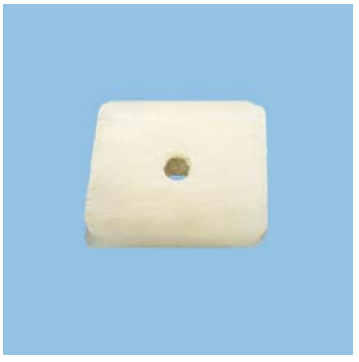
Double bend

ARCH ODL (Open Door Laminoplasty) Spacers
The ARCH ODL allograft spacers, designed by and available through Synthes Spine, are processed by the Musculoskeletal Transplant Foundation (MTF).*

The allograft spacers are designed to:

– Ease the surgical technique by eliminating the need to shape the resected spinous process
– Securely fit the open door where the laminotomy has been performed. Holes in the anterior and posterior sides help to secure the allograft while the preshaped cortical allograft fits the anatomy of the patient
– Accommodate bone void fillers in the center of the allograft

Additionally:
– Notched ends are designed to prevent allograft migration
– Spacers are available in two shapes (parallel and angled) and in five sizes (from 4 mm to 12 mm, in 2 mm increments)



* ODL Spacers are not approved by the AO Foundation.

AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.[1] They are:

– Anatomical reduction
– Stable internal fixation
– Preservation of blood supply
– Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.[2, 3]

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1. M.E. Müller, M. Allgöwer, R. Schneider, and H. Willenegger: *Manual of Internal Fixation*, 3rd Edition. Berlin: Springer-Verlag. 1991.
2. Ibid.
3. M. Aebi, J.S. Thalgott, and J.K. Webb. *AO ASIF Principles in Spine Surgery*. Berlin: Springer-Verlag. 1998.

Indications and Contraindications

Indications
The Synthes ARCH Fixation System is intended for use in the lower cervical and upper thoracic spine (C3–T3) after a laminoplasty has been performed. The ARCH Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

Contraindications
The ARCH Fixation System is not to be used:

- For screw attachment or fixation to the posterior elements of the lumbar spine
- For single- or two-level spondylosis without developmental spinal canal stenosis
- Under any direct load bearing conditions

The ARCH Fixation System is not to be used when there is:

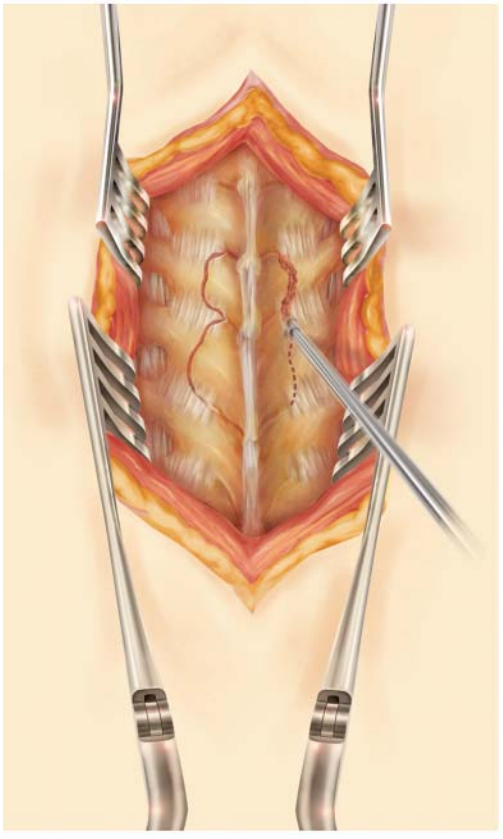
- Focal anterior compression
- Isolated radiculopathy
- Loss of anterior column support resulting from tumor, trauma, or infection

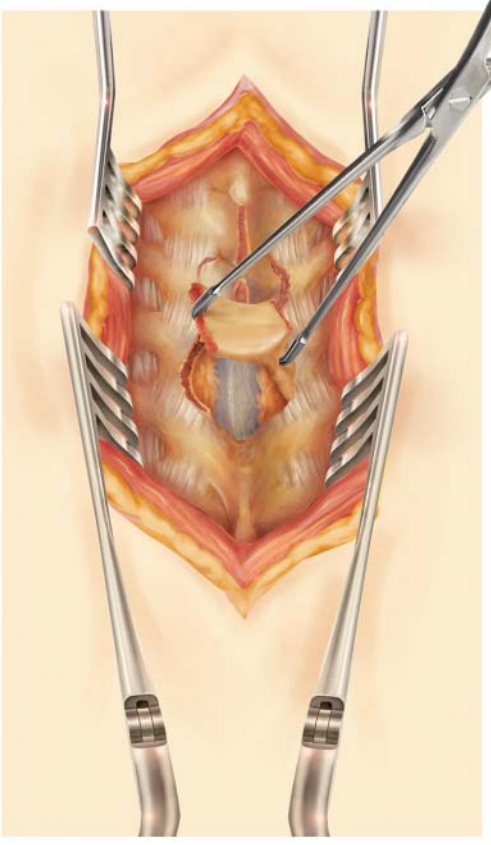
The ARCH Fixation System must always be used with:

- Structural allograft

Approach

The patient is positioned prone in head pins with the neck slightly flexed and posteriorly translated. The head of the bed should be raised to provide a level aspect to the surgical site. A standard midline approach should be used to expose the laminae and the facets at the desired level. Care should be taken to preserve the facet capsules, soft tissue attachments to the facet joints, the spinous processes, and the inter-spinous ligaments.

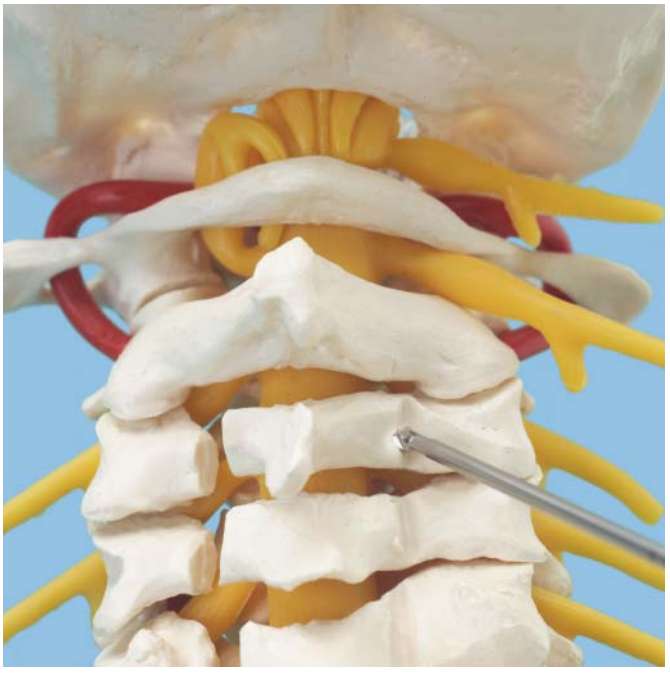


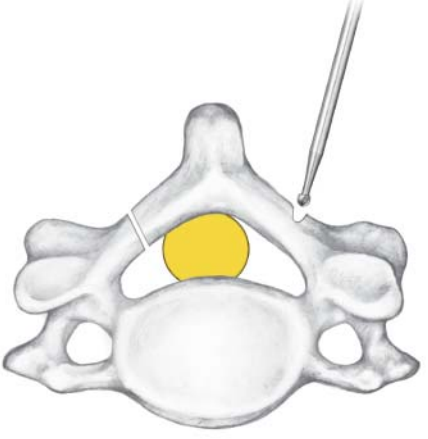


1

Perform laminotomy

After adequate exposure, use the high speed drill to transect the lamina by creating as thin a cut as possible, 1 cm lateral to the midline. An M8 equivalent bit or small burr is typically used to create the cut. Avoid contact with the underlying dura. On the contralateral side, decorticate the lamina by scoring, then cut a half-thickness trough, 1 cm lateral to the midline. Use a high speed drill to create a hinge. Release the ligamentum flavum and bridging vessels, as required.



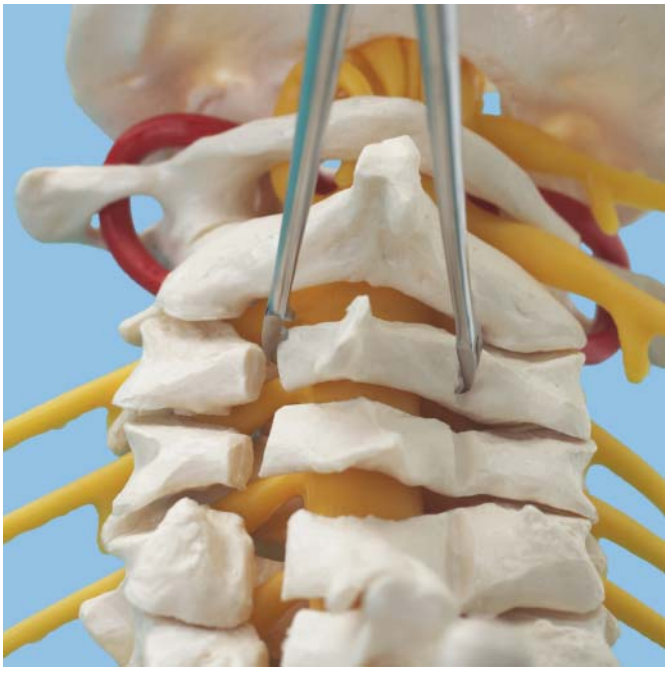


2
Laminar expansion

Instrument	
388.170	Lamina Elevator

Place the tines of one side of the lamina elevator under the ventral surface of the completely transected lamina without disturbing the underlying dura. Place the opposite set of tines on the center of the contralateral, or hinged, lamina so that it will not slip off during laminar expansion. Firmly grasp the lamina with the lamina elevator and expand the gap.

Note: Lack of laminar movement may indicate that deeper scoring is required at the hinge site.



3
Determine allograft size

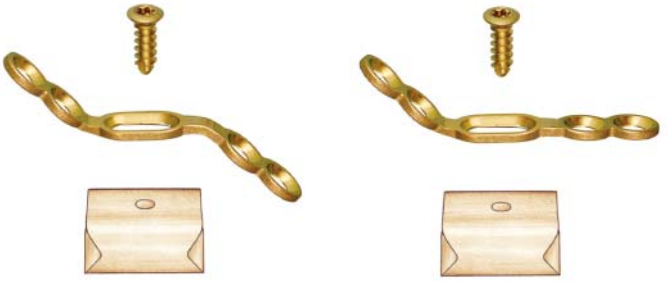
Instrument	
396.466– 396.482	Trial Spacers

With the lamina in expanded position, determine the appropriate allograft size (4 mm, 6 mm, 8 mm, 10 mm or 12 mm) and shape (parallel or angled) by inserting the trial spacers into the laminar gap created. The choice of spacers is surgeon's preference.

The trial spacers are dual-sided to help determine the spacer needed, based on the side (right or left) of the patient on which the procedure is being done.

4
Select miniplate

Instrument	
388.172	Miniplate Holder

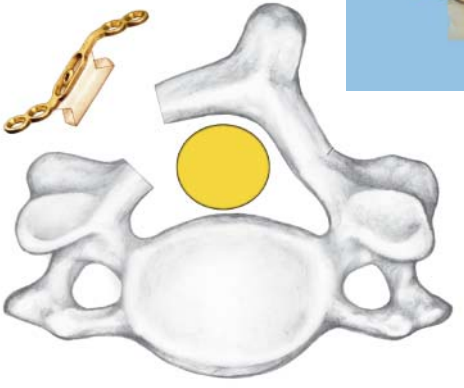


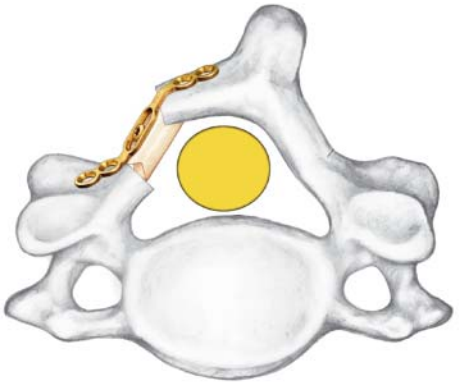
Select a single or double pre-bent miniplate by placing the plates on the laminar expansion using the miniplate holder and determining the best anatomical fit. Several plate lengths (27 mm–35 mm) are available to accommodate a range of allograft sizes (4 mm–12 mm).

Secure the selected miniplate to the graft at the center screw site with a 4 mm long self-tapping screw.

5
Place graft

Instrument	
388.171	Graft Holder





Once the graft and miniplate construct is complete, use the graft holder to place the graft with miniplate at the site. Place the graft so that the cut laminar edges lie securely wedged within the notched ends of the graft. Avoid disturbing the underlying dura. Remove the graft holder once the graft is securely held between the laminar edges.

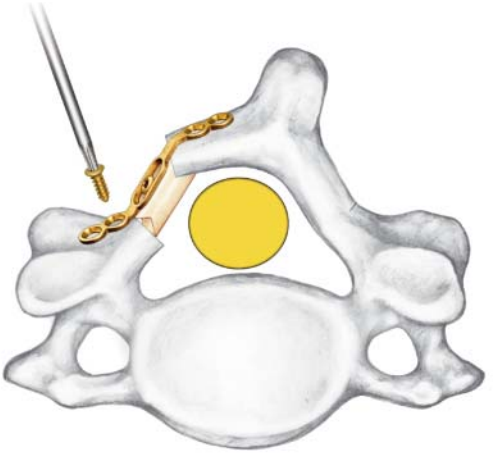
6
Secure miniplate with self-drilling screws

Instruments	
311.03	Handle, with mini quick coupling
313.843	2.0 mm Screwdriver Blade, self-retaining, StarDrive, long

Attach the 2.0 mm StarDrive self-retaining screwdriver blade to the handle with mini quick coupling. Insert appropriate length self-drilling 2.0 mm cortex screws. Typically, two screws are placed on each side of the graft.

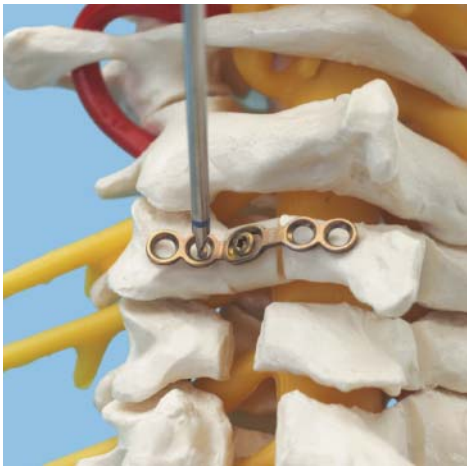
Notes: Center the screw site on the lamina to help prevent screw breakout along the laminar edges.

Also, first insert the screw immediately lateral to the graft for easier placement of subsequent screws.



Alternative technique
Secure miniplate with self-tapping screws

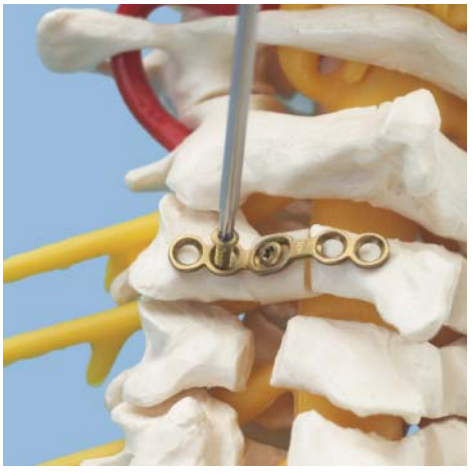
Instrument	
388.174–388.178	1.5 mm Drill Bit with stop (4 mm–12 mm)



Optional instruments	
317.781–317.785*	1.5 mm Drill Bit with stop for use with drill guide (4 mm–12 mm)
317.786*	Drill Guide

Attach the appropriate 1.5 mm drill bit with stop to the handle. Drill to the stop through the desired plate hole.

Attach the 2.0 mm StarDrive self-retaining screwdriver blade to the handle with mini quick coupling. Insert appropriate length self-tapping 2.0 mm cortex screw.



*Also available

A drill guide may be used as a soft tissue protector and for added precision.

Select the appropriate drill bit, specifically designed only for use with drill guide, and attach it to the handle with mini quick coupling. Insert through the drill guide and drill to stop. The drill guide may also be used with the screwdriver while inserting a screw.

Note: The drill guide and 1.5 mm drill bits with stop, designed for use with drill guide only, are identified with orange color coding. These drill bits should not be used without a drill guide.

7

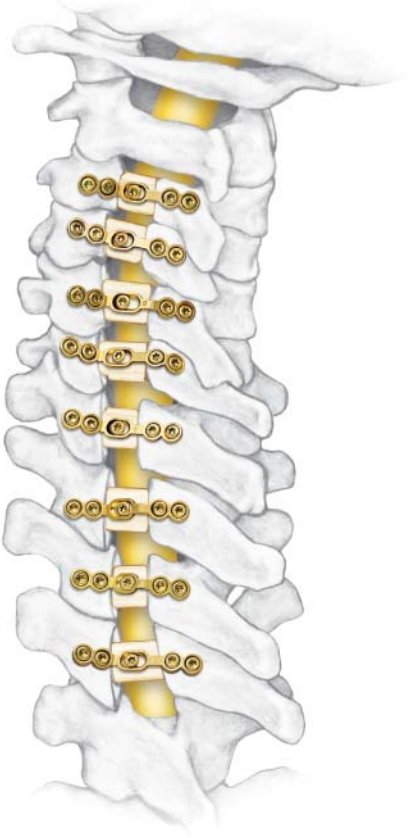
Insert remaining screws

Repeat Step 6 for the remaining screw sites. Typically, two screws are placed on each side of the graft.

8

Complete construct

Repeat Steps 1 through 7 for each level.



Instruments

311.03	Handle, with mini quick coupling	
313.843	Screwdriver Blade, self retaining, StarDrive, long	
388.170	Lamina Elevator	
388.171	Graft Holder	
388.172	Miniplate Holder	
388.173	Small Curette, angled	

Instruments continued

	1.5 mm Drill Bits with stop
388.174	4 mm
388.175	6 mm
388.176	8 mm
388.177	10 mm
388.178	12 mm

391.965	Combination Bending/Cutting Pliers

	Trial Spacers, parallel
396.469	4 mm
396.466	6 mm
396.468	8 mm
396.470	10 mm
396.472	12 mm

	Trial Spacers, angled
396.474	4 mm
396.476	6 mm
396.478	8 mm
396.480	10 mm
396.482	12 mm

ARCH Fixation System (145.892)

The ARCH Fixation System (145.892) consists of the following sets:

145.893	ARCH Fixation System Instrument Set
145.894	ARCH Fixation Titanium Implant Module Set

690.076
(with implant module)

ARCH Fixation System Instrument Set (145.893)

Graphic Case

690.076	ARCH Fixation System Graphic Case

Instruments

311.03	Handle, with mini quick coupling, small
388.170	Lamina Elevator, 2 ea.
388.171	Graft Holder
388.172	Miniplate Holder
388.173	Small Curette, angled
391.965	Combination Bending/Cutting Pliers, for 1.0 mm–2.0 mm plates, 2 ea.

Trial Spacers, parallel

396.469	4 mm
396.466	6 mm
396.468	8 mm
396.470	10 mm
396.472	12 mm

Trial Spacers, angled

396.474	4 mm
396.476	6 mm
396.478	8 mm
396.480	10 mm
396.482	12 mm

Note: For additional information, please refer to package insert.

For detailed cleaning and sterilization instructions, please refer to http://www.synthes.com/sites/NA/MedicalCommunity/Pages/Cleaning_and_Sterilization.aspx or to the below listed inserts which will be included in the shipping container:
—Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
—Processing Non-sterile Synthes Implants—DJ1304

ARCH Fixation Titanium Implant Module Set (145.894)

Module Case

304.924	ARCH Fixation System Module Case

Instruments

311.03	Handle, with mini quick coupling, small
313.843	2.0 mm Screwdriver Blade, self-retaining, StarDrive, long, 2 ea.

1.5 mm Drill Bits with stop, 2 ea.

	Stop depth (mm)
388.174	4
388.175	6
388.176	8
388.177	10
388.178	12

Implants

2.0 mm Titanium Cortex Screws, self-drilling, with StarDrive recess

	Length (mm)	Qty.
401.134.99	4	10
401.136.99	6	20
401.138.99	8	20

2.0 mm Titanium Cortex Screws, self-tapping, with StarDrive recess

	Length (mm)	Qty.
401.354.99	4	10
401.356.99	6	20
401.358.99	8	20
401.360.99	10	20
401.362.99	12	10

2.4 mm Titanium Emergency Screws, with StarDrive recess, 5 ea.

	Length (mm)
401.386.99	6 mm
401.388.99	8 mm
401.390.99	10 mm
401.392.99	12 mm

Implants continued

2.0 mm Titanium Miniplates, single bend, 4 ea.

	Spacing (mm)	Length (mm)
443.164	4	27
443.166	6	29
443.168	8	31
443.170	10	33
443.172	12	35

2.0 mm Titanium Miniplates, double bend, 4 ea.

	Spacing (mm)	Length (mm)
443.174	4	27
443.176	6	29
443.178	8	31
443.180	10	33
443.182	12	35

Also Available

145.891	ARCH Fixation Titanium Implant Module Set, with drill guide Consists of the same implants as 145.894, plus:
304.929	ARCH Fixation System Drill Guide Module
311.03	Handle, with mini quick coupling, small
313.843	2.0 mm Screwdriver Blade, self-retaining, StarDrive, long, 2 ea.
317.781– 317.785	1.5 mm Drill Bits with stop, for use with 317.786, 2 ea.
317.786	Drill Guide, for ARCH Fixation System

145.891

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