
Instructions for Use

ARCH™ Laminoplasty System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Instructions for Use

ARCH™ Laminoplasty System

The ARCH Laminoplasty System supports the open door technique of laminoplasty where the implants are comprised of plates and screws. The system offers two shapes of pre-bent miniplates in a variety of lengths. The shapes include single and double bend miniplates. The system also offers a straight, malleable, 20-hole adaptation plate that can be cut and bent for patient needs. Screws are available as self-tapping or self-drilling cortex screws.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the Instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Material(s):	Standard(s):
Titanium alloy (Ti6-Al7-Nb or TAN)	ISO 5832-11
Commercial pure Titanium (CpTi)	ISO 5832-2

Intended Use

The ARCH Laminoplasty System is intended to maintain an expanded spinal canal in the lower cervical spine (C3–C7) in skeletally mature patients after a laminoplasty has been performed.

Indications

- Ossification of the posterior longitudinal ligament (OPLL) over multiple levels with maintained cervical lordosis
- Congenital canal stenosis with maintained cervical lordosis
- Multilevel cervical spondylosis with maintained cervical lordosis
- Posterior compression from ligamentous hypertrophy with maintained cervical lordosis

Contraindications

The ARCH Laminoplasty System is not to be used:

- For single- or two-level spondylosis without developmental spinal canal stenosis

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

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

Patient Target Group

The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits

Expected clinical benefits of ARCH Laminoplasty System include the symptomatic relief and improvement or maintenance of function.

A summary of safety and clinical performance can be found at the following link (upon activation): <http://ec.europa.eu/tools/eudamed>

Performance Characteristics of the Device

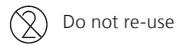
The ARCH Laminoplasty System is designed to maintain an expanded spinal canal and to preserve the protective function of the spine after a laminoplasty has been performed.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

As with all major surgical procedures, there are risks of side effects and adverse events. Possible side effects may include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments), thrombosis, embolism, infection, hemorrhage, neural or vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, complex regional pain syndrome, allergy/hypersensitivity reactions, symptoms associated with implant or hardware prominence, ongoing pain, damage to adjacent bones or discs, dural tear or spinal fluid leak, nerve root or spinal cord compression and/or contusion, nonunion (pseudarthrosis), malunion or delayed union, bending, decrease in bone density due to stress shielding, sensitivity or foreign body reaction, postoperative pain or discomfort, fracture of bony structures, necrosis of bone, axial neck and shoulder pain. Implant breakage, loosening or migration of the implant, partial displacement of the graft, failure of the device resulting in closure of the laminar gap, postoperative spinal instability, spacer migration and impingement of the spinal canal: resulting harm to the patient can include return and possible progression of myelopathic symptoms, nerve damage, pain, poor spinal mechanics, kyphosis, diminished motor function and altered sensory function.

Single Use Device



Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions

It is strongly advised that ARCH Laminoplasty System is implanted only by operating surgeons who are experienced in spinal surgery and who are aware of general risks of spinal surgery and the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.

Surgical approach

Care should be taken to preserve the facet capsules, soft tissue attachments to the facet joints, the spinous processes and the interspinous ligaments.

Select/contour Plate

Determine the best anatomical fit and select a single or double bend miniplate. Alternatively, to pre-bent miniplates the adaption plate can be cut to size and contoured with the Combination Bending/Cutting Pliers.

Plates are weakened when being bent back and forth.

Reverse bending or use of the incorrect instrumentation for bending may weaken the plate and lead to premature implant failure (e.g. breakage). Do not bend the plate beyond what is required to match the anatomy.

Place spacer

Avoid disturbing the underlying dura.

Secure plate

Centering the screw site on the lamina helps to prevent screw breakout along the laminar edges.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices

ARCH Laminoplasty implants are intended to be used with associated ARCH Laminoplasty Instruments. Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the implants of the ARCH Laminoplasty system are MR conditional. These articles can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the ARCH Laminoplasty implant will produce a temperature rise not greater than 5°C at a maximum whole body averaged specific absorption rate (SAR) of 1 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ARCH Laminoplasty device.

Treatment Before Device is Used

Non-Sterile Device:

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Implant Removal

If an ARCH Laminoplasty implant must be removed, the following technique is recommended.

Attach the Screwdriver Shaft PlusDrive to the Handle with Hexagonal Coupling, then engage the assembled driver into the drive recess of the screw to be removed.

Rotate the driver counterclockwise to remove the screw.

Before the last screw is removed, secure miniplate position using Holder for Miniplate.

Once all the screws are removed, remove the miniplate using Holder for Miniplate.

Clinical Processing of the Device

Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling Multipart Instruments" are available on the website.

Disposal

Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.


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