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.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Aug 03, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

 SE_528350 AF 05/2021

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 adaption 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
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Titanium: TiCP (Commercially pure Titanium) according to 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 ARCH Laminoplasty System is intended for use in skeletally mature patients. These products are 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
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that 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.

Expected Clinical Benefits
When the ARCH Laminoplasty System is used as intended and according to the instructions for use and labeling, the device provides maintenance of an expanded spinal canal as a part of laminoplasty surgery, which is expected to prevent deterioration of neurologic function attributed to cervical stenosis.

A summary of safety and clinical performance can be found at the following link (upon activation): https://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 is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; hemorrhage; neural or vascular injury; swelling, abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; complex regional pain syndrome (CRPS); 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; non-union (pseudarthrosis); malunion or delayed union; sensitivity or foreign body reaction; postoperative pain or discomfort; fracture of bony structures; necrosis of bone; axial neck and shoulder pain; implant bending or breakage; loosening or migration of the implant; displacement of the graft; failure of the device resulting in closure of the laminar gap; postoperative kyphosis and/or spinal instability; spacer migration and impingement of the spinal canal, progression of myelopathic symptoms.

Single Use Device


Do not re-use

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

Re-use or clinical 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, re-use 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 the ARCH Laminoplasty System is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with 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.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

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.

Perform Laminoplasty
- Avoid contact with the underlying dura.

Laminar expansion
– Place the tines of one side of the Lamina Elevator under the ventral surface of the completely transected lamina without disturbing the underlying dura.

ARCH Laminoplasty without spacer
Select/contour plate
– 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.

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

ARCH Laminoplasty with spacer
Select/contour plate
– 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
The ARCH Laminoplasty plates (single bend miniplates, double bend miniplates and adaption plate) and screws are applied using the associated ARCH Laminoplasty Instrumentation. The following screw options are available for use with the plates.
– Cortex screw (∅ 2.0 mm) with self-tapping and self-drilling options
– Emergency self-tapping screw (∅ 2.4 mm)

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 first loosen the screw from the ARCH Laminoplasty implant.
– Continue to rotate the driver counterclockwise to remove the loosened screw from the implant.
– Once all the screws are removed, use the Holder for Miniplate to remove the implant.

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.

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com

Instructions for Use:
www.e-ifu.com