Instructions for Use
VA-LCP® Clavicle Plate 2.7 System

These instructions 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: Okt 04, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

 SE_773733 AC 2021-08

Instructions for Use

VA-LCP Clavicle Plate 2.7 System*

02.112.610	02.112.631	04.112.612
02.112.610S	02.112.631S	04.112.612S
02.112.611	02.112.712S	04.112.613
02.112.611S	02.112.713S	04.112.613S
02.112.612		04.112.614
02.112.612S	03.112.610	04.112.614S
02.112.613	03.112.611	04.112.615
02.112.613S	03.112.612	04.112.615S
02.112.614	03.112.613	04.112.620
02.112.614S	03.112.614	04.112.620S
02.112.615	03.112.615	04.112.621
02.112.615S	03.112.620	04.112.621S
02.112.620	03.112.621	04.112.622
02.112.620S	03.112.622	04.112.622S
02.112.621	03.112.623	04.112.623
02.112.621S	03.112.624	04.112.623S
02.112.622	03.112.625	04.112.624
02.112.622S	03.112.630	04.112.624S
02.112.623	03.112.631	04.112.625
02.112.623S	03.112.712	04.112.625S
02.112.624	03.112.713	04.112.630
02.112.624S		04.112.630S
02.112.625	04.112.610	04.112.631
02.112.625S	04.112.610S	04.112.631S
02.112.630	04.112.611	04.112.712S
02.112.630S	04.112.611S	04.112.713S

* Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

Introduction
The DePuy Synthes VA-LCP Clavicle Plate 2.7 System of implantable devices consists of lateral, shaft and medial plates. Plates are available in various sizes in both sterile and non-sterile package configurations. The system also consists of non-implantable templates that correspond to the above listed implants. Templates are intended for implant size selection and are available in non-sterile package configuration.

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 DePuy Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Device(s)	Material(s)	Standard(s)
VA-LCP Clavicle Plates 2.7	316L Stainless Steel	ISO 5832-1/ASTM F138
	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
Templates	316L Stainless Steel	ISO 5832-1/ASTM F138

Intended Use
Bone Fixation Plates (VA-LCP Clavicle Plates 2.7) are intended for temporary fixation, correction or stabilization of bones.

Indications
– Fixation of clavicle bone fragments

Contraindications
– Stable clavicle fractures
– Fixation of sternoclavicular joint
– Systemic infection or infection localized to the site of the proposed implantation

Patient Target Group
The VA-LCP Clavicle Plate 2.7 System is intended for patients where the growth plates have fused or will not be crossed.

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.

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 instructions for use, the surgical procedures, if applicable, and/or the DePuy 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 internal fixation devices such as the VA-LCP Clavicle Plate 2.7 System when used according to instructions for use and recommended technique are:
– Stabilize bone segment and facilitate healing
– Restore anatomical relationship and function

Performance Characteristics of the Device
DePuy Synthes has established the performance and safety of the VA-LCP Clavicle Plate 2.7 System and that it represents state of the art medical devices for fixation, correction or stabilization of clavicle fractures when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
– Adverse tissue reaction, allergy/hypersensitivity reaction
– Infection
– Dislocation
– Poor joint mechanics
– Damage to vital organs or surrounding structures
– Malunion/nonunion
– Neurovascular damage
– Pain or discomfort
– Bone damage including intra- and post-operative bone fracture, osteolysis or bone necrosis
– Soft tissue damage
– Injury to user
– Symptoms resulting from implant migration, loosening, bending or breakage

A series of patient related factors may impact the clinical outcomes, including bone healing. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the individual patient:
– Compromised vascularity in the site of proposed implantation
– Compromised soft tissue coverage and conditions
– Abnormal bone quality
– Overweight
– Occupations or activities that may generate excessive amount of physical loads
– Noncompliant patient
– Potential allergy or foreign body sensitivity to any of the implant materials

Sterile Device

Sterilized using irradiation

Store sterile devices in their original protective packaging and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

See DePuy Synthes brochure "Important Information".

Single-use Device

Do not reuse

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

Reuse 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, 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 DePuy 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

The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the DePuy Synthes brochure "Important Information".

It is strongly advised that the VA-LCP Clavicle Plates 2.7 are implanted only by operating surgeons who are familiar with the general problems and risks of clavicle surgery and its surrounding structures and who are able to master the product-specific surgical procedures.

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

Approach
- The periosteum of bone fragments must not be completely detached in order to preserve available bony blood supply thus enabling proper bone healing. It is critical not to strip any comminuted fragments.

Determine plate type and shape
- Do not bend or implant the templates.

Adapt plate to bone (bending)
- Do not bend the plate more than 10° as it may impact the mechanical performance. Excessive bending may weaken the plate and lead to premature plate failure.
- Avoid reverse bending (i.e. bending and then straightening plate) as it may compromise the strength of the plate or cause it to break.
- Do not make an acute bend directly over a screw hole as it may damage the thread or deform the screw hole. Check the VA portion of holes adjacent to the bending site with a variable angle drill guide after bending to ensure holes have not been deformed.

Screw insertion
- Nominal screw angle is determined by plate design and screw length. If the plate is contoured and/or a screw longer than 40 mm is selected, take care to ensure that screws do not collide with one another. The use of image intensification is recommended.
- Verify the drill bit angle under image intensification to ensure the desired angle has been achieved. Drilling consecutive screw holes off-axis can cause screws to collide.
- Always use a 1.2 Nm torque limiting attachment (TLA) when inserting VA locking screws.
- Do not lock screws using power tools without the 1.2 Nm TLA or at high speeds as this may damage the screwdriver and cause the screw head to strip, making it difficult to remove the implant.

Implant removal
- Do not use the TLA for screw removal.
- The VA-LCP Clavicle Plates 2.7 are designed for patients where the growth plates have fused or will not be crossed. The use of the clavicle plates in patients where the growth plates have not fused or will be crossed may result in premature closure of the physis and bone growth inhibition and therefore, plates must be removed upon fracture healing.

Combination of Medical Devices
- DePuy Synthes 2.7 mm Variable Angle Locking Screws with T8 Stardrive™ recess
- DePuy Synthes 2.7 mm Cortex Screws
- DePuy Synthes 2.7 mm Metaphyseal Screws

Sutures/needles
Ethicon taper point suture needles sized 26 mm ½ C radius are recommended.

DePuy Synthes has not tested compatibility with devices provided by manufacturers other than those listed above and assumes no liability in such instances.

Magnetic Resonance Environment

MR Conditional

Torque, Displacement and Image Artifacts according to ASTM F2213-17, ASTM F2052-15 and ASTM F2119-07 (2013)

Non-clinical testing of a worst-case scenario in a 3 T Magnetic Resonance Imaging (MRI) system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 138 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-19

Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of 12.1 °C (1.5 T) and 6.0 °C (3 T) under MRI conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Templates: MR Safety Information is not applicable. Non-implantable templates are not intended to be used in an MR environment.

Treatment before Device is used

DePuy 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 DePuy Synthes brochure "Important Information".

Implant Removal

While the physician makes the final decision on when to remove the implant, it is advisable – if possible and appropriate for the individual patient – to remove fixation products after the healing process is complete. This holds true particularly in the following situations pending the treating surgeon's risk benefit evaluation:
- Young and active patients.
- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection
- Patient choice

If the surgeon decides to remove the implants, implants can be removed by using general surgical instruments. In case of difficult removal circumstances, a Screw Extraction Set is available.

Preoperative planning for implant removal
To ensure that the appropriate instruments are available for screw removal, the surgeon should have the following information before implant removal:
- Implant type
- Time of implantation
- Material
- Any visible damage to the implant (e.g. broken plate)

Please also consult the warnings and precautions section for implant removal.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the DePuy Synthes brochure "Important Information".

Device-related Storage and Handling Information


Caution, see instructions for use

Disposal
Any DePuy 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.

Surgical Technique Steps
Important: The recommended construct will achieve fixation with four 2.7 mm screws placed bicortically per main fracture fragment. For fractures in the medial clavicle, consider monocortical screw placement in the most medial screw holes to prevent perforation of neurovascular structures or the sternoclavicular joint.

1. Preparation
2. Approach
3. Reduce fracture and temporary fixation
4. Determine plate type and shape
5. Select plate type and shape
6. Adapt plate to bone (optional)
7. Plate insertion and temporary fixation
8. Screw configuration
9. Screw insertion – 2.7 mm Cortex Screws
10. Screw insertion – 2.7 mm VA Locking and Metaphyseal Screws
11. Soft tissue attachment (optional)
12. Confirm reduction and fixation
13. Surgical closure
14. Implant removal (optional)

Legal Manufacturer Name and Address

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