Instructions for Use

Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4 mm

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

Not all products are currently available in all markets.

DePuy Synthes

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Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4 mm

Devices in scope:

Plates:

VA-LCP Two-Column Distal Radius Plates 2.4, volar, narrow, 6 holes, width 19.5 mm

length (mm)	Left/ Right	Head Holes	Shaft Holes	Stainless Steel	
42	R	6	2	02.111.520	02.111.520S
42	L	6	2	02.111.521	02.111.521S
51	R	6	3	02.111.530	02.111.530S
51	L	6	3	02.111.531	02.111.531S
63	R	6	4	02.111.540	02.111.540S
63	L	6	4	02.111.541	02.111.541S
72	R	6	5	02.111.550	02.111.550S
72	L	6	5	02.111.551	02.111.551S

VA-LCP Two-Column Distal Radius Plates 2.4, volar, narrow, 6 holes, width 19.5 mm

length (mm)	Left/ Right	Head Holes	Shaft Holes	Titanium TiCP	
42	R	6	2	04.111.520	04.111.520S
42	L	6	2	04.111.521	04.111.521S
51	R	6	3	04.111.530	04.111.530S
51	L	6	3	04.111.531	04.111.531S
63	R	6	4	04.111.540	04.111.540S
63	L	6	4	04.111.541	04.111.541S
72	R	6	5	04.111.550	04.111.550S
72	L	6	5	04.111.551	04.111.551S

VA-LCP Two-Column Distal Radius Plates 2.4, volar, 6 holes, width 22 mm

length (mm)	Left/ Right	Head Holes	Shaft Holes	Stainless Steel	
45	R	6	2	02.111.620	02.111.620S
45	L	6	2	02.111.621	02.111.621S
54	R	6	3	02.111.630	02.111.630S
54	L	6	3	02.111.631	02.111.631S
66	R	6	4	02.111.640	02.111.640S
66	L	6	4	02.111.641	02.111.641S
75	R	6	5	02.111.650	02.111.650S
75	L	6	5	02.111.651	02.111.651S

VA-LCP Two-Column Distal Radius Plates 2.4, volar, 6 holes, width 22 mm

length (mm)	Left/ Right	Head Holes	Shaft Holes	Titanium TiCP	
45	R	6	2	04.111.620	04.111.620S
45	L	6	2	04.111.621	04.111.621S
54	R	6	3	04.111.630	04.111.630S
54	L	6	3	04.111.631	04.111.631S
66	R	6	4	04.111.640	04.111.640S
66	L	6	4	04.111.641	04.111.641S
75	R	6	5	04.111.650	04.111.650S
75	L	6	5	04.111.651	04.111.651S

VA-LCP Two-Column Distal Radius Plates 2.4, volar, 7 holes, width 25.5 mm

length (mm)	Left/ Right	Head Holes	Shaft Holes	Stainless Steel	
47	R	7	2	02.111.720	02.111.720S
47	L	7	2	02.111.721	02.111.721S
55	R	7	3	02.111.730	02.111.730S
55	L	7	3	02.111.731	02.111.731S
68	R	7	4	02.111.740	02.111.740S
68	L	7	4	02.111.741	02.111.741S
77	R	7	5	02.111.750	02.111.750S
77	L	7	5	02.111.751	02.111.751S

VA-LCP Two-Column Distal Radius Plates 2.4, volar, 7 holes, width 25.5 mm

length (mm)	Left/ Right	Head Holes	Shaft Holes	Titanium TiCP	
47	R	7	2	04.111.720	04.111.720S
47	L	7	2	04.111.721	04.111.721S
55	R	7	3	04.111.730	04.111.730S
55	L	7	3	04.111.731	04.111.731S
68	R	7	4	04.111.740	04.111.740S
68	L	7	4	04.111.741	04.111.741S
77	R	7	5	04.111.750	04.111.750S
77	L	7	5	04.111.751	04.111.751S

Locking Screws:

Variable Angle Locking Screws ∅ 2.4 mm, self-tapping, Stardrive

Length (mm)	Stainless Steel		
8	02.210.108	02.210.108S	02.210.108TS
9	02.210.109	02.210.109S	02.210.109TS
10	02.210.110	02.210.110S	02.210.110TS
11	02.210.111	02.210.111S	02.210.111TS
12	02.210.112	02.210.112S	02.210.112TS
13	02.210.113	02.210.113S	02.210.113TS
14	02.210.114	02.210.114S	02.210.114TS
16	02.210.116	02.210.116S	02.210.116TS
18	02.210.118	02.210.118S	02.210.118TS
20	02.210.120	02.210.120S	02.210.120TS
22	02.210.122	02.210.122S	02.210.122TS
24	02.210.124	02.210.124S	02.210.124TS
26	02.210.126	02.210.126S	02.210.126TS
28	02.210.128	02.210.128S	02.210.128TS
30	02.210.130	02.210.130S	02.210.130TS

Variable Angle Locking Screws ∅ 2.4 mm, self-tapping, Stardrive

Length (mm)	Titanium Alloy (TAN)		
8	04.210.108	04.210.108S	04.210.108TS
9	04.210.109	04.210.109S	04.210.109TS
10	04.210.110	04.210.110S	04.210.110TS
11	04.210.111	04.210.111S	04.210.111TS
12	04.210.112	04.210.112S	04.210.112TS
13	04.210.113	04.210.113S	04.210.113TS
14	04.210.114	04.210.114S	04.210.114TS
16	04.210.116	04.210.116S	04.210.116TS
18	04.210.118	04.210.118S	04.210.118TS
20	04.210.120	04.210.120S	04.210.120TS
22	04.210.122	04.210.122S	04.210.122TS
24	04.210.124	04.210.124S	04.210.124TS
26	04.210.126	04.210.126S	04.210.126TS
28	04.210.128	04.210.128S	04.210.128TS
30	04.210.130	04.210.130S	04.210.130TS

Locking Screws ∅ 2.4 mm, self-tapping, Stardrive

Length (mm)	Stainless Steel		
6	212.806	212.806S	212.806TS
7	212.807	212.807S	212.807TS
8	212.808	212.808S	212.808TS
9	212.809	212.809S	212.809TS
10	212.810	212.810S	212.810TS
11	212.811	212.811S	212.811TS
12	212.812	212.812S	212.812TS
13	212.813	212.813S	212.813TS
14	212.814	212.814S	212.814TS
16	212.816	212.816S	212.816TS
18	212.818	212.818S	212.818TS
20	212.820	212.820S	212.820TS
22	212.822	212.822S	212.822TS
24	212.824	212.824S	212.824TS
26	212.826	212.826S	212.826TS
28	212.828	212.828S	212.828TS
30	212.830	212.830S	212.830TS

Locking Screws ∅ 2.4 mm, self-tapping, Stardrive

Length (mm)	Titanium Alloy (TAN)		
6	412.806	412.806S	412.806TS
7	412.807	412.807S	412.807TS
8	412.808	412.808S	412.808TS
9	412.809	412.809S	412.809TS
10	412.810	412.810S	412.810TS
11	412.811	412.811S	412.811TS
12	412.812	412.812S	412.812TS
13	412.813	412.813S	412.813TS
14	412.814	412.814S	412.814TS
16	412.816	412.816S	412.816TS
18	412.818	412.818S	412.818TS
20	412.820	412.820S	412.820TS
22	412.822	412.822S	412.822TS
24	412.824	412.824S	412.824TS
26	412.826	412.826S	412.826TS
28	412.828	412.828S	412.828TS
30	412.830	412.830S	412.830TS

Cortex Screws:

Cortex Screws ∅ 2.4 mm, self-tapping, Stardrive

Length (mm)	Stainless Steel		
6	201.756	201.756S	201.756TS
7	201.757	201.757S	201.757TS
8	201.758	201.758S	201.758TS
9	201.759	201.759S	201.759TS
10	201.760	201.760S	201.760TS
11	201.761	201.761S	201.761TS
12	201.762	201.762S	201.762TS
13	201.763	201.763S	201.763TS
14	201.764	201.764S	201.764TS
16	201.766	201.766S	201.766TS
18	201.768	201.768S	201.768TS
20	201.770	201.770S	201.770TS
22	201.772	201.772S	201.772TS
24	201.774	201.774S	201.774TS
26	201.776	201.776S	201.776TS
28	201.778	201.778S	201.778TS
30	201.780	201.780S	201.780TS

Cortex Screws ∅ 2.4 mm, self-tapping, Stardrive

Length (mm)	Titanium Alloy (TAN)		
6	401.756	401.756S	401.756TS
7	401.757	401.757S	401.757TS
8	401.758	401.758S	401.758TS
9	401.759	401.759S	401.759TS
10	401.760	401.760S	401.760TS
11	401.761	401.761S	401.761TS
12	401.762	401.762S	401.762TS
13	401.763	401.763S	401.763TS
14	401.764	401.764S	401.764TS
16	401.766	401.766S	401.766TS
18	401.768	401.768S	401.768TS
20	401.770	401.770S	401.770TS
22	401.772	401.772S	401.772TS
24	401.774	401.774S	401.774TS
26	401.776	401.776S	401.776TS
28	401.778	401.778S	401.778TS
30	401.780	401.780S	401.780TS

Cortex Screws ∅ 2.7 mm, self-tapping, Stardrive

Length (mm)	Stainless Steel		
6	202.866	202.866S	202.866TS
8	202.868	202.868S	202.868TS
10	202.870	202.870S	202.870TS
12	202.872	202.872S	202.872TS
14	202.874	202.874S	202.874TS
16	202.876	202.876S	202.876TS
18	202.878	202.878S	202.878TS
20	202.880	202.880S	202.880TS
22	202.882	202.882S	202.882TS
24	202.884	202.884S	202.884TS
26	202.886	202.886S	202.886TS
28	202.888	202.888S	202.888TS
30	202.890	202.890S	202.890TS

Cortex Screws ∅ 2.7 mm, self-tapping, Stardrive

Length (mm)	Titanium Alloy (TAN)		
6	402.866	402.866S	402.866TS
8	402.868	402.868S	402.868TS
10	402.870	402.870S	402.870TS
12	402.872	402.872S	402.872TS
14	402.874	402.874S	402.874TS
16	402.876	402.876S	402.876TS
18	402.878	402.878S	402.878TS
20	402.880	402.880S	402.880TS
22	402.882	402.882S	402.882TS
24	402.884	402.884S	402.884TS
26	402.886	402.886S	402.886TS
28	402.888	402.888S	402.888TS
30	402.890	402.890S	402.890TS

Buttress Pins:

Variable Angle Locking Buttress Pins ∅ 1.8 mm, Stardrive

Length (mm)	Stainless Steel	
8	02.210.078	02.210.078S
10	02.210.080	02.210.080S
12	02.210.082	02.210.082S
14	02.210.084	02.210.084S
16	02.210.086	02.210.086S
18	02.210.088	02.210.088S
20	02.210.090	02.210.090S
22	02.210.092	02.210.092S
24	02.210.094	02.210.094S
26	02.210.096	02.210.096S
28	02.210.098	02.210.098S
30	02.210.100	02.210.100S

Variable Angle Locking Buttress Pins ∅ 1.8 mm, Stardrive

Length (mm)	Titanium Alloy (TAN)	
8	04.210.078	04.210.078S
10	04.210.080	04.210.080S
12	04.210.082	04.210.082S
14	04.210.084	04.210.084S
16	04.210.086	04.210.086S
18	04.210.088	04.210.088S
20	04.210.090	04.210.090S
22	04.210.092	04.210.092S
24	04.210.094	04.210.094S
26	04.210.096	04.210.096S
28	04.210.098	04.210.098S
30	04.210.100	04.210.100S

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

Introduction
Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4 mm

The Variable Angle LCP Two-Column Volar Distal Radius Plate 2.4 mm system consists of a range of plates in various lengths, sizes and screw hole configurations, locking screws, cortex screws, locking buttress pins and are available in both sterile and 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 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 Two-Column Distal Radius Plates, Locking screws, Cortex screws and Locking buttress pins	316L Stainless Steel	ISO 5832-1/ASTM F138/F139
VA-LCP Two-Column Distal Radius Plates	Titanium Grade 4 (TiCP4)	ISO 5832-2/ASTM F67
Locking screws, Cortex screws and Locking buttress pins	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11/ASTM F 1295

Intended Use
Bone fixation plates including Variable Angle LCP Two-Column Volar Distal Radius Plates 2.4 are intended for temporary fixation, correction and stabilization of bones.

Indications
Internal fracture fixation of bones and bone fragments of the distal radius.

Contraindications
No specific contraindications.

Patient Target Group
Intended for patients where growth plates have fused.

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 orthopedic surgery, are aware of general risks of orthopedic 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 orthopedic 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
The expected clinical benefits of internal fixation devices such as Variable Angle LCP Two-Column Volar Distal Radius Plates 2.4 mm, when used according to instructions for use and recommended technique is achievement of bone union.

A summary of safety and clinical performance can be found at the following link: http://ec.europa.eu/tools/eudamed

Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched.

Performance Characteristics of the Device
Synthes has established the performance and safety of Variable Angle LCP Two-Column Volar Distal Radius Plates 2.4 mm and that they represent state of the art medical devices intended for temporary fixation, correction and stabilization of bones in the radius when used according to their instructions for use and labeling. Refer to section Devices in scope of this IFU for device characteristics such as available lengths and diameters of the subject devices.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

Potential Adverse Events
Potential risks and adverse events associated with the use of Variable Angle LCP Two-Column Volar Distal Radius Plates 2.4 mm implants include:
- Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction
- Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis
- Damage to Surrounding Structures
- Infection
- Injury to User
- Malunion/Non-union
- Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage
- Neuro-vascular Damage
- Pain or Discomfort
- Poor Joint Mechanics
- Soft Tissue Damage (including Compartment Syndrome)
- Surgical Delay

Patient related factors:
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 intended site of 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.

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 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

Precaution:
– For final locking, the 0.8 Nm torque limiter is required.

For precautions specific to a surgical step please refer to section Special Operating Instructions.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment

Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052 and ASTM F2119
Non-clinical testing of worst case scenario in a 3 T 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 169 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
Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

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 a MR 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.

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".

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

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

Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:
– Inspect the entire area of the sterile barrier package, and the sealing, for completeness and uniformity.
– Inspect for the absence of holes, channels or voids of the sterile barrier package and the sealing.
Do not use, if the package is damaged or expired.

Implant Removal
In case the physician decides to remove the implants, implants can be removed by using general surgical instruments.

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 Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Additional Device-Specific Information

MR Conditional

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.

Special Operating Instructions

Screw Insertion Techniques
Variable angle technique
Predefined nominal angle technique
a) Use of fixed-angle end of VA-LCP drill sleeve
b) Use of guiding blocks
   – Precaution: Do not use the threaded LCP drill sleeve (323.029) in variable angle locking holes.

Screw Angle Overview

Approach
– Precaution: Leave the volar wrist capsule intact to avoid devascularization of the fracture fragments and destabilization of the volar wrist ligaments.

Implantation
1. Select implant
2. Reduce fracture and position plate
   Option: Plate reduction wires
   – Precaution: The plate reduction wires and Kirschner wires are single use items, do not re-use.
3. Insert proximal screws
4. Drill screw hole for VA locking screws

4a. Drill screw hole for VA locking screw using variable angle technique
   Drill using VA-LCP drill sleeve with funnel
   Drill using VA-LCP drill sleeve for freehand use

4b. Drill using predefined nominal angle technique
   Drill using VA-LCP Drill Sleeve
   Drill using guiding blocks

5. Insert VA locking screws
6. Ensure proper joint reconstruction
7. Final fixation of VA locking screws
   – Precaution: Use of the TLA is mandatory when inserting locking screws into variable angle locking holes.

Postoperative Treatment

Recommendation
Fine contouring of the plate (optional)
– Precaution: The plate holes allow a certain degree of deformation. Significant distortion of the threaded holes will reduce locking effectiveness.
– Precaution: Reverse bending or use of the incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g. breakage). Do not bend the plate beyond what is required to match the anatomy.

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Instructions for Use:
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