Instructions for Use

Variable Angle LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0

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

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DePuy Synthes
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Instructions for Use

Variable Angle LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0

Devices in Scope

VA-LCP PPFx Proximal Femur Plates:
02.221.112
02.221.112S
02.221.113
02.221.113S
02.221.114
02.221.114S
02.221.115
02.221.115S
02.221.120
02.221.120S
02.221.121
02.221.121S
02.221.122
02.221.122S
02.221.123
02.221.123S
02.221.124
02.221.124S
02.221.125
02.221.125S
02.221.130
02.221.130S
02.221.131
02.221.131S

VA-LCP PPFx Proximal Femur Hook Plates:
02.221.084
02.221.084S
02.221.085
02.221.085S
02.221.086
02.221.086S
02.221.087
02.221.087S
02.221.088
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02.221.093
02.221.093S
02.221.094
02.221.094S
02.221.095
02.221.095S

Sizing Templates:
03.221.094
03.221.095
03.221.180
03.221.181
03.221.182
03.221.183
03.221.184
03.221.185
03.221.186
03.221.187
03.221.188
03.221.189

Insertion Handle f/VA-LCP PPFx Proximal Femur Hook Plates:
03.221.250

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 Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0 consists of Stainless Steel plates for periprosthetic fractures and is available in various sizes in both sterile and non-sterile package configurations. The system also consists of an insertion handle for hook plates and 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 PPFx Proximal Femur Plates and Proximal Femur Hook Plates 3.5/4.5/5.0	316L Stainless Steel	ASTM F138 ASTM F139
Sizing Templates	316L Stainless Steel	ASTM A276
	17-4PH Stainless Steel	EN 10088
	Custom 465 Stainless Steel	ASTM F899
Insertion Handle f/VA-LCP PPFx Proximal Femur Hook Plates	Custom 465 Stainless Steel	ASTM F899
	Elastosil R Plus 4001 Silicone Rubber	ASTM F2042 / F2038 (Instrument Polymer)


1

One or more non-implantable components of this device contains the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:
Cobalt; CAS No. 7440-48-4; EC No. 231-158-0
Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

Intended Use
Bone Fixation Plates (VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0) are intended for temporary fixation, correction, or stabilization of bones in the proximal and middle 1/3 of the diaphyseal segment of the femur.

Indications
The DePuy Synthes VA-LCP PPFx Proximal Femur Plates and Proximal Femur Hook Plates 3.5/4.5/5.0 are indicated for the treatment of periprosthetic fractures and fractures in the presence of intramedullary implants in the proximal and middle 1/3 of the diaphyseal segment of the femur, in adult patients.

Contraindications
The DePuy Synthes VA-LCP PPFx Proximal Femur Plating System 3.5/4.5/5.0 is contraindicated for independent fixation if the hip stem requires immediate revision.

The DePuy Synthes VA-LCP PPFx Proximal Femur Hook Plate 3.5/4.5/5.0 with 5 holes (shortest plate) is contraindicated for diaphyseal periprosthetic femoral fractures where distal fixation of the construct is not achievable.

Patient Target Group
The DePuy Synthes VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0 devices are recommended for use in skeletally mature patients.

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

Expected Clinical Benefits
The expected clinical benefit of internal fixation devices such as DePuy Synthes VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0 devices 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 (upon activation): http://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
DePuy Synthes has established the performance and safety of the VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0, and that it represents state of the art medical devices for fixation, correction or stabilization of proximal femur 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 Surrounding Structures
- Malunion/Non-union
- Neuro-vascular Damage
- Pain or Discomfort
- Bone Damage including Intra- and Post-Operative Bone Fracture
- Soft Tissue Damage
- Injury to User
- Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage

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

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 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, 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 VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0 devices are implanted only by operating surgeons who are familiar with the general problems of femur surgery including Total Hip Arthroplasty (THA) and its surrounding structures and who are able to master the product-specific surgical procedures.

Warnings

Preoperative Planning:
- The VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0 should not be implanted in cases where a localized, active bacterial infection is known to be present at the intended site.
- Prosthesis stability, in combination with other patient related factors, may impact the clinical outcome, including bone healing. The decision whether to use the DePuy Synthes VA-LCP PPFx Proximal Femur Plating System 3.5/4.5/5.0 in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the individual patient.

Plate Selection:
- The minimum fixation recommendations listed in these Warnings and Precautions are based on the results of mechanical testing performed on the unique plate constructs and are important to ensure construct stability. Failure to achieve fixation recommendations increases the risk of construct failure, malalignment, and/or delayed bone healing.

Plate/Screw Insertion – Proximal Femur Plate and Proximal Femur Hook Plate:
- For Vancouver Type B fracture fixation, it is recommended to add screws to achieve sufficient mechanical fixation, e.g. by adding bicortical or unicortical screws that cover at least 6 cortices of fixation in the proximal fragment and 6 cortices of fixation in the distal fragment, or by considering additional methods to augment fixation, if needed. Fewer cortices of fixation may result in construct failure or loss of bony fixation.
  - For the proximal plate shaft, it is not recommended to place three screws in diagonally aligned holes. Doing so could potentially cause a stress riser in the bone.
  - If the distal shaft of the Proximal Femur Plate or Proximal Femur Hook Plate is contoured, then the most proximal 4.5/5.0 mm VA-LCP combi hole in the distal shaft must be filled with either a VA locking screw ∅ 5.0 mm or a cortex screw ∅ 4.5 mm to shield the contoured plate distally, reducing the risk of construct failure in the contoured region.

Plate/Cable/Screw Insertion – Proximal Femur Hook Plates:
- Carefully handle the Proximal Femur Hook Plate as these plates have two sharp hooks that may pinch or tear gloves or skin.
- For Vancouver Type A_G fracture fixation, it is recommended to use a minimum of two VA locking screws ∅ 3.5 mm and two cables in the head of the plate, crossing the fracture/osteotomy, and a minimum of 6 cortices of fixation distal to the fracture in the plate shaft. Failure to achieve minimum fixation may result in construct failure or migration of the trochanteric fragment.
- Carefully handle the cable crimps as these have spikes with sharp edges that may pinch or tear gloves or skin.

Precautions

Plate/Cable/Screw Insertion – Proximal Femur Plate:
- Do not contour the plate back and forth, as this may weaken the plate.
- Do not bend the plate at the level of the holes, as this may damage the holes.
- Do not bend the plate head or proximal plate shaft, as this may weaken the plate or damage the holes.
- When using cables in conjunction with a plate/screw construct, all cables should be added to compress the plate down to the bone and/or reduce the fracture before any locking screws are inserted into the plate. Otherwise, reduction across the fracture may not be sufficiently achieved.

Plate/Cable/Screw Insertion – Proximal Femur Hook Plates:
- Do not contour the plate back and forth, as this may weaken the plate.
- Do not bend the plate at the level of the holes, as this may damage the holes.
- Do not bend the hooks, the plate head, or the proximal plate shaft, as this may weaken the plate or damage the hooks or holes.
- Ensure that the insertion handle is fully threaded in, seating flush with the plate, to prevent damage to the insertion handle or plate during insertion.
- All cables should be added to compress the plate down to the bone and/or reduce the fracture before any locking screws are inserted into the plate. Otherwise, reduction across the fracture may not be sufficiently achieved.
- If using a cable passer, feed the cable into the end hole of the cable passer, not the shaft hole. Otherwise, the crimp and plate will prevent release of the cable passer.
- Ensure that cables are not in contact with the prosthesis to prevent loosening or damage of the implants.
- Each cable should be cut as close to the plate as possible, taking care not to damage the adjacent cable.

Screw Insertion:
- All cortex screws must be inserted before insertion of any VA locking screws, if in the same fragment. Placing locking screws before cortex screws may limit compression of the plate to bone and prevent reduction across the fracture.
- Drill guides or drill sleeves must be used for VA locking screw hole preparation to ensure proper locking of VA locking screws to plate.
- Ensure a secure drill path (e.g. avoiding the hip stem, screws or wires used for provisional fixation) to prevent damage to implants or instruments.
- Ensure a secure path for screw insertion (e.g. avoiding the hip stem, screws or wires used for provisional fixation) to prevent damage to implants or instruments.
- Due to the difference in the placement of the head of a locking screw compared to a cortex screw, care should be taken when determining screw length with the depth gauge. Otherwise, the screw chosen may be too short or too long.
- Final tightening must always be done manually using the appropriate torque limiting handle (2.5 Nm for VA locking screws ∅ 3.5 mm and 6 Nm for VA locking screws ∅ 5.0 mm) and screwdriver shaft to ensure secure locking and prevent construct failure. The torque limiting handles should not be used for screw removal as this may damage the instrument.

Implant Removal:
- The torque limiting handles should not be used for screw removal as this may damage the instrument.

Combination of Medical Devices

DePuy Synthes:
- VA Locking Screws, ∅ 3.5 mm and ∅ 5.0 mm
- VA Periprosthetic Locking Screws, ∅ 5.0 mm
- Locking Screws, ∅ 3.5 mm and ∅ 5.0 mm*
- Periprosthetic Locking Screws, ∅ 5.0 mm*
- Cortex Screws, ∅ 3.5 mm and ∅ 4.5 mm
- Cerclage Cable with Crimp ∅ 1.7 mm
- Positioning Pin for VA 5.0, cruciform
- Cerclage Eye for Screws ∅ 3.5 mm and ∅ 4.5 mm
- Connection Screw Stardrive® for Locking Attachment Plate
- VA Locking Attachment Plate 3.5, 4 holes

*Alternative Use of Locking Screws:
Locking screws may be used as an alternative to VA locking screws, if desired. All WARNINGS and PRECAUTIONS apply to both VA locking screws and locking screws, with the following exceptions:
- All locking screws ∅ 3.5 mm must be inserted at zero degrees and on-axis with the screw hole, and final tightened with 1.5 Nm.
- All locking screws ∅ 5.0 mm must be inserted at zero degrees and on-axis with the screw hole, and final tightened with 4.0 Nm.
- Use the available guiding tools to assist with insertion at zero degrees.

The material of implants selected for a procedure (stainless steel vs. titanium) should match.

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

Non-clinical testing has demonstrated the DePuy Synthes VA-LCP PPFx Proximal Femur Plating System 3.5/4.5/5.0 is MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 1.5 T or 3.0 T
- RF excitation limited to Circular Polarization
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m) for 1.5 T or 3.0 T
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 1W/kg for 1.5 T and 2W/Kg for 3.0 T

Under the scan conditions defined above, the DePuy Synthes VA-LCP PPFx Proximal Femur Plating System 3.5/4.5/5.0 is expected to produce a maximum temperature rise of 4°C in 1.5 T and 3.0 T for 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 150 mm from the DePuy Synthes VA-LCP PPFx Proximal Femur Plating System 3.5/4.5/5.0 when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Precaution: It is recommended that the device be kept as far away from the coil wall as possible.

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

Treatment before Device is used

Non-sterile Device:
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".

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices 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. Do not use, if the package is damaged.

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.

Special Operating Instructions

Proximal Femur Plate Surgical Technique Steps:
1. Preoperative Planning and Reduction
– Evaluate Hip Stem Stability
– Complete pre-operative planning
– Reduce fracture

2. Plate Selection
– Determine length of plate to be used. Consider final screw positions while choosing plate length
– Use the respective sizing templates to choose the appropriate plate (Optional)
– Contour the plate, if required

3. Plate Insertion
– Insert the plate proximal to distal, down the length of the bone so plate head is just below the vastus ridge
– If needed provisionally fix the plate
– Check implant position under image intensifier control

4. Cable Application (Optional)
– Additional cables can be added to the plate construct using either positioning pins or cerclage eyes
– Pass the cable around the plate and feed it through the crimp
– Tension, crimp, and cut the cable

5. Screw Insertion
– Determine screw locations and type
– Drill hole based on screw size
– Measure for screw length
– Insert screw using the appropriate screwdriver shaft.
– For locking screws – use the appropriate Torque Limiting Handle to lock the screw to the plate

6. Final Check
– Before closing the wound, confirm implant position and construct integrity
– Reconfirm that all locking screws are locked with the appropriate Torque Limiting Handle

7. Implant Removal (Optional)
In case the physician decides to remove the implants, the following steps shall be followed:
– Remove cables with a cable cutter
– Remove screws with the appropriate screwdriver shaft and handle
– Remove plate

Proximal Femur Hook Plate Surgical Technique Steps:
1. Preoperative Planning and Reduction
– Evaluate Hip Stem Stability
– Complete pre-operative planning
– Reduce fracture

2. Plate Selection
– Determine size/length of plate to be used. Consider final screw positions while choosing plate size/length.
– Use the respective sizing templates to choose the appropriate plate (Optional)
– Contour the plate, if required

3. Plate Insertion
– Insert the plate proximal to distal over the greater trochanter, down the length of the bone. If needed, use a mallet to tap and fully seat the hooks.
– If needed provisionally fix the plate
– Check implant position under image intensifier control

4. Cable Application and Screw Insertion in the Head of the Plate
– Remove crimp from cable assembly. Place crimp in plate head, then pass the cables around the proximal femur and feed it through the plate/crimp.
– Tension the cables
– Insert screws in the head of the plate crossing the fracture
– Crimp and cut the cables

5. Cable Application in the Shaft of the Plate (Optional)
– Additional cables can be added to the plate construct using either positioning pins or cerclage eyes
– Pass the cable around the plate and feed it through the crimp
– Tension, crimp, and cut the cable

6. Screw Insertion in the Shaft of the Plate
– Determine screw locations and type
– Drill hole based on screw size
– Measure for screw length
– Insert screw using the appropriate screwdriver shaft
– For locking screws – use the appropriate Torque Limiting Handle to lock the screw to the plate

7. Final Check
– Before closing the wound, confirm implant position and construct integrity
– Reconfirm that all locking screws are locked with the appropriate Torque Limiting Handle

8. Implant Removal (Optional)
In case the physician decides to remove the implants, the following steps shall be followed:
– Remove cables with a cable cutter
– Remove screws with the appropriate screwdriver shaft and handle
– Remove plate

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

Instructions for Use:
www.e-ifu.com