Instructions for Use
Variable Angle Locking Attachment Plates 3.5

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Variable Angle Locking Attachment Plates 3.5

Devices in Scope:
02.221.174
02.221.174S

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 Locking Attachment Plate 3.5 is offered in Stainless Steel material in both sterile and non-sterile package configurations. It attaches to DePuy Synthes VA-LCP PPFx Proximal Femur Plate or Proximal Femur Hook Plate 3.5/4.5/5.0, VA-LCP Curved Condylar 4.5/5.0, LCP Curved Condylar 4.5/5.0, Straight and Curved Broad LCP 4.5/5.0, and LISS/LCP Distal Femur.

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 Locking Attachment Plate 3.5	316L Stainless Steel	ASTM F138/F139

Intended Use
Bone Fixation Plates (VA Locking Attachment Plate 3.5) are intended for temporary fixation, correction or stabilization of bones in the femur.

Indications
The DePuy Synthes VA Locking Attachment Plate 3.5 is indicated for periprosthetic fractures (Vancouver Type B when used with either the VA-LCP PPFx Proximal Femur Plate 3.5/4.5/5.0 or Proximal Femur Hook Plate 3.5/4.5/5.0; Vancouver Type B and C when used with other DePuy Synthes LCP plates and VA-LCP plates).

Contraindications
No contraindications specific to these devices.

Patient Target Group
The VA Locking Attachment Plate 3.5 is 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 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 the DePuy Synthes VA Locking Attachment Plate 3.5 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 Locking Attachment Plate 3.5, and that it represents state of the art medical devices for fixation, correction or stabilization of femoral 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, 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 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 Locking Attachment Plates 3.5 are implanted only by operating surgeons who are familiar with the general problems of femur surgery and its surrounding structures and who are able to master the product-specific surgical procedures.

Warnings
- The VA Locking Attachment Plates 3.5 should not be implanted in cases where a localized, active bacterial infection is known to be present at the intended site.
- For the VA Locking Attachment Plate 3.5, it is recommended to place VA locking screws ∅ 3.5 mm diagonally opposed, in only two of the four screw holes to achieve best fixation and to prevent a stress riser in the bone.

Precautions

VA Locking Attachment Plate 3.5 Insertion:
- Ensure that the connecting screw insert is tightened with the 6 Nm torque limiter before inserting the VA Locking Attachment Plate 3.5. After insertion of the upper screw, the insert cannot be tightened anymore.
- Final tightening must always be done manually using the appropriate torque limiting handle (2.5 Nm for upper screw of the connecting screw and 6 Nm for the connecting screw insert) 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.
- Do not contour the tabs back and forth, as this may weaken the tabs.

Screw Insertion:
- 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.
- Drill guides or drill sleeves must be used for VA locking screw hole preparation to ensure proper locking of VA locking screws to plate.
- 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 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-LCP PPFx Proximal Femur Plate 3.5/4.5/5.0
- VA-LCP PPFx Proximal Femur Hook Plate 3.5/4.5/5.0
- VA-LCP Curved Condylar 4.5/5.0
- LCP Curved Condylar 4.5/5.0
- Straight and Curved Broad LCP 4.5/5.0
- LISS/LCP Distal Femur
- VA Locking Screws, ∅ 3.5 mm
- Locking Screws, ∅ 3.5 mm*
- Cortex Screws, ∅ 3.5 mm
- Connecting Screw Stardrive® for Locking Attachment Plate

*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.
- 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

These parameters represent testing of the VA Locking Attachment Plate 3.5 in conjunction with the VA-LCP Periprosthetic Proximal Femur Plating System 3.5/4.5/5.0.

Non-clinical testing has demonstrated the DePuy Synthes VA Locking Attachment Plate 3.5 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 Locking Attachment Plate 3.5 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 Locking Attachment Plate 3.5 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.

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

Surgical Technique Steps
The VA Locking Attachment Plate 3.5 is not for standalone use, always use in combination with a main plate, such as the VA-LCP Proximal Femur Plate 3.5/4.5/5.0 or the VA-LCP Proximal Femur Hook Plate 3.5/4.5/5.0.

1. Determine the location of the VA Locking Attachment Plate on the main plate

2. Attach Threaded Insert of Connecting Screw to the main plate

3. Insert and attach VA Locking Attachment Plate
– Position the VA Locking Attachment Plate on the main plate directly above the Threaded Insert of the Connecting Screw
– Insert the Upper Screw of the Connecting Screw through the VA Locking Attachment Plate and into the Threaded Insert of the Connecting Screw
– Use the appropriate Torque Limiting Handle to lock the Upper Screw

4. Contour tabs of VA Locking Attachment Plate (Optional)

5. Screw Insertion
– Determine screw locations
– Drill hole based on screw size
– Measure for screw length
– Insert screw using the appropriate screwdriver shaft
– If applicable, use the appropriate Torque Limiting Handle to lock the screws

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

7. Implant Removal (Optional)
– Remove screws with the appropriate screwdriver shaft and handle
– Remove plate

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