# Instructions for Use
# Variable Angle Locking Anterior Patella Plate 2.7

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
manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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# Instructions for Use

Variable Angle Locking Anterior Patella Plate 2.7

**Device(s) in scope:**
Variable Angle Locking Anterior Patella Plate 2.7
02.137.000S
02.137.001S
02.137.002S
02.137.003S
02.137.004S
02.137.005S
04.137.000S
04.137.001S
04.137.002S
04.137.003S
04.137.004S
04.137.005S

The Depuy Synthes Variable Angle Patella Plating System consists of a variety of pre-contoured locking plates. The Variable Angle Locking Anterior Patella Plate 2.7 is available in three plate configurations and two sizes to provide fixation for various patella fracture patterns. All implants are offered sterile.

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 Locking Patella Plates | Stainless Steel 316L | ISO 5832-1 |
| | Titanium (TiCP) | ISO 5832-2 |

**Intended Use**
The DePuy Synthes Variable Angle Locking Patella Plating System is intended to provide internal bone fixation for simple and complex patellar fractures.

**Indications**
The DePuy Synthes Variable Angle Locking Patella Plating System is indicated for the fixation and stabilization of patellar fractures in normal and osteopenic bone in skeletally mature patients.

**Contraindications**
No contraindications specific for the devices.

**Patient Target Group**
The Variable Angle Locking Patella Plating System is indicated for use in skeletally mature patients.

**Intended User**
This IFU alone does 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 IFU, the surgical procedures, if applicable, and/or the 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 Variable Angle Locking Patella Plates when used according to the instructions for use and recommended technique are:
– Stabilize bone fragments and facilitate healing
– Restore functional integrity of the extensor mechanism

**Performance Characteristics of the Device**
The Variable Angle Locking Patella Plating System provides stable fixation and a versatile locking option for simple and complex patellar fractures.

**Potential Adverse Events, Undesirable Side Effects and Residual Risks**
– Adverse tissue reaction
– Infection
– Poor joint mechanics
– Damage to surrounding structures
– Malunion/Non-union
– Pain or discomfort
– Bone damage including intra-and post-operative bone fracture, osteolysis, or bone necrosis
– Injury to user
– Soft tissue damage
– Symptoms resulting from implant loosening or breakage

**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.


Do not resterilize

Re-sterilization of Variable Angle Locking Patella Plates can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

**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.

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 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**

**Warnings**
– 2.4 mm anterior-posterior locking screws may only be used in small, non-load bearing fragments.
– Do not cut the body of the plate to prevent compromising the structural integrity of the plate.
– When cutting the plate, failure to smooth sharp edges may result in user injury or soft tissue irritation for the patient.
– During plate contouring, do not bend the plate beyond what is required to match the anatomy. Reverse bending or use of the incorrect instrumentation for bending may weaken the plate and lead to premature plate failure.
– To achieve the lowest profile construct, do not use cortex screws for anterior to posterior screw fixation.
– If using cortex screws with a complex fracture, ensure the fragments are not secondarily displaced.
– An augmentation technique (e.g. with suture, independent lag screws) should be considered for peripheral bone fragment fixation with soft tissue approximation to ensure stability of fragments during bone and soft tissue healing.

– For retinaculum repair, ensure the soft tissue can be anchored without tilting the patella and affecting biomechanics of the joint.
– If the plate is used as an anchor point to reapproximate soft tissue, suture should be threaded through the windows of the plate, not the VA locking holes. Threads of locking holes can result in suture breakage. Suture should be placed to avoid migration and loosening.
– When removing the implant, first unlock all locking screws before removing them completely, otherwise the plate may rotate and damage the soft tissue of the patella.

**Precautions**
– Selection of plate material should take into account any known patient allergies.
– To help avoid soft tissue irritation, cut as close as possible to the distal hole without damaging the variable angle hole.
– The patellar tendon should be split longitudinally as needed when using a leg to capture distal pole fragments. Transverse incisions should not be made into the patellar tendon to avoid rupture or other soft tissue damage.
– Bend the plate between the VA locking holes using adjacent holes. Do not deform the threaded part of the holes or overbend the plates during bending as this may adversely affect insertion of variable angle locking screws.
– Plate legs should be placed as to not interfere with the articular surface.
– The sequence of screw insertion is important to note when using polar and rim screws of the 3-hole and 6-hole patella plates. Failure to insert screws in the recommended sequence may result in obstruction with other screws and consequently, inability to deliver a stable construct.
– A minimum of two screws per fragment is recommended; however, if this is not possible due to fragment size, after placing a single screw an additional augmentation technique should be considered. Anterior to posterior directed screws should be unicortical and locking.
– Before drilling, be sure to consider screw trajectory to avoid collision with other screws, Kirschner Wires or other hardware.
– Ensure drill bits do not protrude into the articular surface.
– Free hand drilling is not recommended. It is important not to angulate more than 15 degrees from the central axis of the screw hole. Over angulation may result in difficulty while locking the screw and inadequate screw locking. To ensure that the drill guide is locked correctly, do not angle the drill bit in excess of +/- 15 degrees from the nominal trajectory of the hole.
– During screw placement, do not over-tighten the screws. This allows for the screws to be easily removed should they not be in the desired position.
– Ensure screws do not protrude into the articular surface. Use image intensification, finger palpation or direct visualization as needed to help confirm that screws do not protrude through the articular surface.

**Combination of Medical Devices**
VA Locking Anterior Patella Plate 2.7 can be used in conjunction with the following screw implants:
Variable Angle Locking Screw ∅ 2.7 mm
Cortex Screw ∅ 2.7 mm

In addition, for non-load bearing fragments:
Variable Angle Locking Screw ∅ 2.4 mm
Cortex Screw ∅ 2.4 mm

Synthes has not assessed 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 F 2213-06, ASTM F 2052-14 and ASTM F 2119-07**
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 F 2182-11a**
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 Magnetic Resonance (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**

**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**
1. Unlock all screws from the plate.
2. Remove the screws completely from the bone.
3. Remove the plate.

**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 reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information".

**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.

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