Clavicle Fixation System

Osteosynthesis Plate System

Small and Large Fragment Sets

Small, Narrow and Broad Compression Plates

⅓ Tubular Plate

Cortical and Cancellous Bone Screws

Instructions for Use 191-051-500 Rev. G Issue Date:10/2020

CE 0123

Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

U.S. Federal law restricts this device to sale, distribution and use by or on the order of a physician.

1 General Instructions

The Signature Orthopaedics' Clavicle Fixation System and Osteosynthesis Plate System are intended to fix fractured bones to allow biological healing to take place. Screws and/or plates are applied across the fracture to set the bone fragments.

Prior to undertaking the procedure, patients must be evaluated according to the indications and contraindications of the particular system, as well as the patient selection criteria included in this document. Patients must also be informed of the precautions and possible adverse effects of the procedure, and of appropriate postoperative recovery procedures.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implants, but must also be aware of their mechanical limitations. The device is intended to set the fractured bone temporarily to allow long term biological fixation to take place. The device is not intended to support in-vivo loading indefinitely.

Signature Orthopaedics implants and instruments should only be used with approved devices and accessories.

2 Clavicle Fixation System

The Clavicle Fixation System is intended for use to repair fractures of the clavicle where expected post-operative loading is low. It is the surgeons responsibility to evaluate the suitability of an implant on an individual case basis. The contents of the small fragment set include:

Part Number	Part	Sizes
10-001132 to 20-001147	Mid-Clavicle Plate	Left or right, normal or long, adolescent or regular, 6-10 holes, 75-133mm long
20-001294 to 20-001301	Distal Clavicle Plate	Left or right, hybrid or regular, 10 to 13 holes, 71 to 107mm long
20-001436 to 20-001439	Clavicle Plate Extended	Left or right, 6 or 8 holes, 101 or 105mm long
20-001314 to 20-001324	2.7mm Clavicle Plate Locking Screw	10 to 30mm
551010 to 551030	3.5mm Self Tapping Cortical Bone Screw	10 to 30mm

Use of compatible plates and screws is critical. Adolescent plates accept 2.7mm screws. Adult plates accept 3.5mm screws. Distal plates accept 2.7mm screws at distal locations, and 3.5mm screws in medial and mid-distal locations. Locking screws are only to be used in locking holes.

Components of the Clavicle Fixation System are manufactured from 316LVM Stainless Steel, in accordance with ISO 5832-1 and ASTM F138.

The screws and plates of the Clavicle Fixation System are intended to span and apply compression across the fracture to allow biological healing to take place. For details on the use of the set, please consult the Signature Orthopaedics supplied Surgical Technique.

The Clavicle Fixation System is supplied non-sterile and is intended to be cleaned and sterilized prior to use in accordance with the procedure outlined in section 13 of this document. Implanted components are intended for single use, and must be disposed of following explantation. Implants that are brought into the operating theater but are not implanted may be reused following cleaning and sterilization. Instruments supplied with this set are also reusable, and are to be cleaned and sterilized between uses.

3 Small Fragment Set

The Small Fragment set is intended for use where small bones are fractured and expected post-operative loading is low. This may be the case for fractures of the radius, ulna, humerus, clavicle, fibula or pelvis. It is the surgeons responsibility to evaluate the suitability of an implant on an individual case basis. The contents of the small fragment set include:

Part Number	Part	Sizes
191-05-1002 to 191-05-1012	1/3 Tubular Plate	2 hole, 26mm to 12 hole, 146mm
191-05-2202 to 191-05-2224	Small Compression Plate	2 hole, 25mm to 24 hole, 288mm
191-05-6310 to 191-05-6301	Cancellous (HB) Series 4 Lag Screw	10mm to 100mm
191-05-6410 to 191-05-6401	Cancellous (HB) Series 4 Screw	10mm to 100mm
191-05-5816 to 191-05-5850	Cortical (HA) Series 3.5 Lag Screw	16mm to 50mm
191-05-5310 to 191-05-5303	Cortical (HA) Series 3.5 Screw	10mm to 130mm
191-05-4000	Small Fragment Washer	-

Use of compatible plates and screws is critical. The 1/3 tubular and small compression plate may only be used with the 3.5mm cortical and 4.0mm cancellous screws. The clavicle plates may only be used with the 2.7mm and 3.5mm self tapping cortical bone screws.

Components of the Small Fragment set are manufactured from 316LVM Stainless Steel, in accordance with ISO 5832-1 and ASTM F138.

The screws and/or plates of the small fragment set are intended to span and apply compression across the fracture to allow biological healing to take place. Lag screws are to be used to set bone fragments without the use of plates, such that the threaded portion of the screw engages only the fragment on the far side. Kirschner wires and Steinmann pins may be used to align fragments prior to application of the screws and plates. For details on the use of the set, please consult the Signature Orthopaedics supplied Surgical Technique.

The small fragment set is supplied non-sterile and is intended to be cleaned and sterilized prior to use in accordance with the procedure outlined in section 13 of this document. Implanted components are intended for single use, and must be disposed of following explantation. Implants that are brought into the operating theater but are not implanted may be reused following cleaning and sterilization. Instruments supplied with this set are also reusable, and are to be cleaned and sterilized between uses.

4 Large Fragment Set

The Large Fragment set is intended for use where large bones are fractured and expected post-operative loading is higher. This may be the case for fractures of the tibia or femur. Use of the Large Fragment set may also be required for compound or largely comminuted fractures, where the fracture must be set across a greater length. It is the surgeons responsibility to evaluate the suitability of an implant on an individual case basis. The contents of the Large Fragment set include:

Part Number	Part	Sizes
191-05-2002 to 191-05-2024	Narrow Compression Plate	2 hole, 35mm to 24 hole, 386mm
191-05-2102 to 191-05-2126	Broad Compression Plate	2 hole, 35mm to 26 hole, 418mm
191-05-6230 to 191-05-6101	Cancellous (HB) Series 6.5 Lag Screw	30mm to 150mm
191-05-6625 to 191-05-6615	Cancellous (HB) Series 6.5 Screw	25mm to 150mm
191-05-5414 to 191-05-5445	Cortical (HA) Series 4.5 Screw	14mm to 145mm
191-05-5514 to 191-05-5545	Cortical (HA) Series 4.5 Lag Screw	22mm to 100mm
191-05-6700	Large Fragment Washer	-

Use of compatible plates and screws is critical. The narrow and broad compression plates may only be used with the 4.5mm cortical and 6.5mm cancellous screws.

Components of the Large Fragment set are manufactured from 316LVM Stainless Steel, in accordance with ISO 5832-1 and ASTM F138.

The screws and/or plates of the Large Fragment set are intended to span and apply compression across the fracture to allow biological healing to take place. Lag screws are to be used to set bone fragments without the use of plates, such that the threaded portion of the screw engages only the fragment on the far side. Kirschner wires and Steinmann pins may be used to align fragments prior to application of the screws and plates. For details on the use of the set, please consult the Signature Orthopaedics supplied Surgical Technique.

The Large Fragment set is supplied non-sterile and is intended to be cleaned and sterilized prior to use in accordance with the procedure outlined in section 13 of this document. Implanted components are intended for single use, and must be disposed of following explantation. Implants that are brought into the operating theater but are not implanted may be reused following cleaning and sterilization. Instruments supplied with this set are also reusable, and are to be cleaned and sterilized between use.

5 Indications

The Osteosynthesis Plate system is intended to treat fractures in the pelvis and the diaphysis of long bones, including the clavicle, humerus, radius, ulna, femur and tibia.
The Clavicle Fixation system is intended for:

- Treatment of mid-shaft and distal clavicle fractures and non-unions.
- Neurovascular injury or compromise that is progressive or that fails to reverse with closed reduction of the fracture.
- Severe displacement caused by comminution, with resultant angulation and tenting of the skin severe enough to threaten its integrity and that fails to respond to closed reduction.
- An open fracture that requires operative debridement.
- Multiple trauma, when mobility of the patient is desirable and closed methods of immobilisation are impractical or impossible.
- A floating shoulder with a displaced clavicle fracture and an unstable scapula fracture or with compromise of the acromioclavicular and coracoacromial ligaments.
- Factors that render the patient unable to tolerate closed immobilisation, such as seizure disorders, or other neurovascular disorders.
- Cosmetic reasons.

6 Contraindications

The Osteosynthesis Plate system is contraindicated for:

- Patients with active, systemic infection.
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

The Clavicle Fixation System is contraindicated for:

- A psychologically unsuitable patient, or a patient with limited ability and/or willingness to restrict activities and/or follow directions during the healing process.

- A patient with skin, bone, circulatory and/or neurological deficiency, and/or previous infection that may retard healing.
- Foreign-body sensitivity. Appropriate tests should be made and sensitivity ruled out prior to implantation if foreign-body sensitivity is suspected.
- Active infection.
- Inadequate bone stock.
- A patient under the age of 12 or with a highly undeveloped skeleton.
- A patient with highly osteoporotic bone.

7 Warnings and Precautions

1) U.S Federal law restricts this device to sale by or on the order of a physician.
2) It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device. These instructions must be read in their entirety before use of the device.
3) The sets are supplied non-sterile and are intended to be cleaned and sterilized prior to use in accordance with the procedure outlined in section 13 of this document. Implanted components are intended for single use, and must be disposed of following explantation. Reusing implanted components increases the likelihood of fatigue failure and may lead to cross-contamination between patients, and is strictly prohibited. Implants that are brought into the operating theater but are not implanted may be reused following cleaning and sterilization. Instruments supplied with this set are also reusable, and are to be cleaned and sterilized between use.
4) Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.
5) Correct handling of implants is extremely important. Do not modify implants. Do not notch implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Do not excessively contour the plates.
6) Prior to use, inspect the device to ensure it is not damaged. Do not use a device that is scratched, bent or damaged in any way.
7) Correct selection of the implant is extremely important. The potential for success in open reduction internal fixation procedures is increased by the selection of the proper type of implant. Small plates have inadequate strength to support high post-operative loading, where large plates may impinge surrounding structures or increase the occurence of stress shielding. While proper selection can help minimize risks, the devices are not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
8) Prosthetic components from different manufacturers must not be combined. All devices should only be used according to the package directions in conjunction with the specified surgical technique and instructions for use. Additional warnings and precautions may be included in component literature.
9) Careful attention should be paid to asepsis and avoidance of anatomical hazards. Thorough debridement during the procedure is recommended to reduce the likelihood of infection.
10) Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or the fractured bone. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
11) Do not attempt to implant this device within cartilage epiphyseal growth plates or nonosseous tissue.
12) The implants can loosen or fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
13) The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
14) Signature Orthopaedics does not recommend MR imaging for any patients implanted with the Clavicle Fixation system's or Osteosynthesis Plate system's components without prior consultation with an expert radiologist for assessment of potential adverse events such as device movement, localized burns, torsional or shear strain on the implanted device.

8 Possible Adverse Events

The Signature Orthopaedics' Osteosynthesis Plate System and Clavicle Plate System has the following possible adverse events:

- Delayed union, non-union or pseudoarthrosis of the fracture
- Refracture after plate removal
- Shortening of the limb
- Reduced function or range of motion of the opreated limb
- Soft tissue irritation
- Mild inflammatory reaction
- Foreign body reaction
- Infection
- Allergic reaction

9 Preoperative Planning

A thorough clinical evaluation of the patient must occur prior to undertaking surgery. Radiological scans must be taken to allow assessment of the bony anatomy for possible deformities. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.

At the time of the operation, the corresponding implantation instruments in addition to a complete set of implants must be available. It is important to determine pre-operatively whether the patient is allergic to any of the implant materials.

10 Postoperative Care and Mobilization

Instructions to the patient to reduce stress on the implants are an important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. Patients who are at risk of non-compliance with post-operative activity limitations are contraindicated for this procedure. Immobilization of the fracture site may also be necessary following removal of the plate to reduce the likelihood of refracture.

11 Patient Information

In addition to the contraindications for use, precautions and possible adverse effects, it is critical that the patient is aware that activity increases the risk of device failure. The likelihood of clinical success is increased by appropriate postoperative care and the patient's ability and willingness to adhere to the surgeon's recommendations.

12 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the product or its packaging are damaged please return the component to Signature Orthopaedics.

13 Cleaning and Sterilization

The sets are supplied non-sterile and are intended to be cleaned and sterilized prior to use. Implanted components are intended for single use, and must be disposed of following explantation. Implants that are brought into the operating theater but are not implanted may be reused following cleaning and sterilization. Instruments supplied with this set are also reusable, and are to be cleaned and sterilized between use.

A complete guide for reprocessing unused implants and reusable instruments may be provided upon request.

As a guideline, the following cleaning method is recommended:

Manual Cleaning

Components are to be cleaned immediately after use with warm water and a mild detergent. Components consisting of multiple components must be disassembled prior to cleaning. After cleaning, the parts should be rinsed thoroughly with de-ionized water and dried.

Cleaning before Sterilization

Components may be cleaned using a broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.

Caution:

Do not clean components with products containing Sodium Hypochlorite (NaOCl) or Sodium Hydroxide (NaOH).

Corrosive products or abrasive instruments should not be used during cleaning.

As a guideline, the following sterilization method is recommended:

Method: Steam Autoclave

Cycle: Pre-vacuum

Temperature: 132°C (270° F)

Exposure time: 4 minutes

Drying time: 30 minutes

Note:

Drying time is subject to variation depending on machine load.

Following reprocessing, implants and instruments should be thoroughly inspected to ensure that they are in good condition and operating order.

14 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray.

15 Limited Warranty / Liability

Signature Orthopaedics Europe Ltd. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians having received appropriate training in orthopaedic surgical techniques.

16 Manufacturer Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information.

For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:

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