INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
AUSTOFIX PHP PROXIMAL HUMERAL PLATING SYSTEM

The Austofix PHP provides a method of internal fixation for fractures of the proximal humerus. As with all orthopaedic devices, success varies with the patient and even in less difficult cases there is a risk of complications. The surgeon is cautioned that any of the circumstances listed under categories below may reduce the chances of a successful outcome.

GENERAL DESCRIPTION OF INTENDED USE

The Austofix Proximal Humeral Plate System (PHP) is a set of implants used for fracture fixation in orthopaedic trauma surgery. The Austofix PHP is implanted surgically by trained orthopaedic surgeons to fix fractures in the proximal humerus. There are two distinct types of implants in the system. Plates are flat or curved pieces of sheet metal with holes for placement of screws that hold the bone to the plate. They are designed to be implanted on the surface of the bone. The two calcar screw holes feature Austofix's variable angle screw technology allowing targeted placement of the screws for superior support and use a patented triple start head thread to maximise stability when locked into the plate. Bone screws fix the plate in position relative to the bone and prevent rotation. These screws also have a weight bearing function during the early weeks of fracture healing. Screws may act either by tightening the plate against the bone, or by simultaneously screwing into bone and cutting into the plate. These latter screws are then locked at a fixed angle to the plate and are referred to as locking screws. The PHP instrument set is clearly marked with the product name.

All implantable devices are single use only. PHP plates are supplied sterile in OPA packaging (gamma irradiation); non-sterile screws are to be placed in a caddy located within the instrument tray. Non-sterile product is sterilised by the user, per the Instructions noted in the RESTERILISATION section below. Austofix PHP plates are manufactured from implant grade commercially pure titanium in accordance with ISO 5832-2. All screws are manufactured from implant grade Ti-6Al-4V titanium alloy conforming to ISO 5832-3.

DEFINITION OF SYMBOLS

	Manufacturer	STERILE R	Sterilised using irradiation		Consult IFU or electronic IFU
EU REP	Authorised representative in the European Community	NON STERILE	Non-sterile		Caution
	Date of manufacture		Do not use if package is damaged, consult IFU	MD	Medical device
	Use-by date		Do not re-use	UDI	Unique device identifier
LOT	Batch code	2 STERILIZE	Do not resterilise	MR	MR Conditional
REF	Catalogue number		Double *sterile* barrier system		

INDICATIONS AND CONTRAINDICATIONS

Indications

The Austofix PHP is indicated for the fixation of fractures, non-unions and osteotomies of the proximal humerus, where open reduction and internal fixation (ORIF) are considered necessary. The PHP is indicated for skeletally mature patients, and can be used to address fusions and corrective osteotomies of the proximal humerus, non-unions, malunions, dislocated and non-dislocated two, three and four-part proximal humeral fractures. The Austofix MIPO procedure is designed to address displaced two-part fractures of the proximal humerus. All devices are designed to be used only by trained orthopaedic surgeons in a hospital environment. Devices are designed to be used only by trained orthopaedic surgeons in a hospital environment.

Contraindications

The general principles of patient selection and sound surgical judgement apply. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively. Contraindications to be avoided include:

- Patients with open epiphyseal plates.
- Insufficient quantity or quality of bone, conditions which tend to retard healing, and blood supply limitations.
- Previous or active infection.
- Foreign-body sensitivity.
- Conditions which tend to affect the patient's ability or willingness to restrict activities during the healing period.
- Contraindications for the MIPO procedure include more complex fractures which cannot be reduced with a minimally invasive approach.

POSSIBLE COMPLICATIONS

1. Loosening, bending, cracking, or fracture of the orthopaedic plates or screws, or loss of fixation in the bone, attributable to the factors listed in contraindications above and/or Warnings and Precautions below.
2. Loss of anatomic position with non-union or malunion with rotation or angulation.
3. Infections, both deep and superficial.
4. Fat embolism syndrome.
5. Allergies and other reactions to device materials.
6. Irritation of soft tissues, including impingement syndrome.

In the event of a serious incident involving an Austofix product, users must contact the manufacturer and the Competent Authority of the relevant Member State.

WARNINGS AND PRECAUTIONS

Preoperative

1. Use care in handling and storage of implant components. Cuffing, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or invisible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, and stored at temperatures below 40°C.
2. Patient conditions and/or predispositions, such as those addressed in Contraindications above, should be avoided.

3. An adequate inventory of implant sizes should be available at the time of surgery.
4. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out pre- operatively.
5. Certain special equipment is required to perform this surgery including an image intensifier and an operating table with appropriate fracture attachments. Review of the use and handling of these instruments is recommended.
6. Before the initial use of these implants, we recommend that surgeons acquaint themselves with the devices and attend a technique seminar. Surgical Technique brochures are available upon request at no charge, and should be reviewed by the surgeon prior to initial surgery. Skill in the use of this technique should be acquired on less complicated fractures before attempting its use in unstable, difficult fractures.
7. The patient should be advised that a second more minor procedure for the removal of implants may be necessary.

Operative

1. The proper plate length and width must be selected to match the bone and the fracture site. Care should be taken not to scratch, bend sharply, or cut metal components during surgery for the reasons stated above.
2. The surgeon must ensure the Austofix PHP Smart Guide is removed from the plate prior to wound closure.
3. A stable construct should be achieved and verified by X-ray imaging.
4. Implants should never be reused to avoid cross contamination to another patient. Furthermore, internal stresses (in the implant) that are not visible may lead to early fatigue fracture.
5. Inspection and trial assembly are recommended prior to implantation to determine if instrument components or implants have been damaged during storage or prior procedure.
6. Certain special equipment is required to perform this surgery including an image intensifier and an operating table with appropriate fracture attachments. Review of the use and handling of these instruments is recommended.
7. Excessive drilling or reuse of drills can produce drill wear, bluntness and heat generation, leading to increased operating time and potential osteonecrosis.

Products labelled "do not resterilise" or "do not reuse" must not be re-sterilised or reused, as this may affect the integrity of the device, which can lead to device failure, patient injury, illness, or death. Reuse or reprocessing of single-use devices may create a risk of contamination, which could result in injury or death.

Postoperative

1. Although Austofix plates and screws are designed for maximum strength and performance, it must be well understood that they are not intended to carry the load of full patient activity for extended periods of time. All patients should be cautioned against excessive activity prior to good callus formation. For this reason, patients who are obese and/or non-compliant, as well as patients who could be predisposed to delayed or non-union, must have auxiliary support.
2. Postoperative directions and warnings to patients by physicians, and appropriate nursing care, are extremely important, particularly those warnings that concern early active use of the arm and hand. These activities substantially increase the stress on implants that can lead to complications
3. Periodic X-ray examinations for at least the first three (3) months postoperatively are necessary to detect changes in position, non- union, loosening, bending, or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and early revision considered.
4. Early weight bearing should be considered only in those cases with stable fractures and good bone-to-bone contact.
5. Reusable devices should be continually inspected and maintained between each use. In the event of breakage or significant degradation, return device to manufacturer or dispose in accordance with local laws.
6. The devices have not been clinically evaluated for safety and compatibility in a 'Magnetic Resonance' (MR) environment and have not been tested for heating or migration in a MR environment, unless specified otherwise on the label or in the surgical technique. However, devices have minimal ferro-magnetism with minimal risk in strong magnetic fields since devices are fixed in bone. The Austofix Standard L&C Orthopaedic Plate System is classified as MR Conditional for MRI Environments of 3.0 T, with the following recommendations:

- Static Magnetic Field of 3.0-Tesla; Maximum spatial gradient magnetic of 3.69 T/m; Whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning in the Normal Operation Mode of operation for the MR System.
- 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 an 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.
- When submitted to MRI scanning, it is possible the occurrence of image artifacts that can extend approximately 169 mm when submitted to a magnetic field of 3.0 T.

7. A Summary of Safety and Clinical Performance (SSCP) for this device system has been prepared and is available from the publicly-accessible medical device database, EUDAMED.

PACKAGING AND LABELLING

Implants labelled as sterile have been sterilised by a minimum of 25 kiloGrays of gamma irradiation. Inspect packaging for punctures or other damage prior to surgery. All implants that are provided sterile should be accepted only if the factory packaging and labelling arrive intact. If the sterile barrier has been compromised in any way, the devices should not be used. Any such instances should be reported to the manufacturer and the devices returned via the supplier for evaluation by the manufacturer.

RESTERILISATION

Only the reusable instrument sets are intended to be sterilised by the user, and may be resterilised if necessary, by steam autoclaving in appropriate protective wrapping. The following process parameters are recommended for these devices: Manual Clean: 10L water (max temperature 35°C) dosed with 4mL/L of Viruzyme V. Then Automatic clean: Prewash cold water (3 min), Wash: Neutral Enzymatic Chemistry (Amity Viruzyme-V) dosed at 4mL/L (192ml) @ 60°C, 12 min, Rinse: Incoming Hot Water, 1 min, Thermal Disinfection: Reverse Osmosis Water, 93°C @ 1 min, 0.3ml/L (14, 4ml) Rinse Aid pH Neutral. Sterilise: Pre-vacuum cycle, 4 minutes at 134 C, followed by 20 minutes of drying time. Detailed instructions for reprocessing, including cleaning, disinfection and resterilisation, are provided in the companion document: *F40-LG-07 General Requirements for Reprocessing*.

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