INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
AUSTOFIX VRP 2.0+ DISTAL RADIUS PLATING SYSTEM

The Austofix VRP 2.0+ provides a method of internal fixation for fractures of the distal radius. 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 VRP 2.0+ consists of profiled plates, anatomically shaped to fit the distal radius, which are fixed by 2.5mm locking and non-locking screws. The system is indicated for the fixation of fractures, non-unions and osteotomies of the distal radius. The VRP 2.0+ can be used to stabilize both dorsal and volar displaced fractures as well as intra-articular fractures. The instrument set includes a basic set of bone instruments, K-wires, drills, and specific drill guide instruments to ensure accurate alignment of the screws. The VRP 2.0+ instrument set is clearly marked with the product name.

All implantable devices are single use only. VRP 2.0+ plates are supplied sterile (gamma irradiation) in two layers of OPA packaging, screws and instruments are prided non-sterile 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 VRP 2.0+ 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 VRP 2.0+ system is indicated for the fixation of fractures, non-unions and osteotomies of the distal radius, where open reduction and internal fixation (ORIF) are considered necessary. The VRP 2.0+ can be used to stabilise both dorsal and volar displaced fractures as well as intra-articular fractures. The primary indication for using the Radial Styloid Plate is an extra-articular or intra-articular fracture of the distal radius where a styloid fragment needs support. The Dorsal Plates are intended for fixation of complex intra-articular fractures and osteotomies of the distal radius in adults. 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.

POSSIBLE COMPLICATIONS AND SIDE EFFECTS

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 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.

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1. An adequate inventory of implant sizes should be available at the time of surgery.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out pre- operatively.
3. 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.
4. 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.
5. 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 VRP 2.0+ 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. 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.

MRI Safety Information

Austofix devices should be considered MR Conditional. Devices have minimal ferro-magnetism with minimal risk in strong magnetic fields, since devices are fixed in bone. Austofix recommends the following when using VRP2.0+ plates in an MRI environment.

- Static magnetic field strength (T) 1.5T or 3.0T; Maximum special field gradient 30T/m (3000 gauss/cm); RF excitation Circularity Polarised (CP); RF transmit coil type Integrated Whole Body Transmit Coil; Operating mode Normal Operating Mode; Maximum whole-body SAR (W/kg) 2 W/kg (Normal Operating Mode);
- Scan Duration 1.5T or 3.0T - 2 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 15 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes);
- MRI image artifact - The presence of this implant can produce an image artifact of approximately 32 mm from the system when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

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*.

Disposal

Hospitals should dispose of explanted devices using established procedures for clinical waste.

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