# INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
# AUSTOFIX SINGLE-USE INSTRUMENTS

GENERAL DESCRIPTION OF INTENDED USE

Sterile, single-use surgical instruments, used in conjunction with the reusable procedure kits listed in this document, are necessary to perform orthopaedic surgical procedures. Guidewires and drills are used to prepare bones and facilitate the implantation of Austofix trauma devices. K-wires are required for provisional, temporary fixation and for checking alignment. Guidance on their usage is in each relevant implant's surgical technique manuals.

All Austofix instruments labelled as 'sterile' or 'single-use' are not intended to be reused.

**Intramedullary Nailing Systems**
F1 Procedure Kit
F2 & F3 Procedure Kit
S2 & UTN Procedure Kit
Lower Limb Procedure Kit
PHN Procedure Kit
Ezy-Aim Procedure Kit
Elastic Nail Procedure Kit
Flexible Reamer Procedure Kit

**Orthopaedic Plates and Screw Systems**
VRP 2.0 Procedure Kit
Tectona Procedure Kit
Mini, Small and Large Fragment Procedure Kits
Universal Trauma Procedure Kit
Minimally Invasive Procedure Kits
Foot and Ankle Procedure Kit
Cannulated Screw Procedure Kits

For intramedullary nails, instrumentation is intended to facilitate the insertion of stainless steel or titanium implants into the medullary canals of any of the three long bones (humerus, femur and tibia) for the purpose of fracture fixation in orthopaedic trauma surgery. Instruments also allow for the preparation of bone and cross-drilling of screws to fix nails in place where required.

For orthopaedic plates and screws, instrumentation is designed to facilitate the placement of titanium plates onto the surface of bones for the fixation of fractures via open reduction and internal fixation. Instruments are also used to fix screws to the bone and/or plate, by either tightening the plate against the bone, or by simultaneously screwing into bone and into a tapped hole in the plate.

CLINICAL BENEFITS

The clinical benefits for all Austofix instrumentation depends on the specific indications and applicable intended use of the related implants. All intramedullary nails, orthopaedic plates and screws are intended for the fixation of bone fractures, and the instruments are intended to facilitate their implantation. The goal of all these devices when used together is the successful union of bone fractures, with the patient's return to at or near pre-injury function.

DEFINITION OF SYMBOLS

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|  | Manufacturer |  | Sterilised using irradiation |  | Consult IFU or electronic IFU |
|  | Authorised representative in the European Community |  | Non-sterile |  | Caution |
|  | Date of manufacture |  | Do not use if package is damaged, consult IFU |  | Medical device |
|  | Use-by date |  | Do not re-use |  | Unique device identifier |
|  | Batch code |  | Do not resterilise |  | Double *sterile* barrier system |
|  | Catalogue number | | | | |

INDICATIONS AND CONTRAINDICATIONS

**Intramedullary Nailing Systems**

*Indications*

- Indications for interlocking intramedullary nails include severely comminuted, spiral, long oblique and segmental fractures;
- nonunions and malunions;
- bone lengthening/shortening.
- The general principles of patient selection and sound surgical judgment apply. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

*Contraindications*

- 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. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
- Conditions which tend to affect the patient's ability or willingness to restrict activities during the healing period.
- Skeletal deformity precluding nail use or obliterated medullary canal.

**Orthopaedic Plate and Screw Systems**

*Indications*

*(Mini Fragment Systems)*

- Austofix Mini Fragment plates, including the VRP 2.0 Distal Radius Plate System, are intended for the fixation correction or stabilization of small bones in the hand, wrist, foot and ankle. Specifically, these include:
- Fractures of the phalanges, metacarpals, and wrist bones in the distal radius and ulna;
- Fractures of the phalanges, tarsals/metatarsals, and ankle bones in the distal tibia and fibula;
- Osteotomies and arthrodesis of the interphalangeal joints.

*(Small Fragment Systems)*

- The Small Fragment systems are indicated for the fixation of fractures, non-unions and osteotomies. The 3.5mm plates are designed for the fixation of small bone fragments of the upper and lower limbs where open reduction and internal fixation are considered necessary, and in some cases minimally invasive surgical techniques. The general principles of patient selection and sound surgical judgement apply.
- The generic, reconstruction and T-plates are suitable for fracture fixation and fixation after osteotomies, malunions and non-unions for regions including but not limited to the radius, ulna, humerus, clavicle, tibia and fibula.

*(Large Fragment Systems)*

- The Austofix Large Fragment systems are indicated for the fixation of fractures, non-unions and osteotomies in the upper and lower limbs.
- The 4.5mm and 5.0mm plates are indicated to fix fractures of long bones, including the humerus, femur and tibia., where open reduction and internal fixation are considered necessary, and in some cases minimally invasive surgical techniques.
- The general principles of patient selection and sound surgical judgement apply.

*Contraindications*

- Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively. Certain patient conditions and/or predispositions should be avoided:
- Patients with open epiphyseal plates;
- Insufficient quantity or quality of bone, conditions which tend to retard healing, and blood supply limitations.
- Previous or active infections;
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation;
- Conditions that tend to affect the patient's ability or willingness to restrict activities during the healing period.

POSSIBLE COMPLICATIONS

1. Loosening, bending, cracking, or fracture of the orthopaedic plates, nails 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, etc.
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 the surgeon acquaint himself with them 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. As a general guide, reaming to a diameter at least 1.5mm greater than the nail should always be considered.
7. The patient should be advised that a second more minor procedure for the removal of implants may be necessary.
8. Before the initial use of these instruments, we recommend that the surgeon become acquainted with them and attend a technique seminar. Surgical Technique booklets are available upon request at no charge, and should be reviewed by the surgeon prior to initial surgery. Instruments specific to each type of nail are described in the relevant Surgical Technique booklet.

Operative.

1. Selection of the proper nail length and diameter is extremely important and must be carefully sized to the patient, taking into account the patient's age, weight, and cortical bone quantity. As a general rule, the largest implant that easily fits the canal should be used. Small canals require enlargement by reaming.
2. Inspection and trial assembly are recommended prior to implantation to determine if instrument components or implants have been damaged during storage or prior procedure.
3. Care should be taken not to scratch, bend sharply, or cut metal components during surgery for the reasons stated.
4. Refer to the outer carton labels, surgical technique, or product catalogue for information on the correct size of screws for each nail.
5. A stable construct should be achieved and verified by Xray imaging.
6. Once removed from the patient, implants should never be reused since internal stresses (in the implant) that are not visible may lead to early bending or fracture.
7. 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.
8. Excessive drilling or reuse of drills can produce drill wear, bluntness and heat generation, leading to increased operating time and potential osteonecrosis.

Postoperative

1. Postoperative directions and warnings to patients by physicians, and appropriate nursing care, are extremely important, particularly those admonitions that concern early weight-bearing or active use of the extremities. These activities substantially increase the stress on implants that can lead to complications.
2. 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.
3. Early weight bearing should be considered only in those cases with stable fractures and good bone-to-bone contact.
4. 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.
5. Austofix devices have not been 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. This is well known to operators of MRI machines. See surgical techniques for information.

PACKAGING AND LABELLING

These single use instruments have been sterilised by a minimum of 25 kiloGrays of gamma irradiation. Inspect packaging for punctures or other damage prior to surgery. All devices provided sterile should be accepted only if the factory packaging and labelling arrive intact. If the sterile barrier has been broken, refer to the Resterilisation section below for additional instructions.

RESTERILISATION

Products labelled "do not resterilise" or "do not reuse" must not be re-sterilised or reused, as these 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.

Procedures kits are intended to be reused and resterilised, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all of the original packaging. The following process parameters are recommended for these devices: Ultra sonic solution: Sonic 1; Enzyme cleaners: Medizyne – Neutral pH Enzyme Cleaner (manual clean); Disinfectant: Aidal-Plus (manual disinfect); 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.

STERILE R

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