INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
AUSTOFIX INTRAMEDULLARY NAILING SYSTEM

Intramedullary nails provide a method of internal fixation of long bone fractures. Insertion by closed technique as compared to open techniques provides fixation with minimal trauma, reduced risk of infection, and reduced blood loss. As with all orthopaedic devices, success varies with the patient and even in the less difficult case 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 Intramedullary Nailing System is a family of titanium implants used for fracture fixation in orthopaedic trauma surgery. The Austofix nailing system is implanted surgically by trained orthopaedic surgeons to fix fractures in any of the three long bones: humerus, femur and tibia. There are two distinct types of implants in this system. Intramedullary nails are long narrow solid or tubular rods of circular cross-section, with cross holes for placement of locking screws. They are designed to be implanted inside the hollow 'medullary canal' of the humerus, femur and tibia. Intramedullary screws are bone screws, which fix the nail in position relative to the bone and prevent rotation. The nail and screws function as a type of internal splint, holding the broken bone in place until it grows together again. Around the one-two month period, the fracture should have healed sufficiently to be taking the full weight of the patient, and the implants no longer perform any function. It is safe for them to remain in situ indefinitely, but they are often removed approximately one year after insertion. Hence, the implants themselves have an indefinite life either before or after implantation.

The implants are available in different configurations and sizes for different fracture types and anatomies. However, the same basic fixation techniques apply for each type. The instrument set includes a basic set of surgical instruments, K-wires, drills, and specific drill guide instruments to ensure accurate alignment of the implants. Each instrument set is clearly marked with the product name.

All implantable devices are single use only. Nails and screws are supplied sterile (gamma irradiation) in two layers of OPA packaging. All intramedullary nails and screws are manufactured from implant grade titanium alloy in accordance with 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	MR	MR Conditional		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		Do not resterilise		
REF	Catalogue number		Double *sterile* barrier system		

INDICATIONS AND CONTRAINDICATIONS

Indications

Indications for interlocking intramedullary nails include severely comminuted, spiral, long oblique and segmental fractures, non-unions and malunions, and bone lengthening/shortening. The general principles of patient selection and sound surgical judgement apply. The size and shape of the long bones present limiting restrictions on the size and strength of implants. Specific indications for intramedullary nailing depend on the anatomical location 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. 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.
- Skeletal deformity precluding nail use or obliterated medullary canal.

POSSIBLE COMPLICATIONS AND SIDE EFFECTS

1. Loosening, bending, cracking, or fracture of the 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.

INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
AUSTOFIX INTRAMEDULLARY NAILING SYSTEM

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 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. 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.
6. The patient should be advised that a second more minor procedure for the removal of implants may be necessary.

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 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, implants should never be reused since internal stresses (in the implant) that are not visible may lead to early bending or fracture.
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 Nails are designed for maximum strength and performance, it must be well understood that intramedullary nails are not intended to carry the full load of the patient acutely nor for extended periods of time. All patients should be cautioned against significant weight bearing 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. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries.
2. Additional postoperative precautions should be taken when the fracture line occurs within 5cm of the nail's screw hole, as this situation places greater stress on the nail.
3. 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.
4. 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.
5. Early weight bearing should be considered only in those cases with stable fractures and good bone-to-bone contact.

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 INS 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 2 W/kg whole-body average SAR for 6 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 6 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes); 3.0T 2 W/kg whole-body average SAR for 1 hour (or 60 minutes) of continuous RF (a sequence or back to back series/scan without breaks).
- MRI image artifact - The presence of this implant can produce an image artifact of approximately 27 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.

Manufacturer
Australian Orthopaedic Fixations Pty Ltd
(t/a Austofix)
28 Dalgleish St Thebarton SA 5031 AUSTRALIA
Ph: +61 8 8351 0644
info@austofix.com.au www.austofix.com.au

EU REP
Advena Ltd. Tower Business
Centre, 2nd Flr., Tower Street,
Swatar,
BKR 4013 Malta

CE 2797

MR STERILE R

Austofix

700001 INS IFU Rev 16
March 2026