INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
AUSTOFIX REUSABLE PROCEDURE KITS

Austofix reusable procedure kits are not intended to be single use. Any instruments labelled as 'sterile' are single-use only and provided separately. All devices contained within the instrument sets listed below are intended to be reused, after cleaning and sterilisation has been performed by the user to the manufacturer's instructions. These instructions for reprocessing have been validated by the company and are provided in a separate document: *F40-LG-07 General Requirements for Reprocessing Rev 4*.

GENERAL DESCRIPTION OF INTENDED USE

Procedure Kits include non-sterile devices located in instrument trays intended to manipulate tissue, assist in inserting implantable devices, or guide other instruments such as drills and pins. Instrument trays consist of multiple devices, which include but are not limited to nail-holders, awls, retractors, forceps, tissue guards, drill sleeves, screwdrivers and alignment guides. Instruments are manufactured from aluminium, stainless steel, and some with polymer components such as handles.

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.

Proximal holes on intramedullary nails are located with fixed nail-mounted drill guides. Because of some bending of the nails, the distal holes require a targeting procedure, either by repeated X-ray visualisation or, with the Ezy-aim system, using the principle of electromagnetic pulse induction.

- A Control Box (part# 610055) is powered by re-chargeable batteries and sends pulsed signals through each side of the Transmitter (part # 610056). These signals are received by the Sensor (part# 610057) which is placed inside the nail, but connected to the Control Box.
- The Ezy-Aim Small sensor (610059) will be required for use on 8mm Cannulated Tibial Nails, and 7-9mm Cannulated Humeral Nails.
- When the signals received from each side of the Transmitter are equal, the device is aiming at the hole in the nail. Accurate positioning of the Sensor is obtained by the use of the Sensor Length Stop (part# 610058).
- The Control Box is not sterilised, but the other 3 parts are sterilised by autoclaving.
- Detailed instructions are outlined in the surgical technique: *700402 Austofix Ezy-Aim Electronic Distal Targeting System*.

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 reusable procedure kits 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.

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.

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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. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out pre-operatively.
4. 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.
5. The patient should be advised that a second more minor procedure for the removal of implants may be necessary.
6. Prior to surgery the status of the Ezy-Aim battery charge is checked by pressing the red on/off button, waiting one minute, and observing the display on the screen. If less than half charged, the battery is charged with the Smart Charger (For 2.4-7.2V NiMH/NiCD Battery Packs) which is supplied.
7. The Control Box runs on firmware that is encoded during manufacture, not software. This is not able to be altered by users in the field.
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, and the use of the Ezy-Aim system itself is described in the Ezy-aim Surgical Technique.

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. 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.
5. Other metal objects must not be within 100mm of the targeting area during Ezy-Aim usage.
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.

Postoperative

1. 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.
2. A thorough manual clean before automated cleaning process is considered essential for this kit. The steps in the following table provide suitable cleaning.

Manual cleaning step	**Description**
Pre-Rinse	Pre-rinse instruments in a sink to remove gross debris for 5 min
External Wash	Scrub externally to remove organic soil in soaking bath
Internal Wash	Scrub through cannulations to remove internal contamination
Channel Flush (H2O)	Flush instrument channels using water gun
Channel Flush (Air)	Flush with air over white cloth to determine if any excess soil still present

3. An ultrasonic wash is recommended for all devices after the manual clean and before the automatic washer/disinfector cycle. The following parameters are sufficient to remove any remaining soil while not damaging the devices:

Phase	**Time**	**Temperature**	**Chemical Used**	**Dosage**	**Frequency**
Wash	15 mins	35ºC	Viruzyme V	4mL/L	20kHz

4. The following automatic washer disinfector cycle will remove all external contamination without damaging the devices:

Process / Cycle	**Programmed Exposure Time (minutes)**	**Programmed Temperature (ºC)**
Pre-wash	5	n/a – Incoming cold water
Main wash	13	60
Rinse	2	n/a Incoming hot water
Thermal Disinfection	1.5	95
Drying	n/a	n/a

PACKAGING AND LABELLING

All instruments in Austofix reusable procedure kits are provided non-sterile and are sterilised by the hospital (with the exception of the Ezy-Aim Control Box).

RESTERILISATION

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. Protect from contact with other hard objects. The three components of the Ezy-Aim system, the Transmitter (part # 610056), Sensor (part #610057) and Sensor Length Stop (part 610058) can be sterilised and resterilised using the same method.

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.
The following process parameters are recommended for these devices: Pre-vacuum cycle, 4 minutes at 134ºC, followed by 60 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 Rev 6.*

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
Made in Australia

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

CH REP
Swiss AR Services AG
Industriestrasse 47
CH-6300 Zug

CE 2797

700010 Austofix Procedure Kits Reusable IFU Rev

Rev. 6 Apr 2026