INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS

AUSTOFIX INTRAMEDULLARY NAIL 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

The Austofix Intramedullary Nail System consists of intramedullary nails which contain holes proximally and distally which accept associated cross-locking screws. The locking screws control the impaction and rotation of the bone fragments. Nails & screws are available in a variety of diameters and lengths. All implantable devices are for single use only and are supplied sterile (gamma irradiation). Austofix intramedullary nails & locking screws are manufactured from either implant grade stainless steel (ISO 5832-1 and ISO 5832-9) or implant grade titanium (ISO 5832-3 Ti-6Al-4V). The two materials must NOT be mixed.

INDICATIONS

Indications for interlocking intramedullary nails include severely comminuted, spiral, long oblique and segmental fractures; nonunions and malunions; and 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

1. Patients with open epiphyseal plates.
2. Insufficient quantity or quality of bone, conditions which tend to retard healing, and blood supply limitations.
3. Previous or active infection.
4. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
5. Conditions which tend to affect the patient's ability or willingness to restrict activities during the healing period.
6. Skeletal deformity precluding nail use or obliterated medullary canal.

POSSIBLE ADVERSE 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 nonunion 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.

WARNINGS AND PRECAUTIONS

Preoperative

1. Use care in handling and storage of implant components. Cutting, 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.

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.

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.
6. 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 technique for info.

PACKAGING AND LABELLING

All implants are provided sterile and 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. 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.

STERILISATION

Metal components have been sterilised by a minimum of 25 kiloGrays of gamma irradiation. Inspect packaging for punctures or other damage prior to surgery.

RESTERILISATION

Metal components may be resterilised, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all of the original packaging and labelling. Protect from contact with other hard objects. The following process parameters are recommended for these devices: Pre-vacuum cycle, 4 minutes at 132 C to 135 C, followed by 20 minutes of drying time.

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