INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS
OSSIS SCREWS

Screws provide a method of internal fixation for fractures.
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
All implantable devices are for single use only. Screws are supplied sterile (gamma irradiation). Screws are manufactured from implant grade titanium alloy (ISO 5832-3 Ti-6Al-4V).

INDICATIONS
The general principles of patient selection and sound surgical judgment apply.

CONTRAINDICATIONS
- Patients with open epiphyseal plates, 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.

POSSIBLE ADVERSE EFFECTS
- Loosening, bending, cracking, or fracture of the screws, or loss of fixation in the bone, attributable to the factors listed in Contraindications above and/or Warnings and Precautions below.
- Loss of anatomic position with nonunion or malunion.
- Infections, both deep and superficial.
- Allergies and other reactions to device materials.
- Irritation of soft tissues.

For specific contraindications for Screws it is mandatory to consult the corresponding Surgical Technique.

WARNINGS AND PRECAUTIONS

Preoperative

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.
Patient conditions and/or predispositions, such as those addressed in Contraindications above, should be avoided. An adequate inventory of implant sizes should be available at the time of surgery.
Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively. Certain special equipment is required to perform this surgery including an image intensifier. Review of the use and handling of these instruments is recommended. 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. The patient should be advised that a second more minor procedure for the removal of implants may be necessary.

Operative

The proper screw length 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. A stable construct should be achieved and verified by Xray imaging.
If a device is removed from the patient, implants should never be reused to avoid cross contamination to another patient, and, since internal stresses (in the implant) that are not visible may lead to early fatigue fracture.

Postoperative

Although 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 nonunion, must have auxiliary support.
Postoperative directions and warnings to patients by physicians, and appropriate nursing care, are extremely important, particularly those admonitions that concern early active use of the arm and hand. These activities substantially increase the stress on implants that can lead to complications.
Periodic X-ray examinations for at least the first three (3) months postoperatively are necessary to detect changes in position, nonunion, 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.

PACKAGING AND LABELLING
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. 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
Devices supplied sterile have been exposed to 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 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 134°C, followed by 20 minutes of drying time.

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.

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