perios
medical devices

STERILE SURGICAL INSTRUMENT

CARE AND HANDLING INSTRUCTIONS

Supplied Sterile, Single Use
Carefully read all instructions and be familiar with the surgical techniques prior to use.

DEFINITION OF SYMBOLS


Use by

Method of sterilisation: gamma irradiation


Read usage instructions


Not to be used if package is damaged


Do not resterilise


Single use

Catalogue number

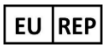
UDI

Quantity


Manufacturer


Manufacture Date

Lot number



Authorised Representative in the European community

MATERIALS

Austofix drills are manufactured from stainless steel (see outer packaging for grade).

INSPECTION

Inspect for damage to package or seal before opening. Sterility is only guaranteed if package is undamaged or unopened.
Carefully inspect instrument for damage. Damaged or defective instruments should not be used. If damaged, do not use and contact Austofix customer service or your local sales representative for a replacement.

WARNINGS

1. Do not reuse surgical instruments labelled for single use only. Reuse could adversely affect performance of the instrument.
2. Do not use cutting tools that are deformed, corroded, damaged or worn. For safe use, instrument must be free of broken or dull cutting edges.
3. Do not subject instruments to excessive force and / or impact as breakage can occur.
4. Surgical accessories like drill bits, blades, burs, chisels, rasps, taps and reamers are intended to be used only by trained medical professionals who are familiar with their use and application.
5. Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid distal migration and possible injury.
6. Delicate structures close to operation site must be protected.
7. Firm control of the instrument must be maintained to avoid injury to patient or operating room personnel.
8. Should the tip section of the instrument come into contact with other metallic objects it may cause instantaneous damage and destructive failure of the device.

PRECAUTIONS

1. Use aseptic technique to open package for delivery of device into sterile field.
2. Medical devices require special handling to prevent damage. As with all medical devices, careful attention should be made to assure that excessive force is not placed on the instrument. Excessive force may result in instrument failure.
3. Surgeons must be skilled in the use of cutting tool surgical instruments.
4. The use of an instrument in any manner or medical procedure other than those for which it is designed and indicated may result in damage or breakage.
5. Drill bit breakage most often occurs when working around metallic implants (prosthetic components, internal fixation devices, etc.). To minimise these incidents, ensure that the tip of the drill bit does not contact an implant. In case of breakage and presence of drill bit fragments, follow the appropriate orthopaedic surgery protocol.

LIMITED WARRANTY

The product is guaranteed for materials, function and workmanship for patient use. Austofix shall not be liable, expressly or implied, for any damages which might arise or be caused, whether by the customer or by any of the users of the product, as a result of:

1. Misuse, mishandling, and / or improper operation.
2. Use in any manner or medical procedure other than those for which it is designed.

PACKAGING AND LABELLING

All implants are provided sterile and should be accepted only if the factory packaging and labeling arrive intact. If the sterile barrier has been broken, refer to the Resterilisation section below for additional instructions. Products labeled "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 labeling. 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.

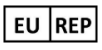
PRODUCT FEEDBACK

All questions or concerns related to quality, reliability and / or durability of this product should be directed to manufacturer customer service or an authorised representative of the manufacturer. Please contact customer service or an authorised representative for a return authorisation.


Manufacturer

Australian Orthopaedic Fixations Pty Ltd
28 Dalgleish St
Thebarton SA 5031
Australia
Ph: +61 8 8351 0644

www.austofix.com.au
info@austofix.com.au



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

CE 2797