



# INSTRUCTIONS FOR USE / WARNINGS & PRECAUTIONS

## OSSIS Single Use Instruments

### Definition of symbols

	Manufacturer		Sterilised using irradiation		Consult IFU or electronic IFU
	Authorised representative in the European Community		Catalogue number		Caution
	Date of manufacture		Do not use if package is damaged, consult IFU		Medical device
	Use-by date		Do not re-use		Unique device identifier
	Batch code		Do not resterilise		MR Conditional
	Double <i>sterile</i> barrier system				

### DESCRIPTION

Ossis surgical instruments are designed to perform specific functions such as pinning, cutting and drilling. Ossis surgical instruments may also be used to facilitate the insertion of surgical implants.

### MATERIALS

Ossis surgical instruments are manufactured from stainless steel.

### 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 the manufacturer's customer service or your local sales representative for a replacement.

### WARNINGS

- Do not reuse surgical instruments labeled for single use only. Reuse could adversely affect performance of the instrument.
- 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.
- Do not subject instruments to excessive force and / or impact as breakage can occur.
- 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.
- Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid distal migration and possible injury.
- Delicate structures close to operation site must be protected.

### PRECAUTIONS

- Use aseptic technique to open package for delivery of device into sterile field.
- 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.
- Surgeons must be skilled in the use of cutting tool surgical instruments.
- 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.
- 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. The manufacturer 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:

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

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND / OR STATUTORY, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS, AND / OR LIABILITIES ON THE MANUFACTURERS PART.

### PRODUCT COMPLAINTS

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.

### SUPPLIED

Supplied sterile. Sterility is guaranteed unless the package is damaged or open. For professional use only.

### STORAGE

Store in enclosed dust free environment away from direct sunlight below 30°C (86 °F). Maintain a relative humidity range of between 20% — 80%.

### 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.

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700023 Ossis Single Use Instruments  
Rev 2 Dec 2025

**CE**  
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