

	<b>INSTRUCTIONS FOR USE</b>	
	<b>CHISELS</b>	<b>TF01-IFU-008</b>
		<b>REVISION 1</b>

### **Intended use**

Chisels are surgical instruments used for incision/cuts and cleaving bone during surgery to reshape or cut bones. They are available in varying lengths and widths.

### **Reuse of Single Use Product**

This Product is designated as 'Single Use' ONLY. It should be used for one-patient, during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient. Along with an increased risk of infection, the safety of the product cannot be guaranteed with multiple use.

### **Product inspection before use**

Inspect device for rust, dents, cracks, pits and pores before use.

### **Warning**

- Do not use if product or sterile barrier system is damaged.
- Products supplied non-sterile must be sterilised before use.
- Please follow our sterilisation instructions prior to use.
- Do not use beyond the expiry date stated on the packaging.

### **Sterilisation**

Instruments can be sterilised using the following methods:

#### **Ethylene Oxide**

Concentration: up to 450mg/l

Temperature: 60°C

Exposure: up to 6 hours

Humidity: up to 100%

#### **Irradiation**

Dose to be validated by user, up to 70kGy.

### **Contraindications**

Instruments should not be used for anything other than their intended use. They are not to be used on patients who have an allergy or sensitivity to stainless steel, or any other component material e.g. Zinc.

### **Intended User**

Our instruments are designed for use by appropriately qualified clinicians, who will have good knowledge of their features and how they should be used. These products are not intended for use by lay persons.

### **Disposal:**

Used instruments should be disposed of in accordance with Local Clinical Waste Guidance.

		 Rociale Healthcare Ltd, Ty Mynydd, Cwm Cynon Business Park (North), Mountain Ash, Rhondda Cynon Taff, CF45 4ER, UK	<table border="1"> <tr> <td>EC</td> <td>REP</td> </tr> </table> <b>Advena Limited,</b> <b>Tower Business</b> <b>Centre, 2<sup>nd</sup> Flr, Tower Street,</b> <b>Swatar, BKR 4013, Malta</b>	EC	REP
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