



GIMA

PROFESSIONAL MEDICAL PRODUCTS

GB - USER'S GUIDE FOR REUSABLE NON-SURGICAL INSTRUMENTS

Read safe use instructions carefully before use. These instruments are intended to be used by medical practitioners who are specially trained on how to use and care of them. The incorrect use, poor or inappropriate maintenance can rapidly lead to deterioration of the instruments. The first time, and in general before and after every use, it is recommended to clean, dry and sterilise, if required, the instruments. The device must be cleaned with warm water, disinfected and rinsed if possible with distilled water. For automated cleaning no particular requirement is requested. For manual cleaning remove visible dust/spots with disposable cloth/paper, use approved and certified detergents. Always follow instructions on how to use the detergent. Also make sure that the product

does not come into contact with acids or other aggressive disinfectants that could corrode it. Disinfectants must conform to the applicable national regulation for disinfectants (such as FDA Approval, and CE Mark).

Instruments that are not dried could suffer damage by corrosion. Always dry the instruments with lint-free disposable cloths (do not use recycled cloths). If sterilization is required, European Standard ISO 17665 i.e. Steam Sterilization for Medical Devices is to be followed. Sterilization is achieved by exposing products to saturated steam at high temperatures (121°C to 134°C). Product(s) are placed in device called the autoclave and heated through pressurized steam to kill all microorganisms including spores. The device's exposure time to steam would be anywhere between 3 to 15 minutes.

Examples of minimum temperatures and times established for adequate level of microbial lethality in sterilization processes (refer table – 1 of ISO/TS 17665-2).

Temperature °C	Time Minutes
121	15
126	10
134	03

In the context of validating the sterilisation process, check the suitability of the specific measures for drying. The humidity in the container can cause the instruments to rust. Often bad, and insufficient drying, is due to the incorrect positioning of the load and the use of unsuitable types of cloths for drying.










There is no advice about maximum number of sterilisation cycles, this depends largely on the state of the product. Repeated processing has minimal effect on the devices; instruments that show signs of corrosion, damage or crack must be immediately replaced and not to be used. Always perform a visual inspection for damage or signs of wear; check for smooth functioning of medical device. It is recommended to store the device in clean and dry condition. Whilst the instruments are under warranty, repairs and/or replacement of all defective parts, for reasons that are accepted by the manufacturer, are free, with the exception of costs for labour, travel, transport, packing, etc. Damage caused by improper use of the product is not covered by the warranty.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Simboli / Symbols / Symboles / Symbole / Simbolos / Símbolos / Σύμβολα / حرف

	<p>IT Fabbricante GB Manufacturer FR Fabricant ES Fabricante PT Fabricante DE Hersteller GR Παραγωγός SA الشركة المصنعة</p>
	<p>IT Non sterile GB Non-sterile FR Pas stérile ES No estéril PT Não estéril DE Nicht steril GR Όχι αποστειρωμένο SA ليس معقم</p>
	<p>IT Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso GB Caution: read instructions (warnings) carefully FR Attention: lisez attentivement les instructions (avertissements) ES Precaución: lea las instrucciones (advertencias) cuidadosamente PT Cuidado: leia as instruções (avisos) cuidadosamente DE Achtung: Anweisungen (Warnungen) sorgfältig lesen GR Προσοχή: διαβάστε προσεκτικά τις οδηγίες (ενστάσεις) SA الحذر: قراءة التعليمات (التحذيرات) بعناية</p>
	<p>IT Leggere le istruzioni per l'uso GB Consult instructions for use FR Consulter les instructions d'utilisation ES Consultar las instrucciones de uso PT Consulte as instruções de uso DE Gebrauchsanweisung beachten GR Διαβάστε προσεκτικά τις οδηγίες χρήσης SA اقرأ بدقة وحرص تعليمات الاستخدام</p>
	<p>IT Conservare al riparo dalla luce solare GB Keep away from sunlight FR À conserver à l'abri de la lumière du soleil ES Conservar al amparo de la luz solar PT Guardar ao abrigo da luz solar DE Vor Sonneneinstrahlung geschützt lagern GR Κρατήστε το μακριά από ηλιακή ακτινοβολία SA يحفظ بعيدا عن أشعة الشمس</p>
	<p>IT Conservare in luogo fresco ed asciutto GB Keep in a cool, dry place FR À conserver dans un endroit frais et sec ES Conservar en un lugar fresco y seco PT Armazenar em local fresco e seco DE An einem kühlen und trockenen Ort lagern GR Διατηρείται σε δροσερό και στεγνό περιβάλλον SA يحفظ في مكان بارد وجاف</p>
	<p>IT Codice prodotto GB Product code FR Code produit ES Código producto PT Código produto DE Erzeugniscode GR Κωδικός προϊόντος SA كود المنتج</p>
	<p>IT Numero di lotto GB Lot number FR Numéro de lot ES Número de lote PT Número de lote DE Chargennummer GR Αριθμός παρτίδας SA رقم الدفعة</p>
	<p>IT Dispositivo medico GB Medical Device FR Dispositif médical ES Producto sanitario PT Dispositivo médico DE Medizinprodukt GR Ιατροτεχνολογικό προϊόν SA جهاز طبي</p>

	<p>IT Dispositivo medico conforme al regolamento (UE) 2017/745 GB Medical Device compliant with Regulation (EU) 2017/745 FR Dispositif médical conforme au règlement (UE) 2017/745 ES Producto sanitario conforme con el reglamento (UE) 2017/745 PT Dispositivo médico em conformidade com a regulamento (UE) 2017/745 DE Medizinprodukt im Sinne der Verordnung (EU) 2017/745 GR Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 SA جهاز طبي يتوافق مع التوجيه (UE) 2017/745</p>
	<p>IT Data di fabbricazione GB Date of manufacture FR Date de fabrication ES Fecha de fabricación PT Data de fabrico DE Herstellungsdatum GR Ημερομηνία παραγωγής SA تاريخ التصنيع</p>
	<p>IT Limite di temperatura GB Temperature limit FR Limite de température ES Límite de temperatura PT Limite de temperatura DE Temperaturgrenzwert GR Όριο θερμοκρασίας SA حد درجة الحرارة</p>
	<p>IT Limite di umidità GB Humidity limit FR Limite d'humidité ES Límite de humedad PT Limite de humidade DE Feuchtigkeitsgrenzwert GR Όριο υγρασίας SA حد نسبة الرطوبة</p>

