GIMA

PROFESSIONAL MEDICAL PRODUCTS

GB - REUSABLE SURGICAL INSTRUMENTS

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 after every use it is recommended to clean, dry and sterilise the instruments. The instruments must always be cleaned prior to sterilisation. For automated cleaning use only washing equipment with approved and certified detergents. For manu- al cleaning use approved and certified detergents, brush and running water. Always follow instructions on how to use the detergent; clean the instruments both when open and closed; rinse for 3 minutes and check that water also enters and exits the blind holes several times. Use completely demineralised water in the final rinse phase. Instruments that are not dried could suffer damage by corrosion. Always dry the instruments. After cleaning, and before sterilisation it is recommended that you treat the instruments with physiologically safe oil, especially the tips, connectors, terminals and all moving parts. Also make sure that the product does not come

into contact with acids or other aggressive disinfectants that could corrode it. The instruments must be sterilized in autoclave by moist heat sterilization method at 132°C for 15 minutes prior to use in surgery. It is recommended that sterilization temperatures should not exceed 137°C. The process of steam sterilisation must take place in accordance with EN ISO 17664. 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. Instruments that show signs of corrosion must be discarded immediately. Always perform a visual inspection for damage or signs of wear: sharp edges must be free of dents and with continuous edges; there should be no distortion of instruments with long parts; the instruments that are part of a larger assembly, must be checked together with other assembly components; always check the rotating movement of hinges, which must not have excessive play; always check that the locking systems are working. 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.

WARNINGS

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 / Símbolos / Simbolos / Σύμβολα / حرف

	**IT** Fabbricante **GB** Manufacturer **FR** Fabricant **ES** Fabricante **PT** Fabricante **DE** Hersteller **GR** Παραγωγός **SA** الشركة المصنعة
	**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
	**IT** Non sterile **GB** Non-sterile **FR** Pas stérile **ES** No estéril **PT** Não estéril **DE** Nicht steril **GR** Οχι αποστειρωμένο **SA** ليس معقم

	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
	**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 προσεχτικά τις οδηγίες χρήσης **SA** اقرأ بدقة وحرص تعليمات الاستخدام
	**IT** Conservare al riparo dalla luce solare **GB** Keep away from sunlight **FR** Á 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
	IT Conservare in luogo fresco ed asciutto **GB** Keep in a cool, dry place **FR** Á 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
REF	**IT** Codice prodotto **GB** Product code **FR** Code produit **ES** Código producto **PT** Código produto **DE** Erzeugniscode **GR** Κωδικός προϊόντος **SA** كود المنتج
LOT	**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
CE	**IT** Dispositivo medico conforme alla Direttiva 93/42/CEE; in accordo alla MDCG 2020-2, sarà reso conforme al Regolamento (UE) 2017/745, per cambio classe. **GB** Medical Device complies with Directive 93/42/EEC; in accordance with MDCG 2020-2, they shall be made compliant with Regulation (EU) 2017/745, for change of class. **FR** Dispositif médical conforme à la directive 93/42 / CEE; conformément au MDCG 2020-2, ils seront mis en conformité avec le règlement (UE) 2017/745, par changement de classe. **ES** Dispositivo médico segun a la Directiva 93/42 / CEE; en conformidad con la MDCG 2020-2, se adecuarán al Reglamento (UE) 2017/745 para el cambio de clase. **PT** Dispositivo médico em conformidade com a Diretiva 93/42/CEE, de acordo com a MDCG 2020-2, deverão estar em conformidade com o Regulamento (UE) 2017/745 devido a mudança de classe. **DE** Medizinprodukt gemäß Richtlinie 93/42/CEE; sie werden in Übereinstimmung mit der MDCG 2020-2 konform mit der Verordnung (EU) 2017/745 für den Wechsel der Klasse gestaltet. **GR** Ιατρική συσκευή σύμφωνα με την οδηγία 93/42 / CEE; Σύμφωνα με το MDCG 2020-2, θα έχουν συμμορφωθεί με τον Κανονισμό (ΕΕ) 2017/745, λόγω αλλαγής κατηγορίας. **SA** جهاز طبي يتوافق مع التوجيه 93/42/CEE

	وفقًا لمجموعة تنسيق الأجهزة الطبية MDCG 2020-2، سيتم جعلها متوافقة مع توجيه لائحة الاتحاد الأوروبي 2017/745 (EU) بموجب تاريخ الفترة وفي غضون مايو 2024.

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