



GIMA

PROFESSIONAL MEDICAL PRODUCTS

GB - USER MANUAL FOR 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 manual 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 physiological 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 recommended method of sterilisation is that of autoclave steam, the temperature of the cycle must not exceed 134°C (273°F) for a maximum of 10 minutes, to avoid damage to the product. 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. For hot air sterilisation, it is recommended to have a temperature ranging between 180° and 200°C. The instruments can also be disinfected in washer disinfectors up to a temperature of 121°C. 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.

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.

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|  | <p>IT Fabbricante GB Manufacturer FR Fabricant ES Fabricante PT Fabricante DE Hersteller GR Παραγωγός الشركة المصنعة AR</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 تاريخ التصنيع AR</p> |
|  | <p>IT Non sterile GB Non-sterile FR Pas stérile ES No estéril PT Não estéril DE Nicht steril GR Όχι αποστειρωμένο ليس معقم AR</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) الحذر: قراءة التعليمات (التحذيرات) بعناية AR</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 اقرأ بدقة وحرص تعليمات الاستخدام AR</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 يحفظ بعيدا عن أشعة الشمس AR</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 يحفظ في مكان بارد وجاف AR</p> |
|  | <p>IT Codice prodotto GB Product code FR Code produit ES Código producto PT Código produto DE Erzeugniscode GR Κωδικός προϊόντος كود المنتج AR</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 رقم الدفعة AR</p> |

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| MD | IT Dispositivo medico GB Medical Device FR Dispositif médical ES Producto sanitario PT Dispositivo médico DE Medizinprodukt GR Ιατροτεχνολογικό προϊόν AR جهاز طبي |
| 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 según 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. AR جهاز طبي يتوافق مع التوجيه 93/42/CEE وفقاً لمجموعة تنسيق الأجهزة الطبية MDCG 2020-2، سيتم جعلها متوافقة مع توجيه لائحة الاتحاد الأوروبي (EU) 2017/745 بموجب |
| UDI | IT Identificatore univoco del dispositivo GB Unique device identifier FR Identifiant unique de l'appareil ES Identificador de dispositivo único PT Identificador exclusivo do dispositivo DE Unique Device Identifier (Eindeutige Kennung des Geräts) GR Μοναδικό αναγνωριστικό συσκευής AR - معرف فريد للجهاز |
| CH REP | IT - Rappresentante autorizzato in Svizzera GB - Authorized Representative in Swiss FR - Représentant autorisé au Suisse ES - Representante autorizado en Suizo PT - Representante autorizado no Suíço DE - Autorisierter Vertreter im Schweizer GR - Εξουσιοδοτημένος Αντιπρόσωπος στο Ελβετός SA - الممثل المعتمد في سويسرا |
| UK REP | IT Rappresentante autorizzato nel Regno Unito GB Authorized Representative in the UK FR Représentant autorisé au Royaume-Uni ES Representante autorizado en el Reino Unido PT Representante autorizado no Reino Unido DE Autorisierter Vertreter im Vereinigten Königreich GR Εξουσιοδοτημένος Αντιπρόσωπος στο Η.Β. SA الممثل المعتمد في المملكة المتحدة |


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