

# PALLONE RIANIMATORE RESUSCITATOR BAG INSUFFLATEUR DE REANIMATION WIEDERBELEBUNGSBALLON BALON DE REANIMACION

# MANUALE D'USO E MANUTENZIONE USE AND MAINTENANCE BOOK INSTRUCTIONS DE FONCIONNEMENT ET ENTRETIEN BETRIEBS UND WARTUNGS ANWEISUNGEN MANUAL DE USO Y MANTENIMIENTO

**ATTENZIONE:** Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.

**AVIS:** Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

**ACHTUNG:** Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.

**ATENCIÓN:** Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

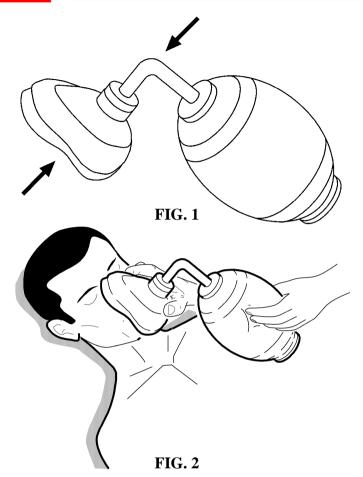


# GIMA Spa - Via Marconi, 1 - 20060 Gessate (MI) - Italia

ITALIA: Tel. 199 400 401 (8 linee r.a.) - Fax 199 400 403 E-mail: gima@gimaitaly.com - www.gimaitaly.com

INTERNATIONAL: Tel. ++39 02 953854209 - Fax ++39 02 95380056 E-mail: export@gimaitaly.com - www.gimaitaly.com





# CARATTERISTICHE

Il pallone di rianimazione è un dispositivo medico adatto al primo soccorso che consente interventi rapidi ed efficaci nei casi di pazienti colpiti da insufficenza respiratoria. Può essere utilizzata con tutti i modelli di maschere di rianimazione.

Il pallone rianimatore è composto da una sacca, da un gruppo di collegamento maschera, contenente la membrana di uscita e da una valvola di ingresso. La membrana di uscita si apre durante l'insuflazione, anche esercitando una lieve pressione e si richiude durante l'espirazione del paziente impedendo così l'ingresso del respiro nella sacca.

Tutti i palloni eccetto i modelli **monouso** possono essere facilmente sterilizzati **in autoclave** a 121°C per il loro riutilizzo.



Il pallone è previsto per l'uso in ambiente sanitario o privato, con il solo scopo di immagazzinare e trasferire l'aria o miscele di aria / ossigeno per la rianimazione di pazienti con insufficienza respiratoria utilizzando idonee maschere di rianimazione.







## FEATURES

The balloon-type resuscitator is a medical device that is ideal for first aid purposes, as it enables fast, effective intervention in cases where the patient is struck by breathing problems. It can be used with every model of resuscitation mask.

The balloon-type resuscitator consists of a sack, a mask connection unit (containing a membrane outlet), and an inlet valve. The membrane outlet opens during insufflation, exercising slight pressure, and closes when the patient exhales, thereby preventing the patient from breathing into the sack.

All balloon parts, except the **disposable** models, can be easily sterilized in a **steam autoclave** at 121°C and then reused.



The bag has been designed to be used in hospital or private facilities with the aim of permitting the storing and/or the shifting of air or air/oxygen mixture for the resuscitation of patients with respiratory failure using proper reanimation masks.

In any case the manufacturer does not assume any responsability for improper uses of the product under the conditions listed below:



Connecting the bag to improper devices which could interfere with the working of the bag; Using the bag for inhalation therapies;

Introducing changes or tampering not authorized by GIMA;

Violating the rules specified on the information report.

# PRESCRIPTIONS

The product is to be used solely by qualified medical personnel with specific experience in medical treatment, so as to ensure patients the highest level of safety.

Since the product is made of corrosion-proof materials suitable for the environmental conditions foreseen for its normal use, does not require special care, however it is necessary to store it in a closed place making sure that is protected from dust and dirt to assure its hygenic conditions. Moreover, it is recommended to store the product in a place which can be reached easily by the personnel in case of necessity.



Check the product periodically, especially their hygienic conditions of the storage place in order to assure the maximum efficiency and safety when used.

# UNPACKING



Always remember that packing elements (paper, cellophane, stitches, adhesive tape, etc.) can cut and/or hurt if they are not carefully handled.

They shall be removed with adequate means and shall not be left at the mercy of irresponsible persons; the same is valid for tools used to remove packages (scissors, knives, etc.).

After opening the packages, first of all it is necessary to check all pieces and parts composing the product. Check that they are all present and in perfect conditions.

We should also remind you that, as the product is packed in non-sterile packaging, before using it for the first time, it must be washed under running water, using neutral, sterilized soap.



To clean and reassemble the product, use sterile latex gloves.







For a correct use the bag must be connected to the mask using the proper tube fitting on the linkage group, fig. 1.

Then start the reanimation pressing the insufflator alternatively to transfer air or air/oxygen mixtures to the patient, according to the medical indications, making sure that the mask adheres to the patient's face, fig. 2.



During use do not turn the air influx zone of the bag to areas contaminated by gas, dust or smoke. If the patient starts vomiting or bleeding from the nose, remove the mask and follow the prescribed medical emergency procedures.

# MAINTENANCE



The following maintenance procedures refer solely to reusable balloon parts; disposable models must be disposed of after being used and may not, under any circumstances, be reused.

After every use, the product must be fully disassembled and carefully washed using water and neutral soap; then, after it has dried thoroughly, the product must be **sterilized**. It may be either cold-sterilized or sterilized in a steam autoclave at 121°C (with non-enveloped cycle).

Once sterile, the product must be kept in a closed space, so as to avoid any contact with dust or dirt, and to ensure the necessary hygienic conditions.



Should the product come into contact with non-sterile agents, it will no longer ensure the necessary hygienic conditions: as a result, cleaning and sterilizing procedures must be carried out once again.

# **GUARANTEE**

Thank you for having acquired our product.

This product meets the most stringent requirements regarding the selection of quality manufacturing materials and also the final control. The product has a 12-month warranty, valid from the date it is delivered by GIMA.

During the guarantee period free repair and/or replacement of any defective parts due to faulty manufacture will be given, labour, postal, transport and packaging charges etc. are not included. The guarantee therefore excludes components subject to wear and tear such as parts in rubber or PVC, doppler probes, SpO<sub>2</sub> sensors, lamps, batteries, electrodes, handpieces, washers and packings, resistances, etc. No compensation will be given for loss of use of the product.

Furthermore replacement or repairs effected during the guarantee period do not lengthen the duration of the guarantee.



This guarantee is void in the event of: repairs effected by unauthorised persons or with spare parts not approved by GIMA, damage or defects caused by negligence, blows, abnormal use of the appliance or faulty installation.

The guarantee will be invalidated if the registration number has been removed, cancelled or altered. Faulty appliances must be returned only to the retailer where the item was bought. Any item dispatched directly to us will be refused.



# MASCHERA DI RIANIMAZIONE REANIMATION MASK MASQUE DE REANIMATION WIEDERBELEBUNGSMASKE MASCARILLA DE REANIMACION

# MANUALE D'USO E MANUTENZIONE USE AND MAINTENANCE BOOK INSTRUCTIONS DE FONCIONNEMENT ET ENTRETIEN BETRIEBS UND WARTUNGS ANWEISUNGEN MANUAL DE USO Y MANTENIMIENTO

**ATTENZIONE:** Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.

**AVIS:** Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

**ACHTUNG:** Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.

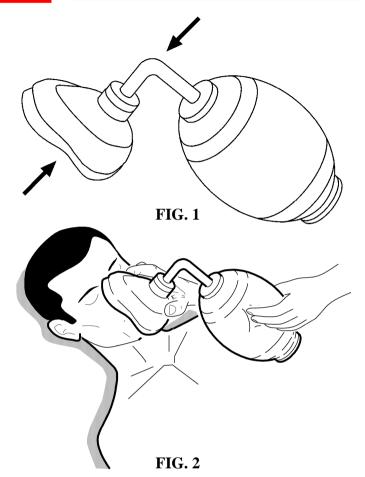
**ATENCIÓN:** Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.



# GIMA Spa - Via Marconi, 1 - 20060 Gessate (MI) - Italia

ITALIA: Tel. 199 400 401 (8 linee r.a.) - Fax 199 400 403 E-mail: gima@gimaitaly.com - www.gimaitaly.com

INTERNATIONAL: Tel. ++39 02 953854209 - Fax ++39 02 95380056 E-mail: export@gimaitaly.com - www.gimaitaly.com





# CARATTERISTICHE

La maschera di rianimazione è un dispositivo medico adatto al primo soccorso che consente interventi rapidi ed efficaci nei casi di pazienti colpiti da insufficenza respiratoria. Può essere utilizzata con tutti i modelli di palloni rianimatori manuali.

Tutti i modelli sono realizzati in silicone ed hanno una forma anatomicamente corretta per assicurare al paziente una perfetta aderenza al viso con una presa facile e comoda per l'operatore. La trasparenza del materiale garantisce inoltre un'ottima visibilità all'interno della maschera utile per osservare le condizioni del paziente.

La maschera può essere facilmente sterilizzata in autoclave per il suo riutilizzo.



La maschera è prevista per l'utilizzo in ambiente sanitario o privato, con il solo scopo di consentire la rianimazione di pazienti con insufficienza respiratoria utilizzando palloni rianimatori di tipo manuale.







# **FEATURES**

Reanimation mask is a suitable device for first aid and it allows to intervene quickly and efficaciously in all these case of respiratory failure. It can be used with all the manual resuscitator bags.

Every model is made of silicone and features an anatomically correct shape that ensures it not only adheres perfectly to the patient's face, but also provides medical personnel an easy, comfortable grip. The use of a transparent material also ensures outstanding visibility inside the mask, which is useful when observing the patient's condition.

The mask can be easily sterilized in a **steam autoclave** and then reused.



The mask is designed to be used in hospital or private facilities with the aim of enabling the resuscitator of patients affected by respiratory failure using hand-operated resuscitator bags.

In any case the manufacturer does not assume any responsibility for improper uses of the product under the conditions listed below:



Coonecting the mask to active-type devices (e.g. automatic resuscitator bag, lung ventilators, etc.);

Using the mask for inhalation therapies;

*Using devices which may interfere with the mask operation;* 

Introducing changes or tampering not authorized by GIMA;

Violating the rules specified on the information report.

# PRESCRIPTIONS

The product is to be used solely by qualified medical personnel with specific experience in medical treatment, so as to ensure patients the highest level of safety.

Since the product is made of corrosion-proof materials suitable for the environmental conditions foreseen for its normal use, does not require special care, however it is necessary to store it in a closed place making sure that is protected from dust and dirt to assure its hygenic conditions. Moreover, it is recommended to store the product in a place which can be reached easily by the personnel in case of necessity.



Check the product periodically, especially their hygienic conditions of the storage place in order to assure the maximum efficiency and safety when used.

# UNPACKING



Always remember that packing elements (paper, cellophane, stitches, adhesive tape, etc.) can cut and/or hurt if they are not carefully handled.

They shall be removed with adequate means and shall not be left at the mercy of irresponsible persons; the same is valid for tools used to remove packages (scissors, knives, etc.).

After opening the packages, first of all it is necessary to check all pieces and parts composing the product. Check that they are all present and in perfect conditions.

We should also remind you that, as the product is packed in non-sterile packaging, before using it for the first time, it must be washed under running water, using neutral, sterilized soap.







To clean and reassemble the product, use sterile latex gloves.

# FUNCTIONING

In case of use, follow the instructions listed below:

- If possible, lay down the patient on a bed or on the ground;
- Remove possible objects from the face and / or clean it in order to avoid hamper to the application of the mask:
- Connect the mask to the resuscitation bag using the appropriate connector / tube ring as shown in the figure 1;
- Apply the mask to the patient as shown in the figure 2 keeping it on the face with one hand, making sure that it adheres to the face along the whole perimeter;
- With the other hand start pressing the resuscitator bag alternatively to transfer air or air / oxygen mixes to the patient, according to the medical indications;
- Finally, follow the medical emergency procedures prescribed.



During use do not turn the air influx zone of the bag to areas contaminated by gas, dust or smoke.

If the patient starts vomiting or bleeding from the nose, remove the mask and follow the prescribed medical emergency procedures.

## MAINTENANCE

After every use, the product must be carefully washed using water and neutral soap; then, after it has dried thoroughly, it must be sterilized. It can be either cold-sterilized or sterilized in a steam autoclave. Once sterile, the product must be kept in a closed space, so as to avoid any contact with dust or dirt, and to ensure the necessary hygienic conditions.



Should the product come into contact with non-sterile agents, it will no longer ensure the necessary hygienic conditions: as a result, cleaning and sterilizing procedures must be carried out once again.

# GUARANTEE

Thank you for having acquired our product.

This product meets the most stringent requirements regarding the selection of quality manufacturing materials and also the final control. The product has a 12-month warranty, valid from the date it is delivered by GIMA.

During the guarantee period free repair and/or replacement of any defective parts due to faulty manufacture will be given, labour, postal, transport and packaging charges etc. are not included. The guarantee therefore excludes components subject to wear and tear such as parts in rubber or PVC, doppler probes,  ${\rm SpO}_2$  sensors, lamps, batteries, electrodes, handpieces, washers and packings, resistances, etc. No compensation will be given for loss of use of the product.

Furthermore replacement or repairs effected during the guarantee period do not lengthen the duration of the guarantee.



This guarantee is void in the event of: repairs effected by unauthorised persons or with spare parts not approved by GIMA, damage or defects caused by negligence, blows, abnormal use of the appliance or faulty installation.

The guarantee will be invalidated if the registration number has been removed, cancelled or altered. Faulty appliances must be returned only to the retailer where the item was bought. Any item dispatched directly to us will be refused.