



INSTRUCTION MANUAL



PROX

Modular Cushion

 **Promedicare**

Feel the ideal posture

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Pro Medicare S.r.l.

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NOTE: The illustrations in the following Instruction Manual may differ from reality; however, the methods of use and operation remain valid at all times. All technical data in this manual are approximate and do not constitute specifications.

INTRODUCTION

Dear User, thank you for choosing a class I non-sterile non-invasive medical device of the *SOLLIEVO* Range manufactured by PRO MEDICARE S.r.l. As manufacturer, PRO MEDICARE declares that the medical device complies with Regulation (EU) 2017/745. Pro Medicare's Quality Management System is certified according to UNI EN ISO 9001 and UNI EN ISO 13485 standards. This manual, drawn up on the basis of the requirements of Regulation (EU) 2017/745 on medical devices, is an indispensable tool for learning how to use the Device safely.

After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, Monday to Friday from 9 a.m. to 1 p.m. and 2:30 p.m. to 6:30 p.m.

In case of emergencies outside the working hours, please send an email to **sales@promedicare.it**.

We will call you back as soon as possible.

In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

PROX is the modular and adjustable cushion equipped with gripping systems; its flexible support base also equipped with reinforcing elements allows to be used on any type of seat with a width of not less than 38cm (e.g. chair, armchair, seat, wheelchair), switching from an extended to a folded non-use configuration by avoiding the repositioning of the modular elements provided.

Its intended use is aimed to adjust the position of the pelvis in situations where it is necessary to relieve and ventilate the medial buttock, coccygeal, sacral, perineal and genital areas of the seated person; the lateral components, in the posterior part keep the central area of the pelvis ventilated, unloaded and not overloaded. Gripping systems allow to adjust the width and length of the cushion by a few centimeters in both reduction and extension to adapt it to the anthropometric measurements of the adolescent and/or adult user. All the devices of the *SOLLIEVO* Range have been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745. It is recommended to always ensure the compatibility of the device on a support base. Pro Medicare is constantly dedicated to innovate its own Devices; this can entail changes in form or technique on the devices and/or related accessories. Therefore, hypothetical complaints on values, images and schemes defined in this manual, will not be accepted. Furthermore, for the complete list of the optional parts and/or accessories, please refer to the latest order form in force.

1. INSTRUCTION OF USE

1.1 Packaging and Transport

The original packaging contains the following components:

- The *PROX* cushion includes:
 - a flexible support base with reinforcing elements inside; gripping systems and handles
 - 3 padded and upholstered modular elements
- labeling and Instruction Manual
- accessories (if ordered).

Upon delivery, please check for the integrity of the package and immediately note any damages or anomalies on the shipping document. Then open up the packaging and check that the various parts do not show dents, deformations or tears. Otherwise note the anomalies found on the shipping document. After performing these checks and if the product has not to be put into immediate use, we recommend to repack and store it in a dry place.

1.2 How to use it

Take the cushion and place it on the base (pic.1: extended cushion); adjust the modular elements (including elements inside them) as needed taking care not to bring them too close together, in particular, pay attention to those in the posterior part of the cushion to prevent the functionality of the cushion from being impaired (see in the standard maintenance section how to position the elements correctly).



pic.1: extended cushion

Be careful at all times during use and check that the cushion does not move in order to prevent it from sliding from the support base (if placed on a seat equipped with wheels, please use fastening systems to fix and secure it). After use, if necessary, the cushion can be folded without moving the modular elements and stored in a humidity-free place (pic.2: folded mode).



pic.2: folded cushion

1.3 Recommendations for Use

In order to guarantee safe use and a long lasting performance of the device, the following are tips about some ways to use the device:

- Carefully follow the instructions reported in this manual;
- Keep the Device away from heat sources;
- Do not make unauthorised modifications or do not use parts not supplied or approved by the manufacturer, they may affect the safety of the Device, may lead to dangerous situations and to the loss of the CE Mark;
- Carry out thorough cleaning and pay close attention to the standard maintenance;
- Do not use on injured skin.

2. GENERAL WARNINGS

All announcements reported in this section describe the conditions and situations that may cause danger to the user or to third parties. Please read carefully before using and putting in service the device.

For further information, please contact the Technical Sales Department at the following number:

+39 0831 777840

- always check the Device is properly fixed to the support base;
- if the device comes in contact with dirt, please carry out an immediate and thorough cleaning of the cover;
- if, after a few days of use, anomalies are found regarding the tightness of the device, please, contact the dealer;
- in the event that an accident causes a loss of performance, do not use the system and contact the dealer;
- it is recommended to perform a thorough cleaning and standard maintenance of the device every 15 days or if necessary checking all parts of the device to avoid any inconvenience. For further information about the maintenance and cleaning, please read the dedicated section.

Severe environmental conditions may affect the features of the materials used, the functionality and performance of the device, so:

- avoid the exposure to extreme temperatures;
- avoid prolonged exposure to sunlight (i.e. do not leave the device in a car);
- avoid extreme humid places;
- do not use the cushion in the shower, pool or environment in contact with water. Some components may be damaged and cause malfunctions;
- avoid contact with seawater.

3. NEGATIVE ADVERSE EFFECTS

Its use should not produce unwanted side effects including allergies or irritation of skin parts or redness. Otherwise, please contact your doctor or the dealer immediately. Daily monitor the skin area which is in contact with the Device for evidence of redness caused by incorrect or outdated adjustments; in this case it is suggested to suspend the use and contact the dealer.

4. STANDARD MANTAINANCE

In order to ensure proper functioning and long-lasting performance under safe conditions, it is necessary for all components to maintain their original composition and to be disinfected frequently. The removable cover can be washed at high temperatures (95°/10 washing maximum or dry clean), can be sterilized at 134°/5 min (10 times maximum) and sanitized with the following detergents/ disinfectants:

- PERSIL EXPERT coldzyme/HENKEL
- 70% etanol
- PERFORM/Schuelke
- TPH PROTECT/Schuelke
- MIKROZID AF liquid/Oktal pharma
- DESCOGEN liquid/Antiseptica
- MANORAPID/Antiseptica
- PLIVASEPT/Pliva
- INCIDIN PLUS/Ecolab

Do not use sodium hypochlorite cleaners. Wash and dry completely before storing; wrinkling may occur on the surface. Padding and structural parts are not to be washed.

Once the component has been disassembled, proceed as follows to reinsert the padding and structural kit:

- the cover of the padded element has a red seam on one side and a grey seam on the other; the side with the red seam will be in contact with the cover;
- insert the padded element into the cover, paying attention to the previous point;
- insert the elements, if necessary, as in pic. 3.



pic.3: elements insertion instruction

5. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

Special maintenance should be performed when one or more structural components deteriorate in such way to compromise the performance and safety. In such a case, it is forbidden to use the device, and the dealer must be consulted immediately, who must promptly notify the manufacturer of the nature of the malfunction and/or of the ascertained faults in order to implement the necessary interventions.

However, it is mandatory to abide by the following instructions:

- Components failure: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
- Breakage or tearing of components: it is mandatory to proceed with their replacement with original parts supplied by the manufacturer
- For all components, any adjustment operations, various repairs are prohibited
- It is recommended to gradually adapt the system to any needs of the user.

Failure to comply with these requirements will automatically result in the forfeiture of the CE marking.

For special maintenance, the End User must refer to the Professional User who has to send the appropriate form "Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance" to the manufacturer within 24 hours of the request for intervention. Preventive maintenance is not provided.

6. PERFORMANCE AND DURABILITY

PRO MEDICARE S.r.l. warrants that the devices have been designed and manufactured in compliance with safety standards as resulting from the relevant Regulation (EU)2017/745.

The benefits provided by the above mentioned medical devices, are therefore suitable and respond to the intended purpose of unloading and ventilating the medial buttock, coccygeal, sacral, perineal and genital areas of the seated person.

The duration of the maintenance of performance, under safe conditions, of the *PROX* cushion is considered to be approximately 2 years.

This value is purely indicative because, although the expected lifetime at the design stage is far greater, it is strongly conditioned by the mode of use (perhaps demanding, continuous and not foreseeable at the design stage) of the device, as well as by proper use and careful maintenance.

In addition, it is reasonable to consider a slight reduction in performance over time due solely to:

- shocks and accidental events
- natural wear and tear of components.

Both performance and relative life span expectancy are however dependent by the periodic verification of suitability, safety of the device in combination with the support base.

The reconditioning of the device is prohibited if not expressly authorized by the manufacturer.



It is recommended to periodically check the skin, gluteal area, and the part of the pelvis to be unloaded especially if the device is used continuously during the day.

7. WARRANTY

Pro Medicare S.r.l. recognizes the warranty of optimum functionality for a period of up to 24 months for manufacturing defects from the 1st commissioning and 12 months on covers, paddings and components replaced under special maintenance starting from the date of commissioning after refurbishment.

The warranty is valid if the device is used as indicated within this instruction manual.

The warranty is voided in the following cases:

- improper use and/or in case of force majeure
- a failure arising from an unauthorized tampering or faulty maintenance by third party that compromises the correct functionality and safety of the products
- any modification made without the manufacturer's authorization
- accidental damages and wear of the essential components
- structural changes of the end user
- failure or damages during the transportation: the user/dealer is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance*" to the manufacturer within 24 hours of the request of intervention. It is also essential for the manufacturer to receive a completed *Warranty Registration Form*.

8. POST-MARKET SURVEILLANCE AND POSSIBLE INCIDENTS

Pro Medicare S.r.l. ensures that their medical devices have been manufactured within the strict compliance, criteria and requirements established by the relevant applicable standards, guarantee functioning under the safety conditions prescribed by Regulation (EU) 2017/745. The post-market surveillance system is set up and implemented in accordance with the quality management system adopted by Pro Medicare S.r.l. and is aimed to actively and systematically collect, record and analyse relevant data on the quality, performance and safety of its devices during their whole life, to establish the necessary conclusions and to determine, implement and monitor any preventive and corrective actions (art. 83 MDR).

These activities are also ensured through accurate market surveillance of the medical devices already present on the market, as also included in Art. 84 of the same Regulation (EU)2017/745.

To ensure Post-Market Surveillance, Pro Medicare S.r.l. shall implement all activities together with Professionals and Stakeholders to establish and keep updated a systematic procedure which is useful to collect and promptly analyze the experience gained on devices that have been placed on market, in order to identify any need for improvement or modification.

This surveillance activity also includes any incidents or serious incidents defined by the MDR as:

- "*incident*": means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (art. 2(64) MDR)
- "*serious incident*": means any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person; b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; c) a serious public health threat (art. 2(65) MDR).

Serious incidents must be reported to the manufacturer and, through EUDAMED, to the competent authority.

Non-serious incidents, on the other hand, do not have to be reported to the competent authority; they must, however, be documented and taken into account in the manufacturer's quality management system and reported in accordance with the requirements of Art. 88 MDR.

It follows, therefore, that upon the occurrence of both serious incidents and possible non-serious incidents to end users and their companions or to professional users in connection with the use of the device **it is mandatory to send to Pro Medicare** a copy of a fully completed "*Annex 2 - Reporting of after-sale incidents*". Pro Medicare S.r.l., as soon as it receives the aforementioned form, will provide the appropriate communications to the professional/end user, including the possible authorization to repair the damaged device or its replacement, also providing for the adoption of measures within its competence, appropriate to the nature and gravity of the incident detected.

In cases of particular urgency **it is mandatory** to contact the manufacturer at the following number **+39 0831 777840** sending to sales@promedicare.it the fully completed *Annex 2* as soon as possible.

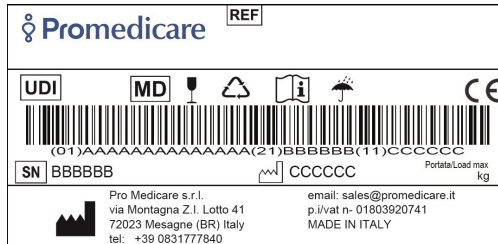
9. DISPOSAL/RECYCLING

Please, follow the local disposal and recycling regulations. Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of the Positioning System accessories):

- Polyurethane and polyethylene plastic foams
- Synthetic fabrics polyurethane, polyester
- Metals
- Plastic and cardboard envelopes for packaging.

10. LABELING

The CE label is attached inside the cover of the base and it is also stucked on the last page of this Manual. Product data are indicated on the label. In case of replacing parts orders and/or reports, the serial number of the product is duly requested. A facsimile of the label is shown below:



MD Medical Device

SN Serial Number

REF Catalog Number

CE CE Mark

Manufacturer

Manufacturing date

Recovery/Recyclable

Handle with care

UDI Unique Device Identifier

Consult Instruction for Use

Keep dry

Annex - A "Technical Features

The cushion comes in one size, 43 cm wide and 40 cm deep. Given the presence of the clinging systems, it is possible to adjust the width and length by a few centimetres both in reduction and extension, making the cushion enough adaptable to the anthropometric measurements of the adolescent-adult user.

Width	43 cm
Depth	40 cm
Anterior height	10 cm externally/3 cm internally
Posterior height	4 cm
Weight	< 1 kg
Maximun load	100 kg

