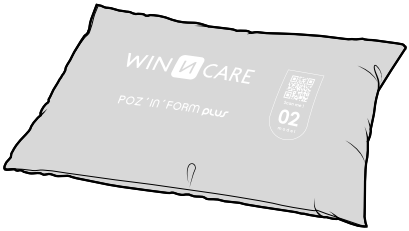
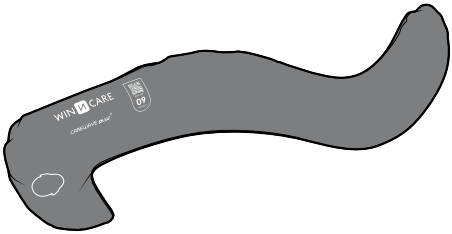
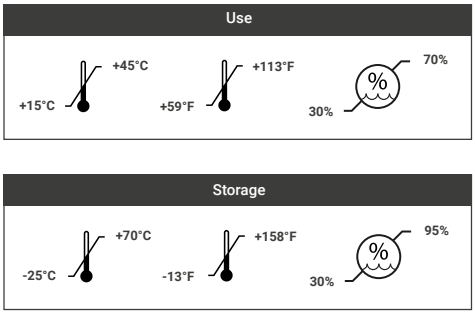
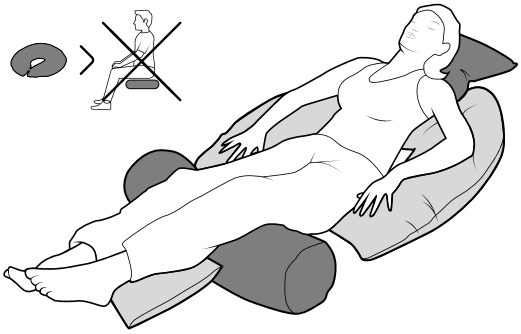




CAREWAVE PLUS

POZ' IN' FORM PLUS





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IFU_PAID

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CE

Version 1 31/05/2024

Read the instructions for use

Date of manufacture

Compliant with Regulation (EU) 2017/745 on medical devices

LOT Batch number

Separate collection at end of life

Warning

PRESSURE RELIEF DEVICES AND POSITIONING SYSTEM

1. INDICATIONS

Device Intended Use

- Compensation for disability.
- Prevention.
- Treatment (aid).

General instructions

Preserve functional integrity (joint position, respiratory function, pain relief) and structural integrity (skin in particular) of areas of the patient's body (impairments, multiple disabilities) during prolonged confinement to bed (for more than 15 hours per 24 hours), whatever the aetiology.

Target patient and user group

People confined to bed with loss of independence in locomotion.

Contra-indications

- Severe deterioration in cardiorespiratory status.
- Chronic pain not relieved by the use of assistive product(s) and/or procedural pain.
- Unstabilised fractures. Children under 12 years of age.
- People of height less than 146cm.

Report undesirable side-effects

Acute and procedural (treatment-induced) pain. Irritation from direct skin contact with the surface of the envelope or cover.

Any serious incident involving the device must be reported to the manufacturer and to the competent authority of the member state in which the user and/or patient is resident. Inform the competent authority if you consider or have reason to believe that the device presents a serious risk or that it is a fake product.

2. CLINICAL BENEFIT, PERFORMANCE, MECHANISM OF ACTION

Performance characteristics of the device

- Microbeads or synthetic fibres contained in a water-penetration resistant, water-vapour permeable, bi-elastic envelope that binds together to maintain an optimum position of the body or part of the body.
- Users must have undergone training in patient positioning and settling in accordance with good professional practice.

Expected clinical benefits

- Maintains an optimum position. Maintains tissue oxygenation by relieving or eliminating pressure on vulnerable areas of the body in contact with the mattress.
- Relief of joint and muscle pain.

Information for health professionals

- Observe the condition of the patient's skin that is in contact with the support several times a day.
- Use pressure relief devices or positioning systems in the case of patients with pressure sore(s).
- Change the position at least every eight (8) hours on a motorised air support with alternating pressure, every four (4) hours on a viscoelastic foam mattress and every two (2) to three (3) hours on all others.

3. PROTECTIVE ACCESSORY

STANDARD COVER

(VPOZxxSG and VCARxxSB):

- PROMUST PU HD Grey (50% polyurethane, 50% polyester),
- PROMUST PU HD Blue (48% polyurethane, 52% polyester).

HYGIENE COVER

(VCARxxHB):

- PROMUST CIC Blue (44% polyurethane, 56% polyester).

COMFORT COVER

(VPOZxxCG and additional cover VHCARxxCB):

- LENZING (52% Viscose, 48% Lyocell/ 100% polyurethane).

References	Cushioning material in textile envelope	Indications	Contra-indications
VCARx / VPOZx From 1 to 17 Alone or in combination See Good practice guide	Microbeads: (CAREWAVE PLUS) 100% expanded polystyrene (EPS) Or Synthetic fibres: (POZ IN FORM PLUS) Polyester 100% (PES) Oeko-Tex 100 Class 1 According to clinical judgment.	Preserve the functional integrity (respiratory, analgesic, etc.) and structural integrity (skin in particular) of the pelvis and thorax during prolonged confinement to bed.	Clinical status contrary to mobilisation (post-traumatic). Pain associated with weight-bearing. Agitation.
		Preserve the functional integrity (joint position and pain relief, in particular) and structural integrity (skin, in particular) of the patient's hip and knee. Relaxation of abdominal muscles.	Agitation. Painful positions.
		Preserve the functional integrity (pain relief, in particular) and structural integrity (skin, in particular) of the patient's heel without risk of equinus foot deformity. Same for elbow and hand.	Pressure sore in contact.
		Preserve functional integrity (hip abduction, pain relief).	Agitation. Painful positions.
		Abduction position of lower limbs when turning over during washing or certain nursing or medical procedures.	Trochanter and anklebone pressure sore in prolonged contact (semi-lateral 90°).
		Prevention of occipital bedsores.	Agitation. Not lucid.

4. PREREQUISITES BEFORE USE AND INSTRUCTIONS FOR USE

Training and qualifications required for using the device

User training must be provided by persons who have been trained and approved by the relevant economic operators, especially as regards safety and the reporting of non-conformities.

Device installation

The device is ready to install.

Preventive maintenance

Inspect the condition of the envelope regularly. Holes, tears, broken weld or seams may cause microbeads or synthetic fibres to spill out, rendering the device non-compliant.

Cleaning and disinfection

› See cleaning requirements on page 4.

Information regarding suitable procedures for re-use

› The product must be physically and bacteriologically clean. Cover material treated with a biocidal substance that poses no risk to the user. Do not use scouring, stripping or solvent products or sharp objects in direct contact with the cover.

5. WARNINGS, PRECAUTIONS FOR USE, MEASURES REQUIRED

Precautions for use

› In a 30° semi-lateral decubitus position, check the alignment of the spine/pelvis inclination and the withdrawal of the subtrochanteric support. The bed is in horizontal position.

› If a pressure sore has formed (from stage 1), avoid prolonged direct contact with the device. Look for alternatives in the event of patient agitation/confusion and/or non-compliance.

Warnings

› With every change of position, observe the appearance of the skin in direct contact with the surface of the device (inner knees, heels, ankle bones in the case of external rotation of a lower limb, etc.).

› At each change of position to a 30° semi-lateral decubitus position, check for redness on the outer edge of the foot and the ankle bone of the foot in contact with the mattress, and on the ear in contact with the device.

› In the case of profuse sweating on areas of the body that are in prolonged direct contact with the surface of the envelope, protect with a layer of fabric (e.g. towel), or use the LENZING overprotection accessory.

Required measures

› Read the recommendations of the manufacturer of the single or therapeutic mattress relating to the use of these associated products,

› Check that parts of the body are not in contact with the structural elements of the medical bed and its accessories,

› Warning: changing the patient's position is not enough to prevent pressure sores; other preventive measures must also be taken:

- Use a therapeutic mattress suitable for the patient's degree of risk, mobility and activity;
- Maintain skin hygiene and avoid wetness;
- In the case of incontinence, change protective items regularly;
- Monitor the condition of the skin on a daily basis, or have someone do so for you;
- Ensure that the patient has sufficient and appropriate food and drink regularly, and in sufficient quantities.

If any of these measures cannot be followed, it is essential to inform your doctor or nurse as soon as possible.

› Keep excess thickness between the body and the support to a minimum, with the exception of a comfort cover that is compatible with the positioning devices, clothing and a complete change if necessary. Opt for cotton clothing that is not too tight, and seamless, if possible, in the support area,

› Ensure there are no foreign bodies such as tubing, crumbs, fat, etc. before positioning the person,

› Important: consult with your prescriber within one month of acquiring these pressure relief devices or positioning systems.

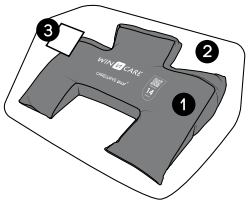
Circumstances in which the user must talk to a healthcare professional

Inform your doctor or nurse as soon as possible of any abnormal events such as fever, pain, reddening or whitening of the weight-bearing areas (head, shoulder, back, hip, shoulder blade, pelvis, hip, etc.)

Information on any known restrictions to combining with devices and equipment

The use of protective devices other than those supplied and specified by WINNCARE France may result in malfunction of the device and/or render it unsuitable for safe use and the maintenance of its performance. A risk assessment may be required.

6. COMPOSITION OF THE PACKAGE



❶ Positioning cushion
❷ Recyclable plastic bag
❸ Traceability label

7. STORAGE, HANDLING, DISPOSAL

Terms of use and storage

CAREWAVE PLUS and POZ' IN' FORM PLUS products should preferably be stored flat and away from direct light and excessive humidity.

Lifetime

The estimated lifetime of the pressure relief devices or positioning system is four (4) years.

Disposal of the product

Do not dispose of the product in the open outside of the designated areas. Use the recycling facilities available in your country.

Cleaning requirements	DATP with no protective cover		PROTECTIVE COVER		
	CAREWAVE PLUS	POZ IN FORM PLUS	PROMUST PU HD	LENZING	PROMUST CIC
Wash at moderate temperature	Not applicable				Not applicable
Do not soak. Hand wash and rinse quickly.		Not applicable	Not applicable	Not applicable	Not applicable
Do not iron.					
Do not dry clean.					
Dry at moderate temperatures (maximum 60°C).	Not applicable	Not applicable			Not applicable
Do not tumble dry.			Not applicable	Not applicable	Not applicable
Use of bleach solution (active chlorine concentrations)					

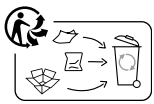
CUSHION WITH PROTECTIVE COVER

Surface cleaning with detergent and/or surface disinfectant products subject to CE marking status and/or biocide status as per Regulation (EU) No. 528/2012.

WIN N CARE

REP

Distributor



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