WIN CARE

User manual
Microbead relief devices and positioning system

POSTURA

CE

DEVICE INTENDED USE
Disability prevention and compensation.

GENERAL INDICATIONS
Bedridden patients with loss of autonomy and mobility with impairment of functional or structural integrity. Helps in the prevention and treatment of pressure ulcers.

TARGET POPULATION
Adults and adolescents 12 years and older

CONTRAINDICATIONS
Severe deterioration of cardiorespiratory status. Acute and/or procedural pain. Non-stabilized fractures.

ADVERSE SIDE EFFECTS
Excessive perspiration on direct skin contact with the cover. Position-related discomfort. Acute and procedural pain.

Any serious incident occurring in connection with the device must be notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Inform the competent authority if you consider or have reason to believe that the device poses a serious risk or has been tampered with.

SPECIFIC (CONTRA)INDICATIONS / MEDICAL DEVICE COMPOSITION / TECHNICAL DATA

Reference VCPxxCIC	Indications	Contraindications	Microbeads Cover
VCP08, VCP09, VCP11	Preserve the functional (respiratory, analgesic,...) and structural (especially cutaneous) integrity of the pelvis and thorax during prolonged bed rest	Adverse clinical condition to mobilization (post-traumatic), pain related to support. Agitation.	Expanded Polystyrene Micro Beads (EPS) 58% Polyester / 35% Polyurethane-Polycarbonate with Ag+ ions Oeko-Tex 100 class 1
VCP04 + VCP01 or VCP12	To preserve the functional integrity (notably the position of the joint and analgesia) and the structural integrity (notably cutaneous) of the patient's hip and knee	Agitation. Painful postures.	
VCP05, VCP06	To preserve the functional integrity (notably analgesia) and structural integrity (notably cutaneous) of the heel in the patient without risk of equinus. Similar application for the elbow and hand.	Pressure sore in contact.	
VCP07	Preserve functional integrity (hip abduction, analgesia)	Agitation. Painful postures.	
VCP02 or VCP03	Abduction position of the lower limbs when turning over during changing or certain nursing or medical procedures.	Trochanteric and maleole pressure sores in prolonged contact (semi-lateral 90°)	

*Consult the terms and conditions for handling products in the EU member state whether they are used alone or in combination.

CLINICAL BENEFIT, DEVICE PERFORMANCE, MECHANISM OF ACTION
Device performance characteristics: microbeads contained in a water-resistant, water-vapour permeable, bi-elastic cover which agglomerates to maintain an adapted position of the body or body part. Users must be trained in patient positioning and installation.
PROJECTED CLINICAL BENEFITS: Maintaining a sustainable position. Maintenance of tissue oxygenation by relieving or removing support from body areas vulnerable to contact with the mattress.
INFORMATION FOR HEALTHCARE PROFESSIONALS: Monitor the condition of the patient's skin in contact with the support several times a day. Use pressure relief devices or positioning systems in patients with pressure ulcer(s). Change position at least every 8 hours on a motorized alternating pressure air support, every 4 hours on a viscoelastic foam mattress and every 2 to 3 hours on all others.

PREREQUISITES BEFORE USE AND INSTRUCTIONS FOR USE
TRAINING AND QUALIFICATION OF THE DEVICE USER: user training must be carried out by individuals trained and approved by the economic operators concerned, notably in terms of safety and non-compliance reporting.
DEVICE INSTALLATION: The device is ready to install.
PREVENTIVE MAINTENANCE: Regularly carry out a visual check of the condition of the envelope. The presence of holes, tears, and the exit of microbeads through the weld makes the device non-compliant.

CLEANING AND DISINFECTION

Cover						
	Do not soak. Hand wash and rinse quickly	Maximum chlorine concentration of 5000ppm	Do not iron.	Do not dry clean	No tumble drying	Use an approved surface disinfectant/detergent

INFORMATION ON APPROPRIATE PROCESSES TO ALLOW ITS REUSE
The product must exhibit physical and bacteriological cleanliness. Item treated with a biocide substance at no risk to users.
Avoid wet contact with the foam. Prohibit all scouring, stripping products or solvents and "piercing-sharp" objects in direct contact with the cover.

WARNINGS, PRECAUTIONS FOR USE, MEASURES REQUIRED
PRECAUTIONS FOR USE
Manually check spine tilt/pelvis alignment and trochanter support removal. The bed surface is horizontal.
In the case of an established pressure sore (from stage 1), avoid direct contact with the device. In the event of patient agitation/confusion and/c compliance use the VCP12CIC circular device versus VCP04CIC.

STORAGE, HANDLING, DISPOSAL
STORAGE AND USAGE CONDITIONS
POSIMO products should preferably be stored flat, away from direct light and excessive humidity.

	Use	Storage
Temperature range	+15°C to + 45°C +59°F to +113°F	-5°C – 60°C +41°F to +140°F
Humidity range	30% - 70%	10% - 90%

SERVICE LIFE
Relief devices or positioning systems have an estimated service life of 3 years.

PRODUCT DISPOSAL
Do not dispose of the product outside of the dedicated area. Respect the established recycling systems in your country.

GUARANTEE
The guarantee duration for the POSTURA range is 2 years. This guarantee starts from the date of purchase of the product from your distribut guarantee does not cover normal wear and tear of the product and its protective cover and is not a substitute for legal guarantees. Please cont distributor about a defective product, specifying the batch number of the product. They will carry out the necessary procedures with Winncar proceed with either repair or exchange.

Class I medical device according to Regulation (EU) 2017/745.
Management systems: Quality: ISO 13485:2016 - Environmental: ISO 14001:2015

Contents of package
1 Positioning cushion
1 user manual