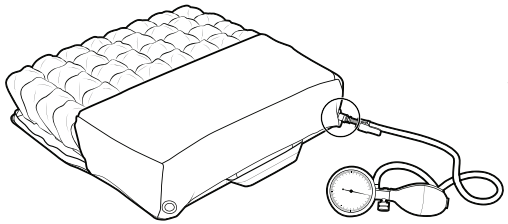
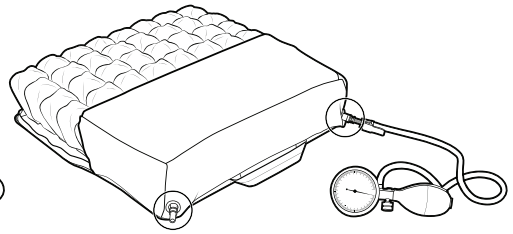
KINERIS AIR CUSHIONS



MONO-COMPARTIMENT

VXX7-1EL / VXX10-1EL



BI-COMPARTIMENT

VXX7-2EL / VXX10-2EL

7 cm	10 cm	Σ	A x B cm	kg	lb	cm	cm
V367	V3610	36	28,5 x 28,5	40 → 55	88 → 121	30 → 34	30 → 34
V427	V4210	42	28,5 x 33	40 → 65	88 → 143	30 → 34	34 → 38
V497	V4910	49	33 x 33	50 → 60	110 → 132	35 → 38	35 → 38
V567	V5610	56	33 x 37,5	40 → 65	88 → 143	35 → 38	39 → 42
V667	V6610	66	36 x 36	50 → 75	110 → 165	35 → 39	35 → 38
V647	V6410	64	37,5 x 37,5	50 → 75	110 → 165	39 → 42	39 → 42
V727	V7210	72	37,5 x 42	50 → 85	110 → 187	39 → 42	43 → 46
V817	V8110	81	42 x 42	55 → 90	121 → 198	43 → 46	43 → 46
V907	V9010	90	42 x 46,5	85 → 120*	187 → 265	43 → 46	46 → 50
V677	V6710	67	43 x 36	50 → 85	110 → 187	40 → 46	35 → 38
V777	V7710	77	43 x 42	50 → 85	110 → 187	40 → 46	42 → 45
V107	V1010	100	46,5 x 46,5	110 → 120*	243 → 265	47 → 51	46 → 50

B A C A x B x C

10 x 7 x 17 cm

Use

+15°C +45°C | +59°F +113°F | 30% 70% | 50kPA 106kPA

Storage

0°C +60°C | +32°F +140°F | 10% 90% | 50kPA 106kPA

Instruction for use and/or technical manual

Complies with the general requirements of Medical Devices Regulation (EU) 2017/745

Manufacturing date

Patient weight range

Batch number

Warning

Moderate wash up to 90°C

Maximum allowable chlorine concentration of 5000 ppm

Tumble dry on low heat

Bleaching prohibited

Do not tumble dry

Do not iron

Do not dry clean

Exclusively distributed by aidacare HEALTHCARE EQUIPMENT

Building 3A, 1 Moorebank Avenue,
Moorebank NSW 2170 Australia

1300 133 120 | aidacare.com.au
sales@aidacare.com.au

WIN CARE

1. INDICATIONS

Intended Use for Product

› Prevention of pressure sores in prolonged seated position.

› Compensation for disability in seated position.

Indications

Patients with difficulty in moving in a seated position, with or without a stability disorder, exposing them to the risk of ischial and/or sacrococcygeal bedsores.

Contraindications

› Patients whose weight is greater than that which the cushion can support.

› Bedsores formed in the support zone (excepting medical advice).

Target patient and user group

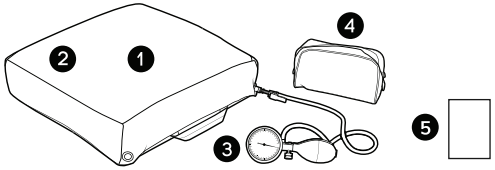
Adult persons with mobility, walking and balance problems, in a prolonged seated position.

⚠ Reporting adverse side effects

Any serious incident related to the product should be notified to the manufacturer and the competent authority of the Member State of the user and/or the patient.

Inform the competent authority if you consider or have reason to believe that the product presents a serious risk or that it is a counterfeit product.

2. COMPOSITION OF THE MEDICAL DEVICE



❶ 1 neoprene cushion (1 or 2 valves),

❷ 1 protective cover (polyester, polyurethane + surface spandex),

❸ 1 manual inflation pump with pressure gauge,

❹ 1 repair kit,

❺ Operating instructions (paper or electronic).

3. CLINICAL BENEFIT, PERFORMANCE, MECHANISM OF ACTION

Performance characteristics of the product

Prevention of pressure sores on the buttocks in contact with the support by immersion of bone protuberances and reduction of shearing forces.

Expected clinical benefits

Maintains tissue oxygenation in the cutaneous and subcutaneous tissues in contact with the support, and/or contributes to the activities required for life support.

Information for health professionals

Observe the condition of the patient's skin in contact with the cushion several times a day. Do not sit the patient down if they have an ischial or coccygeal bedsore. Check that the seat of the chair is in good condition. For wheelchairs, check the height of the arm rests, the footrests etc. as well as its performance in terms of propulsion.

4. INSTRUCTIONS FOR USE

User training

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.

Product installation

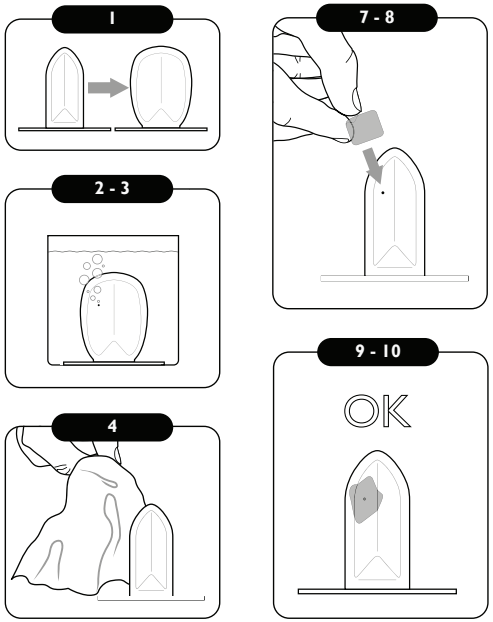
› The cushion must be installed with the cells facing upwards.

› The inflation is carried out using the manual pump supplied with its built-in pressure gauge. The optimal adjustment of the inflation pressure must be carried out in accordance with the weight/height table, using the pressure gauge. Enter the pressure value on the user's card.

› For multi-compartment cushions: the inflation is carried out using the same methodology, ensuring that there is no bottoming by means of an additional manual "estimation" test:

- Sit the patient on the pre-inflated cushion,
- Adjust the inflation pressures taking into account the person's physiological data and the indicative values according to the correlation table provided,
- Check that the cushion has sufficient air by placing the palm hand upward between the buttocks and the base. A sufficiently inflated cushion has a secure air base between 1.5 and 2 cm of air under the ischium,
- The procedure must be repeated on each compartment.

Maintenance and repair



The operations are to be carried out in a dry, clean place, with hands previously washed with soap.

1.Overinflate the cushion.

2. Immerse it in a container filled with clear water only to leak-check. Locate the stream of bubbles that escape from the hole. In the case of a tear, go directly to step 5.

3. Locate the hole to better visualise the leak.

4. Dry the cushion with clean, dry linen. The surface must be perfectly dry and clean to achieve a good grip of the patch.

5. Open the bag containing the compress, alcohol-impregnated at 70°C, unfold it and apply it widely around the lesion.

6. Wait 1 minute.

7. Remove the patch from its support avoiding touching the sticky surface as much as possible.

8. Apply the patch by pressing hard. Use a rounded tool (e.g. back of a teaspoon) going from the centre to the periphery. Delete all bubbles until the patch is completely transparent.

9. Put the cover back on.

10 Adjust the inflation using the matching grid provided with the pressure gauge.

After repair, the use of the cushion will be limited to 15 days. This period allows for the availability of a substitute product so that the repaired product to the can be sent back to the after-sales service.

Cleaning and disinfection

See cleaning requirements on page 1.

Information regarding suitable procedures for re-use

› Each time that it is re-used, the product must be physically and bacteriologically cleaned by performing the procedures given in the technical manual (which can be downloaded at www.winncare.com).

› Replace the cover if the appearance of its surface changes.

5. WARNINGS AND PRECAUTIONS FOR USE

Required measures

A support in itself is not enough to prevent bedsores. Other preventative measures are also required.

› A cushion in good working order must be installed on a seat.

› Ensure that the dimensions of the cushion are compatible with the seat of the chair.

› Check the position of the pelvis, the spine, the head, the height of the armrests and the length of the leg rests and footrests after the patient has been seated on the cushion.

› A cushion in itself is not enough to prevent bedsores/wounds; other preventative measures are also required:

- Change positions at least once every 2 hours.
- Maintain skin hygiene and avoid maceration; do not put any other surface (sheet, towel etc.) between any part of the chair (back and seat) which would cause surface tension to appear, in order to maintain the efficacy of the cushion.
- Once a day, observe, or have observed, the condition of the skin.
- In case of incontinence, change the protective cover regularly,
- Drinks should be taken regularly and in sufficient quantity.

› To ensure that the support is effective, it is important that excessive thicknesses between the body and the support (sheets, adult nappies etc) should be limited. Clothes that have a lot of cotton, if possible, without seams in the support region should mostly be worn.

› Ensure that there are no foreign bodies such as tubing, crumbs, grease, etc. on the upper surface of the cushion.

› Important: please talk with your prescriber in the month following the purchase of the cushion.

› Enhanced monitoring for patients who are at risk of falls (patient profile: disabled, agitated, not lucid).

Circumstances under which the user must consult a healthcare professional

› If one of these measures cannot be implemented, you must inform your doctor or nurse as soon as possible.

› 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 (ischium, coccyx, trochanter, hip, shoulder blade).

Precautions for use

› Bone and/or muscular and/or skin trauma in the pelvic and thigh or spinal regions, that are not stabilised and/or painful, and in direct contact with the support.

› Resumption of sitting after surgery for a bedsore/wound (skin or flap graft).

› When washing, ensure that the valves are closed.

› Please also check the condition of the exposed part of the skin each time that care is provided.

› In the case of an armchair shower, use the cushion without cover or replace it with a dry cover.

Warnings

› (Re)evaluate the patient's risk of trapping in the non-moving parts of the wheelchair equipped with the therapeutic cushion.

› The maximum permissible pressure is 100 mBar. Check the cushion pressure daily.

Service life information

The device may be reused within the initial performance maintenance limits for the duration of its life cycle. Its estimated lifetime is 5 years.

Protective accessories

Only protective accessories for the cushion supplied by the manufacturer can ensure the safety and performance of the complete product.

6. STORAGE/ HANDLING/ DISPOSAL

Specific conditions for storage and/or handling

Store away from light, heat, and damp.

Disposal of the product

Only discard the product in appropriate waste disposal facilities Use the recycling facilities available in your country.

Pressures (max) in mmHg before ageing, using the maximum validated weight

mmHg

	Max Weight user	Max pressure user buttocks
KINERIS	150 kg	154