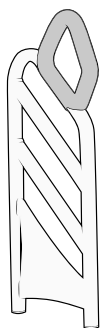
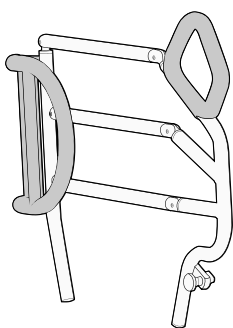


INSTRUCTIONS FOR USE

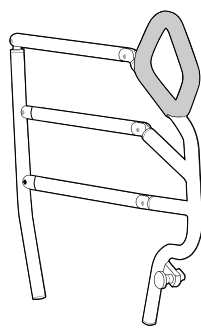
MOBILITY ASSISTANCE SYSTEMS



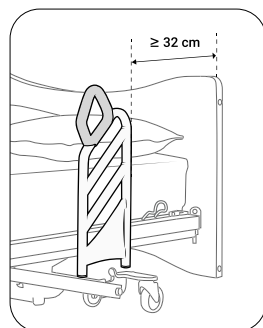
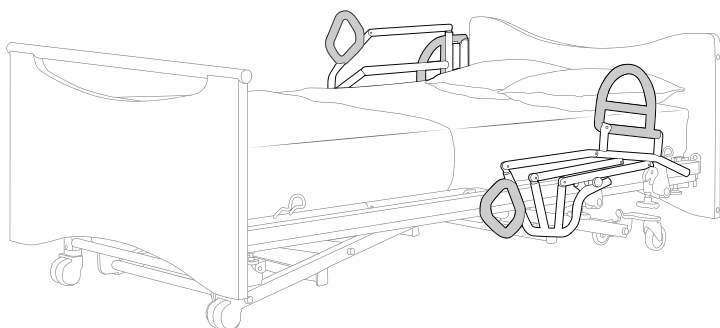
SAM ACTIV



SAM ERGONOM



SAM ERGONOM LIGHT



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580175 Version 24_04_30



580175



Read the instructions and the technical manual.



Compliant with Regulation (EU) 2017/745 on Medical Devices



Separate collection at end of life.



Date of manufacture



Serial Number



Batch number



Patient Weight Range



Warning



Compatible with chlorine-based disinfection solution (1,000 ppm or 0.1% active chlorine).



Dry cleaning excluded, use of solvent-based remover excluded.

1. INDICATIONS

Device Intended Use

- › Compensation for disability. Prevention.

General indications

- › Patients who have difficulty with lying-sitting transfers;
- › Patients suffering from postural and motor maladjustment and posterior trunk imbalance.

Target patient and user group

- › Adult patients who are bedridden, ill or disabled,
- › Patients who are unable to perform lying to sitting movements independently (ERGONOM and ACTIV) and/or who have difficulty lying on their side without an aid system, contributing to the function of rolling over during care or medical procedures.

Contra-indications

- › Fracture of the spine or pelvis,
- › Cardiovascular stress disorder,
- › Localised joint pain in the dorso-lumbar spine,
- › Muscle sprains or strains, vertebral fractures - traumatic or compression fractures - disc injuries, herniated discs.
- › Disabled patient (disability, poor muscle tone), restless, not lucid (confused, disorientated) at risk of falling requiring physical restraint by means of bed barriers on medical prescription,
- › Functional inability to move unaided.



Report undesirable side-effects

Indirect trauma of upper limbs when using a device.

Any serious incident in connection with 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 established. 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

- › Medical bed accessory fixed on the long sections (40*40mm square) of same.
- › The ergonomics of the handle (30° angle) have been designed so that it can be gripped by the upper limb on the opposite side of the bed, without requiring shoulder abduction.
- › The handle can be gripped by the same arm in the case of patients with an impairment of the opposite arm.
- › The position of the grab handle is designed to guide the pattern of movement: 45° lateral roll + 45° anterior flexion. The handle is angled at 30° so it can be held with the elbow to the body.
- › The colour of the handle contrasts with the grip area making it easier to detect for people with ARMD (age-related macular degeneration), presbyopia or cataract.
- › The section of the handle promotes digitopalmar strength (hook grip) in people suffering from osteoarthritis or muscular weakness.

Expected clinical benefits

- › Facilitates the transition from lying to sitting by moving the centre of mass anteriorly.
- › Improvement of lying-sitting movements by a greater lateral displacement than in the absence of technical assistance.
- › Functional independence is a prerequisite for maintaining continence and managing rest and comfort time independently.

Viollet E, and al. A randomised clinical trial comparing a new bed rails and lifting pole in lying-sit transfer in elderly patients. *Annals of Physical and Rehabilitation Medicine*. 2016, Vol 59 - N° Special

Information for health professionals

Training required in order to be able to inform the person of the benefits of using the technical aid when rolling over or sitting up from the lying position and in order to make the user understand the benefits of the functionalities of the technical aid and use it when rolling over and sitting up (notion of compliance).

Specific instructions

FUNCTIONS	SAM ERGONOM	SAM ACTIV	Healthcare Benefits
Lying-sit transfer	<ul style="list-style-type: none"> › Motor maladjustment (psychomotor regression). › Stasobasophobia. › Abdomino-pelvic muscle weakness. › Motor slowing (Parkinson's). › Unstable seated balance. 	<ul style="list-style-type: none"> › Motor maladjustment (psychomotor regression). › Stasobasophobia. › Abdomino-pelvic muscle weakness. › Motor slowing (Parkinson's). › Unstable seated balance. 	<ul style="list-style-type: none"> › Prevention of musculoskeletal disorders. › Decreased workload.
Rolling on side.	<ul style="list-style-type: none"> › Motor maladjustment. › Weakness, paresis of lower limbs. › Stasobasophobia. 	Not applicable.	<ul style="list-style-type: none"> › Remove back-lumbar strain during bed care. › Promote patient mobility.
	Specific contraindication: Degenerative shoulder.	-	-

3. PREREQUISITES BEFORE USE AND INSTRUCTIONS FOR USE

Training and qualifications required for using the device

Training users in the proper use of assistive products (SAMs) must be carried out by persons trained and validated by the manufacturer or a trained third party, particularly in terms of safety and reporting of non-compliance.

Device installation

The device is ready for installation on the long sections of the medical bed (square 40*40 mm).

Preventive maintenance

- Check that the SAM ERGONOM and its rolling aid handle are retracted.
- The elastomer of the handle must be intact (colour, material).
- An annual check should be carried out at the same time as the medical bed is checked (see "Annual bed check sheet" in the medical bed user manual).

Cleaning and disinfection

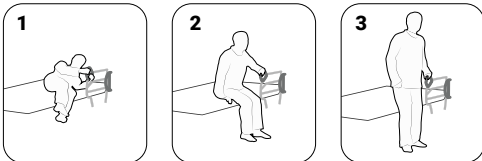
- Biocleaning by applying detergent, detergent-disinfectant and surface disinfectant products suitable for non-critical medical devices and covering the documented microbiological risk. Rinse with clean water and then disinfect, observing the remanence time recommended by the manufacturer.
- Steam process for cleaning and disinfecting structural elements.
- Washing tunnel with spraying of surface disinfectants.

Information regarding suitable procedures for re-use

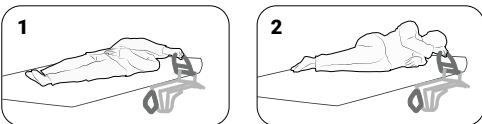
- The product must be physically and bacteriologically clean.
- The elastomer material of the handles used to assist sitting and rolling must be intact.
- Avoid contact with scouring, stripping or solvent products and sharp objects in direct contact with the painted surface of the structural elements and the surface of the elastomer protection.
- The restoration of the articulated and fixed structure is not permitted.

4. INSTRUCTIONS FOR USE

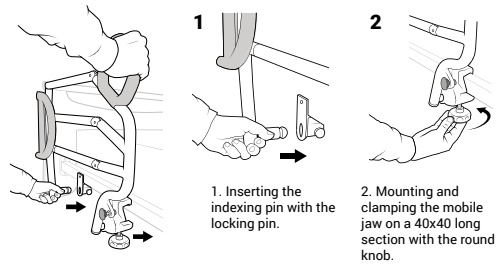
Sitting up: Lying-sitting and sitting standing



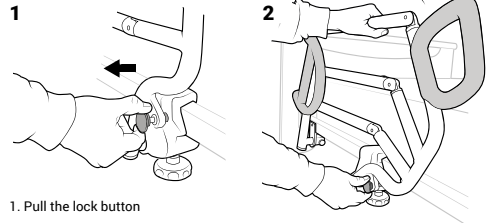
Rolling on side



Assembly/disassembly



Lower/Raise



5. WARNINGS, PRECAUTIONS FOR USE, MEASURES REQUIRED

Precautions for use

- The installer and the healthcare professional should check that the assistive device is firmly attached to the long side(s). It must not move sideways.
- The healthcare professional must assess the patient's ability to understand the functions of the assistive device and to use it to roll over and sit up.
- The daily application of bleach solutions in excess of 1,000ppm is not recommended on elastomer.
- Pressurised jets can cause water or water droplets to penetrate inside the tubes, leading to corrosion of the inner surface and eventual rusting.

Warnings

- Evaluate tolerance in patients who have deteriorated and whose retropulsion makes it impossible to maintain a seated position at the edge of the bed.
- In patients who "fall", ensure that the patient is reassured when rolling onto their side, by standing on the side on which they are positioning themselves.
- If the multi-disciplinary team recommends the use of one-sided equipment, increased monitoring must be put in place against the risk of falling when getting out of bed on the other side equipped with the SAM.

Required measures

- Respect the time it takes to get used to the technical aid by accompanying the person until they have assessed their ability to become independent.
- Adjust the height for getting out of the medical bed according to the person's muscular capacity to stand up after sitting up.
- Installing a barrier on the side opposite the SAM equipment can minimise the risk of the patient falling.

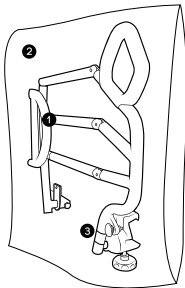
Circumstances under which the user must talk with a healthcare professional

Report any abnormal phenomenon such as back pain, a perceived risk of falling or a fall when getting up to your doctor, nurse, physiotherapist or occupational therapist as soon as possible.

Information on any known restrictions to combination with devices and equipment

SAM ERGONOM and SAM ACTIV mobility systems are compatible with medical beds designed and manufactured by WINNCARE France.

6. COMPOSITION OF COLIS



- 1 Mobility Assistance System
- 2 Recyclable plastic bag
- 3 Traceability label

7. STORAGE, HANDLING, DISPOSAL

Terms of use and storage

SAM ERGONOM and SAM ACTIV products should preferably be stored flat, away from direct light, excessive humidity and impact.

Use

Storage

Lifetime

The estimated lifetime of mobility aid systems is five (5) years.

Disposal of the product

Do not throw the product out into non-dedicated locations in nature. Follow the recycling channels that are in place in your country.



	REP
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Distributor

