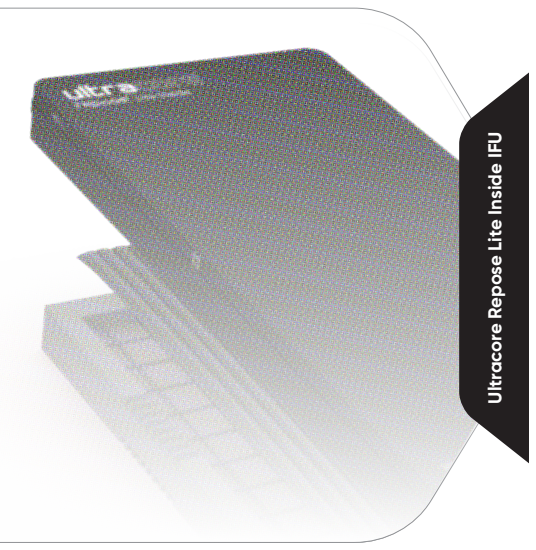

ultracore repose Lite Inside

Instructions for use

Version 3.0 April 2021.

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EN Ultracore Repose® Lite Inside

This user manual contains important information on correct usage, handling, cleaning and decontamination. Please read carefully prior to use.

Should you have any queries, please contact Frontier Therapeutics Ltd on +44 (0)330 460 6030

! IMPORTANT When removing packaging use great care to ensure the cover is not damaged.

Ensure that the surface of the bed frame is clear from debris before placing the mattress as this can damage the coating of the cover.

The label on the mattress has a unique batch number which should be retained and used in the event of a warranty claim. NEVER remove the label, please refer to the section 'Warranty'.

Intended Purpose

Ultracore® Repose Lite Inside is an immersive, reactive air, pressure redistribution, hybrid mattress replacement system, designed to meet the demands of the home care and acute care environments. Ultracore Repose Lite Inside combines several different components that, together, provide healthcare professionals and patients exceptional levels of comfort and pressure redistribution properties. At it's core, is Repose® Lite, which has over 18 years of clinical evidence to support its ease of use, durability and clinical outcomes.

Multiple Randomised Control Trials have demonstrated Repose's ability to reduce peak and average interface pressures consistently (5.2%[1], 4.8%[2], 5.1%[3], 5.2%[4]).

Maximum user weight – 250kg/551lbs

Ultracore Repose Lite Inside consists of the following components:

Ultracore Foam - A high specification, polyurethane U-core foam base with integrated side and profiling sections.

Repose Lite Mattress Inner - A pre-inflated, single-cell, reactive air mattress inner.

Ultracore Cover – A multi-stretch, moisture vapour permeable polyurethane coated, antimicrobial cover, with zip openings on three sides, including a protective zip cover and welded seams, to provide fluid ingress resistance.

Indications

Ultracore Repose Lite Inside mattress replacement system is designed for the prevention and treatment of pressure ulcers, intended to be used in conjunction with an appropriately sized bed frame. Use on solid, mesh, profiling and flatbed bases.

- Those at risk of developing pressure ulcers, including those at very high risk.
- The treatment of all categories / stages of pressure ulcers when used as part of a package of care.

Contraindications

- Not for persons weighing more than 250kg / 551lbs.
- Not for persons with unstable spinal fractures.
- Where body shape is such that the person cannot be fully supported.

Warnings and Precautions

There are no special skills required to operate or use Ultracore Repose Lite Inside. Before use, check Ultracore Repose Lite Inside is free from any damage. If there are any visible signs of damage, do not use and seek a replacement.

- Avoid direct contact with heat and sharp objects.
- Keep away from pets.
- May appear under-inflated if exposed to temperatures below ambient. Warm to room temperature before use.
- Fluctuations in environmental conditions may impact appearance.
- Must not be used on double bed frames.
- Must not be used as a flotation device.
- Should only be used with a pre-inflated Repose Lite Mattress Inner.
- During routine use, the appearance of the Repose Lite Mattress Inner may change, this is normal and to be expected.
- Not suitable for sterilisation.
- The Repose Lite Mattress Inner is supplied with a quick and easy check, which should be conducted routinely and between patient use. See appendix 4.
  - Unzip the cover and remove the mattress inner, placing it on a flat, clean surface.
  - Locate the inflation strap, attached to the mattress inner centre edge, and, without tension, drape across its centre.
  - Ensure the inflation strap is free from creases and kinks. Locate the position of the white marker, comparing it to Appendix 4, FIG 1 and FIG 2.
  - If the white marker is visible beyond the edge of the mattress inner, then it is suitable for use (Appendix 4, FIG 1).
  - If the white marker is visible over the mattress inner, then it is not suitable for use (Appendix 4, FIG 2)
  - Visible artefacts during radiographic imagery are possible.
  - Inspect the patients skin regularly; if any change occurs, immediately consult a healthcare professional.

Patient Target Group

Immobile and less mobile patients who are at risk of developing pressure ulcers, including those at very high risk, or for the treatment of all categories / stages of pressure ulcers when used as part of a package of care.

Intended Users

Intended for professional healthcare facility and domestic environments in combination with standard and profiling bed frames, manual handling equipment and support aids.

Product Dimensions

Repose Lite Mattress Inner	L 1780mm x W 770mm L 70in x W 30in
Ultracore Foam Mattress	L 1980 x W 880mm x H 150mm L 78in x 34in x H 6in

Instructions for Use

Before use:

This mattress replacement system has been delivered in two parts: The Ultracore Mattress and Repose Lite Mattress Inner.

- Remove both parts from the packaging.
- Unzip the blue Ultracore cover and insert the Repose Lite Mattress Inner in to the foam base.
- Close the zips on the cover.
- Prior to use, allow the mattress system to acclimatise to room temperature.

Appendix 1 - Symbols Used on Repose Lite Mattress Inner Labelling

Do Not Wash	Bleaching agent allowed (≤ 1%)	Do Not Tumble Dry	Line Dry	Maximum User Weight	Caution
Consult Instructions for Use	CE Mark	Batch Code (LOT)			

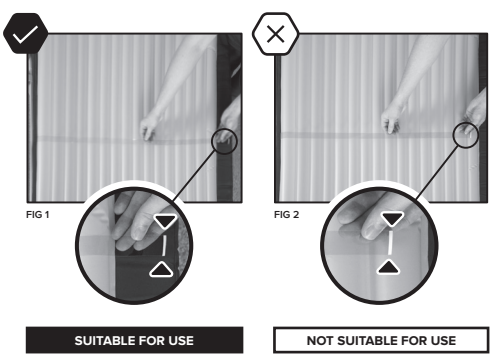
Appendix 2 - Symbols Used on Cover Labelling

65°C for 10 Minutes or 73°C for 3 Minutes (65)	Bleaching agent allowed (≤ 1%)	Maximum User Weight (250 kg)	Do Not Pierce or Cut	Line Dry	Do Not Iron
Do Not Tumble Dry	Consult Instructions for Use	European Authorised Representative (EC REP)			

Appendix 3 - Product Description

Foam Density		Dimensions (cm/in)		
Support Surface	Wall	Width	Height	Length
33/160	39/200	88/35	15/8	198/78

Appendix 4 – Inspection Guide



Appendix 5 - Product Codes

Product Code	Product Description
9200001	Ultracore Repose Lite Inside Cover
6270001	Ultracore Repose Lite Mattress Inner
9200010	Ultracore Repose Lite Inside

Storage & Care

- Store the mattress in a secure location away from the general public.
- Never store other items on top.
- Always store flat, and not in direct contact with the floor.
- Place a protective cover over the mattress during storage.
- Do not store mattresses next to radiators or other heating devices.
- It is recommended that a minimum of two people handle the mattress. Do not drag!
- Do not allow sharp objects to penetrate the cover.
- Regularly inspect the interior and exterior of the mattress.
- Do not store in damp conditions.
- The cover is removable for cleaning purposes, please see section 'Cleaning and Disinfection'.

Cleaning and Disinfection of Repose Lite Mattress Inner and Cover

Cleaning

If visible signs of dirt and contamination are present, Repose including the cover, should be cleaned using detergent and water. In the absence of visible contamination, Repose should be cleaned using detergent and water weekly. All Repose Polyurethane covers can be machine washed at 65°C for ten minutes or 73°C for three minutes. Do not machine wash the Repose inner, ensure it is removed.

Do not use abrasive cloths.

Rinse with clean water and wipe down with single-use, nonabrasive cloth and thoroughly dry.

Disinfection

Light or Heavy Soiling

Decontaminate Repose with a 0.1% (1,000ppm) - 1% (10,000ppm) Chlorine solution. Rinse with clean water and wipe down with a single-use, non-abrasive cloth and thoroughly dry.

Drying

Thoroughly dry in a clean, indoor environment before storage.

Routine Inspection

Inspect the inner and outer surfaces of covers and their zip fasteners regularly for signs of damage. If the cover is stained, soiled or torn, examine the foam and Repose Lite Mattress Inner for signs of contamination which could indicate a breach in the covers bacterial barrier properties. Report damaged or soiled covers to the ward or department manager.

If the foam core of the mattress is wet or stained, withdraw the mattress from service.

Wear disposable gloves and aprons and other appropriate PPE when using chlorine-based disinfectants, please refer to manufacturers instructions for use.

Audit

Audit all mattresses every 6 – 12 months.

Re-Use

Please keep a cleaning record. Ultracore Repose Lite Inside is suitable for repeated use. Before re-use, clean thoroughly, please refer to the section `Cleaning and Disinfection`.

Discontinue Use

If the foam or cover shows any signs of contamination or excess wear, they should immediately be withdrawn from use. Excess wear may include discolouration, fraying, misshaping, thinning, tearing or fluid ingress.

Disposal

The disposal and recycling of used product and packaging must comply with the applicable legal regulation in each country.

CPR

Repose Lite Mattress Inner is a low-profile which contains no exposed metal or electrical elements and can be used safely during CPR.

Fire Testing

Fire Safety Regulations; BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources.

Warranty

The Ultracore Repose Lite Inside mattress warranty is valid from the time of shipping. Please contact Repose customer service on Tel: 0044 (0) 1495 235800 / email: info@reposedirect.com when discovering a defect immediately. Frontier Therapeutics Ltd. does not accept responsibility for damage caused by misuse or non-observance of the instructions set out in this instruction for use document. During the period of the warranty, any products that have become defective due to faulty workmanship or materials will be replaced at the discretion of Frontier Therapeutics Ltd. Product warranty is forfeited should any unauthorised alteration be made to the equipment. Both warranty and fire retardancy certification is null and void if non-Repose spares are used.

Warranty – Ultracore Foam and Ultracore Outer Cover

5 years from the date of dispatch, covering against manufacturers defects.

Frontier does not accept warranty claims that result through normal wear and tear.

All warranties subject to terms and conditions of trading. Please note and submit LOT numbers which can be found printed on the labels.

Warranty – Repose Lite Mattress Inner

1 year from date of dispatch, covering against manufacturers defects.

Frontier does not accept warranty claims that result through normal wear and tear.

All warranties subject to terms and conditions of trading.

Please note and submit LOT numbers which can be found printed on the labels.

Compliance

Ultracore Repose Lite Inside conforms to MDD 93/42/EEC and MDR 2017/745 and the following standards: BS EN ISO 9001:2015 Quality Management Systems. BS EN 13485:2016 Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes. BS EN 14971:2012 Medical Devices. Application of Risk Management to Medical Devices. BS EN ISO 15223-1:2016 Medical Devices. Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied. General Requirements. BS EN ISO 10993-5:2009 Biological Evaluation of Medical Devices. Tests for In Vitro Cytotoxicity. BS EN 10993-10:2013 Biological Evaluation of Medical Devices. Tests for Irritation and Skin Sensitization.

Fire Safety Regulations; BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources.

Repose DOES NOT incorporate as an integral part, a substance, which if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC.

Repose DOES NOT incorporate as an integral part any substance or human blood derivatives as referred to in section 7.4 Annex I of Commission Directive 93/42/EC, nor is it manufactured utilising tissues of animal origin as referenced to in Commission Directive 2003/32/EC.

At the time of publication the Repose range does not contain any substances, over 0.1% by weight, that are described on the Candidate List of substances of very high concern for Authorisation - EC Regulation 1907/2006 – REACH.

Product Complaints

Any healthcare professional (e.g., customer or user of this system) who has any complaints or who have experienced any dissatisfaction in quality, identity, durability, reliability, safety, effectiveness, and performance should notify the distributor or Frontier Therapeutics Ltd.

Further, if any Ultracore Repose Lite Inside "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, notify the distributor or Frontier Therapeutics Ltd. immediately.

If any Frontier Therapeutics Ltd. product ever malfunctions and may have caused or contributed to the death or severe injury of a patient, Frontier Therapeutics Ltd. should be notified immediately by telephone, fax, or written correspondence.

When filing a complaint, provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether or not a written report from the distributor is requested.

Any serious incident that occurs in relation to Ultracore with Repose Lite Inside, should be reported to Frontier Therapeutics Ltd. and the competent authority of the Member State in which the user and/or patient is established.

Further Information

If further information is required,
contact Frontier Therapeutics Ltd. on
Tel: 0044 (0)330 460 6030
Email: info@frontier-group.co.uk
Email: contactus@frontier-therapeutics.com

GP0052_D49_03, April, 2021

References

1. Beeckman et al. (2019) A multi-centre prospective randomised controlled clinical trial to compare the effectiveness and cost of a static air mattress and alternating air pressure mattress to prevent pressure ulcers in high-risk nursing home residents. International Journal of Nursing Studies, June, https://doi.org/10.1016/

2. Van Leen, M. Hovius, S. Neyens, J. Hafens, R, Shols, J. (2011) Pressure relief, cold foam or static air? A single centre, prospective, controlled randomised clinical trial in a Dutch nursing home. Journal of Tissue Viability, 20 (1), 30-34

3. Beeckman et al. (2016) Static air support surfaces to prevent pressure injuries. J Wound Ostomy Continence Nurs. 2016;43(4):375-378

4. Van Leen et al. (2013) Pressure Relief with Visco-Elastic Foam or with Combined Static Air Overlay? A prospective, Crossover Randomized Clinical Trial in a Dutch Nursing Home. Wounds 2013;25(10): 287-292.

5. Rosser, D., 2017. Popliteal vein compression syndrome the MAIN cause of DVT, unrecognised. [Online] Available at: https://www.arteries-veins.com/single-post/2017/01/07/Popliteal-vein-compression-syndrome-the-MAIN-cause-of-DVT-unrecognised [Accessed 12 June 2019].

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