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Reposе IFU

EN Repose® Instructions for Use

Introduction/Intended Purpose

Repose® is a range of static air, pressure redistribution and reduction support surfaces, all with high levels of immersion and envelopment. Immersion is the depth to which the body penetrates a support surface. Envelopment is the ability of a support surface to conform to the irregular shape of the body. Patient movement alters where this immersion and envelopment occurs, and the multi-way stretch, and elasticity of Repose allows for interface pressures to equalise across its surface.

This combination of unique materials and Smart Valve Technology have been clinically proven to deliver statistically significant patient benefits[1]. 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]).

Repose Foot Protector, Foot Protector Plus, Wedge and Flex are designed to completely offload pressures from the heel, redistribute pressure across the patient's calf, and in the case of Repose Flex, introduce a 5-10° angle in the patient's knee which is designed to reduce the risk of DVT[5].

Repose Cushion and Care-sit are designed for use on static chairs with fitted armrests. Repose Contur is designed for use with riser recliner chairs.

Repose Contur, Care-sit and Companion are provided with blue polyurethane coated covers for additional durability, infection control and comfort. Covers are also available for Repose Mattress Overlay and Cushion.

Repose is offered in a variety of configurations to accommodate varied patient anatomy. Information can be found in the appendix, App 2.

All Repose variants are supplied in an air pump unless otherwise stated. Please consult the product catalogue for full details or contact Frontier Therapeutics Ltd. for more information.

Indications

Indications for Repose are as follows;

Those at risk of developing pressure ulcers, including those very high risk.

The treatment of all categories/stages of pressure ulcers when used as part of a package of care.

Contraindications

Contra-indications for Repose are as follows;

Seating solutions and overlays are not suitable for patients with unstable spinal fractures.

Irregular body shapes that cannot be fully supported by Repose.

Patients requiring posture management or those who have a pelvic obliquity are not indicated for Repose seating solutions.

Maximum User Weights

Repose is subject to maximum user weight restrictions.

Product Description	Weight Limit
Mattress Overlay, Long Mattress Overlay, Double Mattress Overlay, Companion, Trolley Companion, Trolley Mattress Overlay	When used on a high specification Repose mattress – 222kg When used on a non-high specification foam mattress – 139kg
Cushion, Care-sit, Contur, Paediatric Mattress, BabyThorn Overlay	139kg
BabyNest Overlay	3kg (There is no lower weight limit)
Foot Protector, Foot Protector Plus, Foot Protector Four Layer, Wedge, Flex, Sole Protector	No weight limit

Warnings and Precautions

There are no special skills required to operate or use Repose. Frontier Therapeutics Ltd provides additional training material which can be found online at https://www.frontier-group.co.uk/elearning/

Before use, check Repose is free from any damage. If there are any visible signs of damage, do not use and request a replacement.

Ensure Repose is fitted correctly and does not cause any obstructions.

Ensure Repose Foot Protector can fully support ankle and shape of the patient's lower leg.

The Repose valve should always be on the outside and away from the patient and should never come in contact with the patients' skin.

To ensure optimal performance, use the correct size product. Sizing information is found within this IFU.

Always inflate and top up Repose with the patient off the product.

If you see a change in skin condition, seek advice from a healthcare professional immediately and if Repose reassess the care plan or discontinue use.

Only use supplied inflation pumps. Replacement or additional inflation pumps are available from Frontier Therapeutics Ltd.

When using bed side rails, please follow the manufacturer's instructions for use. Ensure that Repose is fitted correctly and does not restrict its correct operation, which could result in damage to Repose or reduce the safety features of the side rail.

Not suitable for sterilisation.

Do not smoke while the system is in use.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

Repose Foot Protector Plus contains 6 x Nickel plated magnets (10mm Dia x 3mm thick N35 Neodymium Magnet, Gauss 2800/Tesla 0.28). Please keep at least 150mm away from active devices such as pacemakers.

Repose Foot Protector Plus contains Nickel that is not in contact with the patient. Please take care when using with patients with known Nickel allergies.

Repose valve contains a metal spring. Do not use in proximity to magnetic sources such as Magnetic Resonance Imagery.

Visible artefacts during radiographic imagery are possible.

Do not modify any of the medical device or accessories in any way.

Repose Cushion, Care-Sit and Contur should only be used with chairs fitted with armrests.

Position on the support surface (chair, riser recliner, support surface, trolley/stretcher frame) should be checked regularly to ensure the continued correct and safe use.

Check Repose regularly and 'top-up' within a period of no longer than two weeks, using the pump supplied.

When deflated, keep away from babies and small children as it could pose a suffocation risk.

Keep away from pets.

Not to be used as a sling or flotation device.

Do not clean with phenol-based disinfectants.

Do not use abrasive cloths to clean Repose as this may cause irreversible damage.

Blue polyurethane covers can be machine washed, ensure that the Repose inner is removed before washing.

Please review the above warnings, cautions and any safety considerations on a routine and regular basis, not only upon installation.

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 stages of pressure ulcers when used as part of a package of care.

Intended User

Intended for home healthcare and professional healthcare facility environments.

Instructions for use

Before use, please read the following instructions. Should you have any queries, please contact Frontier Therapeutics Ltd. on +44 1495 235 800.

Choosing the Correct Size

If you are using the Foot Protector, Foot Protector Plus or Flex, correct sizing is important to optimise outcomes. Measure the distance between the back of the knee to the heel and use the corresponding measurement with the table below.

Leg Measurement	Product Size	Colour
460mm - 410mm	Extra Small	Blue
500mm - 450mm	Small	Green
550mm - 490mm	Standard	Yellow
690mm - 550mm	Long	Orange

Maximum calf circumference of 330mm is applicable for the foot protector range only. The Repose valve is colour coded for convenience and easy identification.

Inflation

1. Remove Repose from the tube and refit to form a pump.
2. Connect the valve on the pump to the Repose valve – Push to Fit.
3. Begin inflating and continue until air can be heard escaping from the pump valve. Discontinue inflating and wait to hear an audible click. This signals correct inflation has been achieved.
4. Disconnect the pump and cover the valve with the solid end of the Repose sealing cap.
5. Check Repose regularly and 'top-up' within a period of no longer than two weeks, using the pump supplied.

Fitting Instruction

1. Install Repose with the valve facing down and away from the patient.
2. Secure in place with the integrated retaining straps.

Product Description	Comment
All Mattress Overlay types (without cover)	Use securing straps on top and bottom of the overlay underneath the mattress it is being placed on
Sole Protector	i. Position at the foot end of the bed. ii. Fix Vertical Straps first around the footboard using the clasps provided. iii. Fix Horizontal straps around the footboard using the clasps provided
Wedge and Flex	Place the securing strap underneath the mattress it is being placed on

Product Description	Comment
Cushion (without cover)	Use securing the strap around the back of the chair
3. If using Repose Foot Protector Plus, use the Magnaflix® straps by placing one over the other. 4. If using Repose with a cover, insert lengthways into the cover ensuring that the valve faces down and away from the patient. 5. When attaching covered products please consider the following:	
Care-sit	i. Loop both upper fixing straps over the wheelchair handles. ii. Loop the lower fixing strap around the back of the wheelchair under the arm rest, clipping together and adjusting until secure.
Contur	i. Insert the fixing straps between the seat and the arm rest, looping around the back of the chair, cross them and clip in place at the top. ii. Loop the bottom straps around either side of the footplate.
Companion (all versions)	i. Use straps provided to secure Companion to the desired surface ii. Tuck all excess straps into the loops provided

Deflation

1. With the patient off Repose, detach from the mattress, chair or footboard.
2. Clean and decontaminate as per the instruction below.
3. Once, cleaned and completely dry, remove the sealing cap and fitted the Repose valve.
4. Insert the open end of the sealing cap into the Repose valve, allowing air to escape.
5. Once deflated, with the cap still in place, roll up Repose, starting at the point furthest away from the valve, expelling any remaining air. Repeat this process as necessary.
6. Fold and roll up and place inside the pump for safe storage. Rotate the outer tube until it clicks closed.

Cleaning and Decontamination of Repose and Polyurethane Covers

Repose can be cleaned, decontaminated and reused.

With regular maintenance, Repose is reliable and long-lasting. These instructions have been written to help the user maximise the functional life of Repose but in no way, guarantee the lifetime of the product. It is the user's responsibility to regularly inspect and check the product to ensure that Repose is performing optimally.

Repose is a class I medical device and as such, should be cleaned and handled as per infection control policies. The following is a recommendation made by Frontier Therapeutics Ltd but does not override your local policy and guidelines. If in doubt, please contact Frontier Therapeutics Ltd or your local infection control team.

Cleaning

If visible signs of dirt and contamination are present, Repose including the cover, should be mechanically cleaned using detergent and water. In the absence of visible contamination, Repose should be mechanically cleaned using detergent and water weekly. All Repose Polyurethane covers can be machine washed at 65°C for 10 minutes or 71°C for 3 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, non-abrasive cloth and thoroughly dry.

Disinfection

Light Soiling

Clean with detergent and water to remove any visible signs of dirt and contamination and disinfect with a 0.1% chlorine solution (1,000ppm). Rinse with clean water and wipe down with a single-use, non-abrasive cloth and thoroughly dry.

Heavy Soiling

In cases of gross contamination, clean with detergent and water to remove visible signs of dirt and contamination and then with a 1% chlorine solution (10,000ppm). Rinse with clean water and wipe down with a single-use, non-abrasive cloth and thoroughly dry.

Straps & End Tapes

Straps, end tapes and other accessories can be cleaned and decontaminated in the same way as Repose. Thoroughly dry before storage.

Drying

Dry thoroughly and thoroughly dry in a clean, indoor environment before storage.

Cleaning the Repose Pump

Manufactured from a durable, recyclable, ABS plastic, the Repose Pump should be both mechanically cleaned with detergent and water and chemically disinfected with commonly used chlorine derivatives, to ensure its longevity.

Before cleaning disassemble the pump, inspect for damage and clean as instructed.

Use the same methods described in the light and heavily soiled sections for Repose products.

Once clean, ensure that the pump is thoroughly rinsed with clean water and wiped down to remove any excess.

Re-assemble and pump five or six times to remove excess water from the valve.

Allow to air dry in a clean environment before storage.

Precautions when Cleaning Repose and Repose Pump

Please wear the appropriate personal protective equipment when using disinfectant solutions.

Phenol-based disinfectants should not be used to clean Repose.

Do not use abrasives.

Ensure Repose is thoroughly dry before storage, use and re-use.

Frequent cleaning with a high concentration disinfectant solution (i.e. 10,000 ppm available chlorine) will reduce the life span of Repose.

For suitability, please contact the disinfectant manufacturer to confirm they are suitable for soft surfaces including polyurethanes.

Repose cannot be machine washed, nor should it be immersed. Avoid fluid ingress into the valve. Inflate to clean.

End of life disposal

Cared for correctly, Repose is long lasting and durable. At the end of its life, clean and disinfect according to the instructions within and dispose of with normal clinical waste.

Packaging and Storage

Repose is supplied pre-packaged and should be intact upon receipt. Before use, carefully check all components for completeness and signs of damage. Damaged packages or products should not be used and returned to Frontier Therapeutics Ltd.

Store and keep in a cool, dry space and away from direct sunlight.

Do not store next to radiators or other heating devices.

Handling

Improper use or handling may lead to damage and possible malfunction.

Repose should be checked to ensure it is in working order before use.

Do not use damaged or non-working products.

All Repose products are Latex Free.

Manufacturers Guarantee

Frontier Therapeutics Ltd. warrants Repose for 24 months, against manufacturing defects. The warranty does not include general wear and tear, or failure by other means.

Compliance

Repose complies with the following standards;

The requirements of MDR 2017/745. ISO 10993-1:2018 Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing. ISO 10993-5:2018 - Biological evaluation of medical devices. Part 5: Tests for in-vitro cytotoxicity.

Fire Safety Regulations; BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources, BS 597 parts 1&2 – Furniture – Assessment of the Ignitability of Mattresses and Upholstered Bed Bases, 16 CFR part 1632 - Standards for the Flammability of Mattresses and Mattress Pads, California TB117-2013 – Requirements, Test Procedure and Apparatus for testing the Smolder Resistance of Materials Used in Upholstered Furniture, California TB133-1991 - Flammability Test Procedure for Seating Furniture for Use in Public Occupancies.

Repose is manufactured in accordance with an accredited ISO 13485:2016 – Quality Management Systems for Medical Devices.

Repose DOES NOT incorporate as an integral part any 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 Directive 93/42/EC, nor is it manufactured utilising tissues of animal origin as referenced 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 of Repose) who has any complaints or who have experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and performance should notify the distributor or Frontier Therapeutics Ltd.

Further, if any Repose product "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 serious 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 required.

Further Information

If further information is needed or required, contact Frontier Therapeutics Ltd. on Tel: +44 1495 235 800.

App 1

Product Code/Size	Product Description
6750000 XS 6750001 S 6750002 M	Repose Flex
6930001	Sole Protector
6711100 Fabric Strap 6711111 PU Strap	Wedge
6511100 XS 6521100 S 6541100 M 6021100 L	Foot Protector (Pairs)
6551100 XS 6561100 STD 6511100 STD	Foot Protector Plus (Pairs)
6542000 S 6542001 L	Foot Protector Four Layer (Pairs)
6101100 STD Long 6011100 Long	Mattress Overlay
6131100	Double Mattress Overlay
6601100	Trolley Mattress Overlay
6201100	Cushion
6310001	Contur Overlay
6351001	Care-sit
6990003	Companion
6990050	Trolley Companion
6801100	Paediatric Mattress Overlay
6801101	Babynest Overlay
6401100	Babythorn Overlay

Product Description	Comment
All Mattress Overlay types (without cover)	Use securing straps on top and bottom of the overlay underneath the mattress it is being placed on
Sole Protector	i. Position at the foot end of the bed. ii. Fix Vertical Straps first around the footboard using the clasps provided. iii. Fix Horizontal straps around the footboard using the clasps provided
Wedge and Flex	Place the securing strap underneath the mattress it is being placed on

Product Description	Comment
Cushion (without cover)	Use securing the strap around the back of the chair
3. If using Repose Foot Protector Plus, use the Magnaflix® straps by placing one over the other. 4. If using Repose with a cover, insert lengthways into the cover ensuring that the valve faces down and away from the patient. 5. When attaching covered products please consider the following:	
Care-sit	i. Loop both upper fixing straps over the wheelchair handles. ii. Loop the lower fixing strap around the back of the wheelchair under the arm rest, clipping together and adjusting until secure.
Contur	i. Insert the fixing straps between the seat and the arm rest, looping around the back of the chair, cross them and clip in place at the top. ii. Loop the bottom straps around either side of the footplate.
Companion (all versions)	i. Use straps provided to secure Companion to the desired surface ii. Tuck all excess straps into the loops provided

Deflation

1. With the patient off Repose, detach from the mattress, chair or footboard.
2. Clean and decontaminate as per the instruction below.
3. Once, cleaned and completely dry, remove the sealing cap and fitted the Repose valve.
4. Insert the open end of the sealing cap into the Repose valve, allowing air to escape.
5. Once deflated, with the cap still in place, roll up Repose, starting at the point furthest away from the valve, expelling any remaining air. Repeat this process as necessary.
6. Fold and roll up and place inside the pump for safe storage. Rotate the outer tube until it clicks closed.

Cleaning and Decontamination of Repose and Polyurethane Covers

Repose can be cleaned, decontaminated and reused.

With regular maintenance, Repose is reliable and long-lasting. These instructions have been written to help the user maximise the functional life of Repose but in no way, guarantee the lifetime of the product. It is the user's responsibility to regularly inspect and check the product to ensure that Repose is performing optimally.

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If visible signs of dirt and contamination are present, Repose including the cover, should be mechanically cleaned using detergent and water. In the absence of visible contamination, Repose should be mechanically cleaned using detergent and water weekly. All Repose Polyurethane covers can be machine washed at 65°C for 10 minutes or 71°C for 3 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, non-abrasive cloth and thoroughly dry.

Disinfection

Light Soiling

Clean with detergent and water to remove any visible signs of dirt and contamination and disinfect with a 0.1% chlorine solution (1,000ppm). Rinse with clean water and wipe down with a single-use, non-abrasive cloth and thoroughly dry.

Heavy Soiling

In cases of gross contamination, clean with detergent and water to remove visible signs of dirt and contamination and then with a 1% chlorine solution (10,000ppm). Rinse with clean water and wipe down with a single-use, non-abrasive cloth and thoroughly dry.

Straps & End Tapes

Straps, end tapes and other accessories can be cleaned and decontaminated in the same way as Repose. Thoroughly dry before storage.

Drying

Dry thoroughly and thoroughly dry in a clean, indoor environment before storage.

Cleaning the Repose Pump

Manufactured from a durable, recyclable, ABS plastic, the Repose Pump should be both mechanically cleaned with detergent and water and chemically disinfected with commonly used chlorine derivatives, to ensure its longevity.

Before cleaning disassemble the pump, inspect for damage and clean as instructed.

Use the same methods described in the light and heavily soiled sections for Repose products.

Once clean, ensure that the pump is thoroughly rinsed with clean water and wiped down to remove any excess.

Re-assemble and pump five or six times to remove excess water from the valve.

Allow to air dry in a clean environment before storage.

Precautions when Cleaning Repose and Repose Pump

Please wear the appropriate personal protective equipment when using disinfectant solutions.

Phenol-based disinfectants should not be used to clean Repose.

Do not use abrasives.

Ensure Repose is thoroughly dry before storage, use and re-use.

Frequent cleaning with a high concentration disinfectant solution (i.e. 10,000 ppm available chlorine) will reduce the life span of Repose.

For suitability, please contact the disinfectant manufacturer to confirm they are suitable for soft surfaces including polyurethanes.

Repose cannot be machine washed, nor should it be immersed. Avoid fluid ingress into the valve. Inflate to clean.

End of life disposal

Cared for correctly, Repose is long lasting and durable. At the end of its life, clean and disinfect according to the instructions within and dispose of with normal clinical waste.

Packaging and Storage

Repose is supplied pre-packaged and should be intact upon receipt. Before use, carefully check all components for completeness and signs of damage. Damaged packages or products should not be used and returned to Frontier Therapeutics Ltd.

Store and keep in a cool, dry space and away from direct sunlight.

Do not store next to radiators or other heating devices.

Handling

Improper use or handling may lead to damage and possible malfunction.

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Do not use damaged or non-working products.

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Fire Safety Regulations; BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources, BS 597 parts 1&2 – Furniture – Assessment of the Ignitability of Mattresses and Upholstered Bed Bases, 16 CFR part 1632 - Standards for the Flammability of Mattresses and Mattress Pads, California TB117-2013 – Requirements, Test Procedure and Apparatus for testing the Smolder Resistance of Materials Used in Upholstered Furniture, California TB133-1991 - Flammability Test Procedure for Seating Furniture for Use in Public Occupancies.

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Further, if any Repose product "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 serious injury of a patient, Frontier Therapeutics Ltd. should be notified immediately by telephone, fax, or written correspondence.

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App 2

Product Code/Size	Product Description
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6511100 XS 6521100 S 6541100 M 6021100 L	Foot Protector (Pairs)
6551100 XS 6561100 STD 6511100 STD	Foot Protector Plus (Pairs)
6542000 S 6542001 L	Foot Protector Four Layer (Pairs)
6101100 STD Long 6011100 Long	Mattress Overlay
6131100	Double Mattress Overlay
6601100	Trolley Mattress Overlay
6201100	Cushion
6310001	Contur Overlay
6351001	Care-sit
6990003	Companion
6990050	Trolley Companion
6801100	Paediatric Mattress Overlay
6801101	Babynest Overlay
6401100	Babythorn Overlay

Leg Measurement	Product Size	Colour
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550mm - 490mm	Standard	Yellow
690mm - 550mm	Long	Orange

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FR Repose® Mode d'emploi

Consignes relatives à l'installation

1. Installez le produit Repose de façon à ce que la valve soit orientée vers le bas et à l'opposé du patient.
2. Fixez-le à l'aide des sangles intégrées.

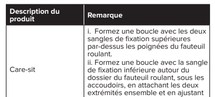
Description du produit	Remarque
All Mattress Overlay types (without cover)	i. Utilisez les sangles situées au-dessus et en dessous du surmatelas et placez-les sous le matelas sur lequel le surmatelas est placé
Sole Protector	i. Placez le produit au pied du lit ii. Fixez d'abord les sangles verticales autour du repose-pied à l'aide des attaches fournies iii. Fixez les sangles horizontales autour du repose-pied à l'aide des attaches fournies
Wedge and Flex	i. Placez la sangle sous le matelas sur lequel le produit est placé
Cushion (without cover)	i. Placez la sangle autour du dossier du fauteuil

3. Si vous utilisez le Repose Foot Protector Plus, employez les « sangles Magnaflix® » et placez l'une par-dessus l'autre.
4. Si vous utilisez un produit Repose recouvert d'une housse, introduisez-le dans celle-ci dans le sens de la longueur en vous assurant que la valve est orientée vers le bas et à l'opposé du patient.
5. Lors de la fixation de produits recouverts d'une housse, veuillez tenir compte des éléments suivants :

Description du produit	Remarque
Care-sit	i. Formez une boucle avec les deux sangles de fixation supérieures par-dessus les poignées du fauteuil roulant. ii. Formez une boucle avec la sangle de fixation inférieure autour du dossier du fauteuil roulant, puis les accoudoirs, en attachant les deux extrémités ensemble en ajustant la sangle jusqu'à ce qu'elle soit bien fixée.
Contur	i. Insérez les sangles de fixation entre le siège et l'accoudoir, en leur faisant former une boucle autour du dossier du fauteuil. Croisez-les et attachez-les pour les maintenir en place au-dessus. ii. Formez une boucle avec les sangles inférieures autour des deux côtés de la plaque.
Companion (all versions)	i. Utilisez les sangles fournies pour fixer le Companion sur la surface souhaitée ii. Glissez toutes les longueurs excédentaires de sangle dans les boucles fournies

Dégonflage

1. Une fois que le patient n'est plus installé sur le Repose, détachez les sangles du matelas, du fauteuil ou du pied de lit.
2. Procédez au nettoyage et à la désinfection selon les instructions ci-dessous.
3. Une fois le produit nettoyé et complètement sec, retirez le capuchon d'étanchéité de la valve Repose.
4. Insérez l'extrémité ouverte du capuchon d'étanchéité dans la valve Repose de façon à ce que l'air s'échappe.
5. Une fois dégonflé, avec le capuchon toujours en place, enroulez le Repose, en commençant par le point le plus éloigné de la valve afin de faire sortir tout l'air restant. Répétez l'opération si nécessaire.
6. Pliez, enroulez et placez le produit à l'intérieur de la pompe afin de le ranger en toute sécurité. Faites pivoter le tube externe jusqu'à ce qu'il se ferme en émettant un clic.



Nettoyage et décontamination des produits Repose et des housses en polyuréthane

Le Repose peut être nettoyé, désinfecté et réutilisé.

Entretenu régulièrement, le Repose est fiable et durable. Ces instructions ont été rédigées afin d'aider l'utilisateur à optimiser la durabilité du produit, mais en aucun cas elles ne garantissent sa durée de vie.

Il est de la responsabilité de l'utilisateur d'examiner régulièrement et de vérifier le produit afin de s'assurer que le Repose fonctionne de façon optimale.

Le Repose est un dispositif médical de classe I. En tant que tel, doit être nettoyé et manipulé conformément aux règles locales relatives à la prévention des maladies infectieuses. Les règles suivantes constituent des recommandations émises par Frontier Therapeutics Ltd. mais ne se substituent en aucun cas aux règles et aux directives locales.

Nettoyage

S'il y a aucun signe de contamination visible, le Repose, doit être nettoyé mécaniquement avec du détergent et de l'eau. Le Repose doit être nettoyé mécaniquement, au moins une fois par semaine, avec du détergent et de l'eau. Tous les produits en polyurétha

Manipulation

Une mauvaise utilisation ou manipulation du produit peut conduire à des dommages ou à des défaillances.

Inspectez le Repose afin de vous assurer qu'il est en état de marche avant toute utilisation.

Ne pas utiliser pas un produit endommagé ou qui ne fonctionne pas.

Tous les produits Repose sont exempts de latex.

Garantie du fabricant

Frontier Therapeutics Ltd. garantit le Repose pour une durée de 24 mois contre les défauts de fabrication. La garantie ne couvre pas l'usure générale ni les déchirures, ou toute autre défaillance.

Conformité

Le Repose est conforme aux normes suivantes ;

Les exigences de la MDR 2017/745. ISO 10993-1:2018 - Évaluation biologique des dispositifs médicaux. Partie 1 : Évaluation et essais. Norme ISO 10993-5:2018 - Évaluation biologique des dispositifs médicaux. Partie 5 : Essais concernant la cytotoxicité in vitro.

Réglementation en matière de sécurité incendie : BS7175:1989 – Méthodes d'essai de l'inflammabilité des couvrepieds et oreillers au feu couvant ou à la flamme vive, BS 597 parties 1 et 2 - Évaluation de l'inflammabilité des matelas et des sommiers rembourrés, 16 CFR partie 1632 - Normes en matière d'inflammabilité des matelas et des alèses, California TB117-2013 - Règlements, Test Procedure and Apparatus for testing the Smolder Resistance of Materials Used in Upholstered Furniture » (Exigences, procédures d'essais et dispositifs pour tester la résistance au feu des matériaux utilisés dans les meubles rembourrés), California TB133-1991 - « Flammability Test Procedure for Seating Furniture for Use in Public Occupancies » (norme pour tester l'inflammabilité des sièges rembourrés destinés à une utilisation publics).

Le Repose est fabriqué conformément à la norme ISO 13485:2016 – Dispositifs médicaux - Systèmes de management de la qualité – Exigences à des fins réglementaires.

Le Repose NE CONTIENT PAS, en tant que partie intégrante, de substance, qui utilisée séparément, puisse être considérée comme un produit thérapeutique tel que décrit dans l'Article 1 de la Directive 65/65/CEE.

Le Repose NE CONTIENT PAS, en tant que partie intégrante, de substances ou de dérivés du sang humain tels que décrits dans la section 7.4, annexe I, de la directive 93/42/CE. Il n'est pas non plus fabriqué à partir de tissus d'origine animale tels que décrits dans la directive 2003/32/CE.

Au moment de la publication, la gamme Repose ne contient aucune substance, à hauteur de plus de 0,1 % en poids, décrite dans la liste des substances extrêmement préoccupantes inscrites sur la liste des substances candidates en vue d'une autorisation - Directive CE 1907/2006 – REACH.

Plaintes concernant le produit

Tout professionnel de santé (par ex. client ou utilisateur de ce système de produits) ayant fait une plainte ou n'étant pas satisfait de la qualité, l'identité, la durabilité, la fiabilité, la sécurité, l'efficacité et la performance du produit, est prié d'en avertir le distributeur ou Frontier Therapeutics Ltd.

En outre, si un produit Repose « est défaillant » (par ex. ne satisfait pas aux exigences de performance ou en ajoutant ou ne fonctionne pas comme il le devrait), ou s'il est suspecté d'une telle chose, veuillez en informer immédiatement le distributeur ou Frontier Therapeutics Ltd.

Si un produit Frontier Therapeutics Ltd. est défaillant et est susceptible d'avoir provoqué ou contribué à la mort d'un patient ou lui avoir causé de graves blessures, veuillez en avertir immédiatement Frontier Therapeutics Ltd. par téléphone, fax, ou courrier.

Lors du dépôt de plainte, veuillez fournir le nom et le numéro du(des composant(s), le(s) numéro(s) de lot, votre nom, votre adresse, la nature de la plainte et préciser si un rapport écrit du distributeur est demandé.

Informations additionnelles

Pour de plus amples informations, contactez Frontier Therapeutics Ltd. par tél. : +44 1495 235 800.

DE Repose® Gebrauchsanleitung

Einführung/Vorgesehener Zweck

Repose® ist eine Reihe von Statikdruck-Unterlagen zur Umverteilung und Druckreduzierung mit hohen Werten. Alle Produkte bieten einen hohen Grad an Einsenkung und Umhüllung. Unter „Einsenkung" wird die Tiefe verstanden, bis zu der ein Körper in eine Unterlage eindringt. Unter „Umhüllung" wird die Fähigkeit einer Unterlage verstanden, sich an die unregelmäßige Form des Körpers anzupassen. Durch die Bewegungen des Patienten verändern sich die Punkte, an denen Einsenkung und Umhüllung auftreten. Da Repose in mehrere Richtungen dehnbar und elastisch ist, kann der Druck an den Kontaktpunkten über die Oberfläche ausgeglichen werden.

Es wurde klinisch nachgewiesen, dass diese Kombination aus spezifischen Materialien und Smart Valve-Technologie Patienten statistisch signifikant helfen kann[1]. In mehreren randomisierten Kontrollstudien wurde die Fähigkeit von Repose nachgewiesen, den Spitzen- und Durchschnittsdruck an den Kontaktflächen konsequent zu reduzieren (5,2 %[1], 4,8 %[2], 5,1 %[3], 5,2 %[4]).

Repose Foot Protector, Foot Protector Plus, Wedge und Flex wurden entwickelt, um den Druck an den Fersen vollständig zu beseitigen und die Druckbelastung über die Wade des Patienten zu verteilen. Im Fall von Repose Flex wird ein Winkel von 5 bis 10° zwischen den Patienten hergestellt, um das DVT-Risiko zu reduzieren[5].

Repose Cushion und Care-sit wurden für die Verwendung mit statischen Armlehnsesseln entwickelt. Repose Contur wurde für die Verwendung mit Aufstehsesseln entwickelt.

Repose Contur, Care-sit und Companion sind mit blauen Polyurethan-beschichteten Bezügen für zusätzliche Haltbarkeit, Infektionskontrolle und Komfort ausgestattet. Bezüge sind auch für Repose Mattress Overlay und Cushion erhältlich.

Repose wird in verschiedenen Konfigurationen für unterschiedliche Patientenanatomien angeboten. Weitere Informationen finden Sie im Anhang, App 2.

Alle Repose-Varianten werden mit einer Luftpumpe ausgeliefert, wenn nicht anders angegeben. Bitte vollständigen Details finden Sie im Produktkatalog. Sie können auch Kontakt mit Frontier Therapeutics Ltd. aufnehmen, um weitere Informationen zu erhalten.

Indikationen

Die Indikationen für Repose sind wie folgt:

Patienten, bei denen ein Risiko für Druckgeschwüre besteht, einschließlich Patienten mit sehr hohem Risiko besteht.

Behandlung aller Kategorien/Phasen von Druckgeschwüren, wenn als Teil eines Pflegepakets verwendet.

Kontraindikationen

Die Kontraindikationen für Repose sind wie folgt:

Sitzlösungen und Überzüge sind für Patienten mit instabilen Wirbelsäulenfrakturen nicht geeignet.

Es liegen irreguläre Körperformen vor, die von Repose nicht vollständig unterstützt werden können.

Repose Sitzlösungen sind für Patienten, deren Körperhaltung unterstützt werden muss, oder für Patienten mit Beckenschiefstand nicht indiziert.

Maximales Gewicht der Patienten

Repose unterliegt Einschränkungen in Bezug auf das maximale Körpergewicht.

Produktbeschreibung	Maximalgewicht
Matratzenauflage, Lange Matratzenauflage, Doppelte Matratzenauflage, Companion, Trolleyauflage, Trolleymatratzenauflage	Bei Verwendung auf einer Schaummatratze, die eine hohe Spezifikation besitzt – 222 kg Bei Verwendung auf einer Schaummatratze, die keine hohe Spezifikation besitzt – 139 kg
Cushion, Care-sit,

Quejas relacionadas con el producto

Cualquier profesional sanitario (por ejemplo, un cliente o usuario de este sistema de productos) que tenga alguna queja o que no esté satisfecho por algún motivo con la calidad, identidad, durabilidad, fiabilidad, seguridad, eficacia y rendimiento del producto, debería notificarlo al distribuidor o directamente a Frontier Therapeutics Ltd.

Además, si cualquier producto Repose «no funcionase correctamente» (es decir, no cumpliese cualquiera de las especificaciones de rendimiento o no ofreciese un funcionamiento similar al previsto), o si se tuviese la sospecha de que no funciona correctamente, notifíquelo de forma inmediata al distribuidor o directamente a Frontier Therapeutics Ltd.

Si cualquier cliente de Frontier Therapeutics Ltd. funcionase de forma incorrecta en algún momento y pudiese haber provocado o contribuido a la muerte o lesión grave de un paciente, se deberá notificar de inmediato dicha situación a Frontier Therapeutics Ltd. por teléfono, fax o mediante correspondencia por escrito.

A la hora de presentar una queja, indique el nombre y número de lote de componente, los números de lote, su nombre, dirección y el motivo de la queja, además de notificar si es necesario o no el envío de un informe por escrito por parte del distribuidor.

Más información

Si necesita más información, póngase en contacto con Frontier Therapeutics Ltd. llamando al siguiente número de teléfono: +44 1495 235 800.

NL Repose® Gebruiksaanwijzingen

Inleiding en beoogd doel

Repose® is een systeem voor ondersteunende drukverdelende en drukvermindernde oppervlakken op basis van statische lucht, die een hoge mate van immersie en ophulling bieden. Immersie staat voor hoe diep het lichaam doordringt in het ondersteunende oppervlak. Ophulling is het vermogen van een ondersteunend oppervlak om zich aan te passen aan de ongelijkmatige vormen van het lichaam. De bewegingen van de patiënt veranderen door de immersie en ophulling, en de stretch en elasticiteit van Repose in meerdere richtingen zorgt ervoor dat de interface-druk gelijkmatig over het oppervlak wordt verdeeld.

Het is klinisch bewezen dat deze combinatie van unieke materialen en slimme ventielen de patiënt statistisch significante voordelen oplevert1. Meerdere gerandomiseerde controlegroepen hebben aangetoond dat Repose de piekdruk en de gemiddelde interfacedruk constant vermindert (5,2%1, 4,8%2, 5,1%3, 5,2%4).

De Repose Foot Protector, Foot Protector Plus, Wedge en Flex zijn ontworpen om de hiel volledig te ontlasten, de drie over de kuit van de patiënt te verdelen en – in het geval van de Repose Flex – de knie te buigen in een hoek van 5-10° om het risico op DVT te verminderen5.

De Repose Cushion en Care-sit zijn bedoeld voor gebruik op vaste stoelen met armleuningen. Repose Contur is bedoeld voor gebruik met sta-optoilets.

Repose Contur, Care-sit en Companion worden geleverd met blauwe, met polyurethaan bedekte hoezen voor extra duurzaamheid, infectiebestrijding en comfort. De hoezen zijn ook verkrijgbaar voor de Repose Oplegmatras en het kussen.

De Repose-producten zijn verkrijgbaar in verschillende configuraties die zijn afgestemd op de lichaamsbouw van de patiënt. Zie App 2 hieronder.

Alle Repose-producten worden geleverd in een luchtpomp, tenzij anders aangegeven. Raadpleeg de productcatalogus voor de volledige informatie of neem voor meer info contact op met Frontier Therapeutics Ltd.

Indicaties

Dit zijn de indicaties voor Repose:

Personen met risico op decubitus, met inbegrip van personen die een zeer groot risico lopen.

De behandeling van alle categorieën/stadia van decubitus als onderdeel van een zorgpaklet.

Contra-indicaties

Dit zijn de contra-indicaties voor Repose:

Zitpolsstangen en oplegmatrassen zijn niet geschikt voor patiënten met instabiele wervelfracturen.

Oneigenlijke lichaamsvormen die niet volledig kunnen worden ondersteund door Repose.

De Repose-zitpolsstangen zijn niet geschikt voor patiënten die behandeling van hun lichaamshouding nodig hebben of een bekkenafwijking hebben.

Maximaal gebruikersgewicht

Er is een maximaal gebruikersgewicht van toepassing op Repose.

Beschrijving van het product	Maximumgewicht
Mattress Overlay, Long Mattress Overlay, Double Mattress Overlay, Companion, Trolley Companion, Trolley Mattress Overlay	In combinatie met een hoogwaardige schuimmatras – 222 kg In combinatie met niet-hoogwaardige schuimmatras – 139 kg
Cushion, Care-sit, Contur, Paediatric Mattress, BabyThern Overlay	139kg
BabyNest Overlay	3kg (er is geen minimumgewicht)
Foot Protector, Foot Protector Plus, Foot Protector Four Layer, Wedge, Flex, Sole Protector	Geen gewichtslimiet

Waarschuwingen en voorzorgsmaatregelen

Het bedienen of gebruiken van Repose vereist geen specifieke vaardigheden.

Frontier Therapeutics Ltd stelt online aanvullend opleidingsmateriaal beschikbaar op: https://www.frontier-group.co.uk/elearning/

Controleer vóór gebruik of Repose onbeschadigd is. Wanneer er zichtbare teekenen van schade zijn, mag u het niet gebruiken en moet u het vervangen.

Zorg ervoor dat het Repose-product correct is geplaatst en geen obstakel vormt.

Zorg dat de Repose Foot Protector de omvang of vorm van het onderbeen van de patiënt volledig kan ondersteunen.

Het Repose-ventiel moet zich altijd aan de buitenkant bevinden, weg van de patiënt, en mag nooit in contact komen met de huid van de patiënt.

Voor optimale prestaties dient u een product met de juiste afmetingen te gebruiken. Deze gebruiksaanwijzingen bevatten informatie over afmetingen.

Tijdens het opblazen en bijvullen van de Repose mag de patiënt zich niet op het product bevinden.

Wanneer u zet dat de conditie van de huid verandert moet u onmiddellijk een professionele zorgverleiner raadplegen en desgevraagd het zorgplan herbeoordelen of het gebruik stopzetten.

Gebruik alleen de meegeleverde pompen. Vervangende of extra pompen zijn verkrijgbaar bij Frontier Therapeutics Ltd.

Houd u bij het gebruik van bedhekken aan de gebruiksinstructies van de fabrikant. Zorg ervoor dat de Repose correct is aangebracht en de juiste werking van het hek niet beïnvloemt, omdat de Repose anders beschadigd kan raken of het hek anders minder veiligheid biedt.

Niet geschikt om te worden gesteriliseerd.

Niet voor gebruik onder water of in de douche.

Uit de buurt houden van hitte, warme oppervlakken, vonken, open vuur en andere ontstekingsbronnen.

De Repose Foot Protector Plus is voorzien van zes vernikkelde magneten (diameter 10 mm, dikte 3 mm, N35 neodymium-magneet, 2,800 Gauss / 0.28 Tesla). Houd het product op ten minste 150 mm afstand van actieve apparatuur zoals pacemakers.

De Repose Foot Protector Plus bevat nikkel dat niet in contact komt met de patiënt. Wees voorzichtig wanneer u het product gebruikt bij patiënten met een nikkelallergie.

Het Repose-ventiel bevat een metalen veer. Niet gebruiken in de buurt van magnetische bronnen zoals MRI-scanners.

Op radiografische beelden kunnen Repose-voorwerpen zichtbaar zijn.

U mag het medische hulpmiddel of de accessoires op geen enkele manier aanpassen.

De Repose Cushion, Care-sit en Contur mogen alleen worden gebruikt op stoelen met armleuningen.

De positie op het ondersteunende oppervlak (stoel, sta-optoilet, ondersteunend oppervlak, trolley of brancard) moet regelmatig worden gecontroleerd met het oog op een voortdurend correct en veilig gebruik.

Controleer de Repose regelmatig en vul het product minstens elke twee weken bij met de meegeleverde pomp.

Indien niet opgeblazen, uit de buurt houden van baby's en kleine kinderen vanwege het risico van verstikking.

Houd huisdieren weg bij het product.

Niet gebruiken als draagband of drijfmiddel.

Niet reinigen met desinfectiemiddelen op basis van fenolen.

Reinig de Repose-producten niet met schurende doeken, die ohnerstelbare schade kunnen veroorzaken.

De bouwer dient de polyurethaan hoezen kunnen in de machine worden gewassen. Zorg dat het binnendeel van de Repose is verwijderd voordat u de hoes gaat wassen.

Neem de bovenstaande waarschuwingen en veiligheidsinstructies routinematig en regelmatig door en niet alleen tijdens de installatie.

Beoogde patiënten

Inwonende en minder mobiele patiënten met een risico op decubitus, onder wie patiënten met een zeer hoog risico, en voor de behandeling van alle stadia van decubitus als onderdeel van een zorgpaklet.

Beoogde gebruikers

Bedoeld voor verzorging in de thuissituatie en in professionele zorginstellingen.

Gebruiksaanwijzingen

Lees vóór gebruik de volgende instructies door. Bij vragen kunt u Frontier Therapeutics Ltd. bellen op +44 1495 235 800.

De gebruiksaanwijzingen staan ook online op: https://www.frontier-group.co.uk/

De juiste maat kiezen

Wanneer u de Foot Protector, Foot Protector Plus of Flex gebruikt is de juiste maat van belang om optimale resultaten te behalen.

Meet de afstand tussen de kniehoek en de hiel en vergelijk het meetresultaat met de onderstaande tabel.

Leg Measurement	Product Size	Colour
460mm - 410mm	Extra Small	Blue
500mm - 450mm	Small	Green
550mm - 490mm	Standard	Yellow
690mm - 550mm	Long	Orange

Reinigen en ontsmetting van Repose en polyurethaan hoezen

U kunt de Repose-producten reinigen, ontsmetten en opnieuw gebruiken.

Wanneer u ze regelmatig onderhoudt, zijn de Repose-producten betrouwbaar en gaan ze lang mee. Deze instructies zijn geschreven om de gebruiker te helpen de levensduur van de Repose-producten te maximaliseren, maar vormen op geen enkele manier een garantie voor de levensduur van het product.

De gebruiker draagt de verantwoordelijkheid om het Repose-product regelmatig te inspecteren en te controleren om ervoor te zorgen dat het optimaal presteert.

Repose is een medisch hulpmiddel van klasse I en dient als zodanig te worden gereinigd en behandeld volgens het lokale infectiebestrijdingsbeleid. De tekst die volgt is een aanbeveling van Frontier Therapeutics Ltd., maar is geen vervanging voor lokale beleids- en richtlijnen.

Neem bij twijfel contact op met Frontier Therapeutics Ltd.

Reinigen

Wanneer er zichtbare teekenen van vuil en verontreiniging zijn, moet de Repose, met inbegrip van de hoes, mechanisch worden gereinigd met een reinigingsmiddel en water.

Wanneer er geen zichtbare teekenen van verontreiniging zijn, moet de Repose wekelijks mechanisch worden gereinigd met een reinigingsmiddel en water.

Alle Repose polyurethaan hoezen kunnen gedurende 10 minuten op 65 °C worden gewassen, en gedurende drie minuten op 73 °C. **Het binnendeel van de Repose niet in de machine wassen, zorg dat het is verwijderd.**

Gebruik geen schurende doeken.

Niet reinigen met stoom water en afnemen met een vochtig, niet-schurend wegwerpdoekje en grondig drogen.

Desinfectie

Uitste verwijling

Eerst reinigen met reinigingsmiddel en water om zichtbare tekenen van vuil en verontreiniging te verwijderen en dan ontsmetten met een 0,1% chlooroplossing (10,000 ppm).

Nasspoelen met schoon water en afnemen met een vochtig, niet-schurend wegwerpdoekje en grondig drogen.

Ernstige vervuiling

Bij ernstige verontreiniging, inclusief reinigingsmiddel en water om zichtbare tekenen van vuil en verontreiniging te verwijderen en dan ontsmetten met een 1% chlooroplossing (10,000 ppm).

Nasspoelen met schoon water en afnemen met een vochtig, niet-schurend wegwerpdoekje en grondig drogen.

Riemjes en tape aan het uitleine

Riemjes, tapes aan het uitleine en andere accessoires kunnen op dezelfde manier worden gereinigd en ontsmet als de Repose-producten. Laat ze goed drogen voordat u ze opbergt.

Drogen

Laat leeglopen en laat binnen grondig opdrogen in een schone omgeving alvorens het product op te bergen.

De Repose-pomp reinigen

De Repose-pomp is gemaakt van een duurzame, recycleerbare ABS-kunststof. De pomp moet mechanisch worden gereinigd met een reinigingsmiddel en water en moet worden gedesinfecteerd met een chlooroplossing (10,000 ppm) of een soortgelijke levensduur.

Vóór het reinigen moet u de pomp demonteren, inspecteren op schade en reinigen volgens de instructies.

Gebruik de meegeleverde O-ringen om beschermen in paragrafen over licht en sterk vervuilde Repose-producten.

Controleer de O-ring voor de pomp grondig is schoongespoeld met schoon water en is afgeveegd om overtollig water te verwijderen.

Zet de pomp weer in elkaar en verwijder overtollig water uit het ventiel door vijf of zes keer te pompen.

Laat de pomp in een schone omgeving aan de lucht drogen alvorens de pomp op te bergen.

Voorzorgsmaatregelen bij het reinigen van de Repose en de Repose-pomp

Draag de juiste persoonlijke beschermingsmiddelen wanneer u desinfecterende oplossingen gebruikt.

U mag Repose-producten niet reinigen met desinfectiemiddelen op basis van fenol.

Gebruik geen schuurmiddelen.

Zorg ervoor dat het Repose-product goed droog is voordat u het opberg, gebruik er hergebruik.

Veelvuldig reinigen met een desinfectiemiddel met een hoge concentratie (bijv. 10,000 ppm chloor) kan de levensduur van Repose-producten verkorten.

Neem voor de vraag of een desinfectiemiddel geschikt is contact op met de fabrikant, die kan zeggen of u het kunt gebruiken op zachte oppervlakken waarin polyurethaan is verwerkt.

Repose-producten mogen niet in de wasmachine worden gewassen en niet worden ondergedompeld. Voorkom dat er vloeistof binnendringt in het ventiel.

Blaas het product op om het te reinigen.

Verwijdering aan het einde van de levensduur

Wanneer u uw Repose-product goed onderhoudt gaat het lang mee en is het duurzaam. Wanneer u het product afdankt, moet u het reinigen en desinfecteren volgens de instructies en het verwijderen met het normale klinische afval.

Verpakking en opslag

Repose wordt voorverpakt aangeleverd en de verpakking moet bij ontvangst intact zijn.

Controleer elke onderdelen vóór gebruik op compleetheid en tekenen van schade.

Beschadigde verpakkingen en producten mogen niet worden gebruikt en moeten worden teruggestuurd naar Frontier Therapeutics Ltd.

Bewaar het product op een koele en droge plek, buiten het bereik van direct zonlicht.

Bewaar het product niet naast radiatoren of andere verwarmingstoestellen.

Hanteren

Verkeerd gebruik en verkeerd hanteren kan schade en een incorrecte werking van het product veroorzaken.

Controleer vóór gebruik of de Repose in werkende staat verkeert.

U mag beschadigde en niet-werkende producten niet gebruiken.

De Repose-producten bevatten geen latex.

Garantie van de fabrikant

Frontier Therapeutics Ltd. biedt 24 maanden garantie op productfeuten in Repose-producten. De garantie is niet van toepassing op normale slijtage of defecten met een andere oorzaak.

Naleving

Repose voldoet aan de volgende normen:

De verenigen van Verordening (EU) 2017/745 betreffende medische hulpmiddelen. ISO 10993-12018 – Biologische evaluatie van medische hulpmiddelen. Deel 1: Evaluatie en beproeving. ISO 10993-5:2018 – Biologische evaluatie van medische hulpmiddelen. Deel 5: Beproeving op in-vitro cytotoxiciteit.

Brandveiligheidseisges: BS7175:1989 – De ontvlambaarheid van dekens en kussen van vlammenwerende ontsteekingsbronnen; BS 597, deel 1 en 2 – Meubilair – Beoordeling van de ontvlambaarheid van matrassen en bestofferede bedbodems; 16 CFR deel 1632 – Normen voor de brandbaarheid van matrassen en kussens, Californie; California TB117-2013 – Vereisten, testprocedure en apparatuur voor het testen van de smeldbestendigheid van materialen die worden gebruikt in gestoffeerde meubels; California TB133-1991 – Procedure om de ontvlambaarheid van zitmeubilair voor gebruik in openbare ruimten te testen.

De Repose-producten worden vervaardigd overeenkomstig een geaccrediteerd ISO 13485:2016-kwaliteitsmanagementsysteem voor medische hulpmiddelen.

In de Repose-producten is als integreerend bestanddeel GEEN stof verwerkt die, indien afzonderlijk gebruikt, kan worden beschouwd als geneesmiddel zoals gedefiniëerd in artikel 1 van Richtlijn 65/65/EEG.

In de Repose-producten is als integreerend bestanddeel GEEN stof of derivaat van menselijk bloed verwerkt als bedoeld in bijlage 1, punt 7.4, van Richtlijn 93/42/EEG. De zijn ook niet gefabriceerd met weefsels van dierlijke oorsprong als bedoeld in Richtlijn 2003/32/EG.

Ten tijde van publicatie bevat het Repose-assortiment niet meer dan 0,1 gewichtspercent van SVHC's (zeer zorgwekkende stoffen in de kandidatenlijst van zeer zorgwekkende stoffen voor autorisatie REACH-verordening (EG) nr. 1907/2006).

Klachten over producten

Iedere professionele zorgverlener (dwz. een klant of gebruiker van dit productassortiment) met klachten of die ontevreden is over de kwaliteit, uitstraling, duurzaamheid, betrouwbaarheid en prestaties van producten, of van producten, moet zich wenden tot de distributeur of Frontier Therapeutics Ltd.

Ook wanneer een Repose-product niet naar behoren functioneert (bijv. wanneer het niet voldoet aan de prestatiespecificaties of anderszins niet werkt zoals bedoeld), of u dat vermoedt, moet u de distributeur of Frontier Therapeutics Ltd. daar onmiddellijk van op de hoogte brengen. Indien een product van Frontier Therapeutics Ltd. niet naar behoren functioneert en mogelijk de dood of ernstig letsel van een patiënt tot gevolg heeft gehad of daaraan heeft bijgedragen, moet u Frontier Therapeutics Ltd. onmiddellijk per telefoon, fax of schriftelijk op de hoogte stellen.

Vermeld bij het indienen van een klacht de naam en het nummer van de onderdeel(delen), de partijnummer(s), uw naam en adres en de aard van de klacht en geef daarbij aan of u een schriftelijk rapport van de distributeur verlangt.

Meer informatie

Voor meer informatie kunt u contact opnemen met Frontier Therapeutics Ltd, tel.: +44 1495 235 800.

IT Repose® Istruzioni per l'uso

Introduzione/Destinazione d'uso

Repose® è una gamma di superfici di appoggio ad aria statica per la riduzione della pressione e dell'attrito, dotate caratteristiche da livelli elevati di immersione e avvolgimento. L'immersione è la profondità alla quale il corpo penetra in una superficie di appoggio. L'avvolgimento è la capacità di una superficie di appoggio di adattarsi alle forme irregolari del corpo. Il movimento del paziente viene alterato nei punti in cui si verificano l'immersione e l'avvolgimento e, grazie al materiale multistretch e all'elasticità di Repose, le pressioni di interfaccia vengono equilibrate su tutta la superficie.

Studi clinici hanno dimostrato che questa combinazione tra materiali esclusivi e una tecnologia a valvola intelligente apporta al paziente benefici statisticamente rilevanti.1 Più studi randomizzati controllati hanno dimostrato la capacità di Repose di ridurre sistematicamente la pressione di interfaccia di picco e media (5,2%1, 4,8%2, 5,1%3, 5,2%4).

Foot Protector, Foot Protector Plus, Cuneo e Flex sono progettati per scaricare totalmente la pressione dal tallone, distribuire la pressione sul polpaccio del paziente e, nel caso di Repose Flex, introdurre un angolo di 5-10o nel ginocchio del paziente per ridurre il rischio di trombosi venosa profonda.5

Repose Cuscino e Care-Sit sono cuscini progettati per l'uso su sedie statiche con braccioli. Il rivestimento Repose Contur è destinato all'uso con poltrone elevabili reclinabili.

Repose Contur, Care-sit e Companion sono dotati di coperture rivestite in poliuretano per la maggiore durata, controllo delle infezioni e comfort. Le coperture sono anche disponibili per Repose Sovramatarasso e Cuscino.

La gamma Repose è offerta in varie configurazioni per adattarsi all'anatomia dei pazienti più diversi. Consultare la seguente App 2.

Se non diversamente indicato, tutte le varianti Repose vengono fornite all'interno di una pompa gonfiabile. Consultare il catalogo prodotti per dettagli completi o rivolgersi a Frontier Therapeutics Ltd. per maggiori informazioni.

Indicazioni

Le indicazioni di Repose sono le seguenti:

Pazienti a rischio di sviluppare ulcere da pressione, inclusi i pazienti a rischio molto elevato.

Trattamento di tutte le categorie/stadi di ulcere da pressione quando i prodotti sono utilizzati come parte integrante di un pacchetto di cure.

Controindicazioni

Le controindicazioni di Repose sono le seguenti:

Le soluzioni di sedute e i rivestimenti non sono idonei per i pazienti con fratture vertebrali instabili.

Corporature irregolari che non possono essere totalmente supportate da Repose.

Pazienti che necessitano di gestione della postura o che soffrono di obliquità pelvica non sono idonei per le soluzioni di seduta Repose.

Peso massimo del paziente

La gamma Repose è soggetta a limitazioni circa il peso massimo del paziente. Consultare la seguente Tabella 2.

Descrizione del prodotto	Limite di peso
Mattress Overlay, Long Mattress Overlay, Double Mattress Overlay, Companion, Trolley Companion, Trolley Mattress Overlay	Quando utilizzati su un materasso in schiuma ad alta specifica: 222 kg Quando utilizzati su un materasso in schiuma non ad alta specifica: 139 kg
Cushion, Care-sit, Contur, Paediatric Mattress, BabyThern Overlay	139kg
BabyNest Overlay	3kg (non c'è un limite inferiore di peso)
Foot Protector, Foot Protector Plus, Foot Protector Four Layer, Wedge, Flex, Sole Protector	Nessun limite di peso

Avvertenze e precauzioni

Non si richiedono competenze particolari per azionare o utilizzare i prodotti Repose.

Frontier Therapeutics Ltd fornisce ulteriore materiale formativo, disponibile online all'indirizzo: https://www.frontier-group.co.uk/elearning/

Prima dell'uso, verificare che il prodotto Repose non sia danneggiato. Se vi sono segni visibili di danni, non usarlo e provvedere alla sua sostituzione.

Verificare che Repose sia correttamente installato e non causi ostruzioni.

Verificare che Repose Foot Protector possa sostenere completamente le dimensioni o la forma della parte inferiore della gamba del paziente.

La valvola Repose deve sempre trovarsi all'esterno e lontano dal paziente e non deve mai entrare in contatto con la pelle del paziente.

Per garantire prestazioni ottimali, utilizzare un prodotto della misura giusta. Nel presente istruzioni per l'uso sono contenute informazioni sulle taglie.

Gonfiare e ricaricare sempre i prodotti quando non sono utilizzati dal paziente.

Se si nota una variazione dello stato della pelle, consultare immediatamente un professionista sanitario e, se avvisati del problema, rivalutare il programma di assistenza o interrompere l'uso.

Usare esclusivamente le pompe di gonfiaggio in dotazione. Pompe di gonfiaggio sostitutive e aggiuntive sono disponibili presso Frontier Therapeutics Ltd.

Quando si usano pompe di gonfiaggio, non superare la pressione per l'uso del produttore. Verificare che il prodotto Repose sia installato correttamente e non sia danneggiato prima di iniziare il funzionamento, con il rischio di danneggiare il prodotto o ridurre le caratteristiche di sicurezza delle sponde laterali.

Non odorea per la sterilizzazione.

Non fumare quando il sistema è in uso.

Tenere lontano da calore, superfici calde, scintille, fiamme vive e altre fonti di ignizione.

Ogni Repose Foot Protector Plus contiene 6 magneti nichelati (magnete al neodimio N35, diametro 10 mm x spessore 3 mm, Gauss 2.800/Tesla 0,28). Mantenere a una distanza minima di 150 mm da dispositivi attivi come i pacemaker.

Repose Foot Protector Plus contiene nichel che non è a contatto con il paziente. Prestare attenzione quando il prodotto viene usato su pazienti con allergia nota al nichel.

La valvola di ogni prodotto Repose contiene una molla metallica. Non usare in prossimità di sorgenti magnetiche come sistemi di imaging a risonanza magnetica.

Possono comparire artefatti visibili durante gli esami radiografici.

Non modificare in alcun modo i dispositivi medici o gli accessori.

Repose Cuscino, Care-Sit e Contur devono essere utilizzati unicamente su sedie con braccioli.

Controllare regolarmente la posizione del prodotto sulla superficie di appoggio (seduta, poltrona elevabile reclinabile, letto di barella) per garantire il corretto funzionamento continuo.

Controllare regolarmente il prodotto e "caricarlo" entro un periodo non superiore a due settimane, usando la pompa in dotazione.

Una volta sgonfiato, tenerlo lontano da neonati e bambini piccoli, poiché potrebbe comportare un rischio di soffocamento.

Tenere il prodotto lontano dagli animali domestici.

Non utilizzare come imbracatura o come dispositivo di galleggiamento.

Non pulire con disinfettanti a base di fenoli.

Non usare pagliette o altri prodotti di pulizia abrasivi che possono provocare danni irreversibili.

Le coperture in poliuretano blu possono essere lavate in lavatrice; assicurarsi di rimuovere il prodotto Repose all'interno prima di lavare.

Rileggere periodicamente, e non solo all'atto dell'installazione, le precedenti avvertenze e precauzioni e le eventuali norme di sicurezza.

Gruppo di pazienti target

Pazienti immobili e meno mobili a rischio di sviluppare ulcere da pressione, inclusi quelli a rischio molto elevato, o per il trattamento di tutti gli stadi di ulcere da pressione, quando sono utilizzati come parte di un pacchetto di cure.

Utenti previsti

Prodotti destinati all'assistenza sanitaria domiciliare e alle strutture sanitarie professionali.

Istruzioni per l'uso

Leggere le seguenti istruzioni prima dell'uso. Per qualsiasi domanda, contattare Frontier Therapeutics Ltd. al numero +44 1495 235 800.

Le istruzioni per l'uso sono disponibili anche online all'indirizzo https://www.frontier-group.co.uk/

Scelta della misura corretta

Se si utilizza Foot Protector, Foot Protector Plus o Flex, è importante scegliere la misura corretta per ottimizzare i risultati.

Misurare la distanza tra il retro del ginocchio e il tallone e confrontare la misura ottenuta con la tabella 2 seguente.

Leg Measurement	Product Size	Colour
460mm - 410mm	Extra Small	Blue
500mm - 450mm	Small	Green
550mm - 490mm	Standard	Yellow
690mm - 550mm	Long	Orange

Pulizia e decontaminazione del prodotto Repose e delle pompe Repose

Il prodotto Repose può essere pulito, decontaminato e rializzato.

Ispezionare periodicamente la guarnizione, il prodotto Repose risulta affidabile e duraturo. Queste istruzioni sono state scritte per aiutare il paziente a massimizzare la longevità del prodotto Repose, ma non ne garantiscono assolutamente la durata indeterminata.

Spetta al paziente ispezionare regolarmente il prodotto Repose per accertarsi che le sue prestazioni siano ottimali. Repose è un dispositivo medico di classe I e, in quanto tale, deve essere pulito e maneggiato in conformità con le politiche locali di controllo delle infezioni. Di seguito, Frontier Therapeutics Ltd fornisce una raccomandazione che comunque non vuole essere un'alternativa alle linee guida locali. In caso di dubbio, contattare Frontier Therapeutics Ltd. o il gruppo locale per il controllo delle infezioni.

Pulizia

Se sono presenti segni visibili di sporcizia e contaminazione, pulire meccanicamente il prodotto Repose, compresa la copertura, con acqua e detergente.

In assenza di contaminazione visibile, pulire meccanicamente il prodotto Repose ogni settimana con acqua e detergente.

Tutte le coperture in poliuretano Repose possono essere lavate in lavatrice a 65 °C per 10 minuti oppure a 73 °C per tre minuti. **Non lavare il prodotto Repose all'interno della copertura: asciugarlo prima di rimuoverlo.**

Non usare pareni abrasivi.

Risciacquare con acqua pulita, passare un panno non abrasivo monouso e asciugare accuratamente.

Sporco eccessivo

In caso di contaminazione evidente, pulire con acqua e detergente per rimuovere qualsiasi segno visibile di sporco e contaminazione e in seguito con una soluzione di cloro all' 1% (10.000 ppm).

Risciacquare con acqua pulita, passare un panno non abrasivo monouso e asciugare accuratamente.

Cicaglie e nastri terminali

Cinghie, nastri terminali e altri accessori possono essere puliti e decontaminati esattamente come il prodotto Repose.

Asciugare accuratamente prima della conservazione.

Asciugatura

Prima della conservazione, sgonfiare e asciugare accuratamente in un ambiente chiuso pulito.

Pulizia della pompa Repose

Realizzata in plastica ABS riciclabile durevole, la pompa Repose deve essere pulita meccanicamente con acqua e detergente e disinfettata chimicamente con clorodervati di uso comune per garantire la durata.

Prima della pulizia, smontare la pompa, verificare che non sia danneggiata e pulita secondo le istruzioni.

Usare gli stessi metodi descritti nelle sezioni relative alle sporco leggero e sporco eccessivo del prodotti Repose sopra.

Una volta pulita, risciacquare accuratamente la pompa con acqua pulita e strofinarla per rimuovere eventuali residui di acqua.

Rimontare la pompa e pompare cinque o sei volte per rimuovere l'acqua in eccesso dalla valvola.

Lasciare asciugare in un ambiente pulito prima della conservazione.

Precauzioni durante la pulizia del prodotto Repose e della pompa Repose.

Indossare gli opportuni dispositivi di protezione individuale quando si utilizzano soluzioni disinfettanti.

Non utilizzare disinfettanti a base di fenoli per pulire il prodotto Repose.

Non usare prodotti abrasivi.

Assicurarsi che il prodotto Repose sia accuratamente asciutto prima di riporlo, usato e riutilizzato.

Frequenti pulizie con una soluzione disinfettante ad alta concentrazione (ad esempio, 10.000 ppm di cloro disponibile) potrebbero ridurre la vita utile del prodotto Repose.

Contattare il produttore del disinfettante per verificare che sia idoneo per l'applicazione su superfici morbide, inclusa quella in poliuretano.

Il prodotto Repose non possono essere lavati in lavatrice o immersi. Evitare la penetrazione di liquidi nella valvola.

Gonfiare il prodotto per pulire.

Smaltimento a fine vita

Se trattato con le dovute cure, il prodotto Repose ha una lunga vita utile. Al termine della vita utile, pulirlo e disinfettarlo secondo le presenti istruzioni e smaltirlo tra i normali rifiuti ospedalieri.

Imballaggio e conservazione

Ogni prodotto Repose viene fornito preventivamente imballato e deve risultare integro all'atto della consegna.

Prima dell'uso, controllare che siano presenti tutti i componenti e che non mostrino segni di danneggiamento.

Se il prodotto o il relativo imballaggio risultano danneggiati, non utilizzare il prodotto e restituirlo a Frontier Therapeutics Ltd.

Conservare in un luogo fresco e asciutto, lontano dalla luce solare diretta.

Non conservare il prodotto vicino a radiatori o ad altri dispositivi di riscaldamento.

Manipolazione

L'uso o la manipolazione improprie del prodotto Repose possono comportare danni irreversibili.

Prima dell'uso, ispezionare il prodotto Repose per assicurarsi che funzioni correttamente.

Non utilizzare prodotti danneggiati o non funzionali.

Tutti i prodotti Repose sono privi di lattice.

Garanzia del produttore

Frontier Therapeutics Ltd. garantisce i prodotti Repose da difetti di fabbricazione per un periodo di 24 mesi. Sono esclusi dalla garanzia l'usura generale e i guasti dovuti ad altre cause.

Conformità

Il prodotto Repose è conforme alle seguenti norme:

MDR 2017/745, EN ISO 10993-1:2018 – Valutazione biologica dei dispositivi medici. Parte 1: Valutazione e prove. ISO 10993-5:2018 – Valutazione biologica dei dispositivi medici. Parte 5: Test di citotossicità in vitro.

Norme di sicurezza antincendio: BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources, BS 597 parts 1&2 – Furniture – Assessment of the Ignitability of Mattresses and Upholstered Bed Bases, 16 CFR part 1632 - Standards for the Flammability of Mattresses and Mattress Pads, California TB117-2013 – Requirements, Test Procedure and Apparatus for testing the Smolder Resistance of Materials Used in Upholstered Furniture, California TB133-1991 – Flammability Test Procedure – Upholstered Furniture for Use in Public Occupancies.

Il prodotto Repose è fabbricato conformemente alla normativa ISO 13485:2016 – Sistemi di gestione della qualità per i dispositivi medici.

Il prodotto Repose NON include, come parte costitutiva, alcuna sostanza che, se usata separatamente, può essere considerata come prodotto medicinale ai sensi della direttiva 65/65/CEE.

Il prodotto Repose NON include, come parte costitutiva, alcuna sostanza o derivato del sangue umano di cui alla sezione 74 Allegato 1 della Direttiva 93/42/CE della Commissione, né è fabbricato utilizzando tessuti di origine animale di cui alla Direttiva 2003/32/CE della Commissione.

Al momento della pubblicazione, la gamma Repose non contiene alcuna delle sostanze, superiori allo 0.1% in peso, descritte nell'Elenco di sostanze estremamente preoccupanti, candidate all'autorizzazione – Regolamento CE 1907/2006 – REACH.

Reclami sui prodotti

Il professionista sanitario (es. cliente o utente di questo sistema di prodotti) che abbia lamentele o sia insoddisfatto della qualità, identità, durata, affidabilità, sicurezza, efficacia o prestazioni del prodotto Repose, o dei prodotti, dovrà informare Frontier Therapeutics Ltd.

Inoltre, in caso di malfunzionamento accertato o presunto di un prodotto Repose (perché non soddisfa una delle specifiche funzionali o comunque non funziona come previsto), è necessario informarne tempestivamente il distributore o Frontier Therapeutics Ltd.

Qualora un prodotto Frontier Therapeutics Ltd. risulti difettoso e possa aver causato, o contribuito a causare, il decesso o gravi lesioni a un paziente, è necessario informarne tempestivamente Frontier Therapeutics Ltd. per telefono, fax o corrispondenza scritta.

Quando si sporge reclamo, indicare nome e numero dei componenti, i numeri di lotto, il proprio nome e indirizzo, la natura del reclamo e la specificazione se sia necessaria o no una relazione scritta da parte del distributore.

Ulteriori informazioni

Se sono necessarie ulteriori informazioni, contattare Frontier Therapeutics Ltd. al numero: +44 1495 235 800.

AR Repose® تعليمات الاستخدام

مقدمة/الغرض المقصود

Repose® هي مجموعة من أسطح الدعم التي تستخدم الهواء الثابت وأعدادًا Repose® كبيرة من الخيارات لتخفيف الضغط وتقليل الاحتكاك. وتوفر هذه الأسطح مستويات عالية من الانغمار والاحتواء. والانغمار هو مدى اختراق الجسم للسطح الداعم والاحتواء هو قدرة سطح الدعم على التوافق مع شكل الجسم. وتغيير وضعية المريض يغير حركة الجزء الذي يعاني من الضغط بطرق مختلفة بسبب انغماره وتحقيق التعادل الكلي. كما أن حركة وتمدد Repose في عدة اتجاهات يؤدي إلى توزيع ضغط الواجهة بشكل متساوٍ على السطح.

أثبت سريريًا تحقيق مزايا Smart Valve (هذا المزيج من المواد الفريدة وتكنولوجيا الصمامات) مزايا إحصائيًا ذات دلالة[1]. كما أثبتت العديد من التجارب العشوائية المضبوطة أن Repose يقلل من الضغط الأقصى للواجهة بنسبة 5,2%[1]، 4,8%[2]، 5,1%[3]، 5,2%[4] في المتوسط.

Foot Protector، Foot Protector Plus، Wedge، Flex مصممة لتخفيف الضغط بالكامل عن الكعب، وتوزيع الضغط على ثلاثة أجزاء من ساق المريض، وفي حالة Repose Flex، ثني الركبة بزاوية 5-10° لتقليل خطر حدوث الجلطة الوريدية العميقة[5].

Repose Cushion و Care-Sit مصممتان لتكونا وسادتين مناسبتين للكراسي الثابتة بمسندين للذراعين. Repose Contur مصممة للاستخدام مع الكراسي القابلة للإمالة.

تتوفر مجموعة من تكوينات Repose لتناسب أحجام الجسم المختلفة. وتجد في App 2 أدناه تفاصيل التكوينات.

ما لم يُشر إلى غير ذلك، تُعبّأ جميع منتجات Repose في مضخة هواء ما لم يُشر إلى خلاف ذلك. Repose يوفر جميع منتجات Repose في مضخة هواء ما لم يُشر إلى خلاف ذلك. يرجى الرجوع إلى كتالوج المنتجات للحصول على مزيد من المعلومات. يمكن التواصل مع Frontier Therapeutics Ltd. للحصول على مزيد من المعلومات.

أنواع الاستعمال

Repose يلبي نتائج دواعي استعمال Repose.

Repose يستخدم مواد استعمال Repose.

Repose يلبي الاحتياجات الخاصة بالمرضى الذين يعانون كسور العمود الفقري غير المستقرة.

Repose يُمكّن المريض غير المتنقلة إلى لا يمكن دعمها بشكل كامل بواسطة مواد الحشو التي ت