

MADE IN EUROPE



This product has been developed and manufactured using both raw materials and with production in Europe.

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(UK) User Manual

39_20250115_UK

Master Comfort Positioning Wedges

Top Class Positioning Wedges



Regulation MDR 2017/745 for medical devices class 1



| REF (Article no.) | HMI no. | Name - Size | UDI-DI/GTIN |
|-----------------------------------|---------|----------------------------------------------------------------|----------------|
| <input type="radio"/> MC 001-8040 | 36382 | Master Comfort Support Wedges | 05744001971543 |
| <input type="radio"/> MC 001-8045 | 133646 | Master Comfort Positioning Wedges - XS <small>(welded)</small> | 05744001974117 |
| <input type="radio"/> MC 001-8035 | 102744 | Master Comfort Positioning Wedge - S | 05744001971512 |
| <input type="radio"/> MC 001-8050 | 34331 | Master Comfort Positioning Wedge - M | 05744001971574 |
| <input type="radio"/> MC 001-8060 | 36383 | Master Comfort Positioning Wedge - L | 05744001971604 |
| <input type="radio"/> MC 001-8038 | 137070 | Master Comfort Positioning Wedge Cover - XS | 05744001974582 |
| <input type="radio"/> MC 001-8043 | 137071 | Master Comfort Positioning Wedge Cover - S | 05744001974599 |
| <input type="radio"/> MC 001-8053 | 137072 | Master Comfort Positioning Wedge Cover - M | 05744001974605 |
| <input type="radio"/> MC 001-8063 | 137073 | Master Comfort Positioning Wedge Cover - L | 05744001974612 |

ISO 09 07 06 07

The Original Nordic
Human Handling Concept



SCAN ME

Developed & Manufactured by:



master-care.dk

Thank you for choosing a product from master care A/S.

We recommend reading the user manual thoroughly before using the product (-s).

The information in this user manual applies to the shown products provided that the products have not been modified or customized and that the products have been used as recommended in this user manual. If the customer changes, repairs or uses the product in other combinations than recommended by master care A/S the CE-approval no longer applies and the guarantee becomes void.

In case of doubt, contact master care A/S or our distributor in your area.

MDR (EU) 2017/745:

Products in this user manual are CE-approved and follows the harmonized standards. This means that the products are in compliance with the essential health and safety directives. The product(-s) comply with the standards in the Medical Device Regulation MDR (EU) 2017/745 – Class 1.

The intended use of the product/-s:

The products can be used by people who have impaired or partial impaired capacity to change body position due to restricted movement or body perception damage and therefore are unable to provide a stable body positioning without support. Furthermore, the products can prevent/ reduce injuries caused by pressure or shearing forces for users who are in risk of pressure or shear ulcers.

The products can also have a stabilizing and calming effect on people with sensory or cognitive impairments and have a pain-relieving effect.

The products increase the support surface, which gives a better distribution of the pressure on the tissue thereby reducing the risk of pressure injuries.

Correct use of the product:

The Master Comfort products can be placed between the user and the area of support and thereby reduce the pressure on the skin. Alternatively, the products can be used to support the sitting position or when lying on the side to prevent falling forward or backwards.

Master Comfort Back Wedges with anti-slip coating on the underside can be used directly on sliding surfaces.

Depending on the user's ability, the product can be placed and used by the user themselves or can be placed by a qualified assistant or e.g. a relative who has received training by a qualified specialist.

The product is suitable for use in beds with adjustable lying surfaces e.g. beds where the headrest can be raised or the knee section of the bed can be bent.

Indications:

The products can be used when the user needs assistance in regard to:

Support with positioning:

- when positioning of individual body parts is not possible without support

Stabilisation during positioning:

- Reduced ability to maintain a stable posture (due to mobility restrictions and/or damage to the body image)

Pressure relief during positioning:

- as part of a medically/nursing coordinated treatment and care process to secure the patient's position and reduce the duration and strength of pressure and shear forces at the pressure-exposed areas and prevent pressure ulcers.

The product can also be used in combination with Turning systems (Master Turner).

Contraindication:

Don't use the products in direct contact with open wounds as this can make healing difficult or worsen the wound. Otherwise there are no known contraindications for the use of the product.

Warning:

It is very important for the patient to reposition themselves, or be repositioned, on a regular basis. This relieves pressure which helps prevent both tissue compression and potential pressure injury formation.

Skin redness is one clinical indicator for skin breakdown.

– Regularly inspect/monitor if your skin develops any redness.

– Immediately contact a healthcare professional, if your skin develops redness.

When using side rails, ensure that the top edge of the side rails is at least 22 cm above the unloaded top edge of the mattress.

Risk assessment:

If the user develops wounds or these do not heal while using the products, we recommend seeking help from an appropriate healthcare professional.

Knowledge of the product/transferring:

It is important that the user of the product has been properly instructed in the use of the product and has read the user manual thoroughly prior to using the product.

master care A/S provide education in the use of products and on our website all user manuals can be found.

Life span:

The expected life span of the products is 1-5 years depending on the use, user's load and how often it is washed and dried.

Products which no longer provide sufficient support, has lost its elasticity, has defect seams, broken material or other deficiencies must be discarded. This way you will always keep a sound and healthy work environment for both helper and user.

Make visual inspections frequently and preferably before every use.

Inspection:

Products which no longer provide sufficient support, has lost its elasticity, has defect seams, broken material or other deficiencies must be discarded. This way you will always keep a sound and healthy work environment for both helper and user.

Make visual inspections frequently and preferably before every use.

Guarantee:

master care A/S provide a 2-year guarantee covering material defects and manufacturing defects if the product has been used correctly.

Unintended events and injuries when misusing the products:

Unintended events must always be reported to the appropriate National Authority and to master care A/S or the distributor in the current country.

master care A/S and our distributors take no responsibility for personal injuries or product damages if the product(-s) have been used in contravention of the by the manufacturer recommended intended purpose or proper use of the product.

User Manual - Master Comfort Positioning Wedges

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Support stomach when side lying (Passive User, one helper):



1. The user is lying on a Master Turner or a Light Turner. Place the chosen Wedge – often size S – next to the waistline.



2. The bigger the stomach, the further away from the body. This way the Wedge always supports the stomach when the user has turned to side lying. If the user is very overweight a size M or L is recommended.



3. Raise the Turnsheet using the hoist and turn the user to side lying. The stomach is supported by the Wedge and keeps the user from rolling forward. The spine is in alignment.

Avoid sliding downwards when lying in bed (Passive user, one helper):



4. The user is lying on a Master Turner or a Light Turner. Elevate the knee-bend fully and place support under the feet from the end of the bed. A Positioning Wedge - S can be used.



5. Place the Positioning Wedges -XS under the Turnsheet so that they follow the thigh bones i.e. from the hollow of the knee to the buttocks – one on each side. The Wedges are placed like a "V" - narrowest at the knees and wider upwards.



6. The Positioning Wedges have a Non-Skid surface on the underside to make them stick to the Mattress Cover. Elevate the head end of the bed. You have the perfect position for sitting in bed without sliding down. For extra comfort place Wedges along the torso's sides.

30° side lying (passive user, one helper):



7. The user is lying on a Master Turner or a Light Turner Turn system. The demented, anxious or perceptually challenged person can benefit from a Positioning Wedge – S next to the torso. Place the Wedge before turning. Elevate the Turnsheet with a hoist.



8. Place Positioning Wedges along the backside of the body **under** the Turner to give the user an optimal comfort. Wedges **under** the Turner allows for adjustments of the body without having to remove or replace the wedges. Lower the hoist and detach the Master Turner.



9. Placing of the wedges **on top** of the Turner makes the position more stable due to the anti-skid on the wedges. The foam will adjust to the body's curves and support the body perception.

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Supporting the body in supine lying (Passive user, one helper):



10. The user is lying on a Master Turner or a Light Turner. Place the chosen Wedges on each side of the pelvis under the Master Turner to create a comfortable cradle.



11. Place the Wedges along sides the torso. Do not force the Wedges under the user. Place them lightly so the user feels a soft but distinct support from each side. This way the user can still move slightly around but feels the support of the Wedges.



12. Place the last Wedges along the user's legs. This way the user feels a comfortable and stable support all the way down on both sides.

Supporting the head:



13. Place a Positioning Wedge on each side of the pillow. This gives the user's head a stable and comfortable support. This will distribute the pressure from the head on to a bigger surface which lowers the risk of tissue injuries and increases the comfort for the user when lying in the bed.

Minimize tissue injury:



14. To avoid tissue injuries our Wedges are made of pressure relieving foam to increase support, stability, and comfort for the user. The outer side feels soft and comfortable when pressed against the body's pressure points.

Stable Wedges:



15. All Master Comfort Positioning Wedges have a non-skid underside. This way they are easy to place, and they stay in place, even when placed on top of a smooth Mattress Cover. The surfaces of the Wedges are so smooth that the Master Turner can still slide and move on top of the Wedges if they are placed under the Master Turner.

Cleaning and re-use:



16. The product can be reused by other users if the foam and cover are clean. To check the foam is dirty, open the zip and pull it out. If the foam is dirty, wash it by hand with warm water and soap. The foam must be allowed to air dry. The cover can be washed separately in the washing machine or cleaned with alcohol or soap and water.

User Manual - Master Comfort Positioning Wedges

Technical Specifications

ISO certifications:

INCO COVER:

DS/EN ISO 12952-1:2010

Textiles – Assessment of the ignitability of bedding items – Part 1: Ignition source: smouldering cigarette.

DS/EN ISO 12952-2:2010

Textiles – Assessment of the ignitability of bedding items – Part 2: Ignition source: match-flame equivalent.

| REF - Product Name: | Size: | Max. user weight (SWL): | Contents: | Package weight: |
|-------------------------------------------------------------|-----------------------|-------------------------|-----------------------------------------------------------------------------------------------------|-----------------|
| MC 001-8040 Master Comfort - Support Wedges | L 40 x W 15 x H 5 cm | Not relevant | Inco Cover: 52% Polyester, 39% Polyurethane, 9% Polyamide. Foam: 100% Polyurethane | 0,28 kg |
| MC 001-8045 Master Comfort Positioning Wedges - XS (welded) | L 40 x W 15 x H 5 cm | Not relevant | Inco Cover: 52% Polyester, 39% Polyurethane, 9% Polyamide. Foam: 100% Polyurethane | 0,28 kg |
| MC 001-8035 Master Comfort Positioning Wedge - S | L 30 x W 25 x H 14 cm | Not relevant | Inco Cover: 55% Polyester, 40% Polyurethane, 5% Polyamide. Foam: 100% Polyurethane | 0,50 kg |
| MC 001-8050 Master Comfort Positioning Wedge - M | L 43 x W 25 x H 14 cm | Not relevant | Inco Cover: 55% Polyester, 40% Polyurethane, 5% Polyamide. Foam: 100% Polyurethane | 0,54 kg |
| MC 001-8060 Master Comfort Positioning Wedge - L | L 60 x W 25 x H 14 cm | Not relevant | Inco Cover: 56% Polyester, 41% Polyurethane, 3% Polyamide. Foam: 100% Polyurethane | 0,66 kg |
| MC 001-8038 Master Comfort Positioning Wedge Cover - XS | L 40 x W 15 x H 5 cm | Not relevant | Green Cover: 38% Polyester, 34% Cotton, 17% Polyurethane, 7% Polyamide | 0,01 kg |
| MC 001-8043 Master Comfort Positioning Wedge Cover - S | L 30 x W 25 x H 14 cm | Not relevant | Green Cover: 42% Cotton, 38% Polyester, 13% Polyurethane, 3% Polyamide | 0,07 kg |
| MC 001-8053 Master Comfort Positioning Wedge Cover - M | L 43 x W 25 x H 14 cm | Not relevant | Green Cover: 39% Polyester, 37% Cotton, 17% Polyurethane, 4% Polyamide | 0,10 kg |
| MC 001-8063 Master Comfort Positioning Wedge Cover - L | L 60 x W 25 x H 14 cm | Not relevant | Green Cover: 39% Polyester, 37% Cotton, 17% Polyurethane, 5% Polyamide | 0,12 kg |

WARNINGS



Never leave the product on the floor.



The use of pillows and wedges can't replace the need of frequent repositioning and daily skin assessment.



Make sure that all relevant brakes are activated before transferring the user.



CE-certification:

This product is CE-approved and follows the harmonized standards. This means that the products are in compliance with the essential health and safety directives. The product(-s) comply with the standards in the Medical Device Regulation (EU) 2017/745 – class 1.

For more information, videos Quick Guide etc., visit www.master-care.dk



Washing:

The cover of this product can be washed in a washing machine at max 85 °C but disinfection with alcohol is preferable to prolong the durability. See information in box 16.



Detergents pH level:

This product tolerates detergents / disinfectants with a pH level between 5-9.



Fabric softener:

Never use fabric softener as this will reduce the sliding properties significantly.



Dry Tumbling:

This product may only be dry tumbled gently and at max 40 °C but air drying is preferable to extend the durability



Surface cleaning:

The surface of this product can be cleaned with a wet cloth and soap.



Disinfectants:

This product tolerates alcoholic disinfectants with a pH level between 5-9.



Ironing:

Do not iron.



Dry cleaning:

Do not dry clean.



Bleach:

Do not bleach.



Maintenance:

Make frequent visual inspections to the non-skid, the incontinence surface, all seams and the zipper and make sure all are intact and fully functional before use. Make tactile inspection to check the pressor absorption of the foam. Discard the product if it has deficiencies.



User Manual:

Always read the User Manual thoroughly before using the product.



Disposal:

Always make sure to follow local guidelines when disposing or discarding the product.