

Introduction

This manual contains important information on how to use and maintain the TEMPURMED® products. To ensure safe and proper use please read it before using the products and keep it for later.

TEMPUR-MED® products are classified as Medical Device, class I and CE marked in accordance with MDR (EU) 2017/745.











TEMPUR-MED® products are intended as supportive equipment in the preventive care for pressure ulcer.

In case of a serious incident with the product, the manufacturer and competent authority in the user's home country must be informed.

To report an incident to the manufacturer please report the incident as a warranty complaint by following the instructions specified in the "warranty" section of this manual.

Symbols



The following symbols are used on product, packaging or in this manual.

<p>Manufacturer</p> 	<p>Manufacturing date</p> 	<p>LOT</p> <p>Lot number</p>	<p>CE marked as class I  medical devices in accordance with the requirements of MDR (EU) 2017/745.</p>
<p>MD</p> <p>Medical device</p>	<p>Product orientation</p>  <p>printed on mattress foam cores</p>	<p>THIS SIDE UP</p> <p>This side up</p>	<p>Consult Instructions  for Use</p>
<p>Item has a presence of natural rubber latex as a material of construction within the product</p> 	<p>MAX XX  </p> <p>Recommended user weight</p>	<p>Avoid open flame</p> 	<p>Humidity limit </p>
<p>Keep dry</p> 			

Safety information - warnings and precautions

In this instruction for use warnings and precautions are illustrated with the following symbol and text:

Please be aware that failure to comply with these instructions may result in critical injuries or damage to the product.

	WARNING	Be aware of situations or practices that may cause death or critical injuries
	CAUTION	Be aware of situations or practices that may cause moderate or minor injuries
	IMPORTANT	Be aware of situations or practices that could result in damage to the product or other property

Intended use

The intended purpose of the TEMPUR-MED® products is to prevent or reduce the risk of developing pressure ulcers in adults.

The TEMPUR-MED® products are suitable for weights up to 150 kg unless stated otherwise (e.g. on certain wheelchair cushions).

It is important that immobilized users are repositioned on a regular basis.

The TEMPUR-MED® product range is intended for hospitals, care environments (for example nursing homes, rehabilitation facilities) and home care.

Product description

The TEMPUR-MED® range consists of mattresses, mattress toppers, pillows, cushions, positioning products, as well as products for dental chairs, operating rooms and scanners.

The TEMPUR-MED® products consist of the following parts:

- Foam core containing visco-elastic pressure redistributing TEMPUR® foam material
- polyurethane incontinence cover

Covers

The TEMPUR-MED® incontinence covers are manufactured with waterproof, stretchable, airpermeable polyurethane material, which allows the TEMPUR® foam material to breathe.

For information about constituent materials – see product label, which is located inside the cover.

For selected TEMPUR-MED® products the incontinence covers are available in both sewn and welded versions. Sewn versions are intended for environments with lower risk of liquids/body fluids (e.g. most bed wards and day centers). Welded versions are intended for environments with higher risk of liquids/body fluids (e.g. operating rooms).

Non-slip coating

Selected TEMPUR-MED® products have a non-slip coating on the underside to help keep the products from sliding during use.

The non-slip properties are not impaired by washing the cover.

Unpacking and installing the TEMPUR-MED® products:


IMPORTANT: When unpacking the product take care not to puncture or damage the cover.

Once unpacked, the product may give off a slight odour. This is harmless and will disappear after a short period of use.

During shipping, the covers of larger items may move from their original position. Once unpacked, allow the product to warm up to ambient air temperature, the cover can then be straightened back into position by hand.


IMPORTANT: Do not unroll TEMPUR-MED® mattress toppers in cold conditions as there is risk of tearing or cracking the foam material. Allow the product to adjust to room temperature before unrolling.


Using the TEMPUR-MED® products


 Warning: Be aware of how users with reduced mobility are positioned on mattress, mattress topper and/or pillow or cushion to avoid risk of suffocation.

We strongly recommend not to smoke in bed or while using the products.


 Warning: Risk of fire: keep products away from open flames.


 Caution: Before using the TEMPUR-MED® products ensure the product is suitable for the user and intended support surface (for ex. bed base, seat surface).

 Caution: Users must be repositioned regularly.

 Caution: Recommended use is with a bed sheet directly on the mattress/mattress topper and a pillowcase on pillows.


Do not use bed pads, blankets, plastic sheets or similar products between TEMPURMED® product and user. Do not use hot water bottles or electric blankets with the TEMPUR-MED® products. Such products may affect or reduce the pressure redistributing properties and thereby the clinical benefits.


 Caution: It is important that there are no foreign objects, folds or seams in clothing or bed sheets located between user and the TEMPUR-MED® product as it may increase risk of pressure ulcer development.


 Caution: Be aware of sharp items and equipment that may damage the cover and cause fluid ingress into the foam core. Fluid will damage the Tempur® foam material which will affect or reduce the product's pressure redistributing properties and thereby the clinical benefits.


Do not stick sharp objects into the cover or product (safety pins, syringes, scalpels or similar objects)

Do not put sharp objects on top of the product (patient lifting pole, IV pole or similar equipment).

 Caution: Ensure that mattresses and mattress toppers are placed with printed side facing upwards. In these products the TEMPUR® pressure redistributing foam material is on the topside of the core.

 Caution: Ensure that wheelchair cushions and other seating cushions are placed with top side up: avoid that the printed TEMPUR-MED® logo on the side of the product is placed upsidedown.

 Caution: Mattress handles are only for lifting the weight of the mattress during handling, f. ex. during bed preparation.

 Caution: X-ray attenuation (scanner mattresses)
The TEMPUR® foam is a high density material which can attenuate x-rays. The x-ray attenuation is equivalent to approx. 1,4 mm Al per. cm TEMPUR® foam material.

IMPORTANT: TEMPUR-MED® mattresses must always be placed on a ventilated base, e.g. springs or slats to prevent moisture from accumulating in the mattress.

IMPORTANT: Covers must be inspected regularly for holes or tears to avoid damage to the TEMPUR® foam material.

IMPORTANT: Do not fold, bend or press your TEMPUR-MED® product into shape as there is risk of damaging the TEMPUR® foam material.

Cleaning and Maintenance

IMPORTANT:

Covers must be inspected regularly for holes or tears to avoid damage to the TEMPUR® foam material. Cover must be replaced if holes, tear or visible signs of wear appear.

IMPORTANT:

- Do not wash the TEMPUR® foam material.
- Do not steam-clean or dry-clean the TEMPUR® foam material.
- Do not autoclave the TEMPUR-MED® products.
- Do not treat TEMPUR-MED® products with ozone, UV light or ionization.

IMPORTANT:


- All TEMPUR-MED® products must be regularly ventilated to remove moisture.


Cleaning of covers

For washing of covers please follow the instruction on the product label which is located inside the cover.

Covers can be wiped off with a mild soapy solution or with normal hospital disinfectants such as: 70% ethanol or 0.1% sodium hypochlorite. Covers must be completely dry before use or storage.

IMPORTANT: Do not use phenol based cleaning solutions, bleach or other abrasive materials.

 Caution: After washing ensure mattress cover is replaced according to the orientation printed on the side of the mattress foam core. The TEMPUR® foam material that provides pressure redistribution is only on the top-side of the core.

 Caution: After washing the covers of seating products/cushions with layers of foam please be aware of the orientation of the foam core when products is being reassembled. The TEMPUR® foam material that provides pressure redistribution is only on the top-side of the core.

Transport, Handling and Storage

 Caution: Mattress handles are only for lifting the weight of the mattress during handling.

Due to the viscoelasticity of the TEMPUR® foam material, both mattresses and rolled up mattress toppers can become slightly compressed during transport or storage. The product will return to its normal size after a short time at room temperature.

Do not bend or press TEMPUR-MED® products out of their original shape as you risk damaging the TEMPUR® foam material.

- Store in a dry environment (maximum 65% relative humidity).
- Before using or storing a cleaned product, make sure the product is completely dry.

- Mattresses must be stored flat, ideally in the original packaging.
- Mattress toppers must be stored flat or rolled up.
- Pillows, cushions and positioning products must be stored in their original shape. - Do not store other items on top of the TEMPUR-MED products, as there is risk of permanent deformation of the foam material.

Reuse of TEMPUR-MED® products

Tempur-MED® products are suitable for repeated use. Expected product lifetime depend on maintenance and intensity of use.

Products must be inspected and cleaned before reuse. Please refer to the “Cleaning and Maintenance” section of this manual.

Disposal

For disposal of your used TEMPUR-MED® product please refer to your local authority within your country market. Product should be cleaned prior to disposal to avoid risk of contamination.

Technical product information

Fire safety standards

 Warning: Risk of fire: keep products away from open flames

TEMPUR-MED® product	Fire safety
Mattresses, mattress toppers	EN 597-1 (cigarette test), EN 597-2 (match equivalent test)
Mattresses, mattress toppers (fire retardant versions)	BS 7177 medium hazard: EN 597-1 (cigarette test), EN 597-2 (match equivalent test) BS 6807 (Crib V) BS 5852 (Crib V on foam)
Pillows, cushions and positioning products (moulded and granulated filling)	ISO 12952-1 (cigarette test), ISO 12952-2 (match equivalent test)
Pillows, cushions and positioning products, moulded (fire retardant versions)	ISO 12952-1 (cigarette test), ISO 12952-2 (match equivalent test) BS 5852 (source 5 on foam)
Pillows, cushions and positioning products with granulated filling (fire retardant versions)	ISO 12952-1 (cigarette test), ISO 12952-2 (match equivalent test) BS 5852 (source 2 on foam)

Further information is available upon request.

Latex

Certain TEMPUR-MED® products are manufactured of layers of foam with the TEMPUR® foam material on top and with an adhesive that contains latex between the layers. Please check the product label inside the cover to see if the product you have purchased contain latex.

The TEMPUR® foam material and the cover do not contain latex

X-ray attenuation (scanner mattresses)

X-ray attenuation is equivalent to approx. 1,4 mm Al per. cm TEMPUR® foam material.

Product dimensions and weight:

TEMPUR-MED® products are available in several different sizes as well as custom sizes. Product weight depend on product size. Further information is available upon request.

Manufacturer



Dan-Foam ApS

Holmelund 43

5560 Aarup

Denmark

*Dan-Foam ApS is a subsidiary of TEMPURSealy International, Inc

Warranty

Foam cores	Product warranty	What is covered
Mattresses, mattress toppers, and scanner toppers	7 years	Defects caused by faulty workmanship or materials, and changes which cause a visible permanent indentation more than 2 cm in the TEMPUR® foam material.
Basic mattresses	3 years	Defects caused by faulty workmanship or materials, and changes which cause a visible permanent indentation more than 2 cm in the TEMPUR® foam material.
Pillows, cushions and positioning products, moulded core	3 years	Defects caused by faulty workmanship or materials, and changes which cause a visible permanent indentation more than 2 cm in the TEMPUR® foam material.
Pillows with granulated filling	3 years	Defects caused by faulty workmanship or materials
Covers	Product warranty	What is covered
PU covers	3 years	Defects caused by faulty workmanship or materials
Basic mattress PU covers	2 years	Defects caused by faulty workmanship or materials

Please check the warranty terms for the country where the product was originally purchased as there may be a different warranty period applicable.

The warranty does not cover ordinary changes in hardness or characteristics that do not affect the pressure redistributing properties of the product. The warranty is valid only if the TEMPURMED® product is used, cleaned and maintained in accordance with the directions in this manual.

The warranty does not cover:

- If a TEMPUR-MED® product has been altered or repaired without the permission of TEMPUR®.
- If instructions for use, cleaning and maintenance have not been followed.
- the product has been deliberately damaged or damaged as a result of neglect, cuts, burns, flooding or any other improper use by you or by any third party.

Complaints should be made to the dealer from whom the product was purchased or to another authorised dealer of TEMPUR-MED products in the country the product is purchased

In case of a complaint, the original invoice must be enclosed as proof of purchase. Do not return the product without prior agreement/instructions from TEMPUR or the dealer.

If products are repaired or replaced under the warranty, the original warranty period is not extended.

The Warranty does not affect a consumer's statutory rights under applicable law but aims to enhance the consumer's rights where applicable.