

Mr / Mrs
Company
Street
Postcode, Town, Country

Geschwenda, 27.03.2018

Urgent safety information


***Updated warning
about the
Geratherm® UniqueResc+
(all batches)***

Dear Sir or Madam,

Please note the following important changes to the information supplied in the instruction manuals for our UniqueResc+ patient warming systems.

Description of the problem, including the underlying cause which has been identified:

After updating our risk assessment for these products, we believe it is essential to append the following warning information relating to how they should be stored.

| | |
|---|---|
|  | <p>When storing the patient warming system, please ensure that it is folded only lightly and without creasing the material. Applying pressure to such creases may damage the heating element. You should also take care to ensure that the connecting cable of the patient warming system is not folded into the material.</p> <p>Warming systems must never be exposed to undue pressure, as this may result in damage being caused to them.</p> |
|---|---|

Improper storage or excess pressure on the heating element may result in the failure of the patient warming system. Although this is unlikely, in extreme cases sparking may potentially occur, resulting in localised overheating of the patient warming system. This might then cause the blanket material to fuse.

No patients have so far come to any harm.

What action should I take?

Forward this information to all users of the patient warming system, and ensure that the products are stored in accordance with the updated warning.

Keep this letter together with the instruction manual for the product.

Please return the enclosed confirmation form to us by 27.4.2018.

Forwarding this information to others:

Please ensure that all operators of the above products within your organisation are made aware of this urgent safety warning, as well as anyone else there who requires this information. If you have passed on the products to a third party, please forward a copy of this information to them, or notify the contact person named below.

The Federal Institute for Drugs and Medical Devices has received a copy of this 'Urgent safety information'.

Contact person:

Geratherm Medical AG
Mr Denny Holland-Moritz
Safety Officer pursuant to Art. 30 Medical Devices Act (MPG)
Fahrenheitstrasse 1
D-98716 Geschwenda
Email: d.holland-moritz@geratherm.com
Tel.: +49 (0) 36205-980
Fax: +49 (0) 36205-98115

Yours faithfully,

D. Holland-Moritz
*Safety Officer pursuant to
Art. 30 MPG*

[Redacted signature]

[Redacted signature]

Encl.
Confirmation form

Urgent safety information

*Updated warning
about the
Geratherm[®] UniqueRec+
(all batches)*

Confirmation form

- We have identified the products affected. They will be stored in accordance with the updated safety warning. This information has been appended to the product documentation.
- We no longer have any of the affected products in use.

Customer / Customer
No.:

Name / Job title

Tel. No.:

Email address:

Date / Signature

Please return this confirmation form to one of the addresses given below:

Fax No.: +49 (0) 36205-98115
Email address: info@geratherm.com
Postal address: Geratherm Medical AG
Fahrenheitstrasse 1
D-98716 Geschwenda