

Eschborn, 19.07.2011

Mr. / Ms.
Name
Street

City

Urgent Field Safety Notice

Dear Sir / Madam,

with this letter we would like to inform you of additional instructions made to the user manual for your CERAGEM-E massage bed.

In accordance with directive 93/42 EEC medical devices are obliged to be released with instructions for safe and proper use and these instructions should be available in written form as a part of the user manual. Therefore, those instructions and information given to you at your local Ceragem centre regarding proper use have been added to the user manual.

We have enclosed a copy of additional instructions and additional information so called 'Healing Reaction or Initial Aggravation'. Please read these updated instructions and keep these with your user manual. This notice should be passed on to all persons who need to be aware or to any persons to whom the potentially affected devices have been transferred.

We kindly ask you to sign the attached form and send it back to us. Please find a stamped addressed envelope for you enclosed.

Should you need further information, please do not hesitate to contact us.

Best regards



Dr. Yong-Sung Lim
Medical Device Safety Officer
[acc. to German Medical Devices Law]

Attachments

Amendment to instructions for use of CERAGEM-E

Reply coupon

Stamped addressed envelope

President: Lee, Moo Soo
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Email: info@ceragem-europe.com

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BLZ: 500 400 00
KTO.-NR.: 381 78 48

Mr. / Ms.

Name

Street

City

REPLY

(Urgent Field Safety Notice)

I confirm that I received the letter of additional instructions made to the user manual for the CERAGEM-E massage bed, dated 18.01.2011.

Please sign here

Amendment to instructions for use of *CERAGEM-E*

Date: 18.01.2011

Intended purpose

CERAGEM-E is intended to help with muscle relaxation therapy, temporary relief of minor muscle and joint pain, stiffness, blood circulation.

Information for use

Use *CERAGEM-E* only in technically perfect condition. Use of a damaged device may cause injuries / burning.

CERAGEM-E is designed for indoor use only. Please do not use the *CERAGEM-E* outdoors.

CERAGEM-E should not be operated where aerosol (spray) products are being used or where oxygen is being administered.

CERAGEM-E should not be operated in wet or moist conditions such as bathrooms or kitchens.

Before and during the operation of *CERAGEM-E* do not use skin care products, cosmetics or pharmaceutical products on your skin.

Sleeping on the product for a long period of time may cause burning or other injuries.

The application to one part of the body should not exceed 2 or 3 minutes. After this period of time the projector should be moved to other parts of the body.

Please strictly follow the usage time and method.

The recommended use of *CERAGEM-E* is 1-2 times per day.

Please only use accessories that are provided by the manufacturer.

Before using *CERAGEM-E* consult with a medical doctor, especially in the following cases:

- Pregnant or suspected pregnancy
- Recent injury or recently operated patients
- Inflammation or open wounds in areas of the body where direct contact would occur using Ceragem
- Advanced osteoporosis
- Persons with limited sensation of pain
- Fever, infections and / or cancer
- Circulatory insufficiency or weak circulation in legs or heart diseases
- Pain without cause defined

At this time there is no evidence to suggest that *CERAGEM-E* interferes or influences the effects of pharmaceutical substances. Therefore people who take prescribed medicines should consult a medical doctor before using *CERAGEM-E*.

Disabled persons and children should use *CERAGEM-E* only under supervision.

Persons who are sensitive to heat should set the device at a low temperature.

CERAGEM-E projectors shall not be used in areas where there is reduced sensitivity or in areas with poor blood circulation.

Do not use *CERAGEM-E* immediately after taking a bath or a shower.

Please make sure that the external projectors do not have direct contact with skin as direct skin contact may lead to skin burning. The projector should always be completely covered with the projector cover provided.

Attention: Never place the external projector directly on your eyes!

Important information on possible symptoms

In some cases there may appear a so-called "initial aggravation". This initial aggravation may begin with a subjective increase of symptoms prior to the desired healing. The effect of initial aggravation is also known from other treatments (for e.g. the science of homoeopathy), which is defined as the reaction of healing and / or the clearing of blockages. The initial aggravation that may occur does not constitute an exclusion criterion of the application of *CERAGEM-E*.

In the case of excessive pain related to pre-existing spinal conditions, distinct hypertension, cardiovascular diseases or dizziness, please first reduce the intensity of usage (duration & temperature).

In cases in which the initial worsening leads to excessive continual pain please stop the therapy and consult a medical doctor immediately to clarify if and under which circumstances the therapy can be continued or ceased.