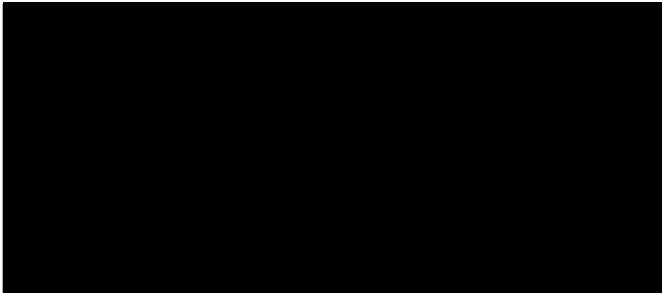


ORTHO-REHA Neuhof GmbH • Gundelfinger Straße 6 • 90451 Nürnberg



Urgent safety information

17.01.2022

Downgrade patient weight Genex Knee

Dear Ladies and Gentlemen,

You have purchased one or more Genex knees from us. We would like to draw your attention to a downgrading of the patient's weight.

The following articles are affected:

205H18=1	Genex Knie
205H18=2	Genex F Knie
205H18=3	Genex FB Knie
205H27=1	Genex P Knie
205H27=2	Genex PB Knie
9205F18	Lotus Adapter für Genex-Knie

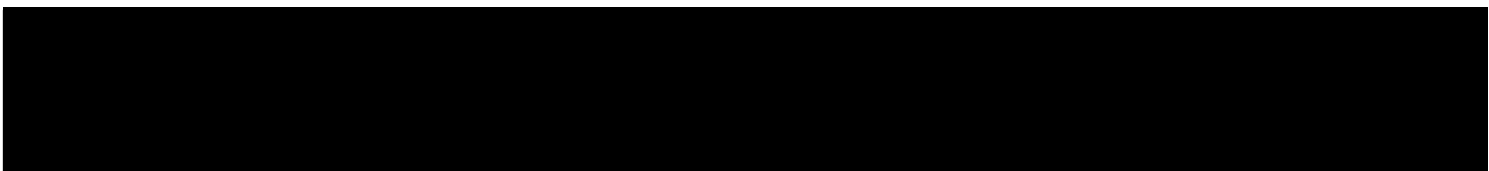
What is the problem?

The product is designed for a total weight = body weight + load to be carried of 125 kg. Unfortunately, we have found that the product has only been tested to a patient weight of 100kg according to the ISO 10328 standard. The 125 kg test will be carried out as soon as possible. However, for safety reasons, we have to reduce the permitted patient weight to 100 kg for the time being.

What should you do?

For the above reasons, the product must not be used on patients whose total weight exceeds 100 kg. Please check which of the following measures are necessary:

- If you are sure that the patient's weight is well below 100 kg, then you do not need to do anything.
- If the patient's weight is close to 100 kg, please contact the patient to confirm whether it can still be used safely with the total weight up to 100 kg.
- If the patient's weight exceeds 100 kg, the product must not be used until further notice.



Furthermore, we must draw your attention to the fact that further use of the fitting is at your own risk if you ignore this message.

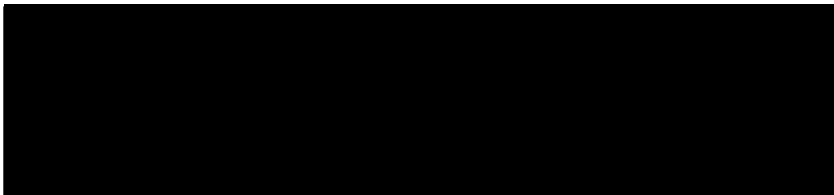
ORTHO-REHA Neuhof GmbH has already notified the responsible authorities.

We hereby apologize for the inconvenience caused to you by this measure. Our goal is to ensure the safety of our products.

Please send the following confirmation back to ORTHO-REHA Neuhof GmbH.

Disclosure of the information described here

Please ensure in your organization that all users of the above products and other persons to be informed are made aware of this urgent safety information. If you have given products to third parties, please forward a copy of this information or inform the contact person given below. Please keep this information at least until the action has been completed.



Confirmation of acknowledgment of safety measure "Downgrading patient weight Genex Knee"

We have received and understood the Urgent Field Safety Notice "Patient Weight Downgrading Genex Knee". We will implement the required measures.

Company Name

Name, Function

Place, Date

Signature

