

Urgent Field Safety Notice

Name of product: Hera II (serial numbers 1379 to 2180)

FSCA-identifier: 18.04.2012

Type of action: Corrective action

Date: 18-04-2012

Attention: Dealers, clients and users of the Hera II bathing & Toileting chair.

Devices affected

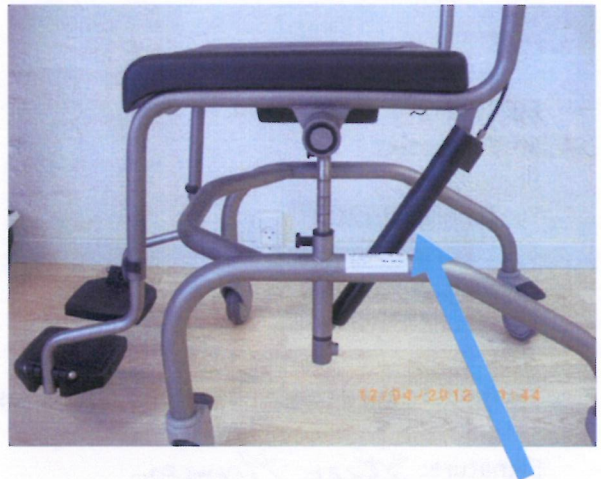
Type of device: Bathing & Toileting chair

Model name: Hera II

Item number: 041-00250, 041-00255, 041-00256,
041-00280, 041-00281

Serial number: 1379 to 2180

Affected part: Gas spring for tilt function (see photo)



Description of the problem

Due to an incident and several claims regarding broken gas springs on the Hera II, and after specific risk analysis, it has been decided that replacement of the gas spring is necessary. The back fixture of the gas spring has been known to break after a significant time of use, resulting in the chair to tilt backwards. If a patient is seated in the chair during this malfunction, there is a risk of the patient hurting the back of the head or getting injured in the neck by the sudden backwards movement! The gas spring has been updated with a reinforced back fixture on products with serial number 2181 and higher. The updated gas spring is compatible to all Hera II and can therefore be used for replacement.

Advice on action to be taken by the user

The gas spring on products in question should be replaced as soon as possible or within 12 month. Replacement is shown in the instruction later in this FSN. Gas spring kit for replacement (047-00047) is available through your local dealer or by contacting Ergolet sales. Information regarding the serial number, of the chair, is required to receive the replacement kit for free, or get a credit nota. The gas spring can be mounted by any competent technician by following the instruction.

Get replacement kits for free

Please fill in, and return, the confirmation form "Hera II – gas spring", when ordering the replacement kit (047-00047)! – If the serial number(s) are unknown, when ordering, you can get a credit nota later by sending the serial number(s) to your dealer or Ergolet sale: tpe@ergolet.dk

This notice does not apply to Bathing & Toileting chair with model name Hera/140.

Transmission of this Field safety Notice

Please ensure that this Field Safety Notice is passed on to all those who need to be aware of it. If the Hera II Bathing & Toileting chair is not in your possession please forward this notice on to the current users.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Steen Hansen
Ergolet ApS,
Taarnborgvej 12C
4220 Korsør, Denmark
E-mail: sha@ergolet.dk

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Signature: *Steen Hansen*

Date: 18-04-2012

NB: Any gas springs with old type back fixture, in spare part stock etc., must be replaced by gas springs with new type back fixture! – Item number: 047-00041 (see photo)



INSTRUCTION FOR GAS SPRING REPLACEMENT:



Gas spring to be replaced.



Type plate with serial number.



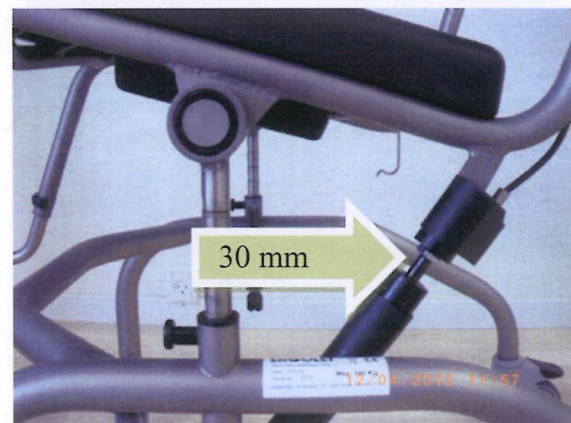
Replacement kit – and tools needed:

Tools needed:

Cloth
Pliers
13 spanner
17 spanner
Poly grab bar



1. Remove the cover tube from the Gas spring top end.



2. Release the gas spring to have 30mm free piston rod, leaving the seat in a backward angle, as in the picture.



3. Unscrew the M8 lock nut.



4. Unscrew the M10 nut. Keep unscrewing until the piston rod thread has come out of the plastic housing.



5. Lock the tilt function with a plastic strip to make the replacement easier.



6. Remove the old gas spring.



7. Fit the cover tube to the new gas spring in the same direction as on the old gas spring. Release the gas spring to have 30mm free piston rod.



8. Fit the gas spring to the threaded tap at the bottom end.



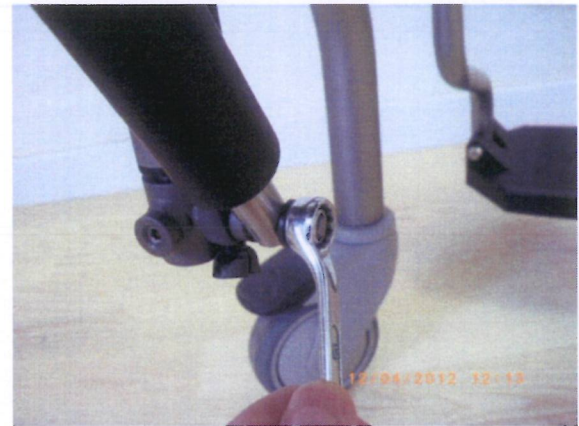
9. Cut the plastic strip and fit the piston rod end to the housing.



10. Screw in the piston rod until the gas spring is released. Use the cloth to protect the piston rod from scratches.



11. Unscrew the piston rod 1 turn* and tighten the M10 nut whilst securing the piston rod.



12. Tighten the M8 nut, with little torque, until the thread shows on the outside.



13. Press the cover tube on to the Plastic housing.

*Check the gas spring release/lock function in the out, middle and in position!

