

Mobilex A/S
Grønlandsvej 5
DK-8660 Skanderborg
Denmark
SRN: DK-MF-000021885



Date: 21.09.2022

Urgent Field Safety Notice

With this letter we would like to inform you that the screw connection of the front wheel to the frame is faulty (screw loosening) and that corrective measures must be taken on the Mobilex arthritis rollator Tiger indoor models.

FSN (see attached delivery note with serial numbers).
Ref. FSCA: 01/2022

To all Users and Dealers of Mobilex arthritis rollator Tiger indoor

Implementation of the corrective measures: We ask for your support to repair the affected devices (see attached delivery note with serial numbers).

Affected Devices: Please note (see attached delivery note with serial numbers).

Dear Users and Dealers of Mobilex arthritis rollator Tiger indoor,

PLEASE READ THIS DOCUMENT CAREFULLY.

Mobilex A/S was made aware of safety issues involving the Tiger indoor models. The front fork can occasionally loosen during use as no Loctite glue was used during assembly of the impacted serial numbers.

Due to the identified risk of screw loosening, an additional risk for the user has been defined. As a supplier of high-quality medical products, we have decided to take corrective action on the listed products.

Risk to the user:

There is a risk of the user falling during use. It could happen that the user falls forward and injures himself. The corrective measures are necessary as a measure for the greatest possible risk reduction according to the state of the art.

Corrective measures:

1. Information for users

Your authorized specialist dealer will contact you with this letter and coordinate/carry out the repair/correction of your product.

The rollators listed above must be taken out of service until they are replaced/reworked.

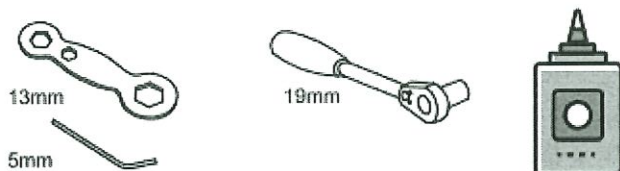
2. Information for dealers

2.1. Please return the completed and signed FSCA 01/2022 confirmation form to Quality@mobilex.dk by December 1, 2022.

The affected rollators (see attached delivery note with serial numbers) must be taken out of service until they are replaced/reworked.

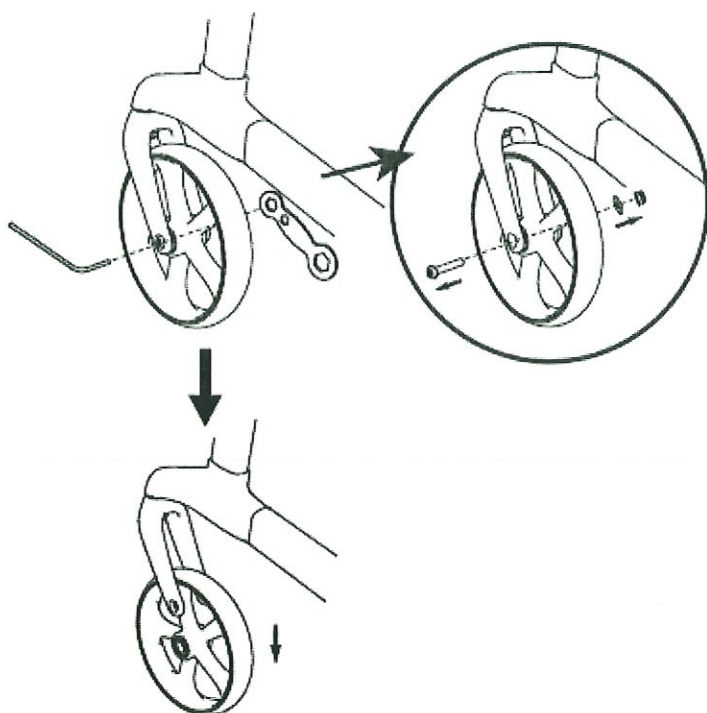
2.2. The screw connection is repaired by adding LOCTITE 243 screw locking glue or a comparable product.

2.2.1. Required tools:

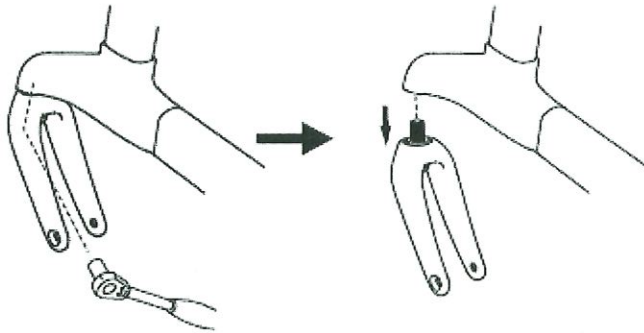


Glue: Loctite 243

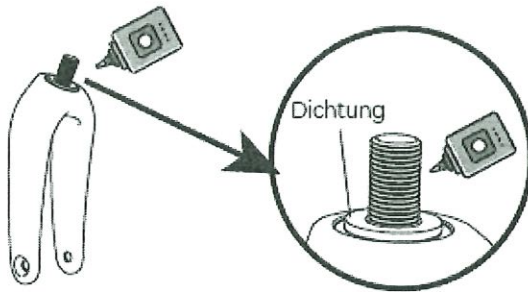
2.2.2. Unscrew the front wheel. Tools:



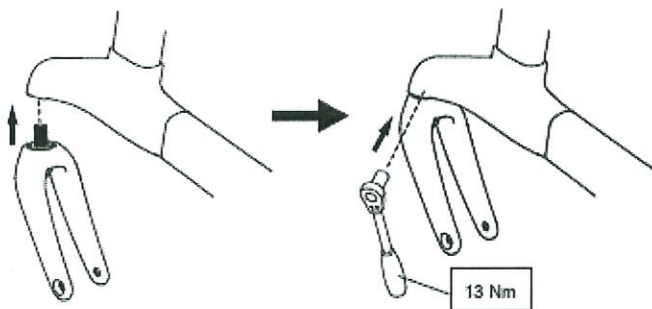
2.2.3. Loosen the M12 bolt and remove the front fork. Tool:



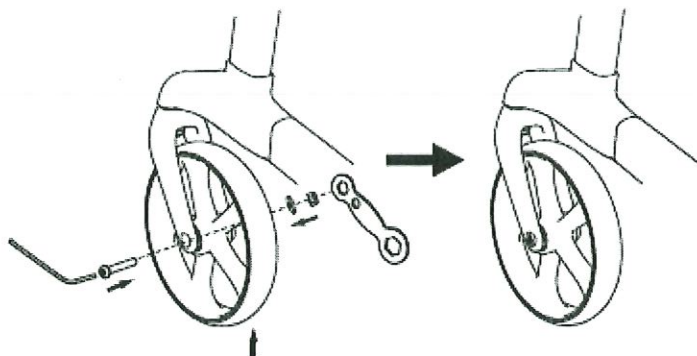
2.2.4. Apply glue to the thread only. Please ensure that the gasket remains on the screw for reassembly.



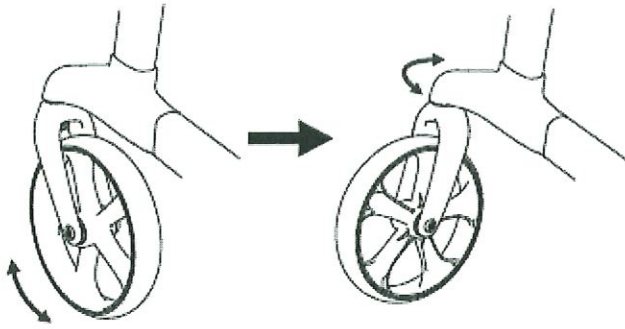
2.2.5 Reattach the front fork to the frame with the M12 bolt. Tighten the bolt with a torque of 13 Nm. Tool:



2.2.6. Screw the front wheel back on. Tools:



2.2.7. Check the wheel for functionality. To do this, make several turns around the axle to see if it turns smoothly.



2.3. We ask for your support to repair the affected devices (see attached delivery note with serial numbers).

Please ensure that all users of the affected products are made familiar with this important safety information. If you have given the products to a third party, please forward a copy of this information or inform the contact person given below. Please keep the letter at least until the action is completed.

If you have any further questions, please contact: Quality@mobilex.dk or +45 30763201.

We would like to take this opportunity to apologize for any inconvenience.

With best regards



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Confirmation form - FSCA 01/2022

Dear Sir or Madam,

please acknowledge receipt of the Field Safety Notice for corrective actions being performed at your site.

If you have any questions about the process, we are of course at your disposal and will be happy to support you. You can reach us at Quality@mobilex.dk or +45 30763201.

Affected devices:

Please note (see attached delivery note with serial numbers) with the listed serial numbers.

Name:.....

Phone:.....

E-mail:.....

Address:

Date:.....

Signature: