

Urgent Field Safety Notice

Recall of *sleep•safe* Sets – Patient line leakages

Date: 05th December 2016

Affected article numbers (for affected batches refer to annex A):

| | |
|-----------|---|
| 5016921 | <i>sleep•safe</i> Set |
| 5016931 | <i>sleep•safe</i> Set Plus |
| 5017391 | <i>sleep•safe</i> Set Paed |
| 5017491 | <i>sleep•safe</i> Set Plus (Japanese Version) |
| F00005377 | <i>sleep•safe</i> Set Plus AP |

Dear customer,

During the continuous monitoring of our *sleep•safe* tubing systems on the market, we have become aware of an increased number of leakages caused by overwelded coils on the patient and the drainage line.

In case of overwelded coils this lead to difficulties in unrolling the patient and drainage line and thus leakages may occur. The possible damages might not be visually detected.

The *sleep•safe* and *sleep•safe harmony* cyclers can also not detect such a leakage. Therefore, there is a potential risk of infection for the patient, particularly the development of a peritonitis.

The problem of overwelded coils has been analysed and solved in our production. A corrective action in the welding process for the coiling of the patient and drainage line of the *sleep•safe* Sets has been already implemented in September 2016 using a new machine.



Until a complete replacement of potentially affected batches is possible, we advise the following handling instructions:

- **Unroll carefully the tube coils of the *sleep•safe* sets**
- **If unrolling is not possible, please discard the sets**
- **If unrolling is successful, please check carefully the patient line for leakages during priming**

Please provide this Recall Notice to all those who need to be aware of it.

We sincerely apologize for the inconvenience and we will provide you with a replacement as soon as possible. You will be contacted by your Fresenius Medical Care representative to organize the exchange.

In case of any further questions do not hesitate to contact:

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Sincerely yours,

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