
Urgent Field Safety Notice

Commercial name of the affected products:

- Navina Rectal Catheter set regular,
- Navina Classic system regular,
- Navina Classic system refill regular
- Navina Consumable set regular,
- Navina Smart system regular

FSCA-identifier: CR-U-201801071

Type of action: RECALL

Date: 2018-12-20

To whom it may concern

Details on affected devices

A serious potential non-conformity has been identified for the “Navina Rectal Catheters **REGULAR**”, with REF 68940 and for LOT(s) 426044, 426366, 426540, 426741, 426889, 427217 and 427703, as printed on each catheter packaging. Se photo of how it appears.



The deficient REGULAR catheters may have been included within other Navina ‘set’ products. See the following table for relevant REFs and the specific LOT numbers. Note that XX indicated the 2 digit country code on the Navina product set’s labels. The additional 2 digits are not printed on any single catheter package.

| PRODUCT (REF) | PRODUCT NAME | LOT # (INCLUDING THE AFFECTED RECTAL CATHETER) |
|---------------|--|--|
| 68940XX | Navina rectal catheter set regular | 427790, 427296, 427474, 427789, 427221, 427476, 427122 |
| 69003XX | Navina Consumable set regular | 427312, 427850, 427473, 427530, 427628, 427154, 427602, 427128 |
| 69005XX | Navina Classic System regular | 427501, 427890 |
| 69006XX | Navina Classic system regular - refill | 427761 |
| 69009XX | Navina Smart System regular | 427678, 427446, 427416, 427169, 427365, 427134 |

Description of the problem:

‘Navina rectal catheters regular’ are used together with either the ‘Navina Classic system regular’ or ‘Navina Smart system regular’, for trans-anal irrigation (also called TAI). The manufacturer has a quality control program with testing of its devices, and during one of these tests carried out on the ‘Navina rectal catheter regular’ a deviation was found which indicated the catheter balloon could potentially burst during use. Additional testing was done and showed the deviation is rare, estimated to a frequency approximately 0,4 % or less in affected LOTs.

This recall is performed as a precaution as a balloon burst during use will not only cause discomfort but can cause an injury to the bowel, and potentially a bowel perforation which is a very rare (1 out of 500,000 irrigations, out of which very few were related to balloon burst) yet extremely serious complication that requires emergency care. Symptoms of bowel perforation include severe or sustained abdominal or back pain or significant rectal bleeding (not just a smearing of blood on the rectal catheter, which is very common and is not a concern).

There are to-date no adverse events or complaints reported to the manufacturer for the affected catheters or related product sets.

Advise on action to be taken by the customer:

1. Urgently Identify and check the REF and LOT numbers on your Navina product(s) packaging, and on the enclosed rectal catheter regular packaging
2. Should both REF and LOT numbers match those listed above, return the catheters or unopened Navina products including catheters, without delay to the following address:

“Recall 20181071”
Wellspect HealthCare
Aminogatan 1
SE-431 53 Mölndal.
Sweden

3. Please confirm receipt of this Filed Safety Notice by immediate response to sender of this message

Any adverse events experienced and suspected related to the use of the affected rectal catheters regular should be promptly reported to your local Wellspect HealthCare contact. Please see the Navina Instructions For Use booklet, provided with the Navina Classic and Navina Smart System for contact details. Local contact information is also found via www.wellspect.com, by selecting your country.

For replacement:

If you are a patient, please contact your health care provider.

If you are a health care provider or distributor please place a new order. Returned product will be reimbursed.

Transmission of this Field Safety Notice

- This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

If you have any questions, you can contact us directly. We will help to answer your questions.

Contact information:

Anna Malmborg, Head of Global Platform Enterology

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

Ingrid Andersson
Vice President Quality Assurance & Regulatory Affairs