

Recall - Urgent Safety Information

BECHTEC

Dear Ladies and Gentlemen,

We would like to inform you about a product recall. Please read our letter carefully. If you have any questions, you are welcome to contact us at any time, by email to info@bechtec.de or by telephone on 07243 52 17 98.

Description of the problem including the identified cause:

Due to production defects, individual catheters of the listed batches cannot discharge urine.

Affected medical devices:

The following products are affected by our recall:

All-silicone catheter Nelaton integral - blue - Ch 12 LOT: 210701

All-silicone catheter Nelaton integral - blue - Ch 14 LOT: 210701 and LOT 220102

All-silicone catheter Nelaton integral - blue - Ch 16 LOT: 210701 and LOT 220102

Measures

As an immediate measure, we would like to ask you to immediately return all affected items to us with the enclosed return slip. You will receive a corresponding replacement delivery. We also ask you to inform us by telephone or e-mail that you have received our letter and that you will return the goods to us immediately.

If you are currently wearing the catheter from the affected batch, please make an appointment for a change in your urological practice immediately. Before the replacement date, please pay special attention to whether the normal amount of urine is discharged through the catheter. If there is any deviation, please go to the urological practice immediately and replace the catheter.

For patients who have already been successfully treated with the above products, there is no risk and no reason for additional follow-up.

Measures for urological practices

Please contact those patients who are currently wearing one of the affected catheters and arrange a replacement appointment immediately. For patients who have been successfully treated with the above products, there is no risk and no reason for additional follow-up. We would like to apologize to you for the inconvenience caused!

Best regards

