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Urgent Field Safety Notice

Document-Identifcation:

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Product: Orsiro Sirolimus Eluting Coronary Stent System

Bülach, January 2026

Dear Physicians and Cardiac Interventional Laboratory Managers,

This letter is to inform you about an important safety measure affecting specific lots of the **Orsiro Sirolimus Eluting Coronary Stent System**. Biotronik AG, a subsidiary of Teleflex Incorporated, is initiating a **voluntary field safety corrective action** to withdraw certain lots of this product from the market.

Description of the problem:

During manufacturing, it was identified that the hydrophilic coating applied to the distal, flexible portion of some Orsiro delivery systems had an inhomogeneous appearance. The hydrophilic coating is designed to enhance the gliding performance of the delivery system during coronary delivery.
Testing of affected stent systems was performed to understand the cause of the inhomogeneous appearance and the potential effect when used. This testing was performed in a worst-case in vitro model that represented tortuous and calcified coronary anatomy and showed that the coatings on affected units may move and delaminate. In some cases, this may lead to release of particles of the coatings that could potentially enter the patient's blood stream and reduce blood flow or cause occlusions in small (<2 mm) diameter coronary arteries.
Root cause investigation determined that some products with inhomogeneous hydrophilic coating had been distributed to the market. To date, Teleflex has not received any reports of malfunctions or adverse events related to inhomogeneous coating or particle release.

Details on affected devices:

The Orsiro Sirolimus Eluting Coronary Stent System is intended to improve coronary blood flow through the reopening of coronary vessels.

This Field Safety Corrective Action applies **only to the lots listed below** and **does not affect any other Orsiro lots**.

Product Name / Dimension	Material # REF	LOT
Orsiro 2.25/22	364499	08250753
Orsiro 2.25/26	364505	08251529
Orsiro 2.25/40	391238	08251531
Orsiro 2.5/18	364488	08252125
Orsiro 2.5/22	364500	08250167
Orsiro 2.5/26	364506	08250903
Orsiro 2.5/30	364512	08250051
Orsiro 2.5/35	391235	08250156
Orsiro 2.5/40	391239	07253181
		08250896
		08253670
Orsiro 2.75/22	364501	08252127
Orsiro 2.75/26	364507	07255150
		08250154
Orsiro 2.75/30	364513	08250267
		08252106
Orsiro 2.75/35	391236	08250155
		08250283
Orsiro 2.75/40	391240	09250494
Orsiro 3.0/15	364484	08252122
		09250039
Orsiro 3.0/18	364490	09250041
Orsiro 3.0/26	364508	08250265
		08252104
Orsiro 3.0/30	364514	08250052
		08251852
		08252107
Orsiro 3.0/35	391237	09250479
Orsiro 3.0/40	391241	07255128
		08250901
Orsiro 3.5/18	364491	08254413
Orsiro 3.5/22	364503	08251447
		08253660
Orsiro 3.5/26	364509	08251317
		08252105
		09250474
Orsiro 3.5/30	364515	08250053
		08250906
		09250332
Orsiro 3.5/35	391018	08250279
		08252133
Orsiro 3.5/40	391020	08250077
		08252134

Teleflex will inform the appropriate Competent Authorities of this Voluntary Field Safety Corrective Action.

Advice on action to be taken:

According to our records, your organisation has received Orsiro devices from the affected lots. We ask for your cooperation in our efforts to complete this Voluntary Field Safety Corrective Action. Therefore, please follow the instructions outlined below.

1. Discontinue any further use of the affected Orsiro lots.
2. Identify all Orsiro units from the affected lots in your inventory, remove them, place them in a secure location, and label them appropriately.
3. Complete, sign and return the Customer Acknowledgement Form enclosed to this Field Safety Notice.
4. A sales representative will contact you to collect all affected Orsiro units. Please hand over all products and the original signed Customer Acknowledgement Form.
5. Bring this Field Safety Notice to the attention of any health care professional in your organisation that needs to be aware.
6. Patients who were treated with a potentially affected device and who have not experienced an adverse event do not require any additional monitoring outside of standard clinical practice and applicable hospital and regulatory requirements.

Contact for Assistance

If you have further questions or need assistance with this Voluntary Field Safety Corrective Action, please do not hesitate to contact your local sales representative directly or:

Biotronik AG (a Teleflex company)
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E-Mail: vigilancevi@teleflex.com

We apologize for any inconvenience caused and appreciate your cooperation in this matter. We are committed to maintaining your confidence in the quality of our products.

Respectfully,

Marcel Schäfer
Senior Director Regulatory Affairs and Post Market Surveillance

Holger Ritzmann
Person Responsible for Regulatory Compliance