

03.12.2024

Ref: FSN-CAPA-004-2024

URGENT FIELD SAFETY NOTICE (FSN)

Dear Customer,

Translumina GmbH is initiating a FSCA of specific lots Sirolimus Eluting Coronary Stent System manufactured in early 2023 due to the suspicion of potential low drug content observed during internal testing on aged devices.

1. Device information

Device	Sirolimus Eluting Coronary Stent System
Commercial Name	Yukon® Chrome PC Yukon® Choice PC
Model / REF Code	Annex A.11 List of Affected Devices Available for Return or Destroy
Device type	Sterile - Single use
Affected Lots	Annex A.11 List of Affected Devices Available for Return or Destroy

2. Manufacturer information

Manufacturer: Translumina GmbH

Contact Person: Akhilesh Singh

Address: Neue Rottenburger Str. 50, 72379 Hechingen, Germany

Phone: +49-7471 9894 320

Email: akhilesh.singh@translumina.de

3. Reason for FSCA

Translumina GmbH has identified suspicion of lower-than-expected Sirolimus drug content in specific lots during long-term stability testing on aged samples. While the risk is acceptable and the benefit risk remains favorable, we are initiating a Field Safety Corrective Action (FSCA) as a precautionary measure to ensure regulatory compliance.

To date, no incidents/complaints involving the affected devices have been reported.

4. Type of Action(s)

4.1. Action To Be Taken by the User

Identify and quarantine the Device listed in Annex A.11

Return or Destroy available Device

4.2. Customer Confirmation

Confirm receipt of this notification by completing and returning the attached Annex A.04 Customer Confirmation Form within 72 hours of receiving this communication.

5. FSN Type

Ref: FSN-CAPA-004-2024

Type: Field Safety Corrective Action – Recall of the affected devices.

Follow-up: No Follow-up FSN expected

6. Transmission of this Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate

7. Notification to the Competent Authority of your country

The Competent (Regulatory) Authority of your country has been informed about this action.

8. List of annexures

Annex A.11 List of Affected Devices Available to Return or Destroy

Annex A.04 Customer Confirmation

Please note that the devices from lots not listed in Annex R.1 are not affected by this FSCA and can be used without any restrictions.

Please be assured that maintaining a high level of safety and quality is our highest priority.

Thank you for your cooperation in this matter. Should you have any questions or require further information, please feel free to contact us, and we will be happy to assist you.

Sincerely;

Akhilesh Singh
Head of QA & RA / PRRC

Eric Kumpa
Managing Director

RETURN & DESTROY CONFIRMATION

By signing this document, I acknowledge the receipt of this FSN.

I confirm that I have understood this FSN and have informed any organization in my territory to which the potentially affected devices have been transferred.

Person signing the Customer Confirmation;

Name & Position: _____

Date & Signature: _____

Contact Details (Phone/Email): _____

Company Name & address: _____

Return & Destroy Record

Lot#	Warehouse / Hospital	Available device	Device Returned	Device Destroyed

Please add more rows if necessary.

Please return this completed confirmation form to the below email addresses within 72 hours of receipt of this FSN.

Eric.Kumpa@translumina.de (Managing Director, Translumina GmbH)

Akhilesh.Singh@translumina.de (Head of QA & RA / PRRC, Translumina GmbH)

Annex R.1 List of Affected Devices Available to Return or Destroy

Sr#	Lot #	Product	Article#	Qty	Country
1	FA07516	Yukon Chrome PC	T-CMG2518PC	1	Spain
2	FA07586	Yukon Chrome PC	T-CMG2512PC	2	
3	FA07835	Yukon Chrome PC	T-CMG3024PC	1	
4	FA07554	Yukon Chrome PC	T-CMG22516PC	1	
5	FA07728	Yukon Chrome PC	T-CMG22518PC	1	
6	FA07969	Yukon Chrome PC	T-CMG2521PC	1	
7	FA07496	Yukon Chrome PC	T-CMG3512PC	2	
8	FA07831	Yukon Chrome PC	T-CMG2512PC	1	
9	FA07521	Yukon Chrome PC	T-CMG3021PC	1	Lithuania
10	FA07981	Yukon Choice PC	YCPC3524	1	Latvia
11	FA07880	Yukon Choice PC	YCPC2721	1	
12	FA07981	Yukon Choice PC	YCPC3524	1	
13	FA07521	Yukon Chrome PC	T-CMG3021PC	1	
14	FA07539	Yukon Chrome PC	T-CMG4028PC	1	
15	FA07998	Yukon Choice PC	YCPC4016	1	
16	FA07635	Yukon Chrome PC	T-CMG27532PC	2	Hungary
17	FA07660	Yukon Chrome PC	T-CMG27521PC	1	
18	FA07969	Yukon Chrome PC	T-CMG2521PC	1	
19	FA07585	Yukon Chrome PC	T-CMG27524PC	1	
20	FA07634	Yukon Chrome PC	T-CMG3521PC	1	
21	FA07737	Yukon Chrome PC	T-CMG27521PC	1	
22	FA07933	Yukon Chrome PC	T-CMG3528PC	1	
23	FA07471	Yukon Chrome PC	T-CMG27518PC	1	
24	FA07617	Yukon Chrome PC	T-CMG27524PC	1	
25	FA07636	Yukon Chrome PC	T-CMG3018PC	1	Croatia
26	FA07603	Yukon Chrome PC	T-CMG3032PC	1	
27	FA07660	Yukon Chrome PC	T-CMG27521PC	2	
28	FA07835	Yukon Chrome PC	T-CMG3024PC	1	Bulgaria
29	FA07877	Yukon Chrome PC	T-CMG3018PC	1	
30	FA07877	Yukon Chrome PC	T-CMG3018PC	1	
31	FA07585	Yukon Chrome PC	T-CMG27524PC	1	
32	FA07585	Yukon Chrome PC	T-CMG27524PC	1	