03.12.2024

Ref: FSN-CAPA-004-2024

URGENT FIELD SAFETY NOTICE (FSN)

Dear Customer,

Translumina GmbH is initiating a FSCA of specific lots of 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 I 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