Urgent Medical Device Recall

BioMatrix Flex™ and BioMatrix NeoFlex™ Drug Eluting Coronary Stent System (DES)
Field Safety Corrective Action - FSCA/2016/0001

26 February 2016

Attention: Interventional Cardiology Department

Dear Valued Customer,

Biosensors is initiating a voluntary recall on certain units of BioMatrix Flex™ and BioMatrix NeoFlex™ Coronary Drug Eluting Stent System (DES) due to potential balloon burst below the rated burst pressure.

Our records show that your facility has purchased one or more of the devices from the affected lots. Please refer to Appendix I for a list of affected devices by model and lot number.

Background

Biosensors discovered during routine lot release testing that several production lots did not meet the balloon rated burst performance specifications. After full investigation, Biosensors concludes that the compromised balloon performance was caused by certain characteristics in the manufacturing process. Biosensors positively identified production lots manufactured between October to December 2015 that could have been similarly affected.

The compromised balloon performance may potentially lead to delay in inflation or deflation of the balloon; or balloon burst when the balloon is inflated above the nominal pressure. This could result in procedural complications and lead to serious deterioration in the patient's state of health during PCI.

Patients who have already been implanted with an affected device are not impacted by this field safety corrective action. No field complaint or patient injury has been reported associated with the compromised balloon performance.

Required Actions by Users and Distributors

- Please **identify** and **quarantine** any devices in your inventory that appear in Appendix I.
- Please complete the enclosed Field Safety/Corrective Action (FSCA) response form **immediately** and return it by fax to: **+41 21 804 8001** or by email to **fieldsafetynotice@biosensors.com**
- Upon receipt of the completed FSCA response form, a Biosensors representative will contact you to arrange for the return of the affected devices and the provision of replacement devices.

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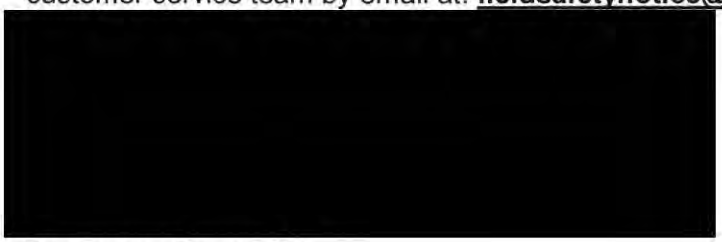
Additional Actions for Distributors

- Provide a copy of this FSN and the FSCA response form to all customers who may have received affected devices.
- Ask these customers to complete the FSCA response form and return it to you.
- Confirm to Biosensors that you have completed the required activity for all of your impacted customers.
- Forward all completed FSCA response forms received from customers to Biosensors at the addresses listed above.

Please provide a copy of this notice to all individuals within your organization, as well as to any third parties with whom you interact, who may have access to or knowledge of affected devices. Please maintain awareness of this Field Safety Notice as appropriate to ensure its effectiveness.

Biosensors has informed and provided a copy of this notice to relevant regulatory agencies.

Biosensors places utmost importance to product quality and safety of our patients. We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. If you have any questions or concerns regarding this recall, please contact your Biosensors representative or our customer service team by email at: **fieldsafetynotice@biosensors.com**.



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APPENDIX I

BioMatrix Flex™ and BioMatrix NeoFlex™ Drug Eluting Coronary Stent System (DES)
FSCA/2016/0001
Field Safety Corrective Action

BioMatrix Flex™ Coronary Drug Eluting Stent System (DES)

Product Reference	Lot Number	Product Description
BMX-3511	K15100009	BioMatrix Flex™ 3.5 mm x 11 mm
BMX-3518	K15100011	BioMatrix Flex™ 3.5 mm x 18 mm
BMX-3518	K15110086	BioMatrix Flex™ 3.5 mm x 18 mm
BMX-3524	K15110054	BioMatrix Flex™ 3.5 mm x 24 mm
BMX-4018	K15100017	BioMatrix Flex™ 4.0 mm x 18 mm
BMX-4018	K15110058	BioMatrix Flex™ 4.0 mm x 18 mm
BMX-4018	K15120029	BioMatrix Flex™ 4.0 mm x 18 mm

BioMatrix NeoFlex™ Coronary Drug Eluting Stent System (DES)

Product Reference	Lot Number	Product Description
BMXP-3511	W15100458	BioMatrix NeoFlex™ 3.5 mm x 11 mm
BMXP-3518	W15100236	BioMatrix NeoFlex™ 3.5 mm x 18 mm
BMXP-3518	W15100237	BioMatrix NeoFlex™ 3.5 mm x 18 mm
BMXP-3518	W15100238	BioMatrix NeoFlex™ 3.5 mm x 18 mm
BMXP-3518	W15110083	BioMatrix NeoFlex™ 3.5 mm x 18 mm
BMXP-4018	W15110086	BioMatrix NeoFlex™ 4.0 mm x 18 mm
BMXP-4024	W15120234	BioMatrix NeoFlex™ 4.0 mm x 24 mm

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Field Safety Corrective Action (FSCA) Response Form

Ref. No.: **FSCA/2016/0001**

Date: **26 February 2016**

Please complete this form even if you do not have any affected product and return by

fax to: **+41 21 804 80 01** or by email to: **fieldsafetynotice@biosensors.com**

I/We acknowledge receipt of the FSCA referenced above and that the information therein has been shared with all recipients/users of the affected devices within our organization, as well as with any third parties to whom we may have transferred any affected devices.

First Name		**Last Name**	
Title/Designation		**Department**	
Organization/ Company		**Email**	
Street Address			
Postal Code		**City**	
Country		**Contact Telephone**	
Signature		**Date**	

☐ We do not have any of the affected devices listed in Appendix I of the Field Safety Notice

☐ We have the following affected devices:

Product Reference	Lot Number	Quantity	Stock Location

Note: Please use separate sheets, if necessary

Upon receipt of this completed form, a Biosensors representative will contact you to arrange the return and replacement of affected devices.

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