BIOSENSORS
INTERNATIONAL

Urgent Field Safety Notice
FSCA/2015/0002 - Update
Chroma™ Coronary Bare Metal Stent (BMS) System
Advice given by the manufacturer regarding the use of the device

April 21, 2015

Attention: Interventional Cardiology Department

Dear Doctor,

The purpose of this communication is to inform you that you may have specific Chroma units with a minor labeling error. There is no impact to product quality. This is not a product removal or request for you to return it.

Affected Devices:
- Chroma™ Coronary Bare Metal Stent (BMS) System.
- Please refer to Appendix I of FSN for a list of the affected devices by reference number and lot number.

Overview:
The Chroma device is compatible with 5 French (Fr) guiding catheter. On a number of isolated manufacturing lots, the label incorrectly states the minimum Guiding Catheter ID compatibility to be 1.24 mm. The correct dimension is 1.42 mm. This reference dimension (in metrics) is provided along with 0.056 inches and 5 Fr. All three dimensions are stated on the label.
Pursuant to this FSCA, all affected lots will be relabeled with the corrected label. The label has been corrected so the next delivery of product will have corrected labels.

Problem Description:
Biosensors internally discovered the labeling error on a number of lots manufactured in 2015. On the product label of affected lots, the minimum Guiding Catheter ID metric is incorrectly stated as 1.24 mm. The correct dimension is 1.42 mm which is equivalent to 0.056 inches or 5 French. The safety and efficacy of the product are not impacted by this minor error. Patients who have already been successfully treated are not impacted by this action.

Required Actions by Users:
- Read the Field Safety Notice carefully.
- Pass this notice to anyone in your facility who needs to be informed including appropriate clinical personnel involved in the use of the Chroma device.
- Identify any affected devices in your possession and review, complete, sign and return 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** or to your **distributor contact.**
- Upon receipt of the completed FSCA response form, a Biosensors representative will contact you to arrange the relabeling of identified units.
- If you have any questions or concerns, please contact your Biosensors representative, or contact our customer service team by email at: **fieldsafetynotice@biosensors.com**

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Required Actions for Distributors:

- Read the Field Safety Notice carefully.
- Please identify any affected devices in your possession and review, complete, sign and return 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**.
- Pass on this notice to all customers who may have received affected devices.
- Upon receipt of the completed FSCA response forms, a Biosensors representative will contact you to arrange the corrective action: relabeling.
- If you have any questions or concerns, please contact your Biosensors representative, or contact our customer service team by email at: **fieldsafetynotice@biosensors.com.**
- Ask your customers to perform the "Required Action by Users" as mentioned in the respective above section and return immediately the FSCA response form completed and any unused affected devices to you.
- Forward all completed FSCA response forms received from customers to Biosensors at the addresses listed above.

Transmission of this Field Safety Notice:
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.

Contact Reference Person:
Alex Budiman, VP Regulatory Affairs & Quality Assurance at **fieldsafetynotice@biosensors.com**.

The undersigned confirms that Biosensors has provided a copy of this FSN to its Notified Body and to the relevant Competent Authorities as required by law.

We regret the inconvenience that this error may have caused you. Biosensors takes pride in the quality of its products and is committed to excellence. This event will result in strengthening our processes and systems to ensure it is not repeated. Thank you for your understanding, support and cooperation.

Alex Budiman [redacted]

VP Regulatory Affairs & Quality Assurance [redacted]
Biosensors International Group

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APPENDIX I. List of the affected devices by reference number and lot number.

- **Chroma™ Coronary Bare Metal Stent (BMS) System**
- **FSCA/2015/0002 - Update**

LOT	REF
W15010094	BCR-2733
W15010095	BCR-2736
W15010096	BCR-3036
W15010097	BCR-2214
W15010213	BCR-3033
W15010236J	
W15030147	BCR-2514
W15030148	BCR-2724
W15030149	BCR-3029
W15030150	BCR-2709
W15030151	BCR-3509
W15030152	BCR-3519
W15030153	BCR-4014
W15030154	BCR-4024
W15030155	BCR-3014
W15030157	BCR-3019
W15030159	BCR-3524
W15030160	BCR-3514

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Field Safety Corrective Action (FSCA) Response Form

Ref. No.: **FSCA/2015/0002 - Update**
Date: **21 April 2015**

Affected Devices

- Chroma™ Coronary Bare Metal Stent (BMS) System
- Please refer to Appendix I of FSN for a list of the affected devices by reference number and lot number.

Please complete this form even if you do not have any remaining affected product in your inventory 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 mentioned in this Field Safety Notice,

- ☐ since used already
- ☐ since distributed to another parties

☐ We have the following affected devices:

Product Reference	Lot No.	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 corrective action: relabeling.

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