URGENT FIELD SAFETY NOTICE

September 8, 2015

Surgeon Name
Facility Name
Address
Country

RE: Voluntary Recall of Specific Serial Numbers of ConforMIS Knee Replacement Systems

Dear Surgeon Name,

ConforMIS has initiated a voluntary recall of specifically identified serial numbers of patient specific knee replacement systems. We initiated this action in response to three recent complaints of moisture on the patient-specific instrumentation. In all three cases, the knee replacement procedures were completed without apparent incident. The Company does not believe that the customized knee implants used in these procedures were themselves affected. While the number of complaints the Company has received is small, and the Company has not received any reports of adverse events related to these complaints to date, the Company initiated this recall voluntarily and is working to resolve the complaints quickly.

Based on an initial assessment, ConforMIS believes that the recalled instrumentation held excess water before undergoing the commonly used ethylene oxide sterilization process and, as a result, may contain small amounts of ethylene glycol residue. Ethylene glycol residue may form when ethylene oxide comes into contact with water. ConforMIS has temporarily suspended its use of the ethylene oxide sterilization process and is working expeditiously to investigate the root cause of the excess moisture and evaluate potential corrective and preventative actions.

The part number, description, serial number, and patient name of units impacted by the voluntary recall are listed below. If any of these kits were not implanted in patients, they must be returned to your ConforMIS representative immediately.

Part Number	Description	Serial Number	Patient Name

As part of our investigation, an independent testing laboratory has determined that no ethylene glycol residue was present on implants tested following sterilization using ethylene oxide. In addition, the independent testing laboratory has determined the risk of ethylene glycol induced toxicity from exposure to the instruments is low, because, in part, ethylene glycol does not represent a practical health hazard from exposure to medical devices for exposures less than 24 hours in duration. Based on the test results to this point, ConforMIS believes no additional monitoring of patients is necessary related to this recall.

Please fill out **Attachment A**, acknowledging receipt of this letter and confirming the status of the affected units. We have notified the appropriate regulatory agencies and will be providing them with surveillance documentation regarding the effectiveness of the recall communication.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions about this notice, please contact your local ConforMIS representative or myself, [redacted], at 001-781-345-[redacted]

Sincerely,

[redacted]
Senior Vice President, Quality and Regulatory Affairs
ConforMIS, Inc.

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ATTACHMENT A – CONFIRMATION OF LETTER RECEIPT & STATUS

Please fill out and return completed form to the ConforMIS Representative or Fax to 001-781-345-0147

ConforMIS has provided and I have read the recall notification informing me of the recall of specific serial numbers. The part number, description, serial number, and patient name for affected units are listed below. If any of these kits were not implanted in patients, they must be returned to your ConforMIS representative immediately. Regarding patients implanted using the recalled product, based on the test results to this point, ConforMIS believes no additional monitoring of patients is necessary related to this recall.

Part Number	Description	Serial Number	Patient Name	Status
				☐ Returned to ConforMIS Representative ☐ Previously Implanted on _____

Surgeon Name: Surgeon Name

Office Address: Facility Name
Address
Country

Surgeon Signature: _____ Date: _____