Tel: +1 (519) 884-5142
Fax: +1 (519) 884-5184
Toll Free: +1 (877) 634-6340
Global: +(800) 634-634-00

Urgent Field Safety Notice

Supplemental Device Communication

concerning

NDI Disposable Reflective Marker Spheres

Date: July 10, 2015

Attention: Hospital Management/Risk Manager, Product users

This notification is to inform you of an urgent voluntary medical device Field Safety Corrective Action (FSCA) involving the lot numbers, as stated below, of NDI Disposable Reflective Marker Spheres.

Products Affected:

41773 Disposable Reflective Marker Spheres (90 pcs)
41774 Disposable Reflective Marker Spheres (270 pcs)
41813 Disposable Reflective Marker Spheres (60 pcs)

Lots Affected:

C100111502	C101611501	C102811401	C103821501	C105151401	C107561301	C109011402
C100161401	C101611503	C102811402	C103881401	C105541401	C107761401	C109171301
C100611401	C101791401	C103091401	C104121401	C106061301	C108121301	C109251401
C100641501	C102061501	C103091402	C104361301	C106521401	C108191401	C109621401
C100641502	C102481501	C103221501	C104401401	C106861401	C108191402	C109621402
C101021501	C102581401	C103271401	C104401402	C106861402	C108471401	C110091401
C101351501	C102581402	C103271402	C104761401	C107371401	C108721401	C110411402
C101561401	C102801501	C103461501	C105071401	C107371402	C109011401	C110721401

Description of the problem:
NDI has determined there is a risk that Disposable Reflective Marker Spheres from these lots may separate at the mid-point where the two halves of the sphere are sealed together. Such separation could occur either during installation onto reference arrays or surgical tools (i.e., when threading them onto posts) or at any time during a surgical procedure. This is due to inadequate curing of the adhesive that joins to two halves of the sphere. The root cause of this failure has been identified as a manufacturing issue in which a piece of the fabric material remained in the path of the UV/Visible light used to cure the adhesive.

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The potential separation into two hemispheres may not be recognized prior to use in a surgical procedure as it will likely only be recognized upon partial or complete separation of the sphere halves. Separation may occur during installation of the spheres onto surgical tools or potentially after installation on tools that are impacted with high forces.

To date, there have been 5 complaints none of which resulted in injury to a patient. All reported failures occurred in North America.

We have established an additional inspection in production to prevent recurrence of this failure.

Risks
The following risks have been identified associated with this failure:

(1) Prolongation of surgery due to the need to replace the broken sphere. We do not expect this would result in a significant increase in surgical time. We expect the probability of harm to be remote.

(2) Potential patient risk should a portion of the sphere come into contact with the patient tissues. Based on the evaluation by an independent clinical expert, however, the probability of this risk is remote.

(3) Contamination of a surgical trays, surgical drapes, or physicians' gloves due to contact by the separated component. The product is sterilized by Ethylene Oxide that has been validated but there is the potential of bioburden inside the sphere post sterilization but we expect the probability of harm to be remote.

Advise on action to be taken by the user:
To reduce the risk to your patients, you should take the following steps prior to each procedure using NDI DRMS spheres for IGS systems.

1. Ensure that only marker spheres which are not damaged or deformed are screwed and tightened onto the post. Upon tightening, inspect again to determine whether any separation between the two halves is evident. If separation is evident, remove and discard the affected sphere. Replace your surgical gloves, and then replace the separated sphere with a new sphere, inspecting it as above. Clean surgical trays or drapes in case they were contaminated. If no separation is evident, proceed with the clinical procedure.

Caution:	Do not affix the sphere to the tool over the surgical area to minimize the risk of a sphere, or any portion thereof, falling onto the patient or into the surgical wound.

2. Communicate this notice to all personnel that are involved with Surgical Navigation procedures to make them aware of the issue.

3. Ensure the Warnings and Cautions specified in the Instructions for Use are followed.

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4. Complete and return the acknowledgement form to Sales Support by email to spheres-eu@ndigital.com or by fax to +49 (77 32) 82 34-199.

5. Should you have any questions with this Field Safety Notice, please do not hesitate to contact Sales Support, identified as the Contact Reference Person below.

As soon as the supply of additionally inspected marker spheres is guaranteed, NDI is starting to replace the affected lots by new additionally inspected lots. This may happen the earliest starting week 33. Please observe this FSCA until the affected lots are replaced.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

We have established an additional inspection in production to prevent recurrence of this failure. NDI is committed to providing high quality, safe and effective products. We apologize for any inconvenience this action may have caused.

Contact reference person:
Should you require any further information or support concerning this issue, please contact:

NDI Europe GmbH
Attn. Artorn Ruksayot
Guttinger Str. 37,
78315 Radolfzell, Germany
(t) +49 (77 32) 82 34 Ext. 123
(e) spheres-eu@ndigital.com.

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

i.A. Michael Boosz
Manager Quality Assurance & Regulatory Affairs

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FSCA Acknowledgment Form

NDI Disposable Reflective Marker Spheres

Please return the completed acknowledgement form immediately to:
Email: spheres-eu@ndigital.com or Fax +49 (77 32) 82 34-199.

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1) I have reviewed and understand this Field Safety Notice.
2) I have forwarded this Field Safety Notice to the appropriate personnel.

[*Please select one of the following*]

☐ We have located DRMS spheres from one or more of the affected lots in our inventory:
[*please enter number of boxes or blister packs*] _____

☐ We don't have any DRMS spheres from one or more of the affected lots in inventory.

Business name and address:
Telefon:
Email:
Printed name:
Date and Signature: