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Urgent Field Safety Notice
NDI Disposable Reflective Marker Spheres (DRMS)
Date: June 25 2015
Supplemental Device Communication

Attention: Hospital Risk Manager

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: All lots with a manufacturing date of 2015-06 or earlier with the exception of the following lot numbers:

C105091502
C105531501
C105731501

Lots with a manufacturing date of 2015-07 or later, including the following lots from 2015-06, are not affected:

C105091502
C105531501
C105731501

See Figures 1 and 2 to locate the lot number and manufacturing date on the product.

Description of the problem:

NDI has determined there is a risk that DRMS 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. To date, there have been no reported patient injuries associated with this issue.

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. Potential separation may be detected in some spheres during a pre-procedure visual inspection of the spheres both before and after the spheres are threaded onto the reference tool.

Risks

The following risks have been identified associated with this failure:

- (1) There is a possibility that a portion of the sphere, its reflective coating, or cured or uncured adhesive could contact patient tissues. The sphere, coating, and adhesive are not intended to be patient-contacting so there is a possibility of patient injury if the sphere, coating, or adhesive come into contact with patient tissues, particularly in the case of long-term contact; and



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- (2) The inside of sphere may contact and contaminate surgical trays, surgical drapes, or physicians' gloves.

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.

- Prior to opening the package containing the spheres, visually inspect the spheres in the blister pack for any signs of separation between the two halves of the sphere. If there is any indication that the spheres may have separated, use a different sphere for the procedure and repeat this step with the new sphere. Discard any and all affected spheres and contact NDI who will refund the cost of the blister pack. If there is no visual sign of sphere separation, proceed to the next step.
- Prior to the start of the procedure, screw each DRMS sphere to the tool and tighten. 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, then replace the separated sphere with a new sphere, inspecting it as above. Contact NDI who will refund the cost of the blister pack. If no separation is evident, proceed with the clinical procedure.
 - o Be sure to discard and replace your surgical gloves any time that a sphere with evident separation is found upon affixing the sphere to the tool.

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.

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.

Contact reference person:

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 undersign confirms that this notice has been notified the appropriate Regulatory Agency

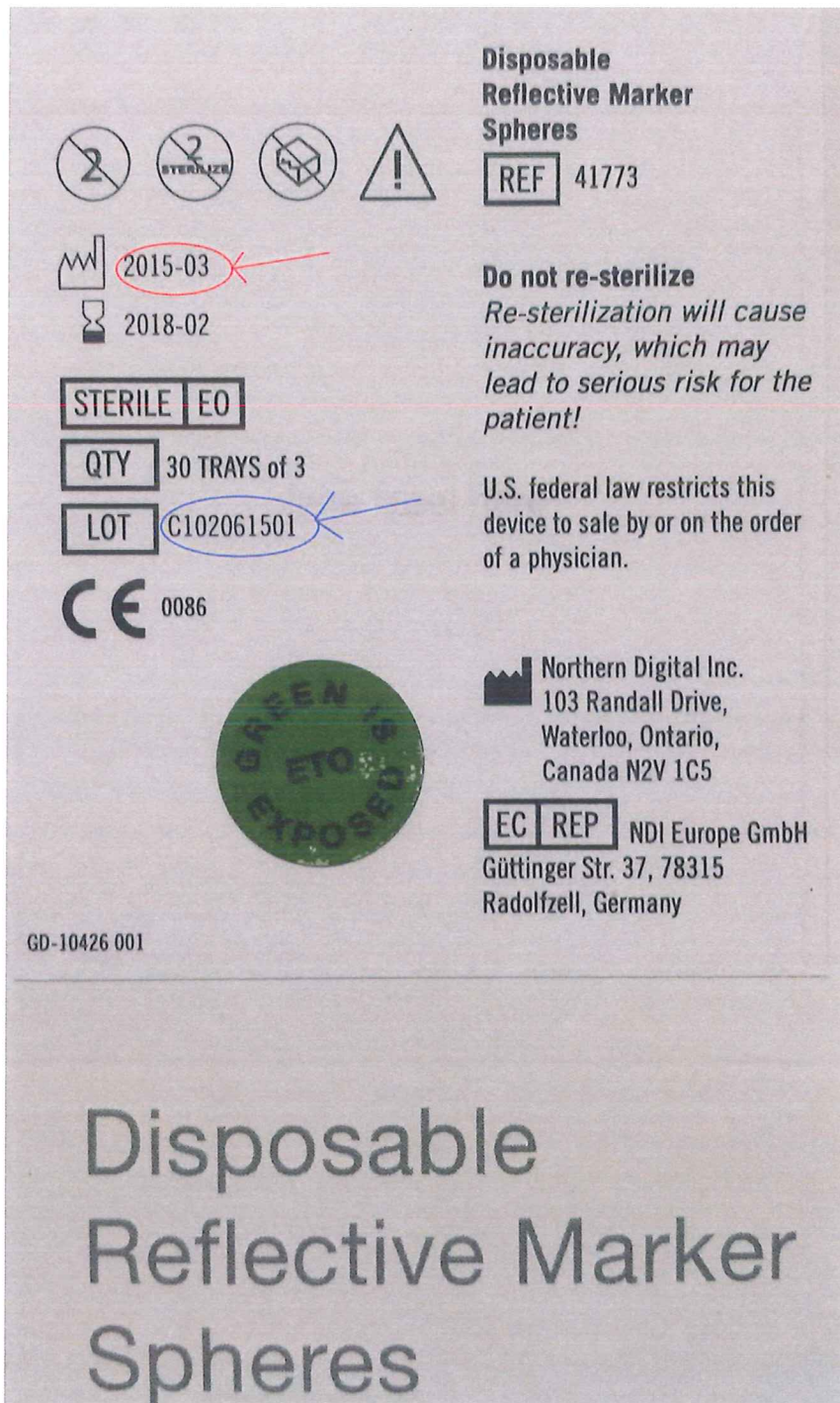
A handwritten signature in blue ink that reads "i.A. Michael Boosz".

Michael Boosz
Manager Quality Assurance and Regulatory Affairs



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Figure 1 – Picture of side of the DRMS box showing the location of the Manufactured Date (in red) and the Lot Number (in blue) on the label.





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Figure 2 – Picture of label on the DRMS blister pack showing the location of the Manufactured Date (in red) and the Lot Number (in blue) on the label.

