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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	Disposable Reflective Marker Spheres (DRMS) for Brainlab Image Guided Surgery (IGS) Systems: DRMS spheres may separate at the mid-point where the two halves of the sphere are sealed together.
Product Reference:	41773G Disposable Reflective Marker Sphere (90 Pcs.) 41774G Disposable Reflective Marker Sphere (270 Pcs.) 41772G Disposable Reflective Marker Sphere (3 Pcs)
Date of Notification:	July 23, 2015
Individual Notifying:	Markus Hofmann, Senior MDR & Vigilance Manager
Brainlab Identifier:	**CAPA-20150722-001452**
Type of action:	Advice regarding use of device.

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We are writing to advise you that Northern Digital, Incorporated (NDI), the supplier for Disposable Reflective Marker Spheres (DRMS) for Brainlab Image Guided Surgery (IGS) systems, has determined an issue with DRMS spheres. Specifically, some DRMS spheres may separate at the mid-point where the two halves of the sphere are sealed together. Separation may occur during installation of the spheres onto reference arrays or surgical tools (i.e., when threading them onto posts), or potentially after installation on tools that are impacted with high forces.

There have been no reported negative effects on any patient associated with this issue.

NDI has identified this failure as an intermittent manufacturing issue for a very low percentage of single spheres. For these spheres, the adhesive holding the two halves together was not adequately cured.

DRMS spheres supplied by NDI are also labelled and distributed by Brainlab, for example as initial stocking with new IGS system shipments (41773G and 41774G, being boxes containing 30 or 90 blister packs of 3 spheres labelled as Article 41772G). For this subgroup of DRMS spheres labelled and distributed by Brainlab, there has been no occurrence of this issue reported to Brainlab to date.

For identification of the Brainlab articles and affected lots, please refer to the Appendix.

Please do not return the product, but address this potential issue with the precautions as outlined below.

Effect:

Less than 0.5% of all DRMS spheres are expected to be subject to this issue. Additionally, despite the majority of potentially affected Brainlab DRMS lots already used, there has been no occurrence of this issue for a sphere labelled and distributed by Brainlab reported by any user site.

Separation of an affected sphere should become visible at the latest upon mounting and tightening the sphere on the tool. However, if initiation of sphere separation is not detected during that step, full separation could occur later, especially when used on tools that are impacted with high forces. Should such a DRMS separate during a surgical procedure, there is a possibility for:

(1) A portion of the sphere, its reflective coating and cured or uncured adhesive contacting patient tissues. The sphere, coating, and adhesive are not intended to be patient-contacting, particularly in the unlikely case of long-term contact through open wounds.

(2) Contamination of surgical trays, surgical drapes, surgical tools or physicians' gloves due to contact with the separated component. Despite the fact that the product is sterilized by Ethylene Oxide with a validated process, there is a potential of remaining bioburden inside the sphere after sterilization.

(3) Prolongation of surgery due to the need to replace the broken sphere. Such replacement is expected to be quick and not to result in any significant increase in surgical time.

The resulting separated sphere halves will not continue to be tracked by the Brainlab Image Guided Surgery system.

In the unlikely case that retrieval from an open wound or contamination would need to be addressed, the abovementioned potential effects could ultimately **result in or contribute to delays in the surgical procedure or even serious patient injury.**

User Corrective Action:

To mitigate the potential effects, you should take the following steps prior to each procedure using Brainlab DRMS spheres for Brainlab 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 blister pack for the procedure and repeat this step with the new pack. Discard any and all affected spheres and inform your Brainlab support representative about the occurrence of the issue. 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 onto 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. If no separation is evident, proceed with the clinical procedure.
    - 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, and every time after a separated sphere was touched.

- 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. Also avoid affixing the sphere over other sterile areas (such as surgical trays) to minimize potential contamination in case of sphere separation.

- Reminder: In general, do not use defective or deformed marker spheres (refer also to the Brainlab Instrument User Guides).

- Reminder: If you use reflective marker spheres on, or in the vicinity of oscillating or vibrating instruments, or when hammering instruments, check the marker spheres at regular intervals to ensure that they are securely attached (refer also to the Brainlab Instrument User Guides).

Disposable Reflective Marker Spheres (DRMS) enable the system to detect the position of the patient and instruments in the surgical field. Brainlab has not validated any marker spheres other than DRMS manufactured by Brainlab or NDI in conjunction with Brainlab IGS systems, and therefore Brainlab is not in a position to determine the accuracy, compatibility or safety of any other marker spheres.

Brainlab Corrective Action:

1. Brainlab provides existing potentially affected customers with this product notification information.
2. 100% testing has been implemented at the manufacturing site of NDI to address this issue for future lots.

Please advise the appropriate personnel working in your department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation.

If you require further clarification, please feel free to contact your local Brainlab Customer Support Representative.

Customer Hotline: +49 89 99 15 68 44 or +1 800 597 5911 (for US customers) or by

E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)

Fax Brainlab AG: + 49 89 99 15 68 33
Address: Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

July 23, 2015

Kind Regards,

Markus Hofmann
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Europe: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.

Appendix

Product identification:

www.brainlab.com

Figure 1: Example of label on the back of the Brainlab DRMS blister pack (Art.No. 41772G, 3 pcs of DRMS spheres)

Figure 2: Example of label on the side of the Brainlab dispenser box Art.No.41773G (containing 30 packs of Art.No. 41772G)

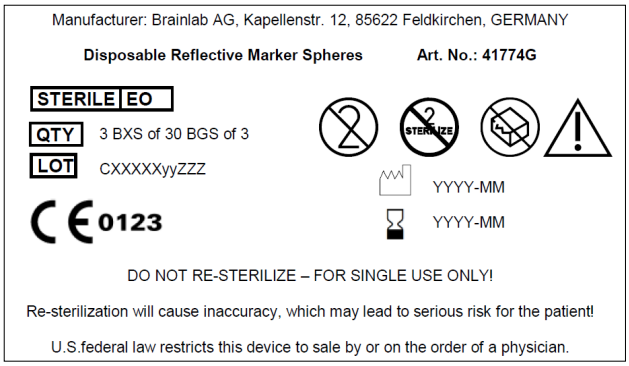

Figure 3: Example of label on Art.No. 41774G (pack of 3 boxes of the Brainlab Dispenser box)

List of affected lot numbers of Brainlab DRMS (Lot number is printed on product labels):

Lot numbers		
1014213001	C103461502	C107761402
C100111501	C1034813001	C108341301
C101021502	C103881402	C108721402
C101161401	C104761402	C109051301
C101611502	C105541402	C109251402
C102311401	C106521402	C1098312001
C102481502	C106721301	C110411401