

## URGENT FIELD SAFETY NOTICE

21-SEP-2015

**TO: All user sites that received TheraSphere® Y-90 Glass Microspheres, Lot #1599211**

**SUBJECT: Potential mislabelling of TheraSphere® Y-90 Glass Microspheres**

| Product Name                         | Lot No  | Manufacturing Date | Calibration Date | Expiry Date |
|--------------------------------------|---------|--------------------|------------------|-------------|
| TheraSphere® Y-90 Glass Microspheres | 1599211 | 03-SEP-2015        | 06-SEP-2015      | 18-SEP-2015 |

Biocompatibles UK Ltd. (BTG) has recently become aware, via a customer complaint, of the mislabelling of one dose vial of TheraSphere® Y-90 Glass Microspheres Lot 1599211 that was distributed in Hong Kong. The TheraSphere® vial was labelled 10 GBq and the actual dose was 5 GBq (total radioactivity was incorrect). Preliminary investigation to date has shown that the mislabeling of the vials is most likely limited to this one customer complaint and one other vial that was dispensed within the same lot, Lot 1599211, and which is still within the control of BTG.

BTG has taken immediate action in contacting potentially impacted customers by telephone and this Field Safety Notice provides the written details and actions to be taken in relation to Lot 1599211.

Due to the short shelf-life of the product, we understand that dose vials from this lot have already been administered. Preliminary investigation to date has shown that all other dose vials measured in the field were appropriately labelled therefore, we are confident that the two mislabeled vials to be isolated incidents.

A mislabeled dose vial may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notice and the recommended actions.**

### Potential Safety Issue

Mislabelling of the TheraSphere Yttrium 90 Glass Microspheres may result in under- or over-dosing of the patient resulting in the patient not receiving their prescribed dose. Under-dosing could result in lack of efficacy, and over-dosing could result in non-target tissue radiation.

### Safety Instructions

1. If you have administered the dose from Lot 1599211 and verified the accuracy of your dose measurement, with the dose therefore being consistent with what was intended, no action is required on your part.



2. If you have administered the dose from Lot 1599211 and did not verify the accuracy of the dose prior to administration, be aware that the patient may have been either under-dosed or over-dosed. Since we believe that this is an isolated incident, we believe under-dosing or over-dosing events are unlikely. Nonetheless, it is prudent to be aware of these possibilities so that appropriate action can be taken.

**Continued Use of  
TheraSphere**

Continue to measure all TheraSphere Y-90 Glass Microsphere doses prior to administration. This recommendation is consistent with the TheraSphere training and reference material that BTG provides to each of our customers.

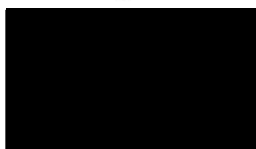
**Regulatory  
Authorities**

BTG/Distributor will inform all applicable regulatory authorities.

Please address all questions to Susan Efler, Quality Director, North America (email: [susan.efler@btgplc.com](mailto:susan.efler@btgplc.com); Phone 613 410 1870; fax: 613 701-4086).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Kind regards,



Paul Sharp  
Director, Group Quality Operations

Please acknowledge receipt of this notice by signing below and returning to Susan Efler, Quality Director, North America (email: [susan.efler@btgplc.com](mailto:susan.efler@btgplc.com); fax: 613 701-4086).

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I, \_\_\_\_\_, have read and understand the Field Safety Notice concerning the potential mislabelling of TheraSphere® Y-90 Glass Microspheres.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date