Biocompatibles UK Ltd
Chapman House
Farnham Business Park
Weydon Lane
Farnham
Surrey GU9 8QL
UK

T. +44 (0)1252 732 732
F. +44 (0)1252 732 777
E. info@btgplc.com
btgplc.com

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 [redacted] Quality Director, North America (email: [redacted]@btgplc.com ; Phone [redacted] fax: [redacted]).

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,

[redacted]

Director, Group Quality Operations

Please acknowledge receipt of this notice by signing below and returning to [redacted] Quality Director, North America (email: [redacted]@btgplc.com; fax: [redacted]).

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

_____ _____

Signature Date