



June 13, 2007

Ms. Pamela Henderson  
Chief  
Medical Branch  
Division of Nuclear Materials Safety  
Region 1  
U.S. Nuclear Regulatory Commission  
475 Allendale Road  
King of Prussia, PA  
19406-1415  
United States

**RE: User Bulletin #TS-2007-1  
Users of TheraSphere®**

Dear Ms. Henderson:

I am writing to inform the U.S. Nuclear Regulatory Commission that at the beginning of May 2007, MDS Nordion distributed the attached User Bulletin #TS-2007-1 to the users of TheraSphere® in the United States. The User Bulletin #TS-2007-1 serves as a reminder to the users to drape sterile towels under the blue stopcock and the catheter connections in the event that leaking is observed.

If you have any questions or require further information please feel free to contact me by telephone at (613) 592-3400 extension 2421 or by email at [mcharette@mds.nordion.com](mailto:mcharette@mds.nordion.com).

Yours sincerely,

A handwritten signature in black ink that reads "Marc-André Charette".

Marc-André Charette  
International Transport & Nuclear Initiatives  
Manager, Regulatory Affairs

Attached: User Bulletin #TS-2007-1

Copy: B. Houghton, MDS Nordion

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REGION 1



**TS-2007-1**

## **USER BULLETIN**

April 30, 2007

**TO: Users of TheraSphere®**

**SUBJECT: Observed Leakage of Administration Set – Outlet Set**

During TheraSphere® administration, there have been reports (~1%) of fluid leaking from the blue stopcock of the Administration Set. These small leaks constituting radioactive contamination on draping material, have been observed at the luer lock fitting connecting the blue stopcock to the outlet line.

**RECOMMENDED USER ACTION:**

The TheraSphere® training program provided to all users recommends that a sterile towel be draped under the blue stopcock and the catheter connections in the event that leaking is observed. The initial infusion pressure as recommended in the Package Insert should be maintained during the first few flushes.

**UNITS AFFECTED:**

The expiry date of the affected units is January 31, 2008 and April 30, 2009.

**MDS NORDION CORRECTIVE ACTION:**

MDS Nordion is completing the design of a new administration set for introduction in 2008.

**FOR FURTHER INFORMATION:**

Customers in North America may contact MDS Nordion Customer Service at 1-866-363-3330. Customers outside North America may call 1-877-474-5999 and request Customer Service. Customers may also email MDS Nordion at [TheraSphere@mdsinc.com](mailto:TheraSphere@mdsinc.com).

**Please complete the attached confirmation indicating that you have received this User Bulletin. MDS Nordion will contact those institutions who do not return this confirmation. Thank you for your cooperation.**