

July 29, 2011

US Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Response to the Apparent Violation in Inspection Report No. 03002006/2011001 (DNMS); EA-11-163

- 1) Reason for apparent violation – As stated in the NRC Executive Summary, page 2, Enclosure, "...failure to recognize the potential for the microcatheter to become blocked as a result of such a high concentrate and an inability to add enough water to suspend the microspheres in a dilute enough concentration to permit flow of the microspheres through the microcatheter."
- 2) Corrective steps taken and the results achieved – As stated in the NRC Report Details, pages 6 - 7, Licensee Corrective Actions, Enclosure.
- 3) Corrective steps that will be taken to avoid further violations - As stated in the NRC Report Details, pages 6 - 7, Licensee Corrective Actions, Enclosure.
- 4) Date full compliance was achieved – June 27, 2011


Please note that an error was made in the licensee's written reports dated May 9, 2011 and June 13, 2011. The authorized user utilized a 2.7 french (Fr) microcatheter instead of a 2.8 french (Fr). Please see the attachment for the manufacturer's specifications (Terumo Progreat Microcatheter 2.7 Fr).

Please call me at 248-551-0538 if you have any questions.

Sincerely,



Cheryl Culver Schultz, M.S.
Corporate Radiation Safety Officer
Beaumont Health System



Kay Beauregard, R.N., M.S.A.
Vice President
Beaumont Hospital Royal Oak




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Each system includes one Progreat Microcatheter, one Glidewire® GT 0.021" core guidewire, one wire stopper, one guidewire introducer, one hemostatic valve, one 2.5 mL syringe and one shaping mandrel

Product Code	Total Length (cm)	Outer Distal		Diameter Proximal		Inner Diameter	
		(Fr)	(mm)	(Fr)	(mm)	(in)	(mm)
MC*PE27111Y	110	2.7	0.90	2.9	0.97	0.025	0.65
MC*PE27131Y	130	2.7	0.90	2.9	0.97	0.025	0.65

Product Code	Flexible Tip (cm)	Max GW (in)	Max Pressure (psi)	Coating Length (cm)	Flow Rate† (mL/sec)
MC*PE27111Y	17	0.021	750	50	3.5
MC*PE27131Y	17	0.021	750	70	3.2

† Flow rates taken at 750 psi and 37°C using Isovue 300

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Royal Oak

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