

Amersham
Health

Amersham Health
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February 7, 2003

Leonard Shabason, Ph.D.
Radiation Oncology
Pennsylvania Hospital
800 Spruce Street
Philadelphia, PA 19107

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**RE: EchoSeed™ Model 6733
Product Complaint No. 0301019**

Dear Dr. Shabason:

Thank you for advising us of your experience with EchoSeed. Lot# M20115A. As a manufacturer, we record and consider each of these reports carefully. This letter provides you with the findings of Amersham Health's investigation into your complaint which I discussed with you during our conversation on January 30, 2003.

Amersham Health manufactures all of our products according to the Food and Drug Administration (FDA) current good manufacturing practices. In addition, all of our products meet stringent internal process control criteria to assure the strength, quality and purity meet internal and FDA specifications.

On January 13, 2003, you reported that one out of 110 seeds ordered at 0.489mCi median calibrated for 10-Jan-03 had broken apart in the Mick Cartridge while being implanted into a patient using the Mick Loader. You stated that the seed fragment was ejected from the Mick Cartridge after removing it, with great difficulty, from the applicator during the implant. A fragment of the seed was recovered which consisted of approximately 20-30% of the titanium shell. The remainder of the shell and wire are assumed to have been implanted since they could not be located after carefully surveying the area. This information was provided to our Quality Assurance Department for investigation and arrangements were made to return this seed fragment for investigation.

You reported that the patient was started on a blocking dose of Lugol's solution after the implant. No detectable radiation was noted in the patient's urine or thyroid on 14-Jan-03. You notified the NRC of this incident on 15-Jan-03.

Amersham Health's Engineering, Manufacturing and Quality Assurance departments received the returned fragment and cartridges. They imaged the fragment, checked the cartridges for damage and attempted to recreate the fracture by using inactive EchoSeed Model 6733 seeds, the Mick 200-TP Applicator and the plastic Mick Cartridge. The returned fragment, based on appearance, was confirmed to have broken off the 6733 seed at one of its ends. There was no visible damage to any of the returned cartridges. Ejecting inactive 6733 seeds using the Mick Applicator, as intended, did not damage or affect the seed in any way. In an attempt to damage or shear the seeds, the stylet in the applicator was gently pushed down as if to eject the seed. With the seed slightly protruding out of the exit hole, and not completely ejected, the cartridge was forcibly removed from the applicator. In most cases, the cartridge magazine tended to snap off without causing any damage to the seed. In three cases, damage to the seed did occur. In two of those cases, the seed actually broke and compared reasonably well to the returned fragment.

The investigation also involved the Amersham Health Radiopharmacy, Bensalem, PA where the seeds were loaded into disposable cartridges. One hundred seeds from the order were loaded into disposable cartridges (10 seeds per cartridge) using reverse action tweezers without incident on 07-Jan-03.

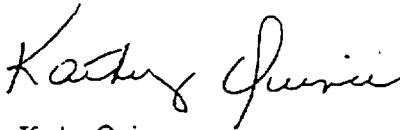
In addition, 10 loose seeds were sent in a vial to be assayed and loaded at your facility. No loose seeds or contamination were found during the surveys performed on the equipment and the hood prior to or at the completion of the loading process. The loading pharmacist stated that there were no abnormalities with the seeds and no irregularities during the loading procedure. The loaded cartridges were inspected to insure that the correct number of seeds were loaded and correctly placed (horizontally) into the cartridge.

Based on these findings, there is no evidence that the seed was damaged prior to loading it into a cartridge or that the seeds were loaded improperly into the cartridges. The integrity of the 6733 seed was established during Design Control which looks at vibration, puncture, temperature, pressure, and impact to the seed. Although EchoSeed has a high structural integrity, it is possible through rough handling, exposure to excessive temperatures or crushing to damage or rupture a seed.

A summary of our investigation has been provided to the NRC.

We appreciate your assistance with our investigation into this matter. We hope that this will address your concerns, and regret that you have had an unfavorable experience with EchoSeed. We hope that you will continue to use Amersham Health products in the future and that you will contact us at 800-654-0118, option #2, #3 if you need further assistance.

Sincerely,



Kathy Quince
Manager, Medical & Professional Services