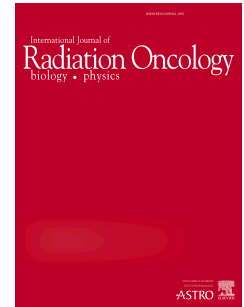


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Medical Device Recalls in Radiation Oncology: Analysis of U.S. Food and Drug Administration Data, 2002-2015

Michael J. Connor, BS, Kathryn Tringale, BS, Vitali Moiseenko, PhD, Deborah C. Marshall, MD, Kevin Moore, PhD, Laura Cervino, PhD, Todd Atwood, PhD, Derek Brown, PhD, Arno J. Mundt, MD, Todd Pawlicki, PhD, Abram Recht, MD, Jona A. Hattangadi-Gluth, MD



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## Medical Device Recalls in Radiation Oncology: Analysis of U.S. Food and Drug Administration Data, 2002-2015

**Short title:** Device recalls in radiation oncology

Michael J. Connor, BS<sup>\*†</sup>; Kathryn Tringale, BS<sup>\*</sup>; Vitali Moiseenko, PhD<sup>\*</sup>; Deborah C. Marshall, MD<sup>\*</sup>; Kevin Moore, PhD<sup>\*</sup>; Laura Cervino, PhD<sup>\*</sup>; Todd Atwood, PhD<sup>\*</sup>; Derek Brown, PhD<sup>\*</sup>; Arno J. Mundt, MD<sup>\*</sup>; Todd Pawlicki, PhD<sup>\*</sup>; Abram Recht, MD<sup>‡</sup>; Jona A. Hattangadi-Gluth, MD<sup>\*</sup>

<sup>\*</sup>Department of Radiation Medicine and Applied Sciences, University of California San Diego, La Jolla, California

<sup>†</sup>Department of Radiation Oncology, University of California Irvine School of Medicine, Irvine, California

<sup>‡</sup>Department of Radiation Oncology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts

### Corresponding Author:

Jona A. Hattangadi-Gluth, MD  
Department of Radiation Medicine and Applied Sciences  
University of California San Diego  
3855 Health Sciences Drive  
La Jolla, CA 92093  
[jhattangadi@ucsd.edu](mailto:jhattangadi@ucsd.edu)  
(858) 822-6040 / (858) 246-1505 (fax)

**Summary:** FDA recalls among radiation oncology devices peaked in 2011 and mostly reflected software issues. These recalls differ significantly from other devices in cause of recall, recall class (severity), quantity in commerce, and time from 510(k) market clearance to recall. The field should demand better design of these systems as well as improved regulatory requirements, software quality efforts, and enhanced post-market surveillance.

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