

# IsoRay Medical

---

William A. Cavanagh

Vice President of Research and Development

IsoRay Medical

March 2011

# IsoRay Medical

---

AMEX: ISR

Founded: 1998

Richland, Washington

Employees: 35

Market Cap (3/3/11): 32.5M

# IsoRay Medical

---

1901: Pierre Curie suggests that a small radium tube be inserted into a tumor thus heralding the birth of brachytherapy.

1903: Alexander Graham Bell made a similar suggestion, completely independently, in a letter to the Editor of Archives Roentgen Ray.

- It was found in these early experiences that inserting radioactive materials into tumors revealed that radiation caused cancers to shrink.

# IsoRay Medical

---

1985: Building on the preliminary work of Hans Holm MD (University of Copenhagen), John Blasko MD and Haakon Ragde MD perform the first transperineal, template and ultrasound guided prostate implant in the U.S. at Northwest Hospital in Seattle.



# IsoRay Medical

---

Teletherapy



Brachytherapy



# IsoRay Medical

---



ELSEVIER

Int. J. Radiation Oncology Biol. Phys., Vol. 51, No. 1, pp. 31–40, 2001  
Copyright © 2001 Elsevier Science Inc.  
Printed in the USA. All rights reserved  
0360-3016/01/\$—see front matter

PII S0360-3016(01)01601-7

**CLINICAL INVESTIGATION**

**Prostate**

## 10-YEAR BIOCHEMICAL (PROSTATE-SPECIFIC ANTIGEN) CONTROL OF PROSTATE CANCER WITH $^{125}\text{I}$ BRACHYTHERAPY

PETER D. GRIMM, D.O.,\* JOHN C. BLASKO, M.D.,\* JOHN E. SYLVESTER, M.D.,\*†  
ROBERT M. MEIER, M.D.,\* AND WILLIAM CAVANAGH, B.S.\*

\*Seattle Prostate Institute, Swedish Medical Center, Seattle, WA; †Puget Sound Tumor Institute, Edmonds, WA

# IsoRay Medical

---



1990s

2000s

Prostate Brachytherapy Adoption



# IsoRay Medical

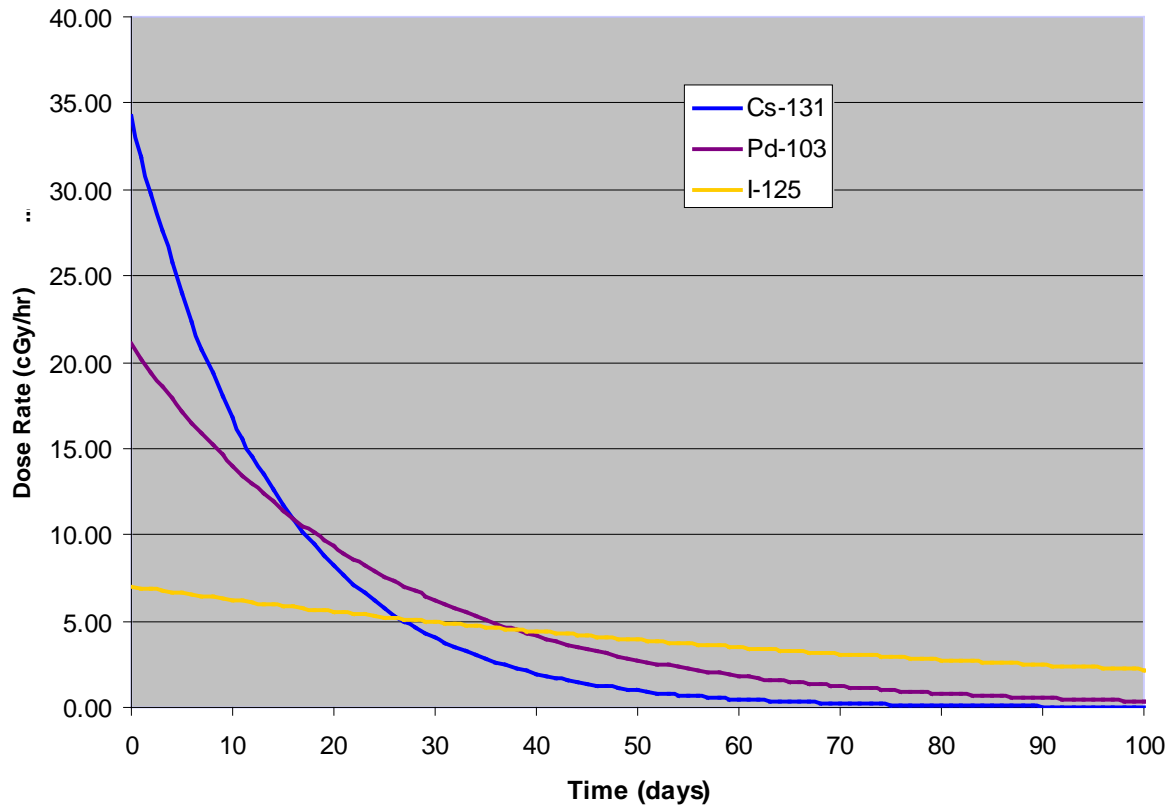
---

Isotope	Half-Life	Energy	90% Dose	Total Dose
Cs-131	9.7 days	30.4 KeV	33 days	115 Gy
Pd-103	17 days	20.8 KeV	58 days	125 Gy
I-125	60 days	28.5 KeV	204 days	145 Gy

Lane Bray Richland, WA: Techniques for purifying Cs-131



# IsoRay Medical



# IsoRay Medical

---

2003: IsoRay receives 510(k) clearance for Cesium-131 for the treatment of cancers of the prostate, head/neck, brain, breast, etc.

2004: First Cesium-131 prostate brachytherapy case at UWMC Seattle, WA

2002 – 2006: Emergence of multiple non-surgical approaches to early stage prostate cancer.

2011: Over 5,000 cancer patients treated to date with Cesium-131.

# IsoRay Medical

---

## APEL Facility



350 Hills St. Richland Washington

IsoRay's "State of the Art" facility is located within the APEL complex. The production facility is completely independent with it's own HVAC and Emergency Power Systems.



# IsoRay Medical

## Seed Production Room #1



- Production line #1 consists of custom built glove boxes and fume hoods. There are 2 completed seed production lines plus a third line that is ~80% complete. The existing facility can support a significant increase in production demand.

# IsoRay Medical

---

## Hot Cell Operations Room



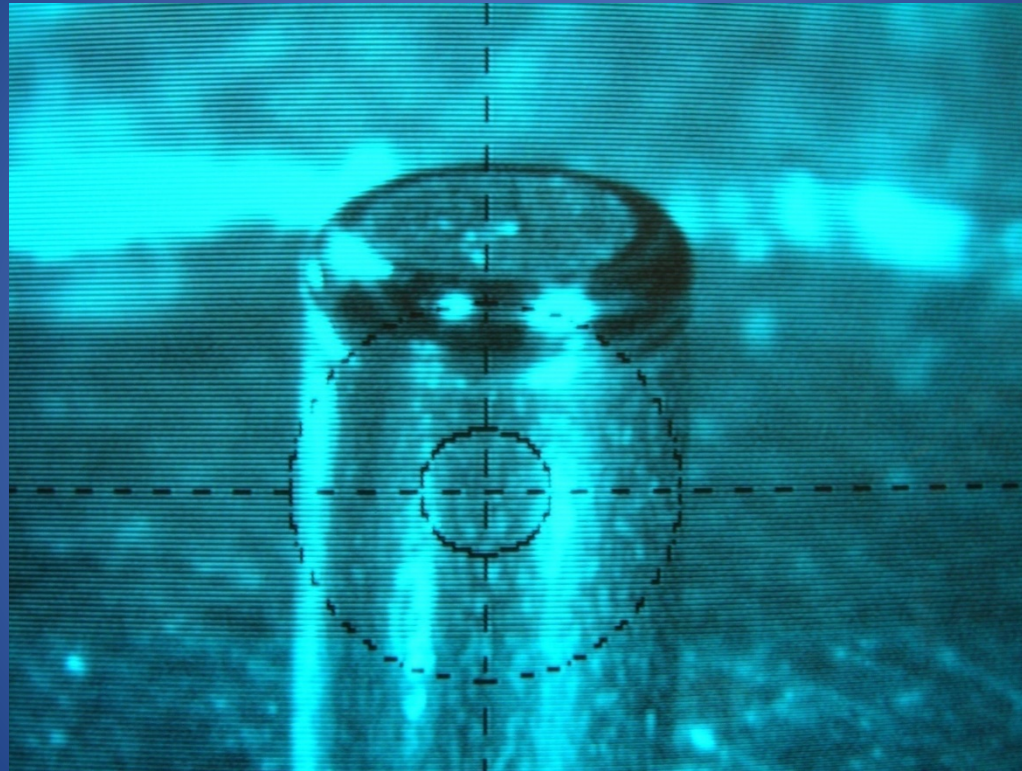
The custom built Hot Cell provides 120mm of lead shielding to protect workers during the chemical separations process utilized to produce ultra-pure Cesium - 131



# IsoRay Medical

---

## High Tech Laser Welding Operations

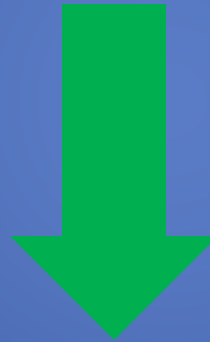


IsoRay employs highly skilled personnel whom perform laser welding of the brachytherapy seeds inside of glove boxes. All laser equipment and optical components were designed and implemented by IsoRay to support their manufacturing operations.

# IsoRay Medical

---

100% Prostate Focused  
("Prostate Company")



**"Brachytherapy Company"**

*The characteristics of Cesium-131 make it  
the ideal brachytherapy source.*



# IsoRay Medical

---

## Brachytherapy as an adjuvant to surgical resection

*Planar implants following surgical resection  
of T1-T2 NSCLC (lung)*

- *Constructed dosing instrument*
- *Circulated study protocol*
- *Agreement signed with WCMC (B. Parashar) to head study*
- *Participating centers coming on board*

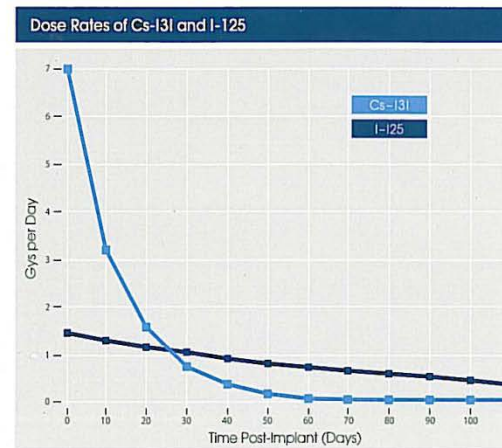
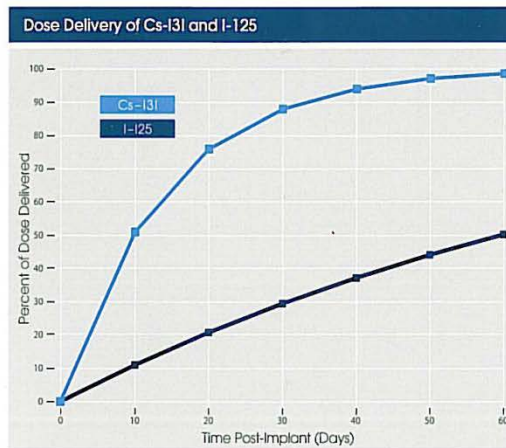


Expanding Brachytherapy Options  
Throughout the Body

## CESIUM-131 IS THE SMARTEST CHOICE IN LUNG BRACHYTHERAPY

Adjuvant lung brachytherapy can significantly increase local control following limited resection for NSCLC<sup>1</sup>. When selecting a brachytherapy isotope, consider that Cs-131 delivers 90% of its dose in 33 days — **six times faster than I-125**.

**Have Confidence that Your Prescription Dose is Delivered as Planned.**



- Cesium-131 has delivered 90% of the intended dose 33 days post implant, compared to 32% of the I-125 dose.
- Cesium-131 has delivered 99.8% of the dose at 90 days, when bioabsorbable sutures/mesh have most likely dissolved, compared to 65% of dose delivered for I-125.
- Cesium-131 delivers uniform and symmetrical radiation penetration for a homogeneous lung implant.
- For the first 26 days after implant, the dose rate from Cs-131 is greater than from I-125.
- After 26 days, the dose rate from I-125 implant exceeds that of Cs-131.
- With Cs-131, radiation safety precautions can be discontinued much sooner than with I-125.

# IsoRay Medical

---

## Brachytherapy as an adjuvant to surgical resection

*GliaSite<sup>®</sup> brachytherapy following surgical removal of high grade gliomas*

- *In-licensed GliaSite and Iotrex IP*
- *Identified contract manufacturers and in-house work where possible; final agreements being negotiated*
- *510(k) submittal in progress*
- *In many cases, out-patient administered*



Expanding Brachytherapy Options  
Throughout the Body



## Re-introducing the gold standard in brachytherapy for brain cancer.

The GliSite® Radiation Therapy System (RTS) is intended for use in the management of surgically resectable brain tumors where adjuvant radiation therapy of the post-resection tissue bed is indicated.

Over 200 GliSite® RTS cases have been detailed in the peer-reviewed literature in reports from multi-institutional studies and academic centers.\*

Brain cancers treated in these reports include primary and recurrent gliomas, as well as resectable metastatic brain tumors.\*

GliSite® RTS is well-tolerated and compares favorably to other management strategies when used as adjuvant radiation therapy in combination with surgical resection.\*

Over 2,000 patients have been treated with GliSite® RTS to date.

\*see reverse side for published references

LUNG · HEAD & NECK · TONSILS · PROSTATE · COLORECTAL · OCULAR MELANOMA · BREAST\* · BRAIN

Manufactured and Distributed by IsoRay Medical, Inc.®  
350 Hills Street, Suite 106 | Richland, WA 99354  
877.447.6729 | [www.IsoRay.com](http://www.IsoRay.com)

ADV-068 RD

# GliSite®



# IsoRay Medical

---

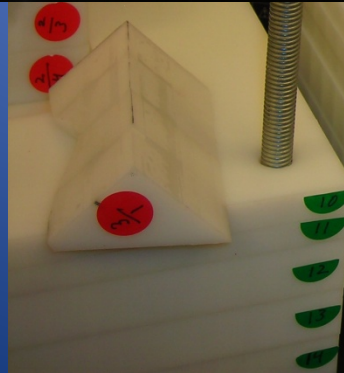
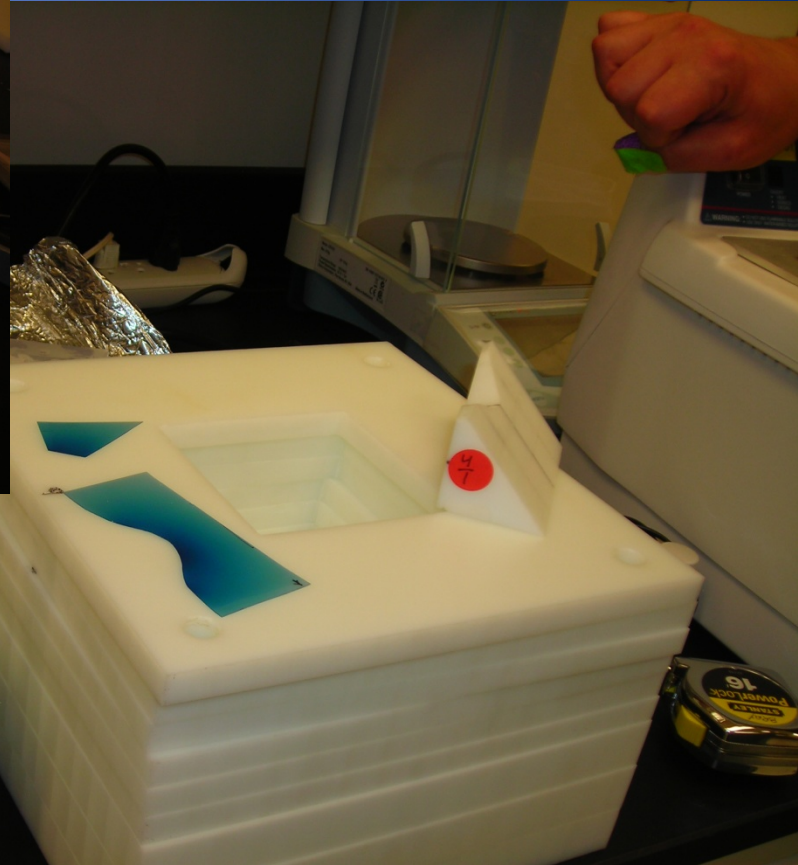
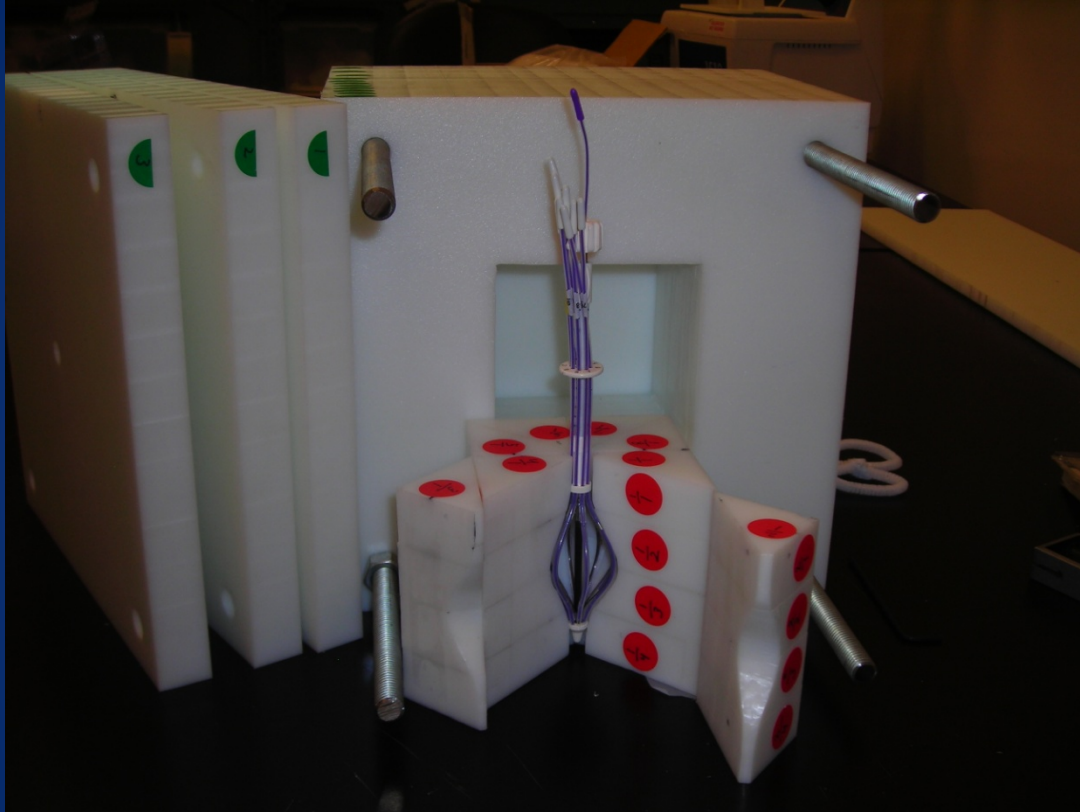
## Brachytherapy as an adjuvant to surgical resection

*Low dose rate (LDR) Accelerated Partial Breast Irradiation (APBI) with Temporary Cesium-131 Implant*

- *Constructed and tested several phantom models with direct dose measurement*
- *Issued “proof of concept” report to potential development partner Cianna Medical*
- *Outpatient model*

# IsoRay Medical

---



# IsoRay Medical

---

## Near Future Needs

*Physician and Institutional Collaborators*

*Opportunities for revenue generation from existing infrastructure and capabilities*

*R&D Funding/Grant Opportunities*

- *New organ site development / trials*
- *Animal modeling*
- *Isotope Production Development*



# IsoRay Medical

---

## Tri-Cities Research District

March 16, 2010

*Thank You*