PUBLIC/PDR

ST JOHN
Health System

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

February 12, 1997

Mr. W. L. Axelson, Director
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

21-11494-01
030-02102

Dear Mr. Axelson:

Please be advised that we are planning to include in our Brachytherapy service the use of Iodine-125 seeds under 10 CFR 35.400 materials. Enclosed please find supplemental materials specifically designed for Iodine-125 permanent seeds used for prostate which are in addition to our previously submitted Quality Management program.

In addition, as we have amended our license, the radiation safety aspects of our brachytherapy service at Oakland General Hospital will be conducted by Dr. Farideh R. Bagne who as NRC well knows, has an excellent reputation in radiation safety aspects of therapeutic sources.

Should you have any questions, please contact Dr. Charles Feinman, the Hospital Radiation Safety Officer at (810) 967-7740, Dr. Bagne at (810) 542-0505, or myself at the above address.

Sincerely,

Robert A. Deputat
President

c: Dr. Bagne
Dr. Bronn
Dr. Feinman
NCR file

enc.

RAD/mrh
C:\97chron\iodi125.doc

RECEIVED
FEB 24 1997
REGION III

Pm: 2-20-97

FEB 24 1997

Oakland General Hospital
Madison Heights, Michigan
SPECIAL RADIATION ISOLATION ORDERS
Iodine-125 Prostate Seed Implant

Addressograph

Activity _____ Assay Date _____ Site of Application _____

Patient Name _____

Attending Physician _____ Phone _____

Date of Insertion _____ Time of Insertion _____

THIS PATIENT IS IN RADIATION ISOLATION UNTIL ORDERS ARE RESCINDED BY RADIATION ONCOLOGIST.

1. No pregnant visitors or visitors under 18 years of age. Visitors should sit at least ___ feet from the patient and limit their stay to ___ minutes per day.
2. Surgical dressings to be changed only by the physician or individual designated by him and trained in techniques applicable to such cases.
3. In the event of the patient's death, contact the radiation oncologist and brachytherapy R.S.O. immediately at 542-0506 or on their pagers.
4. At the time of discharge, please call MIRO at 542-0506.
5. The room cannot be reused until monitored by the physicist.
6. Additional instructions _____

EXPOSURE RATES (mR/hr)

Bedside	Behind Shield	One Meter	Six Feet	Date	Initials

IN CASE OF EMERGENCY, or for further information, call 542-0506

Radiation Oncologists/Medical Physicists	Phone	Pager
Donald G. Bronn, M.D., Ph.D.	542-0506	856-5000
Luciano M. DiCarlo, D.O.	542-0506	856-5006
Madhu Patel, M.D.	542-0506	856-5001
Farideh R. Bagne, Ph.D., J.D., Brachytherapy R.S.O.	542-0506	856-1234
Adib I. Shamaoun, Ph.D.	542-0506	856-5009
G. Michael Klein, M.S.	542-0506	856-5015

If unable to reach, contact OGH operator at 697-7000 for referral for home telephones.

*At time of patient discharge, send this form to the Radiation Safety Office at MIRO. Attn: Dr. Bagne

I125ISO.OGH 31Jan97

ST JOHN Health System **MIRO**

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

BRACHYTHERAPY PATIENT

NOTICE TO ALL PERSONNEL

CERTIFICATION OF RADIATION HAZARD STATUS

At _____ am / pm on _____ (date) the brachytherapy implant procedure of _____ (patient) was completed and the patient was discharged. Further radiation safety precautions are no longer required in connection with this room.

_____
Signature and Title

If any CAUTION signs have been left in place or if you have any questions about the radiation status of this room, please call MIRO or the attending Radiation Oncologist.

Please return this form to MIRO or call 542-0506.

SAFROOM2.OGH 20Jan97

MIRO AFFILIATED RADIATION ONCOLOGY CENTERS
Oakland General Hospital Campus
27415 Dequindre • Madison Heights, MI 48071
(810) 542-0525
Fax (810) 542-3443

I-125 Prostate Seed Implant
Needle Guidesheet

Patient Name_____ ID#_____ Date_____ Done By_____

	Inferior									Superior
Plane#										
Needle #										
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
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21										
22										
23										
24										
25										
26										

Oakland General Hospital
Madison Heights, Michigan

Iodine-125 Therapy Administration
Limits of Exposure

Addressograph

Patient	Room
Administered Dose mCi / Seed	Date

NURSES

1. Not more than _____ minutes in any one hour at bedside.
2. Not more than _____ minutes in any one hour at six (6) feet.

VISITORS

1. Not more than _____ minutes in any one hour at bedside.
2. Not more than _____ minutes in any one hour at six (6) feet (in chair).
3. Do not eat, smoke, drink, or apply cosmetics in patient's room.
4. Pregnant women or minors under 18 years of age should not visit the patient.
5. Visitors and neighboring patients should remain at a distance of more than six feet from patient.

IN CASE OF EMERGENCY, or for further information, call 542-0506.

Radiation Oncologists/Medical Physicists	Phone	Pager
Donald G. Bronn, M.D., Ph.D.	542-0506	856-5000
Luciano M. DiCarlo, D.O.	542-0506	856-5006
Madhu Patel, M.D.	542-0506	856-5001
Farideh R. Bagne, Ph.D., J.D., Brachytherapy R.S.O.	542-0506	856-1234
Adib I. Shamaoun, Ph.D.	542-0506	856-5009
G. Michael Klein, M.S.	542-0506	856-5015

If unable to reach, contact OGH operator at 967-7000 for referral for home telephones.

*At time of patient discharge, send this form to the Radiation Safety Office at MIRO.
Attn: Dr. Bagne

LIMTI125.OGH 31Jan97

ST JOHN Health System

MIRO

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

WRITTEN DIRECTIVE

IODINE-125 PROSTATE SEED IMPLANT

Patient_____ **Date**_____

ID#_____ **Prescribed Dose**_____

Number of Needles_____ **Number of Seeds**_____ **Seed Strength**_____**mCi**

Date Ordered_____ **Date of Implantation**_____

Order _____ **extra seeds for a total of** _____ **seeds**

Clinical Information_____

_____

_____

_____

_____

_____

Radiation Oncologist_____

Signature_____

WRITD125.OGH 31Jan97

MIRO
AFFILIATED RADIATION ONCOLOGY CENTERS
Oakland General Hospital Campus
27415 Dequindre • Madison Heights, MI 48071
(810) 542-0525
Fax (810) 542-3443

NOTICE OF BRACHYTHERAPY TREATMENT

ULTRASOUND-GUIDED IODINE-125 PROSTATE SEED IMPLANT

NAME: ______________________ HOSPITAL # ______________

MIRO #: __________ AGE: _________ DATE OF BIRTH: _________

REFERRING PHYSICIANS: ______________________________

DIAGNOSIS: ______________________________________

= =

DATE OF TREATMENT: _________________________________

SITE: _________________________ PRESCRIBED DOSE: ________

NEEDLE PLACEMENT BY UROLOGIST: ___________________________

NUMBER OF NEEDLES ____________ NUMBER OF SEEDS: __________

SEED STRENGTH: ____________ mCi TOTAL ACTIVITY: ________ mCi

RESPONSE TO TREATMENT:

ADDITIONAL PROPOSED TREATMENT:

FOLLOW-UP SCHEDULE:

cc: Medical Records ____________________

ST JOHN Health System **MIRO**

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RADIATION SAFETY SURVEY FORM

IODINE-125 PROSTATE SEED IMPLANT

Patient_____ _____ **Room**_____ **Date**_____

Activity in mCi per seed_____

1. **Sketch in room, include furniture and storage (urine.)**
2. **Indicate with numbers those locations to be surveyed.**
3. **Record values below.**
4. **Limit nurses and visitors to 2.5 mR in any hour.**
5. **Limit other patients to 100 mRem total--note time of scheduled discharge.**
6. **Make sure some diagnostic isn't interfering with the survey.**
7. **Rooms above, below and adjacent should be surveyed.**
8. **Upon completion of this form, return to Radiation Safety Office at MIRO.**

Location

1.

2.

3.

4.

5.

6.

7.

8.

9.

10.

I125SURV.OGH 19Dec96

ST JOHN Health System

MIRO

Oakland General Hospital
Osteopathic

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Madison Heights, MI
48071-3499

810.967.7000

PATIENT IDENTIFICATION

IODINE-125 PROSTATE SEED IMPLANT

Patient Name_____ **Date**_____

Prior to the administration of any Seed, identify the patient by two or more of the following methods, then compare to the patient's record.

a. **Patient's Name**_____

b. **Birth Date**_____

c. **Address**_____

_____

_____

d. **Social Security Number**_____

e. **ID Wrist Band / Hospital ID**_____

f. **Name on Patient's Medical Insurance**_____

g. **Photo of Patient's Face**_____

h. **Patient's Signature**_____

Done By_____

Signature_____

I125PTID.OGH 19Dec96

ST JOHN Health System

MIRO

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

ULTRASOUND PROSTATE IMPLANT FLOWSHEET

Patient:_____ **Physician:**_____ **Date:**_____ **Done By:**_____

I. Preliminary Studies

Consult Done	Y	N	Date_____
Initial Simulation Films Taken-Complex	Y	N	Date_____
CT Scan for Pubic Arch Study Done	Y	N	Date_____
Ultrasound Volume Study Done	Y	N	Date_____
Ultrasound Images Labeled as to Sequence	Y	N	Date_____
Target Volume Indicated on each Image	Y	N	Date_____
Urethra Marked if Sparing Desired	Y	N	Date_____
Tumor Volume Marked if Special Loading Desired	Y	N	Date_____

Special Dosimetry Instructions for Pre-Plan_____

Desired Isotope_____ Desired MPD_____Gy Prospective Implant Date_____

II. Pre-Plan

Ultrasound Volume Study Sent to Dosimetry	Y	N	Date_____

Number of Seeds Required by Plan_____ Plus_____ _____Extra

Activity of Individual Seeds = _____mCi for MPD = _____Gy

Total Number of Contours Planned_____

Pre-Plan Approved by Physics	Y	N	Date_____
Pre-Plan Returned to Radiation Oncologist for Approval	Y	N	Date_____
Pre-Plan Reviewed and Approved by Radiation Oncologist	Y	N	Date_____

III. Ordering

Written Directive Part I completed	Y	N	Date_____
Seeds Ordered	Y	N	Date_____
Delivery Date Chosen as_____	Y	N	
Number of Seeds Ordered_____ of Activity _____ Assay Date_____			
Copy of Prescription Sent to OGH Nuc Med	Y	N	Date_____

IV. Day of Implantation

Physician Signed a Written Directive, Parts II, III	Y	N	Date_____
Two Methods of Patient ID Documented	Y	N	Date_____
All Factors Checked Prior to Treatment	Y	N	Date_____
Treatment Pre-Plan Signed by Two People	Y	N	Date_____
Treatment Pre-Plan Signed by Radiation Oncologist	Y	N	Date_____
Treatment Administered without Problems	Y	N	Date_____
Patient Surveyed	Y	N	Date_____
All Seeds Accounted for After Implantation	Y	N	Date_____
Patient Given Post-Implant Instructions, Pb Packet & Strainer	Y	N	Date_____
All Radioactive Signs Removed and Stored after Patient Release	Y	N	Date_____
Post-Implant Simulation Films Taken-Complex	Y	N	Date_____

V. Post-Implantation

Check Simulation Films Taken-Simple	Y	N	Date_____
CT Scan of Pelvis with 0.5 cm cuts Done	Y	N	Date_____
Post-Treatment Verification Plan Done	Y	N	Date_____
Post-Treatment Plan Signed by Two People	Y	N	Date_____
Post-Treatment Plan Signed by Radiation Oncologist	Y	N	Date_____
Written Directive Part IV Completed	Y	N	Date_____

Answers of "NO" should be explained if not self-explanatory.

I125SAFE.OGH 19Dec96

ST JOHN Health System **MIRO**

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

PROCEDURE FOR ORDERING I-125 SEEDS

1. **Use standing purchase order #_____ from Oakland General Hospital.**
2. **Determine the activity of the I-125 seeds (6711, I-125, type 109) from the pre-plan _____ mCi of type_____.**
3. **Determine the total number of seeds_____.**
4. **Check with the radiation oncologist to ensure the written directive is completed.**
5. **Oakland General's NRC License is #21-11494-01.**
6. **Oakland General's Amersham account # is 48071-03**
7. **Call: Amersham Healthcare**
   Medi-Physics, Inc.
   2636 S. Clearbrook Dr.
   Arlington Heights IL 60005
   Customer Service 1 800 228 0126
   Technical Information 1 800 554 0157

   Give: --Total # of I-125 Seeds_____

   --Type of Seed: Type 109, 6711

   --Activity per Seed_____

   --Date of Insertion_____

   --Date of Delivery_____ _____

   --Location of Delivery: Hand deliver to Nuclear Medicine Dept. @ OGH

   --Your Name_____

   --Give MIRO's phone # (810) 542 0505.

   --Refer to Oakland General's Account and Purchase Order numbers.
8. **Fax a copy of the prescription to OGH Nuclear Medicine @ 967-7299, attn: Tom Marsh.**
9. **Amersham's Order Number_____**
10. **File this sheet in nurse's I-125 patient book and a copy in the patient's MIRO chart.**
11. **Patient_____ Order date_____**

I125ORDR.OGH 31Jan97

MIRO AFFILIATED RADIATION ONCOLOGY CENTERS
Oakland General Hospital Campus
27415 Dequindre • Madison Heights, MI 48071
(810) 542-0525
Fax (810) 542-3443

CT-Based Pubic Arch Interference Study for I-125 Prostate Seed Implant Patients

To: _____Donald G. Bronn, MD, PhD _____Ahmed E. Ezz, MD, FRCP(C)
_____Luciano M. DiCarlo, DO _____Madhu Patel, MD

From: Farideh R. Bagne, PhD, JD

Date:

Patient Name:_____

Utilizing the Treatment Planning CT Scan, I have evaluated the position of the pubic arch in relation to the prostate gland.

_____**The arch should not impede the progress of the brachytherapy needles.**

_____**The arch will interfere with the treatment.**

_____**Other:**

Done By:

_____

Physician:

_____

PUBARCH.OGH 17Jan97

ST JOHN Health System

MIRO

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

Date:_____

To Patient:_____

You have selected to have a radioactive seed implantation to the prostate performed at Oakland General Hospital in Madison Heights, Michigan, for your prostate cancer.

The purpose of this letter is to inform you that, if for any reason, it is necessary for you to cancel your scheduled procedure:

WE MUST RECEIVE WRITTEN NOTIFICATION OF YOUR DESIRE TO CANCEL OR POSTPONE YOUR PROCEDURE AT LEAST TEN (10) DAYS PRIOR TO THE SCHEDULED SURGERY. IF WE DO NOT RECEIVE SUCH NOTIFICATION, IT WILL BE NECESSARY TO CHARGE YOU THE COST OF THE RADIOACTIVE SEEDS EVEN THOUGH THEY ARE NOT USED.

We regret the necessity for this policy. The seeds are individually ordered for each patient and therefore cannot be easily transferred to another patient; they also have a "limited lifespan" and cannot be held for a significant period of time without being used. When the seeds are shipped to Oakland General, the Hospital is then responsible to the manufacturer for the cost of the seeds, whether or not they are used. Depending on the number and type of seeds ordered, this cost could range from a minimum of $1,500.00 to more than $3,500.00 for which you would be held responsible.

We regret any inconvenience that this policy may cause you and trust that you will understand the necessity for it.

Sincerely,

Donald G. Bronn, MD, PhD
Chief, Radiation Oncology Services
Oakland General Hospital

I have read and agree with the above terms and conditions.

Date_____ **Time**_____**AM/PM**

Patient's Signature_____

Witness_____
SEEDCOST.OGH 19Dec96

MIRO AFFILIATED RADIATION ONCOLOGY CENTERS
Oakland General Hospital Campus
27415 Dequindre • Madison Heights, MI 48071
(810) 542-0525
Fax (810) 542-3443

CONSENT FORM-IODINE-125 PROSTATE SEED IMPLANT

I_____ know that I have a condition requiring radiation therapy. I have authorized Drs. _____ and Associates to perform the radiation therapy procedure known as **Ultrasound-Guided Iodine-125 Prostate Implant Brachytherapy**. I understand that this procedure is for the purpose of **controlling prostate cancer** and, although no specific result has been guaranteed, it is expected to **kill cancer cells in the prostate gland.** I understand that **POSSIBLE** complications are as follows: **Immediately post-op: slight bleeding beneath the scrotum; blood in the urine; bruising and tenderness between the legs. Later: frequent urination; burning with urination; sense of urgency; weakened urinary stream. Possible long term side effects: narrowing of the urethra; impotence; loss of bladder control; damage to bladder; damage to rectum; rare risk of seed migration into a lung; or, rare risk of seed migration into ejaculatory fluid.**

I understand that an identification photograph of my face will be taken. In addition, photographs may be taken of me or parts of my body to be used for medical records. Also, if in the judgement of my physicians, medical research, education, or science will be benefitted by their use, such photographs and information relating to my case may be published and republished, either separately or in connection with each other, in professional journals or medical books or used for any other purpose which they may deem proper in the interest of medical education, knowledge or research, provided, however, that it is specifically understood that, in any such publication or use, I shall not be identified by name.

I acknowledge that the doctors have explained to me the nature and purpose of the procedure and what the procedure is expected to accomplish, together with the known risks. I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees have been made to me as to the results of the operation or procedure. Possible alternate methods of treatment, if any, have been explained, as have the results likely if I remain untreated.

With a full understanding of all the foregoing, and realizing that no guarantee or assurance has been given by anyone as to the results that may be obtained from this therapy, I do hereby request and authorize Drs. _____ and Associates and whomever they may designate to assist them to administer radiation treatments with **Iodine-125** radioisotope therapy to me.

Date_____Time_____AM/PM

Signature of Patient_____

Signature of Closest Relative or Legal Guardian_____

Physician's Signature_____

Witness_____

I125IMPL.OGH 20Jan97

ST JOHN Health System

MIRO

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

Brachytherapy Service
Radiation Oncology Quality Assurance Management Program
Written Directive to be used with _____

PART I

Patient Name_____ Room #_____

History Number_____ Date of Treatment_____

Attending Physician_____

Indication(s)_____

Procedure_____

Radiopharmaceutical Sr-89 P-32 I-125 Pd-103

Dosage_____mCi or Gy Route_____

Authorized User
Signature_____ Date_____

PART II

Ordered for_____MD / DO Date Ordered_____

Assayed by_____ Date Assayed_____

Assayed Value_____ Ordered by_____(Physicist)

PART III

The patient's identity must be verified by at least two of the following:

_____Patient called by name
_____Patient spelled his/her name
_____Patient stated date of birth
_____Patient stated social security number
_____Patient provided positive identification

_____Is patient pregnant?
_____Is patient breast feeding?
_____Booklet given and reviewed?
_____Consent signed?
_____Wrist bend verified?

Patient identification verified by_____

PART IV

DOSE ADMINISTERED ON (Date)_____(Time)_____

Actual Dose Delivered_____mCi

Authorized User_____Date_____ Bioassay needed? Y N

Medical Physicist_____Date_____ Y N
(Signature above indicates presence at administration and assurance that this written directive was followed.)

BRACHQA.OGH 19Dec96

ST JOHN Health System

MIRO

Oakland General Hospital
Osteopathic

27351 Dequindre
Madison Heights, MI
48071-3499

810.967.7000

BRACHYTHERAPY PATIENT

NOTICE TO ALL PERSONNEL-OPERATING ROOM

CERTIFICATION OF RADIATION HAZARD STATUS

At _____ am / pm on _____ (date) the brachytherapy implant of _____ (patient) was completed. Further radiation safety precautions are no longer required in connection with this room.

_____
Signature and Title

If any CAUTION signs have been left in place or if you have any questions about the radiation status of this room, please call MIRO or the attending Radiation Oncologist.

Please return this form to MIRO or call 542-0506.

MIRO AFFILIATED RADIATION ONCOLOGY CENTERS
Oakland General Hospital Campus
27415 Dequindre • Madison Heights, MI 48071
(810) 542-0525
Fax (810) 542-3443

DISCHARGE INSTRUCTIONS

RADIOACTIVE SEED IMPLANT

FOR PROSTATE CANCER

1. You may notice some blood in your urine. This is normal and should subside in approximately 24 hrs. If after 24 hrs the bleeding persists or you begin to pass blood clots, you should contact your urologist.

   It is common to experience frequent urination, burning with urination, a sense of urgency or a decrease in the force of the urinary stream. These symptoms will gradually decrease as the seeds lose their strength, but may be present to some degree for 6-12 months after the implant. Drink plenty of fluids and avoid caffeine containing beverages to help relieve the symptoms.

2. If you experience any light-headedness, dizziness or a temperature over 100°, please contact your urologist right away.

3. Avoid heavy lifting or strenuous physical activity for two days. After that, you may return to normal activity.

4. No restriction on your travel or physical contact with other adults. If a child or pregnant women is in the same room as you for more than 5-10 minutes, they should stay 6 feet or more away. Since the radiation is coming from the prostate, children should not sit on your lap during the initial 2 month period following the implant. Do not sleep in the same bed as a pregnant woman or child.

5. Although rare, an occasional seed may be lost via urination within the first week following the implant procedure. If a seed is passed, it should be retrieved and returned to the Michigan Institute for Radiation Oncology. Strain your urine for the first week following the implant. If a seed is passed, it should be picked up with tweezers and placed in the packet provided.

6. A seed may rarely be passed with the ejaculate during intercourse. Use a condom during intercourse for the first two months following the implant procedure so that any possible seed can be retrieved. It is normal for the ejaculate to be discolored dark brown to black for up to several weeks following the implant procedure. Sexual intercourse may be resumed after two weeks.

7. Objects that you touch or items that are used do not become radioactive. Bodily wastes (urine and stool) are not radioactive.

8. Antibiotics are given after the implant to prevent infection. You should take the antibiotic as prescribed by your physician until the medication runs out. If you develop an allergic reaction, such as a skin rash, stop the medication and contact your physician.

Appointment at MIRO _____

CT Scan _____

Urologist _____

If you have any questions or problems, call your urologist _____ at _____ or the Michigan Institute for Radiation Oncology at (810) 338-0300.

Date_____ Time_____AM / PM

Patient's Signature_____

Witness_____

MIRO AFFILIATED RADIATION ONCOLOGY CENTERS
Oakland General Hospital Campus
27415 Dequindre • Madison Heights, MI 48071
(810) 542-0525
Fax (810) 542-3443

NURSING CHECKLIST

RADIOACTIVE SEED IMPLANT-PROSTATE

Patient _____

Urologist _____

Consultation Date _____

Simulation _____

CT Scan _____

Ultrasound _____

Surgery Date _____

Patient teaching:

- Video viewed by patient _____
- Patient information Booklet _____
- Discharge Instructions-Surgery _____
- Antibiotic Rx -Urologist _____

Consents:

- Notification of Seed Charge _____
- Iodine-125 Prostate Seed Implant Consent _____

Surgical Preparation to be Ordered by Urologist:

- Two (2) Fleets enemas am of Surgery _____
- CBC, Electrolyte, PT, PTT _____
- PAT _____

CT Pelvis-Post Surgery _____

- Simulation Post Surgery _____

Appointments:

- Urologist _____
- MIRO _____

Radioactive Seed Implant Prostate					
Name	Consult	Sim	CT	U.S.	Surgery