

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCE  
(Amended Copy)

NO.: NR187S102S

DATE: DEC 9 1982

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SEALED SOURCE TYPE: Brachytherapy Sources

MODEL: 81-02

MANUFACTURER/DISTRIBUTOR: Best Industries, Inc.  
2224 S. Shirlington Road  
Arlington, VA 22206

MANUFACTURER/DISTRIBUTOR:

ISOTOPE: Gold-198

MAXIMUM ACTIVITY: 33 millicuries

LEAK TEST FREQUENCY:

PRINCIPAL USE: General Medical Use

CUSTOM SOURCE: ☐ YES ☒ NO

8403020193 840209  
PDR FDIA  
HAMMITT84-74 PDR

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DESCRIPTION:

These gold seeds are manufactured by Engelhard Industries of Canada (Part No. 80-451, Drawing Number 88630041). Each batch of seeds received by Best Industries is certified by the manufacturer as to contents and sizes. These seeds are gold (99.99 percent pure) encapsulated in platinum (99.99 percent pure, iridium free). Each seed is 2.5 mm long and 0.8 mm in diameter and contains  $8.6 \text{ mg} \pm 0.6 \text{ mg}$  gold. Batches of seeds are irradiated by Best Industries in a nuclear reactor. Following irradiation and when supplied to Best Industries' customers, each seed may contain up to a maximum of 11 mCi of gold-198. The most commonly used activity is 1 mCi per seed. The customer/user may also use up to 11 millicuries per seeds.

LABELING:

Individual gold seeds are not labeled due to size. The shipping container is labeled in accordance with the following example:

GOLD - 198  
Implant Grains

FOR THERAPY USE ONLY

This radioactive material may be administered to humans only by physicians licensed to dispense drugs in the practice of medicine.

This product is approved for distribution to persons licensed pursuant to Section 35.14 and 35.100, 10 CFR or licensed pursuant to equivalent regulations of Agreement States for Group VI Medical Use.

CAUTION!  
RADIOACTIVE MATERIAL  
(Radiation Symbol)

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LABELING:

FRACTION OF ACTIVITY REMAINING  
HOURS AFTER CALIBRATION

<u>HOURS</u>		<u>HOURS</u>		<u>HOURS</u>	
1	0.9894	22	0.7902	120	0.2767
4	0.9581	24	0.7734	144	0.2140
7	0.9278	36	0.6802	168	0.1655
10	0.8985	48	0.5982	192	0.1280
13	0.8701	60	0.5260	216	0.0990
16	0.8426	72	0.4626	240	0.0766
19	0.8159	96	0.3578	360	0.0212

DO NOT USE AFTER 14 DAYS  
AFTER DATE OF CALIBRATION

CUSTOMER: \_\_\_\_\_

ACTIVITY: \_\_\_\_\_ mCi

GRAINS: \_\_\_\_\_

ACTIVITY PER GRAIN: \_\_\_\_\_ mCi

TIME: \_\_\_\_\_ DATE: \_\_\_\_\_

CAUTION!!

THIS PRODUCT MUST BE  
STERILIZED BEFORE USE.

BEST INDUSTRIES, INC.  
2244 S. Shirlington Road  
Arlington, VA 22206

WARNING!! This product  
should not be administered  
to pregnant or lactating  
women, or to patients under  
the age of 18 years, unless  
exceptional circumstances  
exist.

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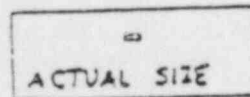
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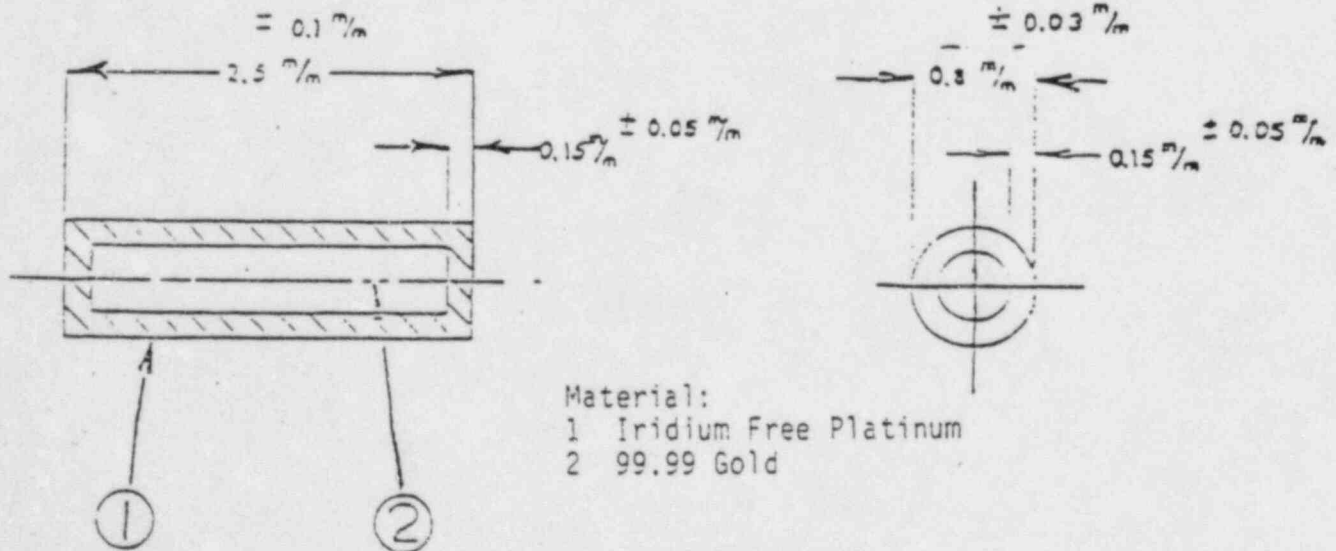
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DIAGRAM:

Platinum sheathed gold seed.



Weight of gold cylinder 8.6 mg.  $\pm$  0.6 mg.  
Nominal size of gold cylinder 0.5 mm Dia x 2.2 mm long



CONDITIONS OF NORMAL USE:

These sources are designed for use in hospital and clinical environments for the treatment of cancer under the normal conditions encountered in clinical practice.

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PROTOTYPE TESTING:

No additional prototype testing was performed by Best Industries, Inc. Best Industries claims that these gold seeds have been in clinical use for more than a quarter century without problems with source design. Both metallic gold and iridium free platinum are insoluble in body fluids.

EXTERNAL RADIATION LEVELS:

- ° For the most commonly used activity of 1 mCi per seed, the dose rate is:

At 5 cm -- 92 milliroentgens per hour.

At 30 cm -- 2.55 milliroentgens per hour.

- ° A 3 1/2" x 5" lead pot with a 1" by 2 1/4" center cavity is used to ship a maximum of 50 seeds. With a maximum activity of 11 mCi per seed on date of shipment, the source container's radiation profile is:

Top.....50 milliroentgens per hour.

Bottom.....60 milliroentgens per hour.

Side.....60 milliroentgens per hour.

QUALITY ASSURANCE AND CONTROL:

Each batch of seeds received from the manufacturer, Englehard Industries, is certified as to contents and sizes. Following irradiation, a Capintec Isotope Calibrator is used for calibrating all gold grains (seeds). The calibrator has been standardized with a standard of known activity by Capintec. The calibrator is double checked with a similar gold seed calibrated in exposure rate. This exposure rate calibration is traceable to the National Bureau of Standards. Each batch of seeds is given a code number for traceability and are grouped so that variation among seeds is not more than  $\pm 5$  percent from the stated average activity. Seeds are smear tested for contamination to an acceptance limit of  $10^{-6}$  microcurie. A Certification of Assay as seen below accompanies each shipment.

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QUALITY ASSURANCE AND CONTROL (CONT'D):

GOLD-198 GRAIN  
CERTIFICATION OF ASSAY

CUSTOMER: \_\_\_\_\_

DATE: \_\_\_\_\_ INVOICE NO. \_\_\_\_\_

LOT NUMBER: \_\_\_\_\_ GRAINS: \_\_\_\_\_

TIME OF ASSAY: \_\_\_\_\_ DATE OF ASSAY: \_\_\_\_\_

AVERAGE NET ION CURRENT PER GRAIN: \_\_\_\_\_ AMP.

FACTOR: \_\_\_\_\_ Amp/mCi (Net Ion Current - Factor) \_\_\_\_\_

EACH GRAIN IS: \_\_\_\_\_ Millicuries AT: \_\_\_\_\_ ON: \_\_\_\_\_

DECAY TIME: \_\_\_\_\_ DECAY FACTOR: \_\_\_\_\_

EACH GRAIN WILL BE: \_\_\_\_\_ Millicuries AT: \_\_\_\_\_ ON: \_\_\_\_\_

SINGLE GRAIN ASSAY:

1	11	21	31	41
2	12	22	32	42
3	13	23	33	43
4	14	24	34	44
5	15	25	35	45
6	16	26	36	46
7	17	27	37	47
8	18	28	38	48
9	19	29	39	49
10	20	30	40	50

AVERAGE: \_\_\_\_\_ VARIATION: + \_\_\_\_\_

PRODUCT PREPARED BY: \_\_\_\_\_ PRODUCT CHECKED BY: \_\_\_\_\_



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QUALITY ASSURANCE AND CONTROL (CONT'D):

<u>HOURS</u>	<u>DECAY FACTOR</u>	<u>HOURS</u>	<u>DECAY FACTOR</u>	<u>HOURS</u>	<u>DECAY FACTOR</u>
1	0.9894	22	0.7902	120	0.2767
4	0.9581	24	0.7734	144	0.2140
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SHIPMENT DATE: \_\_\_\_\_ TOTAL ACTIVITY AT SHIPMENT: \_\_\_\_\_ mCi  
CARRIER: \_\_\_\_\_ WAYBILL: \_\_\_\_\_

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- A. These sources may be distributed to persons specifically licensed pursuant to §§ 35.13, 35.14, and 35.100 Group VI, 10 CFR 35, or under equivalent regulations of Agreement States.
- B. Leak Test Frequency: Not applicable due to 2.7 day half-life of Gold-198.
- C. Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information contained in the references cited below, we conclude that the Best Industries, Inc. Model 81-02 Gold-198 seeds are acceptable for license purposes. These sources are for use by trained radiotherapist for the interstitial treatment of cancer and have a quarter century history of successful use for this purpose. Since the high purity gold encased in platinum is essentially inert, the possibility of contamination from loss of containment is considered minimal. However, the extremely small size of these sources (2.5 mm x 1.8 mm) will require a higher level of accountability during use to prevent source misplacement and loss.

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REFERENCES:

This Certificate of Registration is based on information contained in Best Industries, Inc. license application dated July 24, 1981, letter with enclosures dated September 2, 1981, and document entitled, "Device and Source" for Model 81-02 Gold-198 source signed by Krishnan Suthanthiran, President, dated September 3, 1981.

- Supersedes registry document No. NR-187-S-102-S dated September 11, 1981.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

DEC 9 1982

Date: \_\_\_\_\_

Reviewer: \_\_\_\_\_

DEC 9 1982

Date: \_\_\_\_\_

Concurrence: \_\_\_\_\_