REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-0187-S-101-S DATE: January 14, 2003

SOURCE TYPE: Brachytherapy Seed Source

MODEL: 81-01

MANUFACTURER/DISTRIBUTOR: **Best Medical International, Inc.**
(**Formerly** Best Industries)
7643 Fullerton Rd.
Springfield, VA 22153

ISOTOPE: Iridium-192

MAXIMUM ACTIVITY: 100 millicuries (1.48 GBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (V) **For use in accordance with 10 CFR 35.400 through 35.491 (Subpart F) or the equivalent state regulations**

CUSTOM SOURCE: _____YES ____X____NO

SOURCE TYPE: Brachytherapy Seed Source

DESCRIPTION:

Best Medical International, Inc. (formerly Best Industries) claims that the Model 81-01 sources are identical in design and construction to RAD/IRID, Inc., Model R/1 sources and other sources which have been in use since 1960. Each seed contains Iridium 30% - Platinum 70% alloy source material in the form of a wire doubly encapsulated in Type 304 stainless steel. The capsules are cold welded at each end (machine crimped) to a nominal length of 0.13 inches (3 mm). Nominal outer diameter for the Iridium/Platinum wire is 0.003 inches (0.076 mm). Nominal outer diameter of the inner stainless steel capsule is 0.012 inches (0.305 mm) with a nominal thickness of 0.0085 inches (0.216 mm). Nominal outer diameter of the outer stainless steel capsule is 0.020 inches (0.508 mm) with a nominal thickness of 0.007 inches (0.178 mm).

Following batch irradiation in a reactor, the completed seeds are forced into nylon ribbons which have an inner diameter less than the outer diameter of the sources in order to prevent movement. Spacing of the sources along the ribbon is typically 0.4 inches (1 cm) center to center, however, up to 3 seeds per centimeter can be accommodated. Each ribbon will be supplied with approximately 39.4 inches (100 cm) of inactive leader at one end to facilitate handling and about 1.2 inches (3 cm) on the other.

Seeds and ribbons are supplied in sets. A standard set consists of 14 ribbons containing 12 seeds each with 1 cm spacing. Ribbons can be customized with up to 7.9 inches (20 cm) of active length according to user specifications. The most commonly supplied activity is 10 millicuries per seed.

DIAGRAM:

See Attachments 1 and 2.

SOURCE TYPE: Brachytherapy Seed Source

LABELING:

Because of their small size, individual seeds and ribbons are not labeled but rather, each shipping container will be labeled. Additionally, ribbons may be color coded to designate various activity levels as of the date of shipment. However, color selection is not dependent upon a specific activity level.

Seeds in ribbons are supplied as a set with the activity of each ribbon within a range as specified by the end user. The shipping containers for each set bear labels containing the following:

"CAUTION - RADIOACTIVE MATERIAL"
Radiation Symbol, Isotope, Amount, Date
Best Medical International, Inc.
7643-B Fullerton Road
Springfield, VA 22153

Ship To:

Date of Shipment_____ P.O. Number_____

# of Ribbons	# of Seeds	Activity on Date of Shipment (ma Raea)	Code*	Color**

Note: * Internal code to identify reactor irradiated batch of seeds.

** Ribbons may be color coded to designate the activity on date of shipment (milligram radium equivalent). Typical colors used are white, red, or blue.

SOURCE TYPE: Brachytherapy Seed Source

LABELING (cont'd):

For seeds above 11 mCi (0.407 GBq) the following label will be added:

> CAUTION: These Iridium-192 seeds are considered high activity sources because of the high dose rate. The dose rate per mCi of Iridium-192 seeds at 1 cm is 4.6 R/hr. At 5 cm the dose rate is 184 mR/hr. At 30 cm the dose rate is 5.1 mR/hr and at 100 cm it is 0.46 mR/hr. Use extra care and follow all instructions included in the bill of lading.

CONDITIONS OF NORMAL USE:

The seeds in ribbons are designed for use in hospital or clinical environments for removable interstitial, intracavitary, intraluminal, intravascular, and topical radiation therapy. The sources are designed to withstand autoclave or steam sterilization temperatures up to 270°F (132°C) and pressures up to 15 psi (103 kPa) for up to 10 minutes. However, ethylene gas sterilization methods using temperatures between 120°F (49°C) and 140°F (60°C) are recommended. The sources shall not be subjected to dry heat sterilization.

PROTOTYPE TESTING:

Prototype testing of the sources has not been performed by Best Industries, Inc., due to the fact that essentially identical sources have been manufactured and in use since 1960. The manufacturer has stated that the sources are identical in size and construction to RAD/IRID Model R/1 sources and that neither Best Industries, Inc. nor RAD/IRID have encountered any problems with the sources in clinical practice. RAD/IRID sources have been subjected to~ the following tests:

- Exposed to water and cold and warm isotonic saline solutions (0.25 percent sodium chloride by weight) for periods up to six months without signs of corrosion or deterioration.

SOURCE TYPE: Brachytherapy Seed Source

PROTOTYPE TESTING (cont'd):

- Prolonged exposure to concentrated "aepherin" (antiseptic solution) of up to six months without signs of corrosion or deterioration.

- Sources were autoclaved at pressures up to 350 psi and temperatures up to 250°F for 30 minute periods without any adverse effects noted.

EXTERNAL RADIATION LEVELS:

External radiation levels for a 10 mCi (0.37 GBq) source are as follows:

Distance from source	Ir-192 Seed Activity	Measured radiation levels (mrem/hr)	(mSv/hr)
5 cm (1.97 in)	10 mCi (0.37 GBq)	1840.0	18.4
30 cm (11.81 in)	10 mCi (0.37 GBq)	51.0	0.51

QUALITY ASSURANCE AND CONTROL:

Best Medical International, Inc. (**formerly** Best Industries, Inc.), states that quality assurance and control are provided routinely throughout the manufacture and use of the sources. The stainless steel tubing from which the capsules are made is certified by the manufacturer to be type 304 stainless steel hypodermic needle tubing with chemical composition and mechanical properties tested and notarized.

The manufacturer of the Iridium/Platinum wire (Englehard Industries) certifies it to be an alloy of 30 percent iridium and 70 percent platinum. During seed fabrication, representative numbers are individually inspected with a magnifying glass to ensure the integrity of the cold weld when fabrication is complete. All seeds are individually inspected for uniformity and bent or damaged seeds are discarded. After seeds are irradiated, they

SOURCE TYPE: Brachytherapy Seed Source

QUALITY ASSURANCE AND CONTROL (cont'd):

are comparatively measured with a standard of known activity. Representative seeds are then smear tested for possible contamination.

All Model 81-01, iridium-192 sources and ribbons are calibrated to millicuries using a calibrator which has been standardized by the National Institute of Standards and Technology (NIST). A specific Gamma Ray Constant of 4.6 R $cm^2hr^{-1}mCi^{-1}$ is used for converting millicurie values into milligram radium equivalent.

Best Medical International, Inc. (**formerly** Best Industries) further states that their rigid quality control program insures that iridium seeds are produced with close tolerances and that they are uniform in their activity. All assembled ribbons are calibrated before shipping and no ribbon is sent to customers if it varies more than ±5 percent from the stated average activity.

The factor used for the conversion of millicuries of iridium-192 to milligram radium equivalent is 0.56, assuming a specific Gamma Ray Constant of 8.25 R $cm^2hr^{-1}mCi^{-1}$ for radium-226. Each batch of seeds is given a code number for traceability and ribbons are smear tested for contamination to an acceptance limit of 10^{-6} microcurie/ribbon.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The Model 81-01 source shall be manufactured and distributed according to the requirements of Section 32.74, 10 CFR Part 32 and distributed only to persons specifically licensed by the NRC or an Agreement State.

- The sources shall not be exposed to concentrated acids or alkaline fluids or sterilized by dry heat methods.

- The sources shall not be exposed to autoclave pressures in excess of 15 psi (103.4 kPa) and temperatures in excess of 270°F (132.2°C), nor to these temperatures and pressures for periods in excess of 10 minutes.

SOURCE TYPE: Brachytherapy Seed Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (cont'd):

- The sources shall not be autoclaved in plastic tubing or plastic containers (only autoclave suitable material such as stainless steel, glass, nylon, teflon, lead or tin should be used).

- The sources shall be leak tested at intervals not to exceed six months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.

- REVIEWER NOTE: Repeated sterilization or repeated use could damage the integrity of the ribbons. The iridium seeds in nylon ribbons may be reused only if the ribbons are used inside fully closed catheters, needles, applicators, or brachytherapy devices, and a visual inspection by the user does not indicate any damage to the source ribbons.

- REVIEWER NOTE: Please ensure the safety procedures outlined in 10 CFR Part 35, **Subpart F** are adhered to, especially as they pertain to the handling of the sources. Specifically, ribbons should be used only in closed end catheters or completely closed outer catheters to prevent direct contact with tissue.

- REVIEWER NOTE: Ribbons show brittleness in approximately two months due to radiation. damage, and should not be used after two months from the date of shipment.

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. The sources shall be handled only with appropriate equipment (due to the high activity of the sources forceps are recommended).

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below and the past history of similar source designs, we continue to

SOURCE TYPE: Brachytherapy Seed Source

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SAFETY ANALYSIS SUMMARY (cont'd):

conclude that the **Best Medical International, Inc.** (**formerly** Best Industries, Inc.), Model 81-01 sealed sources are acceptable for licensing purposes.

Furthermore, we continue to conclude that these sources would be expected to maintain their containment integrity for normal and accidental conditions of use which might occur during the uses specified in this registration sheet.

REFERENCES:

The following supporting documents for the **Best Medical International, Inc.** (**formerly** Best Industries, Inc.), Model 81-01 sealed source are hereby incorporated by reference and are made a part of this registry document.

- Best Industries, Inc., application dated July 24, 1981.
- Best Industries, Inc., letters dated September 3, 1981, July 26, 1984, January 15, 1992, April 14, 1992, July 23, 1997, December 9, 1997, and January 8, 1998 (two letters), with enclosures thereto.
- **Best Medical International, Inc., letter dated November 26, 2002, with enclosures thereto, and electronic mail dated January 10, 2003.**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 14, 2003 Reviewer: John P. Jankovich

Date: January 14, 2003 Concurrence: Ujagar S. Bhachu

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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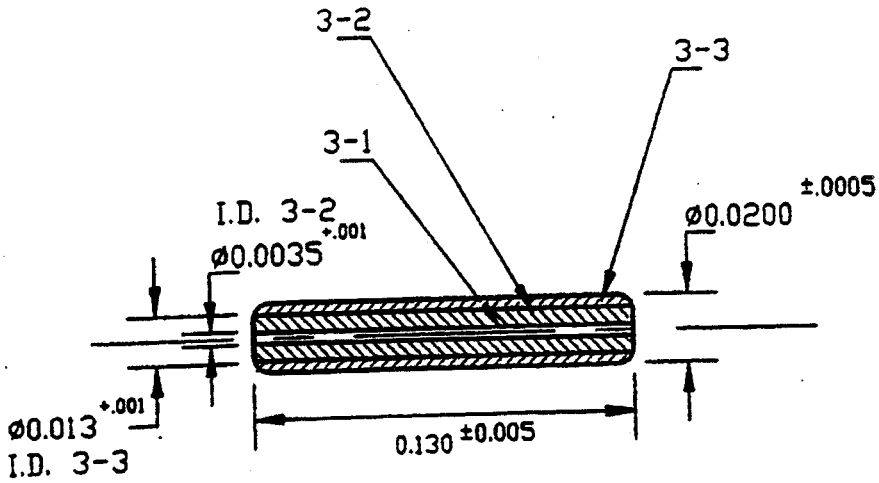
NO.: NR-0187-S-101-S DATE: January 14, 2003 ATTACHMENT 1

SOURCE TYPE: Brachytherapy Seed Source



Note: Both ends are crimped

NO.	DESCRIPTION	MATERIAL
3-3	TUBE O.D. Ø0.020	S.S. 304
3-2	TUBE O.D. Ø0.012	S.S. 304
3-1	WIRE O.D. Ø0.003	Pt - Ir

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NO.: NR-0187-S-101-S DATE: January 14, 2003 ATTACHMENT 2

SOURCE TYPE: Brachytherapy Seed Source

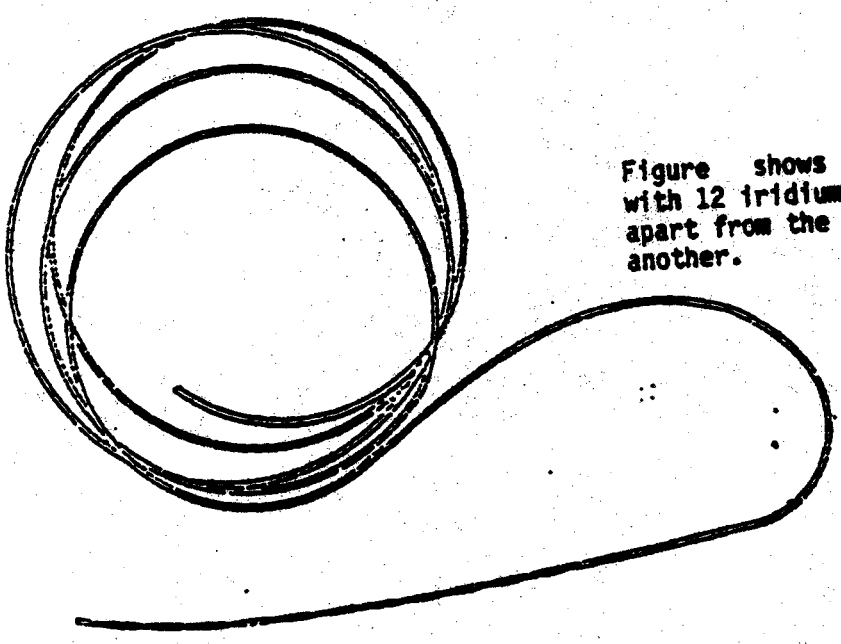

Figure shows one nylon ribbon loaded with 12 iridium-192 seeds spaced 1 cm apart from the center of one seed to another.