Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005
(312) 593-6300

October 28, 1983

Amersham

Mr. S. Baggett
Materials Certification and Procedures Branch
Division of Fuel Cycle & Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Baggett:

Attached is a copy of an application for evaluation of a medical device which Amersham would like to have approved for distribution to Group VI medical licensees licensed pursuant to Part 35.100 of 10 CFR.

The product described contains iridium 192 isotope and does not fall into any of the existing categories listed under Group VI since it is a solid wire mounted in an applicator. It is closely related to item (6) in Group VI and is used for a very similar purpose. The technique which relies on the use of iridium wire as described in this application has found favor with many radiologists and physicians in preference to the iridium ribbon technique as it is considered to exhibit better dosimetry and is particularly useful for treating certain types of cancer. Various publications are attached to the submission detailing the use of this material during the past ten years.

ICW100 is not considered by Amersham to be a sealed source. This is because a number of short half-life contaminants are generated in the source casing during neutron irradiation. However, these are not considered to be a significant practical problem and Amersham is requesting an exemption from the requirement stated in Part 35.14 (b) (5) that the material be contamination free to better than 0.005 μCi. This appears already to have been established for iridium ribbon and has been the subject of verbal discussions between Dr. D. A. Coppell and officers of the Commission during the last year.

In addition, I am attaching applications for approval to distribute some cesium 137 brachytherapy sources to Group VI licensees. These sources are closely related to sources which Amersham has been distributing to Group VI licensees for many years (models CDC.S, CDC.J, CDC.M) but are constructed from stainless steel instead of iridium/platinum alloy. The steel used is high grade of the type found frequently in surgical instruments and has some significant cost advantages over the use of iridium/platinum. There are two types of "tube" source

and two types of clinical "needle". Please evaluate these items and, if they are acceptable, modify Amersham's distribution license (12-12836-05MD), to reflect their addition. I am attaching a check for $550.00 to cover the evaluation fee for all five source models. I understand that the license modification fees can be combined with that for ICW.100. A check for $40.00 is enclosed to cover the amendment of the license.

Should you have any questions concerning this application or require any additional technical information, please contact Dr. M. G. Shilton or Dr. D. A. Coppell. They can be reached on (312) 593-6300.

Sincerely,

Linda A. Bagby

Linda A. Bagby
Manager, Environmental & Safety
Regulatory Affairs

LAB/lub

Enclosure

Application For Approval To Distribute

Amersham Model ICW 100 To

Persons Licensed Under 10 CFR Part 35.100

Group VI (License Number 12-12836-05MD)

Device Type	-	High Energy gamma brachytherapy source wire
Model	-	ICW 100
Manufacturer/Distributor	-	Amersham Corporation 2636 S. Clearbrook Drive Arlington Heights, IL 60005
Isotope	-	Iridium 192
Maximum Activity	-	200 mCi (4 mCi/cm length)
Leak Test Frequency	-	Six months (but note that this is not classified as a sealed source).
Principal Use	-	Medical device for treatment of a variety of types of cancer (in particular, breast cancer and oral cancer).
Custom Device	-	No

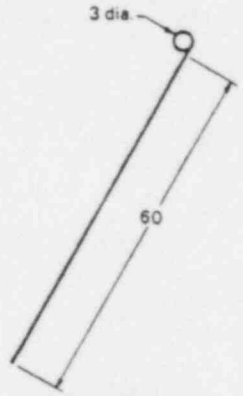
Description

The device consists of an alloy of iridium and platinum which is encased in a pure platinum sheath. This composite is then mechanically drawn into a wire of various diameters ranging from 0.3 mm to 0.6 mm. In all cases, the "inactive" platinum sheath is 0.1 mm thick.

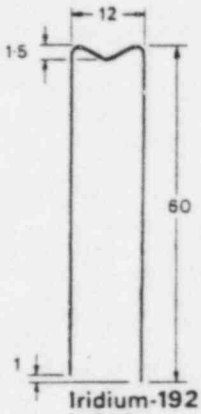
The wire is then irradiated in a reactor resulting in activation of the iridium to iridium 192 nuclide. The material may then be dispatched in a variety of formats. Most frequently, the user requires to cut and mount the wire in holders to specified lengths, but in some cases Amersham can arrange to supply the wire ready mounted in narrow bore plastic tubing. A

sketch of typical wire formats is shown below.

dimens.
in mm



Iridium-192
single-pin



Iridium-192
hairpin

Iridium-192
wire

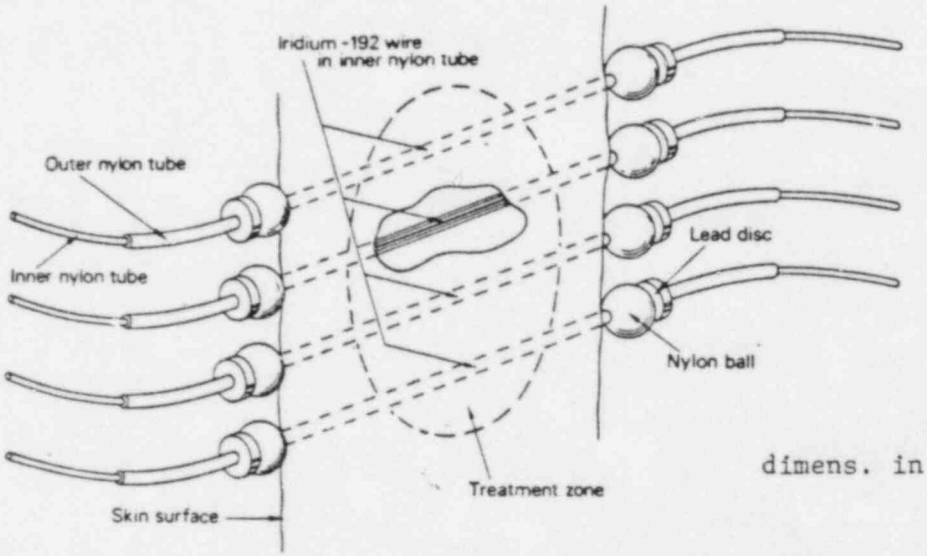
Description of Use

Basically, iridium wire is supplied in two formats for different purposes. In each case, the construction of the wire is the same; the difference lies in the dimensions of the wire and, in particular, in its diameter.

One version has a diameter of 0.3 mm and is consequently highly flexible. It is coiled up in lengths of approximately 50 cm. This product is intended for use in a particular technique called the "Pierquin/Paine Technique". This is essentially an afterloading technique for the introduction of active wire into soft tissue. The wire is first cut into appropriate lengths and heat sealed into a narrow bore plastic tube. This whole process can be accommodated in one of several loading devices designed specifically for the purpose or, in the case of larger hospitals with appropriate equipment, the hospital physicist may wish to devise a custom loading arrangement.

A second plastic tube called a "guide tube" is then introduced into the patient using a steel needle. Once this is in place, the loaded inner tube can be fed into it and secured in place by the use of nylon beads and crimped lead discs. This whole

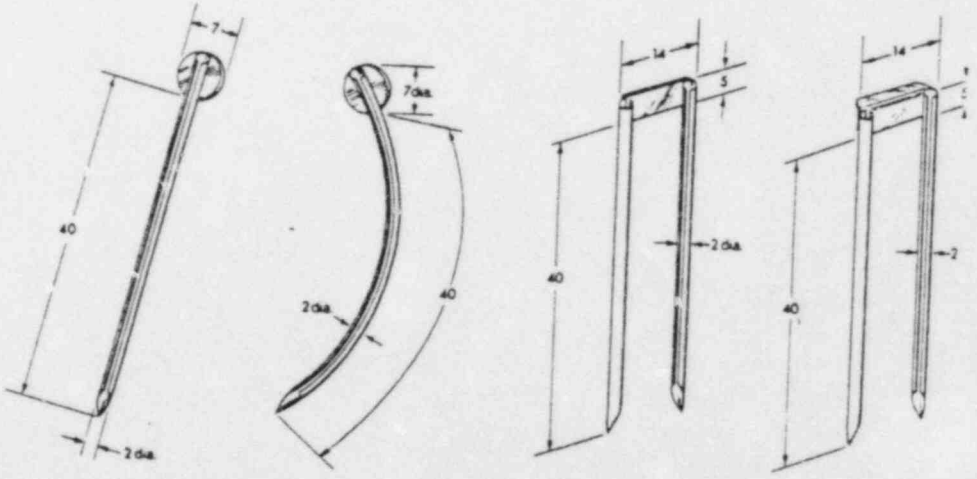
process is explained more thoroughly in the attached Technical Bulletin and the general mode of assembly is shown below.



dimens. in mm

The second type of wire has a larger diameter, being around 0.6 mm. This material is sufficiently rigid to be inserted directly into the tissue with the aid of steel guide pins. A whole range of accessories is available to facilitate insertion of the active pins and some types are illustrated below.

dimensions in mm



In these latter types of application, the wire is not encased in plastic tubing and it is not necessary to cut the wire since it is supplied in shapes which are designed to fit directly into the guides.

Packaging

Various packaging combinations are used depending on the type of source wire enclosed. The packaging is not intended for long term storage, nor is it intended for re-use.

The wire is enclosed in the container in one of several ways. The stiff 0.6 mm diameter wire is wrapped individually in aluminum envelopes and packaged in screw-top aluminum containers. Each container fits into a lead pot which is mounted in a sealed can. The can is mounted in a polystyrene drum and the whole package conforms to U.S. DOT requirements for type A packages.

The 0.3 mm diameter wire is coiled and loaded into a plastic pot which fits inside a lead container. The rest of the packaging is as for the 0.6 mm diameter material.

Labelling

Individual wires are not marked in any way since there is insufficient space to do this. The inner container which the sources are delivered in is labelled as shown opposite.

The outer container which carries the shipment is marked in accordance with the requirements of the U.S. DOT for type A containers.

Handling Instructions

Each unit is accompanied by a set of handling instructions (attached) and also by a copy of Technical Bulletin 78/4. These documents describe the use of iridium 192 wires and pins. In addition a copy of the handling instructions for using iridium wire in two common types of loading equipment are included. The warning label on the transport packaging warns users to read these data sheets carefully before using the material.

Conditions of Use

The device is intended specifically for medical use and exclusively for use in a medical environment. It should be stored, locked, in a restricted area. This device should be used only by competent persons trained in the techniques for which it is required.

Prototype Testing

This material is not regarded by Amersham as sealed, in that it cannot be guaranteed to meet the requirements of less than 5 nCi removable contamination. In consequence, prototype testing to ANSI standards is inappropriate.

Radiation Measurements

The maximum amount of material which a hospital physicist might normally have exposed at one time is 200 mCi. This amount of material would generate a doserate field of the order of that indicated below:

Doserate	Distance
5 cms	35 R/hr
30 cms	1 R/hr
100 cms	90 mR/hr

However, these figures should not be used for planning patient dosimetry. The dosimetry of iridium wire is complex and is dealt with in a number of theoretical papers. (Hall, Oliver, & Shepstone, 1966; and Pierquin, Dutreix, Paine, Chassagne, Marinello and Ash, 1978). The customer is provided with a simple test report (attached) detailing radiation measurements on the material.

Quality Control

All materials used in the fabrication of this product are checked against suppliers specifications prior to manufacture. Finished sources are checked to ensure that removable contamination is not excessive.

Additional Information

This product is not regarded by Amersham as being a sealed source in that it cannot be guaranteed to pass the sealed source wipe test requirements at the time of use. The reason for that is that the product is manufactured by neutron irradiation and the casing of the wire becomes activated to a slight extent. The material used for this casing is pure platinum and this material has been chosen because the activation effect is minimized.

Wipe testing has been performed on both types of iridium-192 wire at the time when the product would normally be released to the customer. In the case of the thicker (0.6 mm diameter) wire, wipe tests revealed removable contamination at around the 2 nCi level. In the case of a typical 50 cm length of wire which might be used for flexible implantations, the amount of removable contamination was between 40 nCi and 50 nCi.

In both cases, the isotopic contaminants were short half-life. About half of the removable contamination exhibited a half life of 2.5 days and the other half showed a half life of around 15 days. No gamma radiation was emitted by these contaminants. Although the presence of this contamination is undeniable and unavoidable, it is considered that the very short half life and low energy of the contaminant isotopes does not represent a serious problem.

Although these sources cannot be subjected to prototype testing in the normal way, they have been through some ANSI simulation tests.

Both the iridium wire and the iridium pins have achieved ANSI performance ratings of C53312 where the criterion for passing was defined as being no significant deterioration in the removable contamination test compared with untested sources. Similarly, all types of wire have passed bend tests in which they were bent around a 2 mm diameter pin and then straightened again.

This product has been in common usage for over 10 years in many hospitals throughout the world including broadly licensed hospitals in the United States. Publications on this subject are attached including:

Paine	(1972)
Paine	(1977)
Pierquin, Chassagne and Cox	(1971)
Malaker, Ellis and Paine	(1976)
Durant and Ellis	(1973)
Payne	(1977)
Collins	(1975)

Radioactive Source Test Report

Model No.: None Radioisotope: Iridium-192 Nominal activity: 60 millicuries

Description: Platinum clad iridium-192 wire (0.3mm diam. 300mm long) Capsule: N/A

ANSI Classification: Not assessed Special Form Certificate No.: None

Classifications are based on the testing of specimen sources and give the levels expected from production sources.

Recommended working life: Not assessed

See other side for explanation

Source Serial number	Measurement		Leakage test		Contamination test
	mR/hr at 1m per mm length	date (at 12.00 GMT)	type	type	type
			See other side for description of tests		
			date passed	date passed	date passed
None	0.0621	3 June 83			

Notes

Product code ICW 1120
Iridium wires are not sealed sources and notes overleaf do not apply.
The platinum cladding is slightly active and should be handled accordingly.

Customer: Milwaukee County Medical Center Customer's Order No.: 21018/R3274

Amersham Order No.: S00594

Signed: Date: June 6, 1983

Amersham Corporation
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005
(800) 323-6695/(312) 593-6300

In Canada
505 Iroquois Shore Road
Oakville, Ontario L6H 2R3
(800) 268-5061/(416) 842-2720

Amersham