Ru-106 Ophthalmic Plaques

Product Information

■ Long Lifetime
Ru-106/Rh-106 has a half life of 374 days and emits beta radiation with a maximum energy of 3.54 MeV. Therefore the plaque can be used multiple times within one year. The dose absorbed in tissue decreases after 7 mm to one tenth of its initial value. This steep dose fall-off protects sensitive structures and renders best treatment results for tumours with a height of up to 5 mm.

■ NIST Traceable Dosimetry
All plaques come with an extended calibration certificate. The certified reference dose rate is traceable to the National Institute of Standards and Technology, USA (NIST). The nominal value of the absorbed dose rate to water for every plaque type, newly defined as the dose rate at the reference point (at the plaque axis 2 mm from the surface), is 80 mGy/min corresponing to appr. 120 mGy/min (12 rad/min) on the surface.

■ Thin Plaque Design
The Ru-106/Rh-106 is encapsulated within pure silver sheets with a total thickness of only 1 mm. This allows very comfortable handling for the ophthalmologist. The applicator requires no assembly, only sterilization before usage. The plaque's surface is polished metal. All plaques are spherically shaped with a radius of 12 to 14 mm and have special eyelets to be sutured to the sklera.

The radiation window on the concave side is an 0.1 mm silverfoil. The backing acts as radiation shield. It absorbs approximately 95% of the beta radiation.

■ Accessories
Dummy plaques: inactive plaques from acrylic glass or pure silver to help to position the plaque and the sutures.
Diaphanoscope: fibre optic light source to illuminate the eye ball and make the tumour visible as a dark spot or shade on the eyeball. This helps to properly position the plaque above the tumour.
Safety Container: for shielded steam sterilization and transport of eye plaques in your clinic.
Plaque Simulator Software: to simulate eye plaque brachytherapy (Ru-106, I-125, Pd-103 and Ir-192 with BEBIG, COMS, ROPES, USC and custom made plaques).
The available types are given in the table on the right. The geometric shapes of the applicators are outlined in figure 2.

<table>
<thead>
<tr>
<th>Type</th>
<th>Diameter</th>
<th>Height</th>
<th>Radius</th>
<th>Number of eyes</th>
<th>Angle between eyes</th>
<th>Order code for active plaques</th>
<th>Order code for acrylic dummies</th>
<th>Order code for silver dummies</th>
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<tbody>
<tr>
<td>CCZ</td>
<td>11.6</td>
<td>2.3</td>
<td>12</td>
<td>2</td>
<td>180°</td>
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<td>ACD.A21</td>
<td>AGD.A21</td>
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<td>CCY</td>
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<td>2.3</td>
<td>12</td>
<td>3</td>
<td>120°</td>
<td>Ru6.A02</td>
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<td>AGD.A21</td>
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<td>2.3</td>
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<td>12</td>
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<td>CGD</td>
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<td>6.1</td>
<td>13</td>
<td>3</td>
<td>90°/145°</td>
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<td>ACD.A27</td>
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<td>8.0</td>
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<td>12</td>
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<td>ACD.A29</td>
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<tr>
<td>COD</td>
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<tr>
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<td>CIB-2</td>
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</tbody>
</table>

*) Active diameter for CXS: 7.7 mm

On request plaques are produced with a slot on the convex side to hold a suturing belt.

Used plaques, for which the life time of 1 year has expired, can be returned to BEBIG for a fee.

Application

For different applications there are 16 plaque types available, shown in figure 2.

- **Uveal and choroidal melanomas:** CCA, CCB, CCC, CCD and CGD
- **Retinoblastoma:** CCX, CCY, CCZ and CXS
- **Ciliary body melanomas or melanomas close to the iris:** CIA, CIB, CIB-2
- **Tumours close to the optical nerve:** COB, COD, COE and COC

This information is not sufficient for a safe and secure handling of the product. Please refer to the Instructions for Use.

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Plaque Simulator

- Interactive 3D treatment simulation
- For BEBIG Ru-106 plaques, I-125, Pd-103 and Ir-192 plaques
- Creates precise 3D and 2D models of both eye and tumor
- Optionally works with CT and/or MR images, fundus camera photographs and ultrasound studies
- Isodose calculation and display in 3D and 2D
- Regular updates available

**Application**

Plaque Simulator is a 3D treatment simulation and modeling package for Ru-106, I-125, Pd-103 and Ir-192 plaque therapy of ocular tumors and macular degeneration.
Plaque Simulator

General Information

BEBIG Plaque Simulator is the substantially enhanced and updated commercial adaptation of the interactive three dimensional treatment planning system for ophthalmic plaque radiotherapy developed by Melvin Astrahan and others at the University of Southern California School of Medicine. It has seen continuous clinical use since 1989. It supports the isotopes Ru-106, I-125, Pd-103 and Ir-192.

Plaque Simulator optionally uses measurements derived from CT and/or MR images, fundus camera photographs and ultrasound studies to build visually realistic and spatially precise three dimensional models of the patient’s eye and tumor. Plaque Simulator comes with detailed “ready-to-go” 3D models of most plaques manufactured by BEBIG, ROPES and Trachsel (COMS plaques), including notched plaques.

Plaque Simulator calculates and graphically displays physical parameters including suture eyelet location, distance from anatomic landmarks and dosimetric parameters such as radiation collimation, dose rate, dose volume, isodose lines and isodose surfaces. The software allows you to simulate the treatment process down to the finest details, resulting in fast surgery and highly conformal dose distributions.

Plaque Simulator is well suited to support most administrative tasks and documentation requirements and is currently the dosimetry simulation program most widely used among ophthalmic oncologists worldwide.

Hardware Requirements

The current version 4 of Plaque Simulator is intended for a PowerMac G3 or G4, iMac, iBook or Powerbook G3 or G4 computer running MacOS 9.1. Plaque Simulator will also run on most older MacOS compatible computers that have a PCI bus, 64MB RAM, an ATI 3D accelerator and that can run MacOS 8.5 or greater.

Further Information and Download of Demo Versions

http://radonc.usc.edu/USCRadOnc/Downloadable/plaquesimulator.html or http://www.bebig.de

Plaque Simulator BEBIG Order no. 000 390

Please note: Plaque Simulator is not medical software in the sense of, for example, FDA regulations, and therefore does not relieve physicians, physicists or dosimetrists from any of their dosimetric responsibilities or liabilities.

The information given above is not sufficient for safe handling of the product. For more detailed information please refer to the instructions for use.

Rev. 06/2001

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BEBIG IsoSeeds® I-125 for medical use (I25.S16) are mostly applied for treatment of uveal melanoma, retinoblastoma, and other special applications. IsoSeeds® I-125 contain a cylindrical-shaped ceramic saturated with an iodine-125 compound, which is enclosed by a laser-welded titanium tube.

- **Application**
  For treatment with IsoSeeds® I-125 additional accessories are required. The seeds are suitable for all common ophthalmic seed-applicators.

- **Planning**
  Treatment planning of an assembled set of seeds is based on the seed data according to the AAPM TG-43 formalism. The applicator influence on the effective dose rate distribution has to be considered.

- **Calibration**
  The source strength certified is traceable to the NIST primary air kerma strength standard.

- **Packaging**
  IsoSeeds® I-125 for medical use are supplied non-sterile in a special transport container.

- **BEBIG accessories for eye plaque radiotherapy**
  Dummy plaques: inactive plaques from acrylic glass or pure silver to help to position the plaque and the sutures.

  Diaphanoscope: fibre optic light source to illuminate the eye ball and make the tumour visible. This helps to properly position the plaque on the tumour.

  Safety container: for shielded steam sterilisation and transport of loose I-125 seeds in your clinic.

  Plaque Simulator software: to simulate eye plaque brachytherapy with BEBIG Ru-106-plaques as well as I-125-, Pd-103-, and Ir-192-seeds.
IsoSeeds® I-125 are brachytherapy sources based on the isotope above with a half-life of 59.40 days. It decays as a result of electron capture by emission of X-rays and γ-radiation in the energy range up to 35 keV. The electrons emitted during this decay will be absorbed by the titanium capsule material.

**Order values**

IsoSeeds® I-125 for medical use are offered by BEBIG in 14 ranges of apparent activity from 0.20 mCi to 25 mCi (see table). These ranges serve as order value for the seed batch to produce.

**Source strength**

The air kerma strength of every IsoSeed® I-125 is measured individually and converted into apparent activity. The standard deviation corresponding to the mean value of the batch is less than ±7%.

**ISO-classification**

IsoSeeds® I-125 are classified in accordance with ISO 2919 as C 63211.

**Expiring date**

The application period for IsoSeeds® I-125 is limited to maximum 6 months after the date of manufacture.

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COMS Eye Applicators

Product Information

COMS Eye Applicators are a reliable and proven tool for I-125 ophthalmic tumour treatment.

**Indication**
For brachytherapy of primary malignant intraocular tumours, such as uveal melanomas, especially with higher thickness, COMS Eye Applicators are a proven treatment option.

**Application**
COMS Eye Applicators (plaques) have been developed in connection with the Collaborative Ocular Melanoma Study. The set of models selected by Eckert & Ziegler BEBIG ensures a good match to individual tumour sizes.

**Defined Geometry**
Positioning of I-125 seeds is well defined using COMS plaques, ensuring good reproducibility in assembling and an accurate dosimetry input. This leads to higher quality treatment planning with loose seeds in comparison with custom made seed applicators.

**User Friendly**
COMS Eye Applicators are available in 5 different sizes with diameters of: 12, 14, 16, 18 and 20 mm. The applicators consist of a gold plaque shell combined with a silicon insert with an optimised slot pattern. The seeds can be easily attached to the slots – no glue is necessary for fixation. This saves time and reduces unintentional exposure.

**Cost Efficient**
The plaque shells can be reused for several years. The seeds may also be reused within a time frame, determined by the source strength.

**Accessory Diaphanoscope**
This fibre optic light source is equipped with two different probes. Both transillumination probes are optimised to aid the ophthalmologist in positioning the applicator.
**COMS Inserts – Slots**

The illustration below shows the configuration of the slots in each insert. The number of slots per insert depends on the diameter of the applicator (see table above). This number corresponds to the maximum number of seeds which can be positioned in the respective applicator.

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**COMS Eye Applicators**

**COMS Plaque Shells Set No. 1222-0901**

<table>
<thead>
<tr>
<th>Article No.</th>
<th>Item Description</th>
<th>Pcs./Set</th>
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<td>1222-0002</td>
<td>COMS Plaque Shell, d=12 mm</td>
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<td>1222-0003</td>
<td>COMS Plaque Shell, d=14 mm</td>
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<tr>
<td>1222-0004</td>
<td>COMS Plaque Shell, d=16 mm</td>
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<tr>
<td>1222-0005</td>
<td>COMS Plaque Shell, d=18 mm</td>
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<tr>
<td>1222-0006</td>
<td>COMS Plaque Shell, d=20 mm</td>
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</table>

All parts of the set can be ordered separately.

**COMS Inserts**

<table>
<thead>
<tr>
<th>Article No.</th>
<th>Item Description</th>
<th>No. of Slots</th>
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</tr>
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COMS inserts are for single use only.

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