

Ru-106 Ophthalmic Plaques

Product Information

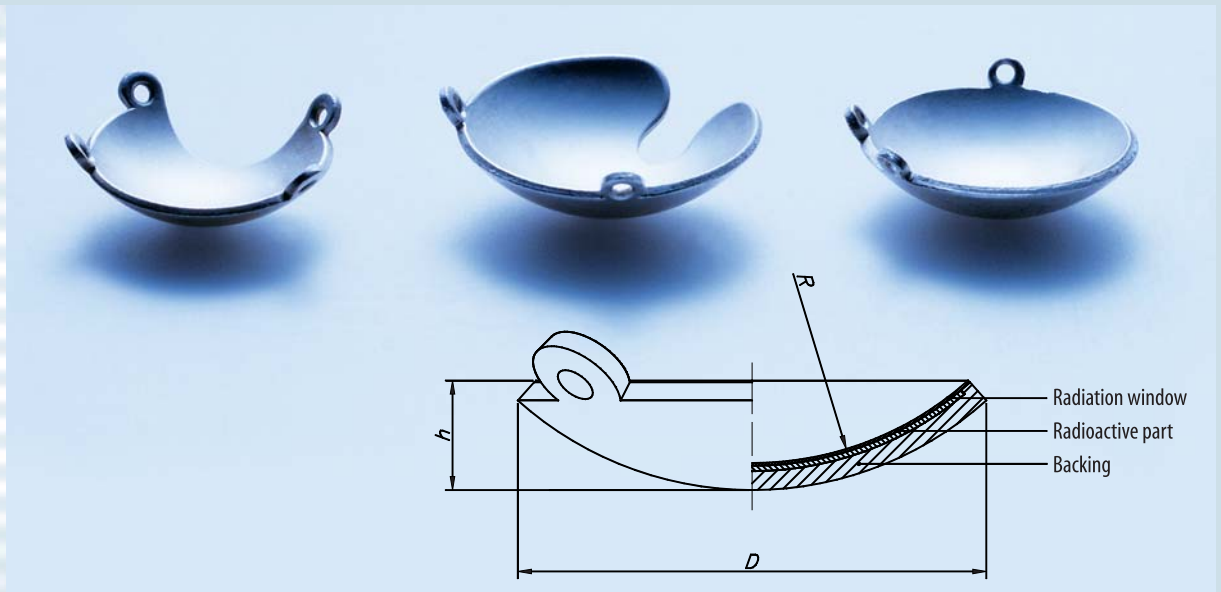


Figure 1:
Scheme of a Ru-106
Ophthalmic Plaque

BEBIG Ruthenium-106 ophthalmic plaques are used for treatment of uveal melanoma, retinoblastoma, melanoma of the iris and other special applications for more than 30 years now. The plaques consist of a thin film of Ru-106, a beta emitter, encapsulated in pure silver.

■ 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 corresponding 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 sclera. 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).

Ru-106 Ophthalmic Plaques

The available types are given in the table on the right. The geometric shapes of the applicators are outlined in figure 2.

Type	Diameter D mm	Height h mm	Radius R mm	Number of eyes	Angle between eyes	Order code for active plaques	Order code for acrylic dummies	Order code for silver-dummies
CCZ	11.6	2.3	12	2	180°	Ru6.A01	ACD.A21	AGD.A21
CCY	11.6	2.3	12	3	120°	Ru6.A02	ACD.A21	AGD.A21
CCX	11.6	2.3	12	2	90°	Ru6.A03	ACD.A23	AGD.A23
CXS	11.6*	2.3	12	2	90°	Ru6.A033	ACD.A23	AGD.A23
CCA	15.3	3.3	12	2	90°	Ru6.A04	ACD.A24	AGD.A24
CCD	17.9	4.3	12	2	90°	Ru6.A05	ACD.A25	AGD.A25
CCB	20.2	5.4	12	2	90°	Ru6.A06	ACD.A26	AGD.A26
CGD	22.3	6.1	13	3	90°/45°	Ru6.A07	ACD.A27	AGD.A27
CCC	24.8	8.0	13	2	90°	Ru6.A08	ACD.A28	AGD.A28
COB	19.8	5.2	12	2	90°	Ru6.A09	ACD.A29	AGD.A29
COD	25.4	7.5	14	2	90°	Ru6.A10	ACD.A30	AGD.A30
COE	19.8	5.2	12	2	90°	Ru6.A11	ACD.A31	AGD.A31
COC	25.4	7.5	14	2	90°	Ru6.A12	ACD.A32	AGD.A32
CIA	15.3	3.3	12	2	180°	Ru6.A13	ACD.A33	AGD.A33
CIB	20.2	5.4	12	2	180°	Ru6.A14	ACD.A34	AGD.A34
CIB-2	20.2	5.4	12	4	120°/60°	Ru6.A15	ACD.A35	AGD.A35

*) Active diameter for CXS: 7.7 mm

Figure 2: 16 types of Ru-106 ophthalmic plaques. The radioactive area is marked hatched.

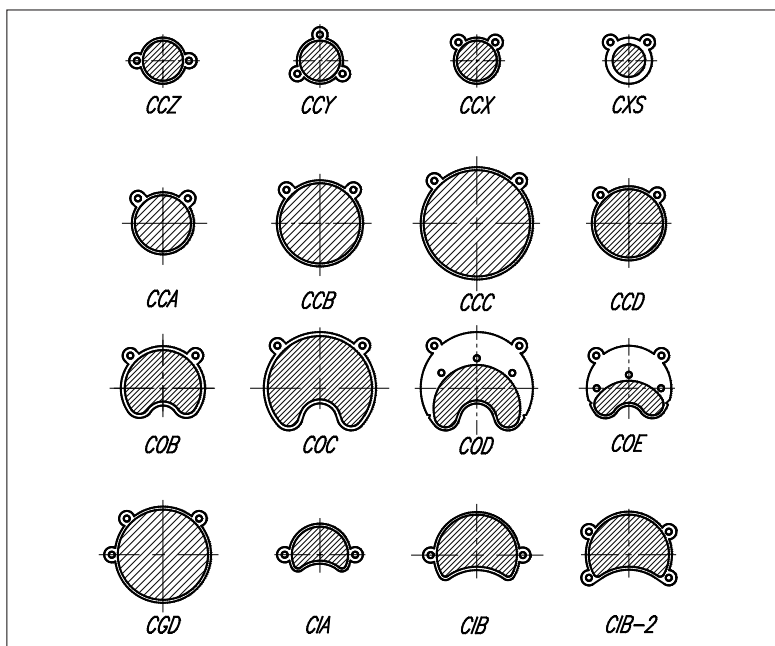
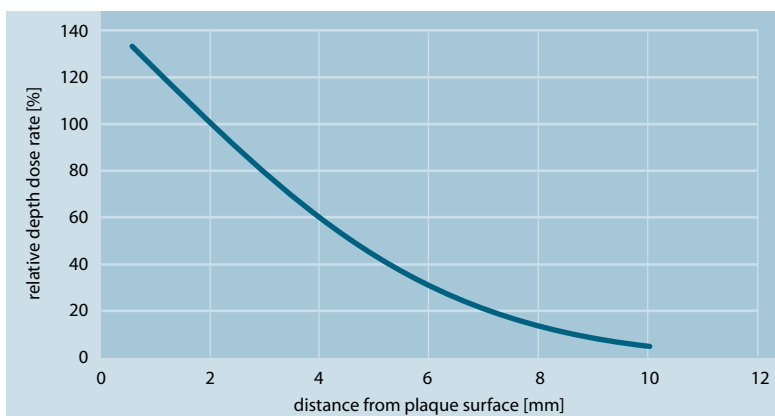


Figure 3: Typical relative depth dose of a CCB plaque



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.

Eckert & Ziegler BEBIG GmbH

Robert-Rössle-Strasse 10
13125 Berlin
Germany
www.ezag.com

Telephone +49 (0) 30 94 10 84-130
Telefax +49 (0) 30 94 10 84-260
E-Mail bebig@ezag.de

Plaque Simulator

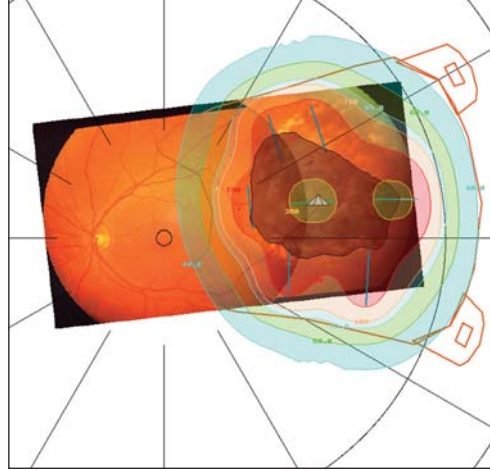


- Interactive 3D treatment simulation
- For BEBIG Ru-106 plaques, I-125, Pd-103 and Ir-192 plaques
- Creates precise 3D and 2D models of both eye and tumor
- Optionally works with CT and/or MR images, fundus camera photographs and ultrasound studies
- Isodose calculation and display in 3D and 2D
- Regular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

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. 07 / 05.2008

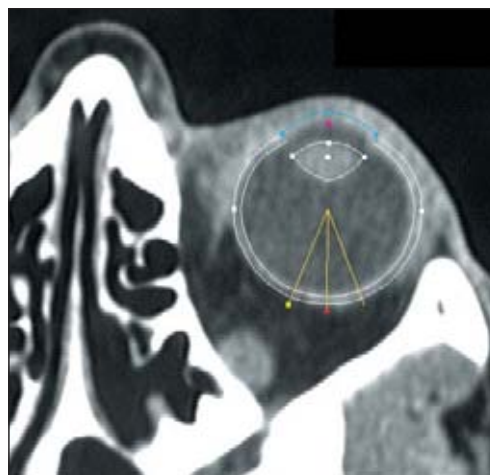
Hardware Requirements

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



Eckert & Ziegler BEBIG GmbH

Robert-Rössle-Straße 10
13125 Berlin, Germany
www.ezag.com
Tel. +49 (0) 30 94 10 84 - 0
Fax +49 (0) 30 94 10 84 - 112
E-Mail: bebig@ezag.de

I-125 Ophthalmic Seeds

Product Information



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 certified source strength 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

COMS Applicators: reusable gold COMS plaque shells and silicon COMS inserts provide defined seed positions for each treatment.

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.

Plaque Simulator software: for training and demonstration of eye plaque brachytherapy with I-125 seeds.

I-125 Ophthalmic Seeds

■ IsoSeed® I-125 details

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.

■ 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 $\pm 7\%$.

■ Activities available

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.

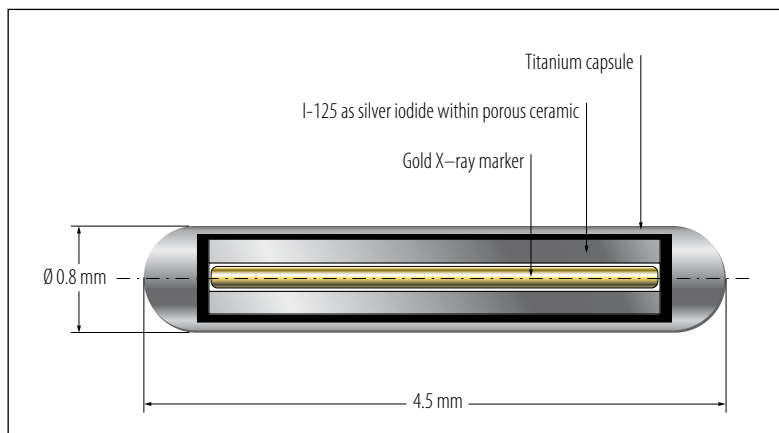
■ ISO-classification

IsoSeeds® I-125 are classified in accordance with ISO 2919 as C63211.

■ Expiring date

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

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



■ IsoSeed® I-125 details

Range	Air kerma strength in $\mu\text{Gy m}^2/\text{h}$	Apparent activity in mCi	Apparent activity in MBq
A01	0.25 – 1.96	0.2 – 1.5	7.4 – 57
A02	1.97 – 3.23	1.6 – 2.5	58 – 94
A03	3.24 – 4.50	2.6 – 3.5	95 – 131
A04	4.51 – 5.77	3.6 – 4.5	132 – 168
A05	5.78 – 7.04	4.6 – 5.5	169 – 205
A06	7.05 – 8.31	5.6 – 6.5	206 – 242
A07	8.32 – 9.58	6.6 – 7.5	243 – 279
A09	9.59 – 11.48	7.6 – 9.0	280 – 334
A10	11.49 – 13.39	9.1 – 10.5	335 – 390
A12	13.40 – 15.93	10.6 – 12.5	391 – 464
A14	15.94 – 18.47	12.6 – 14.5	465 – 538
A17	18.48 – 22.28	14.6 – 17.5	539 – 649
A20	22.29 – 26.09	17.6 – 20.5	650 – 760
A25	26.10 – 31.75	20.6 – 25.0	761 – 925

■ Activities available

Eckert & Ziegler BEBIG GmbH

Robert-Rössle-Strasse 10
13125 Berlin
Germany
www.ezag.com

Telephone +49 (0) 30 94 10 84-130
Telefax +49 (0) 30 94 10 84-112
E-Mail bebig@ezag.de

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 Eye Applicators

■ COMS Plaque Shells Set No. 1222-0901

Article No.	Item	Pcs./Set
1222-0002	COMS Plaque Shell, d=12 mm	1
1222-0003	COMS Plaque Shell, d=14 mm	1
1222-0004	COMS Plaque Shell, d=16 mm	1
1222-0005	COMS Plaque Shell, d=18 mm	1
1222-0006	COMS Plaque Shell, d=20 mm	1

All parts of the set can be ordered separately.

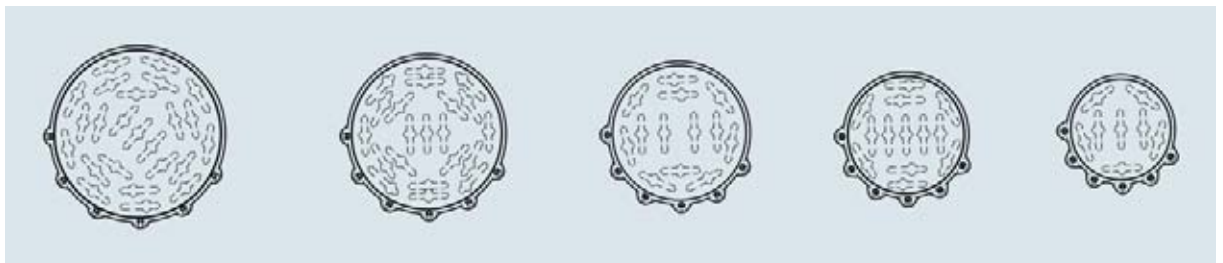
■ COMS Inserts

Article No.	Item	No. of Slots
1222-0102	COMS Insert, d=12 mm	8
1222-0103	COMS Insert, d=14 mm	13
1222-0104	COMS Insert, d=16 mm	13
1222-0105	COMS Insert, d=18 mm	21
1222-0106	COMS Insert, d=20 mm	24

COMS inserts are for single use only.

■ 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.



COMS applicators with inserts.

CE 0044

72200-0170 / Rev. 03 / 05.2008

**Eckert & Ziegler
BEBIG GmbH**

Robert-Rössle-Strasse 10
13125 Berlin
Germany
www.ezag.com

Telephone +49 (0) 30 94 10 84-130
Telefax +49 (0) 30 94 10 84-112
E-Mail bebig@ezag.de