

Ophthalmic Brachytherapy

Inherent precision

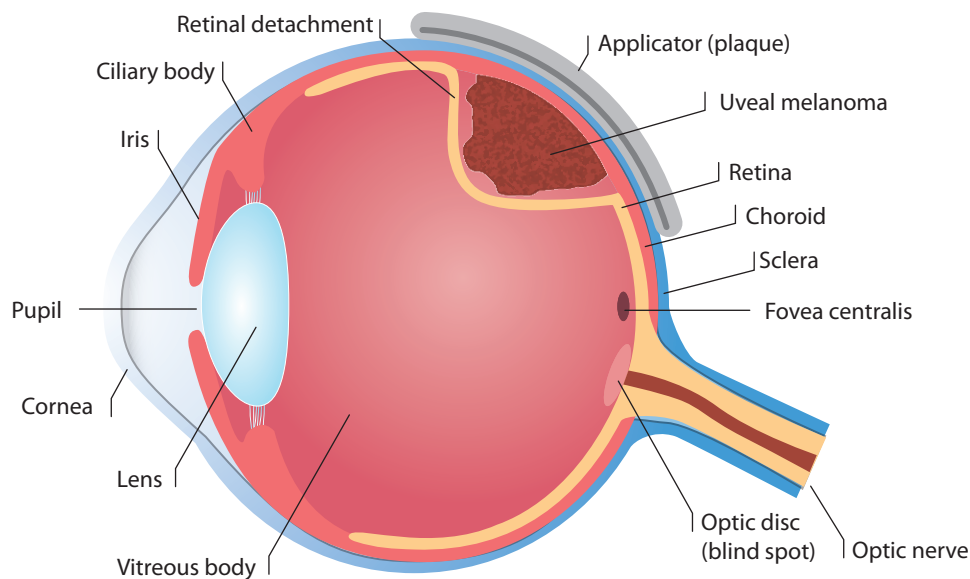


Ru-106 Eye Applicators and
I-125 Ophthalmic Seeds

Brachytherapy for Eye Tumors

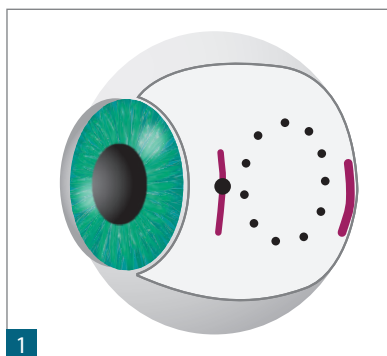
Ophthalmic Brachytherapy

The treatment of ocular tumors is selected according to the size and location of the lesion. Whenever possible, conservation of the eye and vision is attempted. In many centres, brachytherapy is the first choice of treatment for uveal melanomas. This modality is also useful for some retinoblastomas and conjunctival tumors. With this form of radiotherapy, a radioactive plaque containing ruthenium-106 or iodine-125 is sutured to the wall of the eye, adjacent to the tumor, and left in place for several days until the required dose of radiation has been delivered.

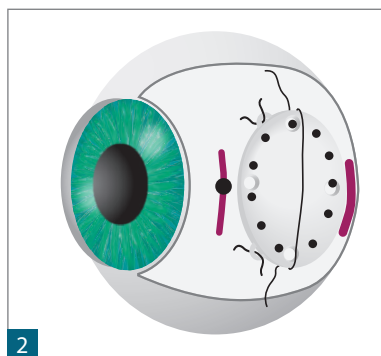


Example of tumor localization within the eye and positioning of an eye applicator

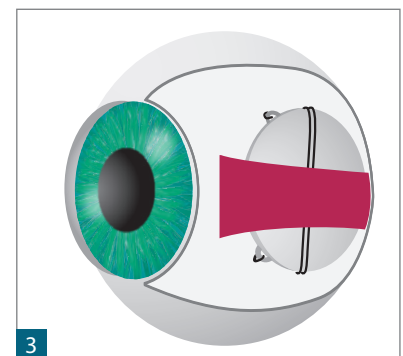
Steps of Ophthalmic Brachytherapy



The conjunctiva is opened and the tumor is located by transillumination. The tumor margins and the intended location of the anterior plaque edge are marked on the sclera. If necessary, any overlying extraocular muscles (red) are disinserted.



The dummy plaque (template) is positioned according to the scleral ink marks and sutured to the sclera by releasable sutures placed through the eyelets of the dummy. The position of the dummy in relation to the tumor is assessed by using a right-angled transilluminator while performing binocular indirect ophthalmoscopy. Once the dummy is well positioned, a mattress suture is inserted but left loose.



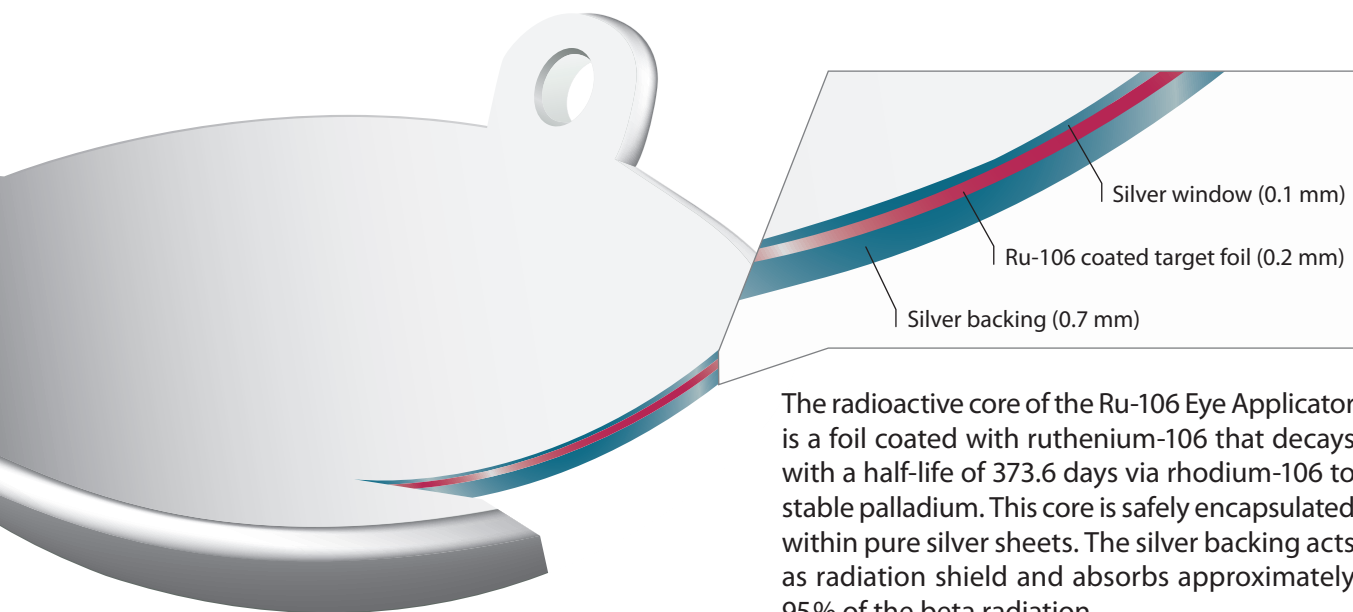
The sutures are untied but left in place. The dummy is removed and replaced by the radioactive plaque, which is secured using the same sutures as the template. All sutures are fastened. Any dis-inserted rectus muscles are re-positioned and the conjunctiva is closed.

Ru-106 Eye Applicators

First Choice Treatment with Ergonomic Design

For more than 30 years, ophthalmologists have favored Ru-106 Eye Applicators because of their superior design and technical features. Owing to the long half-life of Ru-106, the applicators can be used many times over a one year period. They require no assembly, just sterilization before use. Up to 50 cycles are permitted. With their slim design, they are particularly suitable for treating children.

- 16 types for individual tumor match
- Steep dose fall-off spares organs at risk
- Reusable for one year
- Provided exclusively by Eckert & Ziegler BEBIG



Beneficial Beta Radiation Spares Organs at Risk

The beta radiation emitted by Ru-106/Rh-106 has a maximum energy of 3.54 MeV resulting in an advantageous steep dose fall-off. The autoradiography clearly demonstrates that the dose distribution is ideal for treating tumors with a thickness of up to 5 mm. The gamma radiation emitted by Rh-106 contributes with about 1% only negligibly to the total dose in the target volume.



Autoradiography by courtesy of Prof. Lommatzsch showing the characteristic steep dose fall-off.

“ As in most centres, the first choice for treating choroidal melanoma at the Liverpool Ocular Oncology Centre is brachytherapy. Ru-106 plaques have been used there since the service was established, in 1993, with excellent results. Ru-106 offers a particularly limited range of beta radiation, delivering a sufficient dose to the tumor while minimizing collateral damage to healthy parts of the eye. ”

Prof. Bertil Damato is former president of ISOO, OOG and EVER. As an ophthalmic surgeon he specialized in the treatment of adult ocular tumors since 1984 and established the Ocular Oncology Service in Liverpool in 1993, leading it for 20 years. His main research interests relate to ocular melanoma and include the development of novel therapies, prognostication and quality of life studies.

Ru-106 Eye Applicators

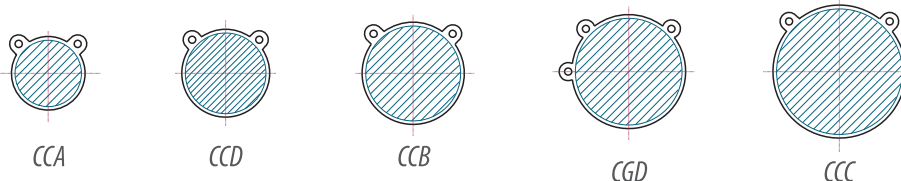
Availability of 16 Different Applicator Types

The applicators are available in 16 different types, to tailor the treatment to each individual tumor according to size and location. The plaques are curved, with a radius of 12 to 14 mm, and have eyelets for suturing them to the sclera. The diameter of the applicators varies from 11.6 to 25.4 mm.

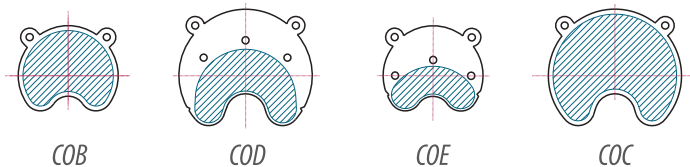
Retinoblastoma



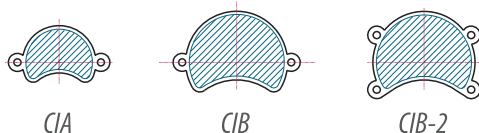
Peripheral uveal/choroidal melanoma



Tumors close to the optical nerve



Ciliary body melanomas or melanomas close to the iris



16 types suggested for different tumor sites and sizes

Slot for Mattress Suture

When placing a radioactive plaque special care must be taken to ensure that the entire applicator is firmly in contact with the sclera. For this reason, the plaques have 2 to 4 eyelets depending on the plaque type. In addition, it may be necessary to prevent any tilting of the applicator by placing a so-called 'mattress suture' over the applicator. If requested, some plaque versions can be produced with a slot on the convex surface of the applicator to facilitate the position of this suture. This applies for CCA, CCD, CCB, CGD, CCC and COB.



Source Strength and NIST Traceable Dosimetry

All plaques come with an extensive individual calibration certificate. The source strength is defined by the reference dose rate measured in the plaque axis at a distance of 2 mm from the applicator surface. Its absolute calibration is traceable to the National Institute of Standards and Technology, USA (NIST).

Ru-106 Eye Applicators

Dummies for Improved Accuracy

Selection of Acrylic Dummies: Damato Template and regular CIB



Selection of Silver Dummies: Type CIA and CCB

Reusable Acrylic or Silver Dummies help to optimize the positioning of the Ru-106 Eye Applicators. They are available for all 16 versions of the plaque.

The Damato Templates offer an additional feature: Four holes allow checking the position of the template with respect to the tumor by inserting the tip of a fine right-angled transilluminator through each hole and observing its location by indirect ophthalmoscopy. These special Acrylic Dummies are available for the applicator types CCA, CCB and CCC.

Safety and Sterilization Container

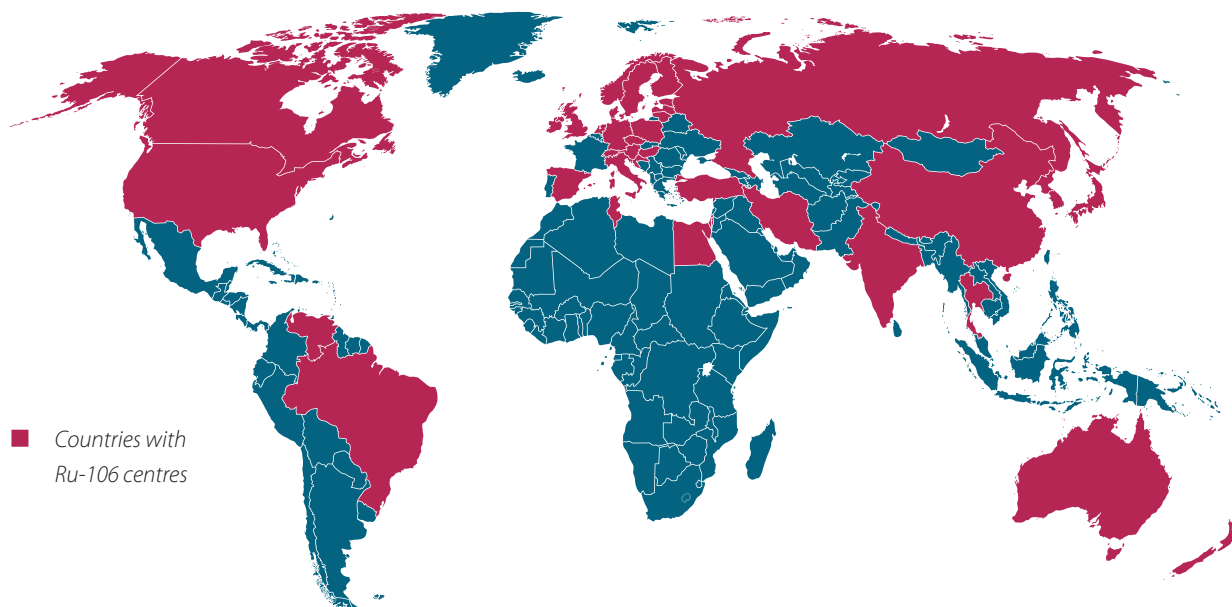


This specialized container combines an aluminum insert and an outer stainless steel shield for optimized shielding of beta and gamma radiation. It facilitates safe and convenient steam sterilization and transport of Ru-106 Eye Applicators within the clinic. Neither for the treatment room nor for the storage are any structural measures required.

Steam sterilization	
Temp	134 °C
Pressure	3 bar
Duration	5 min

Eckert & Ziegler BEBIG: The ONLY Global Supplier for Ru-106 Eye Applicators

Every single applicator is produced, tested and certified in Berlin, Germany, according to high quality standards.

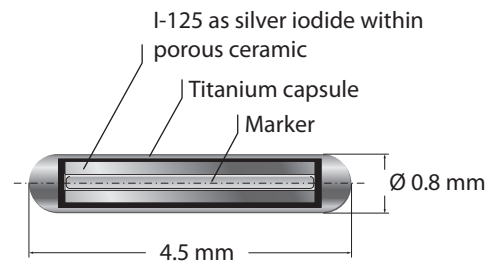


I-125 Ophthalmic Seeds and COMS Eye Applicators

IsoSeed® I25.S16

With a maximum photon energy of 35 keV, iodine-125 is suitable for treating medium and large uveal melanomas and retinoblastomas, with an apex height of up to 10 mm. IsoSeed® I25.S16 is available in a wide range of apparent activities up to 25 mCi, according to clinical requirements. The number and location of seeds on each plaque can be adjusted to tailor the dosimetry to each individual tumor. They can be reused for up to 6 months, depending on the activity.

- **Treatment of even medium and large tumors**
- **For use with COMS or individual applicators**



IsoSeed® I25.S16 details

COMS Applicators

For application, IsoSeed® I25.S16 can be inserted via silicone inserts into COMS Plaque Shells, both available from Eckert & Ziegler BEBIG in different sizes.

After steam sterilization, the individually assembled COMS Applicator is ready for use.



Silicone COMS insert allows for reproducible seed positioning.

COMS Plaque Shell made of a gold alloy that serves as carrier and shield.

Calibration Traceable to PTB

The certified source strength is based on air kerma measurement of IsoSeed® which is calibrated traceable to the primary standard of the National Metrology Institute of Germany PTB (Physikalisch Technische Bundesanstalt).

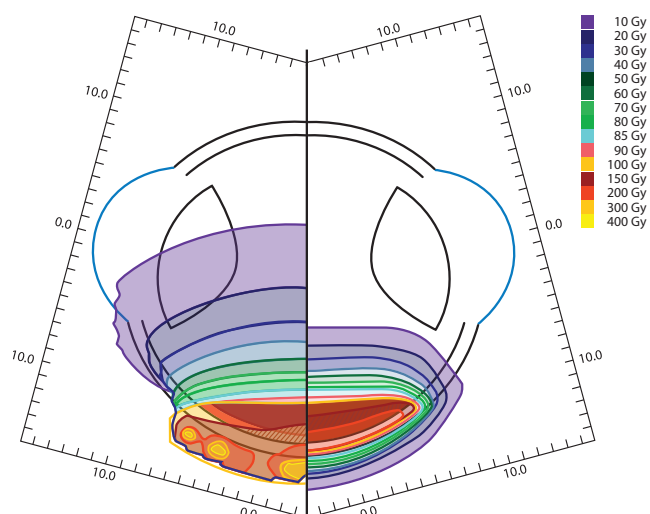
PTB as well as NIST (National Institute of Standards and Technology) are members of the Mutual Recognition Agreement.

IsoSeed® I25.S16 is also suitable for other ophthalmic seed applicators.

Comparison of Ru-106 and I-125 Applicators

Dosimetric Comparison

A plot of the 2D dose distributions clearly shows the differences between Ru-106 and I-125 plaques. In their publication, Wilkinson et al. demonstrate that for the treatment of thin melanoma Ru-106 plaques generally deliver the dose to a smaller volume and with less side-scatter than I-125 plaques of the same size.



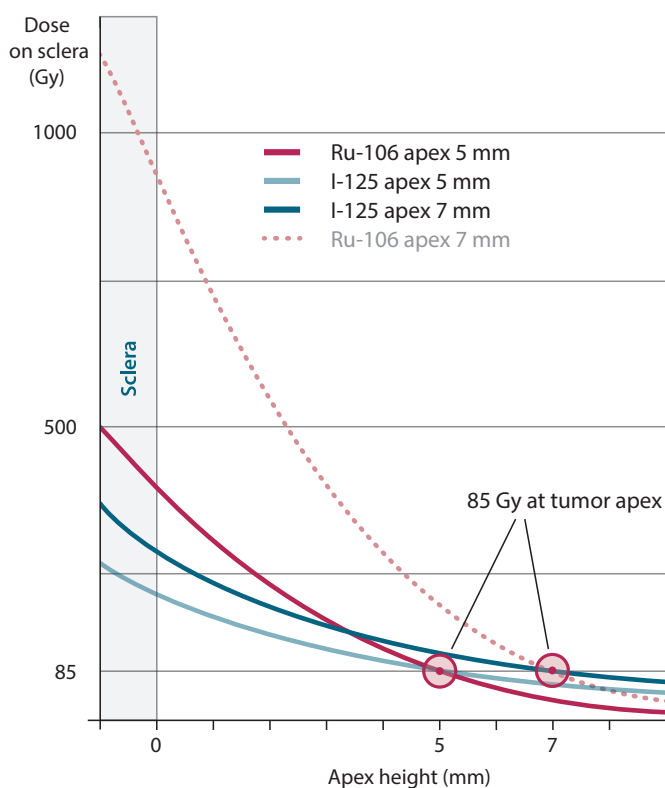
Comparison of the 2D dose distributions of two plaques with 18 mm diameter. Both planned with a dose of 85 Gy to the apex of a thin tumor. I-125 shown on the left and Ru-106 on the right.

Individual Advantages of Ru-106 and I-125

The graph of the dose-depth curves of Ru-106 and I-125 plaques of similar size clearly shows the individual advantages of the two nuclides. Ru-106 is characterized by a particularly steep dose fall-off, which allows delivery of a sufficient dose to the tumor while effectively sparing adjacent healthy tissue. Beyond a tumor thickness of 5 mm, I-125 provides a sclera dose within well-accepted limits.

“ In addition, for a given tumor, treatment modeling with a Ru-106 plaque gives statistically significant smaller doses to the optic disc and macula. This is advantageous when assessing the risks for radiation retinopathy and radiation optic neuropathy. ”

The British Journal of Radiology, 81 (2008), Comparison of Ru-106 and I-125 plaques for treatment of shallow choroidal melanoma lesions, Wilkinson DA, Kolar M, Fleming PA, Singh AD.



Dose depth curves for Ru-106 and I-125 plaques of similar sizes (CCB and COMS Ø20 mm). The solid lines illustrate the situation for a tumor with 5 or 7 mm apex height. The dashed line shows the theoretical values for a treatment with Ru-106 beyond 5 mm tumor thickness.

Eckert & Ziegler BEBIG Today

Eckert & Ziegler BEBIG is a European-based group active in the medical device segment of the health care industry. Its core business is the production and distribution of medical products for the treatment of cancer using brachytherapy. The company headquarters are in Belgium, with production facilities in Germany and in the USA, as well as subsidiaries throughout Europe, the USA, India and Brazil. In addition, Eckert & Ziegler BEBIG has a worldwide network of distributors and agents, to support the international marketing and distribution of its product line. The company's products and equipment are intended for use by oncologists, radiotherapists, urologists, ophthalmologists and medical physicists. Eckert & Ziegler BEBIG employs approximately 200 people. The company has been listed on the Euronext stock exchange since April 1997.



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