

I-125 Ophthalmic Seeds

Individual Eye Tumor Treatment with COMS Eye Applicators

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Eckert & Ziegler BEBIG's Ophthalmic Seed is an IsoSeed® I-125 (I25.S16) with a particularly high activity for eye tumor treatments.



COMS Eye Applicators provided by Eckert & Ziegler BEBIG offer exact seed positioning and accurate dose distribution.

Indication

IsoSeed® I25.S16 is used for the treatment of eye tumors, such as uveal melanomas and retinoblastomas. With apparent activities covering a wide range up to 25 mCi, it is even suitable for treating medium-sized to large eye tumors, opening up treatment options beyond Ru-106 Eye Applicators.

Application

IsoSeeds I25.S16 are delivered non-sterile. For application, they can be inserted via silicone inserts into COMS Plaque Shells, both available from Eckert & Ziegler BEBIG. After steam sterilization, the individually assembled COMS Applicator is ready for use. With IsoSeed® I25.S16, treatment planning is carried out based on the seed data of IsoSeed® I25.S06 according to the AAPM TG-43 formalism.

COMS Eye Applicator

COMS Eye Applicators were developed following the plaque therapy used in the Collaborative Ocular Melanoma Study. They are available in 5 different sizes, between 12-20 mm in diameter. For the treatment, the reusable gold COMS Plaque Shell is combined with a single-use silicone COMS Insert, individually loaded with IsoSeeds. The number of seeds needed for an implant depends on the size of the applicator and the respective loading scheme (see rear page for more details on slot positions). In order to fix the insert securely into

the plaque shell, a few droplets of adhesive silicone are placed directly on the inner rim of the shell. After subsequent steam sterilization, the applicator is ready for implantation.

Calibration

The certified source strength is based on air kerma measurements of IsoSeed® which are traceable to the primary standard of the PTB (Physikalisch-Technische Bundesanstalt = National Metrology Institute of Germany). Along with the NIST (National Institute of Standards and Technology), the PTB is a member of the Mutual Recognition Agreement.

Guaranteed Biocompatibility

The titanium capsule of IsoSeed® I25.S16 meets ASTM F67 requirements, and COMS Plaque Shells are also tested according to international standards. Silicone COMS Inserts are made from Silastic® MDX4-4210 BioMedical Grade Elastomer. These features ensure overall biocompatibility of both Eckert & Ziegler BEBIG Ophthalmic Seeds and COMS Eye Applicators.

„Made in Germany“ Quality

Our Ophthalmic Seeds and COMS Eye Applicators are manufactured in Germany in compliance with strict quality standards. Each single item has to pass an individual quality check at every production stage before proceeding to the next step. Eckert & Ziegler BEBIG is certified in accordance with ISO 13485.

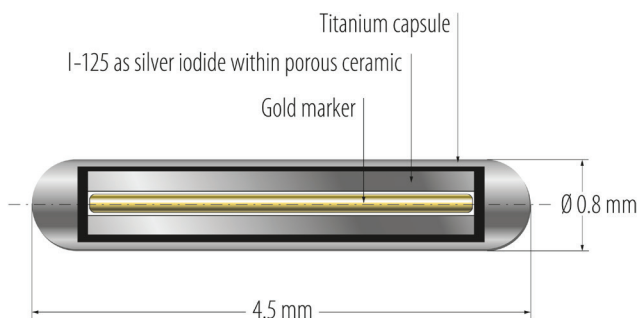


Eckert & Ziegler
Contributing to saving lives

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IsoSeed® I-125 (I25.S16) Details

IsoSeeds I25.S16 are brachytherapy sources based on iodine-125, with a half-life of 59.41 days. I-125 decays by electron capture, followed by the emission of γ -radiation and X-rays covering an energy range up to 35 keV. The electrons emitted during this decay are absorbed by the titanium capsule.



IsoSeed® I-125 (I25.S16) details

Source Strength

The air kerma strength of every IsoSeed® I25.S16 is measured individually and converted into apparent activity. The mean air kerma strength of the seeds of each individual batch is stated on the certificate. The maximum deviation corresponding to the mean value of the batch is less than $\pm 7\%$.

ISO Classification and Expiration Date

In accordance with ISO 2919, IsoSeed® I25.S16 is classified as C63X11. Eckert & Ziegler BEBIG Ophthalmic Seeds can be reused for up to 6 months, depending on the activity.

COMS Plaque Shells Set No. 1222-0901

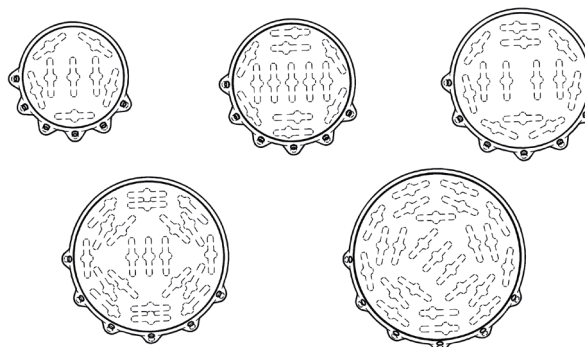
Article No.	Item	Pc./Set
1222-0002	COMS Plaque Shell, d=12 mm	1
1222-0003	COMS Plaque Shell, d=14 mm	1
1222-0004	COMS Plaque Shell, d=16 mm	1
1222-0005	COMS Plaque Shell, d=18 mm	1
1222-0006	COMS Plaque Shell, d=20 mm	1

All parts of the set can also be ordered separately

IsoSeed® I-125 Article No. I25.S16

Class Number	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

Activity classes



COMS Applicators showing the slot configuration of each insert

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

Silastic is a registered trademark of the Dow Corning Corporation. IsoSeed is a registered trademark of Eckert & Ziegler GmbH and its subsidiaries. The mentioned products are not available in all markets. Please contact your local Eckert & Ziegler BEBIG representative for more information.

Manufacturer:

**Eckert & Ziegler
BEBIG GmbH**
Robert-Rössle-Str. 10
13125 Berlin
Germany

Phone +49 30 94 10 84 130
Fax +49 30 94 10 84 112
info@bebig.com

Regional Sales, Marketing and Service:

Europe, Middle East, Africa,
Latin America, Asia Pacific

**Eckert & Ziegler
BEBIG GmbH**
Robert-Rössle-Str. 10
13125 Berlin
Germany

Phone +49 30 94 10 84 130
Fax +49 30 94 10 84 112
info@bebig.com

North America

**Mick Radio-Nuclear Instruments, Inc.
An Eckert & Ziegler BEBIG Company**
521 Homestead Avenue
Mount Vernon, NY 10550
USA

Phone +1 914 667 3999
Fax +1 914 665 8834
sales@micknuclear.com

www.bebig.com
www.micknuclear.com