LDR Prostate Brachytherapy

Hitting cancer on the spot

Dedicated solutions for real-time prostate seed implants

www.bebig.com

Eckert & Ziegler
Contributing to saving lives
Effective Treatment of Prostate Cancer

Prostate cancer is the second most frequent cancer in men worldwide, but can be treated very effectively when detected at an early stage. Prostate seed implantation, also called LDR (Low Dose Rate) prostate brachytherapy or permanent brachytherapy, is an effective and well-tolerated minimally invasive treatment option for early stage prostate cancer.

In this treatment, small radioactive iodine-125 sources, also known as seeds, are placed inside the prostate. Each seed has a length of 4.5 mm and a diameter of 0.8 mm and emits a specific low dose of radiation to the surrounding prostate tissue. By placing the seeds homogeneously throughout the organ, the prostate is covered with the designated dose required to destroy the cancerous cells. Since irradiation is mainly localized around the radioactive source, neighboring tissues are spared unnecessary damage.

The cure rates of LDR brachytherapy are comparable to those of external beam radiation therapy and prostatectomy for early stage prostate cancer. In the group of low risk patients, outcomes were even superior. LDR brachytherapy is known to have a favorable side effect profile with regard to both incontinence and impotence compared to prostatectomy, as well as with regard to gastrointestinal secondary effects compared to EBRT.

Patient Selection Criteria

Prostate seed implantation is especially suitable for patients with early stage prostate cancer. The cancerous tissue should be limited to the prostate gland. T1 and T2 tumors are designated as locally confined prostate carcinoma that can be classified as low-, intermediate- or high risk tumors.

1 Grimm et al, Comparative analysis of prostate-specific antigen free survival outcomes for patients with low, intermediate and high risk prostate cancer treatment by radical therapy. BJU Int. 2012 Feb; 109 Suppl 1: 22-9
3 Pardo, Y. et al, Quality-of-Life Impact of Primary Treatments for Localized Prostate Cancer in Patients Without Hormonal Treatment, J Clin Oncol. 2010 Nov 1; 28(31): 4687-96
We strongly believe in LDR brachytherapy as a safe and effective treatment for prostate cancer. It better preserves urinary continence, erectile and rectal function, in comparison with other treatment options and therefore results in an enhanced quality of life. Our company has established itself as a leading European LDR prostate brachytherapy provider with over 4 million seeds sold and 55,000 patients treated. Besides Europe, we have been selling our LDR prostate products throughout North and South America, Africa, Asia and Australia. “Made in Germany” quality combined with fast product delivery and reliable service defines our demand of being a full service LDR prostate brachytherapy provider.

Dr. Harald Hasselmann
Managing Director Eckert & Ziegler BEBIG

Eckert & Ziegler BEBIG offers a wide range of LDR prostate brachytherapy products with different types of sources, treatment planning software, on-site service, a comprehensive range of consumables and accessories, ultrasound and OR equipment, as well as tools for calibration and seed assay:

- Loose Seeds in Mick™ Magazines
- Stranded seeds
- Treatment planning software
- Consumables
- Ultrasound equipment
- Equipment for calibration and seed assay

“Since 2007, we have successfully performed almost 1,000 permanent seed implantations and received permanent outstanding service from Eckert & Ziegler BEBIG. All seeds have always been supplied on time and within the required specification.”

OUSA – Onkologický ústav sv. Alžbety (Oncological Institute of St. Elizabeth)
Brachytherapy Department
Bratislava, Slovakia
IsoSeed®: Well-established Seed Model

IsoSeed®
Loose Seed Placement with the Mick™ TP/TPV Applicator

IsoSeed® is a loose seed for use with the Mick™ TP/TPV Applicator and available in two sealed source model designs:

- IsoSeed® I25.S06 contains a thin gold marker specifically designed for artifact-free visibility in CT imaging.
- IsoSeed® I25.S17plus features a silver marker for imaging under fluoroscopy and MRI.

IsoSeed® is manufactured to unparalleled quality standards. Available with either a gold (IsoSeed® I25.S06) or silver (IsoSeed® I25.S17plus) radiographic marker, Eckert & Ziegler BEBIG’s I-125 sealed source model designs provide visibility under ultrasound, fluoroscopy, CT, or MRI.

| Activity classes IsoSeed® I25.S06 for Prostate Cancer Treatment |
|------------------|------------------|------------------|------------------|
| Class number     | Air kerma strength in μGy m²/h | Apparent activity in mCi | Apparent activity in MBq |
| -5               | 0.240 – 0.259       | 0.189 – 0.204       | 6.99 – 7.55       |
| -4               | 0.260 – 0.281       | 0.205 – 0.221       | 7.59 – 8.18       |
| -3               | 0.282 – 0.305       | 0.222 – 0.240       | 8.21 – 8.88       |
| -2               | 0.306 – 0.330       | 0.241 – 0.260       | 8.92 – 9.62       |
| -1               | 0.331 – 0.358       | 0.261 – 0.282       | 9.66 – 10.43      |
| 0                | 0.359 – 0.390       | 0.283 – 0.307       | 10.47 – 11.36     |
| 1                | 0.391 – 0.423       | 0.308 – 0.333       | 11.40 – 12.32     |
| 2                | 0.424 – 0.459       | 0.334 – 0.361       | 12.36 – 13.36     |
| 3                | 0.460 – 0.498       | 0.362 – 0.392       | 13.39 – 14.50     |
| 4                | 0.499 – 0.540       | 0.393 – 0.425       | 14.54 – 15.73     |
| 5                | 0.541 – 0.586       | 0.426 – 0.461       | 15.76 – 17.06     |
| 6                | 0.587 – 0.637       | 0.462 – 0.501       | 17.09 – 18.54     |
| 7                | 0.638 – 0.690       | 0.502 – 0.543       | 18.57 – 20.09     |
| 8                | 0.691 – 0.749       | 0.544 – 0.590       | 20.13 – 21.83     |
| 9                | 0.750 – 0.813       | 0.591 – 0.640       | 21.87 – 23.68     |
| 10               | 0.814 – 0.882       | 0.641 – 0.694       | 23.72 – 25.68     |
| 11               | 0.883 – 0.958       | 0.695 – 0.754       | 25.72 – 27.90     |
| 12               | 0.959 – 1.039       | 0.755 – 0.818       | 27.94 – 30.27     |
| 13               | 1.040 – 1.127       | 0.819 – 0.887       | 30.30 – 32.82     |
| 14               | 1.128 – 1.223       | 0.888 – 0.963       | 32.86 – 35.63     |

| Activity classes IsoSeed® I25.S17plus for Prostate Cancer Treatment |
|------------------|------------------|------------------|------------------|
| Class number     | Air kerma strength in μGy m²/h | Apparent activity in mCi | Apparent activity in MBq |
| -5               | 0.240 – 0.259       | 0.189 – 0.204       | 6.99 – 7.55       |
| -4               | 0.260 – 0.281       | 0.205 – 0.221       | 7.59 – 8.18       |
| -3               | 0.282 – 0.305       | 0.222 – 0.240       | 8.21 – 8.88       |
| -2               | 0.306 – 0.330       | 0.241 – 0.260       | 8.92 – 9.62       |
| -1               | 0.331 – 0.358       | 0.261 – 0.282       | 9.66 – 10.43      |
| 0                | 0.359 – 0.390       | 0.283 – 0.307       | 10.47 – 11.36     |
| 1                | 0.391 – 0.423       | 0.308 – 0.333       | 11.40 – 12.32     |
| 2                | 0.424 – 0.459       | 0.334 – 0.361       | 12.36 – 13.36     |
| 3                | 0.460 – 0.498       | 0.362 – 0.392       | 13.39 – 14.50     |
| 4                | 0.499 – 0.540       | 0.393 – 0.425       | 14.54 – 15.73     |
| 5                | 0.541 – 0.586       | 0.426 – 0.461       | 15.76 – 17.06     |
| 6                | 0.587 – 0.637       | 0.462 – 0.501       | 17.09 – 18.54     |
| 7                | 0.638 – 0.690       | 0.502 – 0.543       | 18.57 – 20.09     |
| 8                | 0.691 – 0.749       | 0.544 – 0.590       | 20.13 – 21.83     |
| 9                | 0.750 – 0.813       | 0.591 – 0.640       | 21.87 – 23.68     |
| 10               | 0.814 – 0.882       | 0.641 – 0.694       | 23.72 – 25.68     |
| 11               | 0.883 – 0.958       | 0.695 – 0.754       | 25.72 – 27.90     |
| 12               | 0.959 – 1.039       | 0.755 – 0.818       | 27.94 – 30.27     |
| 13               | 1.040 – 1.127       | 0.819 – 0.887       | 30.30 – 32.82     |
| 14               | 1.128 – 1.223       | 0.888 – 0.963       | 32.86 – 35.63     |
IsoCord® & IsoStrand®: Full Radiation Protection

IsoCord®
Stranded Seeds in a Convenient Magazine
IsoCord® is a seed chain with up to 70 seeds packaged in a radioprotective magazine. It consists of seeds and hourglass-shaped spacers in standard seed-spacer configuration, embedded in braided monofilament suture. This special design enables reliable fixation within prostate tissue and helps to reduce seed migration. IsoCord® is available with either I25.S06 or I25.S17plus source model designs.

IsoCord® Needle Loading Station
Strand Cutting under Full Radiation Protection
With the IsoCord® Needle Loading Station, the desired amount of seeds is moved out of the magazine into the illuminated positioning unit. IsoCord® is then cut into the desired length and subsequently loaded into the attached implantation needle with the integrated mandrel. The process of strand cutting and needle loading is performed under full radiation protection, without the need to handle strands manually.

- Up to 70 stranded seeds in a convenient magazine
- Fast intra-operative strand cutting under full radiation protection
- Optimal fixation of strands in prostate tissue

IsoStrand® and IsoStrand® Cutting Fixture
Facilitating Seed Assay
IsoStrand® consists of 10 IsoSeed® spaced 1 cm apart. The hourglass design of the bioabsorbable spacers and the braided suture carrier ensure reliable strand placement. IsoStrand® is cut under radiation protection using the cutting fixture.
**Needles and Accessories**

**Needles for Use with the Mick™ TP/TPV Applicator**

- Applicator Needle 17G/18G x 20 cm – hollow needle with 5.0 mm markings, trocar tip stylet, and slim needle hub

**Needles for Use with IsoCord® and IsoStrand®**

- IsoCord® Needle 18G x 20 cm – steerable, bevel-shaped needle tip
- Post Loading Needle 18G x 20 cm – steerable, bevel-shaped needle tip, cone-shaped needle hub for easy accommodation of postloading transfer tubes

**Needles for Prostate Stabilization**

- Prostate Stabilization Needle 18G x 20 cm
- Pajunk Delta-Fix Fixation Needle 18G x 20 cm

**Transfer Tube**

- For safe and easy transfer of strands from the Needle Loading Station to the needle

**Needle Rack**

- Storage solution for needles loaded in advance with easy distinction of loaded needles and practical handle for transport to the operating room
Equipment and Consumables

**Ultrasound Systems**
- BK Ultrasound – Flex Focus
- BK Ultrasound – Pro Focus
- Other ultrasound systems available upon request

**Steppers**
- CIVCO – Classic Stepper
- CIVCO – EX³ Stepper
- DK³ – Stepper

**Transducers/TRUS Probe**
- BK Ultrasound – Endocavity Biplane 8848
- Other transducers available upon request

**Grids/Templates**
- CIVCO – Disposable Template Grids, 17G or 18G
- Mick™ – Reusable Template, 17G or 18G
- Mick™ – Disposable Template, 17G or 18G
- DK³ – Reusable Template
- Other grids/templates available upon request

**Products for Calibration and Seed Assay**
- PTW-Freiburg – UNIDOS® E Universal Dosemeter
- PTW-Freiburg – SOURCECHECK® 4 pi Type 33005
- Standard Imaging – HDR 1000 Plus Well Chamber and IVB 1000 Well Chamber
- Other products for calibration and seed assay available upon request

**Endocavity Balloon**
- CIVCO – Latex-Free Endocavity Balloon

**Drapes**
- CIVCO – Sterile Disposable System Drapes

---

1 BK Ultrasound, Flex Focus and Pro Focus are trade names/trademarks of Analogic Corporation or its affiliated companies.
2 CIVCO and EX³ are trade names/trademarks of CIVCO Medical Instruments Co., Inc.
3 DK is a trade name/trademark of D&K Technologies GmbH.
4 PTW and SOURCECHECK are trade names/trademarks of PTW Freiburg GmbH. UNIDOS is a registered trademark of PTW Freiburg GmbH.
5 Standard Imaging is a trade name/trademark of Standard Imaging Inc.
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’s 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 145 people. The company has been listed on the Euronext stock exchange since April 1997.

Corporate Head Office:
Eckert & Ziegler BEBIG SA
Rue Jules Bordet
Zone Industrielle C
7180 Seneffe
Belgium
Phone +32 64 520 811
Fax +32 64 520 801

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

Regional Sales, Marketing and Service:
Europe, Middle East, Africa, Latin America, Asia Pacific

Eckert & Ziegler BEBIG SA
Rue Jules Bordet
Zone Industrielle C
7180 Seneffe
Belgium
Phone +32 64 520 811
Fax +32 64 520 801

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

IsoSeed, IsoCord and IsoStrand are registered trademarks of Eckert & Ziegler BEBIG SA and its subsidiaries. Mick is a trade name of Eckert & Ziegler BEBIG SA and its subsidiaries. The mentioned products are not available in all markets. Please contact your local Eckert & Ziegler BEBIG representative for more information.