LDR Prostate Brachytherapy

Hitting cancer on the spot

Dedicated solutions for real-time and pre-planned 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\(^1\). 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\(^2,3\).

Patient Selection Criteria\(^4\)
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.

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\(^1\)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
Expertise in LDR Brachytherapy

Eckert & Ziegler BEBIG – Your Complete Brachytherapy Provider

“Our mission is to develop and provide customers around the world with innovative medical devices for the effective treatment of cancer while preserving the patient’s quality of life. Through on-time delivery, consistent high quality, and constant self-improvement, we strive to meet the needs of our customers. Thanks to our expertise in LDR brachytherapy and our commitment to the method, we hold a long clinical record with more than 60,000 patients treated with Eckert & Ziegler BEBIG implant products.”

Dr. Edgar Löffler
Managing Director Eckert & Ziegler BEBIG

Eckert & Ziegler BEBIG offers a complete range of LDR prostate brachytherapy products for both, real-time and pre-planned implants, with sources in different types and configurations, treatment planning software, on-site service, a wide 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 with standard and variable seed spacing
- Pre-loaded needles
- Treatment planning software
- Consumables
- Ultrasound equipment
- Equipment for calibration and seed assay

“Eckert & Ziegler BEBIG has been a reliable and helpful supplier to us since we worked with them as our LDR brachytherapy seed supplier in 2006. In this time, we received outstanding service and training.”

Duncan McLaren, MD
Radiation Oncologist
Western General Hospital, Edinburgh
United Kingdom
IsoSeed®: Excellent Visibility

IsoSeed®
Loose Seed Placement with the Mick™ Applicator
IsoSeed® is a loose seed for use with the Mick™ 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 metal marker for excellent imaging under fluoroscopy and MRI.

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

<table>
<thead>
<tr>
<th>Activities IsoSeed® I25.S17plus</th>
<th>Activities IsoSeed® I25.S06</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class number</td>
<td>Air kerma strength in μGy m²/h</td>
</tr>
<tr>
<td>-5</td>
<td>0.240 – 0.259</td>
</tr>
<tr>
<td>-4</td>
<td>0.260 – 0.281</td>
</tr>
<tr>
<td>-3</td>
<td>0.282 – 0.305</td>
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<tr>
<td>-2</td>
<td>0.306 – 0.330</td>
</tr>
<tr>
<td>-1</td>
<td>0.331 – 0.358</td>
</tr>
<tr>
<td>0</td>
<td>0.359 – 0.390</td>
</tr>
<tr>
<td>1</td>
<td>0.391 – 0.423</td>
</tr>
<tr>
<td>2</td>
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</tr>
<tr>
<td>3</td>
<td>0.460 – 0.498</td>
</tr>
<tr>
<td>4</td>
<td>0.499 – 0.540</td>
</tr>
<tr>
<td>5</td>
<td>0.541 – 0.586</td>
</tr>
<tr>
<td>6</td>
<td>0.587 – 0.637</td>
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<td>7</td>
<td>0.638 – 0.690</td>
</tr>
<tr>
<td>8</td>
<td>0.691 – 0.749</td>
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<tr>
<td>9</td>
<td>0.750 – 0.813</td>
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<tr>
<td>11</td>
<td>0.883 – 0.958</td>
</tr>
<tr>
<td>13</td>
<td>1.040 – 1.127</td>
</tr>
</tbody>
</table>

IsoSeed® I25.S17plus contains a thin gold marker specifically designed for artifact-free visibility in CT imaging.

IsoSeed® I25.S06 contains a metal marker for excellent imaging under fluoroscopy and MRI.
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 radio-protective magazine. It consists of seeds and hourglass-shaped spacers in standard seed-spacer configuration, embedded in braided monofilament suture. This special design enables optimal 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 unique 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 1.0 cm apart. The unique hourglass design of the bioabsorbable spacers and the braided suture carrier ensure excellent strand placement. IsoStrand® is cut under radiation protection using the unique cutting fixture.
**AnchorSeed®: Unique Polymer Technology**

**AnchorSeed®
Loose Seeds with Strand-like Performance**

AnchorSeed® is designed for use with the Mick™ Applicator, consisting of loose, low dose rate brachytherapy sources encapsulated in a proprietary synthetic bioabsorbable polymer which is also used in the Eckert & Ziegler BEBIG portfolio of strand products.

AnchorSeed® is designed to improve seed fixity and reduce misalignment, migration, and seed displacement\(^1,2,3\). This design allows seeds to better maintain their position within tissue, while keeping the flexibility offered by the Mick™ Applicator.

AnchorSeed® Kits include a choice of 17 or 18G Applicator Technique Needles in separate, sterile pouches. Currently, the source encapsulated by the innovative Anchor Technology is the silver core seed, model 6711.

AnchorSeed® has been designed to:

- **Improve seed fixity**
- **Reduce misalignment**
- **Minimize migration and seed displacement**

The fixity provides added confidence in placing seeds:

- **Closer to the periphery**
- **Within the peri-urethral areas**
- **Closer to the apex and base**

The unique fixity of AnchorSeed® to remain in position after deployment from the Mick™ Applicator may particularly aid in focal therapy.

**Available Activities of AnchorSeed®**

<table>
<thead>
<tr>
<th>Apparent activity in mCi</th>
<th>0.183</th>
<th>0.199</th>
<th>0.215</th>
<th>0.234</th>
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<tbody>
<tr>
<td>0.254</td>
<td>0.275</td>
<td>0.299</td>
<td>0.324</td>
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<tr>
<td>0.352</td>
<td>0.382</td>
<td>0.414</td>
<td>0.449</td>
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<td>0.487</td>
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<td>0.574</td>
<td>0.623</td>
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<tr>
<td>0.676</td>
<td>0.733</td>
<td>0.796</td>
<td>0.863</td>
<td></td>
</tr>
</tbody>
</table>

Apparent Activity (mCi) to Air Kerma Strength (µGy·m\(^2\)/h, or U) conversion for I-125: 1 mCi = 1.27 U

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\(^1\) Badwan et al, AnchorSeed for the reduction of source movement in prostate brachytherapy with the Mick™ Applicator implant technique, Brachytherapy 9 (2010) 23-26

\(^2\) Bowes et al, A randomized trial comparing seed displacement of coated seeds to regular loose seeds at 30 days postimplant, Brachytherapy 12 (2013) 362-367

\(^3\) Sarkar et al, Prostate implant dosimetric outcomes and migration patterns between bio-absorbable coated and uncoated brachytherapy seeds, Brachytherapy 12 (2013) 356-361
VariStrand™ & StandardStrand™: Pre-loaded Kits

VariStrand™ and StandardStrand™ in Pre-loaded Needles
Accommodating any Loading Pattern
The pre-planned technique remains a popular method of performing low dose rate prostate brachytherapy implants, and Eckert & Ziegler BEBIG offers a full range of product options to accommodate any pre-loaded procedure.

Strands and loose spacers are made from a proprietary combination of synthetic, bioabsorbable polymers. Strands and loose spacers are absorbed via enzymatic reaction over 180 to 220 days.

- For pre-planned prostate seed implants
- Strands encapsulated in a synthetic bioabsorbable polymer
- Pre-loaded in unique pre-plugged SeedLock3™ needles

VariStrand™ is the original customized strand, capable of accommodating any conceivable loading pattern, such as urethral spacing, back-to-back seeds or baseline loading.

StandardStrand™ exhibits a standard loading pattern of 1.0 cm center-to-center spacing
Comprehensive and Intuitive Treatment Planning Software
PSID™ has been developed by Eckert & Ziegler BEBIG to meet user needs and to support new developments in permanent seed brachytherapy. The comprehensive software, with user friendly interfaces, supports the various stages of the planning process: pre-plan, real-time, and post plan. Designed with a wide range of dedicated features, PSID™ facilitates a streamlined workflow in treatment planning for LDR prostate brachytherapy.

Focal Therapy Support
Straightforward matching of live ultrasound images with other images or even with a pre-registered and fused dataset makes PSID™ an optimal solution for focal therapy support. Prostate lesion localization images, e.g., multiparametric MRI or Histocanning, can be fused with the live ultrasound images, offering live guidance for both focal brachytherapy procedures and precise transperineal focal biopsies.

Automatic Contour Tracing
Automatic contour tracing supports the transfer of ultrasound screen drawn contours with a single click. The prostate and organs at risk can be easily contoured on live ultrasound images using the comprehensive contouring features. The digital frame grabber provides the seamless connection to the ultrasound device.
Projected Structure Outline
The projected structure outline displays the entire structure boundary in every plane of the 2D view. When a non-isocentric 3D margin is applied, these contours are also visible.

Variable Spacing and Different Seed Activities
PSID™ fully enables planning with loose, stranded and variably spaced seeds. PSID™ supports the planning of two different seed activities of the same source model design.

Convenient Post Planning Capabilities
Through DICOM import, post planning of the implant can be performed on any oblique plane as well as on DRRs. The DRR provides a superior overview where all seeds can be clearly recognized at once. The automatic seed finder is a fast and convenient tool to reconstruct implanted seeds on CT images.
Needles and Accessories

**Needles for use with the Mick™ Applicator**

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

**Needles for use with IsoCord®/IsoStrand®**

- IsoCord® Needle 18G x 20 cm – steerable, bevel-shaped needle tip

**Needles for use with IsoCord®/IsoStrand® and VariStrand™/StandardStrand™**

- Prostate Seeding Needle SeedLock3™ 18G x 20cm – advanced synthetic bioabsorbable plug of SeedLock3™ is a constant 1.5 mm in length and is consistent in its position, ensuring the first seed is always 5.0 mm from the needle tip

**Needles for prostate stabilization**

- Prostate Stabilization Needle 18G x 20cm

**Transfer tube**

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

**Needle Rack**

- Ideal storage solution for needles loaded in advance with easy distinction of loaded needles and practical handle for transport to the OR

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

**Ultrasound**
- B-K FlexFocus
- B-K ProFocus
- Hitachi HI VISION

**Stepper**
- Brachystepper CIVCO Classic
- Brachystepper CIVCO Ex III
- DK-Tech Stepper

**TRUS-probe**
- B-K 8848, Simultaneous Biplane Transducer
- Hitachi EUP-U533 Biplane Ultrasound Probe

**Grids**
- CIVCO Disposable Brachygrid, 17G or 18G
- Mick™ Template Grid, reusable
- DK-Tech Template for BK, reusable

**Products for Calibration and Seed Assay**
- Universal dosemeter UNIDOS E
- PTW SourceCheck
- Standard Imaging Well Chamber

**Brachyballoon**
- CIVCO Latex-Free Endocavity Balloon

**Brachydrap**
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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The mentioned products are not available in all markets. Please contact your local Eckert & Ziegler BEBIG representative for more information.