



**LDR PROSTATE BRACHYTHERAPY WITH
CIVASTRING®**

**^{103}Pd POLYMER-ENCAPSULATED
BRACHYTHERAPY LINE SOURCE**

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The content of this document is based on early studies and data that may include forward looking statements and hypotheses regarding CivaString® treatment outcomes.

Introduction

CivaTech is proud to introduce a unique linear low-dose-rate (LDR) brachytherapy source – the CivaString® (Figure 1). The CivaString® is **FDA 510(k) cleared** to treat localized, solid tumors as primary or combined therapy. The source contains Pd-103 using low-Z polymers along the full length of the device. The polymer construction and linear radioactive distribution of the CivaString® creates a very homogenous dose distribution (Figure 2).

CivaString® treatment plans may offer several advantages for the radiation oncologist, the Medical Physicist and the patient. CivaString® treatment pre-plans use **fewer needles and sources**, which:

- **Reduces planning time;**
- **Reduces implant, anesthesia, and operating room times;**
- **Reduces post-treatment dosimetry time;**
- **May reduce patient’s pain, bruising and urinary toxicity; and**
- **May provide a more robust implant.**



Figure 1: Photograph of a 1 cm CivaString®. CivaStrings® can be provided in lengths ranging from 1 cm to 6 cm in 1 cm increments. One gold marker is centered in each 1 cm segment.

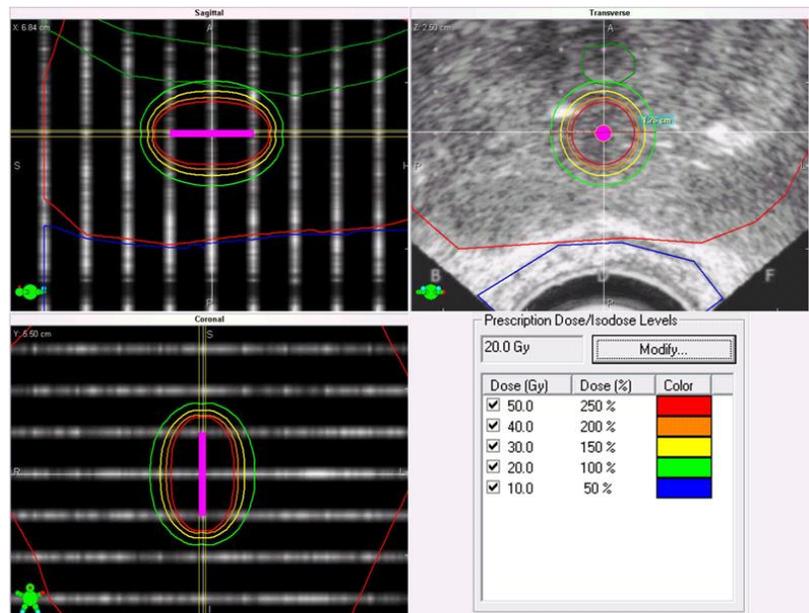


Figure 2: A VariSeed screen shot showing the dose profiles that would be obtained from a 1 cm CivaString® in orthogonal planes. Note the homogeneity of the dose profile.

Product Specifications

CivaStrings® are manufactured to prescription and are available in continuous lengths ranging from 1 cm to 6 cm in 1 cm increments. The source strength can be provided from 0 to 4 U/cm and can be either uniform along the full length or can have 0 U/cm segments in 1 cm increments. CivaStrings® have passed rigorous physical leak testing and are licensed by the NRC as a Sealed Source.

The CivaString® seamlessly integrates into current clinical paradigms. From imaging to post-implant dosimetry, the CivaString® works well with standard 18 gauge brachytherapy needles, imaging modalities and treatment planning tools. The polymer surface of a CivaString® is readily visualized by ultrasound (Figure 3) and the gold markers are easily visualized in CT images (Figure 4).

The CivaString's® dose uniformity and visibility on post-implant CT images enables fewer needles and sources to provide good dose coverage to the prostate.

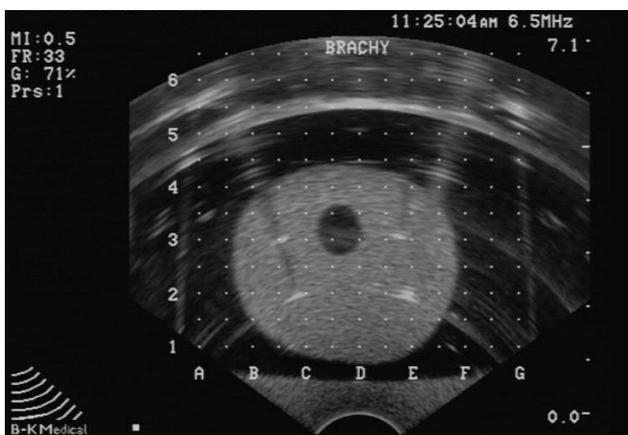


Figure 3: An ultrasound image slice of CIRS-053 prostate phantom containing four CivaStrings®, inserted perpendicular to the plane of the page. The white spots at C2, C3, E2 and E3 are the CivaStrings®.

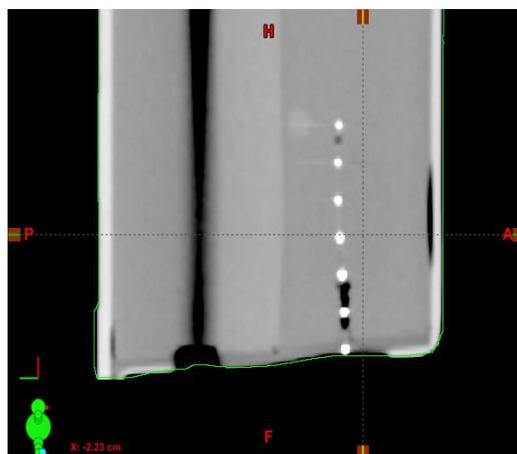


Figure 4: Reconstructed cone beam CT slice of CivaString® in a cylindrical water phantom. Gold markers spaced 1 cm center-to-center appears white on the reconstructed image.

Sample Treatment Plans

CivaStrings®

- Are easy to identify on post-implant CT images
- Are contiguous line sources for a robust implant
- Have a homogeneous dose distribution
- Can be provided with multiple source strengths

CivaStrings® can be provided with different source strengths. Because the location of the continuous sources can be readily identified on post-implant CT images, plans can be constructed that use two different source strengths with confidence that post-implant identification and dosimetry will be straightforward.

A model CivaString® treatment pre-plan employs a regular pattern of multiple interior and peripheral sources. This pre-planning study indicates interior CivaStrings® with a lower source strength than the peripheral sources will reduce the dose to the urethra. For small prostates, two interior and eight peripheral sources provide prescription dose coverage. For large prostates, four interior and ten to twelve peripheral sources are used. For intra-operative planning, additional CivaStrings could be provided for additional customization.

Figure 5 presents an example CivaString® treatment plan for the ~60 cc prostate in a CIRS-053 phantom. In this example, the interior and peripheral sources have air kerma strengths of 2.4 U/cm and 3.4 U/cm, respectively. A total of 16 CivaStrings® would be used. The dose volume histogram (DVH) shows that the urethral, rectal, and prostate doses would be within acceptable clinical limits (Figure 6). A CivaString®-based retrospective treatment pre-plan of a 54 cc prostate demonstrates excellent dose coverage with ten 4.2 U/cm peripheral sources and four 2.8 U/cm interior sources (Figures 7 and 8).

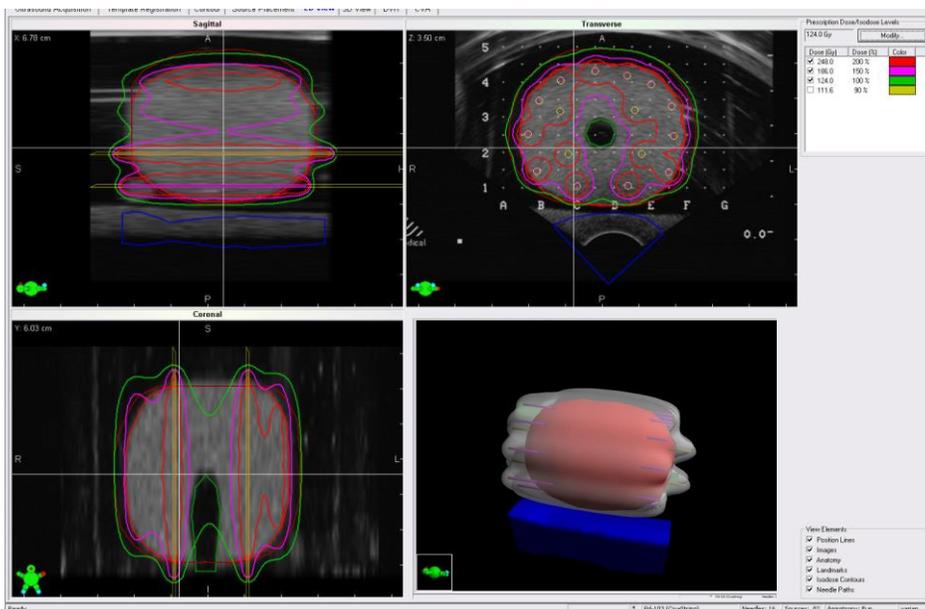


Figure 5: A CivaString® treatment plan for the prostate in a CIRS-053 phantom requires 16 needles to deliver the prescribed dose. The four interior 6 cm CivaStrings® have an air kerma strength of 2.4 U/cm. The two 4 cm and ten 5 cm peripheral CivaStrings® have an air kerma strength of 3.4 U/cm.

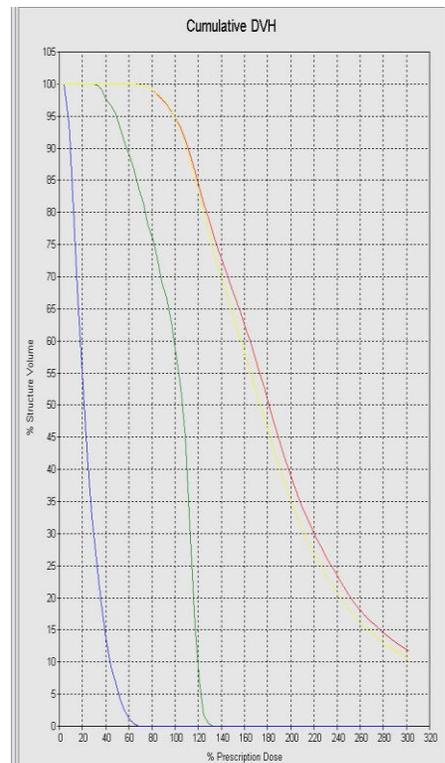


Figure 6: The CIRS-053 phantom treatment plan DVH. The prostate D90 and V100 are 111.78% and 94.81%, respectively.

This treatment planning philosophy has several advantages. The planning time itself will be less than a traditional seed implant because for a given prostate size, only the length and source strength need to be determined. Fewer sources and needles also implies a quicker implant and less time in the operating room. Post-implant dosimetry should also require less time because there are a small number of regularly spaced gold markers that should be easy to identify either automatically with VariSeed Software or manually. For the patient, the greatest advantage will likely be the use of fewer needles. Because the number of needles is related to the swelling and inflammation the prostate will experience, reducing the needle count should lead to significantly less acute perineal pain and bruising as well as reduced urinary toxicity (1, 2).

Utilizing variable activity strengths of CivaStrings® may also provide other treatment plan options. For example:

- CivaStrings® with ends that are more radioactive than the center could provide better dose coverage for the base and apex of prostate
- Lower strength interior CivaStrings® could spare urethral dose

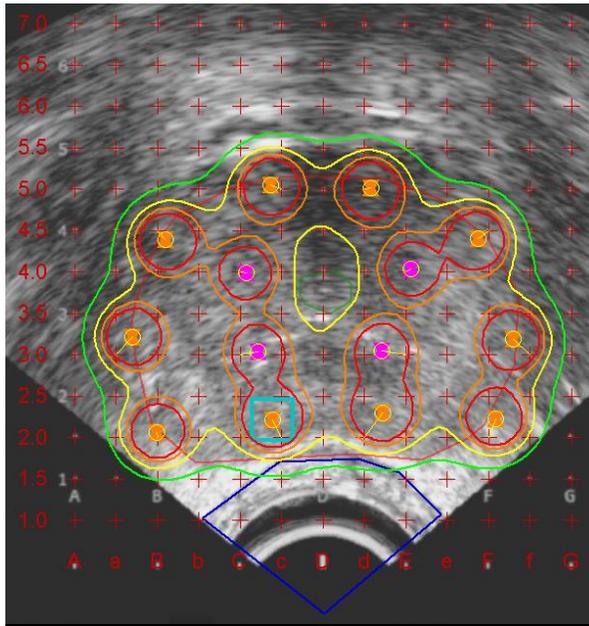


Figure 7: A retrospective CivaString® treatment pre-plan for a 54 cc prostate. By combining two source strengths, one can achieve good dose coverage for the prostate and good dose sparing of organs-at-risk with the advantage of fewer needles to deliver the implant than a conventional seed-based plan.

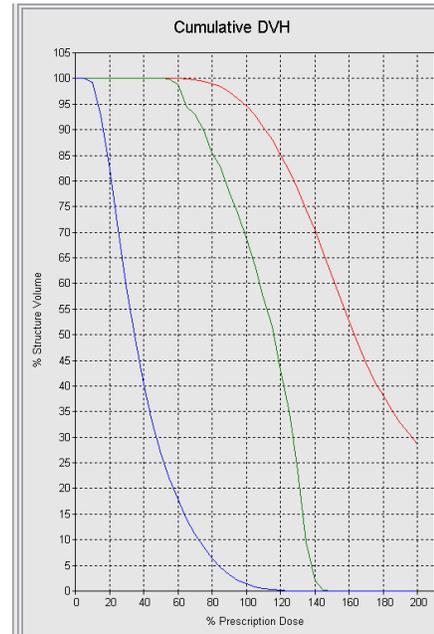


Figure 8: The DVH for the treatment plan in Figure 7. The V100 is 94.71% and D90 is 111.3%. The urethra and rectum doses are within clinical limits.

Summary

A CivaString®-based LDR brachytherapy treatment offers the Radiation Oncologist and Medical Physicist an advantageous treatment option for prostate cancer. CivaString® treatment plans can be created using far fewer needles than traditional seed treatment plans and yet meet match the D90 dose coverage. For a 54cc prostate, the number of needles can be reduced from 24 to 14, a 40% reduction. Fewer needles could lead to less implant site trauma, particularly swelling and inflammation, potentially leading to less procedure related urinary toxicities (1-4). Treatment plans that use fewer needles and sources are also likely to take less time than seeds during the planning, implanting and post-implant procedures.

Acknowledgements

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References

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Contact us for coding guidelines and TG-43 parameters.