

representative to discuss these and other key features of VariSeed.

VARISEED TREATMENT PLANNING SYSTEM FEATURE SHEET

The VariSeed™ LDR treatment planning system provides a logical tab-based workflow for low-dose rate brachytherapy planning. Its workflow flexibility supports practitioners new to seed implants or those doing complex real-time procedures. Introduced in 1997, VariSeed is well established with 1,600 systems in use in over 40 countries worldwide.

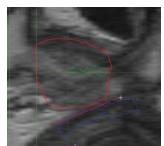
Flexible Intuitive Proven KEY FEATURES OF VARISEED: • Straightforward structured workflow for treating prostate, breast, and other LDR implants • Real-time planning on live images (Implant View*) • Supports angled needles and seeds for plan accuracy • Optimize remaining seeds midimplant based on dose alreadydelivered to patient (Volume Optimization*) Fuse CT or MR images with ultrasound (Image Fusion*) Image reformatting • Direct video (BK-OEM interface) to enhance workflow · Biopsy planning, tracking and recording (VariPath*) PreOp (including • Create and view up to 10 dosimetric PostOp MR pre-planning) quality alerts • Physician and physicist plan approval **GUIDED WORKFLOWS** • Flexibility to use with most WITH VARISEED ultrasounds, steppers, sources and techniques Real-Time IntraOp Biopsy planning, tracking (Implant View*) and recording (VariPath*) Contact your Varian BrachyTherapy

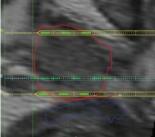
COMPREHENSIVE TREATMENT PLANNING

FFATURES

Imaging and data acquisition

- Automatic capture of transverse or longitudinal images[†] for speed, improved resolution, and reduced prostate distortion
- Multiple image acquisition methods:
- -Video frame capture**
- -Digital image transfer (BK*** & DVI**)
- DICOM RT interface allows import of images and structures from CT, MRI, SPECT, US
- DICOM RT export of images, structures, source and dose information
- Interface with BK improves workflow and image quality by eliminating calibration of the ultrasound image within VariSeed. Transfer contours drawn on the ultrasound without intervention and automatically compensate for image zoom.
- Reformat CT or MR images to angle of the template or angle of the ultrasound to create preplans





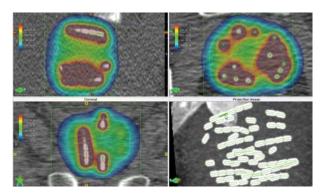
VariSeed supports the creation of a treatment plan on MR that has been reoriented to match the expected orientation of the ultrasound in the operating room.

Contouring

- Structure templates
- Regions can include or exclude various structures for dose calculation
- Create, copy, edit, and adjust contours in any plane using the brush or freehand tool in the three main axes with multiplanar contouring
- Automated interpolation of the contours
- Shape Stamper with a single click, choose a shape to identify an area in the transverse view
- Sweep Structure quickly generates a cylindrical structure of the urethra by drawing a line in the sagittal view or on live images in implant view.
- Auto-margin tool creates an asymmetrical margin of a structure.

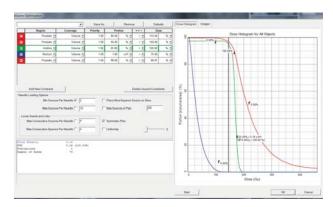
Planning flexibility

- Efficient and easy to use
- Support for strands, loose and linked seeds in manual and automatic placement
- Support for angled and curved needles
- Support for angled seeds on both pre and post planning
- Needle placement tool generates needle positions based on contoured volumes in less time than manual placement and allows different packaging to be set for peripheral and interior needles
- · Place seeds
- Manually (individually or multiple)
- Automatically using geometric placement patterns
- Automatically based on dose and needle constraints (Volume Optimization*)
- Needle Editor longitudinal representation of a selected needle for automated loading, viewing and editing
- Plan templates allow needle and seed positions to be stored and used for other patients. Useful if a regular pattern of needles is preferred.
- Store multiple variations of the plan for the same patient or create a copy of the entire study



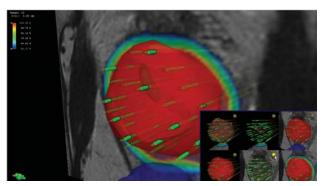
Plan evaluation and analysis

- Sector Analysis divides a target structure into 8 or 12 sectors for prospective or retrospective analysis. Specify and calculate dosimetric parameters for each sector.
- Maximum Intensity Projection (MIP) seed navigator assists in identifying and adjusting seed positions with greater clarity by creating a 3D MIP that shows only high density objects (e.g., bones and seeds). By rotating the MIP in any direction and selecting a high density area, the multiplanar view navigates to the center of the selected area.
- Dosimetric quality alerts create up to 10 alerts in the source placement and implant views based on dose quality parameters (e.g., V100, D90, D2cc, NDR, CI, COIN, DHI, DNR)



The volume optimization workspace offers a range of objective options including the ability to optimize the remaining part of a partially implanted plan.

- 2D and 3D isodose and color wash displays
- Advanced configurable 3D view displays the dose and structures as well as images from the primary volume.
 Provides new scene settings that allow for store and switch from one view set up to another in two clicks.



Save or recall scene settings with two clicks

- Display dose at the cursor
- Dose volume histograms (DVH) and contiguous volume analysis (CVA) for determining dose coverage and homogeneity
- Study summary report print or export configurable dosimetric quality parameters
- View two plans side by side by opening multiple instances of VariSeed

Plan reports

- Extensive range of reports for reviewing, preparing and performing the implant including:
- Needle loading and strand-cutting
- Seed position
- Therapy visualization (2D planes)
- Patient set up
- Dose evaluation
- Dose volume histograms

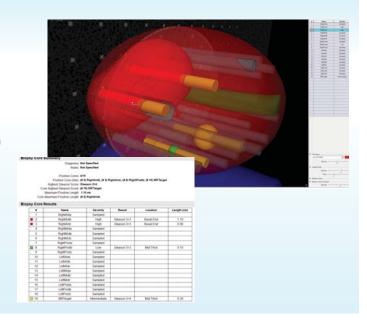
System and source management

- Patient database with archive and restore capabilities
- Review and configure source data using the SourceEdit application. Data changes are password protected.
- Import and export individual source data files to further support the introduction of updated source data
- Source data supplied with related QA tests
- Uses TG43 dose calculation formalism, and supports anisotropic constant, factor, and function calculations

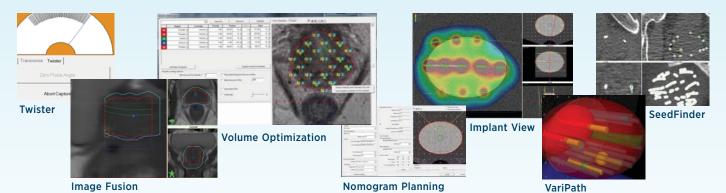
VariPath™ biopsy module*

The VariPath biopsy module supports transperineal template-based biopsy to plan biopsy locations and track them in real time. The planned core can be moved and tilted along with the biopsy needle and marked as sampled.

The detailed biopsy report lists the sampled cores with each abnormal core entered as either a percentage or sector of the core. Tumor volumes are created based on the severity and position of the abnormal cores. Abnormal core positions and/or the tumor volumes can be exported along with the images and any other structures, as DICOM RT structures. These assets can then be imported into other compatible systems for recording or planning purposes.



PURCHASABLE OPTIONS



Twister™ 3D ultrasound acquisition module

Acquire target data by rotating the probe in longitudinal capture, potentially capturing higher resolution volumes by reducing prostate distortion resulting from pulling probe in and out, and providing better visibility of structures and implanted seeds.[†]

Image Fusion module

Increase visualization and contouring capabilities by fusing up to seven image sets. An initial alignment based on the center of existing contours allows time savings when fusing. Enables pre plans created on another image set (e.g., MR) to be imported directly into the ultrasound study. Aligns initial image set, structures and plan to the ultrasound using the template and reference plane.

Volume Optimization/Inverse Planning module

Generate a plan adhering to any site-defined clinical protocols through user-defined upper and lower dose constraints, including needle content constraints (e.g., symmetry).

Maintain the packaging dictated by the predefined needles. Lock loaded needles making them unchangeable. Factor in the dose from any implanted seeds to re-optimize the plan during the implant. Utilize an alternative volume optimization if a plan is to be generated without predefined needle positions.

Implant View™ seed planning module

Real-time planning. Use the plan to guide the implant and track the dose being delivered on live images. Make adjustments to any non-implanted seeds during the implant process or evaluate the treatment once complete to determine if additional seeds are needed.

Angle and bend the needles to align with the implant. Individually tilt loose seeds to mirror implantation. Move and angle strands and links as a unit to maintain spacing.

SeedFinder[™] seed extraction module

Save time during post-planning by automated detection of implanted seeds in structure or volume of interest within the CT image. Detects orientated seeds if using high-resolution images.

Nomogram Planning module

Helpful for clinics using peripherally loaded implants. After entering nomograms and defining targets, determines the number of seeds and needles required based on volume and size of the prostate. Adjust spacing of peripheral and interior needles based on the patient's anatomy.

VariPath biopsy module

Supports structured ultrasound-guided transperineal biopsy procedures. Plan biopsy locations and track them in real time. Move and tilt the planned core along with the biopsy needle and marked as sampled.



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Intended Use Summary

Varian Medical Systems' software, afterloaders, and applicators are intended to provide radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety

Radiation treatments may cause side effects varying with the part of the body being treated. This may include, but not be limited to irritation to the mouth, respiratory system, digestive system, genitourinary system, fatigue, nausea, skin irritation, and hair loss. In a minority of patients, side effects can be severe. Typically, the side effects are temporary. Radiation treatment is not appropriate for all cancers. Treatment sessions may vary in complexity and time. Side effects of applicator placement and/or implantation may occur. These side effects may include, but are not limited to, localized discomfort, bleeding, and infection or other localized side effects based on the location the applicator is placed. Patients should discuss the treatment and side effects with their physicians before starting.

Medical Advice Disclaimer

Varian as a medical device manufacturer cannot and does not recommend specific treatment approaches. Individual treatment results may vary.

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^{*}Purchasable option

^{**}Requires purchase of additional equipment

^{***}BK Medical's Pro Focus™ and Flex Focus™. with sufficient license from BK Medical

[†] Twister license required for longitudinal image capture. A tracked stepper is required for automatic capture.