The Varian SRS Package includes specifically-designed features that provide the clinician with confidence to deliver Stereotactic Radiosurgery (SRS). Additionally, the features help reduce overall time and resources required for SRS when compared to traditional methods. This can lead to an increase in the volume of procedures performed and lower per procedure costs for the hospital when compared to traditional surgery procedures.

Frameless SRS may be administered using real-time tracking capabilities offered in the SRS package. Even slight motion has the potential to be assessed in real-time with the help of Varian’s optical technology and 3D mapping of the patient’s external surface – all while minimizing dose to healthy tissue.

**Stereotactic radiosurgery is growing as a technique**

New technology advances are expected to extend clinical applications, increase patient throughput and help reduce side effects.* Targeted treatment is driving radiotherapy growth. SRS treatment volume is expected to grow 93% from 2010 to 2020.**

**Growth Factors in SRS:**

- Mounting pressure to increase efficient equipment utilization that reduce treatment times
- Use of fewer treatment sessions is preferred by both patients and clinicians
- Decreases in overall costs
- SRS delivers strong margins for oncology and neuroscience programs*

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*Source: Sg2 Intelligence, Technology Guide, EBRT Platforms, 2013
**Source: Sg2 Intelligence, Technology Guide, SRS/SBRT, 2013

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**Package features:**

**OPTICAL SURFACE MONITORING SYSTEM**

The Varian SRS Package uses non-ionizing real-time surface tracking to monitor patient motion after patient set up has been completed. Real time and accurate assessment of target location during beam delivery is combined with the instantaneous beam gating capability of Varian linacs. This combination can allow clinicians to reduce uncertainty margins, which is critical when delivering to a wide range of targets in the brain.

- The system’s 3D imaging technology produces high resolution and accurate 3D surface data referenced to the treatment isocenter
- The user has the ability to compare the treatment position with the reference surface both inside the treatment room and remotely
- Highly accurate tracking of cranial position for all couch angles throughout treatments allowing non-coplanar treatments
- A continuously updating display with a refresh rate optimized for tracking intracranial targets shows motion in all six degrees of freedom and may be viewed throughout treatment
• Direct calibration to treatment beam isocenter
• Seamless integration with beam gating for out-of-threshold patient or target motion
• SRS Phantom for QA (matched to within +/-0.1 mm tolerance) and levelling plate

### Table 1: Optical Surface Monitoring System (Select Specifications)

| Accuracy | 3D surface data: Root Mean Square (RMS) error of surface data < 1 mm  
Positioning accuracy: RMS target registration error (TRE) < 1 mm 
FSD measurement: RMS error < 2 mm  
Calibration drift: Typically < 1 mm per month |
|----------|--------------------------------------------------------------------|
| Speed | 3D reconstruction time: Static capture (average processing time): ~3 seconds, monitoring mode: typically < 1 second  
Auto-positioning time: ~1 second (for standard corrections), acquisition time (single frame): 2 ms – 25 ms  
Time from user initiation of capture until acquisition of data: < 1 second |
| Coverage | Typically 10,000-20,000 3D points per reference model |

### INTEGRATED CONICAL COLLIMATOR VERIFICATION & INTERLOCK (ICVI) SYSTEM

Patient safety may be increased during intracranial SRS treatments by using the Integrated Conical collimator Verification & Interlock (ICVI) system.

• Provides an automated and electronic correlation of plan requirements for cone sizes with the physical cone present in the system
• Includes 7 conical collimators of the following sizes: 4, 5, 7.5, 10, 12.5, 15 and 17.5 (all sizes in millimeters)
• Jaws automatically set to 5 cm x 5 cm
• Winston Lutz Testing QA Tooling Kit

### Table 2: ICVI System Specifications

| Average Leakage<sup>1, 2</sup> | < 0.1% |
| Maximum Leakage<sup>1, 2, 3</sup> | < 0.2% |
| Penumbra at Dmax<sup>2, 3</sup> | < 2.0 mm |
| Electronic verification of collimator and jaws | Yes |
| Collimator material | Tungsten |
| Mount alignment to isocenter (measured with cone installed) | ±0.2 mm 
Expected performance at ±0.1 mm |
| Reproducibility of conical collimator insertion into mount | ±0.2 mm 
Expected performance at ±0.1 mm |
| Energy compatibility | 6X and 10X High Intensity Modes, 6 MV, 10 MV |

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<sup>1</sup> Leakage specified for 6X and 10X High Intensity energy configurations per IEC 60601-2-1, Leakage through Beam Limiting Devices

<sup>2</sup> For additional IEC conical collimator leakage performance specifications for 6 MV and 10 MV, please refer to 100042130 TrueBeam®, TrueBeam® STx, and Edge™ IEC Type Tests, 100042132.

<sup>3</sup> Penumbra defined as 20-80% leaf end, measured using 10 cm x 10 cm field size, 6X High Intensity energy configuration at Dmax, 100 cm SAD.
ECLIPSE CONE PLANNING

Eclipse Cone Planning provides planning and dose calculation for treatments utilizing stereotactic cones.

Support for frame or frameless immobilization gives clinical staff the flexibility to choose the ideal treatment approach and continue to expand treatment techniques in their oncology program.

These key features assist with planning stereotactic treatments:

- Supports MR pre-planning
- Visualize immediate dose updates and display in 2D image datasets

The software includes advanced editing tools for arc field and arc set:

- Move single or all isocenters
- Adjust isocenter spacing and rebalance weight to help avoid hot spots between multiple isocenters
- Change order of treatment fields

Additional features include:

- Software includes pre-defined arc set templates, plan reports and checklists
- Attached clinical protocol references
- Verify cones at the treatment console
- Open plans with multiple reference points
- Edit couch rotation graphically

IMMOBILIZATION ACCESSORIES FROM QFIX™

Immobilization accessories offered in the Varian SRS Intracranial Package have been specifically chosen to be used in a stereotactic treatment environment.

**Fibreplast™ Open View Mask**

The Open View design of the mask enhances comfort by allowing the patient to see and breathe easier. It is compatible with the Optical Surface Monitoring System for enhanced patient setup and real-time tracking. The Split-Frame design maximizes the rigidity of the mask and there is additional chin reinforcement for extra stiffness.

- Fibreplast Split-Frame Head-Only S-Frame, Long, 3.2 mm, 20% perforation
- Quantity in package: 10

**kVue™ Portrait™ Insert (CURVE board)**

The kVue Portrait Insert offers patient immobilization using S-Frame masks. Locating bar is included.

- Length: 1328 mm
- Aluminum Equivalence: -0.6 mm @ 100kVp
- Water Equivalence: 6 mm @ 6 MV
- Quantity in package: 1
Silverman Q2 Head Support

The Head Support minimizing overstretching of the mask while simultaneously offering cranial support.

- Quantity in package: 5

MOLDCARE® Cushion

The MOLDCARE Cushion provides customized head support for enhanced patient comfort during positioning and treatment. The cushion is composed of a soft fabric bag containing expanded polystyrene beads coated in a moisture-cured resin. The pillow becomes rigid when activated with water and conforms to the contours of the patient’s head and neck. With the Silverman Head Support, it creates the most comfortable and repeatable head support.

- 20 cm x 35 cm
- Quantity in package: 10

The Varian SRS Intracranial Package is dedicated to radiosurgical ablation and represents a major advancement in the way radiosurgery is delivered. Clinics may be able to treat more patients because of the speed, precision and streamlined features integrated in this package. The Varian SRS Intracranial Package makes it possible for you to invest in the future to advance cancer care.

Pre-Requisites for Varian Intracranial SRS Package for TrueBeam®:
- TrueBeam System version 2.0 or higher
- Motion Management Interface for TrueBeam

Additional Pre-Requisites for the Edge SRS package:
- HD120™ MLC
- PerfectPitch™ 6 degrees of freedom couch
- High-Intensity Mode (6X or 10X)

Pre-Requisites for the Varian Intracranial SRS Package for Clinac®:
- Clinac software version 8.0 or higher
- 4DITC version 10.2 or higher
- Millennium™ MLC
- Custom Coding – 4 slot custom coding
- Motion Management Interface for Vision RT
- Fine Beam Isocenter Accuracy
  - FBIA is needed to meet ICVI performance specifications, otherwise the standard isocenter accuracy specification applies
- PortalVision™ (As1000)

Specifications are subject to change without notice. Not all features or products are available in all markets.

Intended Use Summary
Varian Medical Systems’ linear accelerators are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety
Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary or reproductive systems, fatigue, nausea, skin irritation, and hair loss. In some patients, they can be severe. Treatment sessions may vary in complexity and time. Radiation treatment is not appropriate for all cancers.

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