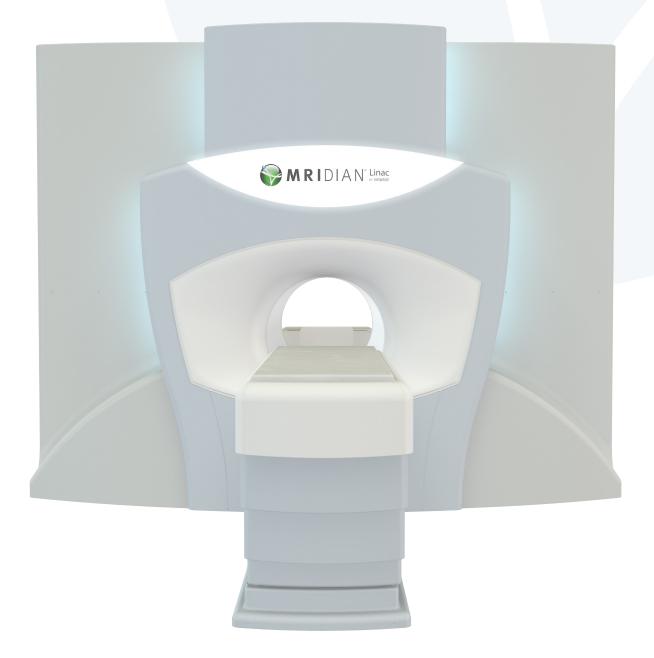
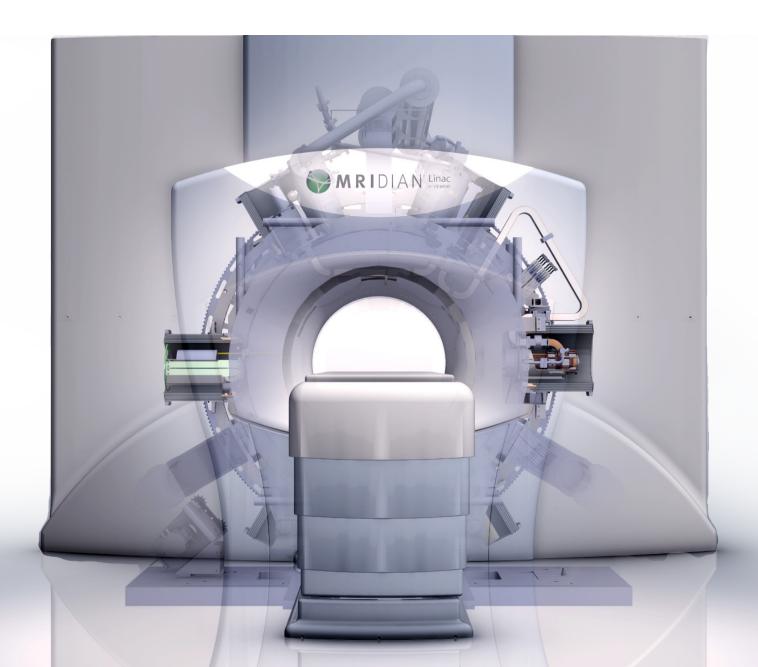
# MRIdian<sup>®</sup>Linac Advantage







# MRI + LINAC THE FUTURE IS HERE



# SIMULTANEOUS **IMAGING AND TREATMENT** because organ motion matters

It is a simple truth. Voluntary and involuntary lifesustaining movements don't stop while your patients are receiving radiation therapy. As your patient moves, the tumor and healthy organs move too preventing accurate treatment and sparing of healthy tissues!

At ViewRay<sup>®</sup>, we understand that the best way to deliver an accurate dose of radiation to a moving target is to be able to see inside the body at the time of treatment. That is why we designed MRIdian<sup>°</sup>, the world's first and only MRI-Guided Radiation Therapy System that can image and treat cancer patients simultaneously. MRIdian was an early breakthrough allowing the world's first clinical MRI guided radiation treatments, having treated over 1,200 patients in clinics worldwide.

The MRIdian<sup>®</sup> Linac, is ViewRay's latest breakthrough technology. It is based on the clinically proven MRIdian imaging and treatment planning platform. The nextgeneration radiotherapy solution that integrates a linac with MRI technology in a compact design, together with our proprietary software to locate, target and track the position and shape of tumors while radiation is delivered. MRIdian Linac uses the same split-magnet MRI system used in MRIdian and is designed to fit in standard radiotherapy vaults replacing X-Ray guided linear accelerators.

MRIdian Linac can provide continuous soft-tissue imaging during linac-based radiation treatment. Being able to constantly see both the tumor and surrounding organs means you can accurately align the tumor to the treatment beams, adapt or reshape the treatment volume to accommodate changes in the shape and location of the tumor and healthy tissues, and track soft tissues in real time to avoid missing a moving tumor or irradiating sensitive internal structures.

MRIdian Linac's proprietary deformable image registration based auto-contouring, Monte Carlo based dose computation, and treatment plan optimization software allow you to review and adapt the treatment plan while the patient is on the table. Over 3000 on-table adaptive treatment sessions have been delivered on the MRIdian platform, as described by Acharya et al. [1]. Our MRI-based technology improves tumor visibility and spares as much healthy tissue as possible while powerful tracking tools make sure only the precise amount of radiation prescribed is delivered. The treatment sequences are recorded so you can evaluate the therapy session at any time or share it with your patient for added peace of mind.

With MRIdian Linac's enhanced visualization and motion management tools you can treat your patients with clinical confidence, knowing that you will be able to target the tumor accurately and deliver less radiation to your patients' healthy tissue. Image and treat simultaneously with MRIdian Linac because organ motion matters! The dosimetric value of reshaping the dose distribution based on daily MRI visualized anatomy basis has been demonstrated by Henke et al. [2, 3] and the dosimetric value of realtime soft tissue target tracking in reducing treatment margins has been demonstrated by Acharya et al. [4].

- [1] Acharya, S., et al (2016). Online Magnetic Resonance Image Guided Adaptive Radiation Therapy: First Clinical Applications. IJROBP, 94(2), 394-403,
- [2] Henke, L., et al. (2016). Simulated Online Adaptive Magnetic Resonance-Guided Stereotactic Body Radiation Therapy for the Treatment of Oligometastatic Disease of the Abdomen and Central Thorax: Characterization of Potential Advantages. UROBP, 96(5), 1078-1086
- Henke, L., et al. (2017). Phase 1 trial of stereotactic MR-guided online adaptive radiation therapy (SMART) for the treatment of [3] sectable primary malgnancies of the abdomen. Radiother Oncol. S0167-8140 (17) 32761-5. In Press

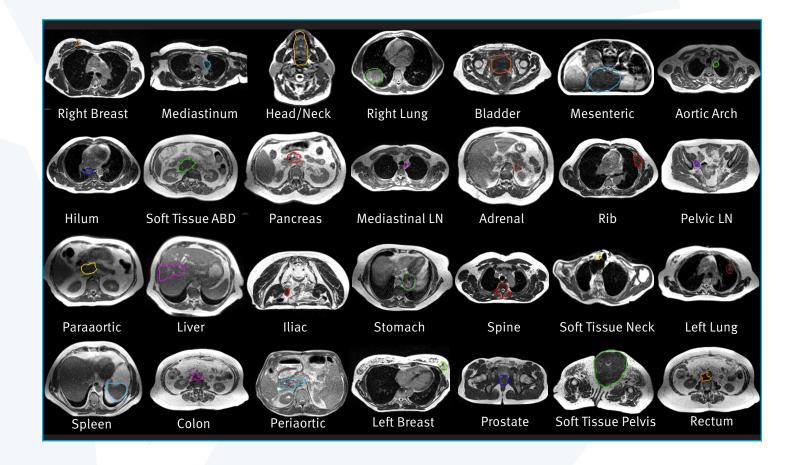
[4] Acharya, S, et al. (2016). Magnetic Resonance Image Guided Radiation Therapy for External Beam Accelerated Partial-Breast Irradiation: Evaluation of Delivered Dose and Intrafractional Cavity Motion, IJROBP. 96(4), 785-792



# ALIGN ADAPT AND TRACK

MRIdian Linac

- Improves tumor visibility and patient alignment
- Tracks tumors and manages patient motion
- Provides on-table adaptive RT planning
- Accurately records delivered radiation dose
- Supports advanced therapy techniques
- Fits into existing treatment paradigms and workflow











# ULTRA-FAST TREATMENT PLANNING without compromising quality

MRIdian<sup>®</sup> Linac offers an adaptive, automated and integrated treatment planning system that uses a linac to deliver modulated radiation therapy. Our proprietary Monte Carlo Treatment Planning System (TPS) is ultra-fast without compromising quality. MRIdian Linac TPS supports existing treatment paradigms and can be used to create treatment plans for three-dimensional conformal radiation therapy (3D-CRT); intensity modulated radiation therapy (IMRT); stereotactic radiosurgery (SRS); stereotactic body radiation therapy (IGRT); and image-guided radiation therapy (IGRT); across a broad spectrum of disease sites.

Both Treatment Planning System (TPS) and Treatment Delivery System (TDS) workstations have a minimum of fourteen processor cores, 128 GB RAM, 4 GB video card, 2 x 512 GB hard disk space and an oversized LCD display.

Treatment Planning and Delivery System (TPDS) refers to the treatment delivery system. Treatment plans may be created on the TPS workstation using volumetric CT, MRI, or PET images. The TPS is designed to create optimized 3D-CRT, IMRT, SRS and SBRT, conformal and combinations of IMRT and conformal treatment plans. The TPDS workstation supports proprietary Monte-Carlo based re-optimization or re-planning for on-table adaptive therapy if changes in tumor or surrounding anatomy are observed on daily MR positioning images.



# MRIdian<sup>®</sup> Linac Treatment Flow

#### **MRI Positioning Scan**



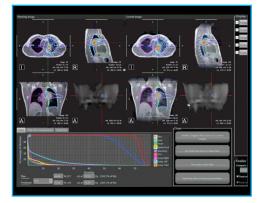
Auto-Contour



#### **On-Table Dose Prediction**



#### **On-Demand Optimization**



# DAILY TREATMENT FLOW under 20 minutes

### ALIGN

#### **MRI** Positioning Scan for Patient Setup

An integrated MRI unit captures volumetric soft-tissue images for accurate pretreatment positioning in just a few seconds. The highquality soft-tissue contrast allows you to locate the tumor and align the patient to the treatment beams accurately without using X-ray, CT or surrogate for registration markers. MRIdian<sup>®</sup> Linac allows accurate automatic patient alignment..

## ADAPT

#### Auto-Contour

MRIdian Linac provides real-time imaging that clearly defines the targeted tumor from the surrounding soft tissue and other critical organs. Using an MRI image captured at the beginning of each therapy session, the system automatically identifies and maps the patient's soft tissue anatomy in 3D. It then transfers contours to the daily image using a rigid or deformable registration.

#### **On-Table Dose Prediction**

On-table dose prediction rapidly produces dose distributions and DVHs to predict the anticipated dose delivery. While the patient is on the treatment table the system compares the pre-treatment MRI image to the planning image and automatically calculates the original plan and displays how it would be delivered to the target based on the anatomy of the day. The user can then compare the results to the original prescription.

#### **On-Demand Optimization**

Utilizing our proprietary Monte Carlo algorithm and software, MRIdian Linac calculates the optimal treatment plan for the patient at the time of treatment. MRIdian Linac has the ability to automatically recalculate the dose and adapt the treatment plan to changes in the patient's anatomy at the time of treatment. You can re-optimize and re-plan your treatment session in less than two minutes while the patient is on the table.



#### TRACK

#### Track Tissue and Manage Patient Motion

MRIdian<sup>®</sup> Linac captures multiple soft-tissue imaging planes concurrently during treatment, refreshing the image multiple times per second. This real-time imaging allows you to track the movement of the tumor and the surrounding healthy tissue directly as well as verify the target and tracking boundary. If a specified percentage of tumor or critical organ moves beyond a physician-defined boundary, the treatment beam automatically pauses. When the tumor moves back into the predefined boundary, treatment automatically resumes. Beam control is especially important in situations where tumors may be in close proximity to critical organs.

#### Treatment

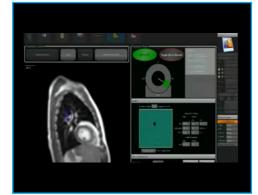
MRIdian Linac can be used for 3D-CRT, IMRT, IGRT, SBRT and SRS across a broad spectrum of disease sites. MRIdian Linac's increased target accuracy allows you to treat patients with higher doses of radiation over fewer treatment fractions. This, combined with improved tumor visibility and accurate dose recordings, means you can treat patients who would not previously have been considered radiation therapy candidates. MRIdian Linac also captures and records a video of the delivered treatments, called MRIdian Movie<sup>™</sup>, for later evaluation or for sharing with your patients.

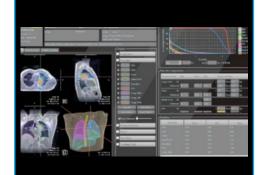
#### **Physician Review**

MRIdian Linac calculates the dose delivered after each treatment and records the level of radiation exposure that the tumor has received, allowing you to review and adapt the prescription between fractions on demand. MRIdian Linac provides you with complete information and a wide range of powerful review and assessment tools, allowing you to deliver targeted, personalized radiotherapy for each patient.

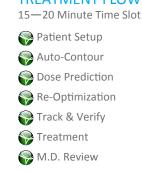
ALIGN, ADAPT AND TRACK WITH VISUAL CLINICAL CONFIDENCE







# TREATMENT FLOW





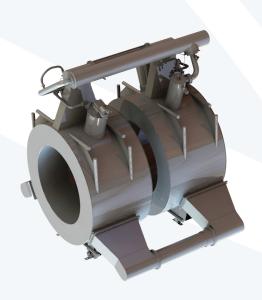
# SOPHISTICATED SCIENTIFIC DESIGN optimal field strength for radiation therapy

#### **MRI SYSTEM**

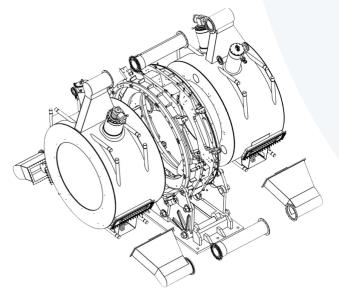
One of the most significant advantages of MRIdian<sup>®</sup> Linac is that it integrates an MRI system with a Radiation Delivery System.

The MRI component of MRIdian Linac captures soft tissue images of the patient's body simultaneously during treatment. We have engineered our MRI system to be able to produce high-quality images using a low field strength 0.35 Tesla magnet.

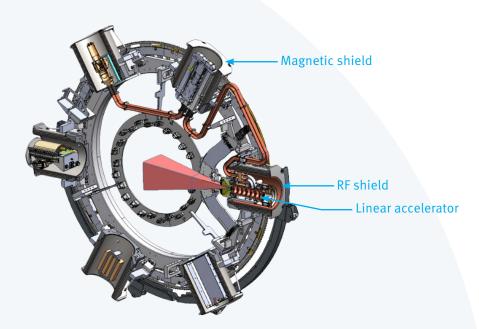
One of the key benefits of this design is that it provides optimal field strength for radiation therapy. The 0.35 Tesla magnet allows the system to avoid the image artifacts and distortions in the dose distribution that occur when using a high field strength magnet. MRIdian Linac's low field MRI allows for geometrically precise images, without susceptibility distortions or chemical-shift artifacts, and accurate dose distributions. Furthermore, at 0.35 T, owing to the lower RF excitation frequency, RF induced tissue heating is a non issue, allowing uninterrupted MR imaging of the patient. The MRI imaging system fits in standard vaults and has unique pop-apart design as shown below to enable nondestructive rigging.



Another feature of our patented design is the split superconducting magnet. This addresses technical complications that can arise from combining an MRI with a LINAC because the split magnet allows for unobstructed beam path through a central gap.





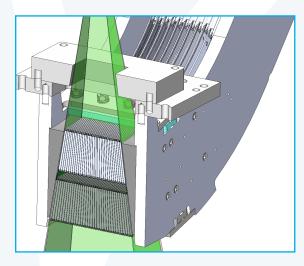


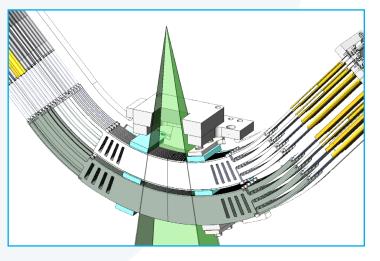
## **RADIATION DELIVERY SYSTEM**

Radiation is delivered from a compact inline S-band 6 MV standing wave linac with side coupled cavities. The flattening filter free linac is designed to deliver 600 cGy/ min. The highlight of the MRIdian<sup>®</sup> Linac design is the patented magnetic and RF shielding that isolates the workings of a linac and the MRI system from each other. A Linac emits RF energy that may interfere with the MRI image acquisition process and affect MRI image quality. MRIdian Linac uses copper shields enforced with carbon fiber for RF shielding. The combination of the materials reduces RF leakage from the linac to almost zero, ensuring zero impact on the MR image quality. The linac gantry is located in the central gap of the split super conducting magnet. ViewRay has developed specialized magnetic shielding technology consisting of concentric

steel shells that create a central magnetic void at the linac components, in the otherwise uniform magnetic field of the MRI.

The linac is equipped with a 138-leaf double focused double stacked multi-leaf collimator (MLC) with minimum penumbra to shape the beam for precision radiation therapy treatments. The double stack double focused 138 leaf MLC (34 leaf pairs – upper stack, 35 leaf pairs – lower stack). Each leaf projects with a nominal width of 8.30 mm at 90 cm SAD. However, the double stack MLC uses an offset between the top and bottom stack to achieve an effective leaf width of 4.15 mm at 90 cm SAD. The MLC is designed to project field sizes up to 27.4 cm x 24.1 cm at isocenter.







# FULLY INTEGRATED SYSTEM for intuitive workflow

# INTERVENTIONAL MRI-IMAGING SYSTEM

Split Superconducting Magnet

- 0.35 T MRI does not distort patient images or dose distributions
- 50 cm diameter of spherical volume (DSV)
- Allows unobstructed beam path
- Designed for simultaneous soft-tissue imaging during therapy
- Low-field ensures no RF induced heating in patients
- State-of- the-art split gradient coil with massive cooling capacity for unlimited fast scanning
- Low- density uniformly radiation-attenuating receive coils ensure superior image quality and optimal dose distributions
- 70 cm bore diameter accommodates large patients
- Fits in standard vaults with "pop-apart" design for nondestructive rigging and installation

# LINAC BASED RADIATION THERAPY SYSTEM

- Flattening filter free design enables dose rate >600 cGy/min
  - Enables fast IMRT, SBRT or conformal external beam radiation therapy
- 138-leaf Double-Focused Double
  Stacked Multi-Leaf Collimator (MLC) system for reduced
  penumbra and minimum interleaf leakage

# INTELLIGENT AUTOMATED SOFTWARE

- On-table Adaptive Treatment Planning with autocontouring, deformable image registration, real-time Monte Carlo calculation and full scale IMRT and SBRT optimization in under 2 minutes
- Real-Time MRI-guided tracking of soft tissue to control beam delivery via on-the-fly target registration and real-time beam control
- Comprehensive Database and Informatics System captures all simulation, treatment planning and the treatment delivery information
- Automatic archiving of all parameters, images, treatment plans and accumulated dose to target via deformable image registration and Monte Carlo simulation



**On-Table Dose Prediction** 

Soft Tissue Tracking

# INTEGRATED WORKFLOW

**Operators Console** 

• Integrated console for patient positioning, on-table dose prediction, treatment plan optimization and replanning, real-time tissue tracking and treatment

Treatment Planning Station

• Support for multi-modality image based reviewing, contouring, treatment planning and treatment monitoring

Automatically Updated Database Server

• Captures all patient and machine data





# **KEY SYSTEM SPECIFICATIONS**

Parameter	
Beam Energy	6 MV
Accelerator Type	Standing Wave
Microwave Source	Magnetron
Dose Rate	> 600 cGy/min (FFF) in water at 90 cm SAD, for a 10 cm x 10 cm field
Isocenter Distance	90 cm
MLC	138 leaves, double focused, double stacked
MRI System Parameters	
Field Strength	0.35 T
Magnet type	Superconducting
Bore diameter	70 cm
Homogeneity over 45 cm DSV	< 25 ppm
Field of View	50 cm
Spatial integrity	< 0.2 cm over 35 cm DSV < 0.1 cm over 20 cm DSV
Patient couch weight limit	440 lbs
Patient couch repositioning accuracy	<u>+</u> 0.1 cm
Patient couch travel range inside bore	Vertical: 0 to -20 cm Lateral: -7 to +7cm

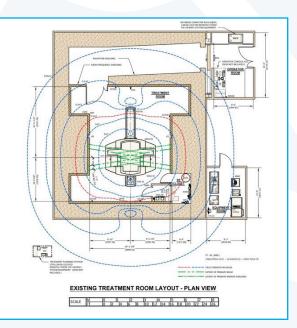


# EASY SITE PLANNING system fits into a standard vault

## SPACE REQUIREMENTS

Recommended Vault Size: 5.9 m x 7.6 m Minimum Finished Ceiling Height: 2.9 m Minimum Clear Opening into Vault: 1.2 m W x 2.1 m H Recommended RF Closet Size:

1.1 m x 1.2 m



MRIdian<sup>®</sup> Linac is designed to fit into a typical radiation therapy vault, similar to other replacement linear accelerators. All of the components fit through standard hospital vault entrances for easy assembly.



ViewRay<sup>®</sup>, Inc. (NASDAQ:VRAY) is a medical device company developing advanced radiation therapy technology for the treatment of cancer. ViewRay holds the exclusive worldwide license for its combination of MRI and radiation therapy technologies.

MRI-guided radiation therapy was conceived by company founder James F. Dempsey, Ph.D., while he was a member of the radiation oncology faculty at the University of Florida in 2003.





exclusively focused on MRI-guided radiation therapy

# As the innovators of practical and clinical MRI-guided radiation therapy ViewRay continues to add to a growing list of industry firsts,

- First on-table adaptive RT system
- First patient treated with MRI-guided RT
- First FDA-cleared MRI-guided RT system -MRIdian<sup>®</sup>
- First CE-marked MRI-guided RT system
- First to provide direct soft tissue tracking
- First exclusively Monte Carlo TPS
- First MRI-guided system to fit in standard vaults
- First commercially available MRI-guided Linac system

At ViewRay we believe that MRI-guided radiation delivery should be the standard of care for radiation therapy. We are partnering with top-tier hospitals including leading university research and teaching hospitals in a global effort to educate radiation oncologists about the capabilities and resulting benefits of MRI-guided radiation delivery over traditional radiation therapy systems.

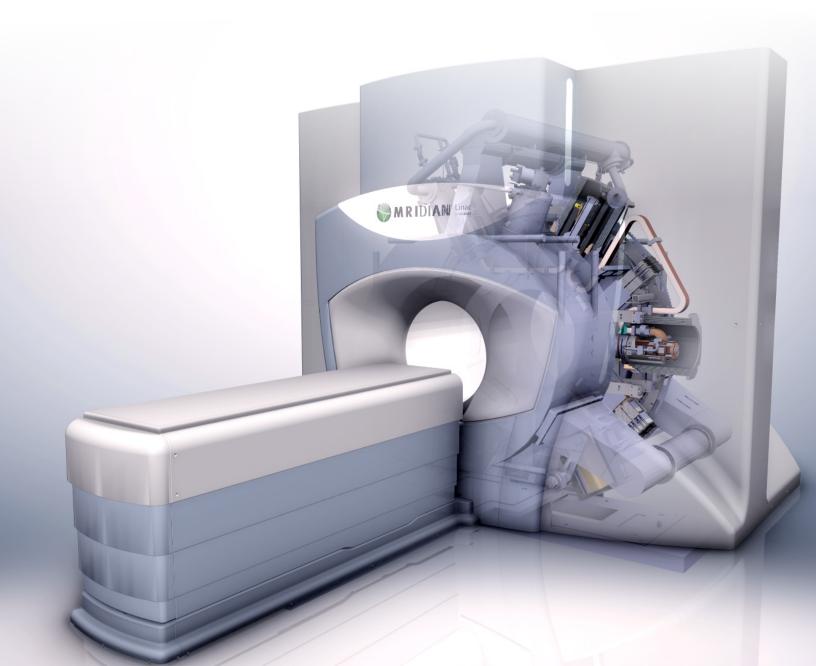
We will maintain our competitive lead in MRI- guided radiation therapy and adaptive treatment planning by committing to continued innovation. We are working with leading cancer centers and early adopters of best-in-class technology to collect and publish data on clinical efficacy, treatment times and clinical results for patients who have been treated on our first FDA cleared product - MRIdian<sup>\*</sup>. ViewRay will continue to support the publication of clinical and scientific data and analysis, work with key opinion leaders, present at leading academic conferences and engage in outreach at leading hospitals worldwide.

Utilizing professional feedback to guide product development, we plan to continue to introduce enhancements to the system that will maximize the efficiency and effectiveness of our products for our customers and improve patient outcomes.

ViewRay is exclusively focused on MRI-guided radiation therapy. By continuing to invest in our technology we are confident that we will maintain our leadership position in the emerging MRI-guided radiation therapy market.



# World Leader in MRI Guided Adaptive Radiation Therapy



# www.viewray.com

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