# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Date of Report: May 27, 2015

(Date of earliest event reported)

MRI INTERVENTIONS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 000-54575 (Commission File Number) 58-2394628 (I.R.S. Employer Identification No.)

5 Musick Irvine, California (Address of principal executive offices)

92618 (Zip Code)

(949) 900-6833 (Registrant's telephone number, including area code)

Not Applicable (Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01. Regulation FD Disclosure.

MRI Interventions, Inc. (the "Company") is posting an updated investor presentation to its website at http://ir.stockpr.com/mriinterventions/presentations. A copy of the investor presentation is being furnished herewith as Exhibit 99.1. The Company may use the investor presentation from time to time in conversations with analysts, investors and others.

The presentation is furnished by the Company pursuant to Item 7.01 of Form 8-K and will not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

The information contained in Exhibit 99.1 is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission ("SEC") and other public announcements that the Company may make from time to time, by press release or otherwise. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

See Exhibit Index immediately following signature page.

### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz
Harold A. Hurwitz
Chief Financial Officer

Date: May 27, 2015

### EXHIBIT INDEX

Exhibit No. Description

99.1 MRI Interventions, Inc. investor presentation dated May 2015



Ticker: MRIC

Investor Presentation

May 2015



Transforming minimally invasive neurosurgery by enabling real-time visualization with MRI

### Forward-Looking Statements

Certain statements in this presentation may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forwardlooking statements often can be identified by words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," or the negative of these words or other words of similar meaning. Forward-looking statements by their nature address matters that, to different degrees, are uncertain and involve risk. Uncertainties and risks may cause MRI Interventions' actual results and the timing of events to differ materially from those expressed in or implied by MRI Interventions' forward-looking statements. Particular uncertainties and risks include, among others: demand and market acceptance of our products; our ability to successfully expand, and achieve full productivity from, our sales, clinical support and marketing capabilities; availability and adequacy of reimbursement from third party payors for procedures utilizing our products; the sufficiency of our cash resources to maintain planned commercialization efforts and research and development programs; future actions of the FDA or any other regulatory body that could impact product development, manufacturing or sale; our ability to protect and enforce our intellectual property rights; our dependence on collaboration partners; the impact of competitive products and pricing; the impact of the commercial and credit environment on us and our customers and suppliers; and our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, our ClearTrace system. More detailed information on these and additional factors that could affect MRI Interventions' actual results and the timing of events are described in our filings with the Securities and Exchange Commission, including, without limitation, the quarterly report on Form 10-Q filed on August 11, 2014. Except as required by law, MRI Interventions undertakes no obligation to publicly update or revise any forward-looking statements made in this presentation to reflect any change in MRI Interventions' expectations or any change in events, conditions or circumstances on which any such statements are based.

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### **MRI Interventions Opportunity**

### Large Market

- Market is large and growing
  - 55,000 potential ClearPoint procedures across multiple therapies

# Navigation System for Multiple Therapies

- Deep Brain Stimulation electrode placement
- Laser Ablation for reduction of epileptic seizures or ablation of Brain Tumors
- Brain Tumor Biopsy for deep seated tumors
- Precise Drug Delivery to target lesions

# Large Opportunity Attracting Multiple Players

- Area of interest to large medical device companies
  - Medtronic, St. Jude and Boston Scientific investing in neuro market
  - MRI Scanner Companies embracing MRI-guided therapies
  - Drug Companies pursuing direct delivery

# Uniquely Positioned

- MRIC is uniquely positioned to capitalize on these market dynamics
  - Delivery platform for multiple therapies
  - Strong, proprietary position



# MRI Interventions: Real Time MRI Guided Surgery

### **Company Highlights**

First-to-market technology platform enabling real-time MRI guided surgery

Significant commercial traction: FDA-cleared, CE-marked and 40+ ClearPoint sites

Attractive razor/razorblade business model with strong margins

Compatible with all major MRI manufacturers; Interoperability w/ Medtronic, Monteris, neuro products

Strong intellectual property portfolio

Strong management team with extensive medical device commercialization experience: Intuitive, Medtronic, Kyphon, Boston Scientific, Edwards Lifescience, Cordis

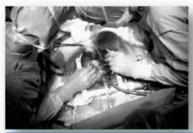
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# Leadership – Significant Med Device Experience



# Minimally Invasive, Visualized Procedures

Revolutionized Multiple Medical Specialities, Benefitted Millions of Patients



# Cardiovascular Surgery Revolutionized by fluoroscopy in the late 1970's

Today: 1.5 million procedures/yr





#### Orthopedic Surgery

Revolutionized by arthroscopy in the 1980's

Today: 1.2 million procedures/yr





#### Abdominal Surgery

Revolutionized by laparoscopy in the late 1980's

Today: 4.0 million procedures/yr

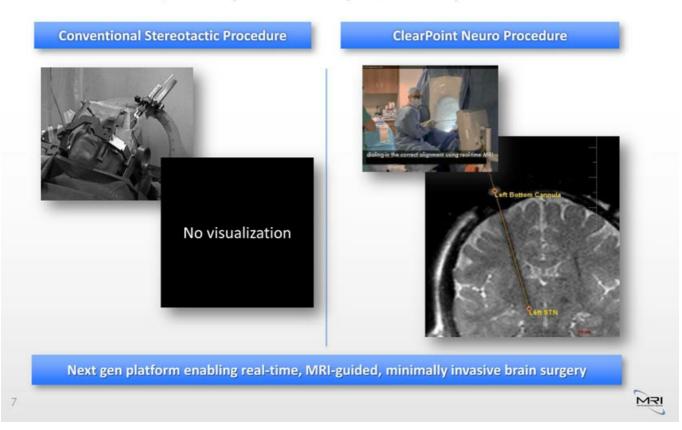




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# Minimally Invasive Neurosurgery with ClearPoint®

Without ClearPoint, minimally invasive neuro procedures are performed "blind"

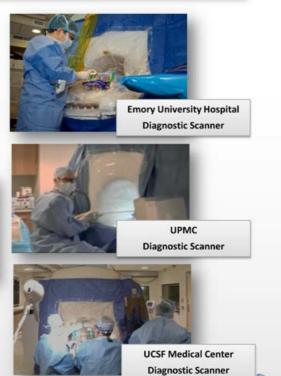


# **ClearPoint Surgical Platform**

### ClearPoint procedures are performed in standard, diagnostic MRI Scanners



- Over 5000 MRI scanners installed in U.S. hospitals
- Ability to ClearPoint-enable diagnostic MRI suites
- 510(k) clearance and CE Mark approval
- Over 700 procedures performed to date
- Procedures can also be performed in intra-op MRI suites

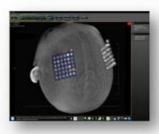


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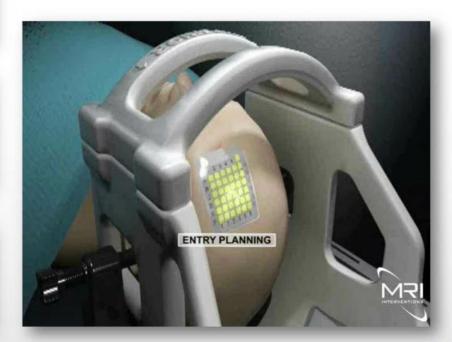
# **ClearPoint Procedure Overview**











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# **ClearPoint Procedure Overview**

### **Trajectory Alignment & Device Insertion**

### SmartFrame® Trajectory Guide



SmartFrame® Hand Controller



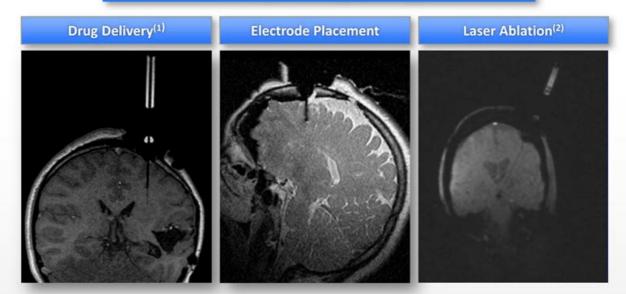


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### **ClearPoint Procedure Overview**

### **Delivery of Neurological Therapy**



- Drug Delivery The SmartFlow® cannula received \$10(k) clearance for injection of cytarabine, a chemotherapy drug, to the ventricles or removal of CSF from the ventricles during intracranial procedures. Delivery of other therapeutic agents, and delivery of agents to other areas of the brain, using the SmartFlow cannula is investigational.
   Laser Ablation MR Thermometry is an MRI-based functionality available on most MR scanner platforms and it is a feature built into products from several third party vendors.
   The ClearPoint system enables MRI-guided procedures and allows physicians to use this inherent MR capability during a procedure.



### **ClearPoint Hospital Economics**

#### **Increase Patients**

Opportunity to reach additional patient populations that may otherwise forego surgery

### **Established, Attractive Reimbursement**

 Move procedures from the more expensive OR to the less expensive MR suite, with equivalent reimbursement

#### Improved Utilization of Existing MRI's

- 1 hour of MR Scanner time used for diagnostic imaging could generate \$1,200<sup>(1)</sup>
- 1 hour of MR scanner time used for a ClearPoint procedure could generate \$5,275<sup>(2)</sup>
- Utilizes existing MRI's already in hospital



<sup>(1)</sup> Estimated average US hospital-based MRI suite revenue per hour for outpatient diagnostic scans, based on data gathered by MRI Interventions. Excludes professional fees. Actual revenues will vary by hospital, procedure and payor.

<sup>(2)</sup> Based on a weighted average payment to MRI Interventions' customers (as of September 2014) for an electrode placement procedure for Medicare and private insurance patients, calculated by MRI Interventions using a payor mix weighted 67% to average Medicare reimbursement and 33% to average private insurance reimbursement. Average Medicare reimbursement calculated as the weighted average Medicare payment for MRI Intervention' customers (as of September 2014) for an electrode placement procedure under MS-DRGs 025, 026 and 027. Average private insurance reimbursement calculated as 1.5x Medicare reimbursement, based on published data. Hourly amount assumes 4.5 hour procedure duration. Excludes professional fees. Actual revenues will vary by hospital, procedure and payor.



# **Multi-Therapy MRI-Guided Navigational System**

### **Implemented Across All Major Scanner Platforms**











### **Compatible With Multiple Therapies**









### **Strong Peer-Reviewed Journal Support**







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### **Strong Base of Clinical Support**

### **Leading Neurosurgeon Supporters**



**ASSFN Past President** 



UCSF & VA



Dr. Robert Gross **Emory University** 



Mayo Clinic -Jacksonville



Dr. Krys Bankiewicz Bankiewicz Lab, UCSF



OSU - NIH

The ClearPoint System "represents a major step forward in our ability to treat complex neurological diseases." Dr. Karl Sillay, Neurosurgeon, University of Wisconsin

> "ClearPoint allows me to surgically treat patients I would not be able to treat using other platform systems."

Dr. Hooman Azmi, Neurosurgeon, Hackensack Univ. Med. Center

80% of neurosurgeons/neurologists surveyed believe real time MRIguidance will or can become the future of functional neurosurgery. (1)

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# **Patient Impact**

### Martin's Story ClearPoint-Enabled Electrode Placement



# **Patient Benefit - Minimally Invasive Procedure**

7 days after ClearPoint procedure – Arrow Indicates Surgery Site



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### The ClearPoint Difference

Without ClearPoint (Stereotactic)	With ClearPoint
No direct visualization; Performed in an operating room	Direct, high resolution visualization; Performed in an MRI Suite
Patient may be awake for own brain surgery(1)	Patient may be under general anesthesia <sup>(1)</sup>
Long procedures – Can be up to 8 hours	Shorter procedures – Can be 3 hours or less
Complex procedure, requires extensive training	Straightforward procedure, brief training
Poor economics for hospital and physician	Attractive economics for hospital and physician

### ClearPoint is a win-win-win

**Patients** 

Surgeons

Hospitals

(1) Microelectrode recording and macrostim are processes that involve listening to neuronal firings (i.e., physiological recordings) and observing physiological responses to stimuli during brain surgery. In connection with our \$10(k) clearance in 2010, the FDA requested a warning within ClearPoint's Instructions for Use based on the lack of data with respect to deep brain stimulation (DBS) procedures. The warning states that the ClearPoint system, alone, should not be used to guide a DBS lead to a specific brain target and that final placement of DBS leads requires physiological recordings to confirm that they are located in the correct brain target and functioning as intended.



### MRIC's Unique Opportunity in Drug Delivery

Provides MRIC with "biotech-like upside" without "all or nothing downside"

#### Major Challenges in Delivering Drugs to the Brain

- Blood brain barrier blocks systemic delivery of almost all drugs 98% of small molecules
- Direct injection without ClearPoint is blind, so target is frequently missed
  - Neopharm Trial 51% of 572 catheters failed to meet all positioning criteria

#### Major Benefits of Drug Delivery with ClearPoint

- Neurosurgeon sees that target is reached
- Eliminates the blood brain barrier issue; Reduces/eliminates unwanted systemic side effects; Reduces dosage levels (as little as 1/300th of systemic volumes)

#### Business Model - MRIC Partners with Drug Companies and Researchers

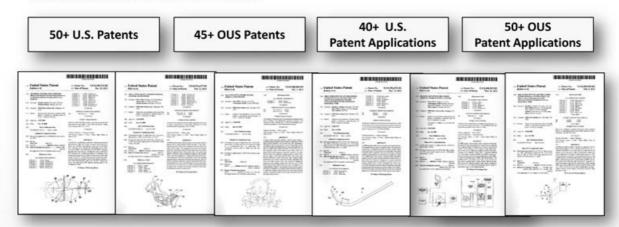
- MRIC provides ClearPoint; Drug company provides drug candidate
- Drug company/sponsor pays for trial
- If drug is approved, MRIC gets device revs (~\$7000/case); Drug co gets drug revs



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# **Strong Intellectual Property**

MRI Interventions Patent Portfolio



Issued patents cover areas such as: MRI-guided surgical systems that include software and devices; the SmartFrame® trajectory guide; other ClearPoint® disposable components; active intracranial probes; MRI-compatible catheters; MRI-safety technology

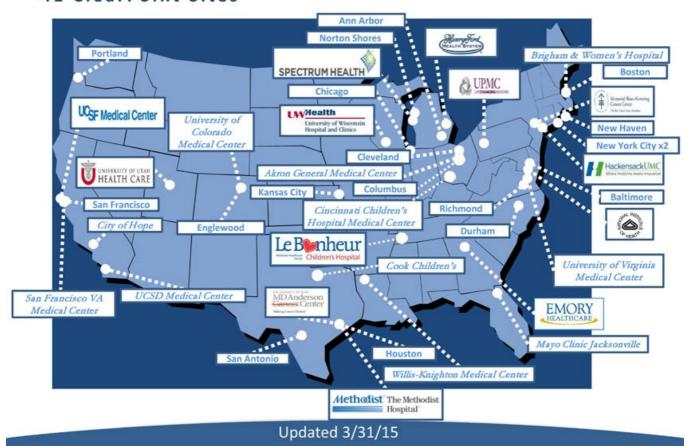
Key ClearPoint-related patents do not begin to expire until 2027

#'s as of Aug.11, 2014



### **Growing the ClearPoint Footprint**

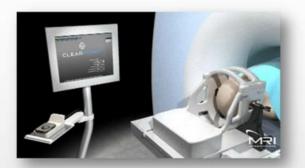
### 41 ClearPoint Sites



### **ClearPoint Revenue Model**

### **BUSINESS MODEL - RAZOR / RAZORBLADE**

- ClearPoint Hardware/Software: \$100,000 \$150,000 ASP
- ClearPoint Disposables: \$7,500 ASP per procedure with strong margins
- Recurring revenue from the sale of disposables
- Procedures covered by existing inpatient DRG reimbursement codes
- Platform system for multiple neurosurgical procedures





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# ClearPoint U.S. Market Opportunity – Current

Demographics	Parkinson's	Epilepsy	Brain Tumors
Prevalence	1,500,000	2,200,000	N/A
Incidence (New diagnosis /yr)	60,000	150,000	180,000
Surgeries (2012)	3,125	7,660	Resections: 80,000 Stereotactic Biopsy: 10,000

#### **Current Potential ClearPoint Surgical Candidates**

ClearPoint-enabled Approach	Electrode Placement (e.g. DBS)	Laser Ablation RNS <sup>(1)</sup>	Laser Ablation & Biopsy
Prevalence (Drug Treatment Resistant)	125,000	264,000	N/A
Incidence	7,500	18,000	80,000
Potential Annual ClearPoint Procedure <sup>(2)</sup>	12,500 55,000+	28,500 Potential Procedures	14,500 Per Year
Growth Drivers	- 65% opt out rate	- Replaces craniotomy	- Replaces craniotomy

- Medtronic (Visualase)

/Monteris

Note: Prevalence and incidence based on either market research conducted by a third party on behalf of MRI interventions or research conducted by MRI interventions of publicly

- New DBS companies

coming to market

<sup>(1)</sup> Responsive neurostimulation device (RNS)
(2) Potential Annual ClearPoint Procedures based upon 5% of prevalence and 85% of incidence; Potential Annual ClearPoint Procedures for brain tumors based on market research conducted by a third party on behalf of MRI Interventions.



- Medtronic (Visualase) /Monteris

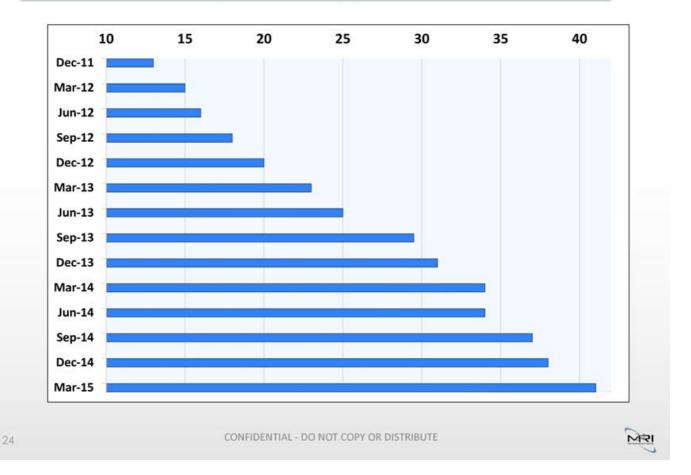
# ClearPoint U.S. Market Opportunity – Future

Disease	Therapy	Regulatory Status of Therapy	Total Patient Population	# of Potentially Addressable Cases	Total Potential Addressable Cases
ClearPoint Us	se - Active				
Dystonia	DBS	HDE	250,000	25,000	
OCD	DBS	HDE	3,300,000	100,000	182,500
Brain Mets	Laser Ablation	Approved	115,000	57,500	
ClearPoint Us	se – Clinical Trials	į			
Brain Tumor (HG Glioma)	Drug Delivery	Clinical Trials - Phase I	11,000	11,000	1 511 000
Parkinson's	Drug Delivery	Clinical Trials – Phase I	1,500,000	1,500,000	1,511,000
ClearPoint Us	se – Pre-Clinical				
Huntington's	Drug Delivery	Pre-Clinical	30,000	30,000	C0 000
ALS	Drug Delivery	Pre-Clinical	30,000	30,000	60,000
ClearPoint Us	se – Research On	ly			_
Major Depression	DBS	Trials	6,000,000	1,200,000	1,700,000
Alzheimer's	DBS	Trials; Research	5,400,000	500,000	1 2,7 00,000

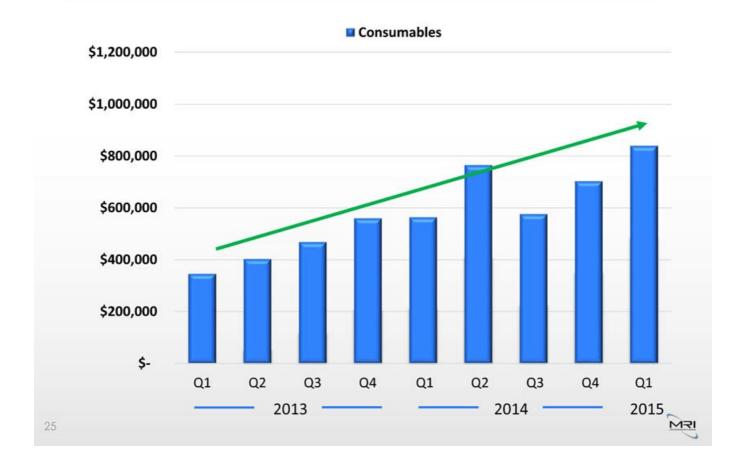
Note: Total Patient Population and # of Potentially Addressable Cases based on either research conducted by MRI Interventions of publicly available sources or market research conducted by a third party on behalf of MRI Interventions.



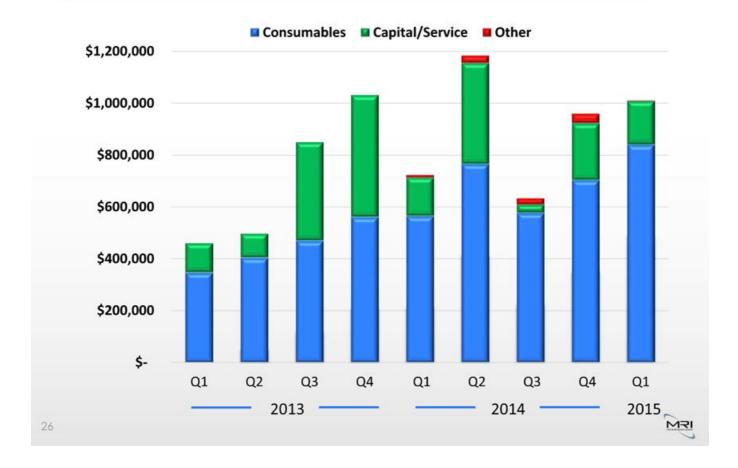
# ClearPoint Sites, end of Q1, 2015



# **ClearPoint Consumable Revenues**



# **Total Product Revenues**



### **Commercial Priorities**

#### Increase Utilization

#### Enhance Communication

### Expand Account Base

### Develop Future Applications

- Target high volume Deep Brain Stimulation (DBS), Epilepsy and Tumor neurosurgeons; gain greater share of their procedures
- Expand use of ClearPoint beyond DBS within existing accounts
  - Laser ablation
  - Tumor biopsy
- Enhance case repeatability through case standardization and enhanced staff training

- Increase peer-to-peer events, presence at trade shows
- Highlight existing data on ClearPoint applications
- Communicate value proposition across procedures:
  - Accuracy
  - Real time visualization
  - Improved workflow
  - Increase patient volume

- Engage both
  Functional and
  Oncologic
  Neurosurgeons in
  discussion of
  ClearPoint
- Continue ClearPoint Placement Program
- Ensure product compatibility with existing and future focal neuro therapies; seamless integration with other technologies
- Support current drug delivery trials as they progress; grow the number of drug delivery trials involving ClearPoint
- Develop next generation of ClearPoint products

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# At the Center of an Emerging Industry Trend





Ticker: MRIC MRI Interventions, Inc.

Irvine, CA

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ir@mriinterventions.com



# **ClearPoint Neuro Intervention System**

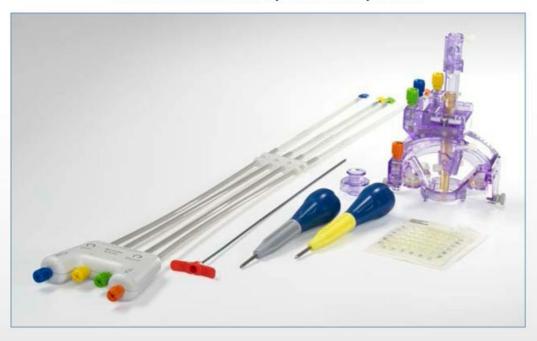
ClearPoint Draping in Preparation for a Case in a Diagnostic MRI Suite





# **ClearPoint Neuro Intervention System**

### **Selected ClearPoint Disposable Components**



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