Advanced Implanted Markers for High Precision IGRT Localization

FusionCoil Marker

1. Introduction

The use of implanted fiducial markers and daily imaging to improve tumor localization was introduced in the early 1990s, and this methodology has now become the standard of care in cases where inter or intra fraction motion is likely to occur. The high precision localization gained via the use of fiducial markers has allowed for reduced treatment margins, which in turn greatly reduces complication from radiotherapy. Furthermore, the advent of stereotactic body radiation therapy (SBRT) is well accommodated by the improved localization achieved when using implanted markers.

Design engineers are now looking to improve on the current marker offerings by carefully recognizing the unique needs of specific treatment sites and requirements of the varying image guided radiation therapy (IGRT) offerings.

2. FusionCoil

The first FusionCoil Marker was a 1.0mm diameter by 20mm long open helix gold coil with a unique biocompatible-segmented titanium alloy at its center. (Fig. 1) It was designed to image well in all x-ray based systems (including CT, MV-CBCT, kV-CBCT, MV and kV planer images) and magnetic resonance (MR) images. It provides clear landmarks from which the user can fuse any combination of image datasets. This includes CT/ MR for planning and all combinations of on-board imagers (OBI) for daily set up.

The design criteria set forth for the FusionCoil Marker were as follows:

- Biocompatible and suitable for permanent implantation,
- Non-migrating,
- Flexible body,
- Visible in CT,MR, all MV and kV IGRT systems,
- Achieve FDA 510k requirements for sale.

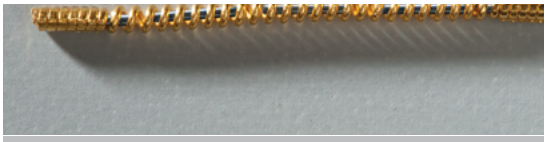

Figure 1

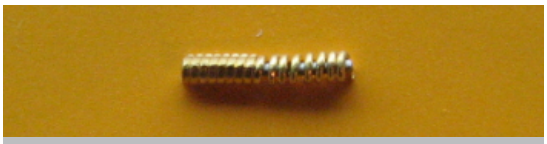

Figure 2

It is flexible and is designed to remain fixed once deployed in soft tissue. Since the release of the initial FusionCoil (Figure 1) a 5mm long FusionCoil (Figure 2) has also been made available.

3. FusionCoil Testing

To demonstrate biocapability a cyclic polarization (ASTM F2129) corrosion test was performed. The combination of dissimilar metals in the marker did not exhibit any breakdown potential and was deemed safe from a corrosion perspective.

The marker was then tested for MR compatibility using four separate tests defined by the American Society for Testing and Materials (ASTM) as listed below. In all cases a 3-Tesla, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, active-shielded, horizontal field scanner was used for testing.

1. ASTM F2052 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment

The markers were suspended from a thin, lightweight string (weight, less than 1% of the weight of the device) attached at the 0° indicator position on the protractor. The length of the string was 20cm, which was long enough so that the device could be suspended from the test fixture and hang freely in space. Motion of the string with each device was not constrained by the support structure of the protractor.

Results:
Mixed Media Marker: Gold Titanium

	Deflection Angle (degrees)
Measurement #1	4
Measurement #2	4
Measurement #3	4

Deflection Angle (degrees, m ± SD)
4 ± 0

Regarding this test, the ASTM standard reads, “If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth’s gravitational field.” FusionCoil passed this test easily.

2. ASTM-F2213 - Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment

The marker was placed on the test apparatus in an orientation 45° relative to the static magnetic field of the 3-Tesla MR system. The use of 45° increments is deemed appropriate for a qualitative assessment of torque for an implant or device. The marker was directly observed for possible movement with respect to alignment or rotation relative to the static magnetic field of the 3-Tesla MR system. The investigator viewed the inside of the MR system bore during the test procedure, thus facilitating the observation process. The marker was then moved 45° relative to its previous position and again observed for alignment or rotation. This process was repeated to encompass a full 360° rotation of positions for each device in the 3-Tesla MR system. The entire procedure was conducted three times and a mean value was calculated for each device with it orientated along its long axis and short axes.

Results:
Torque

Long Axis	Short Axis
0	0
0	0
0	0

Torque (m ± SD)

Long Axis	Short Axis
0 ± 0	0 ± 0

3. ASTM F2182 - Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

This report pertains to the MRI-related heating test conducted at 3-Tesla on the FusionCoil Marker. MRI-related heating was assessed for this device using a plastic phantom that was filled with a semi-solid, gelled-saline that was prepared to simulate human tissue. The ASTM head/torso phantom has a configuration and dimensions to approximate the human head and torso. Fluoroptic thermometry probes were attached to the marker and temperature changes measured and described on page 3.

Results:
Mixed Media Marker: Gold/Titanium

Thermometry Probe	Highest Temperature Change (°C)
Probe #1	+1.6 °C
Probe #2	+1.6 °C
Probe #3	+1.6 °C
Probe #4	+0.7 °C
Background Probe (without implant/device)	+1.5 °C
Background Reference Probe (without implant/device)	+0.7 °C

4. ASTM - F2119 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

MR imaging artifacts were assessed for the marker in association with the use of a 3-Tesla MR system. This test was accomplished by performing MR imaging of the marker inside a gadolinium-doped, saline filled plastic phantom. MR imaging was conducted with the marker placed inside of the phantom. The marker was attached to a plastic frame to facilitate positioning and MR imaging within this phantom and the artifact results were recorded and are describe below.

Results:
Mixed Media Marker: Gold/Titanium

Signal Void Size	73-mm^2	8-mm^2	168-mm^2	49-mm^2
Static Magnetic Field (T)	3	3	3	3
Pulse Sequence	T1-SE	T1-SE	GRE	GRE
TR (msec.)	500	500	100	100
TE (msec.)	20	20	15	15
Flip Angle	N/A	N/A	30°	30°
Bandwidth	16 kHz	16 kHz	16 kHz	16 kHz
Field of View	24 cm	24 cm	24 cm	24 cm
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10 mm	10 mm	10 mm	10 mm
Imaging Plane	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)

(T1-SE, T1-weighted spin echo; gradient echo; N/A, not applicable)

The marker had acceptable readings for all four tests and was deemed MRI compatible.

The marker was then placed in a tissue equivalent phantom and all of the aforementioned imaging studies were performed. The marker is clearly visible in each of the imaging platforms.

4. FusionCoil Clinical Application

An initial study to determine the visibility of the FusionCoil across multiple imaging devices (CT and MR) was defined and a single FusionCoil Marker was implanted in the right side of the prostate and a simple hollow gold coil was placed in the left side. (Figures 3 and 4)

The first ten cases had this marker arrangement to determine the visibility of the two markers in both imaging modalities. Both markers image well in CT but only the FusionCoil is visible in the MR. This was true for all ten cases.

The FusionCoil is applicable in any situation where MR / CT fusion is considered for treatment planning and the use of any image guided radiotherapy system is utilized for daily localization.

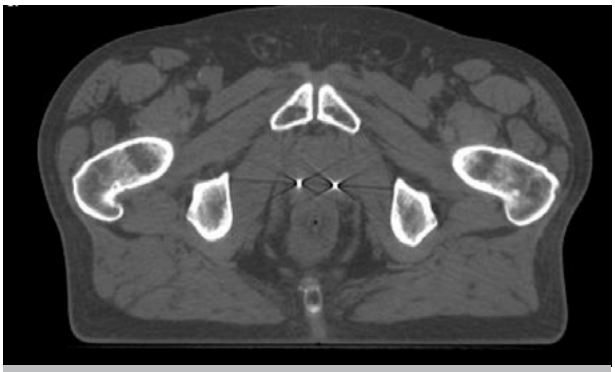

Figure 3 - CT

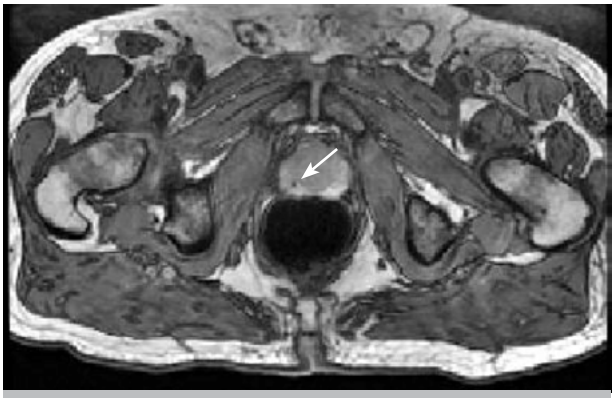

Figure 4 - MR

5. Specification

The FusionCoil Marker is currently available in two lengths: 5 and 20mm. All FusionCoil Markers are 1.0mm in diameter. They are preloaded in typical 18 GA by 20cm long (seeding) needle. They are sterilized in a Tyvek pouch and ready for clinical use (Figure 5).

All markers are FDA certified for marketing and CE marked for sale in the European Union.

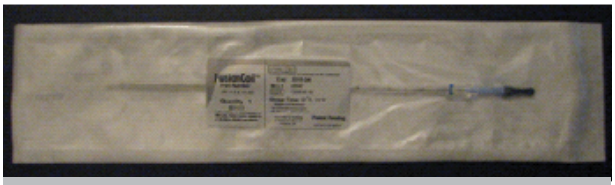

Figure 5

6. IGRT Systems

The FusionCoil has been validated in all of the current IGRT systems used for daily localization.

The 5mm FusionCoil was designed for “point-based” IGRT systems. For example, the Accuray CyberKnife uses a tracking algorithm based on three or more markers that are 1mm x 5mm in size. It acquires an orthogonal pair of images and compares the locations of the implanted markers to a predetermined location associated with the treatment plan and adjusts the treatment beam to accommodate any changes in position. This sequence of image and then irradiate is continuous throughout the entire treatment process.

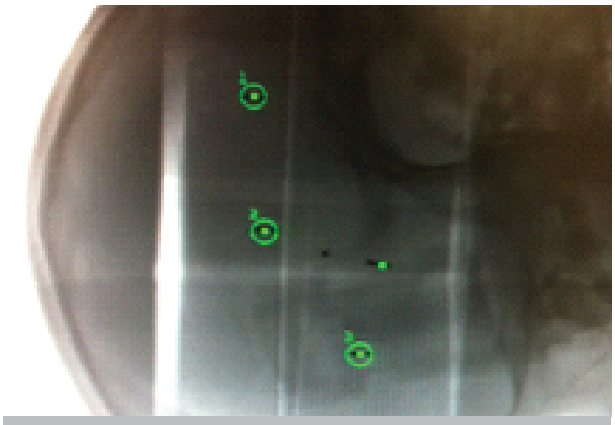

Figure 6

The validation testing of the 5mm FusionCoil on CyberKnife was performed using a cranial phantom. The phantom was aligned to imaging center, thus zeroing out the couch position. The couch was moved a predetermined amount in all three translations (X, Y and Z) to offset the phantom from the imaging center. A second pair of images was acquired and tracked (Figure 6). If the markers are tracking correctly, the imaging system will calculate couch moves that are equal in magnitude to the predetermined shifts but in the opposite direction.

The comprehensive test for this phantom required that the CyberKnife tracking system be able to correctly identify

the implanted markers and calculate a return to alignment after the test engineer made a predetermined couch move. This was done by first moving the phantom with a 10mm offset in all three translational paths. A second study was performed by moving 5mm in all 3 paths. In both cases the CyberKnife correctly tracked the markers and displayed the moves with a maximum difference of 0.2mm (Figure 7).

Figure 7

The 20mm FusionCoil was tested with a variety of linac based IGRT systems. Typically two FusionCoil markers are placed in a prostate, one on the right and one on the left side of the gland. Both kV (Figure 8) and MV (Figure 9) planer images can be used to accurately locate the target for treatment. In either situation a comparative digitally reconstructed radiograph (DRR) of the FusionCoil Marker is generated and either automatically or manually compared to daily planer images.

Cone beam CT and BrainLAB's ExacTrak can also be used to identify and localize the FusionCoil marker and FusionCoils image very well with TomoTherapy's MV imaging beam.

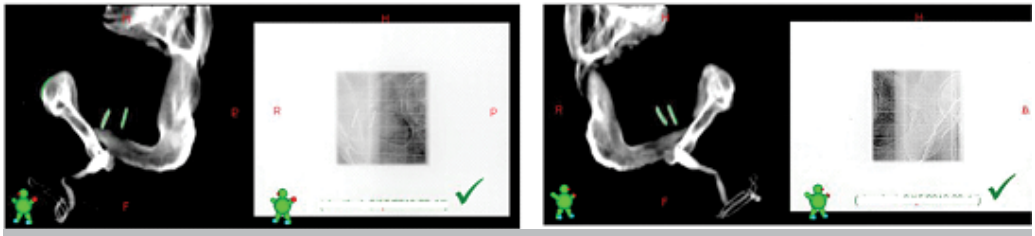

Figure 8

7. Conclusion

The new FusionCoil markers are the optimal solution in cases where highly accurate fusion of MR and CT datasets are required for improved treatment planning. The 5mm and 20mm FusionCoil markers display clearly in both CT and MR imaging systems and all current IGRT systems. They have been validated with all of the aforementioned IGRT systems.

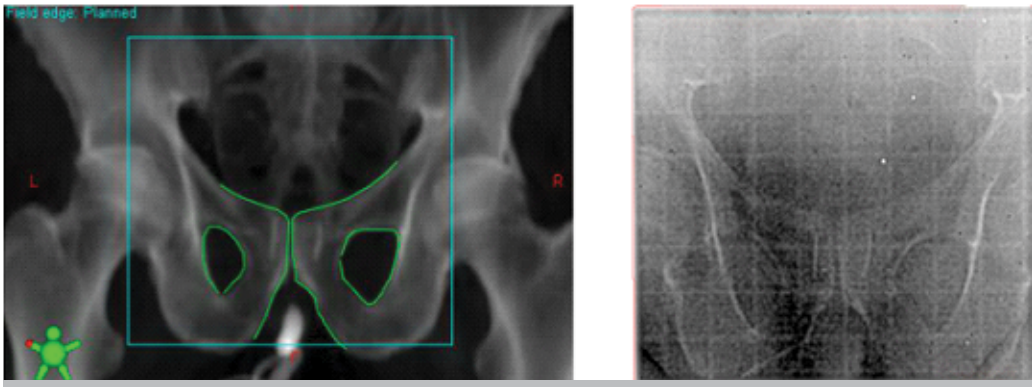

Figure 9

All markers in this report are available from CIVCO Radiotherapy, (www.CivcoRT.com) or 800 842 8688.