# Accusyte™ 3-D Fiducial Marker System

**White Paper**

**Surgical Radiation Products, LLC**


CQ MEDICAL®
Care Smarter

# ACCUSYTE 3D FIDUCIAL MARKER SYSTEM

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DISCLOSURE: NONE

## ACCUSYTE 3D FIDUCIAL MARKER SYSTEM

According to the American Cancer Society over 266,000 new cases of invasive ductal breast cancer and 64,000 cases of DCIS will be diagnosed of which 41,000 patients will die in 2018. This volume will increase to a Radiotherapy market worth 9.47 billion USD by 2022.

Breast conservation of Lumpectomy with Sentinal Node Biopsy and post operative radiation is currently the treatment of choice and the standard of care over mastectomy. Currently whole breast radiation therapy (WBRT) is most frequently used since the post operative location of the previous tumor site cannot be identified. Accelerated Partial Breast Irradiation (APBI) has been in existence as a potential option. However since there is no way to focus on the Cavity Volume to be able to deliver this relatively new concept it has not been widely accepted and offered to the potential candidates ( U of Chicago Breast Cancer Conference (2018). The ACCUSYTE 3D Fiducial Marker would limit the large field of radiation by identifying and localizing the exact cavity thus eliminating the unnecessary radiation of the surrounding healthy tissue as well as adjacent organs such as the heart, lungs, esophagus, muscles, ribs, skin, and other uninvolved tissue in the area of the breast.

Target cavity mapping where the malignancy was removed is now necessary and requires a high degree of accuracy to destroy any residual malignancy in the local area. This target area is currently obscured by mammographic and clinical changes such as; disfiguration of the cavity by change in shape as the skin is closed. This problem is increased over time with local edema, re-absorption of the seroma, and changes in tissue morphology. Hence the Oncologist has to expand the PTV (planned target volume). The area can only be covered by a larger area or volume of radiation with the inherent surrounding tissue damage and yet it is still unclear as to whether the post op bed cavity is actually been treated with the intended goal

A 3D fiducial marker has eliminated the localization problem. This device consists of a marker placed on a dissolvable suture that is positioned in the lumpectomy cavity at the time of surgery by the operating surgeon for pin point accuracy. After removal of the tumor, 4-6 sutures are placed in the wall of the cavity (superior, inferior, medial, lateral, anterior, and posterior). At the time of placement the surgeon knows this exact area. These sutures will not migrate because they are sewn in place and they will continue to delineate the cavity no matter what the shape is at any time. The markers will become encapsulated and remain in place for the life of the patient. These markers offer a precise, stable target for post operative radiation as well as follow up for movement as an indicator for recurrent tumor. Radiation is given only to the location of the tumor bed. The markers themselves are easily placed in the exact location indicated, and cannot be manipulated by the patient movement.

The 3D approach allows imaging from all angles and sides. Imaging modalities such as, KVCT, 2D Linac-based kilavoltage and megavoltage x-ray imaging systems and KV cone beam CT may be utilized.

I have detailed the use of the ACCUSYTE 3D fiducial markers used in the treatment of breast cancers, but this is only a small beginning. As can be imagined localization of all tumors of any organ is just as safe and effective. Some examples are as follows:

### Liver:

Whether a small tumor, or the entire lobe of the liver, the marker can be sutured so as to indicate the tumor cavity or area and the remaining healthy liver will be spared allowing it to regenerate.

### Stomach and Esophagus:

The anastomosis and surrounding area can be marked as a target. Even with breathing and movement the radiation can be delivered accurately and the area followed for recurrent tumor.

### Pancreas:

Accusyte markers are placed in the head of the pancreas as well as along the resected edge which will be used as a target and an indicator for recurrence. Eliminating large areas of radiation to this organ will reduce the amount of intestinal adhesions and ulcers.

### Colon:

Rectal tumors are best treated with post operative radiation. Because we now have the ability to target these tumors, we can now treat tumors throughout the entire colon.

### Uterus:

ACCCUSYTE 3D fiducial markers may target areas of interest in hysterectomys, if adhered to the bladder or sidewall. The vaginal cuff may be closed with the Suture-Marker system to delineate the area of highest recurrence. This is more accurate and reduces pelvic adhesions as well as giving a boost to the areas of most concern.

### Lungs:

Markers are placed on vessels and the bronchus of partial or complete lobectomy,s. Radiation can be accomplished with the patient breathing using the target, with less risk of damaging additional pulmonary tissue. Reducing the chances of making the patient a pulmonary cripple.

### Head and Neck:

By varying the size of the Accusyte marker system we can target areas of the head and neck and oral cavity, again reducing post operative recurrence.

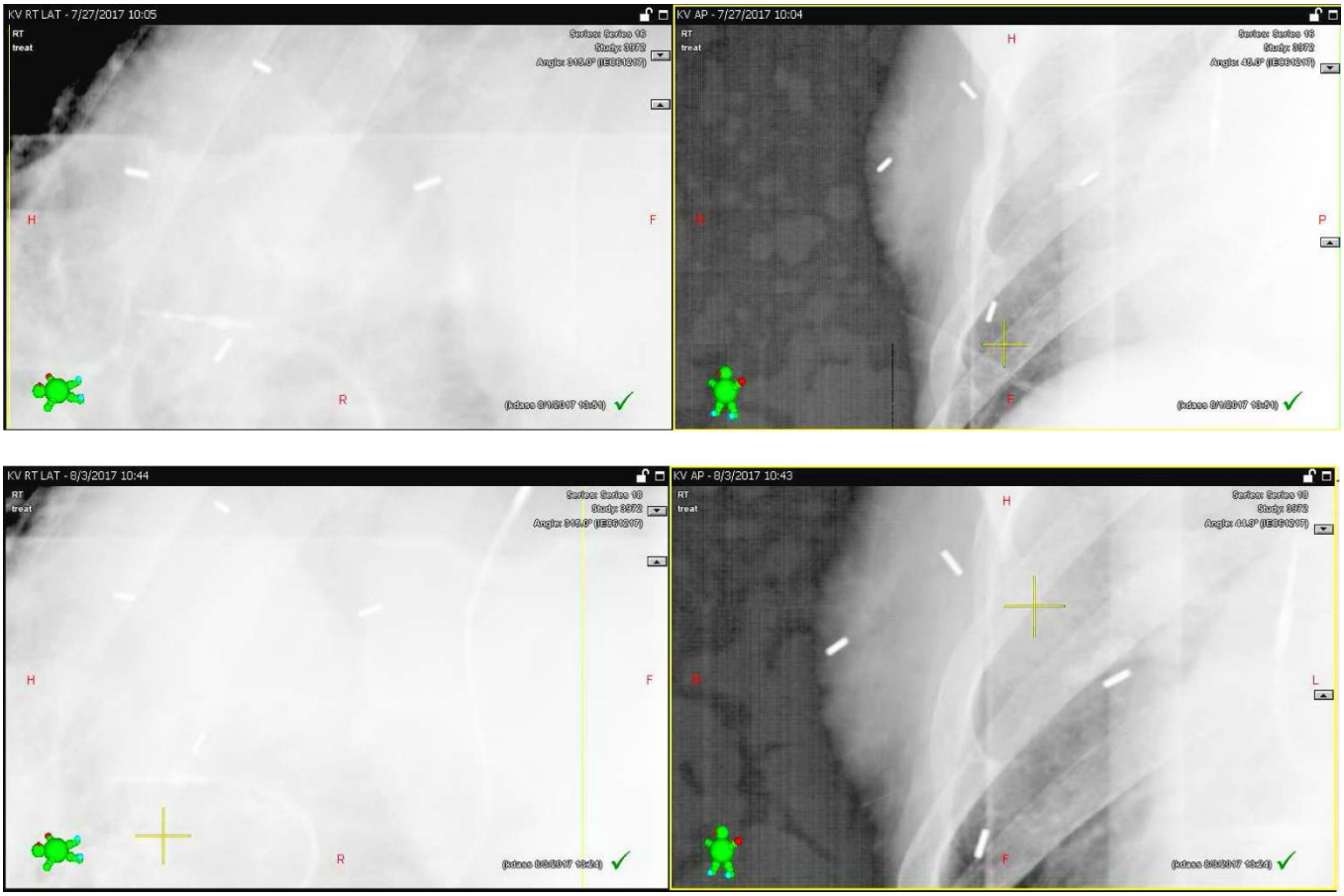
**Prostate:**There is known to be significant tumor left behind in prostatic surgery. Targeting the local area of removal should help improve the incidence of recurrence. The ability to use a smaller cone of radiation will help to reduce the number of post operative complication, such as, erectile dysfunction, incontinence, urinary strictures and others. These markers may be placed robotically, laparoscopically or in open cases. In addition follow up imaging (MRI and CT) *scans will assist the Diagnostician to detect any small recurre .*

Accusyte markers are manufactured under strict FDA guidelines. They were bench tested for stability and visualization. An IDE study protocol was conducted by Western IRB and the results submitted to the FDA for review and approval. 510K clearance was received July 18, 2018.

**See attached images from clinical study and 1-year post implantation below:**

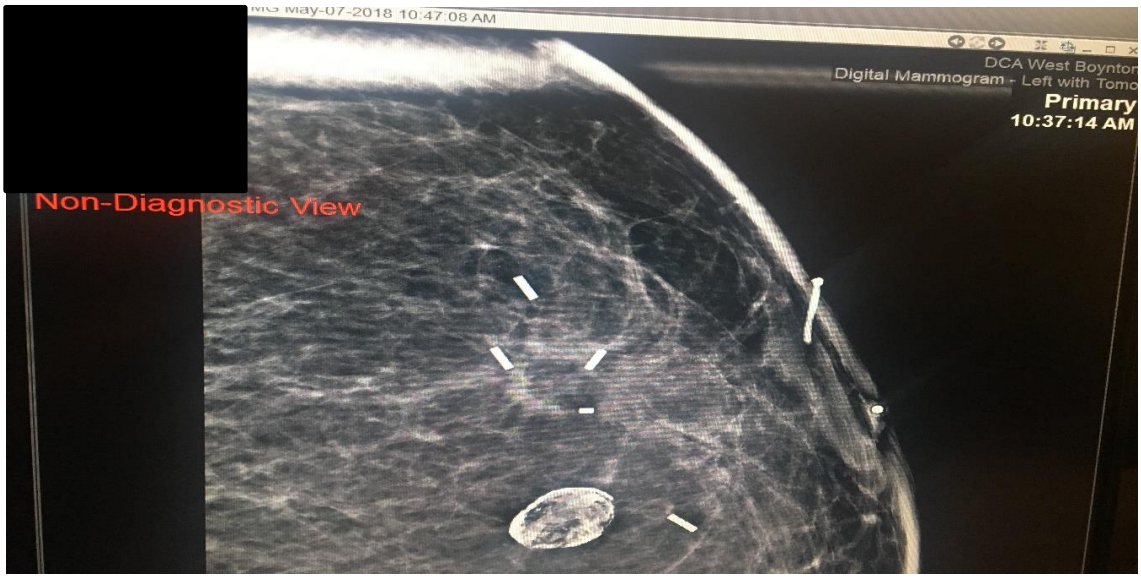
## Radiographic Images from Clinical Study

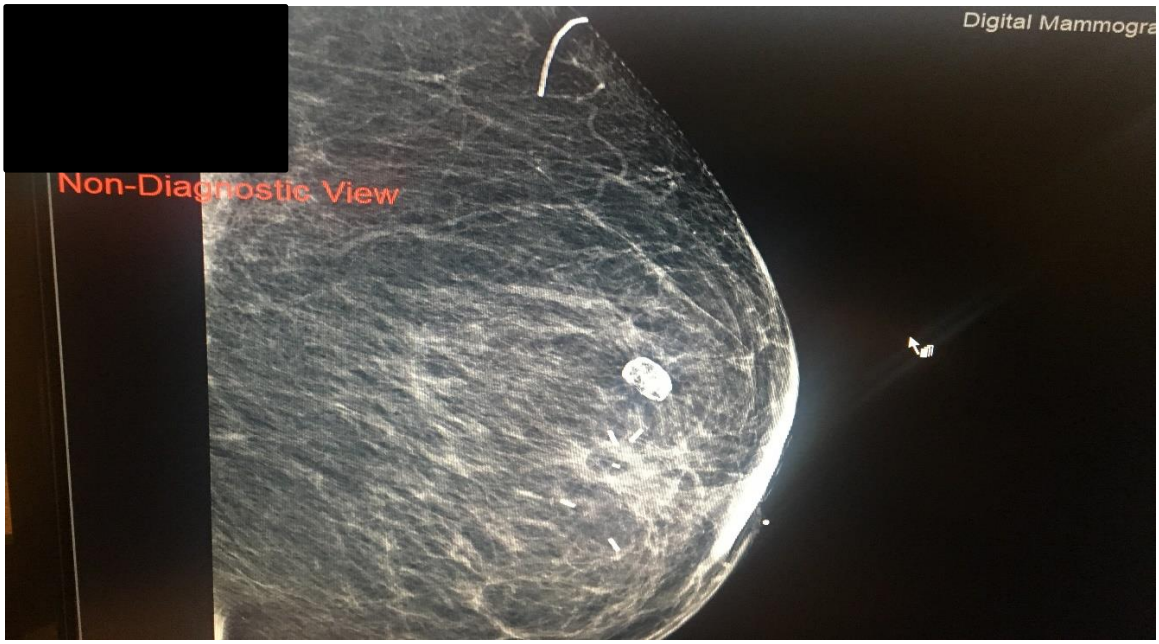
## 6-8 weeks Post Implantation



# Radiographic Images from Clinical Study

## 1-year Post Implantation



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