

# A great fiducial marker for abdominal and thoracic organs



Minimally invasive



°A,

**Instant stability** 

**Great visibility** 

# Gold Anchor is a fiducial marker with unique features and benefits





Minimally invasive Industry leading thin needles

**Great visibility** Also on MRI, thanks to unique material Instant stability Multiple cut-outs allow the marker to fold

# Gold Anchor for safe reach to inner organs



### **Endoscopic implantation**

If the Gold Anchor marker is transferred over to longer EUS-FNA or EBUS-TBNA needles, Gold Anchor can also be placed in

- Pancreatic,
- Rectal,
- Esophageal and
- Central lung tumors.



### **Percutaneous implantation**

- Abdominal organs such as pancreas, liver, kidney, adrenal gland and metastases in various places
- Head & neck applications such as tonsil, nodules, base
  of tongue and close to the larynx
- Lung
- Breast
- Prostate, cervix, bladder wall

### **Gold Anchor in Pancreas using endoscopy**



The image shows a 0.28x10 mm Gold Anchor marker implanted in pancreas. Image courtesy of Osaka International Cancer Institute, Japan.



"EUS guided fiducial marker placement (EUS-FP) is an important method to place a fiducial marker safely and precisely especially into pancreatic cancer. Gold Anchor is an ideal marker for EUS-FP as it is easily back loaded into a FNA needle."

#### Gastroenterologist & Interventional Endoscopist Reiko Ashida MD, PhD, Co-Director, Departments of Cancer Survey and Gastrointestinal Oncology, Osaka International Cancer Institute, Japan

# **Endoscopic placement of Gold Anchor**

Placement of Gold Anchor through endoscope in pancreas, central lung, esophagus and rectal tumors is possible by using the Gold Anchor Introducer\*.

Gold Anchor Introducer is delivered pre-loaded with the Gold Anchor MR+ (1.5% Fe) marker inside. It comes in a blister single pack, sterilized, ready for use, with the marker length clearly indicated on the package.

The Introducer is used to transfer the marker over into a 22G endoscopic ultrasound aspiration needle ("EUS Needle").

When pushed out of the EUS Needle during implantation, the marker will collapse and fold to different shapes, anchoring immediately in the tissue.

The marker can be visualized under ultrasound, magnetic resonance (MRI), computed tomography (CT), fluoroscopy or 2D X-rays at the planning stage and daily during radiotherapy.





### How to transfer the marker



Instruction video here: <a href="https://youtu.be/r72JYHsyXxg">https://youtu.be/r72JYHsyXxg</a>

- 1. Retract the stylet of the EUS Needle about 8 cm (3 inches) and keep the EUS Needle tip inside its sheath.
- 2. Hold the EUS Needle sheath vertically and place the Introducer on top of the sheath.
- 3. Gently insert the EUS Needle sheath all the way to the top of the inspection hole.
- 4. Lock the position of the EUS Needle sheath to the Introducer with a steady grip.
- 5. Push the stylet of the Introducer all the way to its end position to deploy the marker.

# **Clinical publications**

"Visibility, artifact and migrations using three types of fiducials for pancreatic ductal adenocarcinoma (PDAC) patients receiving stereotactic body radiation therapy (SBRT)". Includes 55 patients that got 167 markers implanted endoscopically in pancreas during the period Aug 2014 – Feb 2017. Gold Anchor represented 62% out of the markers used. <u>– Abstract from Johns Hopkins University, Maryland, USA</u>

**"EUS-guided fiducial marker placement in patients with pancreatic cancer: a comparative analysis for safety and technical feasibility".** Includes 377 patients that got 1076 markers implanted endoscopically in pancreas during the period Jun 2010 – Apr 2017. Gold Anchor (GAF) represented 65% out of the markers used.

- Abstract from Johns Hopkins University, Maryland, USA

#### "Endoscopic ultrasound-guided fiducial marker placement for neoadjuvant chemoradiation therapy for resectable pancreatic cancer"

Background: Preoperative neoadjuvant chemoradiation therapy (NACRT) is applied for resectable pancreatic cancer (RPC). To maximize the efficacy of NACRT, it is essential to ensure the accurate placement of fiducial markers for image-guided radiation. However, no standard method for delivering fiducial markers has been established to date, and the nature of RPC during NACRT remains unclear.

Methods: This was a prospective case series of 29 patients (mean age, 67.5 years; 62.1% male) with RPC referred to our facility for NACRT. Under EUS guidance, a single gold marker was placed into the tumour using either a 19- or 22-gauge fine-needle aspiration needle. The differences in daily marker positioning were measured by comparing simulation computed tomography and treatment computed tomography.

Conclusion: EUS fiducial marker placement following NACRT for RPC is feasible and safe. The RPC is mobile and is affected by not only aspiration, but also food and fluid intake and bowel condition.

Article from World Journal of Gastrointestinal Oncology, 2020

# **Instant stability**



# Multiple cut-outs allow the marker to fold

The marker is passive and will form different shapes depending on implantation technique.

- Line shaped markers are useful for detecting plastic deformations and tilting.
- Completely folded markers are suitable for systems with automatic marker detection.



### Benefits

- Anchors directly
- Trust each marker
- Save lead time and travel

Watch how-to video: <a href="https://youtu.be/fchnEvzl9nQ">https://youtu.be/fchnEvzl9nQ</a>

# **Anchors directly**

Gold Anchor gets a great tissue attachment when the marker folds.

The ball shaped marker becomes thicker than the needle tract.

Even as a line shaped marker the cut-outs in the Gold Anchor marker ensure a strong tissue attachment. The flexibility of the marker also allows it to absorb tissue deformation effectively.



# **Great visibility**



### Thin marker in unique material (Int. Patents)

The marker is only 0.28 or 0.40 mm thick, which improves the surface-to-volume ratio.

The marker is made of an alloy of pure gold and 1.5% pure iron for improved MR visibility.

### Benefits

- · Clearly visible on kV and ultrasound
- Ideal for proton therapy
- Reduce CT artifacts
- Exceptional MRI visibility

# **Gold Anchor in Pancreas percutaneous implantation**



Gold Anchor is available in the same type of ultrathin 25G needles that has been used for over 60 years for fine needle aspiration cytology (FNAC) with no to very little harm.

Gold Anchor can be implanted percutaneously in pancreas using either CT or ultrasound.







# Minimally invasive





### Fine needles for cytology

- Have been used >50 years
- In all parts of the human body
- With no to very little harm

Gold Anchor comes pre-loaded in needles of the same size

### Advantages:

- Reduced risk of pneumothorax
- Reduced patient discomfort
  - Less need for anesthesia
- Less risk of infection and bleeding
- · Less risk of seeding of cancer cells



Fausto Labruto, M.D., Associate Professor, Department of Radiology, Karolinska University Hospital, Sweden

Watch video testimonial: http://youtu.be/TprljEvaUsE

### **Testimonial – Abdominal organs**

"I have used the spinal needles (25G, that is 0.5 mm) for ultrasound guided biopsies and ultrasound guided deposition of gold markers for seven years. In my clinic we perform at least 120 such interventions per month. I have put these needles through all abdominal organs, including hollow organs such as the stomach, the colon or the small bowel, and the urinary bladder. I have taken biopsies by access through the abdominal aorta, the inferior vena cava, the liver veins and the jugular vein. In the last seven years I have not recorded (personally or for the rest of my unit) a single complication that ever required any therapeutic measure whatsoever."

"In most cases, I use no anesthesia when I insert the 25G needles. After the intervention, our patients go home without observation."

"It is easier to implant Gold Anchor than to perform Fine Needle Aspiration Cytology, which requires cell sampling from an exact location. Oncologists who refer the patients for implantation tell us that it is enough that the fiducial marker is delivered in the vicinity of the lesion. With the ultra-thin needle of 0.5 mm, we do not have to order blood coagulation tests, unless the patient is on blood-thinners. Furthermore, when using the thin Gold Anchor needle on liver lesions, we never observe any bile leakage that causes painful irritation of the peritoneum."



Gregory K. Bell, M.D; Interventional Oncology, Austin Cancer Centers, USA

### **Testimonial – Lung and abdominal organs**

"In our radiation and interventional oncology practice at Austin Cancer Centers, we have found that by using the Gold Anchor system; this has allowed us to treat soft tissue tumors that were once considered inaccessible. Given the small gauge size of the needles, this has added a significant margin of safety that we had not previously enjoyed."



Radiotherapy equipment:	Linac with	CyberKnife &	TomoTherapy	Proton therapy with kV	
	kV imaging	Radixact tracking /	(MVCT) and	imaging	
		TrueBeam ABH	Viewray		
Implanted marker shape:	Ball or line	Ball	Ball	Ball	Line
Breast	2208-10-В	2208-10-В	2208-20-В	2208-10	2208-10-В
Head & neck* and peripheral lung	2515-10	2515-10	2215-20-В	2515-10	
Abdominal organs**	2515-10	2515-10	2215-20-В	2515-10	2515-10 2215-10-В
Prostate – transrectal implantation***	2220-10-В	2220-10-В	2220-20-В		2220-10-В
Prostate – transperineally and Cervix	2020-10-В	2020-10-В	2020-20-В		2020-10-В
Pancreas, esophagus, central lung rectal wall, through endoscope****	GATD-10	GATD-10		GATD-10	
Bladder and rectal wall, through rigid cystoscope/rectoscope	2035-10-В	2035-10-В			

#### Comments

The products mentioned above are those most typically used for a certain application. If you prefer more visibility, choose a bigger marker.

If you find it important to minimize CT artifacts, implant the marker with a line shape or choose a smaller marker. If the 2515 needle is too flexible for a certain application, try the stiffer 2208 or 2215 needle instead.

#### Notes

\*Head & neck applications include for example tonsil, nodules, base of tongue and tissue close to the larynx.

\*\*Abdominal organs include for example liver, pancreas, kidney, adrenal gland and metastases in various places.

\*\*\*If you need a longer needle, use 2225-10-B or 2225-20-B instead.

\*\*\*\*The Gold Anchor Introducer (GATD-10 and GATD-20) comes preloaded with the Gold Anchor marker inside. The introducer makes it easy to transfer the the marker over into the tip of a 22G EBUS-TBNA or 22G EUS-FNA needle. Currently available in Europe; some medical teams in other regions have chosen to use 2515-10 or 2515-20 for the same purpose.

### Gold Anchor MR+ Product Codes

### Product codes for products with markers made of 98.5% pure gold and 1.5% pure iron

Needle Ø 25G (		25G (0.5 mm)	<b>22G</b> (0.7 mm)				<b>20G</b> (0.9 mm)	
Length (cm)		15	8	15	20	25	20	35
Marker (mm)	0.28 x 10	2515-10	2208-10	2215-10	2220-10	2225-10	2020-10	
	0.28 x 20	2515-20			2220-20			
	0.40 x 10		2208-10-В	2215-10-В	2220-10-В	2225-10-В	2020-10-В	2035-10-B
	0.40 x 20		2208-20-B	2215-20-В	2220-20-В	2225-20-В	2020-20-В	



### A great fiducial marker Ideal for Intrafraction Motion Management



Please visit <u>www.goldanchormarker.com</u> for more information and links to publications.