

A great fiducial marker for Prostate



Minimally invasive



Instant stability



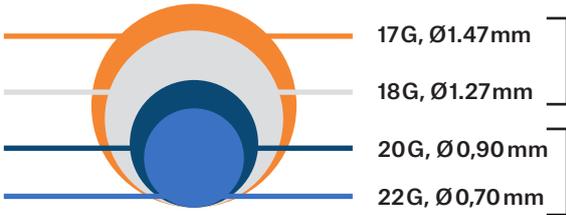
Great visibility





Minimally invasive

Industry leading thin needle



Benefits

- Reduce implantation time
- Reduce patient discomfort
- Reduce complications from implantation



Enrique Castellanos, MD, PhD, Dept. of Oncology, Karolinska University Hospital, Sweden

Testimonial – Transrectal implantation

“The application process for Gold Anchor is much easier than for other fiducial markers. With Gold Anchor we do not have to use local anesthesia – giving local anesthesia would be more painful than implanting the fine needle marker.

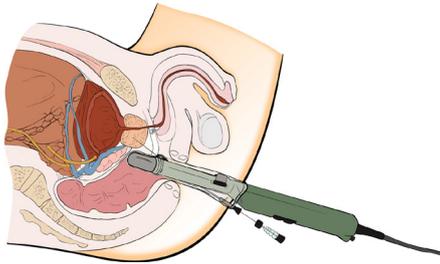
We have between 5-8 patients per week and have had almost no infections since we started using Gold Anchors in 2009 [see graph to the right]. When we started with gold markers, we used prophylactic antibiotic, Ciprofloxacin 500 mg twice daily, for three days before implantation, but since autumn 2010 we use two Bactrim Forte pills as a single dose two hours before the implantation.”



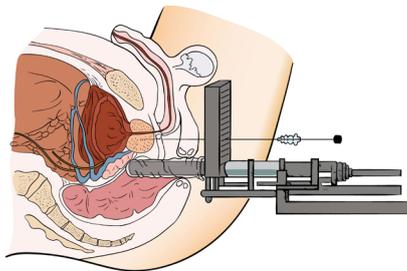
Watch the testimonial on video

Reduce implantation time

We generally recommend transrectal implantation of Gold Anchors. With Gold Anchor this is a low risk procedure that does not require anesthesia. Three Gold Anchors can typically be implanted by the doctor in less than five minutes.

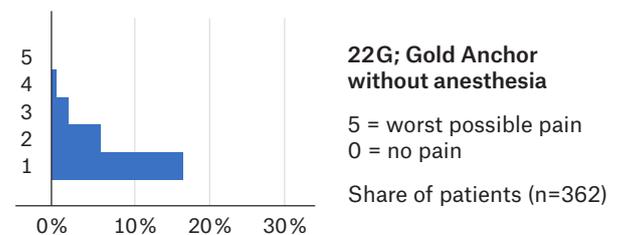
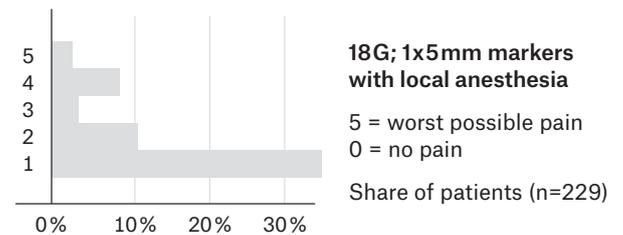
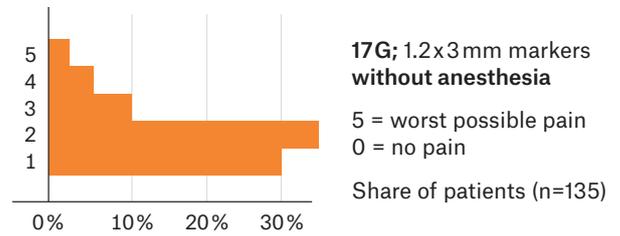


If you prefer to implant the markers transperineally you can also avoid local anesthesia by using an EMLA patch 30 minutes before implantation.



Reduce patient discomfort

Intensity of pain during transrectal implantation in prostate (not showing those answering "no pain").



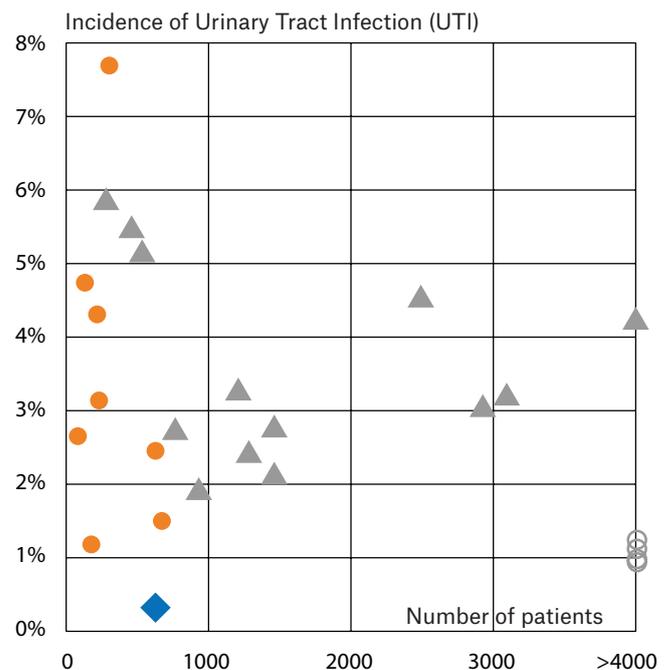
Sources: (17G): Igdem S, Akpınar H, Alço G, et al. Implantation of fiducial markers for image guidance in prostate radiotherapy: patient-reported toxicity. Br J Radiol 2009;82:941-945.; (18G; 1x5 mm): S Gill, J Li, J Thomas, et al. Patient-reported complications from fiducial marker implantation for prostate image-guided radiotherapy. Br J Radiol. 2012; (22G): Wioletta Mista, Leszek Miszczyk. An evaluation of side effects after gold markers (Gold Anchor™) implantation to prostate gland in patients with prostate cancer. Onkologia Info 2011;8;2:110-111. Jul;85(1015):1011-7.

Reduce complications from implantation

Gold Anchors can be implanted transrectally in prostate with a very low risk of infection vs. other transrectal procedures, see graph to the right.

These results from Karolinska suggest that the thin Gold Anchor needles reduce the risk of UTI despite the use of only a single dose of non-broad-spectrum antibiotics as prophylaxis.

- Implantation of other fiducial markers (18G-17G)
- Biopsies: series >10,000 patients
- ▲ Biopsies: smaller series
- ◆ Gold Anchor study from Karolinska (22G needle)



Source: Castellanos E, Wersäll P, Tilikidis A, Andersson A. Low Infection Rate After Transrectal Implantation of Gold Anchor™ Fiducial Markers in Prostate Cancer Patients After Non-broad-spectrum Antibiotic Prophylaxis. DOI: 10.7759/curius.3526

Instant stability



Multiple cut-outs allow the marker to fold (Int. Patents)

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
- Save lead time and travel



Bengt Johansson,
MD, PhD, Dept. of Oncology,
Örebro University Hospital,
Sweden

Testimonial – Transperineal implantation

“We use two Gold Anchors per patient – one with line shape and one with ball shape. We give one pill of Eusaprim Forte in the morning of the implantation and we have never seen any events of infection.

When we use these very thin needles we have stopped to give local anaesthesia – the tiny needles are usually tolerated very well by the patient. Instead we use a small EMLA patch. We do the CT planning on the same day as the gold marker implantation.”



Watch the testimonial on video

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.



Scot Ackerman, MD,
Radiation Oncologist,
Medical Director, Ackerman
Cancer Center

Testimonial - Efficiency, Safety, Accuracy

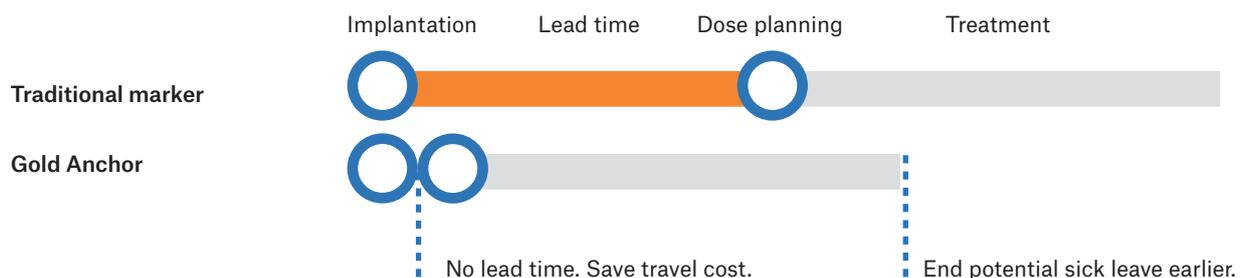
“Since incorporating The Gold Anchor into my practice, we have been able to treat patients with an increased level of efficiency, safety, and accuracy. Its thin needles allow for a more tolerable fiducial marker, which has led to significantly lower infection rates post placement.

The unique design minimizes migration after placement, which leads to consistent CT imaging as treatment continues. All of this allows for quick and accurate care.”

Save lead time and travel

With Gold Anchor there is no need to wait the usual 7–21 days before dose planning. The thin Gold Anchor needle, that causes minimal bleeding and swelling, in combination with the strong tissue attachment of the marker, makes it possible to proceed with CT and/or MR for dose plan on the same day as implantation.

Note: Most centers that use traditional markers send their patients home for 7-21 days after implantation to allow the traditional markers to “settle in”, i.e. to allow the potential bleeding and swelling subside to reduce the risk that the traditional markers migrate in the tissue.





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.

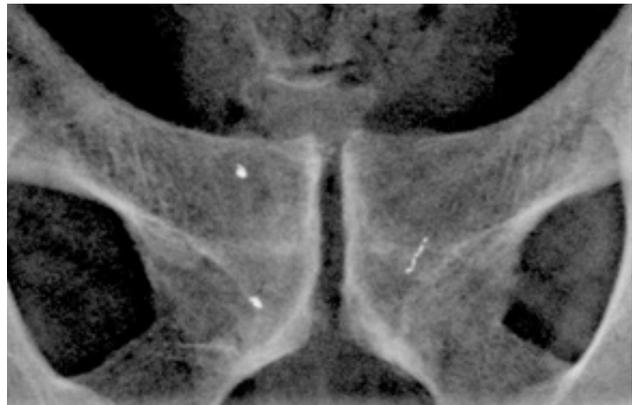
The marker is made of an alloy of pure gold and 1.5% pure iron for improved MR visibility.

Benefits

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

Clearly visible on kV

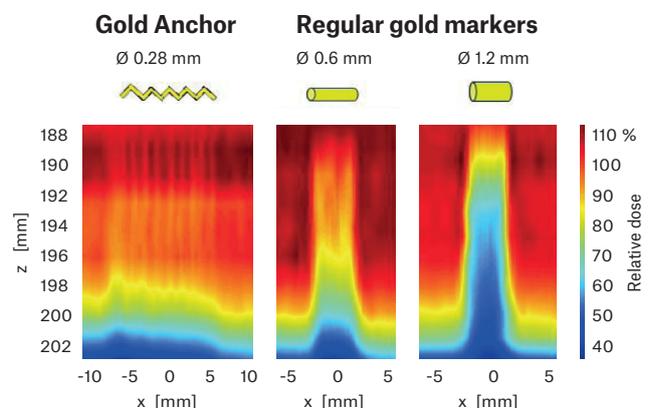
Gold Anchor has been designed for use with kV imaging. The kV x-ray is heavily attenuated whenever it passes through a material of high density, such as gold. A high kV, approximately 130 kV, should be used to fade away the skeleton structures.



Ideal for proton therapy

The thin Gold Anchor marker causes minimal dose perturbation.

The film measurements to the right show dose perturbation downstream of the markers with the markers oriented perpendicular to the beam axis near the end of the SOBP (Spread-Out Bragg Peak). The dose is normalized to an unperturbed region.

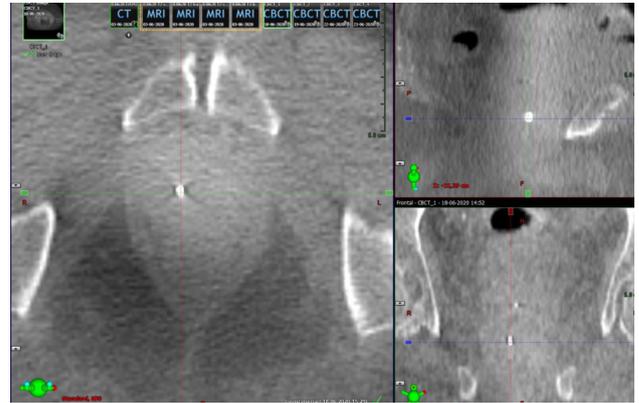


Source: Z. Uludag, "Investigation of dosimetric effects of radiopaque fiducial markers for use in proton beam therapy with film measurements and Monte Carlo simulations"

Reduce CT artifacts

The small Gold Anchor markers cause limited CT artifacts.

To further minimize artifacts the Gold Anchor markers can be implanted with a line shape.



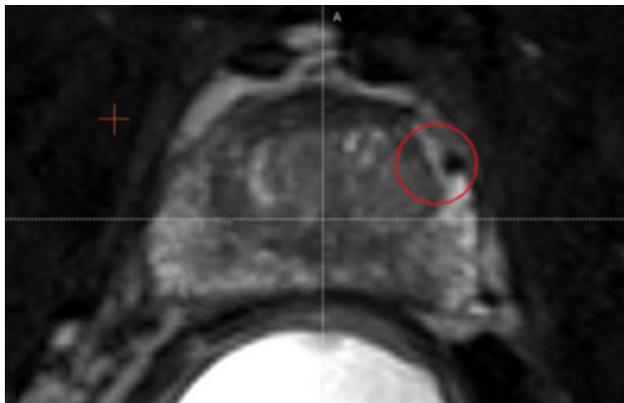
CBCT: 0.28x10 mm marker with ball shape.

Exceptional MRI visibility

Gold Anchor MR+ provides exceptional MRI visibility, even on T2-weighted images, which are typically used for prostate delineation. This is helpful when fusing CT and MR images and when moving to MRI-only workflows.



MRI: T2-weighted image of 0.28x10 mm marker with ball shape.



MRI: T2-weighted image of 0.40x10 mm marker with line shape. Image courtesy of Dr. Marcio Fagundes at Miami Cancer Institute.



MRI: T2-weighted image of 0.40x10 mm marker with ball shape.

Many of our customers place Gold Anchors at the same time as SpaceOAR® hydrogel. CT and MRI can then be registered based on the markers.

The image to the right is a 70/30 fusion CT/T2.

Note:
SpaceOAR® is a registered trademark of Boston Scientific.



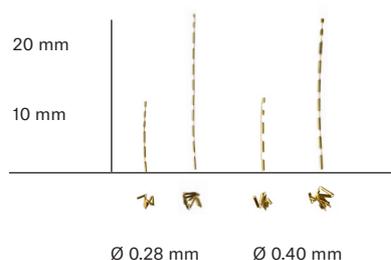
Product family



Needles

The needles have echogenic tip for ultrasound verification and cm-scale.

Four different markers



Needle Ø	● 25G (0.5 mm)	● 22G (0.7 mm)				● 20G (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-B	2215-10-B	2220-10-B	2225-10-B	2020-10-B	2035-10-B
0.40 x 20		2208-20-B	2215-20-B	2220-20-B	2225-20-B	2020-20-B	

FDA cleared, CE marked, International Patents, Manufactured in Sweden

Recommended products for prostate

Radiotherapy equipment:	Linac with kV imaging	CyberKnife & Radixact tracking / TrueBeam ABH	TomoTherapy (MVCT) and MR-linac	Proton therapy with kV imaging
Implanted marker shape:	Ball or line	Ball	Ball	Line
Prostate – transrectal implantation*	2220-10-B	2220-10-B	2220-20-B	2220-10-B
Prostate – transperineally	2020-10-B	2020-10-B	2020-20-B	2020-10-B

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.

Notes

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

Naslund Medical AB



Naslund Medical AB is a privately held medical products company focused on the improved management and care of patients receiving radiation therapy. As the pioneer and leader in developing new technology for fiducial markers, Naslund Medical markets Gold Anchor worldwide. Gold Anchor enables quicker and more effective radiation therapy treatment with increased patient safety. Naslund Medical is based in Sweden with subsidiaries in the U.S. and France and with contracted distributors on a global level. Naslund Medical is certified to SS-EN ISO 13485:2016 and according to the Directive 93/42/EEC on Medical Devices, Annex II, Full Quality Assurance System.

Gold Anchor has been invented and developed by Ingemar Naslund, M.D., Assoc. Prof., for 20 years head of the Division of Radiation Therapy, Radiumhemmet, Karolinska University Hospital, Stockholm, Sweden, where he was one of the inventors of the SBRT technique in 1991.

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