Beacon Care Package for Prostatic Bed Instructions for Use

Varian Medical Systems
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INTRODUCTION

Before implanting the Beacon® transponders contained in this Beacon Care Package, complete the Calypso® training program and carefully read all sections in this document. This document describes the Beacon Care Package components, implantation procedure instructions, and transponder placement into the peri-prostatic tissue following prior surgical removal of the prostate (i.e., implantation into the prostatic bed). This document describes postoperative transrectal and intraoperative direct implantation use.

Each patient should be evaluated to determine if the patient is a candidate for implantation, including whether their size limits them to setup for treatment or setup and tracking during treatment. This must be evaluated prior to Beacon transponder implant, following the guidelines outlined in the *Calypso System User's Manual*.

PRODUCT DESCRIPTION

Beacon transponders are small, passive, electrical components encapsulated in biocompatible glass, which are permanently implanted in or near the treatment target for use during radiation therapy. Beacon transponders were developed specifically for use with the Calypso System in order to provide a reliable and accurate method for target localization and continuous, real-time tracking during radiation therapy treatments. The Calypso System temporarily excites the implanted Beacon transponders; each Beacon transponder then briefly emits a unique response signal, which is detected, measured, and used to determine the location of the patient's treatment target. The Calypso System works in tandem with implanted Beacon transponders to continuously report the current position of the target relative to the treatment isocenter.

This Beacon Care Package contains three single-use 14-gauge introducer needles (introducers) and Beacon transponders for implantation into a single patient. Each Beacon transponder is manually loaded into the introducer for implantation.

INDICATIONS FOR USE

The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders.

Implanted Beacon transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures.

Permanent Beacon transponders are indicated for implantation in the prostate and the peri-prostatic tissue (i.e., prostatic bed) to align and monitor the treatment isocenter in real time during radiation therapy.

CONTRAINDICATIONS

- Prosthetic implants in the pelvic region that contain metal or conductive materials (e.g., an artificial hip).
- Use of anti-coagulants or anti-platelet drug therapy (not including aspirin).

WARNINGS

- The effect of the Calypso System operation on active implanted devices, such as pacemakers and defibrillators, in patients is unknown. Be aware that the operation of the Calypso System may impact the normal functioning of such active implanted devices.
- Beacon Care Packages are gamma (radiation) sterilized and are supplied sterile and non-pyrogenic. Use standard operating procedures to maintain the sterility of the devices during unpacking and use. Do not use if package has previously been opened or appears to be damaged.
- Beacon transponders and introducers are for single use only. Do not re-sterilize or reuse.
- Each Beacon transponder has unique characteristics and should be implanted in the recommended region of the prostatic bed. The introducers are uniquely labeled and color coded to indicate the implant region.
- Beacon transponders must be implanted either using transrectal ultrasound imaging for guidance at least 2 - 3 weeks after prostatectomy or using direct visual inspection during open prostatectomy.
- In the event that a Beacon transponder should drop onto the sterile drape during handling, use only a gloved hand to pick up the transponder and place it in the hub end of the introducer; do not use metal tweezers to pick up the transponder as it may damage the transponder surface. If you must use metal tweezers to pick up the transponder, discard the transponder. If the transponder drops on a non-sterile surface, do not use the transponder.
- In the event that an introducer is damaged prior to use, do not use the introducer for implant and dispose of it properly.
- Compatibility with surgical clips has not been evaluated.
- For transrectal implantation of the transponders, the transponders should be implanted at least 2 - 3 weeks post-prostatectomy to allow for reduction of edema and initiation of fibrosis in the prostatic bed, in order to avoid movement of the transponders.
- Implantation through a transperineal approach has not been evaluated.
- Beacon transponders have not been evaluated for implantation via robotic surgical instrumentation.

PRECAUTIONS

- When using ultrasound imaging to guide implantation, always follow the ultrasound transducer manufacturer's instructions when preparing the transducer to be used in an implant procedure.
- Non-clinical testing has demonstrated that Beacon transponders are MR conditional. A patient implanted with Beacon transponders can be safely scanned under the following conditions:
  - Static magnetic field of 1.5T or 3T;
  - Static magnetic field gradient of 2.5T/m;
  - Maximum whole-body-averaged specific absorption rate of 2.0 W/kg for 20 minutes, in the normal operating mode of MR scanning

  MR artifacts may extend up to, and in some cases more than, 2 cm from the transponder for a spin echo sequence.
- Use caution when the following additional therapies are required: brachytherapy treatment (permanent seeds or HDR), electrosurgical procedures (e.g., harmonic scalpel, transurethral needle ablation, radio frequency (RF) ablation), cryoablation, lithotripsy, and laser vaporization. Avoid direct contact with the Beacon transponders when administering these therapies. Beacon transponder functionality and encapsulation after administration of these therapies has not been assessed.
- Beacon transponders should be implanted only by physicians who have received Calypso implant training.
- Beacon Care Packages should be implanted before the sterilization expiration date on the package.
- Beacon Care Packages should be stored at standard room temperature (greater than -18 degrees C and less than 55 degrees C) and kept dry.
- Beacon Care Packages contain introducer needles. Handle introducers according to departmental sharps protocols.

COMPONENT DESCRIPTION

Beacon Transponders

Each Beacon transponder consists of a sealed, biocompatible glass capsule containing a miniature passive electrical circuit (Figure 1). The Beacon transponders are visible on kilovoltage radiographs, CTs, and ultrasound images. Each Beacon transponder is packaged in a transfer capsule (Figure 2). The transfer capsule is color coded and labeled A, L, or R to indicate the implant site for the Beacon transponder. The transfer capsule is used to load the Beacon transponder into the introducer.

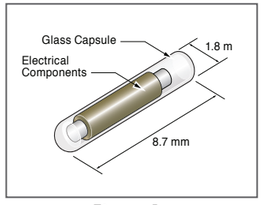


Figure 1

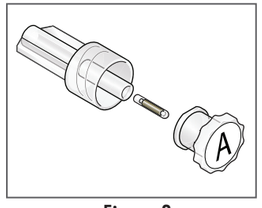


Figure 2

Introducers

- A separate introducer is used to implant each Beacon transponder into a region in or near the treatment target. Each introducer consists of a customized, 14-gauge needle assembly and an internal removable stylet. A color mark on the hub indicates where the distal tip of the needle bevel is located.
- Each pouch contains one introducer and one Beacon transponder. The Beacon transponder must be loaded into the introducer prior to implant (see the section titled "Preparing the Introducers for Implantation" for complete instructions).
- A clip secures the extended stylet to the needle hub (see Figure 3). The clip should be reattached after the Beacon transponder is loaded in the introducer and should be left in place until the time of implant to prevent accidental premature deployment of the Beacon transponder.

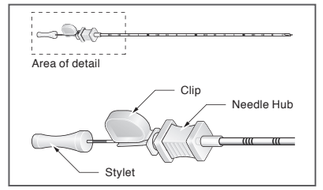


Figure 3

- Each Beacon transponder has a unique frequency associated with a specific region of the treatment target (A, L, and R). The introducer stylets and hubs are color coded (blue, white, and green) to distinguish them (see Figure 4).

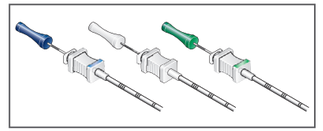


Figure 4

PREPARING THE INTRODUCERS FOR IMPLANTATION

Each Beacon Care Package consists of three pouches. Each pouch contains one introducer and one Beacon transponder packaged in a Beacon transponder transfer capsule. Open one pouch at a time to ensure the correct Beacon transponder is loaded in the corresponding introducer.

To load the Beacon transponder into the introducer:

1. Place a sterile drape on a flat surface.
2. Remove the transfer capsule and introducer from the pouch.
3. Remove the stylet from the introducer, leaving the clip attached to the stylet, and place both the stylet and the introducer on the sterile drape.
4. Hold the transfer capsule upright and unscrew the cap from the transfer capsule, making sure that the Beacon transponder does not fall out of the capsule (see Figure 5).
5. Continue to hold the transfer capsule upright and screw the hub of the introducer needle onto the transfer capsule (see Figure 6). This should be a snug not tight fit.
6. Turn the introducer tip downward so that the Beacon transponder drops into the end of the introducer. If the transponder does not drop on its own, gently tapping the center of the capsule with your finger will cause the transponder to drop into the introducer (see Figure 7). A slight crimp in the end of the introducer prevents the Beacon transponder from falling out.

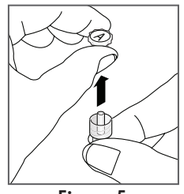


Figure 5

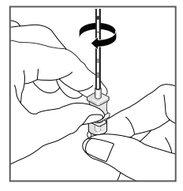


Figure 6

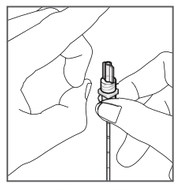


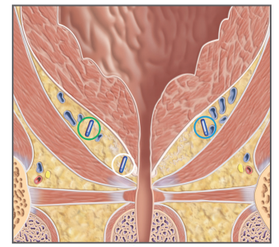
Figure 7

7. Holding the introducer tip pointed downward, unscrew the transfer capsule from the introducer hub.
8. Ensure the clip is attached to the stylet before reinserting the stylet into the introducer.
9. Continue to hold the introducer pointed downward and slowly insert the stylet into the introducer until the clip securely anchors the stylet, being careful not to accidentally advance the Beacon transponder out of the needle.
10. Place the loaded introducer on the sterile drape and repeat this procedure for the remaining introducers.

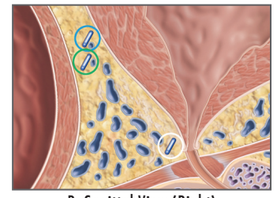
IMPLANT SITE RECOMMENDATIONS: POSTOPERATIVE TRANSRECTAL IMPLANTATION INTO PROSTATIC BED SOFT TISSUE

Using transrectal ultrasound imaging, determine the optimal target implant sites for each of the 3 Beacon transponders before beginning the implantation procedure. It is important to consider the following criteria when selecting target implant sites for the Beacon transponders to ensure optimal localization accuracy:

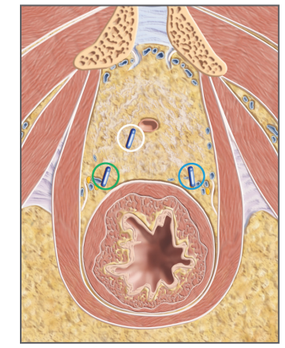
- Each Beacon transponder has unique characteristics, and the individual Beacon transponders are to be placed in the regions of the prostatic bed indicated by the label and color coding of the introducer.
- Two Beacon transponders will be placed between the bladder and rectal wall, one on the right side and one on the left side, behind the trigone. One Beacon transponder will be placed on the right side of the anastomosis site.
- Avoid implanting the Beacon transponders in the urethra or bladder wall.
- Implant the Beacon transponders so that they are equidistant and in a triangular pattern in the prostatic bed.
- The recommended distance between the Beacon transponders is 1 cm (recommended minimum distance is 1 cm and recommended maximum distance is 7.5 cm). If the prostatic bed is too small to accommodate this spacing, select target implant sites so that the Beacon transponders will be as far apart from each other as possible (refer to Figure 8).



A: Anterior/Posterior View



B: Sagittal View (Right)



C: Transverse View

Figure 8:
Optimal Transponder Implantation Locations

TRANSPONDER IMPLANTATION INSTRUCTIONS: POSTOPERATIVE TRANSRECTAL IMPLANTATION INTO PROSTATIC BED SOFT TISSUE

Patient Preparation Prior to Day of Implantation

- The Beacon transponders should be implanted at least 2 - 3 weeks following prostatectomy surgery to allow for reduction of edema and initiation of fibrosis in the prostatic bed, in order to avoid shifting of the transponder position.
- Patients should be fully healed from the prostatectomy surgery as determined by the urologist prior to transponder implantation.
- Per institutional guidelines, consider antibiotic prophylaxis for fiducial implantation of the prostatic bed and use of local anesthesia.

Preparation on Day of Implantation

- Have the patient perform routine bowel preparation to enable transrectal ultrasound (TRUS) imaging prior to the procedure.
- Load the Beacon transponders into the introducers and place them on a sterile drape prior to patient arrival as described in the "Preparing the Introducers for Implantation" section of this document.
- Prepare the patient for transrectal ultrasound (TRUS) examination.
- Ensure that the patient and a sterile field have been prepared for placement of the introducers, as is normally done for a gold marker fiducial implantation or prostate biopsy procedure.
- If necessary, attach a sterile needle guide that will accommodate the 14-gauge introducers to the transrectal ultrasound probe.

Identify Target Implant Sites

11. Insert the transrectal ultrasound probe.
12. Per institutional guidelines, administer local anesthetics early in the procedure to provide time to take effect.
13. Perform the TRUS study of the prostatic bed. Using both sagittal and transverse TRUS planes, survey the prostatic bed.

14. Determine the three target implant sites (refer to Figure 8). Two Beacon transponders should be placed between the bladder and rectal wall, one on the right side and one on the left side, behind the trigone. One Beacon transponder will be placed on the right side of the anastomosis site.
15. Select target implant sites to ensure best use with the Calypso System (see Figure 8).

Color	Implantation Position in Prostatic Bed - Postoperative Transrectal
White (Apex)	On the right side of anastomosis of the urethra
Blue (Left)	Between bladder and rectal wall, left side (behind trigone)
Green (Right)	Between the bladder and rectal wall, right side (behind trigone)

Prepare and Insert First Introducer

16. Select the appropriate introducer device for the first target implant site (see above table), as indicated by the label and color of the introducer's clip and stylet.
17. Remove the protective plastic sheath from the introducer, but leave the clip in place until the introducer is positioned within the prostatic bed to prevent premature deployment of the Beacon transponder. Insert the introducer into the needle guide.
18. While holding the ultrasound transducer still, position the introducer needle within the prostatic bed so that the tip of the needle is positioned at the first target implant site and the entire beveled tip of the needle is seen. In the ultrasound image, the needle and bevel tip may be seen at the end of two bright parallel lines (refer to Figure 9). If two bright lines are not visible, the needle bevel may be seen as two bright points representing the proximal and distal tips of the bevel.

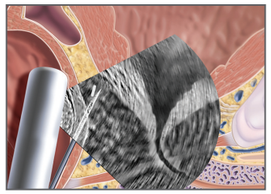


Figure 9

The entire beveled tip of the introducer needle must be seen at the target implant site prior to deployment of the Beacon transponder. Avoid implantation in the bladder wall (see Figure 10 A) and the rectal wall (see Figure 10 B).

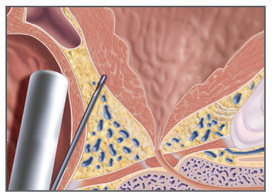


Figure 10 A

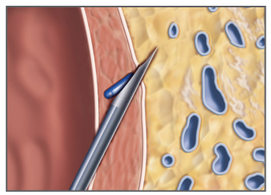


Figure 10 B

Deploy the Beacon Transponder

19. Remove the clip from the introducer. Once the clip has been removed, hold the introducer hub until the needle tip is positioned at the target site to prevent premature deployment of the Beacon transponder.
20. While continuously holding the introducer in a stable position, so that the tip remains stationary at the target site, gently but steadily push the stylet forward while slightly retracting the cannula (Figure 11) until the Beacon transponder is completely released from the introducer and seen on the ultrasound image.

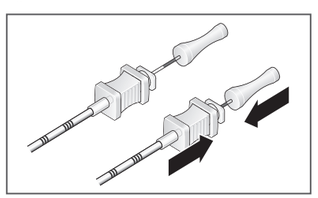


Figure 11

Dispose of Used Introducer Needle

21. Withdraw the introducer needle. Dispose of the used introducer needle in an appropriate sharps biohazard waste container.

Implant Remaining Beacon Transponders

Repeat steps 16 through 21 to implant the second and third Beacon transponders using the appropriate introducer for each implant region of the prostatic bed.

After-Implantation Procedure

- Survey the prostatic bed with TRUS and locate the Beacon transponders.
- Follow standard practice for subsequent patient care following fiducial implantation or biopsy of the prostate.
- Instruct the patient on post-operative care and potential complications.
- Wait 4 to 14 days after the implantation procedure to allow the region and Beacon transponders to stabilize.
- Acquire treatment planning CT images, using either 1.0-mm or 1.5-mm slice spacing throughout the prostatic bed.
- Perform treatment planning for external beam radiation therapy per standard institutional protocol.
- Perform external beam radiation therapy per standard institutional protocol.
- The implanted Beacon transponders can either be used as radiographic markers with kV x-ray imaging or be used with the Calypso System to facilitate and optimize target localization and tracking during radiation therapy. Refer to the *Calypso System User's Manual*.

IMPLANT SITE RECOMMENDATIONS: INTRAOPERATIVE DIRECT IMPLANTATION INTO PROSTATIC BED SOFT TISSUE

Using direct inspection of the surgical bed, determine the optimal target implant sites for each of the 3 Beacon transponders before beginning the implantation procedure. It is important to consider the following criteria when selecting target implant sites for the Beacon transponders to ensure optimal localization accuracy:

- Each Beacon transponder has unique characteristics, and the individual Beacon transponders are to be placed in the regions of the prostatic bed indicated by the label and color coding of the introducer.
- Possible implantation sites include the following:

Color	Implantation Position in Prostatic Bed - Intraoperative Direct Surgical
White (Apex)	The tissue adjacent to the anastomosis of the urethra
Blue (Left)	The left prostate pedicle adjacent to the removed seminal vesicle superiorly
Green (Right)	The right prostate pedicle adjacent to the removed seminal vesicle superiorly

- Note: The tissue available for implant after radical retropubic prostatectomy may be limited; thus, the following areas may also be used as alternate implant sites: (See Figure 12 B):
  - The peri-rectal fat medial to the neurovascular bundle in front of the rectum
  - The remnants of Denonvilliers' fascia along the rectum
- Avoid implanting the Beacon transponders in the urethra, bladder wall, or levator ani muscle.
- Avoid rectal perforation.
- Implant the Beacon transponders so that they will be equidistant and in a triangular pattern in the prostatic bed.
- The recommended distance between the Beacon transponders is 1 cm (recommended minimum distance is 1 cm and recommended maximum distance is 7.5 cm). If the prostatic bed is too small to accommodate this spacing, select target implant sites so that the Beacon transponders will be as far apart from each other as possible.

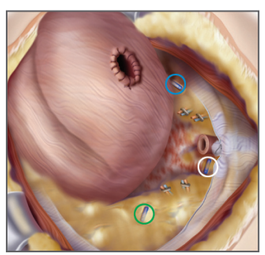


Figure 12 A:
Optimal Transponder Implantation Locations

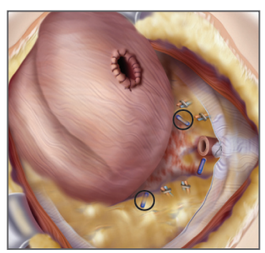


Figure 12 B:
Alternate Transponder Implantation Locations

TRANSPONDER IMPLANTATION INSTRUCTIONS: INTRAOPERATIVE DIRECT IMPLANTATION INTO PROSTATIC BED SOFT TISSUE

Patient Preparation Prior to Day of Implantation

Per institutional guidelines, consider antibiotic prophylaxis for open radical retropubic prostatectomy surgery.

Preparation on Day of Implantation

Load the Beacon transponders into the introducers and place them on a sterile drape prior to patient arrival as described in the "Preparing the Introducers for Implantation" section of this document.

Identify Target Implant Sites

1. Directly inspect the prostatic bed to identify possible implant sites.

Prepare and Insert First Introducer

2. Select the appropriate introducer device for the first target implant site (see above table), as indicated by the label and color of the introducer's clip and stylet.
3. Remove the protective plastic sheath from the introducer, but leave the clip in place until the introducer is positioned within the prostatic bed to prevent premature deployment of the Beacon transponder.
4. The entire beveled tip of the introducer needle must be completely within the tissue prior to deployment of the Beacon transponder.

Deploy the Beacon Transponder

5. Remove the clip from the introducer. Once the clip has been removed, hold the introducer hub until the needle tip is positioned at the target site to prevent premature deployment of the Beacon transponder. While continuously holding the introducer in a stable position, so that the tip remains stationary at the target site, gently but steadily push the stylet forward while slightly retracting the cannula (see Figure 11) until the Beacon transponder is completely released from the introducer.

Dispose of Used Introducer Needle

6. Withdraw the introducer needle. Dispose of the used introducer needle per institutional guidelines for sharps biohazard waste.

Implant Remaining Beacon Transponders

Repeat steps 1 through 6 to implant the second and third Beacon transponders using the appropriate introducer for each implant region of the prostatic bed.

After-Implantation Procedure

- Visually inspect the prostatic bed and locate the Beacon transponders.
- Follow standard practice for subsequent patient care following open radical retropubic prostatectomy.
- Instruct the patient on post-operative care and potential complications.
- Wait 4 to 14 days after the implantation procedure to allow the region and Beacon transponders to stabilize.
- Acquire treatment planning CT images, using either 1.0-mm or 1.5-mm slice spacing throughout the prostatic bed tissue.
- Perform treatment planning for external beam radiation therapy per standard institutional protocol.
- Perform external beam radiation therapy per standard institutional protocol.
- The implanted Beacon transponders can either be used as radiographic markers with kV x-ray imaging or be used with the Calypso System to facilitate and optimize target localization and tracking during radiation therapy. Refer to the *Calypso System User's Manual*.

ADVERSE REACTIONS

Beacon transponders are implanted in the prostatic bed using standard introduction techniques for gold marker implantation and biopsy of the prostate (e.g., transrectal). The most frequent adverse events include:

- Bleeding (e.g., hematuria, hematochezia)
- Pain (e.g., procedural, anal, perineal, bowel movements, unspecified)
- Dysuria
- Infection (e.g., urinary tract infection)
- Fever

Other observed adverse events include:

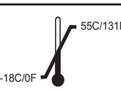
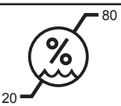
- Urinary retention
- Urinary obstructive symptoms (e.g., urinary frequency, weak stream, etc.)
- Implant migration

The following adverse events also have been documented in the literature following transrectal biopsy; however, they occur in <1% of patients:

- Nausea or sickness
- Allergic reaction to antibiotic prophylaxis
- Perineal swelling
- Sepsis
- Epididymitis
- Temporary fecal incontinence
- Urethral perforation
- Deep venous thrombosis
- Vascular embolization of the implant (e.g., pulmonary embolism)
- Vasovagal episode
- Cardiac arrhythmia

SYMBOLS AND DESCRIPTIONS

The following symbols are used in association with the Calypso System and Beacon transponders.

Symbol	Description	Symbol	Description
	MR conditional		Use by
	Do not re-sterilize		Batch code
	Do not use if package is damaged		Sterile using irradiation
	Do not reuse		Temperature limitation
	Consult operating instructions		Humidity limitation
	Caution, consult accompanying documents		Keep dry

REFERENCES

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Kupelian PA, Langen KM, Willoughby TR, Wagner TH, Zeidan OA, Meeks SL. Daily variations in the position of the prostate bed in patients with prostate cancer receiving postoperative external beam radiation therapy. Int J Radiat Oncol Biol Phys. 2006;66(2):593-596.

Schiffner DC, Gottschalk AR, Lometti M, et al. Daily electronic portal imaging of implanted gold seed fiducials in patients undergoing radiotherapy after radical prostatectomy. Int J Radiat Oncol Biol Phys. 2007;67(2):610-619.

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