



The CyberKnife® System



Prostate Cancer Treatment

Information Guide

You have more options than ever for successfully treating prostate cancer. The “best” option for you is the one that fits your life – from the specifics of your cancer and your overall health, to your age and lifestyle.

This guide provides information about the **CyberKnife® System**.



Quick facts about the CyberKnife® System



- The FDA provided clearance for the CyberKnife® System in 2001 for the treatment of tumors anywhere in the body, including the prostate
- More than 20,000 patients with prostate cancer have been treated to date with the CyberKnife System
- The CyberKnife System delivers stereotactic body radiation therapy, providing high doses of radiation with precise sub-millimeter accuracy
- The CyberKnife System maximizes treatment effectiveness and minimizes dose to surrounding tissues, which can help reduce negative side effects on urinary, bowel and sexual function that can impact a patient's quality of life
- Compared to surgery, the CyberKnife System is a non-surgical, non-invasive and outpatient procedure that does not require general anesthesia. Most patients will not require hospitalization or a long recovery time
- Compared to brachytherapy, the CyberKnife System is a non-invasive procedure and avoids the inconvenience and risk associated with seed or catheter implants, local anesthesia, potential infection, hospitalization stay, and long recovery time

Key CyberKnife Highlights

- Clinically proven long-term cancer control
- Clinical studies show preserved urinary, bowel and sexual function achievable for significant percentage of men treated
- Non-surgical and non-invasive
- Treatments completed in as little as 4-5 sessions over 1-2 weeks
- Most patients can continue normal activity throughout treatment



Overview of Radiation

What is radiation therapy?

Radiation therapy is a treatment that uses high-energy x-rays (photons) to kill, shrink, or control the growth of tumors. Radiation therapy works by damaging cells, disabling them from growing and dividing. The goal of any radiation treatment is to destroy cancer cells while minimizing the side effects on healthy tissue. As imaging technologies have improved over the last several decades, radiation therapy has integrated those improvements to enhance dose delivery and minimize side effects.

Radiation may be recommended as a primary treatment, as an alternative to surgery or in addition to other therapies. There are several kinds of radiation therapy. The CyberKnife® System delivers a type of radiation therapy known as stereotactic body radiation therapy (SBRT).

What is SBRT?

Stereotactic Body Radiation Therapy (SBRT) couples a high degree of targeting accuracy with very high doses of extremely precise, externally delivered radiation, thereby maximizing the cell-killing effect on the tumor(s) while helping minimize radiation-related injury in adjacent normal tissues.

What are the advantages of SBRT?

1. SBRT treatment takes into account the interaction between prostate cancer cells and radiation. Studies have indicated that prostate cancer cells have a high sensitivity to the amount of radiation delivered in each treatment session. This sensitivity suggests that a larger radiation dose delivered in a smaller number of sessions may result in better long-term control of the disease.²

2. SBRT reduces treatment time. Additionally, compared to conventional radiation therapy that typically requires approximately 30-40 sessions over 8-10 weeks, prostate SBRT can be completed in 4-5 sessions over 1-2 weeks.

How does my doctor typically determine if I am a candidate for CyberKnife® treatment?

Following a prostate cancer diagnosis, men are faced with numerous options including: active surveillance, radical prostatectomy, and radiation therapy. Each man should consult his physician regarding his own specific case. Among the considerations that a physician will factor into a treatment recommendation is the patient's health, age, lifestyle, and particular cancer aggressiveness, often referred to as "risk" profile.

The American Urological Association (AUA), the American Society for Radiation Oncology (ASTRO), and the Society for Urologic Oncology (SUO) support SBRT (such as the CyberKnife® System) for select low- and intermediate-risk prostate cancer.³

► More on Risk Stratification

Risk stratification assesses the possibility of recurrence by a combination of PSA, Gleason score, and clinical stage from biopsy.

D'Amico Prostate Cancer Risk Stratification⁴

	PSA	GLEASON	CLINICAL STAGE
LOW-RISK	≤10	≤6	T1-2a
INTERMEDIATE-RISK	10-20	7	T2b
HIGH-RISK	>20	≤8	T2c-3a

- *For more information on Risk Stratification, check the National Cancer Institute website: <http://www.ncbi.nlm.nih.gov>. Also, please be aware that there are other classification approaches that your doctor may use in evaluating your cancer and assessing your best treatment option.*



What are the advantages of CyberKnife® prostate treatment?

It is the precision of the CyberKnife® System, delivered by its robotic arm, and continual tracking and automatic synchronization of the beam in real-time throughout treatment, that makes such a difference for patients. In fact, CyberKnife accuracy is sub-millimeter, meaning its pinpoint precision is less than the thickness of a coin.



CyberKnife advanced robotics

The CyberKnife System has an image-guided linear accelerator mounted to a robotic arm that is specifically designed to deliver beams of stereotactic radiation from multiple angles.

The robotic arm moves in multiple directions to precisely target the prostate. With this robotic range of motion, the CyberKnife System can minimize radiation dose to healthy tissue and deliver a highly individualized treatment that conforms to the shape of the patient's tumor (see Figures 1 and 2).

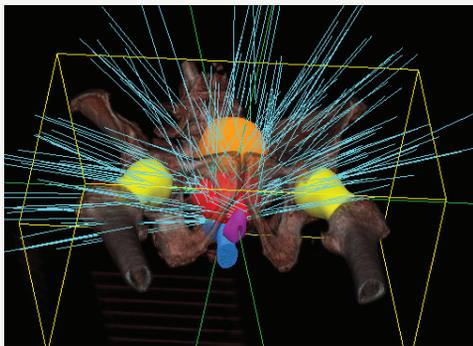


Fig. 1 The CyberKnife System can deliver beams from multiple unique angles around the patient.

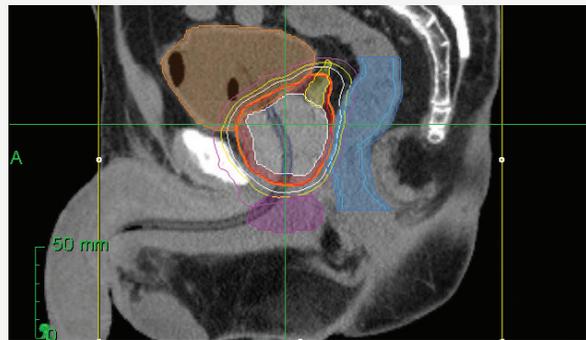
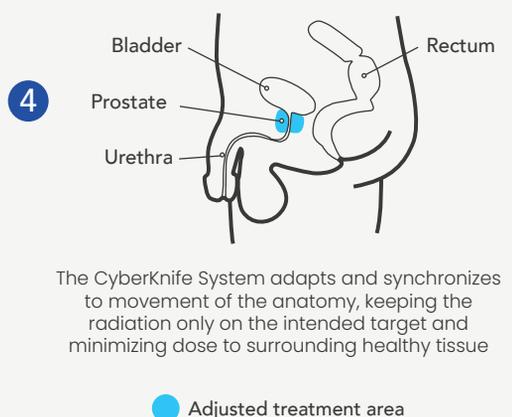
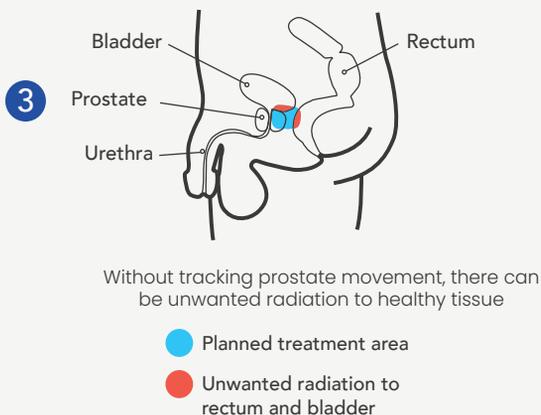
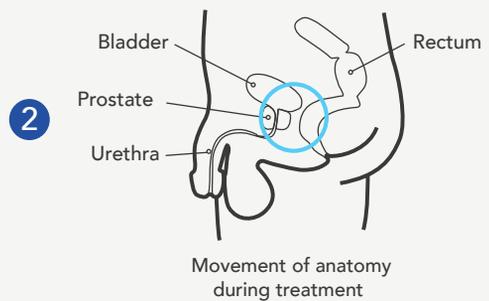
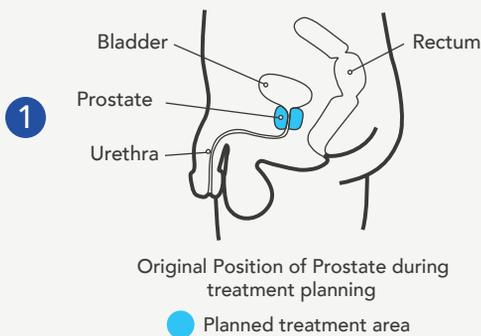


Fig. 2 A 3-D CT image of a CyberKnife System treatment plan shows that the highest concentration of radiation is directed to the prostate.

The CyberKnife® System uniquely adapts and synchronizes the delivery of the radiation beam with prostate movement

The prostate gland can move unpredictably throughout the course of treatment, making the ability to track, detect and correct for motion critically important. In fact, the prostate has been documented to move as much as 10 mm in as little as 30 seconds due to normal patient bodily functions – such as filling of the bladder, gas in the bowel, or even slight patient movement during the procedure.^{5, 6, 7, 8}

Unlike any other radiation treatment, the CyberKnife® System continually tracks, automatically adapts and synchronizes treatment delivery with movement of the prostate in real-time throughout the entire treatment session. This helps ensure the radiation dose is delivered precisely to the target – maximizing treatment effectiveness while minimizing dose to surrounding tissues which can help reduce the incidence of side effects.





More than two decades of clinical proof

The CyberKnife® System is commonly used for treating low- to intermediate-risk prostate cancer and is the only radiotherapy device supported by years of published clinical follow-up with a large number of patients.



KEY FINDINGS

EFFECTIVE

Prospective, multi-institutional study data supports the efficacy of CyberKnife for men with low- and intermediate-risk prostate cancer.^{9,10}

EXCELLENT LONG-TERM OUTCOMES

Clinical studies report CyberKnife can provide excellent long-term disease control for prostate patients.^{11, 12, 13, 14, 15, 16, 17}

EXCELLENT SURVIVAL RATES

Studies show that at five years following CyberKnife prostate SBRT, the disease free survival (DFS) rates were:

- 97% - 100% for low-risk patients, superior to the 92% - 94% from conventional radiation therapy historic data^{11, 12, 18} and equivalent to low dose rate (LDR) brachytherapy^{13, 14} and high dose rate (HDR) brachytherapy¹⁵ without the inconvenience and risk associated with invasive seed and catheter implants.
- 88% - 97% for intermediate-risk patients, equal to or higher than the 85% - 90%

reported with conventional radiation therapy^{16, 17} without the inconvenience of daily visits over several weeks.

At 10 years following CyberKnife prostate SBRT, the DFS rates were:

- 93% for low-risk patients, superior to the 81% - 85%^{19, 20} from conventional radiation therapy historical data and similar to HDR at 92%²¹.

MINIMAL SIDE EFFECTS

Clinical studies have found that serious side effects were uncommon and similar to other radiation therapy procedures without the need for invasive rectal balloons or spacers to spare the rectal wall.

- Data indicate that the level of grade 2 or higher acute genitourinary toxicity in the stereotactic body radiation therapy (SBRT) arm of the trial is lower for patients treated with the CyberKnife System than it is for patients treated on a conventional linear accelerator.²²

What do prostate cancer patients have to say about their CyberKnife[®] System experience?

The CyberKnife Coalition, a not-for-profit advocacy organization, conducted a survey with 304 participants who were asked about their satisfaction with their CyberKnife SBRT treatment. Here is what they said:²³

- 99% of patients indicated that they would again choose to be treated with the CyberKnife System
- 93% of patients indicated that SBRT did not interrupt their normal life routine
- 98% of patients indicated they would recommend SBRT treatment to others





What is a typical CyberKnife® System treatment process?

- ▶ The CyberKnife® System treatment process begins with a consultation with a radiation oncologist who will provide perspective on this as a treatment option specific to the patient’s condition. The physician will review the patient’s PSA, Gleason score, biopsy results, imaging, and other medical conditions.
- ▶ Should the patient and doctor agree to proceed with CyberKnife procedure, gold pellets (fiducials) will be implanted. These fiducials are used in many SBRT procedures as imaging reference points so that the tumor can be tracked. These three to four gold pellets are implanted about 2 weeks before the actual treatment sessions in an outpatient procedure, like a prostate biopsy, under conscious sedation.



- ▶ About one week after the fiducials are implanted, the patient will return for imaging that then allows the radiation team to develop an individualized treatment based on the patient’s unique anatomy.
- ▶ Approximately one week later the treatment sessions will begin. There are usually 4-5 sessions of short duration over 1-2 weeks*. The patient lies on the table, and the CyberKnife System uses the Synchrony tumor tracking software to synchronize the radiation beam with movement of the prostate caused by natural bodily functions.

The procedure to implant fiducials would be performed under local anesthesia. The

- ▶ treatment sessions themselves are non-invasive outpatient procedures, and no anesthesia is required.

***Actual treatment plans and timelines may vary and are as advised by a physician**

Your life. Your treatment.

True robotic precision for personalized radiotherapy.





What are the side effects of treatment?

Despite the higher dose rate associated with SBRT, multiple studies have validated that there are no worse side effects with CyberKnife® SBRT than with traditional radiation.¹⁹ The ability to deliver precise doses of radiation enables clinicians to decrease exposure to surrounding healthy tissue and potentially minimize negative side effects on urinary, bowel, and sexual function that can reduce a patient's quality of life. Most patients resume normal activity immediately after treatment sessions. Nonetheless, urinary incontinence, bowel issues, and erectile dysfunction are all possible complications with any treatment option, and should be discussed with your physician.



Important Safety Information:

Most side effects of radiotherapy, including radiotherapy delivered with Accuray systems, are mild and temporary, often involving fatigue, nausea, and skin irritation. Side effects can be severe, however, leading to pain, alterations in normal body functions (for example, urinary or salivary function), deterioration of quality of life, permanent injury, and even death. Side effects can occur during or shortly after radiation treatment or in the months and years following radiation. The nature and severity of side effects depend on many factors, including the size and location of the treated tumor, the treatment technique (for example, the radiation dose), and the patient's general medical condition, to name a few. For more details about the side effects of your radiation therapy, and to see if treatment with an Accuray product is right for you, ask your doctor.

What if I am not a candidate for the CyberKnife® System?

Not every patient's prostate cancer is effectively treated with SBRT. Talk to your physician about your best options and come to a joint decision. If whole-bed pelvic radiation – radiation for disease outside the prostate – is required, the

Radixact® or TomoTherapy® Systems from Accuray may be a good option. The Radixact and the TomoTherapy Systems leverage CT-image guidance to ensure highly conformal dose delivery to the tumor with each treatment.

Is CyberKnife® SBRT covered by private insurance and Medicare?

As of January 2020, SBRT treatment for prostate cancer is covered by Medicare in all 50 states and the District of Columbia in the United States. In addition, many private insurance payers cover SBRT treatment for prostate cancer. It is always best to check your insurance policy and if applicable, be sure to review your employee contract

to determine if your insurance coverage benefits are limited. The CyberKnife® Center that you have chosen to provide your treatment should be able answer insurance related coverage questions.

What other questions should I ask?

Many patients find it helpful to bring someone with them to their physician appointment to take notes. It can be difficult to focus during conversations about the diagnosis and treatment options, so having a caring partner in the room can be advantageous when later trying to recall the details.

SPECIFICALLY, TAKE THE TIME TO UNDERSTAND:

- What are the most common treatment options?
- Which treatment option would best preserve my quality of life?
- What is my recommended treatment option – and why?
- Am I a candidate for CyberKnife treatment?
- What results should I expect?
- What are the side effects and risks of the procedure; and which side effects are short-term, and which ones may be long-term?
- How are these side effects managed and can they be prevented?

Additional resources

www.CyberKnife.com

Cancer Support Community

www.cancersupportcommunity.org

**PCRI (Prostate Cancer
Research Institute)**

www.pcri.org

**PHEN (Prostate Health
Education Network)**

www.prostatehealthed.org

Us TOO

www.ustoo.org

**Veterans Prostate Cancer
Awareness with ZERO Prostate
Cancer Veterans**

www.zerocancer.org/veterans

**Zero – The End of
Prostate Cancer**

www.zerocancer.org



**The
CyberKnife®
System**

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ACCURAY

The CyberKnife® System



www.CyberKnife.com/prostate-cancer

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