

CYBERKNIFE®

COMPARED TO *da Vinci*® SURGERY FOR PROSTATE TREATMENT†

	<i>da Vinci</i>® Surgical Prostatectomy	CyberKnife® Prostate SBRT
Is this treatment experimental?	No (FDA Cleared in 2001*)	No (FDA Cleared in 2001**)
When were the first prostate treatments performed?	May 2000 (Frankfurt, Germany)	Oct 2002 (Seoul, Korea)
Is surgery involved?	Yes² (Prostate is removed by surgical resection)	No (Non-invasive high-dose irradiation of the prostate)
Does treatment involve anesthesia?	Yes² (Typically involves general anesthesia)	No⁹ (No anesthesia is required and patients relax comfortably during treatment)
Is treatment performed by a robot?	No¹ (<i>da Vinci</i> cannot act on its own and treatment is performed by a surgeon)	Yes⁹ (The CyberKnife Robot automatically delivers a pre-planned treatment under expert supervision)
Is a hospital stay required?	Yes² (Typically 1-3 days of hospitalization)	No⁹ (Treatment is performed in 4-5 outpatient visits)
Are there risks of surgical complications?	Yes² (Risks include infection, bleeding, cardiac, pulmonary complications & death)	No⁹ (Surgery is not performed)
Is a urinary catheter required after treatment?	Yes¹⁰⁻¹² (Patients are sent home with a urinary catheter for 7-10 days after surgery)	No⁹ (A catheter may be used during treatment but is not required once treatment is completed)
Do patients typically experience urine leakage after treatment (Urinary incontinence)?	Yes^{2,12-15} (All patients require a catheter after surgery) • 20-50% have persistent urine leakage in the first 6 months requiring them to wear pads • 4-20% have permanent urine leakage	No^{3-7, 16} (Incontinence is not typically observed)
Are there risks of other less serious urinary side effects?	Yes¹⁷⁻¹⁸ (Urinary stricture, retention, urinary tract infection in reported in 1-3% of patients)	Yes^{3-7,16} (Low-grade urinary retention, urgency, or hesitancy reported in 2-10% of patients)
Are there significant risks of serious rectal injury?	No^{19,20} (Serious rectal injury during surgery reported in only 0-2% of patients)	No^{3-7,16} (Mild rectal bleeding, urgency noted in only 0-5% of patients)
Is sexual function preserved in a majority of patients?	Yes^{2,12-13,22-23} • There is a large reduction in sexual quality of life immediately after surgery and some recovery over the first year after surgery • Current nerve sparing techniques preserve erectile function in 61-90% of men***	Yes^{6,16,24} • Little effect on sexual quality of life immediately after treatment • Current MRI targeted techniques preserve erectile function in 60-87% of men***
Is this treatment effective in treating prostate cancer?	Yes²⁵ (93% PSA recurrence-free at 5 years)	Yes⁴ (93% PSA recurrence-free at 5 years)

* *da Vinci*® was FDA cleared in 2000 for prostate cancer surgery

**The CyberKnife system was FDA cleared in 2001 to be used to treat tumors, lesions and medical conditions anywhere in the body where radiation is indicated

***Because sexual quality of life is a complex, multiply determined construct, the estimates that are presented focus on erectile function per se. They were based on answers to patient questions that specifically addressed the frequency and/or quality of erections. For example, both the EPIC and the SHIM questionnaires ask patients whether they have erections sufficient for penetration, and how reliably. In other studies patients are asked directly about their ability to have an erection. There may be other studies that report results that fall outside of this range but that do not meet this criteria for construction of the stated ranges for this endpoint.

†Comparative data in table is not from a head-to-head study but rather from published independent studies

CYBERKNIFE® PROSTATE SBRT FAQs

This document is intended to answer some of the frequently asked questions about CyberKnife® prostate SBRT (Stereotactic Body Radiotherapy)*

Is the CyberKnife system cleared by FDA?

Yes. In 2001 the CyberKnife System received 510K clearance from the U.S. Food and Drug Administration (FDA) to treat anywhere in the body where radiation is indicated, including the prostate.

CyberKnife treatment is often referred to as SBRT or Radiosurgery. Why, and what does that mean?

SBRT stands for Stereotactic Body Radiation Therapy. SBRT and Radiosurgery (also known as SRS) are techniques used in Radiation Oncology to ablate (destroy) diseased tissue, often malignant tumors, by precisely directing very high doses of radiation at the diseased tissue while avoiding surrounding normal tissue as much as possible. Unlike conventional radiation therapy, SBRT and SRS treatments are given over a small number of treatment sessions, usually between 1 and 5.

The CyberKnife System was specifically designed to perform SRS and SBRT treatments with high degrees of accuracy. The CyberKnife System takes images continually throughout each treatment session to ensure that the radiation beam is aimed at the target. If any motion of the target is detected by these images, the CyberKnife System can precisely adjust the position of the radiation beam under robotic control to keep it on target and away from normal tissue.

SRS is typically used to describe treatments specific to the head and neck, while SBRT commonly refers to treatments anywhere else in the body.

What is CyberKnife Prostate SBRT?

Despite its name, the CyberKnife System is not a surgical procedure. In fact, there is no cutting involved. Instead, the CyberKnife System delivers high doses of radiation directly to the prostate cancer over a 4 to 5 day period. Each of these treatment sessions is called a "fraction."

The CyberKnife System is a linear accelerator mounted to a robotic arm that is specifically designed to deliver stereotactic radiation from hundreds of different angles. Given this robotic maneuverability, less healthy tissue is affected and higher doses targeting the prostate can be delivered exactly where it counts most.

The prostate gland can move unpredictably throughout the course of treatment, this makes the ability to track, detect and correct for motion critically important. The CyberKnife System continually tracks and automatically corrects for the movement of the prostate in real time. This enables the system to correct the beam direction so that it is focused on the prostate throughout the entire treatment. The robot constantly monitors and aligns the real time location of the prostate to ensure any adjustments in the beam delivery match the prepared treatment plan while automatically

correcting for any movement during a treatment by relaying critical logistical information to the system software. Safety mechanisms are in place to ensure that the beam of radiation is 'locked on' to the intended target should the prostate move out of acceptable range.

What are the benefits of CyberKnife prostate SBRT?

CyberKnife SBRT provides an alternative to conventional radiation therapy and to surgery, including *da Vinci*® robotic surgery for organ confined prostate cancer. Unlike surgery which is invasive and typically requires general anesthesia and hospitalization for 1 to 3 days, CyberKnife prostate SBRT is noninvasive and is performed on an outpatient basis. The risks that are often associated with prostate surgery, such as infections, bleeding, pulmonary complications, and death are avoided by the non-invasive nature of CyberKnife prostate SBRT. Unlike the 6-8 weeks of conventional radiation therapy treatment, treatment is typically completed over a week in 4-5 short outpatient treatment sessions and most patients continue with their normal daily activities throughout treatment. There is typically little to no recovery following CyberKnife prostate SBRT as opposed to surgery which requires patients to go home with a urinary catheter and to endure several weeks to months of post surgical recovery. CyberKnife prostate SBRT's accuracy enables sparing of normal tissues surrounding the prostate, maximizing the preservation of quality of life for patients.

What is the typical follow-up schedule after CyberKnife prostate SBRT and how does this compare to the follow-up after prostate surgery?

Follow-up procedures after surgery or after CyberKnife SBRT are typically quite similar. These could include periodic office visits and PSA testing. Post treatment imaging is typically not required for patients with organ confined prostate cancer after treatment, but this practice may vary depending on specific physician practices. The frequency of PSA testing will vary according to your physician and your results of previous tests. Following prostate treatment, PSA typically falls to zero immediately, often consistent with a successful treatment and patients are monitored to detect any new PSA levels that may indicate prostate cancer recurrence. Following CyberKnife prostate SBRT, PSA levels typically decline continuously following treatment and reach very low levels over a 1-to 2- year period that are often indicative of a successful treatment. For both prostate surgery and CyberKnife prostate SBRT, PSA is monitored typically for 5 years after treatment to ensure there is no rise in measured levels that may be consistent with cancer recurrence. Patients for both treatments are also assessed at each follow-up for any potential side effects that they may be experiencing.

What are my treatment options after CyberKnife SBRT if the cancer returns? Am I still a candidate for radiation therapy or surgical treatment?

Although less than 10% of patients have a recurrence of their prostate cancer within the first 5 years of treatment following CyberKnife prostate SBRT, it is important to understand the options available should a recurrence be detected. Recurrences following CyberKnife prostate SBRT, prostate surgery or following conventional radiation therapy may all occur either within the region of the prostate or prostate resection area or outside of this area in another region of the pelvis or body. Because of the CyberKnife System's highly accurate delivery and small treatment margins sparing surrounding normal tissues, retreatment by either radiation therapy and/or surgery is possible following CyberKnife prostate SBRT if it is determined that the recurrence is within the prostate. Since recurrences are uncommon, and since they may occur outside of the prostate, treatments available to each patient will vary. Each case is typically evaluated by clinicians, taking into consideration a patient's specific clinical picture and disease pattern to determine the best plan for retreatment specific to a patient's individual needs.

Does CyberKnife have long-term data supporting its use?

Yes. Here is a link to the published studies: www.Accuray.com/healthcare-professionals/clinical-publications/CyberKnife-publications

What option is right for me to cure my prostate cancer?

As each patient is different, so is his prostate cancer. And although there are a number of effective treatment options such as surgery, conventional radiation therapy, and CyberKnife prostate SBRT, there is a lack of comparative evidence and studies comparing outcomes of current technologies and treatments. We encourage you to talk to your physician so you can decide on what treatment option is best for you.

**References for these statements can be found in the table above*

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For more information on CyberKnife Prostate SBRT visit www.cyberknifeforprostate.com