The CyberKnife® System

ACCURAY

CyberKnife[®] Robotic Radiosurgery System

Information Guide

You have more options than ever for successfully treating a cancerous or benign tumor, or a neurologic disorder. The best treatment option for you is one that fits your life — from the specifics of your disease and your overall health, to your age and lifestyle.

This guide provides information about one treatment option — the **CyberKnife® System**.

Quick facts about the CyberKnife[®] System

- The CyberKnife[®] System was cleared by the FDA in 1999 to treat diseases in the head and base of the skull. In 2001, the FDA cleared the CyberKnife System for the treatment of tumors anywhere in the body
- The system is used to treat conditions throughout the body, including the brain, head and neck, spine, lung, liver, pancreas, kidney and prostate, and can be an alternative to surgery for patients who have inoperable or surgically complex tumors
- CyberKnife accuracy is sub-millimetric, which can help significantly reduce the risk of the side effects that too often disrupt the lives of patients during and after treatment



- CyberKnife treatments are typically performed in 1 to 5 sessions
- The CyberKnife System has more than two decades of clinical proof
- Hundreds of thousands of patients have been treated with the CyberKnife System

Key CyberKnife Treatment Benefits

- Typically pain-free
- Non-surgical and non-invasive
- No anesthesia required
- Outpatient procedure
- Majority of patients can continue normal activity during and immediately following treatment
- No invasive head or body frame
- No breath holding or "respiratory gating" required during 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 due to the damage done 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 surgey 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 radiosurgery (SRS) and stereotactic body radiation therapy (SBRT).

What are SRS and SBRT?

SRS and SBRT couple 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 the dose on other nearby organs.

SRS and SBRT treatments are a form of hypofractionated radiation therapy. Hypofractionation entails delivering a higher dose per session (called a fraction) across fewer total sessions. In comparison, conventional radiation therapy treatments involve the delivery of a lower dose of radiation, typically delivered in numerous sessions across several weeks.

CyberKnife[®] Advanced Robotics



The CyberKnife[®] System is the only radiation delivery system which features a linear accelerator (linac) directly mounted on a robot to deliver the high-energy x-rays or photons used in radiation therapy. The robot moves and bends around the patient, approaching the tumor from potentially thousands of unique angles, significantly expanding the possible positions from which radiation beams can be delivered. The more angles and points in space from which to approach the tumor, the better a physician will be able to maximize radiation dose delivered to the tumor and help minimize dose to surrounding healthy tissues. The CyberKnife System can essentially "paint" the tumor with a high-dose of radiation by targeting the tumor from almost any conceivable angle.



The CyberKnife System is the only device designed to accommodate all forms of patient and tumor motion, even while the treatment is being delivered. The CyberKnife System uses advanced technologies to track tumors anywhere in the body, while its unique robotic design synchronizes the radiation to the target. Before delivering the radiation beam, the CyberKnife System is the only device that verifies the exact tumor position, then adjusts the robot to precisely target the tumor. This helps to ensure radiation is delivered where the tumor is, enabling smaller treatment margins around the tumor and helping to minimize the amount of healthy tissue exposed to high dose radiation.

The CyberKnife System eliminates the need to use invasive and uncomfortable methods to minimize movement. These immobilization techniques can include attaching a metal frame directly into a patient's skull, compression of the abdomen to limit breathing and movement during treatments, stabilizing body casts, and placement of rectal balloons into the rectum to stabilize the prostate, to name just a few.

The CyberKnife[®] System uniquely adapts and synchronizes the delivery of the radiation beam with tumor and patient movement

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Being able to precisely and accurately deliver radiation makes a difference in terms of controlling cancer and can help reduce the risk of side effects. But tumor or patient movement as a result of normal body functions, including regular breathing, filling of the bladder, or gas in the bowel can shift the tumor, which can make it challenging to accurately target the radiation and result in under- or over-dosing of the tumor. Too much radiation may increase the risk of side effects while too little may reduce the effectiveness of the treatment. Tracking the tumor's movement – and synchronizing the delivery of radiation with that movement – helps to maximize treatment effectiveness, while minimizing dose to surrounding tissues, which can help reduce the incidence of side effects.

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CyberKnife

How does my physician typically determine if I am a candidate for CyberKnife[®] treatment?

Following a cancer diagnosis, patients may be faced with numerous treatment options. Each person should consult their physician regarding their own specific case. Among the considerations that a physician will factor into a treatment recommendation are their clinical experience, the tumor type, location and size of the tumor, and extent of disease. Other factors that may influence their opinion are the patient's health, age and lifestyle. It is important to keep in mind that sometimes there are many different approaches and opinions can differ. The CyberKnife[®] System is versatile and can treat cancers from early stages to advanced disease and, in some cases, the treatment can be partnered with surgery, chemotherapy, immunotherapy and conventional radiation therapy. The CyberKnife System may provide an effective radiation treatment option even for patients who have previously received radiation therapy.



If you are interested in finding out if CyberKnife treatments are right for you, please contact your local CyberKnife center. CyberKnife locations can be found online at www.CyberKnife.com.

What is a typical CyberKnife[®] System treatment process?

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The CyberKnife[®] System is designed to treat tumors throughout the body. Below is a typical treatment process for a man diagnosed with prostate cancer as an example.

- 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.



What are the side effects of treatment?

Despite the higher dose rate associated with SRS and SBRT, multiple studies have validated that treatment with the CyberKnife[®] System is well tolerated with minimal side effects. The ability to deliver precise doses of radiation enables clinicians to decrease exposure to surrounding healthy tissue and minimize negative side effects that can impact a patient's quality of life. The majority of patients can continue normal activity during and immediately after treatment. Nonetheless, as with any radiation treatment, side effects can also be severe in some patients and lead to permanent injury or even death. Discuss your specific case with your physician/s to fully understand the potential risks associated with your treatment.

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.

Insurance coverage

Medicare and private insurance carriers in most states cover CyberKnife treatments.

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 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 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?



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