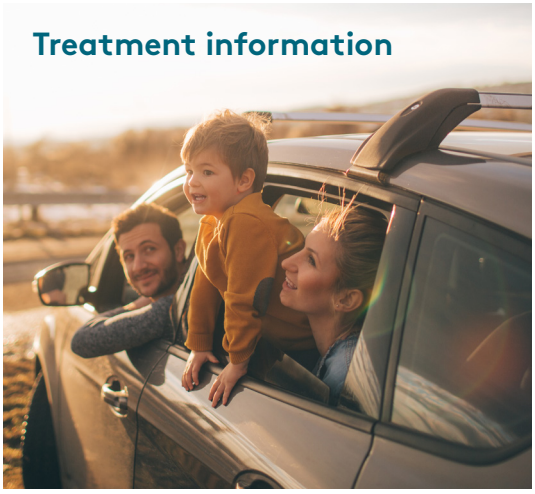
Elekta

Leksell Gamma Knife® Icon™

Treatment information



You may be feeling frightened or overwhelmed by your recent diagnosis.

It can be confusing trying to process a diagnosis, understand a new and challenging vocabulary and weigh life-altering decisions about your course of treatment. Your physician recommends treatment with a highly specialized technology called Leksell Gamma Knife® Icon™. This guide intends to empower you with information and resources to better understand your procedure, called Gamma Knife® surgery.

More than 80,000 patients undergo Gamma Knife surgery every year.[1]

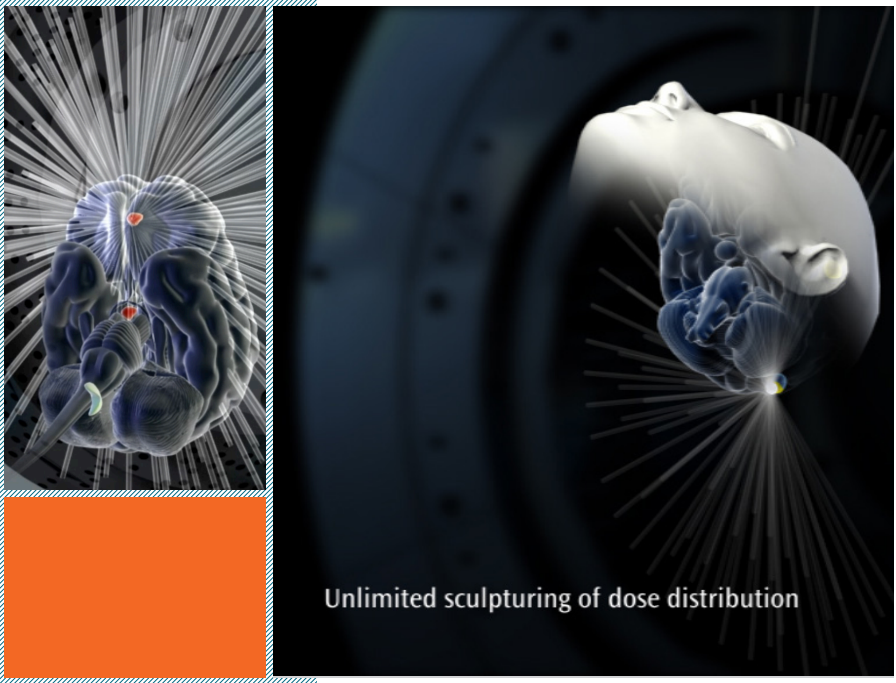
[1] Leksell Gamma Knife Society

Why Leksell Gamma Knife Icon?

Gamma Knife surgery is a clinically proven method to treat select intracranial (within the skull) locations – such as the brain, brain stem, or the trigeminal nerve. Despite its name, Gamma Knife is not a blade that cuts, but highly sophisticated non-invasive technology that uses radiation to damage targeted tissue in a very precise manner while minimizing exposure to healthy surrounding tissues and critical structures. This highly precise and focused treatment is called stereotactic radiosurgery (SRS). SRS reduces the risk of potential side effects that might impact normal brain function and your quality of life.

Your physician will determine the type of Icon treatment you receive, based on your diagnosis and your specific treatment needs. For many indications, Gamma Knife treatment is delivered in a single session. For others, you may be offered fractionated stereotactic radiosurgery, which divides the total radiation dose over several treatment sessions. Fractionation extends Gamma Knife precision and accuracy to previously challenging tumors, including large lesions or those abutting very sensitive areas such as the optic chiasm (where the left and right optic nerves partially cross to the opposite side of the brain).

Icon is able to reach areas deep in your brain. The radiation delivery is extremely precise, which means tissue surrounding the treatment area is spared. The technology's level of precision and accuracy allows delivery of highly effective doses of radiation exactly where needed while preserving healthy surrounding tissue that may impact function and quality of life.



How does it work?

During Icon treatment, up to 192 radiation beams are precisely directed to one or several intracranial lesions, so the tissue where the beams intersect receives a concentrated dose of radiation. The source of radiation is cobalt, and the shape and dose of the radiation is optimized to focus on the exact point desired without damaging healthy tissue or nearby critical structures.

Depending on your diagnosis Icon may:

— Destroy or stop the growth of tumors by damaging cell DNA

— Alter function, as in the case of hormone-producing tumors in the pituitary gland or pain sensations in the trigeminal nerve

— Generate changes in blood vessels in the brain (arteriovenous malformations)

Icon can be used to treat a number of neurological disorders, including:

— Benign or malignant tumors

— Brain metastases

— Medically refractory essential tremor

— Recurrent glioblastomas

— Trigeminal neuralgia

— Vascular malformations

Steps to Icon Treatment

1. Consultation

It all begins with your consultation.

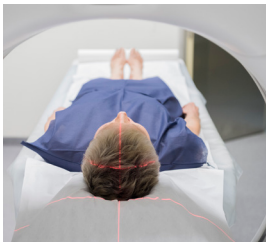
You meet with a neurosurgeon or radiation oncologist to discuss your condition, your medical history and your treatment options. Once Icon is identified as your preferred treatment option, your treatment is scheduled and details are discussed. You may wish to bring a trusted friend or loved one to this visit to help you record and remember details and answers to your questions.

Because precision and accuracy are so critical to the success of your treatment, it is important that your head not move while the radiation is administered. This is achieved one of two ways: frame-based or frameless (mask) immobilization. The method of immobilization depends on the nature of your disease or medical condition, as well as the size, shape and location of the tissue being treated.

2. Defining the target: imaging

Images are captured to enable the most effective treatment plan possible. Magnetic resonance imaging (MRI), computed tomography (CT) or angiography images help define the exact size, shape and position of your lesion(s), as well as important surrounding tissues and nearby critical structures.

Imaging is usually scheduled on a day prior to your treatment day. Frame-based patient imaging sometimes takes place the day of your treatment, once your head frame has been fitted.



Treatment recommendations depend on tumor type and grade, location and size, and other factors such as your age and general health.


Your physician discussion includes treatment details specific to your case.

3. Securing accuracy: stereotactic frame or mask

Stereotactic Frame

— When you arrive you are given a mild sedative to help you relax.

— Your physician places the stereotactic head frame on your head, which allows pinpoint treatment accuracy and keeps your head from moving during your imaging/treatment sessions.

— After the administration of a local anesthetic to numb four areas, the frame is secured to your head with four pins.

— For imaging, a coordinate box is placed on the head frame. The purpose of the coordinate box is to provide reference points on the images, to be used for treatment planning. After imaging, the coordinate box is removed.

Stereotactic Mask

— Prior to your actual treatment day, you come to the clinic to have a custom face mask made.

— Once you check in, you are escorted into the treatment suite, where you lie down on the treatment couch.

— The mask is made of breathable material that becomes flexible when heated. While the material is flexible, it is placed over your face and shaped to your specific facial contours, with an opening around your nose.

— After a few minutes the formed mask begins to set up and is removed.

— Your mask continues to set up so, once fully set, it will securely hold your head still. When you are positioned for your Icon treatment, you will notice that it fits snugly.

— A cushion is also custom shaped to support your head during your treatment session.

Stereotactic Frame

Stereotactic Mask

4. Treatment precision: planning

Once your images are captured, your physician works with a specialized medical physicist to calculate exactly how the treatment should be performed – the number of beams and where they must intersect to deliver the most effective treatment while protecting surrounding tissue and structures. This team references your images and utilizes advanced, dedicated computer software to develop exact instructions for Icon to deliver irregular overlapping beams that closely conform to the tumor or other treatment target.

It may take an hour or more to develop your individualized treatment plan. Often, this is calculated between visits prior to your treatment day. Frame-based plans may be completed while you rest at the center with the frame still in place, watching television, reading, or visiting with loved ones who accompanied you.

5. Icon treatment

When it is time for your treatment you are helped onto the treatment couch and positioned for treatment, guided by your clinical team. Your head frame or mask is secured to the couch and, if you are a mask-based patient, an adhesive marker is attached to the tip of your nose to allow continual motion monitoring. If you wish, a warm blanket is provided, the lights may be dimmed, and you may have the option of listening to music. Your team will explain how to signal them if you become distressed or need a break, as the treatment can be stopped at any time and resumed when you are ready to continue. Once you are comfortably positioned, the staff leaves the room to continually monitor your treatment.

Icon allows imaging at the time of your treatment, so your team can ensure your treatment conforms to the most current characteristics of your tumor. You may sense the movement of the imaging arm and hear a humming sound as it rotates around you, but it does not touch you. Working closely together, your treatment team can accommodate for any recent changes that may have occurred in your anatomy, which supports the utmost accuracy.

When treatment begins, the door panels open and the couch moves you into the dome section of the unit. While you remain in place on the treatment couch, the positioning system automatically moves you according to your programmed treatment plan, to ensure your treatment is delivered exactly as prescribed to the treatment area(s). Icon allows High Definition Motion Management, which detects motion. The system will instantly block the radiation if you move beyond the strict parameters established.

The process may last from a few minutes to more than an hour, depending on the size, shape and complexity of the target(s) being treated. The treatment itself is painless – in fact, some patients even fall asleep. You can communicate with your treatment team at any time by intercom or hand signal.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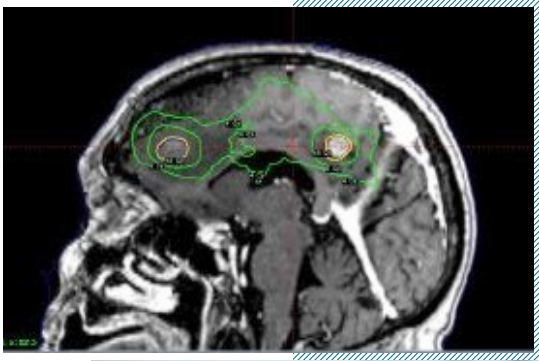
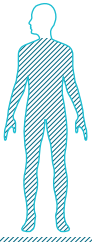


Gamma Knife by the numbers

1 million patient procedures[1]

2-4x better sparing of normal brain tissue compared with other stereotactic platforms[2]



up to 130x lower dose to the rest of the body compared with traditional linear accelerators[3]

For more information, visit **www.gammaknife.com**

Once your session is completed, your mask or frame is released and you are escorted from the treatment area. If you had a frame-based treatment, the frame is now removed and you are prepped for discharge.

Most patients are discharged home within the hour – however, your physician may want you to stay overnight for observation. Some frame-based patients experience a mild headache or minor swelling where the head frame was attached, but most report no problems.

After your treatment

Normal activities can usually be resumed in a day or so.

Whether you undergo frame-based or mask-based treatment, the desired effect is for the radiation treatment to damage the DNA of the targeted cells and prevent them from reproducing. Treatments are designed to stop the growth of tumors or dysfunctional tissue, which means that the effects are observed over a period of weeks or months. Your physician will stay in contact to assess your progress, which may include follow-up visits and imaging.

Your treatment team can help connect you with patient organizations and websites relevant to your diagnosis, where you can find important support and tools to help you and your family cope with challenges you may encounter along the way. Always consult your physician if you have any questions at all.

Side effects

Gamma Knife is so precise that minimal damage occurs to healthy tissues surrounding the treatment target. There may actually be a lower risk of side effects than with other types of radiation therapy. Be sure to discuss with your physician the potential side effects specific to your case.

Affix practice label

References

[1] Leksell Gamma Knife Society, September 2016

[2] Ma L, Nichol A, et al. Variable dose interplay effects across radiosurgcial apparatus in treating multiple brain metastases. Int J Comput Assist Radiol Surg. 2014; 9(6):1079–1086. Published online 2014 Apr 20. doi: 10.1007/s11548-014-1001-4

[3] Lindquist C and Paddick I. The Leksell Gamma Knife Perfexion and comparisons with its predecessors, Neurosurgery 61: ONS 130-141 2007; Vlachopoulou V, Antypas C, Delis H, et al. Peripheral doses in patients undergoing Cyberknife treatment for intracranial lesions. A single centre experience. Radiation oncology (London, England) 2011;6:157