

Clinic / Doctor:



Patient data:

englisch

area to be treated with radiotherapy:

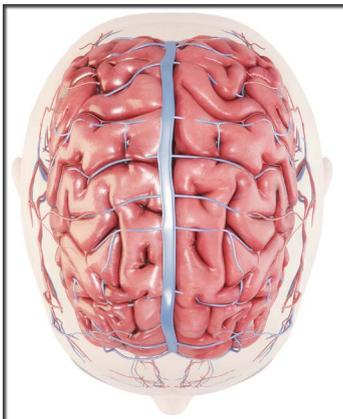
**Dear patient,**

your brain tumour is to be treated with radiotherapy.

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the treatment suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

### HOW RADIOTHERAPY WORKS

Tumour cells are cells which divide and multiply uncontrollably. In the process, tumour cells are usually more sensitive to radiation than normal tissue. Radiation therapy makes use of this fact by splitting the radiation dose into several, smaller doses applied in several treatment sessions (fractionation). This will allow for healthy tissue to recover in between the sessions, while the



tumour tissue is increasingly damaged with every treatment session. Modern technology has also made it possible to apply radiation specifically, thus sparing the tissue around the specific area. This helps reduce the side effects of radiotherapy and maximize the desired destructive effect on the tumour cells.

With brain tumours, radiotherapy is used in various cases:

- Radiotherapy after surgical removal of the tumour** (adjuvant radiotherapy):

After surgery, depending on the size of the tumour, those areas at risk of developing a new tumour (recurrence) are treated with radiation.

- Radiotherapy without surgery**

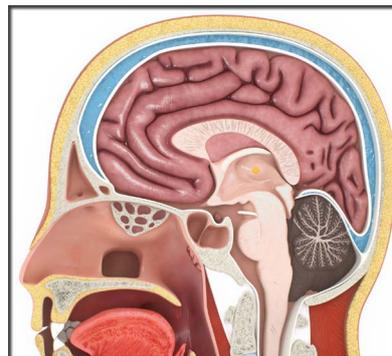
In consultation with the doctors in charge, surgical removal of the tumour has been forgone. This can be for various reasons, for instance if surgery would result in significant loss of function or if it is impossible due to the size of the tumour. The tumour will then be treated with radiotherapy only without surgery.

- Radiotherapy prior to surgical removal of the tumour** (neo-adjuvant radiotherapy):

- with X-rays     mit with electron beam radiation
- with proton beam therapy, heavy ion therapy
- tumour therapy with medication

Radiotherapy is carried out prior to surgery in order to shrink the tumour to the extent needed to make surgery easier.

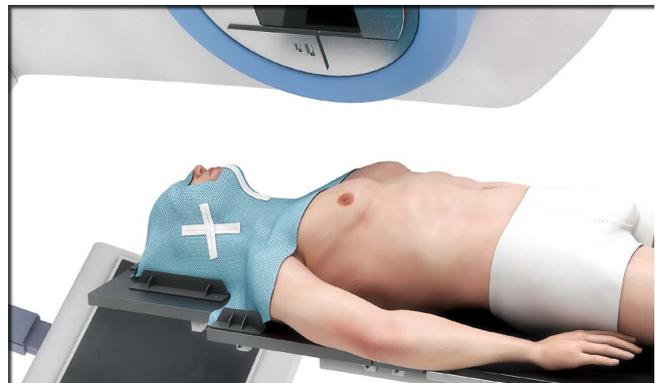
Depending on the type and stage of the tumour, radiotherapy is often combined with treatment involving medication, such as chemotherapy, hormone therapy and antibody therapy. This can be applied before, during and after radiotherapy.



Since some brain tumours form metastases via the brain fluid in other regions of the brain and even the spinal cord, the entire brain and, if needed, also the spinal cord will have to be treated in those cases.

### PLANNING OF RADIOTHERAPY TREATMENT

Preparing for radiotherapy and calculating the radiation dose needed usually takes several days.



The radiation therapist will determine the exact area to be treated with radiation depending on the tumour situation. A computer tomography examination will be carried out prior to the commence-

ment of radiotherapy to facilitate this and also to allow for the calculation of the exact doses to be applied in your individual case. A CT may require the administration of contrast media. Further examinations, such as an MRI or scintigraphy, may also be undertaken if need be.

In order for you to be placed in the exact same position on every day of treatment, allowing for radiation to be applied precisely, so-called positioning aids are needed. These may be face masks, bite blocks or other holding devices custom-made for you.

Sometimes, the radiation volume will be checked again with a therapy simulator using special X-ray images. Your doctor will decide whether this is required.

During the planning stage, the radiation fields will be drawn on the mask or your skin.

### COURSE OF RADIATION TREATMENT

The frequency of radiotherapy treatment will be adjusted to your particular situation. One session per day on five days per week is the norm. In particular situations, radiation can be carried out twice a day, or only once per day on some days of the week. Your doctor will create a radiation schedule especially for you.

Individual sessions normally involve the following:

First of all, you will be placed on the radiation table in the exact position determined during the planning stage with the help of the positioning aids as well as the laser instruments installed in the radiation room. This may take several minutes.

If need be, your position will be double-checked with X-ray images or a short CT directly on the radiation device.

The radiation duration per session can range from seconds to several minutes. During the actual radiation phase, you will be on your own in the radiation room. However, you will be connected with the treatment team via in intercom and video device. The team consists of the radiation therapist as well as medical technical assistants specifically trained in radiotherapy and, if needed, a medical physicist. It is of utmost importance that you remain absolutely still during the radiation treatment.

With children, an anaesthetic may have to be administered to ensure absolute motionlessness.

### ALTERNATIVE METHODS

There are various methods available nowadays for treating tumours, which, depending on the type and stage of a tumour, can also be combined. Your doctor will explain to you which procedure is best in your particular case.

**Alternative treatment methods available:**

### PROSPECTS OF SUCCESS

Radiotherapy is a highly effective method in treating tumours. Through improved radiation technology and additional administration of medication, the prospects of success could be improved significantly in recent years. In addition, the possible side effects of radiation therapy can be treated more effectively nowadays. Your doctor will inform you regarding the prospects of success of radiotherapy in combination with other treatment methods (surgery, tumour treatment with medication) in your particular case.

### GUIDELINES FOR PATIENTS

Please follow the instructions of the doctor and of the nursing personnel closely. Unless specifically instructed otherwise, please adhere to the following guidelines:

**Prior to radiotherapy:**

Please bring any previous X-ray or CT images or findings with you.

If **markings** have been made on your skin, please do not remove them. If the markings have been removed, therapy planning may have to be repeated.

**Medication:** Please inform your doctor of any medication you take or inject on a regular basis. Please also cite any medication (over-the-counter or herbal remedies) you have recently taken from time to time.

Radiotherapy and/or any chemotherapy administered in addition may result in **impaired fertility** in patients. If you are planning to have children, please let your doctor know so you can discuss the possibility of egg cells or semen being preserved through freezing.

**During the radiation treatment series:**

There are usually no acute side effects, or they are very minor, meaning that you won't be limited in your everyday life.

Please avoid **mechanical irritation** of the treated skin area. You should also be very gentle when washing the treated skin or not wash it at all. Please only use the prescribed creams, salves and powders for **skin care**.

During the spring and summer, you should avoid **direct exposure to sunlight** and wear a **head covering** outside.

Please inform your doctor **immediately** or come to the clinic should you experience **a fever, severe skin reactions, inflammation, severe headaches, nausea, vomiting, vision disorders, convulsive seizures, paralyses, sensory disturbances** or any other symptoms. These may call for further examinations or treatment with cortisone or mannitol solution.

If treatment is carried out on an **out-patient/partial in-patient basis**, you need to be aware of the fact that your ability to participate in road traffic may be impaired. Therefore, for the period of time indicated, you should **not actively participate in road traffic** and refrain from any **risky activities**. On the whole, you should refrain from physical exertion during the radiation treatment series; please consult your doctor should you have any questions with regard to this.

During and possibly even for some time after radiotherapy, you should use safe methods of **contraception** since radiation can damage germ cells (egg cells, sperm) as well as an embryo.

### RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. If complications occur, they may sometimes require additional treatment or surgery and, in extreme cases, can sometimes even be **life-threatening** or lead to permanent damage – even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

In radiotherapy, a differentiation is made between **acute side effects**, which occur during radiotherapy, and **chronic side effects**, which may occur months or even years after radiotherapy.

**Acute side effects** are often inevitable and usually always occur to a certain extent during radiotherapy. They usually disappear entirely after radiotherapy has been completed and can be treated with supportive measures.

**Chronic side effects** fortunately don't occur very often and are usually minor. Also, whether they are a result of radiotherapy, the tumour itself or the surgical removal of the tumour cannot always be determined.

A common side effect of radiotherapy is **reddening of the skin** and **dry flaking** in the area of the radiation fields. Simultaneously,

**hair loss** occurs very often in the treated area. Both will disappear for the most part after treatment has been finished. On rare occasions, **permanent skin alterations** will occur, such as brown discolouration or thinning, hardening and shrinking of subcutaneous tissue. Permanent hair loss may occur if the radiation dose was higher than intended in some areas.

You may suffer from **headaches** accompanied by **nausea**, **vomiting** and **convulsive seizures**. Administering medication will usually alleviate those symptoms. In addition, **tiredness** and **a loss of appetite** may occur.

If the pituitary gland (hypophysis) is within the treated area, your **hormonal balance may be affected** since this gland is the centre for regulating hormone production. This can lead to impaired thyroid function, fluid balance, sexual function and, in children, growth. Your doctor will let you know whether regular check-ups are needed. Any impairments can then be detected in time and be treated with appropriate medication.

Radiotherapy can lead to **impaired brain function** with your ability to concentrate and remember things being affected. This risk varies significantly depending on the patient's age, the type of tumour and therapy. Children may not do as well as before in school. A **slowing down of mental processes** and **increased fatiguability** can be long-term consequences.

If the eyes or optical nerves are included in the treated area, **clouding of the lens** as well as **conjunctival irritation** or **optical nerve damage** can occur. In extreme cases, these can result in the patient losing their eyesight. A clouded lens can be removed or replaced, as is done in cataract surgery.

If the inner ear is within the treated area, **hearing impairments** or even **deafness** can occur in the affected ear as well as **dizziness**.

An unnatural connection may form between the cerebrospinal space and the nose or ear (**liquor fistula**), which may have to be closed surgically.

**Accumulation of fluids in the brain** (cerebral oedema) may require permanent treatment with medication.

Within the treated area, **death of brain tissue, soft tissue or bone tissue** may result.

If the treated area is operated on a later point in time, **wound healing disorders** may occur.

**Allergic reactions**, for instance to medication or latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening circulator shock** are rare. They may then result in permanent organ damage, such as brain damage, paralyses or kidney failure.

**Damage to the skin, soft tissue or nerves** - for instance through injections, inflammation, disinfectants or despite proper positioning - rarely occurs. Numbness, paralysis and pain may then result. They are usually temporary. Permanent nerve damage, tissue death and permanent scarring occur very rarely.

Particularly if chemotherapy is used in addition, **changes in the blood count** involving a decrease in white and red blood cells can occur. The risk of infections is then increased and blood components may have to be administered.

Radiotherapy leads to a minor increase of the risk of developing another **tumour** or **leukaemia** after years or even decades.

**Additional risks involved in the treatment of the spinal cord with radiation:**

If the pharynx, oesophagus or the stomach or parts of the colon are within the area of the radiation fields, it may result in **trouble swallowing, heartburn, stomach aches, diarrhoea** and **hoarseness**. An **ulcer of the stomach or colon** can develop long-term.

Temporary or, in rare cases, permanent **paralyses** e.g. of the bladder, colon, an arm or leg, in extreme cases **paraplegia**, can occur.

Children may suffer from **impaired growth** accompanied by spinal curvature.

If the thyroid is within the treated area around the throat, a decrease in or even **total failure of the production of thyroid hormones** may result, requiring life-long hormone replacement therapy.

## Important Questions for Outpatients

Wichtige Fragen für ambulante Eingriffe

Who will pick you up when you are discharged from the hospital/clinic/surgeon's practise? Wer wird Sie abholen, sobald Sie aus Klinik/Praxis entlassen werden?

Name and age of the person picking you up: [Name und Alter des Abholers]

Where can you be reached within the 24 hours after surgery?

Wo sind Sie in den nächsten 24 Stunden nach dem Eingriff erreichbar?

Street, house number, postcode, place: [Straße, Hausnummer, PLZ, Ort]

Telephone: [Telefonnummer]

Name and age of person looking after you: [Name und Alter der Aufsichtsperson]

Who is your physician (the one whose care you are in/who referred you/family surgeon)? Wer ist Ihr überweisender Arzt / Hausarzt / weiter betreuender Arzt?

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]

## Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

### Information about medications:

Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days?  yes  no

Aspirin® (ASS),  Clopidogrel,  Eliquis®,  Heparin,  Marcumar®,  Plavix®,  Pradaxa®,  Efiect®,  Brilique®,  Ticlopidin,  Xarelto®,  Iscover®.

**Angaben zur Medikamenteneinnahme:** Werden regelmäßig blutgerinnungshemmende Mittel benötigt oder wurden in der letzten Zeit (bis vor 8 Tagen) solche eingenommen/ge-spritzt?  Aspirin® (ASS),  Clopidogrel,  Eliquis®,  Heparin,  Marcumar®,  Plavix®,  Pradaxa®,  Efiect®,  Brilique®,  Ticlopidin,  Xarelto®,  Iscover®.

Any other: \_\_\_\_\_

Sonstiges:

When was the last dose taken? \_\_\_\_\_

Wann war die letzte Einnahme?

Do you take any other medications?  yes  no

Werden andere Medikamente eingenommen?

If so, which ones: \_\_\_\_\_

Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Are you pregnant?  not certain  yes  no  
Sind Sie schwanger?  nicht sicher

Do you smoke?  yes  no

If so, what and how much daily: \_\_\_\_\_

Rauchen Sie? Wenn ja, was und wie viel täglich:

Do you drink alcohol regularly?  yes  no

Trinken Sie regelmäßig Alkohol?

If so, what and how much: \_\_\_\_\_

Wenn ja, was und wie viel:

Have you ever been treated with X-rays?  yes  no

Wurde schon einmal eine Strahlentherapie durchgeführt?

If so, when? \_\_\_\_\_

Wenn ja, wann?

Have you ever had chemotherapy?  yes  no

Wurde bei Ihnen schon einmal eine Chemotherapie durchgeführt?

If so, when? \_\_\_\_\_

Wenn ja, wann?

Have you had another medical anti-cancer therapy, for instance with antibodies?  yes  no

Erhielten Sie eine andere medikamentöse Tumorbehandlung z. B. mit Antikörpern?

Have you ever had surgery on the spine?  yes  no

Wurden Sie schon einmal an der der Wirbelsäule operiert?

Have you ever had surgery on the head?  yes  no

Wurden Sie schon einmal im Kopfbereich operiert?

Do you have or have you ever had any of the following diseases:

Liegen oder lagen nachstehende Erkrankungen vor:

Allergies / Oversensitivity?  yes  no

Medications,  foods,  contrast media,  iodine,  sticking plaster,  latex (e.g. rubber gloves, balloons),  pollen (grass, trees),  anaesthetics,  metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

**Allergie/Überempfindlichkeit?**  Medikamente,  Lebensmittel,  Kontrastmittel,  Jod,  Pflaster,  Latex (z.B. Gummihandschuhe, Luftballon),  Pollen (Gräser, Bäume),  Betäubungsmittel,  Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Any other: \_\_\_\_\_

Sonstiges:

Do you have a congenital or acquired immune defect?  yes  no

Immunsystem? Leiden Sie an einer angeborenen oder erworbenen Immunschwäche?

If so, which ones? \_\_\_\_\_

Wenn ja, welche:

Do you have any autoimmune disease (such as scleroderma)?  yes  no

Leiden Sie an einer Autoimmunerkrankung (z. B. Sklerodermie)?

Blood clot (thrombus) / blood vessel occlusion (embolism)?  yes  no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Metabolic diseases?  yes  no

Diabetes (sugar sickness),  Gout.

**Stoffwechsel-Erkrankungen?**  Diabetes (Zuckerkrankheit),  Gicht.

Any other: \_\_\_\_\_

Sonstiges:

Thyroid diseases?  yes  no

Underactive thyroid,  overactive thyroid.

**Schilddrüsenerkrankungen?**  Unterfunktion,  Überfunktion.

Any other: \_\_\_\_\_

Sonstiges:

Communicable (contagious) diseases?  yes  no

Hepatitis,  tuberculosis,  HIV.

**Infektionskrankheiten?**  Hepatitis,  Tuberkulose,  HIV.

Any other: \_\_\_\_\_

Sonstiges:

Any other acute or chronic diseases / illnesses?  yes  no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: \_\_\_\_\_

Bitte kurz beschreiben:

If certain answers are preselected, please correct them if anything has changed.)

## Medical documentation for the informative interview

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:

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- with X-rays     mit with electron beam radiation  
 with proton beam therapy, heavy ion therapy  
 tumour therapy with medication

### Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is **capable of making a decision** on the recommended procedure on his/her own and giving his/her consent for the procedure.

Der/Die Patient/in besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.

- The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. The child is represented by a parent/both **parents** or a legal guardian. These persons are capable of making a decision in the best interest of the patient/the child.

Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsvorsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht bzw. das Kind von seinen **Eltern**/einem Elternteil oder einem Vormund vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten/des Kindes zu treffen.

- Custodian's card     healthcare proxy     advance healthcare directive has been submitted.

Betreuerausweis     Vorsorgevollmacht     Patientenverfügung    liegt vor.

Place, date, time [Ort, Datum, Uhrzeit]

Doctor's signature [Unterschrift der Ärztin/des Arztes]

## Patient's refusal **Ablehnung**

The doctor \_\_\_\_\_ has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me. Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab.

Place, date, time [Ort, Datum, Uhrzeit]

Refusal of the patient / parent(s)\* / legal guardian(s) / witness, if any  
(Ablehnung Patient / Eltern\* / Betreuer / Vormund / ggf. des Kindes / ggf. des Zeugen)

## DECLARATION OF CONSENT

Einwilligungserklärung

Please tick the appropriate boxes and confirm your statement with your signature below:

- I hereby confirm that I have understood all sections of this form.** I have read the entire form (5 pages). During the pre-procedure interview with the doctor \_\_\_\_\_, I received detailed information regarding the course of the scheduled procedure, the risks, complications and side effects associated with it as they apply to my particular case as well as the advantages and disadvantages of any alternative methods.

**Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt wurde ich über den Ablauf der geplanten Maßnahme, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.

- I deliberately refrain from obtaining a more detailed explanation.** However, I hereby confirm that the doctor \_\_\_\_\_ instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks.

**Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.

- I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed.** I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

**Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu.** Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen, sowie auf erforderliche Änderungen oder Erweiterungen des Maßnahme.

I confirm that I am capable of following the instructions given to me by my doctor.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

- I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of the patient / parent(s)\* / legal guardian(s) [Unterschrift Patientin / Patient / Eltern / Betreuer]

Copy/Kopie:

- received/erhalten  
 waived/verzichtet

Signature Copy received/waived  
Kopieerhalt/-verzichtet

\*If only one parent signs, then by so doing this parent declares that he/she has sole rights of custody or is acting with the consent of the other parent.

