

LUMBAR DISCECTOMY

BANDSCHEIBENOPERATION IM LENDENWIRBELSÄULENBEREICH

Information and medical history for patients for preparation of the required pre-procedure interview with the doctor

┌ Clinic / Doctor:

┌ Patient data:

┌ Procedure scheduled to take place on (date):

┌ Affected spinal segment: _____

Dear patient,

you are suffering from low back pain (lumbago) and/or pain radiating into the legs (sciatica). Diagnostic measures undertaken thus far have established a lumbar disc herniation as the root cause. Since treating your symptoms with conservative therapy has proven unsuccessful, your doctor recommends that you undergo lumbar discectomy surgery. Its aim is to alleviate your pain and impaired movement in the area of the lumbar column as well as the pain radiating into your legs.

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 procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

CAUSES OF THE DISEASE

The discs constitute besides vertebral joints and ligaments the connection between two vertebrae and keep the spine flexible. Every human has a total of 23 discs in the cervical, thoracic and lumbar spine. Over the years, particularly the lower discs of the lumbar spine suffer wear and tear since they are the most strained. Every disc consists of an elastic outer fibrous ring and a soft, gel-like centre. If a herniation of the outer fibrous ring occurs as a result of overexertion, part of the nucleus can protrude. This can then result in low back pain. If the protruding part of the nucleus then puts pressure on nearby nerve roots, pain radiating into the legs, sensory disturbances and paralyses will result. If functionally significant paralyses or problems urinating or defecating occur or if non-operative measures have proven mostly unsuccessful, lumbar discectomy is recommended.

If only the disc is affected, without the other parts of a mobile segment being worn down, the option to insert an artificial disc replacement (disc prosthesis) may be available in individual cases, ensuring that the affected spinal segment remains mobile.

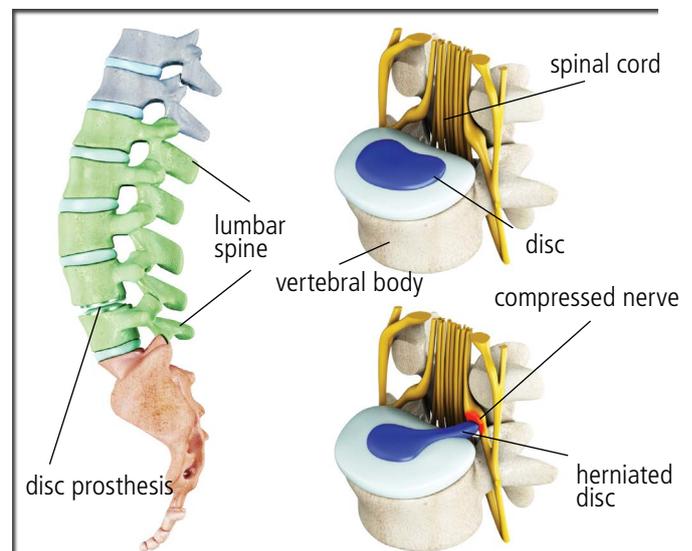
COURSE OF OPERATION

The operation will be carried out under general anaesthesia, regarding which you will be informed separately. As a preventive measure, a peripheral venous cannula will be inserted into your lower arm, through which medication can be administered to you.

Removing the protruding part of the nucleus

During the open surgery planned, the herniated disc will be removed under visual guidance, using a surgical microscope among other things, in order to take the pressure off the nerves. In order to take the strain off the area to be operated on, you will be positioned either on your stomach or on your elbows and knees. The incision of several centimetres in length will be made above the palpable spinous processes. Then, the muscles will be moved

aside until the vertebral canal becomes visible. Sometimes, bone material from the vertebral arch will have to be removed for this purpose. The protruding part of the nucleus can then be removed with small pincers. If disc tissue has become separated from the disc entirely, it will also be removed. Examining hooks will then be used to feel around inside the disc space in order to remove any additional loose tissue.



Disc prosthesis

If a disc prosthesis is to be inserted, the area will be accessed via abdominal incisions or incisions in the flank (ventral access). The vessels, intestinal loops and the ureter located in front of the spine are moved aside to the degree needed in order to be able to gain access to the affected disc. The degenerate disc will be removed and replaced by the prosthesis.

□ Other methods: _____

When the wound is sutured, small plastic tubes (surgical drains) can be inserted to drain fluids or blood from the wound.

POSSIBLE ADDITIONAL MEASURES

If further findings requiring medical intervention are uncovered during lumbar discectomy surgery, such as compression of nerves through bony protrusions for instance, it is often possible to treat them during the same procedure. In order to avoid having to undergo a separate procedure at a later point in time, you can already agree to any necessary changes or additional measures now.

ALTERNATIVE METHODS

In most cases, the symptoms in the lower back and legs can usually be improved through physical therapy, medical gymnastics and ergotherapy. Long-term treatment with analgesic and anti-inflammatory medication can decrease your pain levels.

If, however, your symptoms cannot be alleviated satisfactorily using these conservative treatment methods, surgery is recommendable. Open surgery providing a direct view of the area to be operated on is the standard procedure in that case. Minimally invasive surgery may also be an option in particular cases. During the interview, the doctor will explain to you why open surgery under visual guidance is currently the best treatment method in your case.

PROSPECTS OF SUCCESS

The goal of lumbar discectomy is to take the pressure off the compressed nerve roots and thus alleviate the pain, or even a pain-free state, as well as significant improvement of any paralyses and sensory disturbances in the leg. If the vertebrae have already deteriorated to a large extent, the symptoms can usually only be improved slightly. If the nerve roots do not recover sufficiently, the symptoms may persist or even become worse after surgery.

The herniated disc has led to a weakening of the spine in the affected area. Within six weeks, a solid scar will form within the disc space. This will ensure normal everyday exertion with little impairment of mobility. The goal of disc replacement is to maintain mobility in the affected mobile segment.

Occasionally, severe scarring and adhesions will occur in the surgical area. Disc tissue protruding again in the same spinal segment or a neighbouring segment also occurs in rare cases. If this results in the nerve roots being compressed again, similar symptoms may reoccur (recurring pain). This may then require additional surgery.

Your doctor will explain to you which outcome is most likely in your particular case.

DIRECTIONS FOR PREPARATION AND AFTERCARE

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

Preparation:

Medication: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASA], Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Eliquis®, Lixiana®, Xarelto®, Pradaxa® and metformin-containing antidiabetic medicines, so-called biguanides) or have taken over the course of the past eight days prior to the procedure (for instance pain killers such as ibuprofen, paracetamol). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you should stop taking your medication.

Aftercare:

Post-surgical pain can usually be alleviated with medication.

After surgery, the patient is usually kept in a supine position for 24 hours. On the following day, you will receive instructions regarding medical gymnastics and everyday behaviour appropriate for the spine. Please do your exercises conscientiously as instructed.

With regard to additional measures to be taken by you, such as taking medication or protecting your spine from strain, please follow the instructions of your doctor closely.

Lumbar discectomy surgery requires an extended rehabilitation period. Your doctor will discuss **rehabilitation treatment** after your stay at the clinic with you as it applies to your case.

During the first few days, neurological check-ups will be undertaken. Please inform your doctor immediately should you experience **problems urinating** or **defecating** or recurring **muscle weakness** or **sensory disturbances in the legs**.

Should you experience increasing **severe pain** and **swelling, warmth** and **redness** of the operated area, **a fever, chest pain** or **trouble breathing/circulatory problems**, please inform your doctor or the clinic immediately. These symptoms may appear even days after the procedure and must be examined immediately.

In order to assess the success of the operation, aftercare examinations are needed. Please attend those doctor's appointments conscientiously.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. They may sometimes require additional treatment or surgery and, in extreme cases, they can 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 rare cases, significant **aggravation of paralyses** or **problems urinating and defecating** may occur such as with **paraplegia**. These symptoms will have to be examined immediately and additional surgery may be required.

The surgical procedure can result in inadvertent **injuries of nerves** or the **meninges**. If the **meninges** are injured, a **liquor leak** (liquor fistula) can result. Occasionally, this will then lead to severe **headaches** caused by the loss of brain fluid (liquor). These often disappear through drinking ample fluid, medication and bed rest. A fistula may persist for several weeks and may have to be treated with puncture procedures or additional surgery. In extreme cases, a bruise (**subdural haematoma**), a collection of fluid (**hygroma**) or impairment of cranial nerves may result in the area of the brain. Permanent functional loss, such as **visual or hearing impairment**, is very rare.

Other structures, such as **vertebral joints** or **ligaments**, may be weakened; these symptoms usually disappear without treatment. In front of the spine, **vessels, intestinal loops, ureter** and other organs like **liver** or **lungs** are located, which may be injured in very rare cases. An extension of the surgery may then become necessary. If access to the lower lumbar spine was gained ventrally, male patients may suffer from ejaculation going into the bladder after surgery (retrograde ejaculation). This can have a negative effect on fertility.

A **disc prosthesis can slip** and may then have to be reinserted properly. Scars around the prosthesis can also impair mobility.

Infections of the soft tissues can usually be treated effectively with antibiotics. An **infection** of the **bone** may require surgical treatment. In certain cases, an implanted artificial disc must be removed. In rare cases, a local **stiffness of the spine** may occur. In some cases, **meningitis** may develop as the result of an infection. This may lead to permanent brain damage. An infection that has spread beyond control can lead to **dangerous blood poisoning** (toxaemia).

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 circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralysis or kidney failure requiring dialysis. An allergic reaction to the materials in the implant may occur in rare cases. This causes the implant to loosen, possibly necessitating surgical treatment. Small nerves in the skin can be severed during surgery and lead to temporary or, in rare cases, even **permanent numbness** around the surgical scar.

Should **severe blood loss** occur, the use of donor blood/blood components (**transfusion**) may be required. In very rare cases,

this can lead to transmission of diseases, such as hepatitis (inflammation of the liver), HIV (AIDS), BSE (brain disease) or also of other dangerous – even unknown – diseases. Lung oedema leading to lung failure, a decrease in kidney function or other dangerous immune responses can be triggered.

Damage to the skin, soft tissue or nerves (for instance through injections, disinfectants or positioning during the procedure) may occur. Sensory disturbance, numbness, bleeding and pain may then result. Most of these symptoms are temporary; in very rare cases will they be permanent, or scars may remain.

Especially in cases of prolonged movement impairment, blood clots (**thromboses**) may form, causing obstruction of a blood vessel. Such blood clots may then travel to other parts of the body and block the vessels of other organs (**embolism**). This may then lead to e.g. lung embolism, stroke or kidney failure resulting in permanent damage. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, it may result in severe coagulopathy (HIT), leading to thromboses and obstruction of blood vessels.

In the area where the incision in the skin was made, **proliferation of scar tissue** or discolouration of the skin may occur.

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®, Efiënt®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Angaben zur Medikamenteneinnahme: Werden regelmäßig blutgerinnungshemmende Mittel benötigt oder wurden in der letzten Zeit (bis vor 8 Tagen) solche eingenommen/gespritzt? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efiënt®, 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.)

Have you ever had surgery on the spine? yes no

Wurden Sie schon einmal an der der Wirbelsäule operiert?

Do you have any metal implant (such as artificial hip)? yes no

Haben Sie ein Metallimplantat (z. B. eine künstliche Hüfte)?

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 have or have you ever had any of the following diseases: Liegen oder lagen nachstehende Erkrankungen vor:

Blood diseases / blood clotting disorders? yes no

Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), tendency to bruise (frequent bruising possibly for no particular reason).

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

Do you have any blood relatives with signs of blood disease / clotting disorders? yes no

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

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

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

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:

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

Heart, circulatory or blood vessel diseases? yes no

Heart attack, chest pain and/or tightness (angina pectoris), heart defect, irregular heart rhythm, inflammation of heart muscle, heart valve disease, shortness of breath while climbing stairs, heart surgery (possibly with insertion of an artificial heart valve, pacemaker, defibrillator), high blood pressure, low blood pressure, stroke, varicose veins, inflammation of a vein, thrombosis, embolism.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhythmusstörungen, Herzmuskelentzündung, Herzklappenerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Thrombose, Embolie.

Any other: _____
Sonstiges:

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:

Predisposition to impaired wound healing, abscesses, fistulas, excessive scar formation (keloids)? yes no

Neigung zu Wundheilungsstörungen, Abszessen, Fisteln, starker Narben-Bildung (Keloide)?

Any other acute or chronic diseases / illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____
Bitte kurz beschreiben:



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:

Affected spinal segment: _____

- Removing the protruding part of the nucleus
- Disc prosthesis
- Other methods: _____

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. These persons are capable of making a decision in the best interest of the patient.
Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten 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 patient / legal guardian / witness if applicable
[Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]

DECLARATION OF CONSENT

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 / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer]

Copy/kopie:

- received/erhalten
 waived/verzichtet

Signature Copy received/waived
Kopierhalt-/verzichtet