

Patient Information- Informed Consent

Artificial Disc Replacement Lumbar Activ-L or STALIF

Dear Patient,

The information of the patient is an essential part of the physician's consultation and treatment. The law requires the physician to demonstrate evidence of patient-information.

The patient is also required to participate Actively.

We are going to repeat the main points of your consultation in written form and ask some further questions.

Please read over this information- brochure carefully. If questions remain or if you have comments regarding it, please discuss them with your physician. By signing this document, you declare your consent and express that you have been given precise information about the planned medical treatment and the method to be used.

Considering a need for peace of mind before surgery, you may decide to disregard any further information but in spite of, you have to fill out the date of today's day and write your full signature on every page.

A guarantee of success can not be given

Every medical treatment aims has the goal improve, relieve or cure an illness or impairment.

In spite of constant research and progress in the science of medicine, a guarantee, related to the prospective results, cannot be given. The human organism is not a machine, each person reacts differently to medication, anaesthesia and to surgical treatment. The same procedure does not necessarily lead to the same result in every individual patient.

Furthermore, also the worsening of a condition is possible, in spite of extended care and professionalism. However, failures are considered exceptions, as a rule the planned surgical prospective will be achieved.

Risks and dangers

Even the smallest medical procedure bears risks. In extreme cases the procedure can, in spite of extended care, lead to complications and incidents.

Human existence is not to imagine without risks and dangers, take for instance diseases, alcohol, nicotine, sport-injuries and other conceivable threats. It is not possible to show you every medical risks that could appear, therefore we refer to the most common risks and complications related to the treatment:

Anaesthesia (local, regional, general) and drug-administration:

Possible risks:

allergic reactions; cardiovascular-respiratory-complications; heart-failure

Complications related to a surgical procedure:

General possible risks:

haemorrhage; thrombosis; embolism; damage of soft-tissue or bone fracture; damage of vessels and nerves or of the protection-layer (dura) with the corresponding function failure. Bleeding, lymph leakage etc etc see detailed list in this document further on

Complications during post-operative-period:

General possible risks:

haemorrhage; hematoma; lamfatoma, subsidence, subluxation protracted wound healing; infection; pain; worsening of the pre-operative-condition; loss of sensation; hypersensitivity etc etc see detailed list in this document further on

Statement of the Patient after the informative conversation

Planned medical treatment Artificial Disc Replacement Aesculap Activ L Lumbar spine

-I hereby declare having been informed well understandable, during a personal consultation and by the information provided in this form, about:

- the method, purpose and course of the planned medical treatment/surgery
- advantages/disadvantages in comparison to different treatment-methods
- the possible disadvantages of not treating the illness

0 *(please mark!)*

I had the opportunity to ask the for me important questions. The information was well understood. I was not put under pressure, was clear minded and my dependent position to the present day surgeons is not abused to let me sign this information form.

0 *(please mark!)*

to my knowledge, I have not left out any information about my health-condition

0 *(please mark!)*

I have no further questions

1. wait and see, be conservative, is no option for the patient
2. Endoscopic surgery, abrasion or classic hernia surgery will fail: no indication
3. Fusion is an option but not very attrActiv, because of adjacent segment disease
5. Questionable is the risk remnant symptoms because of unknown pathology
6. Questionable is the risk remnant symptoms because of behavior of facets (no contra-indication)
7. Discography should be discussed during visitation before surgery
8. No indication for stenosis surgery: there is no real spinal stenosis syndrome
9. Activ L Artificial disc replacement seems best and acceptable alternative of all surgeries
10. Subsidence always is a risk but not when bone quality is in between limits (DEXA scan)
11. No guarantee possible (never); questionable relation between lother diseases and lumbar disc
12. infection + thrombosis prevention by medication
13. complications-form should read over and signed before date of surgery
14. Alternatives, all risks, succes will be discussed between you and docter at date before surgery
15. risk of blood transfusion, but cell saver will be available as necessary, hematoma always possible
16. intraoperative EMG monitoring, but remnant legpain could be possible
17. Surgeon has freedom of technique
18. Patient knows that Artificial Disc Replacement techniques are a new area
19. The Activ L implant is an improved evolution of former artificial discs, Activ L available since 2004
20. The advantages of the Activ L Artificial Disc Implant will be explained during consultation
21. Everything above will be extensively discussed at the date before surgery
22. Patient is completely responsible herself for making decision to have ADR surgery done
23. Patient is aware of the possibility of remnant back pain or other complaints. Patient will never call the present-day surgeons to account about problems in the future which could be a reason for a second intervention, in spite of her consciousness that she is in a dependent position to her present day surgeons.
24. Patient is aware of the possibility of postoperative impairments, she declares hereby not to account the present day surgeons for her impairments in the future

Declaration of consent

Date:

Signature:

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I hereby agree and wish to receive the following treatment:

Artificial Disc Replacement (Activ L) or Cage fusion if necessary

In general anaesthesia.

I give my consent for eventual additional measures or changes in the planned treatment, if judged as being necessary or advisable during the performance of the treatment itself.

I understand that a guarantee related to the prospective results cannot be given.

Special remarks:

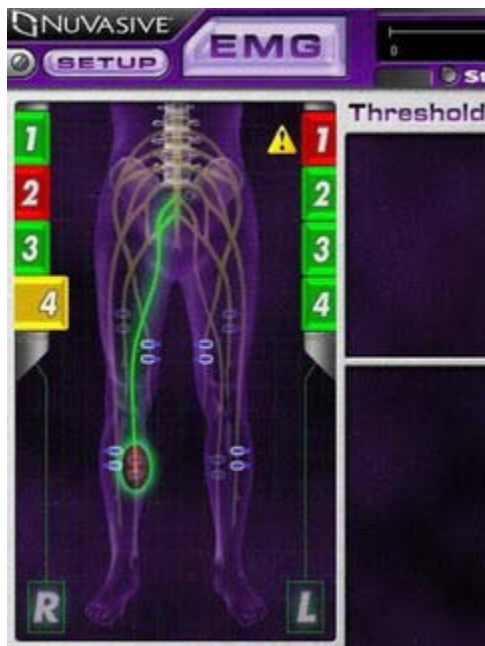
Date

Signature of the patient / legal guardian

FAQ on complications of anterior lumbar disc replacement (ADR) and anterior lumbar fusion**1. Backpain or legpain is still there****risk: small (10-15%) soluble: yes**

This is the most feared complication. The lumbar spine has five lumbar segments and where is the pain coming from? Therefore an accurate intake with questionnaires, x-rays, MRI, muscle testing and discography is so important and decisive. With an exact diagnosis and meticulous implantation technique, the risk of enduring complaints is low, mostly depending on the condition and age of the spine. During the anterior removal of the bad disc, most dorsal impediments near the spinal canal will also be removed to give room to the underlying nerve roots. If there is too much distraction of the spinal segment after implantation, or in case of remnant disc material in the neighbourhood of the nerve root, legpain could continue. Mostly temporary. In that case the normal movement of an artificial disc could be a disadvantage. Also an irritated nerve root can remain irritated.

During Artificial Disc Replacement surgery doctor Zeegers is using a new safety system in the operating room. The so called EMG NeuroVision allows monitoring of the activity spinal nerves during spine surgery, in real time and throughout the entire operation. When introducing the artificial disc implant an alarm tone rings if the implant is too close to one of the nerve roots. The position of the artificial disc implant easily (because doctor Zeegers is not using keel-shaped implants) can be adjusted until monitor shows that the surgeon is in the limits of the safe area. NeuroVision is the latest technology offered in spine surgery.



NeuroVision increases the safety of spinal procedures and shortens the duration of surgery. The monitoring limits the frequency of X-ray control. It is absolutely pain free and bears no risk for the patient. NeuroVision increases the safety of spinal procedures and shortens the duration of surgery. The monitoring limits the frequency of X-ray control. It is absolutely pain free and bears no risk for the patient. The new method of consecutive nerve-monitoring throughout the duration of a spine-surgery is based on the principals of electromyography: The nerves of our spine branch downwards into their specific muscles which they affect and control via electric impulses. This – very humble – bodily electricity can be measured via electrodes attached to the muscles by very sensitive and precise instruments. The NeuroVision-system satisfies this high demand. The measurements are induced into a high-performance processor that converts the information on to a monitor - in real-time and throughout the entire surgery. The monitoring perfectly supplements the X-ray control, by providing additional information to the surgeon that was formerly not available. The system is programmed to inform the surgeon prior to any risk of

nerve-instrument contact. The surgeons who work with the NeuroVision, appreciate the additional safety feature: it makes their job a little easier and the surgery even safer than before.

2. Thrombosis**risk: very small (0,5%) prevention: anticoagulant drug soluble: partially yes**

Thrombosis in the pelvis or in the lower legs is caused by abnormal blood clotting in the vessels of lower abdomen and legs during or direct after surgery. Before and after the operation anti-thrombotic medications are given which makes the risk of thrombosis very low. The risk of such a blood clot is low and mostly of genetic origin. Females who are **smoking** and taking **anticonceptive treatment** are at a slight higher risk. Stopping the anticonceptive drug some weeks before the surgery could be preventive. If such a clot happens, it can be well handled by blood thinners in the next months, but it is not predictable if there will be a 100% re-canalisation of the thrombotic vessel in the long term. We never encountered a lung embolism after artificial disc replacement. Consequently stop anticonceptives 6 weeks before surgery.

3. Irritation of the nerves

risk: low, soluble: yes

Sometimes there is a temporary numbness of the thigh, that will be restored within one year. Some patients feel a more warmed up left leg after surgery. This is the so-called sympathetomy-effect because of temporary disturbance of the sympathetic nerve chain on the left side from the repaired spine-segment. It is not unpleasant and most women quite like this effect, but it will not last longer than 9-12 months. See also paragraph 1.

4. Facet joint deformation

risk: low, soluble: yes

Deformation of the facet joint is depending on the quality of the lumbar spinal segment, the implantation technique, the model and size of the implant. In general there is some unloading of the facet joints after exact positioned artificial disc prosthesis, but overloading is also possible. Despite many biomechanical statements in practice those facet joints have a good adaptation and are not a cause of pain after implantation. Sometimes the facets protest, but it never has been proved that the implant has to be held responsible for this so-called facet joint disease. If the facet joints are suspected for persistent or recurrent pain in facet joints, a SPECT bone scintigraphy is indicated. Rarely in case of symptomatic facet joint arthritis a fusion of the facets or any other dorsal fusion is needed.

5. Subsidence of the implant: some migration into the vertebral body

risk: female >40 (5 %), male (1%) soluble: yes

Until now the nearly anatomical shape of the modern **Activ L** artificial disc implant (if well positioned) never showed subsidence in doctor Zeegers' practice. However, a poor or moderate bone quality of the vertebral bodies could lead to some subsidence into the endplates of the spinal segment. Therefore the biggest possible size of implant will be chosen for implantation. A bigger size can lean better on the all-around bony rim to prevent subsidence. It is not always possible to implant the most suitable size because of difficulties in the bypassing of the soft tissues and vessels. Then we have to make a compromise. A moderate subsidence doesn't give extra complaints. If there is any suspicion of painful subsidence, nowadays a so-called vertebroplasty could be an effective treatment: percutaneous injection of Cortess® paste and/or bone cement in the vertebral body where the subsidence is located. This procedure can be done in local or general anesthesia and has almost no risks. After that injection, in general the pain is gone and the position of the metal endplate is stable again. Seldom, if the subsidence has not been repaired, it can be solved by re-implantation or dorsal pedicle screw fusion of that lumbar segment. Mild subsidence in the long term happens mostly without any complaints or complications. Injection procedure almost never needed.

6. Short time of life expectation

risk: very low soluble: yes

The function of an artificial disc implant is related to the correct position and loading inside the mobile lumbar segment. Although the human implantation experience is not longer than the period since 1984, the implants seem to have a longer life than the patient himself. The metal plates are indestructible, the wear of the plastic core is minimal if well centered. Only in undersized and eccentric implantations, the wear and tear in the core can be at risk in the long run. Occasionally polyethylene abrasion at the rim of the Charité core has been reported. That is one of the reasons doctor Zeegers is using since 2004 the newest generation **Activ L** artificial disc: the core is not at risk at all. In case of subsidence, generally the implant will subside very slowly and will be encapsulated without pain, imitating an easy-going progressive fusion. Revisions of artificial disc implants are rare, but if so it can be very demanding if the implant has a big keel inside the vertebral body. The **Activ L** implant has no keel. Doctor Zeegers will never implant an artificial disk with a big keel, to prevent unnecessary serious problems in case of a revision.

7. Retrograde Ejaculation

risk: very small (0,2%) prevention: skilled surgeon soluble: mostly temporary, rarely persistent

Only at the L5/S1 level there is a minor risk of ejaculation failure after anterior spine surgery. Heavy overweighted people (also people with vascular diseases and heavy smokers) are more at risk. Forceful compression of the overlying sympathetic nerve web (during pushing away the peritoneal sac) can disturb those tiny nerves. The internal functional balance of a small prostate muscle can be disturbed. This causes dry retrograde ejaculation: during the sexual climax the sperm will be ejected into the bladder instead of ejaculated out of the penis. Erection and climax remain always okay. Depending on the skills of the surgeon

and the age of the patient this risk at L5/S1 is 0,1- 0,4% . In the more upper levels the risk is neglectable. If there is a wish for children in the future, deposit a sperm monster in a spermbank to be quite on the safe side. The approach for a lumbar artificial disc is the same as for a stand alone fusion cage. (STALIF)

8. Possible disturbance of the intestines

risk: very small (1%) soluble: yes

The surgery is done via the lower abdomen. The intestines are pushed away to the right and down. Only the hand pressure on those intestines can “shock” them by lowering their contractility in performing digestion. This burdens the intestines only temporary. To prevent overloading of the intestines during surgery, a nasal-gastric tube is draining the stomach. This tube will be removed before wake up. Most of the time the duration operation of the surgery is short enough to prevent a shock effect and does not give this complication. Directly after the operation one does not receive anything to eat. No extra bed rest, early mobilisation will wake up the intestines. If the intestinal noises in the abdomen are audible again, or air is produced out of the anus, that are the symptoms that the intestines have begun to work normally, and one can receive something light to eat. Most of the time one can eat almost normally the second day. Rarely the intestines stay in shock for a number of days. Mostly when opiate medication has been taken before surgery. If ignored the abdomen can become swollen because of limited passage of fluids and food. The solution of this problem is resuming drainage by a temporary nasal-gastric tube and nothing to eat. This complication is rare and always solvable.

9. Extra loss of blood

risk: small (10 %) soluble: yes

Vascular damage is extremely rare. A real dangerous vascular injury has not been encountered since 1990. The main abdominal veins and arteries are carefully held to the side with a retractor. Rarely over distraction can lead to an injury of little vascular side-branches, extremely seldom but mostly at the wall of the iliac vein. Such an extra loss of blood stops immediately after repair of the leak. A vascular surgeon is always standby to deal with the problem, although this complication happens very seldom. Mostly the extra loss of blood is due to a perspiration of blood during preparing the endplates and dorsal side of the disk space. That’s very individual, depending from patients’ physical and spinal condition. Sometimes diffuse bleeding from the epidural space is inevitable. During surgery with a so called cell-saver standby your loss of blood is collected, filtered and re-infused. Since using the self saver, there is almost no need for blood-transfusions anymore. Nevertheless two packed cells of blood units are in the background for safety reasons. Sometimes this sweating of blood out of the bone persists for a while after the surgery. Therefore there is a drainage tube out of the deep wound to collect superfluous blood for one day after surgery. Rarely leakage continues and is lowering the blood pressure. If necessary you will be transferred to the intensive care of a neighbouring university hospital to have an optimal monitoring of the extra loss of blood. Such a transfer happened very very seldom (1 time only since 1998) and will only indicated after consultation with the vascular surgeon. The complication of extra loss of blood is always solvable and we never experienced a permanent damage. Very rare the anticoagulant drug medication (Low dose Heparin) will be stopped to prevent persistent haemorrhage. Until now re-intervention was not necessary. The blood clot (hematoma) fades away in the next 6-12 weeks. Three times we had a lymphatoma after small injuries of lymph vessels. Also solvable.

10. Damage to the ureters (urine tubes)

risk: almost nihil (0% since 1989) soluble: yes

Theoretically damage to the ureters is possible, but this complication has not been seen since our experience with our anterior spine surgeries from 1980 on. This has nothing to do with the implant, just the approach.

11. Infection

risk: almost nihil (0% since 1989) soluble: yes

Results from the past are not a guarantee for the future, but since our start in 1989 we didn’t encounter any infection at all: zero. One can get a deep infection, despite all the antibiotics given, proper sterilization, etc. In case of a deep infection, revision of the surgery will not be absolutely necessary, but cleaning of a deep wound abscess is mandatory. Maybe removal of the prosthesis, replacing it with a bone transplant from the pelvic rim could be the best solution, but until now we never encountered such a complication. Up to the present: there have been no infections at all. For patients with spinal implants, after the spinal surgery, we recommend antibiotic prophylactic treatment for dental work if there is a possibility of soft tissue bleeding.

12. Rejection of the implant**risk: nihil (0% since 1989) soluble: yes**

Rejection of the implant was never encountered since 1984. The endplates of the artificial disk are made of a chrome cobalt alloy and never has given rise to any allergy. The core is made of the same polyethylen material as in hip and knee implants. Cages are made of peek-carbon fibre or stainless steel and neither cause allergic reactions or rejection.

13. Wound healing**risk: very low soluble: yes**

An incision is made in the lower abdomen horizontal or vertical from about 7-25 cm depending on body shape and level of surgery. Overweight body shape needs longer and bigger incisions. Dissolvable subcutaneous suturing makes removal of stitches unnecessary. Horizontal incisions could give rise to some folding of the abdominal skin, therefore most women with a nice flat belly choose for a longitudinal incision. Disturbances of abdominal wound healing are rare, mostly depending on the condition of your abdominal wall, and always solvable.

14. Dislocation of the implant: migration to anterior or posterior**risk: almost nihil (0% since 1997) soluble: yes**

In the **Activ L** artificial disc implant we never experienced any dislocation or other hardware problem. Although we encountered some anterior (forward, ventral) sliding of the artificial disk in the past, with the new rough surface of the endplates and better implantation technique there hasn't been a displacement anymore. A dorsal (backwards, posterior) migration has never been encountered, so there is no danger for the spinal canal. To keep the risk as low as possible we advise to keep rather calm in the first six weeks after surgery, but walking, climbing stairs, driving etc. are allowed shortly after the surgery. If the X rays are all right at six weeks postoperative, there are no restrictions anymore, because afterwards there has never been any slippage of the implant. The artificial disc is anchored by its teeth and the enormous inter segmental pressure of the spinal column. The implant is a three part implant, but we never encountered coming the endplates and core apart. All implants have special rounded edges and are used to keep on track with the normal alignment of the lumbar spine. The prosthesis normally will stay in place for ever, even in a case of a traffic accident. There is absolutely no need for extra fixation, cement, screw or glue. We never experienced shifting of a cage implant. In the **Activ L** artificial disc implant we also never experienced any dislocation or other hardware problem.

15. Worn disc prosthesis**risk: metal metaal: 0%, core: almost nothing (until now 0% with the **Activ L** implant)****prevention: right implant choice + skilled surgeon (nice positioning of the prosthesis)****solvable: yes**

In the lower back doctor Zeegers nowadays uses the **Activ L** disc prosthesis, because of superior quality of the implant. The current generation disc prosthesis still contains two metal support plates with a plasmapore coating for optimal stability. In between the plates there is a mobile, protected, high quality polyethylen core. The current design of the new generation **Activ L** disc-prosthesis guarantees optimal protection of the polyethylene core. The more or less anatomical shape of the **Activ L** implant assures a symmetrical positioning in the lumbar spine. This guarantees that the plastic core is not overloaded. The constant pressure between the vertebrae reassures that the prosthesis remains stable. The shape of the prosthesis and the bioactive rough surface of the metal plates guarantee extra primary fixation. All these facts minimise abrasion or even worn out of the polyethylen core.

16. Bone transplantation**risk: almost neglectable: 0%****Prevention: small incision of iliac crest, 2 cm distance from the anterior crest part****Solvable: yes, some possible remnant iliac crest pain fades out in 6 weeks**

The bone transplant is the key to the healing of the fusion in and around the stand-alone cage (**STALIF**)