

**Steven F. Harwin, MD, FACS: Informed Consent for Treatment and Surgery - Risks and Complications**

<b>Arthroscopic Surgery</b>	<b>Right</b>	<b>Left</b>	<b>Knee</b>	<b>( ) with ACL Reconstruction</b>
<b>Arthroscopic Surgery</b>	<b>Right</b>	<b>Left</b>	<b>Shoulder</b>	<b>( ) with Rotator Cuff Repair and/or Labral Repair</b>
<b>Primary Revision</b>	<b>Right</b>	<b>Left</b>	<b>Total Hip Replacement</b>	<b>Total Knee Replacement</b>
<b>Other or Additional Procedures:</b>				

The treatment of disorders of the hip, knee and shoulder (including the related bones, joints, muscles, nerves and other structures) carries with it a degree of risk that you, your family, parent or guardian should be aware of before you sign below. ***The following risks and complications are very rare!*** But despite our best efforts to eliminate their occurrence, they can happen. In order to achieve the best possible outcome and to minimize these complications, I urge you read this completely and to follow my recommendations, including the prescribed pre- and post-operative instructions and physical therapy. The following list is a description of some, but not necessarily all, of the possible complications of surgery and their effect on your outcome.

1. Allergic and other troublesome reactions and side effects to drugs and blood administration can occur.
2. These side effects and reactions to drugs, blood and other substances can develop in anyone. While usually minor and transient, they can be more serious, occasionally permanent, and rarely, even fatal. All medicines and substances prescribed for you are given only if the anticipated benefits are felt to outweigh the risks associated with taking them.
3. Disorders of the kidneys, urinary tract and bladder, leading to disturbed function or abnormal urination and/or infection can occur.
4. Disorders of the digestive system, including stomach and intestinal ulcers with bleeding, distention, obstruction and perforation, liver infections and inflammation (hepatitis), and stones in various organs and systems such as the gall bladder have also been observed as well as flair up of gout and prostate problems.
5. Disturbances of the heart, including abnormal beat and function can occur, as well as heart attack, with serious and rarely, even fatal consequences.
6. Pneumonia (infection of the lung), collapse of all or part of the lung, with pulmonary edema (fluid in the lungs) may occur and can have serious and rarely, even fatal consequences.
7. Changes in mental function, confusion and even a stroke can occur. Mental changes and confusion usually improves, clearing completely after some time, but if a stroke occurs it is likely to have some permanent effects.
8. Nerve and blood vessel damage may result as a consequence of mobilization of joint structures, or operating near a nerve or blood vessel itself. Nerves may be stretched, compressed, damaged or even cut in the process, which may result in weakness or paralysis. This is more of a risk when contractures, deformities and shortening of the limb are present. The damage may be transient with return of some or all function, but it could be long lasting or permanent. Paralysis may involve partial or complete loss of sensation, muscular function and movement of the part of the body that is involved. Numbness, tingling, burning and pain may occur. The recovery process may be prolonged depending on the extent of damage and the nerve involved.
9. Wound, joint and bone infection with poor and delayed wound healing may occur. Re-operation may be needed to clean the bone and joint. If a joint replacement was performed, the prosthesis may need to be removed for an extended period of time or even permanently, to allow the infection to heal. In most cases, after an infection is successfully treated with antibiotics and surgery, a prosthesis can then be re-implanted. This can result in a stiff and painful joint. If massive infection occurs and it cannot be treated successfully, in very rare circumstances even amputation may result.
10. Blood clots in an artery may cause a block in circulation. In the very rare circumstance that the blood vessel supplies the bulk of blood supply to the extremity and it cannot be repaired, gangrene or amputation may result. Blood clots in the vein may cause pain and swelling and they may travel to the lungs or brain causing chest pain, shortness of breath, stroke and rarely death. Medication recommended for you during and after your hospitalization will help to minimize this complication. Failure to follow the prescribed medication and therapy protocol after surgery will put you at greater risk.
11. After total knee replacement, you must perform exercises and have physical therapy to regain a normal range of motion within 6 weeks. If not, the joint may require manipulation. This requires another anesthetic and hospitalization. Rarely, this can result in tearing of muscles and tendons and even fracture.

12. Over time, any implant can loosen, break, dislocate, wear out or generate debris that damages the bone. This may result in the need for further surgery or revision. Noises such as clicks and squeaks in the new joint may occur. In some cases, an undesirable change in the length of the operated leg may occur, with either shortening or lengthening. While all efforts are made to achieve optimal outcomes, there can be no assurance that all pre-operative symptoms will be relieved and all pre-operative expectations will be achieved.
13. Complications related to anesthesia can occur. If you have questions regarding your anesthesia, you may ask them when you meet our Anesthesiologist at the time of your surgery.

As described above, most complications have only temporary consequences and will not affect the ultimate outcome of the operation. However, to a greater or lesser extent, they tend to complicate, prolong and/or lead to the need for additional treatment and may require consultation or treatment by other specialists. Complications often increase the length and cost of hospitalization and convalescence. A minor complication may cause nothing more than some additional discomfort and inconvenience, but may increase the period of disability and recovery. A major complication, however, may be much more serious and rarely, even devastating, leading to significant distress for you and your family. It may require the need for intensive care and/or additional surgery and cause a major prolongation of hospitalization and disability, and increased expense. Rarely, it could cause abandoning the original treatment plan or operation, and have an adverse effect on the outcome of the procedure, causing permanent physical damage and impairment. Our surgical, anesthesia and nursing staffs are all aware of these possible complications and are trained to monitor your condition, recognize early signs of trouble, and treat complications when they arise, to try to minimize the consequences to you.

I use a team approach in the surgical treatment of hip, knee and shoulder disorders. My team includes physicians, nurses, operating room technicians, physician assistants, anesthesiologists, physical therapists, social workers and other specialists who are trained to provide orthopaedic care. We have worked together on a regular basis for many years. It has been demonstrated that the quality of the outcome is directly related to the experience and volume of procedures performed by the surgeon. I perform a high volume of joint replacement, arthroscopic and reconstructive procedures every year. While I perform the operation for you myself, I do have a team of surgical assistants in the operating room with me, who each have a specific task to perform during each type of procedure. I alone perform the most important parts of each operation. My personally trained assistants, who have operated with me for many years, perform some of the less important parts of the procedure. We have no interns, residents or fellows.

Since I am a designer of Total Hip and Total Knee Prostheses, orthopaedic instruments, and the author of many surgical technique manuals and videos, I often have visiting surgeons or observers in the operating room who are there to watch and learn my surgical techniques. They do this by either observing from afar, watching video, or by being scrubbed in the sterile operative field. They only observe, and do not participate in the surgery. Representatives of the company making the implants I use are often present in the operating room, not scrubbed, in order to make sure we have proper inventory. As a designer and inventor of implants, I do have a financial relationship with the manufacturer of some of the devices I use. However, by law, I have no financial benefit or incentive from any implant that I personally use.

**If you have any questions regarding the benefits, risks, alternatives and possible complications of your operation...or any questions about any of the above subjects, please ask and discuss it with me so that you will be satisfactorily informed before giving your consent to the planned procedure.**

*(2-09)*

**By signing below, I acknowledge that I have read this document completely and fully understand it. I am aware that I am entitled to ask questions regarding any aspect of this document and my medical care. After the benefits, risks and alternatives of various treatment options were discussed, I have decided to proceed with surgery. I also acknowledge that I have been given my pre-operative instruction packet for the operation indicated above and I understand that I must follow all post operative instructions in order to be best prepared for surgery and to obtain the most successful outcome possible.**

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**Signature of Patient, Parent or Legal Guardian**

**Witness** \_\_\_\_\_

**Date** \_\_\_\_\_