

MOUNTAIN VIEW REHABILITATION MEDICAL ASSOCIATES

AUTHORIZATION FOR PROCEDURE

Autologous Re-implantation of Bone Marrow Nucleated Cells into a Joint
(Also known as "The Regenexx-SD Procedure")

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used, so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent for this procedure.

I voluntarily request Joel D. Richnak M.D. as my physician, and such associated technical assistants and other health care providers as he/she may deem necessary, to treat my condition, which has been explained to my satisfaction in layman's terms.

Diagnosis: You have a condition known as arthritis or degenerative joint disease. This means that the cartilage and/or other structures in your joints are breaking down, leading to pain and loss of function of the joint.

Explanation of Procedure: I understand that the following procedure is planned for me, and I voluntarily consent and authorize these procedures(s) (lay terms): Re-injection of own bone marrow nucleated cells (a mixture of cells from my bone marrow that contains my stem cells and other cells) into my joint or other structure such as meniscus, labrum, or ligament. The procedure may include a pre-injection and 1-2 follow up injections into joint. The pre-injection into this joint will occur several days before the bone marrow procedure. This will involve the injection of a substance to cause a brief inflammatory response and/or my concentrated blood platelets. This will be followed by a bone marrow aspiration procedure (separate consent form), an intravenous blood draw from my arm, and a re-injection of concentrated cells from my bone marrow into the joint. This reinjection will also include concentrated blood platelets and the use of two prescription drugs used off-label. Off-label means these medications are not being used for their FDA approved indications. Finally, several days after the bone marrow/fat procedure, I may receive an injection of my concentrated blood platelets and the same prescription drugs.

I understand that my physician may discover other different conditions which may require additional or different procedures than those planned. I authorize my physician, and said such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

No Guarantee and Research Disclosure: I understand that no warranty or guarantee has been made to me as to the result of this procedure or anticipated care. I understand that my results may be used in a published research study without my name being identified or without additional prior consent. In addition, I understand that I will be tracked by a treatment registry run by the medical clinic where I am receiving care. This will include someone contacting me via e-mail or phone, my filling out questionnaires, answering questions, etc... at certain times and that this is planned to continue indefinitely or until I elect out of the registry in writing.

Possible Side Effects of Procedure: Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical and/or diagnostic procedures planned for me. I realize that general risks of all procedures of this type (injections into joints) are infection, blood clots in veins and lung, hemorrhage, allergic reaction, or even death. I also realize the following hazards may occur depending on this particular procedure: 1. Local pain 2. Bruising/bleeding 3. Infection 4. Cellulitis at an IV site. 5. Allergic drug reaction 6. Numbness 7. Increased pain 8. Paralysis 9. Injury to the bone, muscle or nerve 10. Drop in blood pressure 11. Loss of consciousness 11. Abnormal heartbeat 12. Vaso-vagal reaction with vomiting and possible aspiration 12. Increased cancer risk 13. Kidney failure (this has only been observed when injecting high volumes of marrow intravenously) 14. Structural failure at the treatment site 15. Bony fracture related to instability 16. Bone infection. The above risks and complications are not the only possible side effects.

Possible Side Effects of Anesthesia (if any): I understand that I can elect to have anesthesia and that it involves additional risks and hazards. Anesthesia means that I will be given a vein injection of medication or a numbing injection or both. I realize the anesthesia may have to be changed, possibly without explanation to me, depending on my pain tolerance, body weight, and sensitivity to medications. I understand that certain complications may result from the use of any anesthetic, and that these range from minor discomfort to injury to vocal cords, teeth or eyes. If IV anesthesia is needed, one rare complication could be loss of ability to breathe on my own for which I would need medical assistance to breathe until the medications wear off. In all instances, general anesthesia carries the very rare risk of death. I understand that other risks and hazards resulting from spinal or epidural anesthetics include headache and chronic pain. If IV anesthesia is not used, which is most common for spinal procedure, then a local anesthetic will be used to numb tissues. Possible side effects could include nerve or blood vessel injury from the numbing injection, allergic reaction to the anesthetic, bruising, swelling, or deformity.

Investigational Procedure Acknowledgement: This medical procedure is still considered experimental. This means it is not yet standard of care in the medical community. While your doctor may believe it can help you, there are no large research studies that show it is effective. This means that it may do nothing to relieve your pain, cure your condition, or otherwise repair your tissues.

Treatment Alternatives: These include: total or partial joint replacement with an artificial joint, arthroscopic surgery to “clean up” the joint in an attempt to repair or remove damaged tissue, medications, physical therapy, or alternative medicine remedies.

Risks of Not Receiving Treatment: Since degenerative joint disease (arthritis) is a progressive condition, it’s more likely than not that your joint(s) will continue to degenerate. This is most frequently associated with more pain and loss of function. However, nobody can easily predict how fast that will happen. It’s also possible that your condition could stay the same as it is now.

Treatment Complications: Just like any other medical procedure, the treatment of complications will be your responsibility. This may mean that if you have a serious complication or side effect and have

health insurance, you could incur additional co-pays, deductibles, and co-insurances. If you have no insurance, the treatment of complications could mean incurring significant out of pocket expenses.

Insurance Coverage for this Procedure: By signing this form, you understand that there is no insurance coverage for this procedure. This means that all costs for this procedure that you have been quoted by our office will not be reimbursed at a later date by a health insurer.

To the Physician: I attest that I have explained the risks, benefits and alternatives of this procedure to this patient/representative.

Physician Signature _____ Date _____

To the patient: I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedure(s) to be used, risks and hazards involved, and other disclosures and information contained in this form. I have sufficient information to give this informed consent. My physician has answered my questions to my satisfaction.

Patient Name _____

Patient or Guardian Signature _____ Date _____

Witness _____ Relationship _____ Date _____
(if applicable)