Informed Consent for Placental Derived Allograft

Patient Name: _____ Date: _____

Area(s) to be treated: _____

The purpose of this consent is to inform you about Placental Derived Allograft referred to as a structural extracellular matrix derived from placental connective tissue and the potential side effects or risks. It is important that you read this information carefully and completely. If any part of this content is not clear, please ask for clarification before signing this document.

A Placental Derived Allograft is a minimally manipulated acellular, highly hydrophilic, structural extracellular matrix derived from placental connective tissue intended for homologous use to supplement tissue. The allograft is sterilized and pre- packaged in a syringe ready for use in one patient on a single occasion. It is a natural product that contains growth factors including cytokines, peptides, hyaluronic acid and other powerful anti-inflammatory and healing properties. placental derived allograft allograft is intended for use during soft tissue and local inflammation of any joint or spinal condition.

All policies and procedures for donor screening, serologic and microbiologic testing meet current regulations established by the FDA and other State and local governing bodies**.** Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on specimens in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493. placental derived allograft allograft is registered with the FDA.

Benefits: No downtime, very little discomfort, minimal preparation and restrictions, suitable for most soft tissue injuries and joints. You may receive relief of pain and swelling immediately following the implantation. Achieving optimal change and improvements may require more than one procedure. The number of procedures and the frequency of the procedures will depend on the medical judgement of your physician.

Risks: There have been no reported adverse reactions associated with placental derived allograft allograft, however general risks and complications of implantations may include, but are not limited to infection, bleeding, injury to nerves, etc. Any adverse reactions that may be related to the use of placental derived allograft allograft should be reported immediately to your physician.

Complications: No complications have been reported with placental derived allograft allograft implantations.

Importance of Client Follow-Up: Client follow-up, both before and after a procedure is imperative. Instructions must be followed in order to avoid possible complications and to ensure optimal results. Please review and clarify regimens with your doctor before signing this document.

Unsatisfactory results: Satisfactory results from this procedure are not guaranteed nor implied. Each individual is different, with different outcomes and levels of success.

Additional procedures: Additional treatments may be required to reach an optimal level of result. Please discuss with your physician for more details.

ADDITIONAL TREATMENTS NECESSARY: There are many variable conditions that influence the long-term result of any regimen. Even though risks and complications occur rarely, the risks cited are potentially associated with these regimens. Though desired results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

I recognize that during the course of treatment, unforeseen conditions may necessitate additional procedures(s). I authorize _____ and their representatives to perform such other procedures that are, in the exercise of their professional judgment, necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatments and are not known at the time the regimen has commenced. I understand that success of the procedure varies with each individual and the type of condition they are experiencing. I voluntarily request **placental derived allograft implantation** by the physician. This procedure has been explained to me, and my questions regarding such procedure, its alternative(s), its complications, and its risks have been answered. The information that I have been given has been in terms clear to me, and I understand the risks and complications. My questions have been fully and completely answered for me, and I have read this document and understand its contents. I hereby give my full and unrestricted informed consent for the procedure. **I acknowledge that no guarantee has been given by anyone as to the results that may be obtained**.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT AND FEEL THAT YOU UNDERSTAND IT. DO NOT SIGN THIS FORM IF YOU HAVE TAKEN MEDICATIONS THAT MAY HAVE IMPAIRED YOUR MENTAL ABILITIES OR IF YOU FEEL RUSHED OR UNDER PRESSURE.

Client Name or Person Authorized to Sign for Client under 18 Years of Age (print):

_____

Client or Person Authorized to Sign for Client Under 18 Years of Age Signature:

_____

Date:

Witness Name (print):

Witness Signature: