



Consent for Amniotic and Placental Allograft Injections for Orthopedic Conditions

Introduction

Amniotic and Placental Allograft injections are a regenerative medicine treatment that uses structural tissue allograft derived from human placenta tissue. These structural proteins, glycosaminoglycans and proteoglycans are processed to preserve the native state of tissue in FDA-registered labs before being provided for medical use. Your provider will inject the structural tissue allograft into an affected joint to potentially help promote healing and reduce pain.

It is important to understand that the use of these injections for orthopedic conditions is not FDA-approved. This therapy is considered part of the practice of medicine not as an FDA-approved drug or biologic therapy and is used at the discretion of licensed providers. Results vary between patients, and no specific outcomes can be guaranteed.

Key Disclosures (Please Initial Each Statement)

___ I understand that placental derived structural tissue allograft injections are not FDA-approved for orthopedic conditions.

___ I understand that placental derived structural tissue allograft injections are not necessarily the standard of care but falls under the scope of the Practice of Medicine.

___ I understand that the science of regenerative medicine is still developing, and long-term studies are limited.

___ I understand that results vary—some patients may benefit, while others may not experience improvement.

___ I understand that no guarantees of success have been made by Physioregenix or my provider.

___ I understand that potential risks include pain, swelling, bleeding, infection possibly requiring antibiotics or surgery, allergic reaction, tissue damage, nerve injury, or lack of improvement. Rare but unknown risks may exist.

___ I understand that alternatives include physical therapy, medications, steroid injections, surgery, or no treatment.

___ I understand that this treatment is not covered by insurance and that I am financially responsible for all charges.

___ I understand that there are no refunds.

___ I understand that I may decline treatment at any time before the procedure.

Additional Considerations

- Your provider may adjust the treatment plan if unforeseen conditions arise.
- Local anesthesia may be used, and as with any anesthetic, there are risks.
- Any tissues not needed after processing may be disposed of according to medical standards.

Consent Statement

I acknowledge that I have read and understood the information above. I have had the opportunity to ask questions, and they have been answered to my satisfaction. I understand the risks, benefits, alternatives, and limitations of placental derived structural tissue allograft injections and I voluntarily consent to undergo this procedure.

Patient Name: _____ Date: _____

Patient Signature: _____

Provider Name: _____ Date: _____

Provider Signature: _____