



## Consent for Umbilical Stem Cell Injection for Orthopedic Conditions

### Introduction

Umbilical stem cell therapy is a regenerative medicine treatment that uses stem cells collected from donated umbilical cord tissue. These cells are processed in FDA-registered labs before being provided for medical use. Your provider will inject the stem cells into an affected joint or soft tissue area to potentially help promote healing and reduce pain.

It is important to understand that the use of umbilical stem cells 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 umbilical stem cell therapy is not FDA-approved for orthopedic conditions.

\_\_\_ I understand that stem cell treatment is not necessarily the standard of care but it is 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 umbilical stem cell therapy, and I voluntarily consent to undergo this procedure.

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

Patient Signature: \_\_\_\_\_

Provider Name: \_\_\_\_\_ Date: \_\_\_\_\_

Provider Signature: \_\_\_\_\_