



Allograft Cellular Intra-articular/Soft tissue Injections

Allograft Cellular Therapy has not been approved by the FDA and treatment is considered investigational and experimental in regenerative medicine.

***This product contains Dimethyl Sulfoxide(DMSO) which is an organosulfur compound. It is not recommended to proceed on patients with known DMSO or sulfur based allergies.

Commonly used protocol for orthopedic conditions:

One injection of 5M to 10M cells delivered directly to the joint through an intra-articular injection or directly to the affected soft tissue.

Intravenous infusion of 30M cells is often utilized in conjunction with intra-articular injections for **MSC's** trophic and immunomodulatory properties that can help in tissue repair/regeneration. (See IV infusion protocol for preparation and infusion instructions)

Preparation for IA infusion:

Recommended Supplies:

- 10M /1cc (1.0×10^7)- Liveyon Umbilical Cord Derived MSCs
- Tape, dressing/band aid
- 1 – 10ml syringe
- 0.9% Normal Saline (NS) or PRP for injection
- 1 – 18ga x 2in. needle
- Gloves
- Alcohol pads or Chloro-prep
- Absorbent Pad (for clean workspace)
- Extra gauze as needed

Product (**MSC's**) preparation:

Liveyon Umbilical Cord Derived **MSC's are transported** directly from the laboratory to the medical practice for use. Our MSC product is shipped in a frozen suspension using CryoStor® under cryogenic compliance on dry ice and must be prepared in an appropriate manner prior to infusion or direct injection.

Upon arrival of the product, verify the product for appropriate concentration. Intravenous infusion doses are marked (3.0×10^7) and will be 30M cells/1ml of volume. Intra-articular/direct injection doses are marked in (1.0×10^7) and are a concentration of 10M cells/1ml of volume.

Cryogenic Cell preparation:

- Unpack internal packaging from the shipping container.
- Remove the vial of **Liveyon MSC's** and retain donor and cell information for data collection.
- Thaw product.

A device such as ThawSTAR® may be used for automated, hands free operation. The use of an automated thawing system such as ThawSTAR® has been shown to improve product consistency with highly consistent thawing endpoints, reduced risk of contamination and improved cell viability.

If a device such as ThawSTAR® is not available: allow product to thaw in a water bath at 37°C or manual thaw by holding the vial in a hand or roll vial gently between the hands until crystal is thawed.

**Do not rapid thaw or use a high heat device during the thawing process. Over heating or significant agitation of the product during or after thaw may significantly impair cell viability.



Preparation of product for Intra-Articular Injection:

Using sterile technique:

- Place 18ga needle on syringe.
- Draw 2-3ml 0.9% NS into syringe. (Normal Saline can be replaced with PRP which may improve cell viability)
- Remove screw top cap from product vial and place needle into vial at a 45-degree angle to draw the product into the syringe.
(Result will be 3-4ml of NS/PRP **and MSC's** combined in the syringe.)
- Remove all air from the syringe.
- Using universal safety precautions, place cap on the needle then place syringe on tray and prepare patient for the injection.

Patient preparation:

- Physician determines the best approach to gain access directly to the joint capsule or soft tissue.
- Prepare the patient skin for the injection with chloraprep solution, alcohol or betadine solution.
- Allow prep solution to completely dry prior to injection.

Patient Injection:

- Select the appropriate needle for the injection and place on the syringe.
*****Minimum recommended 23ga or larger needle.
- Based on training and experience of the MD gain access to the desired joint or area of injection.
- Deliver complete stem cell preparation to area of interest.

Completion of patient infusion:

Using universal precautions and standard technique.

- Remove needle from site of injection.
- Discard syringe in the appropriate medical disposal containers. All needles should be discarded in an appropriate sharps container for proper disposal.
- **Note the donor number on the client's chart before** discarding packaging
- Patient should remain on site for a minimum of 20-30 minutes after infusion to monitor for any adverse reactions.