LevaSOL™

Human Amniotic Fluid Allograft-

Material of Choice for Regenerative Healing and Repair in Wounds, Burns, Bone, Muscle, Cartilage, Tendon, and Nerves

LevaSOL™ Is a Cryopreserved, Cell-Free, Amniotic Fluid Allograft that is prepared by utilizing advanced purification and sterilization processes. Components of LevaSOL™ interact with Multiple Tissue Types to enhance the body's own healing process and stimulate normal regeneration to provide strength in healing.

0.5 cc vial of LevaSOL™

LevaSOL™ Applications

- Wounds & burns
- Urethroplasty
- Hypertrophic scars
- Penile adhesions
- Erectile Dysfunctions
- Urinary Incontinence
- Esophageal fistula
- Esophageal strictures
- Finger Strictures
- Contractures
- Bowel fistula
- COPD (Aerosolized)
- TMJ discomfort
- Joint arthritis
- Carpal Tunnel
- Torn Rotator Cuff
- Plantar Fasciitis
- Peyronie's Disease

To date, LevaSOL™ manufacturer has supplied over 1,500 units of Amniotic Fluid for the stated applications. This list is not inclusive of all potential applications. Not all uses and applications listed have successfully completed IRB approvals. Some of these applications are currently undergoing clinical trials. It is up to the clinician to determine its' usefulness or effectiveness.

"As a liquid allograft, amniotic fluid can be delivered in a unique form including injection into wounds or joint spaces. Amniotic fluid is composed of a complex solution of growth factors, cytokines, proteins, carbohydrates, lipids, hormones, electrolytes, hyaluronic acid, as well as other nutrients, which function to protect and cushion, modulate inflammation and enhance mobility in utero" .[1, 2, 3]

LevaSOL™ Composition of Cytokine/ Growth Factor Arrays

(Post-Sterilization)

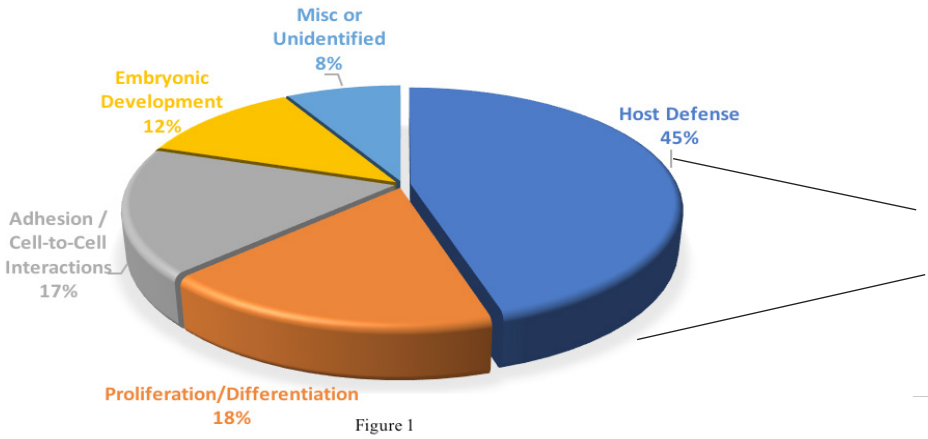

Figure 1

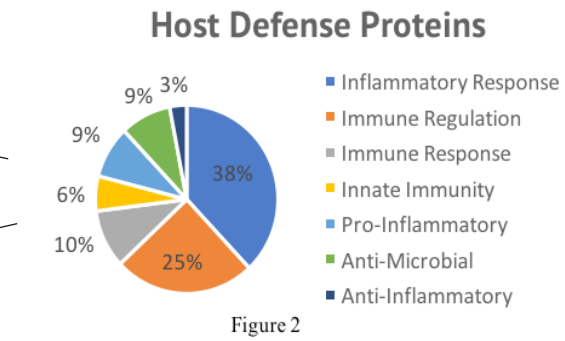

Figure 2

Figure 1: Protein arrays of post-sterilized amniotic fluid revealed that of 400, 285 or 59% of proteins tested were present in LevaSOL™. Classification of the proteins indicated that they were involved in various functional activities that include cell adhesion, proliferation embryonic development, angiogenesis and host defense. Proteins assigned to the miscellaneous category included proteins involved in Ca++ regulation, apoptosis, cell migration lysosomal sorting and ectodermal organ morphogenesis. Figure 2: Upon sub-categorized of the host defense proteins a number of proteins were found to be associated with the inflammatory response, innate immunity or as an anti-microbial.

(LevaSOL™ viscosity rating: 0.9+/-0.1 cP)

(Pierce et al. Collection and characterization of amniotic fluid from scheduled C-section deliveries. Cell and Tissue Banking. Intl Journal for Banking Engineering and Transplantation of Cells and Tissue Incorporating Advances in Tissue Banking. Spinger 2016. DOI 10.1007/s10561-016-9572-7)

Levana BIOLOGICS

The Evolution of Medicine

Levana Biologics 700 N. Colorado Blvd. #122 Denver, CO 80206

Published Experience

{Journal of Bone and Joint Surgery, 1938 [4] }"In sixty-eight cases in which amniotic-fluid concentrate has been employed in the treatment of various pathological conditions of joints, the use of the fluid concentrate has not been attended by a single unfavorable reaction. Its action is probably both biological and mechanical. It speeds up a defense-repair mechanism within the joints. The results obtained have been impressive in intra-articular fractures, and encouraging in selected cases of atrophic arthritis, as well as in persistent joint effusions. It successfully prevents the formation of new adhesions after closed manipulation of joints. It is a valuable prophylactic after arthrotomy of any type. Its use both in soft tissues and in other serous cavities is suggested." [4]

"Though clinical data on amniotic fluid are limited, a number of cases have demonstrated that injection of amniotic fluid is safe and anecdotal results suggest that amniotic fluid reduces pain and promotes healing."[4,5]

"Additional in vivo preclinical models have demonstrated that amniotic fluid promotes healing in a variety of applications including healing of wounds, burns, bone, cartilage, tendon and nerves."[6, 9]

"Protein and molecular characterisation of a clinically compliant amniotic fluid stem cell derived extracellular vesicle fraction capable of accelerating muscle regeneration through the enhancement of angiogenesis." [10]

"The progenitor cells derived from amniotic fluid and placenta are pluripotent and have been shown to differentiate into osteogenic, adipogenic, myogenic, neurogenic, endothelial, and hepatic phenotypes in vitro."[11]

"Furthermore, they do not develop into teratomas when transplanted, a consequence observed with pluripotent stem cells. In addition, their multipotent differentiation ability, low immunogenicity, and anti-inflammatory properties make them ideal candidates for bone regenerative medicine."[12]

Functionality & Regenerative Properties

- Anti-microbial
- Anti-inflammatory
- Promotes homeostasis
- Enhances angiogenesis
- Reduces pain
- Promotes re-epithelialization
- Promotes stem cell proliferation and migration
- Accelerates tissue and muscle regeneration
- Secretes collagen and fibronectin
- Reduces scar tissue formation
- Lubricates and increases mobility
- Osteo-promotive
- Non-tumorigenic
- Low or negligible immunogenicity

Nutrients & Growth Factors

- Carbohydrates, proteins, lipids, lactate, pyruvate, electrolytes, enzymes, and hormones
- Hyaluronic acid
- Epidermal Growth Factor (EGF)-angiogenic
- Transforming growth factors (TGFa & TGFb)
- Insulin-like growth factor (IGF)

Sizes and Ordering

LS-0025 - 0.25 cc
LS-0050 - 0.50 cc
LS-1000 - 1.00 cc
LS-1500 - 1.50 cc
LS-2000 - 2.00 cc
LS-3000 - 3.00 cc

Quality | Safety | Handling

- LevaSOL™ 100% pure amniotic fluid- free of additives or cryoprotectants
- Cutting-edge sterile filtration technology- ensures maximum safety while preserving high quantities of the beneficial "native" properties
- Some applications may qualify for third party reimbursement
- Non-invasive and safe. Can be performed in an out-patient setting
- Can be sprayed, aerosolized or injected
- Safe for subcutaneous or intramuscular injection into joints, tendons and connective tissues (Not safe for intravenous injection)
- Levana Biologics provides practitioners with a complimentary consultation with our Chief Scientific Officer
- Human Amniotic Fluid has been utilized in over 10,000 applications with no known or reported adverse reactions
- LevaSOL™ qualifies as a human tissue allograft (HCT/P) as outlined in 21 CFR 1271 under Section 361 of the Public Health Service Act
- Must be stored at -20°C or colder (Can be thawed and ready to use in 10 minutes)
- Aseptically packaged in a single-use, sterile cryovial and ready for use upon thawing
- Over 1,500 units of LevaSOL™ have already been successfully transplanted

Manufacturer

Levana Biologics is partnered with a world-renowned Cell Therapy and Regenerative Medicine Academic Institution and University to manufacture LevaSOL™ and other biomaterials. LevaSOL™ manufacturer utilizes a cutting-edge sterile filtration technology, that delicately extracts dead tissue and debris to ensure maximum patient safety while preserving high quantities of the beneficial "native" properties. Each lot has been obtained from a pre-screened, healthy and qualified volunteer donor during full-term Cesarean section delivery. Collection, processing, preservation and storage are performed in compliance utilizing a proprietary process (patent pending) by an FDA registered, AATB, FACT, CAP accredited, CLIA certified laboratory.

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References: {1} Underwood MA, et al. Amniotic fluid: not just fetal urine anymore. Journal of Perinatology. 2005;25(5):341–348. {2} Hui AY, et al. A systems biology approach to synovial joint lubrication in health, injury and disease. Wiley Interdisciplinary Reviews: Systems Biology and Medicine. 2012;4(1):15–37. {3} Burns C, et al. Cytokine levels in late pregnancy: Are female infants better protected against inflammation? Frontiers in Immunology. 2015;6:318 {4} Shimberg M. The use of amniotic-fluid concentrate in orthopaedic conditions. Journal of Bone and Joint Surgery: American Volume. 1938;20 (1):167–177. {5} Bhattacharya N. Clinical use of amniotic fluid in osteoarthritis: a source of cell therapy. In: Bhattacharya N, Stubblefield P, editors. Regenerative Medicine Using Pregnancy-Specific Biological Substances. London: Springer; 2011. pp. 395–403. {6} Bazrafshan A, et al. Activation of mitosis and angiogenesis in diabetes-impaired wound healing by processed human amniotic fluid. Journal of Surgical Research. 2014;188(2):545–552. {7} Karacal N, et al. Effect of human amniotic fluid on bone healing. Journal of Surgical Research. 2005;129(2):283–287. {8} Ozgenel GY, et al. Effects of human amniotic fluid on cartilage regeneration from free perichondrial grafts in rabbits. British Journal of Plastic Surgery. 2004;57(5):423–428. {9}Ozgenel GY, et al. Effects of human amniotic fluid on peritendinous adhesion formation and tendon healing after flexor tendon surgery in rabbits. Journal of Hand Surgery: American Volume. 2001;26(2):332–339 {10} Mellows et al. Protein and molecular characterisation of a clinically compliant amniotic fluid stem cell derived extracellular vesicle fraction capable of accelerating muscle regeneration through the enhancement of angiogenesis – Stem Cells Development 2017 Jul 5. doi: 10.1089/scd.2017.0089 {11} Dawn M. Dello et. al. Methods in Enzymology, VOL. 419 Extraembryonic and Perinatal Stem Cells- (Chapter 17) Amniotic Fluid and Placental Stem Cells, Copyright 2006, Elsevier Inc. DOI: 10.1016/S0076-6879(06)19017-5. 12} Pipino C1 et al. Osteogenic differentiation of amniotic fluid mesenchymal stromal cells and their bone regeneration potential. World J Stem Cells. 2015 May 26;7(4):681-90. doi: 10.4252/wjsc.v7.i4.681.

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