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mvrcell™

Adipose Tissue Transfer Therapy System

MAVERA®
Surgery

Mvrcell™ Adipose Tissue Transfer Therapy System & Accessories

Mesenchymal Stem Cell

Mesenchymal stem cells, which are the main cells of the connective tissue, are the adult stem cell type. Although mesenchymal stem cells originate from the mesoderm layer, they also form the basis of the 'stroma cell', which is the supporting part of the tissues.

Found in bone marrow, adipose tissue, umbilical cord, umbilical cord blood, liver, brain, dental pulp, skin and fetal tissues; These are stem cells that are not differentiated, have high reproductive capacity, have the ability to renew themselves without differentiation, and have high mesodermal differentiation ability.

The most used MSCs source are Bone marrow, Adipose tissue and Umbilical cord blood.

Adipose Tissue

Adipose tissue is a heterogeneus biological tissue that lies between platelet-rich plasma and concentrated bone marrow aspirate with respect to stem cell content and cellular heterogeneity. This tissue is also capable of delivering modest levels of grown factors.

Multipotent cells isolated from adipose (fat) tissue are called adipose stem cells (ASC). Adipose stem cells can be found in all types of white adipose tissue containing subcutaneous and omental fat, and they are obtained from the vascular-rich stromal (Stromal vascular fraction; SVF) region of adipose tissue.

The benefit of concentrated adipose tissue include:

- ✔ Very minimally invasive process for the removal and collection of stem cells(Compared to removal of bone marrow)
- ✔ Excellent natural scaffolding
- ✔ High concentrations of MSCs (Average $10\times10^4 \pm 10^4$/1 gr. Adipose tissue)
- ✔ High colony forming capacity and isolation success. (Compared to bone marrow and umbilical cord blood)

The quality of adipose tissue graft material is an important consideration before performing any lipograft procedure.

The MvrCell system is designed for the safe and rapid preparation of a purified MSC-rich graft from a small tissue sample at the patient's point of care. The concentrated adipose tissue provides a physical scaffold of multiple cellular compenents.

The MvrCell™ Adipose Tissue Transfer Therapy System & Accessories System significantly reduces tissue samples to provide a graft with a high stem cell count and core cell count while significantly reducing excess fluid that causes graft volume loss.

To achieve high quality, the system concentrates tissue samples to deliver a graft with high stem cell and nucleated cell counts while significantly reducing excess fluids that contribute to graft volume loss.

Lipoaspirate processing with the system provides several critical advantages, such as:

- ✔ Retains and concentrates the tissue stromal vascular fraction (SVF), which includes all of the cell types and the structural matrix to promote graft survival and the cellular complement to aid in tissue regeneration
- ✔ Removes excess infranatant fluid, minimizing graft resorption and the need to overfill
- ✔ Removes excess oils, lipids and cellular debris that may induce an inflammatory response in patients

Retention of the Tissue Stromal Vascular Fraction (SVF)

Tissue SVF contains the entire adipose tissue microenvironment, including a variety of cell types, such as adipocytes, pre-adipocytes and MSCs. Tissue SVF also contains a structural matrix to which cells can attach, supporting cell viability and proliferation and promoting graft retention.

Harvesting | *Adipose stem cells are obtained from healthy donors from the abdominal-hip areas (under local anesthesia-liposuction method), and large amounts of adult fat stem cells are autologically derived from adipose tissue.*

Removal of Excess Infranatant Fluid, Oils and Lipids

Excess infranatant fluid in a graft sample makes it challenging to estimate an accurate graft volume for a procedure because this fluid is resorbed by the body. To account for this resorption, physicians typically overfill the treatment site with lipoaspirate, which can cause increased swelling and an undesirable initial aesthetic result. Removal of excess fluid can minimize the need for overfilling and offer a more predictable aesthetic outcome.

Oils, lipids and cellular debris that are present in lipoaspirate may cause an inflammatory response that prolongs graft healing and can prove toxic to the cellular components of the graft itself. Removal of these materials may promote graft survival.

RELIABILITY: PROVEN RESULTS

In addition to generating purified MSC-rich grafts in just 10 minutes, the MvrCell biologic concentration technology also has the following advantages:

- Generates biologic treatments without manual adjustment from patient to patient
- Produces concentrated, high-quality, injection-ready biologics with simple operation
- Delivers a consistent MSC-rich product
- The MvrCell system is Automatic Processing, thus reducing the number of steps versus a manual method and simplifying training among multiple users.
- Designed to Reduce the Risk of Contamination
- It isolates fats and lipids using a lipid barrier disc technology.

The MvrCell ™ Adipose Tissue Transfer Therapy System & Accessories are indicated for aspiration, harvesting, transferring and reinjection of autologous adipose tissue when concentration of harvested adipose tissue is desired for increasing the regenerative capacity of the tissues in: Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery and Orthopaedic Surgery.

WHY ADIPOSE DERIVED STEM CELL?

Since it is obtained from the person's own adipose tissue, allergic side effects are not expected.
It contains a minimum of 3 times more and a rich variety of stem cells compared to bone marrow and umbilical cord blood; therefore, the efficiency in treatment is increased.
Average $10x10^4 \pm 10^4$ / 1gr. Fat tissue. Cell number; patient's age, gender, health status, etc. change.
(Sen A, YR Lea-Currie, D Sujkowska, DM Franklin, WO Wilkison, YD Halvorsen and JM Gimble. (2001). J Cell Biochem 81: 312–319.)
Fat tissue harvesting more easy compared to bone marrow.
Treatment is carried out within a maximum of 1 hour without the need for cultivation and waiting for the patient for weeks.
On the one hand, the patient gets rid of unwanted fat in the abdominal or hip area, while at the same time reaches the treatment he needs.
While mechanical stimulation (filtering, filtering, hydrostatic pressure, compression, pulling and dropping) prevents the conversion of stem cells from adipose tissue to adipose tissue cells, it increases the conversion of cartilage, tendon, bone, muscle etc. cells.
(R. M. Delaine - Smith et al. Muscles, Ligaments and Tendons Journal 2012; 2 (3): 169-180)
Since it contains a wide variety of stem cell populations, it can be used in many different diseases.
It is non-toxic and does not contain synthetic ingredients.
The results are fast and permanent.

Intended Use

The Adipose Tissue Transfer Therapy System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. MvrCell™ system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. MvrCell™ Adipose Tissue Transfer Therapy System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired. Neurosurgery, Gastrointestinal Surgery Urological Surgery, Plastic and Reconstructive Surgery, General surgery, Orthopedic Surgery.

The adipose tissue transfer therapy addresses to adult patients of both sexes, ages from 18 and older. No clinical study presented and consulted for pediatric patients, pregnant women and disabled persons within the scope of this report. These products are not directly intended to be used in pediatric cases, pregnant women and disabled persons.

Brand	Version/Model	Product Definition	Ref#
MvrCell™	MVRC-01-V1.00	Adipose Tissue Transfer Therapy System	MVRSPP

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Mavera Medical Devices Inc. guarantees that the products are designed, manufactured and packaged on application of EN ISO 13485 certified quality management with all possible care, using the most suitable state-of-the-art processes and applying the principle of integrating safety into its design and manufacture. This system is designed to guarantee the safe use of device when it is employed under condition and for the purposes for which it is intended, in accordance with precautions described in the operator's manual and/or instructions for use and to minimize the risks associated with the use of the device as far as possible, although they cannot be totally eliminated. The device must only be used under the responsibility of specialist medical personnel, taking account of the unavoidable risks and the possible side effects and complications of the treatment for which, it is designed, including those referred to in other sections of these instructions for use.

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