NEOGENESIS
Global Leader Enterprise of Autologous Cell Therapies

UNISTATION™

2nd Version

The simplest & easiest way to
various cellular therapies

Unique all-in-one solution

FDA CE KFDA

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The simplest & easiest way to
various cellular therapies

Unique all-in-one solution

Background of Development

- Zuk method
- CAL

Detailed Information

- Composition
- Specification
- Consumables & Accessories

Protocols

- ADSC isolation
- Cell counting

Comparison & References

- Comparison of other devices
- References

NEOGENESIS
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Upgrades on UNISTATION™

2nd Version

The simplest & easiest way to various cellular therapies

Unique all-in-one solution

Upgrades on UNISTATION 2nd version

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UniStation 1st Version (2013)	UNISTATION™ 2nd Version
	
Plain design	*Modern and state of the art design*

Upgrades on UNISTATION 2nd version

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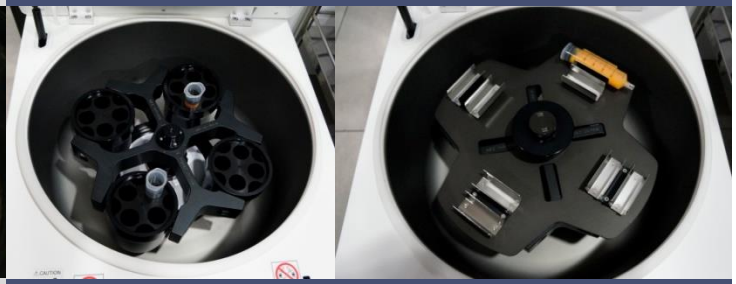
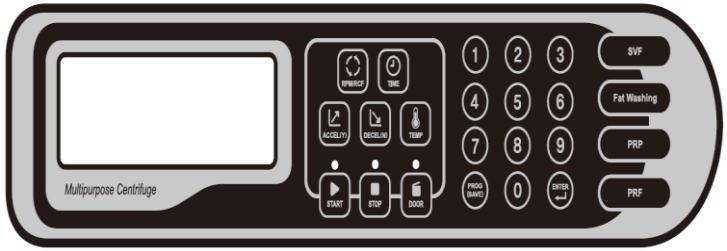
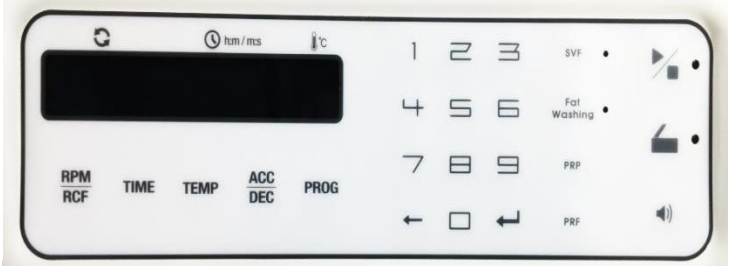
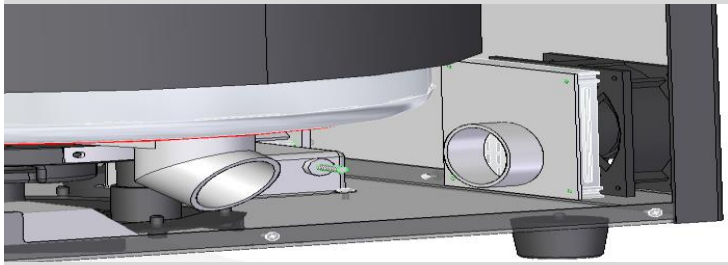
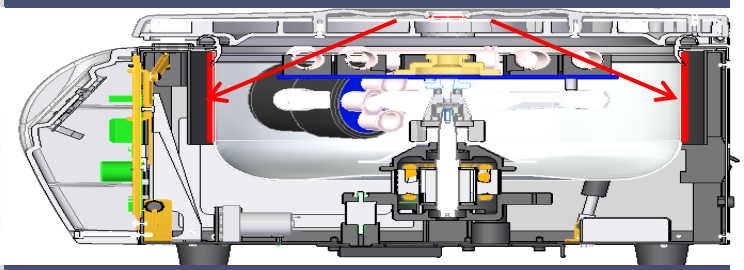
UniStation 1st Version (2013)	UNISTATION™ 2nd Version
	
Some parts not autoclavable (eg. Tuberack and shaking plate)	***Autoclavable*** All parts are autoclavable
	
Button push style keypad	***Touch screen keypad*** No button push/ Modern style
	
Air heater type incubator Normal incubation method	***Silicon heater type incubator*** Safer and faster incubation method

Upgrades on UNISTATION 2nd version

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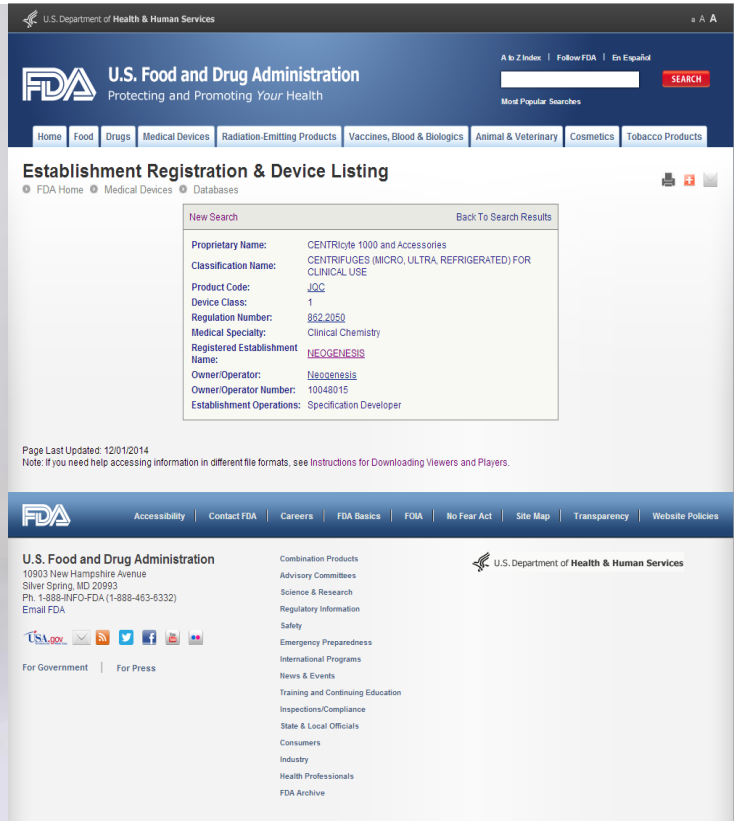
UniStation 1st Version (2013)

FDA (US) not registered
CE, KFDA

UNISTATION™ 2nd Version



FDA (US) registered
FDA, CE, KFDA

Introduction

NEOGENESIS
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UNISTATION™ is,

All-in-one Device

for diverse autologous cell therapies

UNISTATION™ is a specially designed medical device to satisfy diverse demands for various autologous cell therapies with only one device.

Youtube Link of UNISTATION Introduction
http://youtu.be/-Jy3t4y1ny0

Youku Link of UNISTATION Introduction (Chinese)
http://v.youku.com/v_show/id_XODI0MjUzODk2.html

Application areas of various treatments

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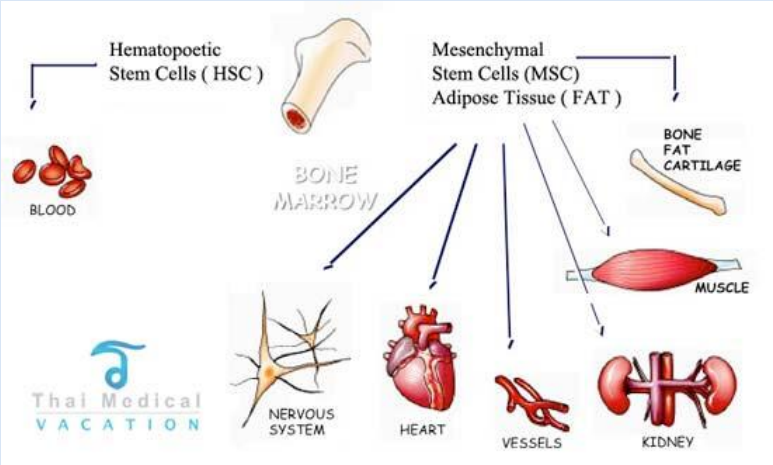
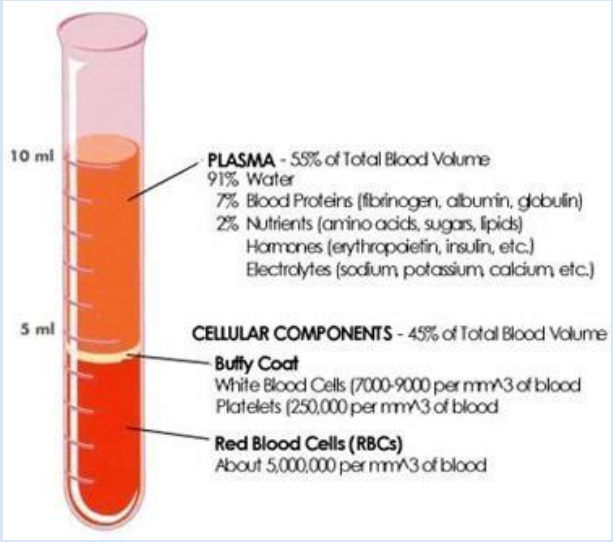
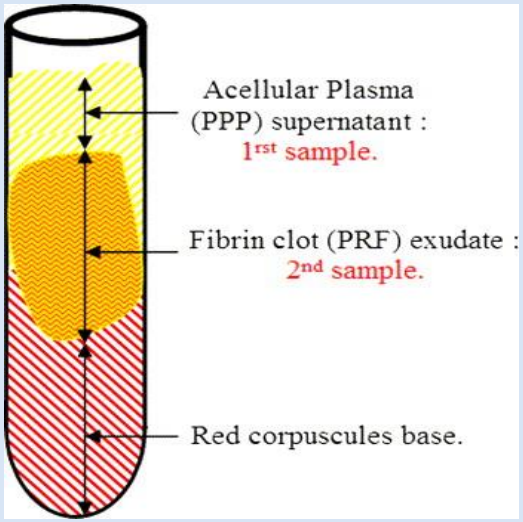
Adipose Derived Stem Cell

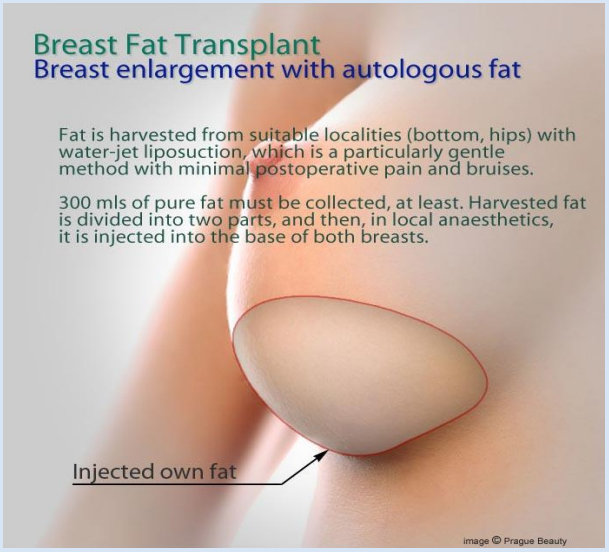


Platelet Rich Plasma





Platelet Rich Fibrin



Fat Purification

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Background of Development

Background of Development

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What is **Stem Cell**?

- Stem cells are multi potent cells and its multi-diversification capability is considered as the core future of medical fields demanding various cell therapies for a number of incurable diseases.
- There are various types of stem cells, embryonic stem cells, umbilical stem cells, and adult stem cells and adult stem cells includes adipose derived stem cells, peripheral blood stem cells, bone marrow stem cells, and etc.
- However, embryonic stem cells have controversial ethical problems and possible harvesting period of umbilical stem cells are very limited to the time of delivery, so the use of them from human sources are extremely prohibited or limited.
- Thus, the need for harvesting a large amount of healthy adult stem cells is increasing.

What is **ADSC** (Adipose Derived Stem Cell)?

- Adipose tissue is one of the richest sources of MSCs. When compared to bone marrow, there is more than 500 times more stem cells in 1 gram of fat when compared to 1 gram of aspirated bone marrow. Adipose stem cells are currently actively being researched in clinical trials for treatment in a variety of diseases.
- In 2001, Dr. Patricia Zuk first published a thesis explaining how stem cells from adipose tissue were successfully obtained and cultured by their research team. (Tissue Engineering. 7:212-228, 2001)
- Due to the spreads of the publication, adipose tissue started to be known as the best source of stem cells among scholars and doctors due to the easy harvesting technique that Dr Zuk showed in his thesis and due to the obtainability in large amounts as well.

Reference: Tissue Engineering. 7:212-228, 2001

Background of Development

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TISSUE ENGINEERING
Volume 7, Number 2, 2001
Mary Ann Liebert, Inc.

Multilineage Cells from Human Adipose Tissue: Implications for Cell-Based Therapies

PATRICIA A. ZUK, Ph.D.,[1,2] MIN ZHU, M.D.,[1,2] HIROSHI MIZUNO, M.D.,[2] JERRY HUANG, B.S.,[2] J. WILLIAM FUTRELL, M.D.,[3] ADAM J. KATZ, M.D.,[3] PROSPER BENHAIM, M.D.,[2] H. PETER LORENZ, M.D.,[2] and MARC H. HEDRICK, M.D.[2]

ABSTRACT

Future cell-based therapies such as tissue engineering will benefit from a source of autologous pluripotent stem cells. For mesodermal tissue engineering, one such source of cells is the bone marrow stroma. The bone marrow compartment contains several cell populations, including mesenchymal stem cells (MSCs) that are capable of differentiating into adipogenic, osteogenic, chondrogenic, and myogenic cells. However, autologous bone marrow procurement has potential limitations. An alternate source of autologous adult stem cells that is obtainable in large quantities, under local anesthesia, with minimal discomfort would be advantageous. In this study, we determined if a population of stem cells could be isolated from human adipose tissue. Human adipose tissue, obtained by suction-assisted lipectomy (*i.e.*, liposuction), was processed to obtain a fibroblast-like population of cells or a processed lipoaspirate (PLA). These PLA cells can be maintained *in vitro* for extended periods with stable population doubling and low levels of senescence. Immunofluorescence and flow cytometry show that the majority of PLA cells are of mesodermal or mesenchymal origin with low levels of contaminating pericytes, endothelial cells, and smooth muscle cells. Finally, PLA cells differentiate *in vitro* into adipogenic, chondrogenic, myogenic, and osteogenic cells in the presence of lineage-specific induction factors. In conclusion, the data support the hypothesis that a human lipoaspirate contains multipotent cells and may represent an alternative stem cell source to bone marrow-derived MSCs.

INTRODUCTION

THE THERAPEUTIC POTENTIAL of multilineage stem cells for applications such as tissue engineering and gene therapy is enormous. Conceptually, there are two general types of stem cells potentially useful for these applications: embryonic stem cells (ESCs) and autologous stem cells. Although theoretically appealing because of their pluripotentiality, the practical use of ESCs is limited due to potential problems of

[1]Dr. Zuk and Dr. Zhu are co-first authors.
[2]Laboratory for Regenerative Bioengineering and Repair, Departments of Surgery and Orthopaedic Surgery, UCLA School of Medicine, Los Angeles, California.
[3]Division of Plastic and Reconstructive Surgery, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania.

Isolation and culture of stem cells—PLA and MSCs

Human adipose tissue was obtained from elective liposuction procedures under local anesthesia (HSPC #98-08 011-02). In this procedure, a hollow blunt-tipped cannula was introduced into the subcutaneous space through small (~1 cm) incisions. The cannula was attached to gentle suction and moved through the adipose compartment, mechanically disrupting the fat tissue. A solution of saline and the vasoconstrictor epinephrine was infused into the adipose compartment to minimize blood loss and contamination of the tissue by peripheral blood cells. The raw lipoaspirate (~300 cc) was processed according to established methodologies to obtain a stromal vascular fraction (SVF).[33,34] To isolate the SVF, lipoaspirates were washed extensively with equal volumes of phosphate-buffered saline (PBS), and the ECM was digested at 37°C for 30 min with 0.075% collagenase. Enzyme activity was neutralized with Dulbecco's modified Eagle's medium (DMEM), containing 10% FBS and centrifuged at 1200 × *g* for 10 min to obtain a high-density

SVF pellet. The pellet was resuspended in 160 mM NH_4Cl and incubated at room temperature for 10 min to lyse contaminating red blood cells. The SVF was collected by centrifugation, as detailed above, filtered through a 100-μm nylon mesh to remove cellular debris and incubated overnight at 37°C/5% CO_2 in control medium (DMEM, 10% FBS, 1% antibiotic/antimycotic solution). Following incubation, the plates were washed extensively with PBS to remove residual nonadherent red blood cells. The resulting cell population was termed a processed lipoaspirate (PLA), to distinguish it from the SVF obtained from excised adipose tissue. PLA cells were maintained at 37°C/5% CO_2 in noninductive control medium. Cells did not require specific FBS sera lots for expansion and differentiation (data not shown). For immunofluorescence studies, a population of MSCs was obtained from human bone marrow aspirates according to the protocol of Rickard *et al.*[17] and maintained in control medium. To prevent spontaneous differentiation, cells were maintained at subconfluent levels.

Reference: Tissue Engineering. 7:212-228, 2001

What is **Zuk Method**?

- The Dr Zuk`s adipose derived stem cell isolation technique was called Zuk Method in academics and a modified method from Zuk Method was also developed to satisfy human reinjection condition.

- For example, FBS (Fatal Bovine Serum) was replaced by Human Serum, and PBS (Phosphate Buffered Saline) was replaced by Normal Saline to satisfy human reinjection condition and this method was called Modified Zuk Method based on which some companies developed their ADSC isolation products (UNISTATION™ also adopted this Modified Zuk Method).

Background of Development

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What is **CAL** (Cell-Assisted Lipotransfer)?

- Since harvesting technique of ADSC was published by Dr Zuk (Tissue Engineering. 7:212-228, 2001), a number of research has been conducted for years to develop applications of ADSC .
- In 2008, Dr. Yoshimura, professor of plastic surgery department of Tokyo University in Japan, proved the efficacy of his theory that stem cells would increase the survival rate of fat transfer by angiogenesis / vascularization effect of stem cells, resulting in smoother oxygen supply and higher survival rate of injected fat (Aesth Plast Surg 2008;32:48-55).
- He conducted the research and he proved that the stem cell-rich lipotransfer can, in fact, enhance the fat survival rate up to 70%, compared to 30-40% of general lipotransfer.
- The research was a very extensive clinical test spending more than 2 years with breast augmentation cases of 40 patients (Aesth Plast Surg 2008;32:48-55) and with 6 facial treatment cases with LEP disease (Dermatol Surg 2008;34:1178–1185).
- And based on the success of the research, he named the stem cell rich fat transfer as CAL (Cell Assisted Lipotransfer).
- And many plastic surgeons, dermatologists, and urologists wanted to conduct the CAL surgery in their private practices because they had been tired of complaints from their customers for the high absorption rate of previous fat transfer.
- At that time, CAL was a very difficult surgery to be conducted by private practitioners though, due to the lack of facilities for stem cell isolation.
- However, after releases of several devices for ADSC isolation, including Multi Station, CHA-STATION, Celution, TGI, and etc, CAL treatment became available even for private practitioners. Thus CAL treatment became prevalent in private practices.

Reference: Aesth Plast Surg 2008;32:48-55 Dermatol Surg 2008;34:1178–1185

Background of Development

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Clinical Result of CAL by Dr. Yoshimura – Breast Augmentation

ORIGINAL ARTICLE

Cell-Assisted Lipotransfer for Cosmetic Breast Augmentation: Supportive Use of Adipose-Derived Stem/Stromal Cells

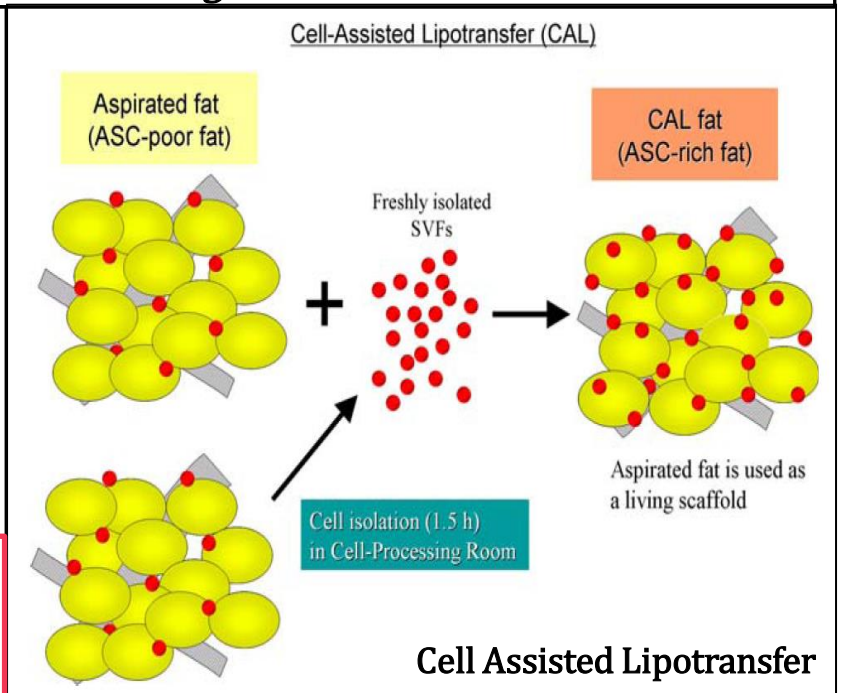
Kotaro Yoshimura · Katsujiro Sato · Noriyuki Aoi · Masakazu Kurita · Toshitsugu Hirohi · Kiyonori Harii

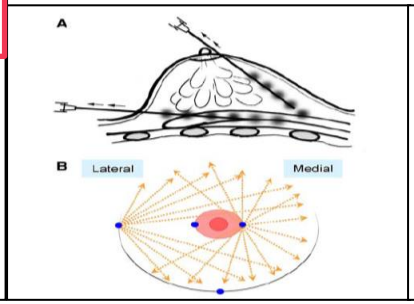
Mean Injection: 270cc
Result after 2 years: Max 200cc
Survival Rate: Max 74%

Received: 27 April 2007 / Accepted: 22 May 2007 / Published online: 1 September 2007

Abstract
Background Lipoinjection is a promising treatment but has some problems, such as unpredictability and a low rate of graft survival due to partial necrosis.
Methods To overcome the problems with lipoinjection, the authors developed a novel strategy known as cell-assisted lipotransfer (CAL). In CAL, autologous adipose-derived stem (stromal) cells (ASCs) are used in combination with lipoinjection. A stromal vascular fraction (SVF) containing ASCs is freshly isolated from half of the aspirated fat and recombined with the other half. This process converts relatively ASC-poor aspirated fat to ASC-rich fat. This report presents the findings for 40 patients who underwent CAL for cosmetic breast augmentation.
Results Final breast volume showed augmentation by 100 to 200 ml after a mean fat amount of 270 ml was injected. Postoperative atrophy of injected fat was minimal and did not change substantially after 2 months. Cyst formation or microcalcification was detected in four patients. Almost all the patients were satisfied with the soft and natural-appearing augmentation.
Conclusions The preliminary results suggest that CAL is effective and safe for soft tissue augmentation and superior to conventional lipoinjection. Additional study is necessary to evaluate the efficacy of this technique further.

Keywords Adipose-derived stem/stromal cells · Breast augmentation · Cell therapy · Lipoinjection · Tissue engineering





Reference: Aesth Plast Surg 2008;32:48-55

ADSC enhances **Fat Survival Rate** up to **70%**, compared to 30% of previous Lipotransfer

Background of Development

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Clinical Result of CAL by Dr. Yoshimura – Breast Augmentation

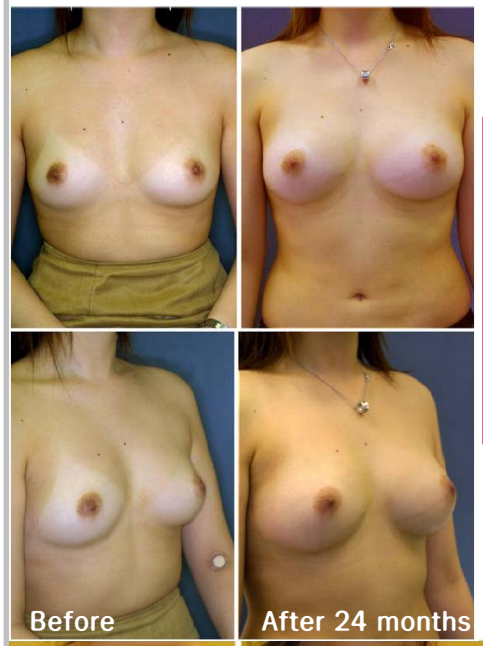
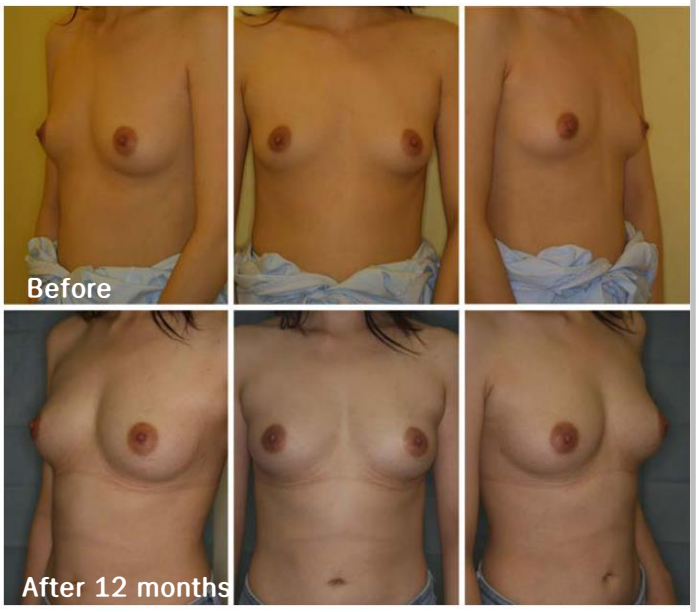


Fig. 4 Clinical views of a patient in group A (patient 1). Preoperative (*left*) and postoperative (*right*) views at 24 months. A 22-year-old woman underwent breast augmentation using cell-assisted lipotransfer (CAL) (290 ml in each breast), with satisfactory results at 24 months. Her breast circumference increased by 5 cm, and her augmented breast mounds remained soft and natural appearing without injection scars or subcutaneous indurations



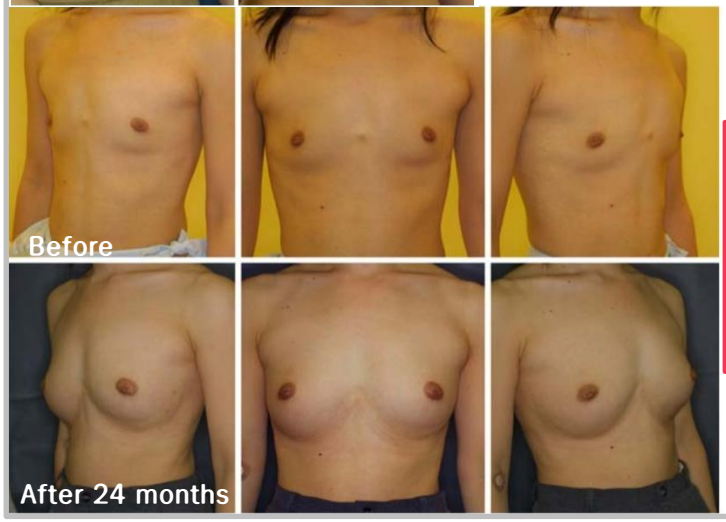


Fig. 8 Clinical views of a patient in group C (patient 3). Preoperative (*top*) and postoperative (*bottom*) views at 24 months. A 30-year-old woman underwent breast augmentation with cell-assisted lipotransfer (CAL) (310 ml in each breast). Her breasts were dramatically augmented with an increase in breast circumference difference by 8 cm at 24 months. The breast mounds were soft with no subcutaneous indurations. An original inframammary fold on the left breast is slightly visible, but injection scars are not visible

Fig. 6 Clinical views of a patient in group C (patient 2). Preoperative (*top*) and postoperative (*bottom*) views at 12 months. A 32-year-old woman underwent breast augmentation with cell-assisted lipotransfer (CAL) (280 ml in each breast). Her breast circumference difference increased from 9 cm (baseline) to 14.5 cm (at 12 months). The breast mounds are soft and natural appearing with no visible injection scars

Background of Development

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Clinical Result of CAL by Dr. Yoshimura

Cell-Assisted Lipotransfer for Facial Lipoatrophy: Efficacy of Clinical Use of Adipose-Derived Stem Cells

Kotaro Yoshimura, MD,* Katsujiro Sato, MD,† Noriyuki Aoi, MD,* Masakazu Kurita, MD,† Keita Inoue, MD,* Hirotaka Suga, MD,* Hitomi Eto, MD,* Harunosuke Kato, MD,* Toshitsugu Hirohi, MD,§ and Kiyonori Harii, MD‡

BACKGROUND Lipoinjection is a promising treatment, but its efficacy in recontouring facial lipoatrophy remains to be established.

OBJECTIVE The objective was to evaluate the efficacy and adverse effects of lipoinjection and supplementation of adipose-derived stem/stromal cells (ASCs) to adipose grafts.

METHODS To overcome drawbacks of autologous lipoinjection, we have developed a novel strategy called cell-assisted lipotransfer (CAL). In CAL, stromal vascular fraction containing ASCs was freshly isolated from half of an aspirated fat sample and attached to the other half of aspirated fat sample with the fat acting as a scaffold. This process converts relatively ASC-poor aspirated fat into ASC-rich fat. We performed conventional lipoinjection (non-CAL; $n=3$) or CAL ($n=3$) on six patients with facial lipoatrophy due to lupus profundus or Parry-Romberg syndrome.

RESULTS All patients obtained improvement in facial contour, but the CAL group had a better clinical improvement score than did the non-CAL patients, although the difference did not reach statistical significance ($p=.11$). Adipose necrosis was found in one non-CAL case who took perioperative oral corticosteroids.

CONCLUSION Our results suggest that CAL is both effective and safe and potentially superior to conventional lipoinjection for facial recontouring.

The authors have indicated no significant interest with commercial supporters.

Facial lipoatrophy is a disfiguring and socially disabling problem that accompanies several inherited and acquired diseases (see Ascher et al.[1] for review). Lupus erythematosus profundus and scleroderma en coup de sabre (en coup de sabre morphea) frequently give rise to facial lipoatrophy, which is often the most problematic manifestation of the disease for the patients even though they require medication, such as oral corticosteroids, to suppress other symptoms associated with the systemic morbidities. Facial lipoatrophy is also seen in patients with human immunodeficiency virus (HIV) infection and Parry-Romberg syndrome (hemifacial progressive atrophy or idiopathic hemifacial atrophy), which involves not only facial lipoatrophy but also bony defects.[2] Thus far there is no medical treatment to correct facial lipoatrophy.

Lipoinjection has been used for treating lipoatrophy such as that associated with HIV infection with moderate success,[3,4] while microsurgical tissue transfer has been a standard surgical treatment for recontouring facial defects seen in Parry-Romberg syndrome. However, the surgical procedure leaves conspicuous scars on the face and the donor site.[5,6] Autologous lipoinjection is a promising treatment for soft tissue augmentation because there is no associated incision scar or complications associated with foreign materials. Although

*Department of Plastic Surgery, University of Tokyo School of Medicine, Tokyo; †Cellport Clinic Yokohama, Yokohama; ‡Department of Plastic Surgery, Kyorin University School of Medicine, Tokyo; §Ritz Cosmetic Surgery Clinic Tokyo, Tokyo, Japan

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TABLE 1. Summary of Patients' Data

	Method					
	Non-CAL			CAL		
Case	1	2	3	1	2	3
Sex	Male	Female	Female	Male	Female	Female
Age (year)	25	42	42	35	33	48
Diagnosis	LEP	LEP	LEP	PRS	LEP	LEP
Severity grading	3	5	2	4	5	4
Perioperative oral corticosteroids	–	+	–	–	+	–
Donor site	Abdomen	Abdomen	Abdomen	Abdomen	Abdomen	Abdomen
Volume of injection (mL)	100	250	50	110	90	100
Follow-up periods (month)	10	9	9	13	9	9
Clinical results	Fair	Good	Fair	Excellent	Good	Good
Complications	–	Adipose necrosis	–	–	–	–

LEP, lupus erythematosus profundus; PRS, Parry-Romberg syndrome.

ADSC enhances **Fat Survival Rate** up to **70%**, compared to 30% of previous Lipotransfer

Background of Development

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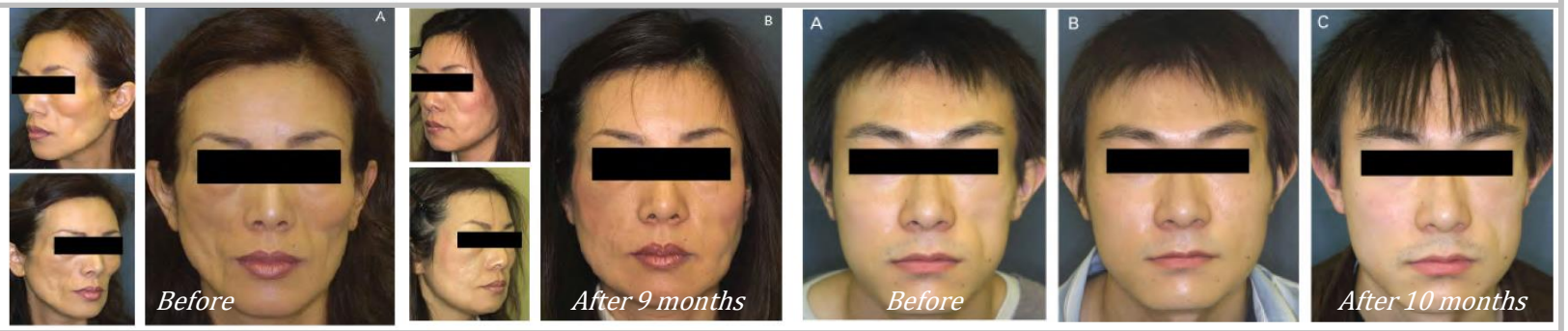
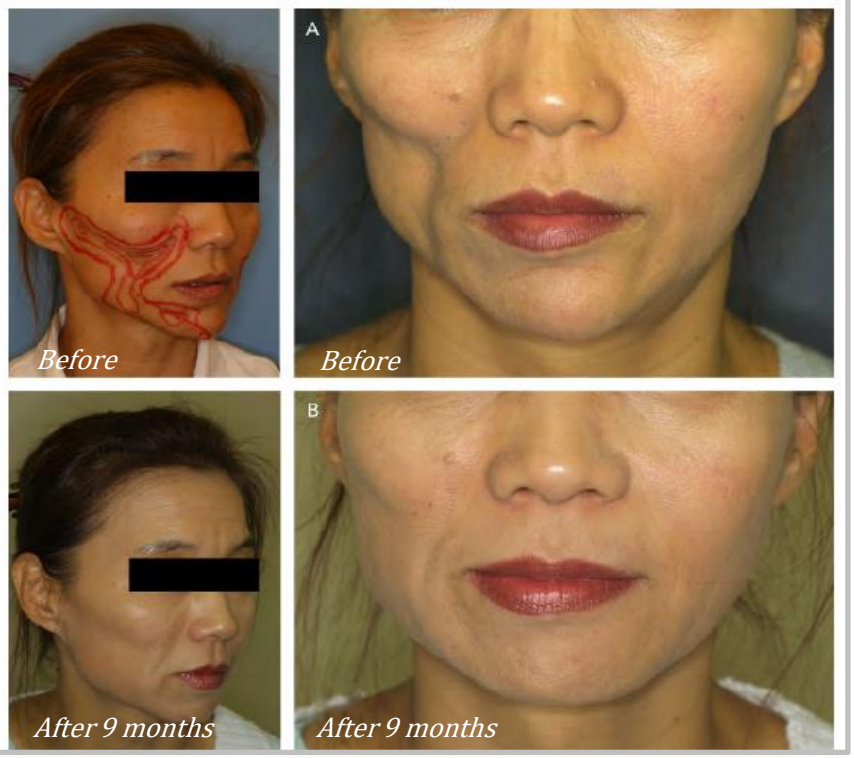
Clinical Result of CAL by Dr. Yoshimura

NON CAL



CAL



Background of Development

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Limitations of Previous ADSC Devices

- Even though there have been several ADSC isolation devices, there have been also many technical problems, for example, air contamination possibility, long isolation time, high consumable costs, and so on.

- To solve those problems and to develop an upgraded form from the previous devices, NeoGenesis Co., Ltd. has conducted extensive research work for many years.

Development of **UNISTATION™**

- NeoGenesis recruited research and marketing expertise in Adipose Derived Stem Cell field.
- NeoGenesis successfully developed a technique for preventing contamination possibility entirely.
- NeoGenesis successfully simplified the entire process of ADSC isolation with lowest consumable costs.
- NeoGenesis finally developed the simplest and most convenient ADSC isolation device ever, UNISTATION™.
- NeoGenesis added PRP, PRF isolation, and fat purification function to UNISTATION™.
- UNISTATION™ is just now developed to satisfy the very needs of many surgeons who have yearned for treating patients with various cell therapies.

With UNISTATION™, nothing is impossible!

NEOGENESIS
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Detailed Information

Composition

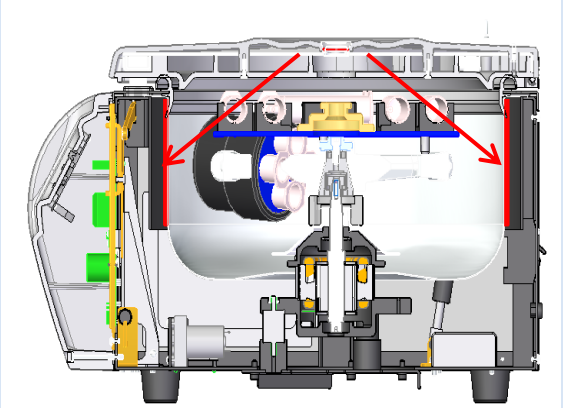
NEOGENESIS
Global Leader Enterprise of Autologous Cell Therapies

Centrifuge

High volume of 800cc at once

Incubator

Heat release for incubation from silicon heater

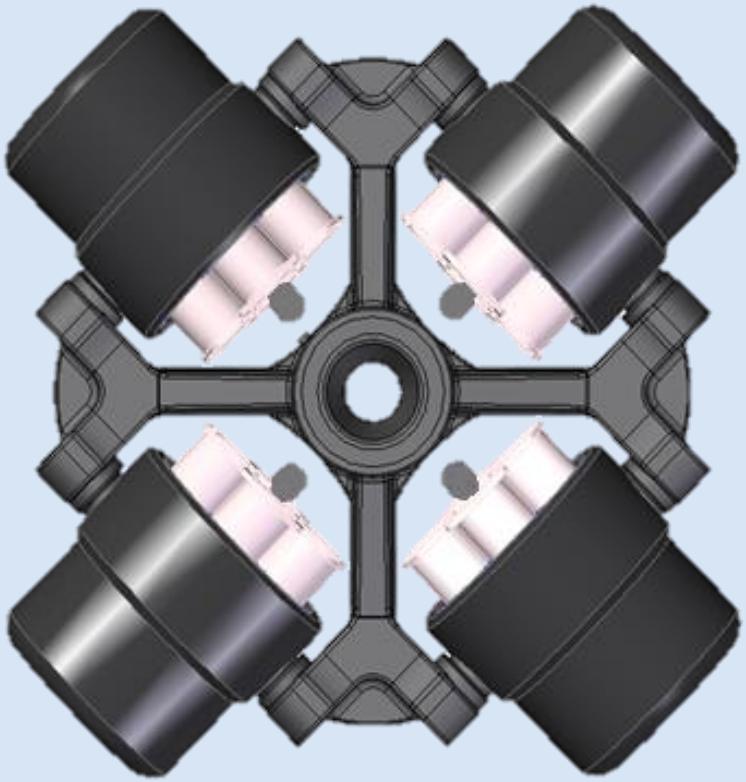


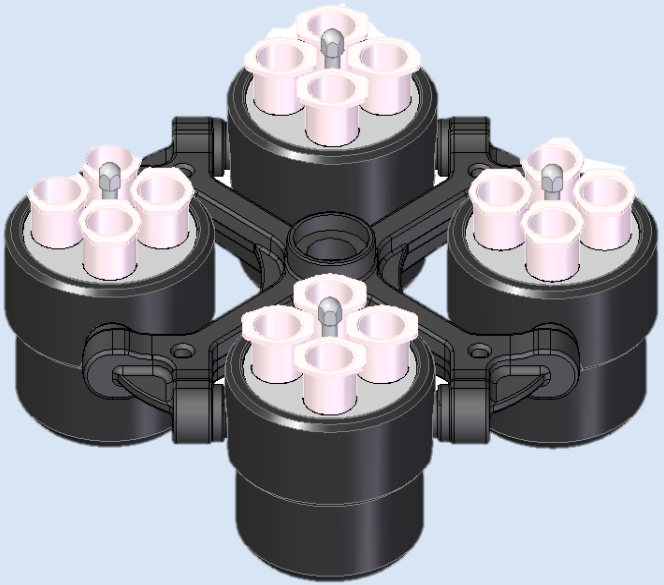
Shaker

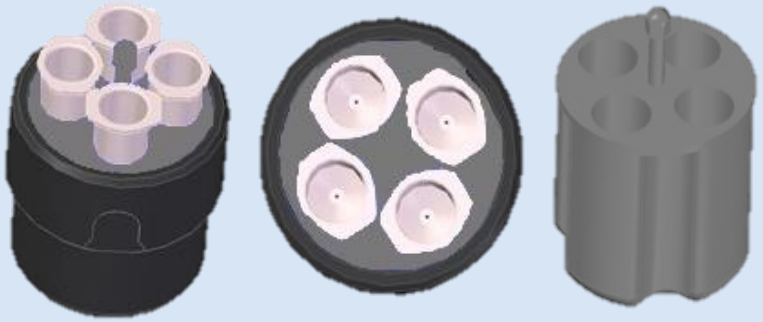
Shaking by spinning back and forth

Centrifuge & Incubator & Shaker in One Device
Smallest & Simplest system for stem cell isolation

Composition - Centrifuge







16 UNIKITs can be installed. (4 UNIKITs per 1 Bucket)

Maximum capacity for centrifugation

50cc X 16 UNIKITs = 800cc High Volume Process at Once

Composition - Incubator

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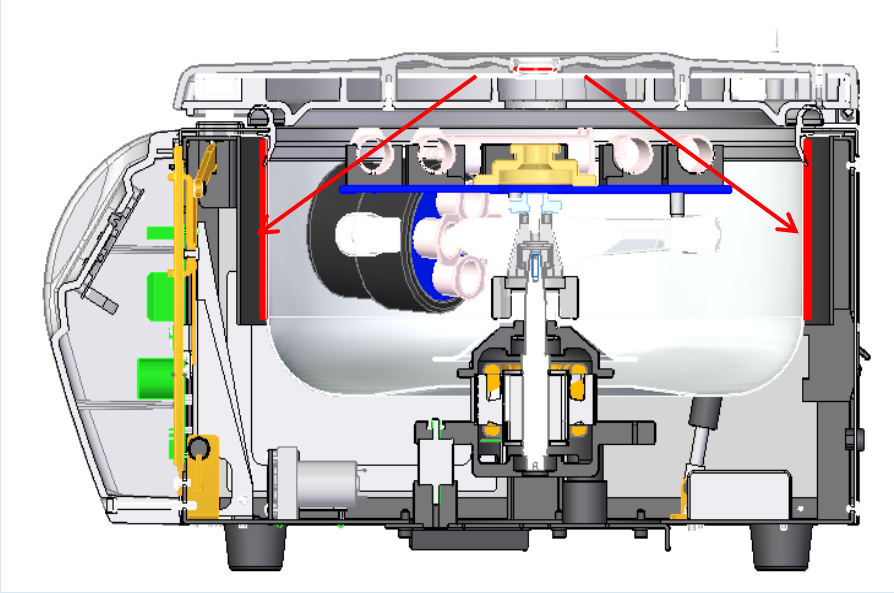
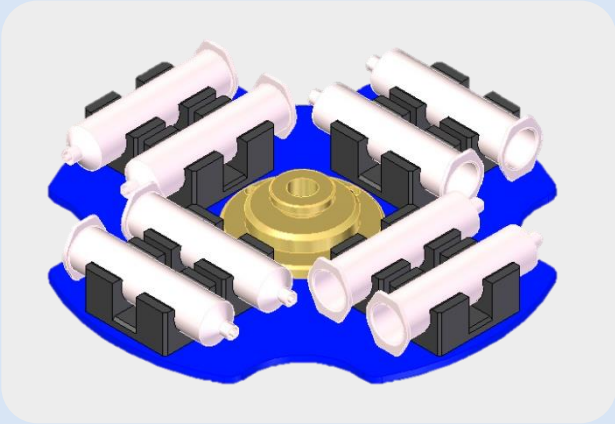
Heat Release for Incubation from Silicon Heater





With Silicon Incubator installed inside,
we keep the inner temp 37°C with the highest stability.

The most stable incubation system with SILICON INCUBATOR

Composition - Incubator

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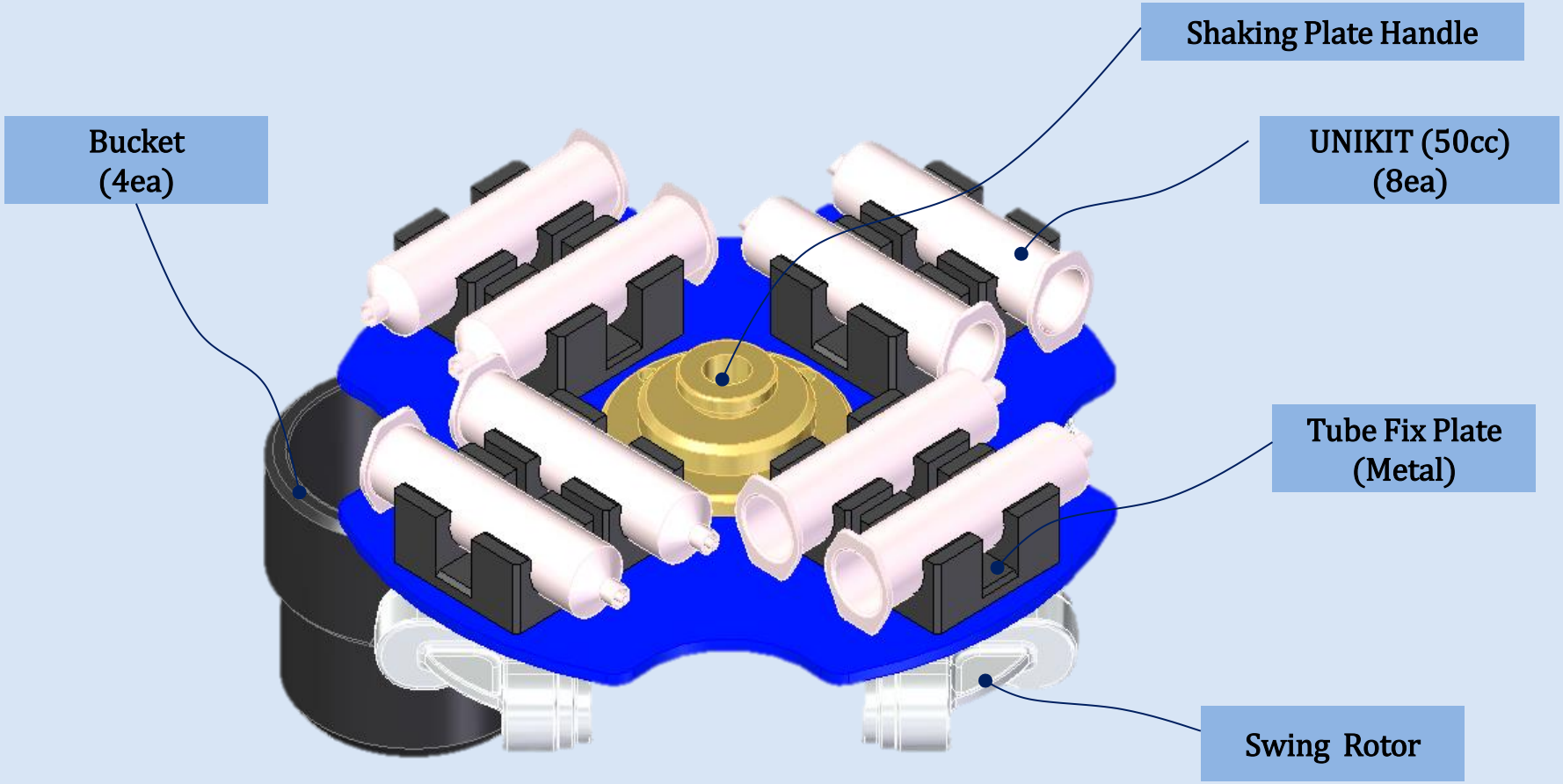

The most stable incubation system with SILICON INCUBATOR

Composition - Shaker

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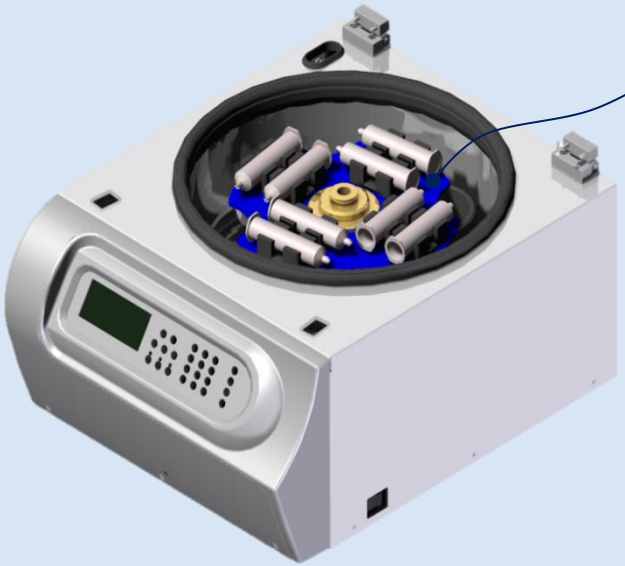


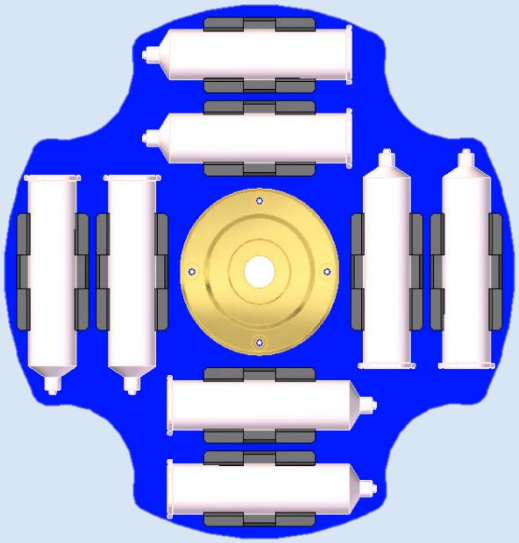
Image of Installed Shaking Plate

Motor spins back and forth so that UNIKITs can be shaken.

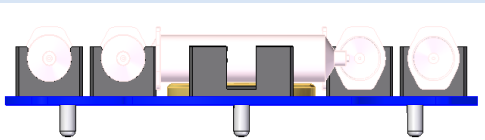
Locking System

1. For Safety – When electricity out, it keeps the plate safe

2. For Easier Use – Place anywhere without trying to find holes



Top View



Side View

The simplest Unified Shaking System

Composition - Display

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Global Leader Enterprise of Autologous Cell Therapies

■ Control Display

• Easy Touch Screen → Easy and Fast Order and Modification

• 10 Steps of Acceleration and Deceleration → Suitable for Research with Sensitive Separated Layers

• RPM/RCF Auto-Calculation

• Timer Modifiable during Working

• Up to 1 Hour 59 Minutes 59 Seconds Time Setting

• Memory Function (100 Memories)

• Temperature Control (Room Temp ~ 40C)

■ Safety

• Auto Alarm System

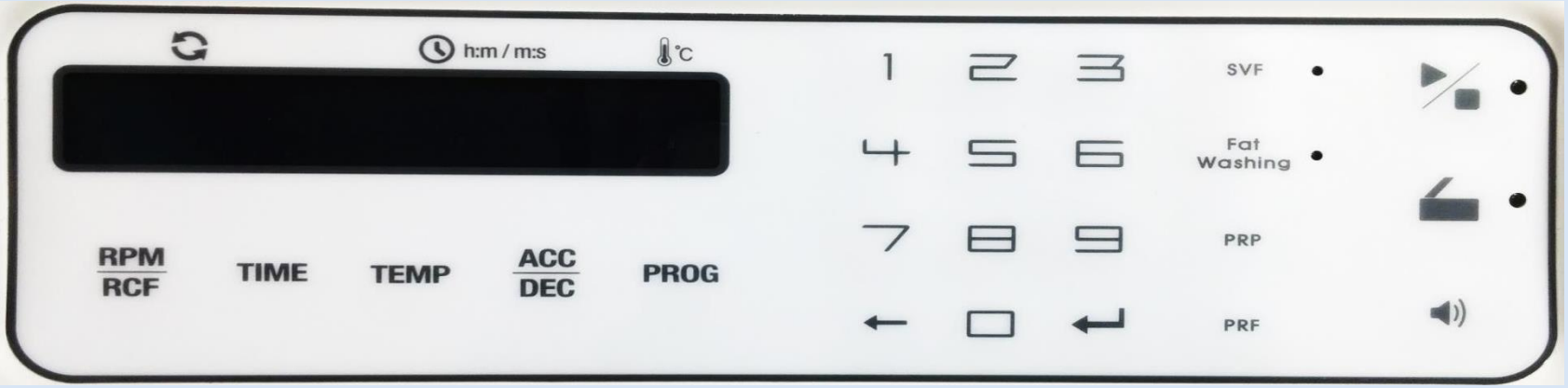
• Imbalance Sensor

• Door Lock Safety

• Second Door Function

• RPM Error Sensor

• Motor Overheat Sensor



The simplest One Button Protocol system & modern display

Composition - Display

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Waiting Display

Working Display: Screen displays which process its working on

A: SVF in process

B: Fat washing in process

C: PRP in process

D: PRF in process

** Deceleration
Step 0: Natural braking
Steps 1~8: Slow stop
Step 9: Fast stop

Specification

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Specifications of UNISTATION™	
Max. RPF/RCF (Swing out)	3,600 rpm / 2,898 xg
Max. Capacity (cc)	50cc x 4 x 4 (Total 800cc)
Temp. range (℃)	Room Temperature ~ +40℃
Pre-Warm Up Function	Yes (Set as A1 or A2)
Time control	different for each mode
RPM/RCF conversion	Yes
Noise level (dB)	≤60
Acc/Dec	9/10 steps
Program memory	100
Imbalance cutout	Yes
Display	Blue LCD
Safety lid lock	Yes

■ Features

- Angle & Swing Rotor
- Max 800ml (50ml UNIKITs x 4 holes x 4 buckets)
- The Most Compact Design
- Touch Screen Key Pad
- RPM/RCF Auto-Calculation
- 100 Protocol Memorization
- Separate Protocol Buttons for SVF, Fat, PRP, PRF each

Consumables & Accessories

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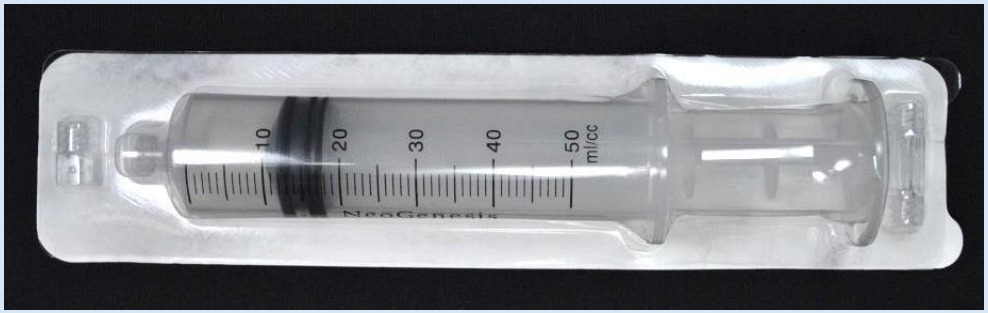
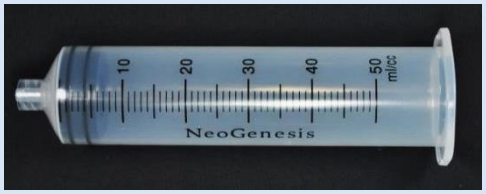


UNIKIT (Kit body, cap, transfer.)

**Each part of the kit
(UNIKIT, hand-piece, cap, transfer)
are 1 set

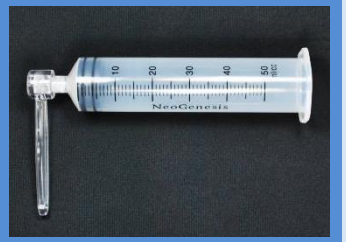


UNIKIT body

UNIKIT hand-piece

Cap

Transfer



Closure (Autoclavable)

**Used for closing cap or transferring

We provide Consumable kits at lowest consumable price.

Consumables & Accessories

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Various figures & sizes of buckets are available for other applications and experiments.

S750T-4B

TM96-4S

A100S-6

Consumables & Accessories

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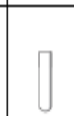
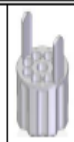
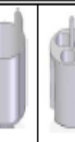
S500T- 4B No.12

Type	Swing Rotor ∠90°
Max. RPM	4,500 rpm
Max. RCF	4,392xg
Radius	194 mm
Dim.	262x262x62

B500	B500 Lid	TM96-4S
		
Round Bucket 500ml capacity	Sealing Cap	MicroTiter Plate rack

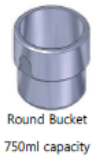
Tube Capacity (ml)	5	10	15	50	100(85ml)	250	500	50	15	MTP	
Dimensions Øx L mm	12x75	16x100	16x114	29x104	38x105.7	61.8x123	69.5x170.2	30x115	17x120		
Tube Type											
Adapter											
Tube per Adapter	9	9	9	4	1	1	1	3	7	-	
Tube per Rotor	36	36	36	16	4	4	4	12	28	4	
Max.RCF	4,256	4,279	4,290	4,290	4,290	4,290	4,347	4,302	4,313	3,486	
radius (mm)	188.0	189.0	189.5	189.5	189.5	189.5	192.0	190.0	190.5	154.0	
RPM	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,500	4,000	
boring Ø x L mm	13x64	17x64	16.5x85	30x85.5	38.5x84.5	62x100	73x101	30x90	17x95.5	-	
Color / Material	Green	Cyan	Khaki	Sky Blue	Brown	Violet	Chartreuse	Blue	Pink	-	
Cat.NO.	TR5-9	TR10-9	TR15-9	TR50-4	TR100-1	TR250-1	TR500-1	TR50-3C	TR15-7C	-	
Max. length Ø x L	13x150	17x151	16.5x151.5	30x151.5	38.5x151.5	62x151.5	73x154	30x152	17x152.5	-	

Combi 514R
Max. RPM : 4,500 Max. RCF : 4,392 xg

Combi 408
Max. RPM : 4,000 Max. RCF : 3,470 xg

S750T - 4B No.13

Type	Swing Rotor ∠90°
Max. RPM	4,000 rpm
Max. RCF	3,515 x g
Radius	196.5 mm
Dim.	277x277x55

B750	B750 Lid	TM96-4S
		
Round Bucket 750ml capacity	Sealing Cap	Micro Titer Plate rack

Tube Capacity (ml)	5	10	15	50	250	500	750	50	15	50	MTP
Dimensions Øx L mm	12x75	13x100	16x114	29x104	61.8x123	69.5x170.2	97x152	30x115	17x120		
Tube Type											
Adapter											
Tube per Adapter	26	26	19	7	1	1	-	5	14	5	-
Tube per Rotor	104	104	76	28	4	4	4	20	56	20	4
Max.RCF	3,433	3,417	3,438	3,288	3,463	3,458	3,515	3,452	3,413	3,336	2,925
radius (mm)	191.9	191.0	192.2	183.8	193.6	193.3	196.5	193.0	190.8	186.5	163.5
RPM	4,000	4,000	4,000	4,000	4,000	4,000	4,000	4,000	4,000	4,000	4,000
boring Ø x L mm	13x70	14x89.5	17x99.5	29.2x81	62.2x99	75.5x99	99x105	29.5x99.5	17x89	27x65	-
Color / Material	Magenta	Yellow	Green	White	Cyan	Violet	-	Blue	Sky Blue	Black	-
Cat.NO.	T5-26	T10-26	T15-19	T50-7	T250-1	T500-1	-	T50-5C	T15-14C	TS50-5	-
Max. length Ø x L	13x153.5	14x152.5	17x151	29.2x145	62.2x155	75.5x 55	99x158	29.5x146.5	17x152	27x90	-
Adapter											
Tube per Adapter	30	24	17	4	1	1					
Tube per Rotor	120	29	68	16	4	4					
Max.RCF	3,336	3,336	3,336	3,336	3,336	3,336					
radius (mm)	186.5	186.5	186.5	186.5	186.5	186.5					
RPM	4,000	4,000	4,000	4,000	4,000	4,000					
boring Ø x L mm	13 x 55	13.5 x 80	17.3 x 80	29 x 80	62 x 80	74 x 80					
Color / Material	Crimson	Yellow	Green	White	Red	Blue					
Cat.NO.	T5-30	T10-24	T15-17	T50-4	T250-1	T500-1					
Max. length Ø x L	13x148	13.5x148	17.3x148	29x148	62x148	74x148					

Combi 514R
Max. RPM : 4,000 Max. RCF : 3,515 xg

Combi 408
Max. RPM : 4,000 Max. RCF : 3,515 xg

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Protocols

SVF (Stem Cell) Isolation Protocol

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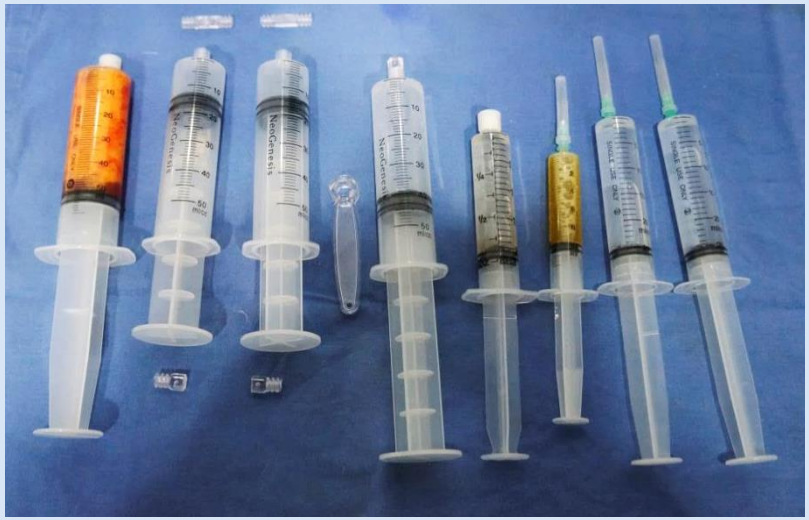
Preparations for CAL surgery



UNISTATION™ - 1
UNIKIT – 3
Closer – 1
40ml Suctioned fat – 1
20ml Collagenase – 1
5ml Patient's serum – 1
30ml Normal Saline - 1

We provide the most
reasonable consumable price

SVF (Stem Cell) Isolation Protocol

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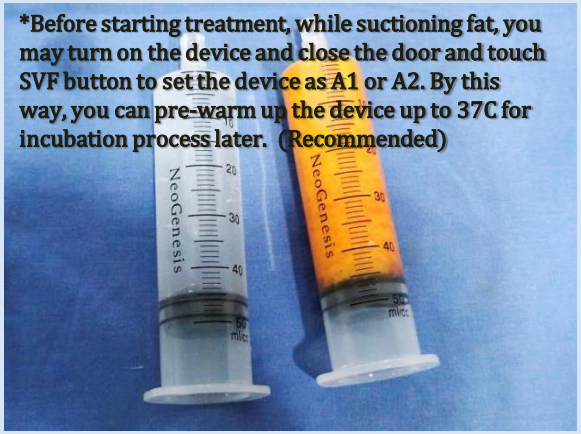
Step 1 : Fat Washing (A1)

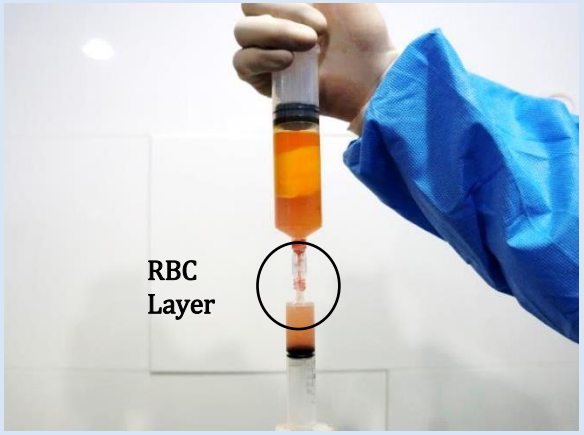


1. Suctioned fat (40ml) and water for balance (40ml) in UNIKIT

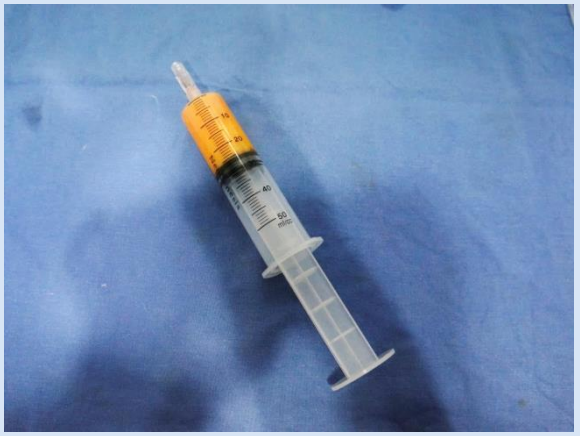
2. Put them in UNISTATION™ centrifuge

3. Touch SVF button once (Display shows A1)

4. Touch start button if A1 is shown



5. After centrifugation, remove RBC layer at the bottom and keep only pure fat



6. 20ml pure fat after removing RBC layer

SVF (Stem Cell) Isolation Protocol

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Step 2 : Collagenase Digestion (A2)

1. Prepare 20ml of 0.1% Collagenase Solution

2. Transfer the Collagenase Solution into the pure fat

3. Place Shaking Plate and put the pure fat with collagenase on it and close the door

4. Touch SVF button once again (Display shows A2)

5. Touch Start button if A2 is shown

6. Wait for 30 min for shaking incubation and take the fat out after finishing shaking incubation

SVF (Stem Cell) Isolation Protocol

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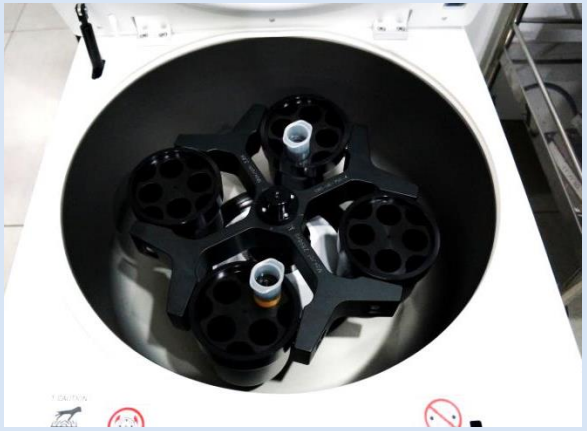
Step 3 : SVF Collection (A3)



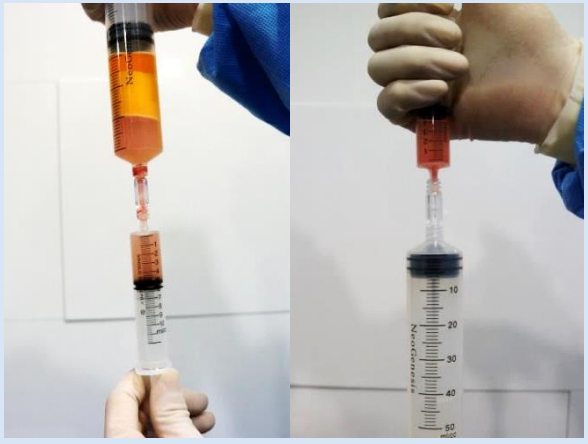
1. Put the fat in UNISTATION™ centrifuge

2. Touch SVF button once again (Display shows A3)

3. Touch start button if A3 is shown

4. After centrifugation, take out UNIKIT very slowly so that layers don't get mixed. (Stem cells are at the bottom within 5ml SVF)

5. Before removing cap, pull the hand piece upwards slightly so that stem cells doesn't stay in the cap. Slightly pull so that measurement marking stays under 1ml . *The same should be done after centrifugation steps of A3 and A4.



6. Open the cap and use transfer to connect the Unikit to syringe to extract bottom 5ml of stem cell. Transfer the 5ml to new unikit.

SVF (Stem Cell) Isolation Protocol

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Step 4 : Neutralization and washing of SVF (A4)

1. Transfer 5ml PPP into the 5ml SVF

2. Transfer 30ml normal saline into the 10ml of SVF and PPP

3. Put in UNISTATION™ centrifuge

4. Touch SVF button once again
(Display shows A4)

5. Touch start button if A4 is shown

6. After centrifuation, transfer 5ml SVF at the bottom into 5ml or 10ml syringe

SVF (Stem Cell) Isolation Protocol

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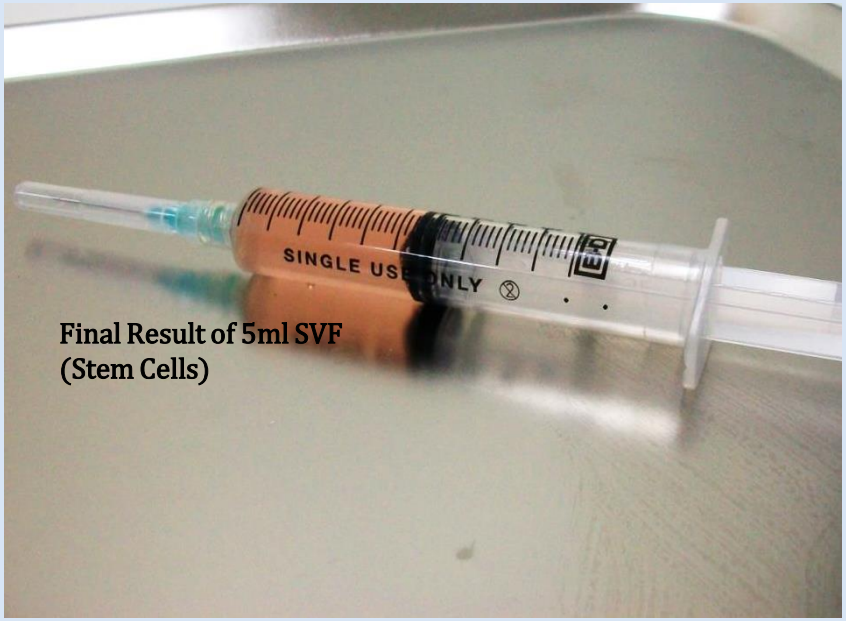
Preparation for injection



Final Result of 5ml SVF
(Stem Cells)

Transfer the final result of 5ml SVF into the 20ml pure fat for injection.
Inject stem cell rich fat to the treatment area.
(For IV injection, cell strainer must be used before injection.)

SVF (Stem Cell) Isolation Protocol

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Training videos

Youtube Link of SVF / ADSC Isolation Video

http://youtu.be/Cpoz-8f_qAw

Download Link of SVF / ADSC Isolation Video

https://docs.google.com/a/neogenesis.co.kr/file/d/0Bznemsb5skHkdkpESlVSeTMxNnc/edit

Youku Link of SVF / ADSC Isolation Video (Chinese)

http://v.youku.com/v_show/id_XODI0MjU2Njc2.html

SVF (Stem Cell) Pictures & Counting

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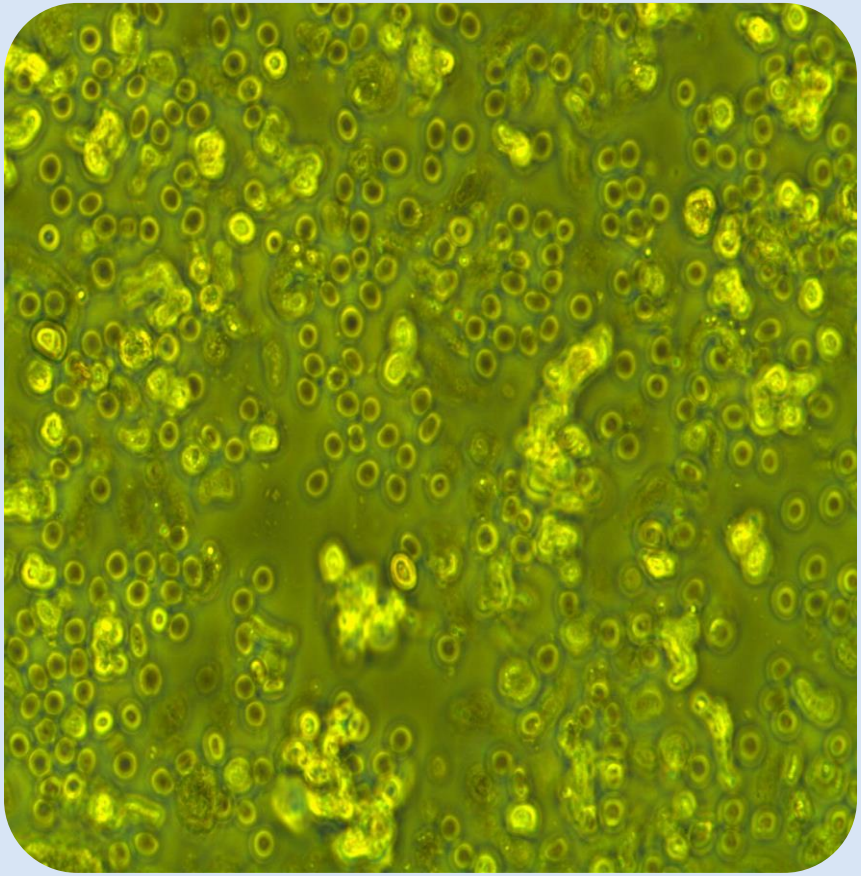
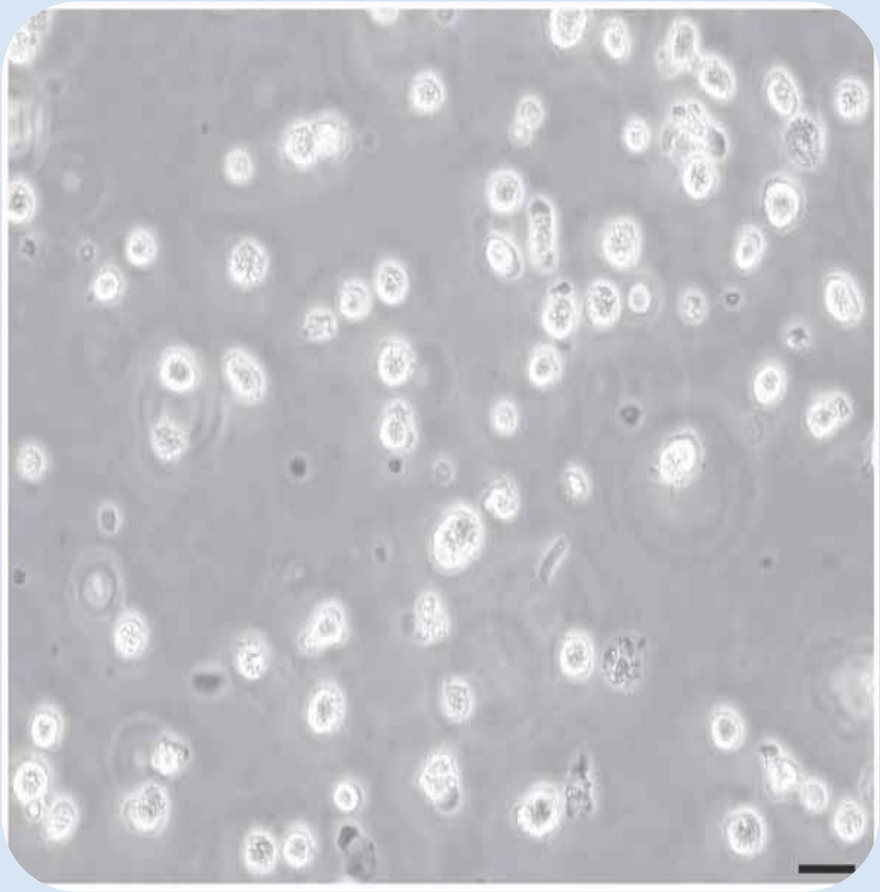


ADSC for clinical use (SVF)
-Fluorescent color



Purified ADSC after RBC lysis

SVF (Stem Cell) Pictures & Counting

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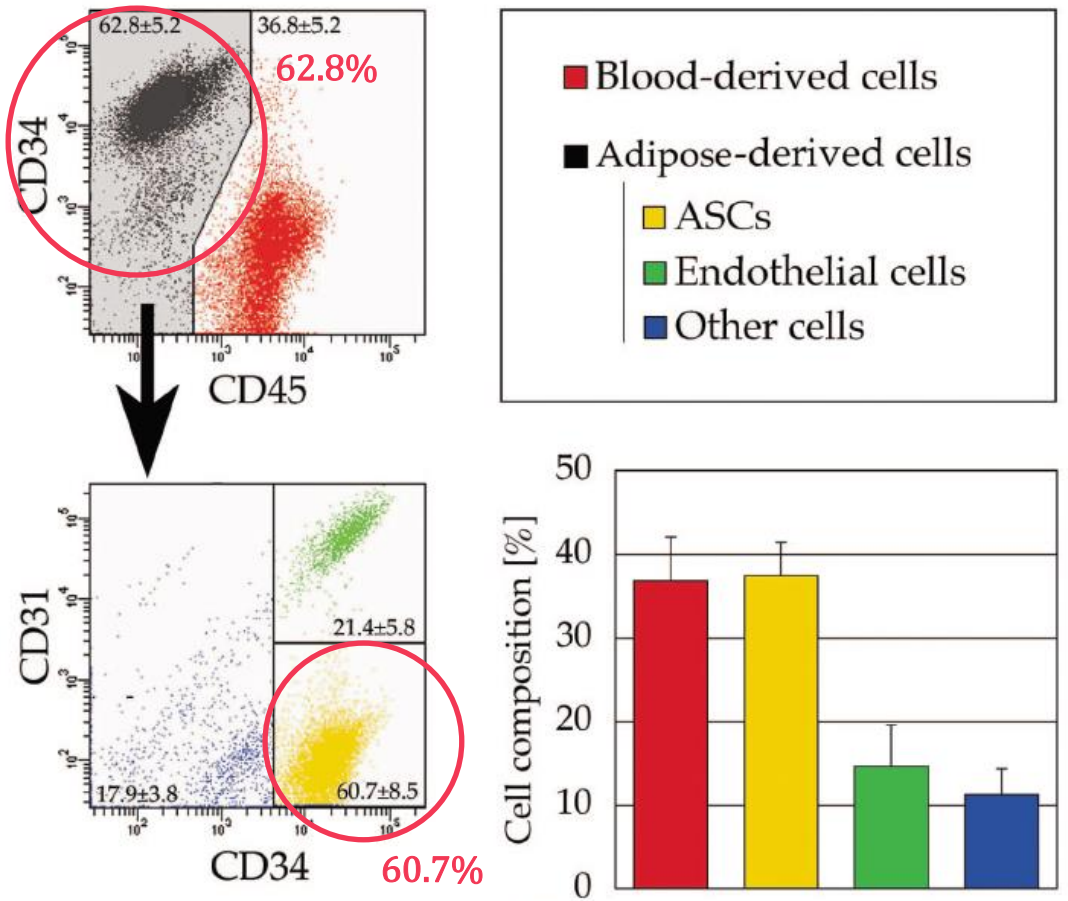

Fig. 9. Multicolor flow cytometric analysis of cells in the bottom layer. CD45$^+$ cells were regarded as blood-derived cells. CD45$^-$ cells were regarded as adipose-derived cells and were processed to the next analysis. CD45$^-$CD31$^-$CD34$^+$ cells were regarded as adipose-derived stem/stromal cells (*ASCs*), whereas CD45$^-$CD31$^+$CD34$^+$ cells were regarded as endothelial cells.

*Reference: *Plast. Reconstr. Surg.* 122: 111, 2008.

- **Cell Proportion in SVF**

1. Blood Derived Cells (CD45+) = 36.8%±5.2
2. Adipose Derived Cells (CD45-) = 62.8%±5.2

- **Stem Cell Proportion in Adipose Derived Cells**

  - Adipose Derived Stem Cells (CD45-, CD31-, CD34+) in Adipose Derived Cells = 60.7%±8.5

- **The Ratio of ADSCs in SVF**

  62.8% X 60.7% = 38.1%

- **The Ratio of ADSCs in SVF after RBC Lysis**

  = 60.7%

The ratio of ADSC cells in SVF cells

62.8% X 60.7% = 38.1%

The ratio of ADSC cells in SVF cells after RBC lysis =60.7%

SVF (Stem Cell) Pictures & Counting

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Comparison of cell counting with other products

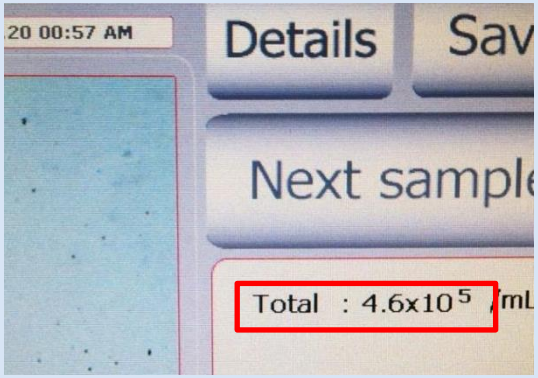

Table 1. Yield and viability of cells isolated by the Celution™ system

Lot number	Yield (cells/ adipose mL)	Viability (%)	Adipose volume (mL)
1	241 800	85.0	50.0
2	449 500	90.0	50.0
3	278 471	88.0	121.0
4	189 000	80.6	55.0
5	380 586	89.7	145.0
6	231 701	86.0	97.0
Average	295 176	86.6	
SD	99 540	3.5	

Comparison of cell counting with other products

	UNISTATION™ (n = 1)	CHA-STATION (n = 2)	Multi Station (n = 1)	Cellution (n = 6)
SVF cells (per adipose 1cc)	460,000	300,000	350,000	295,176
ADSC cells (per adipose 1cc)	287,274 (n=10)	180,000	210,000	177,105
Viability (%)	90.1%	85.1%	90.0%	86.6%

- 62.2% higher number of ADSC compared to Cytori
- 45.8% higher number of ADSC compared to CHA-Station
- 36.8% higher number of ADSC compared to Multi-Station

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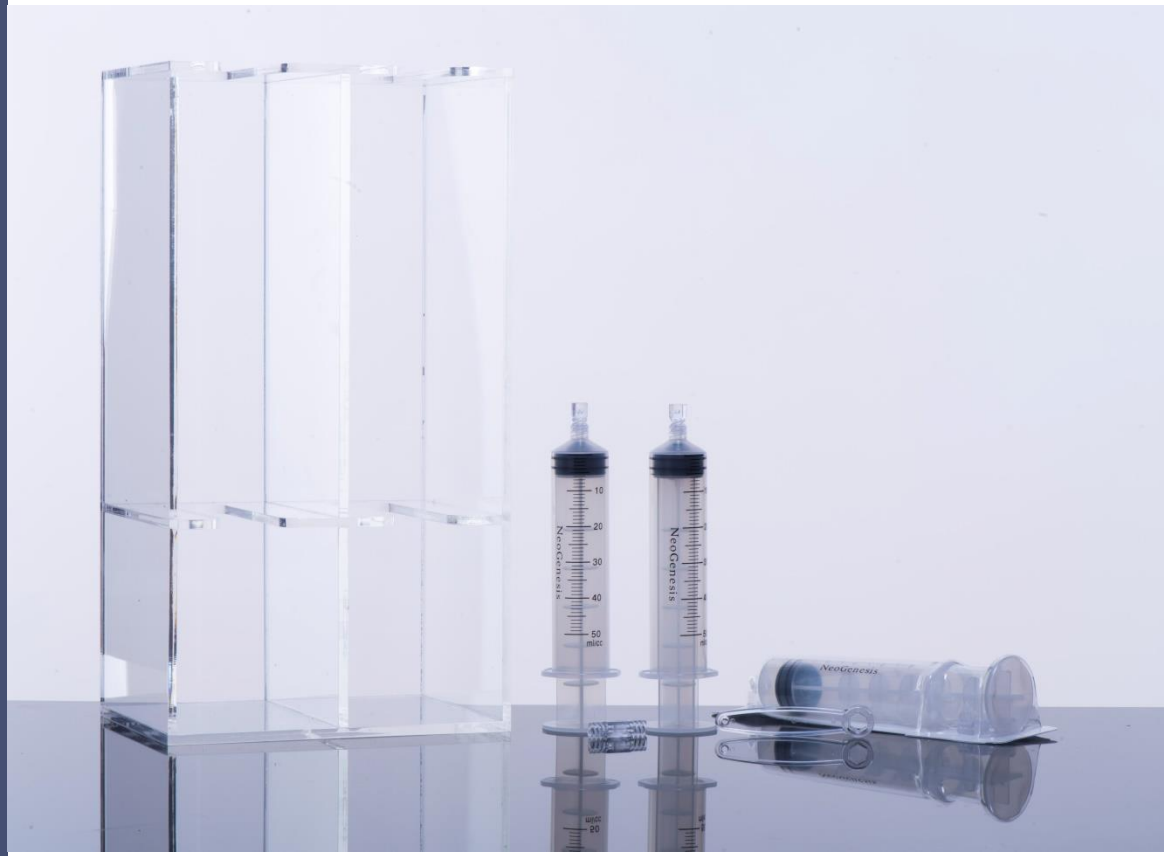
Comparison & Reference



Comparison Study

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	UNISTATION™ - NeoGenesis	CHA-STATION	Multi Station	Sceldis (HuriCell)	Celution-Cytori	Tissue Genesis Cell Isolation System-TGI
Separation Time	50 min	50 min	120 min	90 min	90 min	60 min
Automatic / Manual	Semi Automatic	Semi Automatic	Manual	Automatic	Automatic	Automatic
Closed Type (Contamination Prevention)	O	O	X	O	O	O
Weight (Approximate)	70Kg	150Kg	200Kg	150Kg	70Kg	50Kg
Demo Possibility	O	X	X	X	O	O
Cell Counting Function	X	O	X	X	X	X
Max Volume	800cc	160cc	400cc	150cc	400cc	60cc
Price (Approximate)		USD 66,000	USD 40,000	USD 66,000	USD 150,000	USD 150,000
Consumable Price (One Set for One Time Operation, Approximate)	USD 150	USD 200	USD 100	USD 500	USD 2,000-11,000	USD 5,000
Good Things to Consider	Easy to Use / Low Consumable Price / Small Size / High Volume	Easy to Use / Cell Counting Function	High Volume / Low Consumable Price	Automatic	Automatic / High Volume	Automatic
Bad Things to Consider		Too Large / Small Volume / Low Durability	Contamination Possibility / Hard to Use / Too Large	Low Volume / Frequent A/S / Animal Enzyme Use / High Consumable Price	Expensive Consumable Price / Expensive Device Price / No Registration	Expensive Consumable Price / Expensive Device Price / No Registration / Low Volume
Customer Satisfaction	★★★★★	★★★★	★★★	★★★	★★	★★

**Red Colored means comparatively better than competitors*

References

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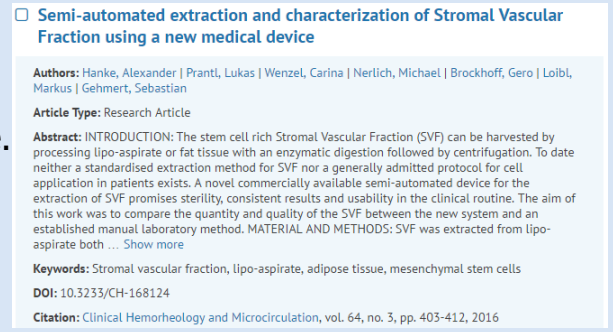
Semi-automated extraction and characterization of Stromal Vascular Fraction using a new medical device. -Clinical Hemorheology and Microcirculation, vo. 64, no. 3, pp. 403-412, 2016

Abstract:

INTRODUCTION: A novel commercially available semi-automated device for the extraction of SVF promises sterility, consistent results and usability in the clinical routine. The aim of this work was to compare the quantity and quality of the SVF between the new system and an established manual laboratory method.

MATERIAL AND METHODS: SVF was extracted from lipo-aspirate both by a prototype of the semi-automated **UNiStation™ (NeoGenesis, Seoul, Korea)** and by hand preparation with common laboratory equipment. Cell composition of the SVF was characterized by multi-parametric flow-cytometry (FACSCanto-II, BD Biosciences). The total cell number (quantity) of the SVF was determined as well the percentage of cells expressing the stem cell marker CD34, the leucocyte marker CD45 and the marker CD271 for highly proliferative stem cells (quality).

DISCUSSION: **The semi-automated closed system provides a considerable amount of sterile SVF with high reproducibility.** Furthermore, the SVF extracted by both methods showed a similar cell composition which is in accordance with the data from literature. This semi-automated device offers an opportunity to take research and application of the SVF one step further to the clinic.



Semi-automated extraction and characterization of Stromal Vascular Fraction using a new medical device

Authors: Hanke, Alexander | Prantl, Lukas | Wenzel, Carina | Nerlich, Michael | Brockhoff, Gero | Loibl, Markus | Gehmert, Sebastian

Article Type: Research Article

Abstract: INTRODUCTION: The stem cell rich Stromal Vascular Fraction (SVF) can be harvested by processing lipo-aspirate or fat tissue with an enzymatic digestion followed by centrifugation. To date neither a standardised extraction method for SVF nor a generally admitted protocol for cell application in patients exists. A novel commercially available semi-automated device for the extraction of SVF promises sterility, consistent results and usability in the clinical routine. The aim of this work was to compare the quantity and quality of the SVF between the new system and an established manual laboratory method. MATERIAL AND METHODS: SVF was extracted from lipo-aspirate both … Show more

Keywords: Stromal vascular fraction, lipo-aspirate, adipose tissue, mesenchymal stem cells

DOI: 10.3233/CH-168124

Citation: Clinical Hemorheology and Microcirculation, vol. 64, no. 3, pp. 403-412, 2016

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(7) A Hanke et al. Semi-automated extraction and characterization of Stromal Vascular Fraction using a new medical device. Clin Hemorheol Microcirc 64 (3), 403-412. 2016.

Thank you

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Address. #302, 146, Seonyu-ro, E&C Dream Tower,
Yeongdeungpo-gu, Seoul, South Korea (07255)
Tel. +82-2-583-1348
Fax. +82-2-2038-0848
Email. info@neogenesis.co.kr
Homepage. www.neogenesis.co.kr

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LUNA-STEM™

Dual Fluorescence Cell Counter

LUNA-STEM™

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LUNA-STEM™

Advanced
Dual fluorescence optics

Fast
Images generated from three channels in 30-60 s

Accurate
Distinguishes nucleated and non-nucleated cells

Convenient
East-to-use software with a simple counting procedure

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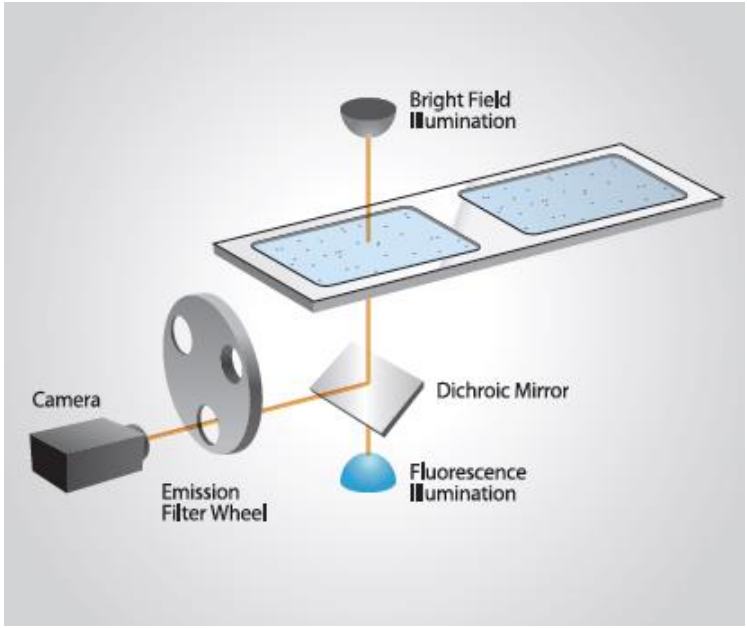
LUNA-STEM™

Dual Fluorescence + Bright Field Optics

The LUNA-STEM™ is a quantum leap forward for automated cell counting and viability analysis. Using Acridine Orange (AO) and Propidium Iodide (PI) to stain live and dead cells, respectively, the LUNA-STEM™ provides highly sensitive and accurate results for most cell types, including stem cells and SVF cells.

The various cells within the SVF can be recognized and counted as non-nucleated cells or live and dead nucleated cells, which is not possible with other cell counters.



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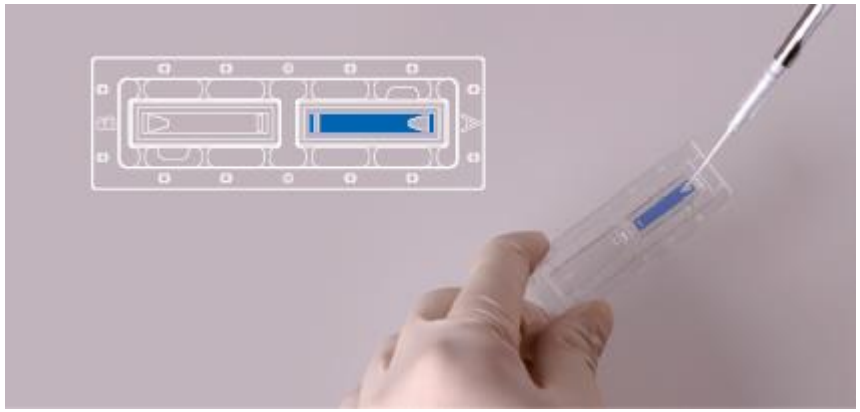
LUNA-STEM™

PhotonSlide™

The PhotonSlide™ has been developed to have ultra-low autofluorescence. Its patented precision chamber has a height that allows for the even distribution of cells throughout the counting chamber.



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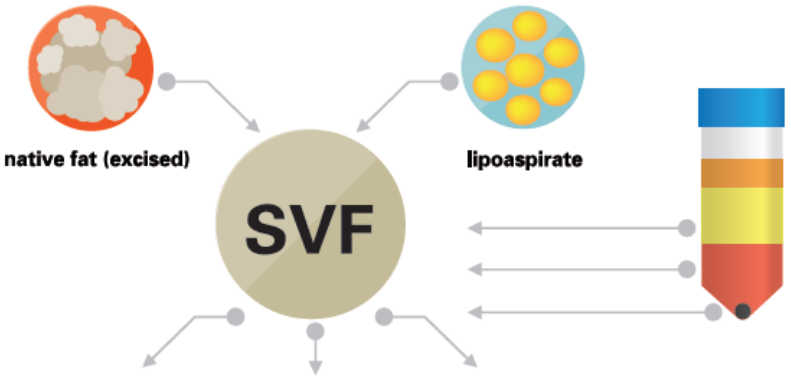
LUNASTEM™

Nucleated & Non-Nucleated Cell Analysis

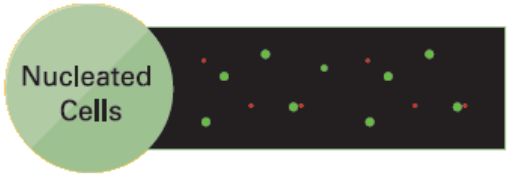


mature	genitors	stem
Adipocytes	Endothelial Progenitor Cells (EPC)	Mesenchymal Stromal Cells (MSC)
Fibroblasts	Preadipocytes	Hematopoietic Stem Cells (HSC)
Smooth Muscle Cells	Vascular Progenitors	
Endothelial Cells	Hematopoietic Progenitors	
Blood Cells		

Nucleated

RBCs
ECM
Microvascular elements
Noncellular objects

Non-Nucleated



- Live cells – AO positive (green)
- Dead cells – PI positive (red)

- Cells – AO/PI negative

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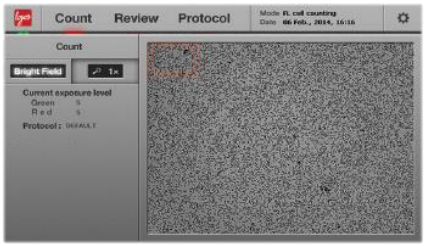
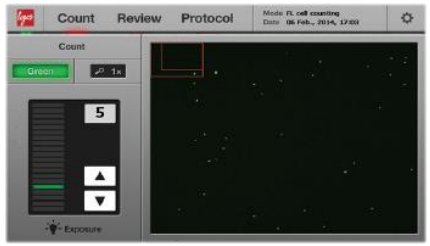
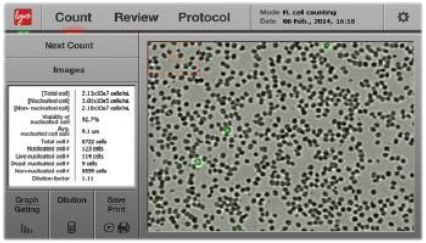
LUNA-STEM™







Interactive Softwar Interface

Powerful On-Board Analysis

Built-in software automatically generates cell viability data upon cell counting. For validation purposes, live and dead cells are tagged with green and red circles, respectively.

Image Overlay

Images are captured from three channels (brightfield, green, and red) and can be merged directly on the screen. The brightness of each color can be adjusted individually for accurate detection. All images can be saved to an external USB drive.

Data Report

Data can be exported as a PDF report or CSV file. The LUNA-STEM™ generates comprehensive PDF reports complete with the cell count and viability data, cell images, and relevant histograms.

Luna™ Printer

The results of each count may be printed out immediately with the LUNA™ printer.

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LUNA-STEM™

Specifications

Sample Volume	10 µL
Cell Counting Time	30 - 60 sec (depending on sample conditions)
Cell Concentration Range	5×10^4 - 2×10^7 cells/mL(optimal range)
Cell Size Range	Detectable Range: 1 - 90 µm Optimal Range: 5 - 60 µm
Excitation wavelength	470 ±20 nm
Emission wavelength	530 ±25 nm, 600 nm (LP)
Light Source	LED
Image Resolution	5 MP
LCD Display	7 inches (800 x 480 pixels)
Dimensions (W×D×H)	22 × 21 × 9 cm (8.6 × 8.3 × 3.5 inch)
Weight	1.8 kg (4 lb) *without the AC adaptor

Ordering Information

Cat #	Product	Quantity
L30001	LUNA-STEM™ Automated Fluorescence Cell Counter	1 unit
L12005	PhotonSlide™, 50 Slides	1 box
L12006	PhotonSlide™, 500 Slides	10 box
L12007	PhotonSlide™, 1000 Slides	20 box
F23102	LUNA™ Fluorescence Calibration Beads	1 x 0.5 mL
F23001	Acridine Orange/Propidium Iodide (AO/PI) Stain	2 x 0.5 mL
F23002	Acridine Orange (AO) Stain	2 x 0.5 mL
F23003	Propidium Iodide (PI) Stain	2 x 0.5 mL
F23212	Cell Dilution Buffer	5 x 20 mL
P10001	LUNA™ Printer	1 unit
P10002	LUNA™ Printer Paper - thermal, 700 prints	3 x 2 rolls
P13001	LUNA™ Printer Cleaning Pen	1 unit
U10004	USB Drive, 4 GB	1 unit

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Address. #302, 146, Seonyu-ro, E&C Dream Tower,
Yeongdeungpo-gu, Seoul, South Korea (07255)
Tel. +82-2-583-1348
Fax. +82-2-2038-0848
Email. info@neogenesis.co.kr
Homepage. www.neogenesis.co.kr

Genesis PRP

The Simplest and Easiest Way to Collect
the Most Concentrated PRP (Platelet Rich Plasma)

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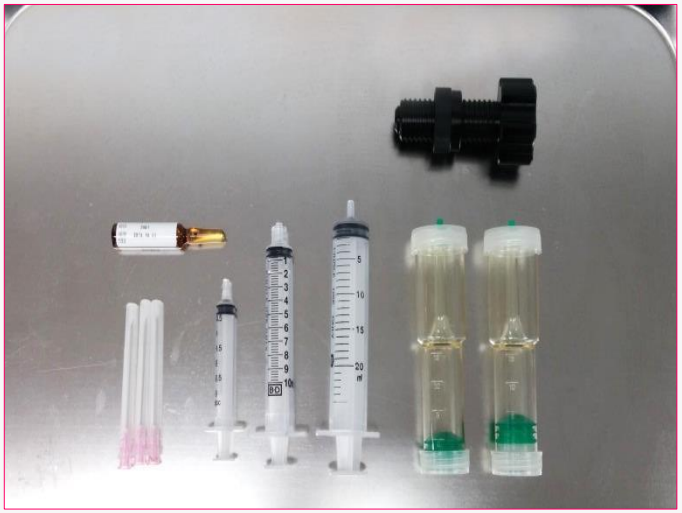
Genesis PRP

Special Features of Genesis PRP

- Transparent cylindrical kit allows a **clear visibility** and easier extraction
- The **curved neck** design reduces the possible cell loss
- PRP and PPP can be extracted from a **single kit** by **one-time centrifugation**
- High concentration rate of Platelets (about **13** times)
- Does **not** use a **needle** when collecting PRP or PPP
- Can **control** the volume of **Plasma** according to the treatment plan
- **Closed system** to prevent from air contamination possibility
- Always yields the **maximum** amount or PRP regardless of the operator's skill
- **Compatible** with any swing type centrifuge
- **Competitive** price

Genesis PRP

Instruction Manual of Genesis PRP – Preparation



❖ The following accessories do not come with Genesis PRP kits.
❖ The size of syringes can vary according to the user's preference.

- Needle (3ea)
- Anti-coagulant (1ea)
- 3cc syringe for PRP extraction (1ea)
- 10cc syringe for PPP extraction (1ea)
- 20cc syringe for drawing blood (1ea)
- Genesis PRP kit (1ea)
- A tube for balancing Centrifuge (1ea)
- Buffy controller (1ea)

1) Collect **1.5cc of anti-coagulant** into a syringe

2) Using a different needle, draw **15cc of patient's blood** into the same syringe and gently invert the syringe.

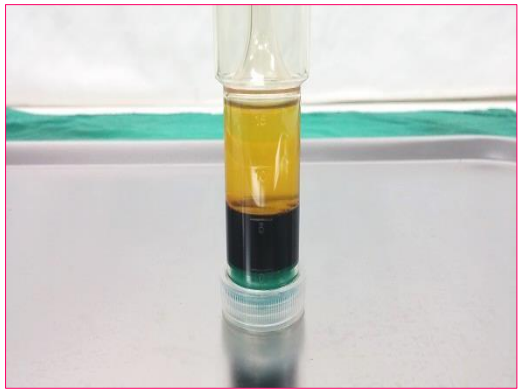
Genesis PRP

Instruction Manual of Genesis PRP – PRP & PPP Extraction

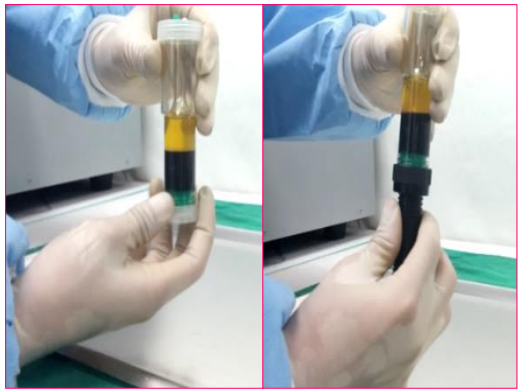
1) Inject the prepared blood into the kit by using an 18 gauge needle.

2) Place another Genesis PRP kit (or any kind of tube is fine) filled with water/saline in the same weight to balance the centrifuge .

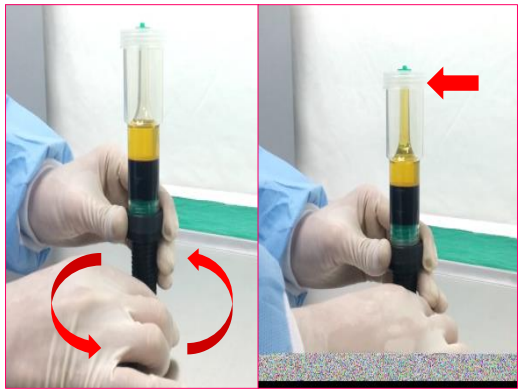
3) Centrifuge the kits at **1700G (RCF) for 5 minutes**, or press the "PRP" button in UNiStation; it will automatically centrifuge the kits at 3,000 rpm for 5 minutes.



4) Results divided into 3 different layers



5) Replace the bottom cap of the kit with Buffy controller's cap, and assemble the pusher.

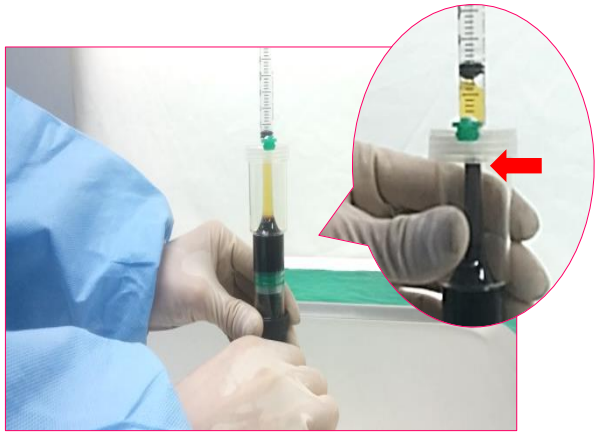


6) Turn the bottom of the Buffy controller counterclockwise until Plasma reaches the top.

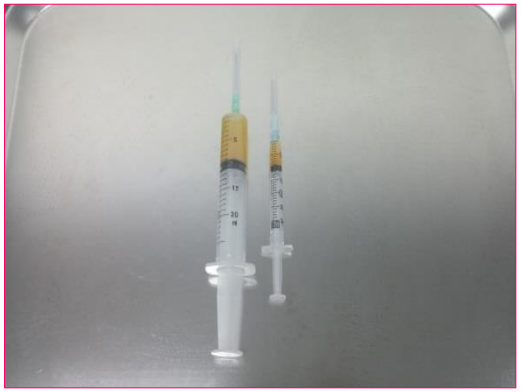
Genesis PRP

Instruction Manual of Genesis PRP – PRP & PPP Extraction

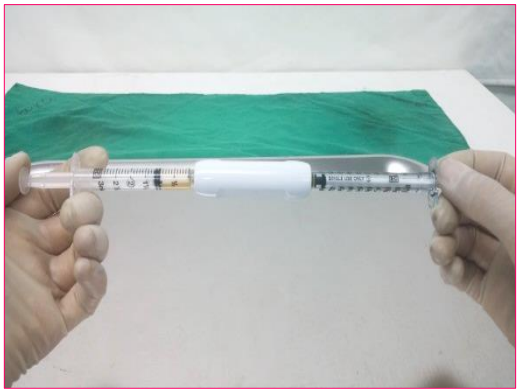
7) Connect a **PPP** collecting syringe, and rotate the controller until the RBC layer reaches the "**1.0**" line on the kit.



8) Connect a **PRP** collecting syringe, and rotate the pusher until the RBC layer reaches the top.



9) PPP (left) and PRP (right) extraction finished.



10) PRP activation is possible with NeoGenesis' **PRP Activation Kit**

If PPP extraction is not necessary, keep turning the controller without connecting a syringe so that Plasma can overflow into the empty space, and then connect the PRP collecting syringe and extract as much PRP as needed.

Genesis PRP

Training videos

Youtube Link of Genesis PRP Manual Video

http://youtu.be/494YeLv6mZE

Download Link of Genesis PRP Manual Video

https://drive.google.com/file/d/0BwNSediveEuBbop6MWhoNGpxVnM/edit?usp=sharing

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Address: #302, 146, Seonyu-ro, E&C Dream Tower, Yeongdeungpo-gu, Seoul, South Korea (07255)
Tel: +82-2-583-1348 **Fax**: +82-2-2038-0848
Email: info@neogenesis.co.kr
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