StromaCell[™] Mechanical Cell Separation



- Autologous
- Point-of-Care
- Minimal Manipulation

StromaCell[™] is a single-use collection and centrifugation canister, used for the rapid preparation of an autologous nucleated cell concentrate from a sample of lipoaspirate at the patient's point of care.



StromaCell

StromaCell[™] was developed by MicroAire Aesthetics to provide surgeons with an affordable and simple method for concentrating nucleated cells from adipose tissue without enzymatic digestion.

For many years, researchers and physicians have known that it's possible to obtain a viable and therapeutic stromal-vascular fraction (SVF) from adipose tissue merely by centrifuging the tissue.^{1, 2} The problem was extracting only the precise layer of concentrated nucleated cells from within the tube after centrifugation. Until now, a cannula had to be inserted down into the density stacked tissue in the tube to manually remove the desired layers, involving fuss, mess and guesswork.

StromaCell[™] was created to solve this problem. Simply put, StromaCell[™] is a well-designed and patentpending new type of centrifuge canister, in which the concentrated nucleated cells are isolated inside of a special chamber for easy extraction directly into a Luer syringe.

The single-use canister maintains a closed and sterile environment to collect up to 500ml of lipoaspirate, inline, during a typical liposuction case. The collected tissue is spun at 1000xg for ten minutes to concentrate the nucleated cells at proportions of approximately 2,500 mesenchymal stromal cells (MSC) per ml of lipoaspirate input. So with 500ml of collected lipoaspirate, the average yield from one StromaCell[™] canister is more than one million MSCs.³ The nucleated cells are suspended in15ml of tumescent fluid inside the special chamber, and ready to be withdrawn directly into a syringe.

When used in combination with the PAL[®] system and its patented reciprocating cannula, StromaCell[™] collects lipoaspirate that is rich in free-floating MSCs. This means that the yield of nucleated cells is the same whether you fill the canister with lipoaspirate and adipose tissue, or with only the aspirated tumescent fluid. So stop throwing away those valuable cells! Now there is an easy and affordable way to collect them using StromaCell[™].

Unlike other products that use collagenase-based enzymatic digestion (a process that faces regulatory challenges in the United States), StromaCell[™] uses no enzymes to collect and concentrate nucleated cells from lipoaspirate. StromaCell[™] uses only autologous tissue at the patient's point-of-care, with minimal manipulation. The process is simple, affordable and fast.

² Isolating Adipose-Derived Mesenchymal Stem Cells from Lipoaspirate Blood and Saline Fraction Francis, M.P., et al, *Organogenesis (2010)*

³ StromaCell Output Characterization Study John Chapman, Ph.D., Sacramento State University, 2013. Data on file.

¹ Characterization of Freshly Isolated and Cultured Cells Derived From the Fatty and Fluid Portions of Liposuction Aspirates Yoshimura, K., et al, *Journal of Cellular Physiology 208:64–76 (2006)*

The science behind StromaCell[™]

Characterization of Output³

MSC Culture using CFU-F Assay

- Serial two-fold 1ml dilutions of nucleated cell concentrate in MSC culture assay
- Cultured for 10 days
- Fixed and stained CFU to microscopically determine maximum dilution containing MSC colonies
- MSC yield per ml of lipoaspirate processed:

 Samples 	N=16
• Mean ± SEM:	2,010 ± 342
• Median:	1,966
Range:	400 to 4,587
• MSC yield per 500 ml canister:	~1 million

Microscopic view shows healthy cell-colony formation.

 $1.5 \pm 0.6\%$ (Range due to RBC variability)

Image Cytometry using Chemometec NucleoCounter® NC-3000[™] Image Cytometer

• Cell count, viability, and relationship with CFU-F assay results:

Samples	N=7
 MSC yield (CFU/ml of cell concentrate): 	17,565
 Viable nucleated cells/ml of cell concentrate: 	1,409,979

- Viable nucleated cells/ml of cell concentrate:
- Percent viability:
- Percentage of MSCs within total cell concentrate:





55%

Acridine Orange (AO) Stain (left) detects the number of nucleated cells generated by StromaCell[™] and the DAPI-Blue Stain (right) detects the number of non-viable cells. *By subtracting the DAPI count* from the AO count, the number of viable cells generated by StromaCell[™] is determined.

Comparison of MSC yield from Bone Marrow Aspirate to StromaCell™ Lipoaspirate

Cell Source	Samples	MSC Yield - CFU-F/ml Cell Concentrate (Mean \pm SEM)
Bone Marrow Aspirate	N=20	4,908 ± 750
StromaCell [™] Lipoaspirate	N=16	51,971 ± 9,607

StromaCell[™] Step-by-Step



1. Place canister in stand



2. Attach liposuction tubes



3. Preload 20cc sterile saline



4. Fill with lipoaspirate



5. Remove tubes



6. Flush fat from cell chamber



7. Spin at 1000xG for 10 min



8. Nucleated cells are captured



9. Remove cell concentrate

Single-Use StromaCell[™] Kit Contents









StromaCell[™] Canister

10' Vacuum Tube

35cc Syringe

Transfer Tube

Reusable Accessories (sold separately)



Canister Stand (STM-STAND)



Counterbalance (STM-BAL-WGT)

Laboratory-Quality Centrifuge Thermo-Fisher Stovall ST-40 750ml Swinging-Bucket Rotor (STM-CTFG-US) or (STM-CTFG-OUS)





Ordering Information

EF Number Description		U/M
REF STM-LRG-VOL	StromaCell™ Kit	EA
REF STM-STAND	StromaCell [™] Stand	EA
REF STM-BAL-WGT	StromaCell [™] Counterbalance	EA
REF STM-CTFG-US	StromaCell [™] Centrifuge - 120v, 60Hz	EA
REF STM-CTFG-OUS	StromaCell™ Centrifuge - 230v, 50/60Hz	EA



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