MyStem is developing, producing and marketing medical devices for autologous stem-cell transplantation. Within 10 - 15 minutes a surgeon can remove, concentrate and re-administer the stem cells to improve healing process and outcome.
We see that almost all the leading manufacturers in the fields of wound healing and orthopedics have next to their regular products now interest in biologics as SVF, a very attractive and fast growing market.
Main "competitors" today are cell factories, enzymatic digestion kits, non-enzymatic centrifugation kits.

How does the MyStem kit work in the OR?

The MyStem concept is to allow surgeons to obtain an autologous graft fraction rich in regenerative components.
The disposable kit works performing a single-step intra-OR autologous tissue minimal manipulation using a GMP-in-a-box concept.
It takes about 10 minutes from harvesting to regenerative fraction final product.
The output of the MyStem device is used with scaffold on Day 0, without scaffold during follow-up injections.
Patients with malignancies should be excluded.
Others limitations may apply according to surgeon considerations.
There are no other system drawbacks – workflow, user difficulties.

What is the biologic content of the stem suspension which is generated in the final step?

The biologic content is based on native tissue composition. Our device does not perform any extensive manipulation nor cell expansion.
Our technology select a tissue portion called Stromal Vascular Fraction using a minimal tissue manipulation.
International Peer-reviewed literature suggest that this fraction is natively rich in Regenerative Cells (Precursor Cells, MSCs, etc.) that showed positive impact on tissue regeneration cascade.
Number of stromal vascular fraction cells (SVF) per ml is around $2x10^5$ per harvested tissue ml. It means 100ml tissue processed with MyStem leads to 20.000.000 SVF cells.

USP and differentiation

MyStem differentiate from above mentioned competitive procedures as follows:

Cell factories	MyStem option is cheaper, not a drug as cultured cells
Enzymatic digestion kits	Enzymatic digestion is banned by EU regulations, MyStem is NOT enzymatic digestion
Non-enzymatic centrifugation kits	MyStem removes everything out of regenerative cells, with centrifugation this precise fractioning is not possible due to G-force that pack all the cells (regenerative or not) down

Further USP - Adult Stem cells in Tissue Regenerative Fraction accelerates healing processes more than any other product available. MyStem has a proprietary kit that collects and concentrates regenerative fraction without extensive manipulation in only 10 – 15 minutes. MyStem is simple, no centrifuge needed, quality sampling is not operator dependent, up to 1000 times more than the bone marrow MSC + Growth Factors.
There is a huge advantage in autologous stem-cell transplantation compared to allogenic or even xenogenic stem cell transplantation.
The difference between non-centrifuged and centrifuged stromal vascular fraction cells is that centrifuged SVF cells requires a pre-filtering phase after enzymatic digestion (see Zuk protocol) otherwise debris goes down into pellet due to centrifugaton G-force. Non-centrifuged but microfiltrated cell fraction (MyStem) is purified from debris, RBCs (Red Blood Cells) and further concentrated using MyStem kit components.

Shelf life of the product

5 years.

Scientific Evidence

There is published scientific evidence of this method on PRS (Plastic & Reconstructive Surgery) Journal.
Another clinical study is published for spine applications in Journal of Neurosurgical Sciences 2015 June 17.
Other unpublished ortho clinicals are performed according to ICRS guidelines.
There are studies ongoing for Burns, Maxillary Bone Graft Augmentation, Knee Cartilage Regeneration, Diabetic Foot Syndrome, Non-Healing Fistulas.

Regulatory

MyStem is a Class IIA medical device for Autologous stromal tissue graft fractioning.
MyStem is ANVISA, TGA cleared and CE certified.
The device was designed to and actually comply with current EMA and FDA Regulation (i.e. Minimal Manipulation, Intra-OR, Autologous Use).
FDA and EU Regulations in this field were recently updated focusing on regenerative fraction minimal manipulation and GMP grade protocols, positioning MyStem Kit as the only complaint kit into US and European medical device market (see EMA/CAT/600280/2010 Rev.1)

IP Protection

MyStem Kit is covered by WIPO International Patent.
MyStem Logo is covered as Trademark(TM)

Target Market Segments

The target market are hospitals, clinics and specialized practitioners with a focus on surgery, orthopedics, spine, wound healing, severe burns treatment, dentistry, aesthetic/plastic surgery, sports, veterinary medicine.
Further use can be OA knee/hip/small joints, tendinopathy, bone growth enhancement, burns, chronic ulcers, skin rejuvenation, Hair Regrowth.

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