

# SituDen Above and Beyond Limitations

## THE MARKET:

The use of UCB-derived Stem Cells for both allogenic and autologous Cell Therapy is rapidly expanding. Until now, this emerging field of cord blood banking (with hundreds of thousands of annual collections and rapidly expanding demand), has lacked both a reliable qualitative method, as well as dependable device for efficient and optimal UCB collection. The number of UCB collections by Cord Blood Banks -- both private and public -- is increasing at a double digit annual rate and reached over 1.1 million collections in 2014.

While Bone Marrow-derived Stem Cells (BMSC) therapy is currently restricted to treating hematological disorders and requires excellent tissue compatibility, CBSC therapy can be applied toward the treatment of a large number of different diseases and disorders. Full tissue compatibility is not required as CBSC are more tolerant to donor mismatch.

It is no wonder that stem cell research is considered "cutting edge" and today's "next big thing" in the health industry.

## THE PROBLEM

The limited volume of blood collected from the Umbilical Cord substantially limits the ability to fully exploit its potential. Currently, the average volume of blood collected restricts the therapeutic use of Cord Blood Stem Cells (CBSCs) to patients weighing an average of only 35kg (77 lbs), which eliminates the majority of adult patients. There is a need for a simple, reproducible, low-cost -- fully sterile -- not contaminated method to increase the quality and quantity of Cord Blood collected and the number of Stem Cells extracted.

## THE SITUGEN SOLUTION

Becoming the International Cord Blood Collection Industry leader, SituGen has developed the SG1040™ novel device for effective, reproducible, cost-effective, fully sterile and not contaminated method to increase the quality of Cord Blood and the number of Stem Cells extracted.

The SG1040™ is a disposable, comprehensive, all-inclusive kit for CBSC collection, designed to solve the problem of blood quantity and maximize the volume of UCB and the quality of Stem Cells extracted.

The SituGen novel device is needle-free, relieving the "bottleneck" affect created due to a needle. The SituGen device is fully disinfected and sterilized according to the requirements for all blood collection devices.

## PRODUCT REGULATION & AVAILABILITY

Regulation process (FDA + CE) is expected to be completed during 2017. The SG1040™ is scheduled to be available to market in H2-2017

## INTELLECTUAL PROPERTY (IP)

SituGen's novel SG1040™ device and method's patent was granted in June 2016. It is a breakthrough in the industry, unique, Self - contained and developed as a disposable kit for a willing and ready market.

## FURTHER R&D

SituGen is active in Research & Development in the fields of Stem Cells, Cord Blood and Placenta-Umbilicus Coagulation. The company was founded around its recent development of the novel, efficient and low-cost SituGen device for a maximum-volume extraction of umbilical cord blood (UCB) for the purpose of stem cell (SC) harvesting. SituGen's R&D team has been concurrently running other projects, like the Patent pending SituGen Collection Active Bag -- the SG2025™

SituGen Ltd. is an Israel-based company, a part of the Rad-Bynet Group of multi-National technology leading companies.

# The Breakthrough Device in CBSC collection



SituGen's Novel patented disposable device and single-use kit for CBSC collection -- optimizes the extraction of the Umbilical -- Cord System's available Cord Blood, thereby increasing the quantity of Stem Cells available for harvesting.



## SG1040™ Advantages:

- First and only device capable of extracting sufficient quantities of Stem Cells for transplantation in most adult patients
- Completely Closed & Sterile environment collection
- Significant increase in Stem Cell quantity -- up by 69% for Private Banks, 21% for Public.
- Less dependent on collector expertise
- Needle Free
- Disposable
- Cost effective, High ROI

### Traditional method

Traditional, Passive Method 16G (1/2mm diameter) needle inserted into a 4mm vein causes a bottle-neck

Average of 60 mL -  $4.7 \times 10^8$  TNC (less than half the blood in the Placenta) in private Banks, 89 mL -  $10.4 \times 10^8$  TNC in Public Banks.

Maternal Cells presence in up to 15% of the samples

Serves only patients weighing up to 35 kg (77 lbs) in Average

Mainly children

The Blood Donor Bag is one component in the Collection Kit

### SituGen SG1040™

"Open" collection in a complete, fully sterile, hermetically Closed environment, needle-free!

Average of 102 mL -  $10.1 \times 10^8$  TNC > +68% (73% of the after birth residual blood in the Placenta)

Maternal Cells presence in 0% of the samples

Serves patients weighing 59 kg (145 lbs) in Average

Children & adults

SG1040™ is a comprehensive, all-inclusive Collection Kit(\*)



(\*) A sterile blister including everything -- from Umbilical Clamps, Umbilical Forceps Scissors, preps, towels, sterilization solution, to packing bags for shipping - each in a sterile pouch. Investigative Device, currently not FDA approved