

**SMART CELLS™**  
*Storing the Stem Cells of Life.*

## Cord Blood & Cord Tissue Banking

Preserving your new-born  
baby's stem cells



Through every enrollment in any of our  
programs, a donation is offered to the  
**CHILDREN'S CANCER CENTER OF LEBANON**  
& **CHANCE CHILDREN AGAINST CANCER**

# Smart Cells International Limited

## Who is Smart Cells International?

Smart Cells International (SCI) is a privately owned UK based stem cell company that has been safely and successfully storing cord blood stem cells since 2001, with over 50,000 cord blood units stored for children from around the world.

Smart Cells International was the first cord blood stem cell storage company in the United Kingdom; it has now over 15 offices worldwide and is seeking to continue its expansion.

Smart Cells International (SCI) has been audited by the UK's regulatory body – The Human Tissue Authority (HTA) – and is fully licensed to procure, import and export, process and store cord blood stem cells and tissues.

Smart Cells International is not only a safe and secured vault to store cells and tissues, but it is also a team of over 30 scientists driven by knowledge and state-of-the-art technology, devoted to help people around the world in an ethical, trusted and innovative way.

## Our Mission:

SCI is the only private cord blood bank in the UK to have released previously stored cord blood units towards transplant centers in order to treat children with life threatening illnesses (Thalassemia, Leukemia and Cerebral Palsy). We have shipped cord blood stem cells to Europe, Far East and North America, where they have been successfully used in transplants.

We, at SCI, can only be satisfied and thrilled when we succeed in lending a hand to people in need or to institutions with great and noble missions, devoted to help patients, especially young ones, without discrimination of any kind.

Our team of professionals is dedicated to answer families' and patients' questions, train healthcare providers on how to properly collect umbilical cord blood and tissue, and above all, continuously update them on the most recent breakthroughs in stem cell science. This has always been and will remain our priority in order to maintain the highest level of professional work and scientific knowledge.

## Human Tissue Act and Regulations

Smart Cells International is regulated and licensed by the Human Tissue Authority (licence number 22522).

Smart Cells International is proud to have been appointed London's Life Sciences Exporter of the year 2010.



## What are stem cells?

Stem cells are highly immature and primitive cells which, in the right conditions, have the ability to produce many types of cells and tissues found in the human body. Stem cells are found throughout the body in tissues such as bone marrow, skin and the digestive tract.

Umbilical cord is one such source of these cells, and this is one of the reasons so many parents are choosing to save their baby's cord blood & cord tissue at the time of birth.

"A stem cell transplant was the only way to cure Ahmed. Ahmed is now growing in height and is transfusion and medication free. He loves school and enjoys just being like the other children"

Mohamed, a Smart Cells customer from UAE whose son Ahmed was treated with his sister's cord blood stem cells.

## Umbilical cord blood stem cell storage

Stem cells are highly intelligent cells capable of restoring and repairing the damaged tissues of the body. Collecting your baby's umbilical cord blood & cord tissue stem cells at the time of birth is a unique opportunity to preserve these precious cells for potential future use by the whole family.

Since the first transplant in 1988, cord blood stem cell transplants have become a routine procedure in the treatment of leukemia and other related blood disorders. There is now a focus on cord blood and cord tissue stem cells to store them for potential uses in regenerative medicine to treat a range of degenerative diseases. To date, there have been over 25,000 successful transplants worldwide used for the treatment of more than 45 different diseases or conditions.

## Storing the Stem Cells of Life

## Why store my baby's cord blood?

Cord blood stem cells can be used to replace damaged or abnormal blood cells as part of the treatment of some malignant blood disorders, such as leukaemia. This is an alternative to bone marrow transplantation.

The potential benefits of cord blood stem cells transplantation are that the cells are immediately available if needed, they can be transplanted into siblings and parents and they carry a reduced risk of transplant rejection and infection.

Ongoing research has shown the potential of cord blood stem cells in the possible treatment of a wide variety of diseases.

After your baby has been born, cord blood is collected from the cut cord using our specially designed collection kit.

Dr Peter Hollands, Senior Lecturer in Biomedical Sciences at the University of Westminster, states *'I would like to see umbilical cord blood storage offered to every pregnant woman. It is a simple process which really can be a life-saver.'*



Why store my baby's stem cells?

## Storing the Stem Cells of Life

## What are cord blood stem cells used for?

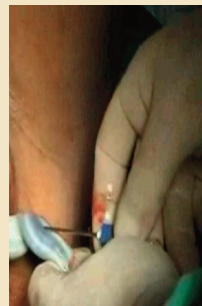
The first successful transplant of cord blood stem cells took place in France in 1988 to treat a child suffering from Fanconi's anaemia – a rare blood disorder.

More recently, cord blood stem cells were shown to be able to form other tissues in the body such as nerves, bone and muscle cells, and hormone producing cells.

This means that cord blood plays also a major role in the field of regenerative medicine. There is a huge potential in the treatment of such conditions as traumatic nerve damage, degenerative bone and muscle diseases. Research has revealed encouraging results in a variety of medical conditions, including ischemic heart disease, Alzheimer's disease, Parkinson's disease, Huntington's disease and multiple sclerosis.

Today, cord blood stem cell therapy is an accepted method of treating many diseases such as:

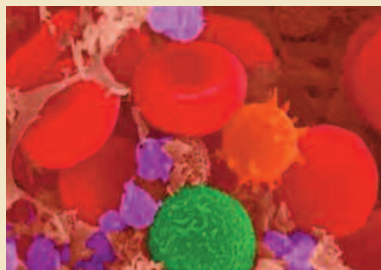
- blood related disorders, leukaemia, sickle cell anaemia and thalassaemia.
- some immune system disorders.
- metabolic storage disorders, such as Hurler's syndrome.
- neurological diseases such as Cerebral Palsy.



Cord blood transplant uses blood forming stem cells to replace diseased cells with healthy new cells and rebuild an individual's blood and immune system. For the transplant to be a success, the cord blood cells must match the patient's own as closely as possible although successful cord blood transplants have been carried out with up to a 50% mismatch.

The advantages of a cord blood transplant, compared to a bone marrow transplant, are that:

- it is easier to find a match from cord blood stem cells than from bone marrow.
- rejection is less likely when using cord blood stem cells.
- there are less delays with a cord blood stem cell transplant if the cord blood has been stored for family use. Delays are inevitable in the case of bone marrow transplants when you need to search in public registries and contact would-be donors.



Why store my baby's stem cells?

Storing the Stem Cells of Life

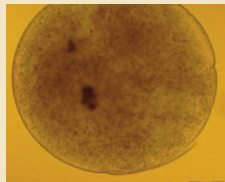
## Mesenchymal Stem Cells (MSC)

Umbilical cord blood stem cells transplantation have been routinely performed with excellent success over the last few decades.

Reports by leading scientists have shown that Wharton's Jelly of umbilical cord (the gelatinous tissue in the cord), is a rich source of a different, but equally important, type of stem cells – called Mesenchymal Stem Cells (MSC).

MSCs have been studied extensively and the potential therapeutic value they offer for treatment in a wide range of diseases is increasing all the time.

MSCs can be very easily and successfully isolated from a section of the umbilical cord that is collected at birth. Once collected, the cord is safely and efficiently transported in a special solution designed to preserve the stem cells during the transportation process to our high-tech laboratory. Once it arrives at the laboratory, the cord is processed immediately, and placed in storage where it will remain for use in the future should it be needed.





MSCs have been shown to differentiate into bone, cartilage, nerve, adipose, cardiac, smooth muscle, hepatic and skin cells and are therefore extremely promising in regenerative medicine.

Co-transplantation of MSCs with hematopoietic stem cells (from the cord blood), reduces the possibility of graft versus host disease where only partially compatible hematopoietic stem cells are available for transplant.

Current trials are underway evaluating MSCs for the treatment of:

Multiple sclerosis, Stroke, Diabetes, Parkinson's disease, Autoimmune and inflammatory conditions such as Rheumatoid Arthritis and Crohn's disease, artificial valves and capillaries, gene therapy for delivery of anti-tumor agents for cancer treatments.

The future of MSC based therapy appears very promising indeed!

In accordance with current scientific opinion, Smart Cells International firmly believes that storing the umbilical cord tissue as well as the cord blood is the safest and most reliable way to store stem cells.



## Smart Cells Processing and Storage

When your baby's cord arrives at our laboratory, it is analysed to determine the volume of blood and the number of cells it contains.

Our processing procedure separates and removes the red blood cells and plasma from the cord blood and retains the cells needed for transplant:

This is referred to as "Red Cell Depletion" or "Plasma Reduction", a highly recommended technique for future transplants because it reduces graft rejection and other complications.

Once processed, the unit is put in a dual-compartment bag and placed into the vapor phase of liquid nitrogen at  $-180^{\circ}\text{C}$  to avoid cross-contamination between units. This allows a long term preservation of cells without any deterioration.

An advanced facility management system for automated environmental monitoring controls the laboratory through sensors installed all over the building to feed data on air pressure, air particle count, and liquid nitrogen level. The computer displays facility status room by room. The storage facility is highly secured and continuously monitored.



## Frequently asked questions

### What are Stem Cells?

Stem cells are a unique type of early primitive cells that can grow into many other cell types found in the human body. The umbilical cord blood has been found to be a very rich source of stem cells.

### What illnesses can these cells treat?

Stem cells transplants have been available since 1988 and since then umbilical cord blood has been used as a treatment for a variety of diseases and conditions mainly thalassemia, sickle cell anemia and leukemia. Cord blood stem cells can also be used to restore the bone marrow following high dose chemotherapy. Potentially, stem cells may be used to treat illnesses such as heart disease, nerve and brain damage as well as muscle diseases. Research is still ongoing in these areas and others where no treatments are currently available.

### What is the possibility of matching within my family?

There is a one in four (25%) chance of there being an identical tissue match between siblings. This probability decreases with each generation step from the child, but since those cells are so primitive in their development, a greater number of HLA mismatches can be tolerated. Most transplants to date have been to siblings and parents.

### What tests are performed on maternal blood?

According to HTA regulations, mothers should have blood tests up to 30 days before or 7 days after the baby is born. Currently, those tests are HIV, Syphilis, Hepatitis B, and Hepatitis C and are performed using PCR technology and serology technique. This allows an early detection of all tested viruses, even during their incubation period.

### Do you store whole blood or do you process the blood first?

In accordance with the international gold standard in cord blood processing, we process the cord blood and discard all other components except the mononuclear cells. Furthermore the sample is checked for bacterial contamination before storage.

### What is the geographic location of the storage facility?

Our processing and storage facility is located in West London, close to Heathrow International Airport. This privileged location reduces transit time and ensures fast and efficient transportation and processing.

### How long have you been storing blood?

Smart Cells has been safely storing cord blood units since March 2001.

### What happens if Smart Cells ceases to trade?

Adequate provision has been made in Smart Cells accounts to pay for the continued storage of your baby's cord blood stem cells. Details of these provisions are contained within our independently audited company accounts - copies of which can be downloaded from Companies House.

## A guide to choose your bank

Once you have decided to bank your baby's cord blood and tissue, it is important to find the appropriate cord blood bank. This may seem like a daunting task as many private banks offer their service. However, some factors have to be considered when weighing your options.

If you're not sure where to begin or what to look for in a cord blood bank, consider the following points as guidelines for your research:

### 1- Accreditations/Certifications

#### **What accreditations or certifications does the cord blood bank hold?**

The bank you select should be fully accredited by the local accrediting body such as HTA (Human Tissue Authority) in the U.K.

**Why SCI:** *SCI has been accredited for the processing and storage of stem cells for several years and just got routinely inspected for an additional three-year period.*

### 2- Variety of stored Stem Cells

#### **Does the company offer you the ability to bank more stem cells by collecting both cord blood and cord tissue-derived stem cells or is stem cell collection limited to cord blood only?**

By collecting stem cells from both your baby's umbilical cord blood and cord tissue, you significantly increase the number of stem cells banked. This improves the potential for a successful transplant should your family ever need the stem cells you're storing.

**Why SCI:** *In addition to storing umbilical cord blood stem cells, SCI has been offering since 2009, to its local and international clients, the possibility to store Mesenchymal Stem Cells from umbilical cord tissues. This practice increases by far the number of stem cells collected. Today, these cells are being used in the treatment of bone, joint and skin diseases.*

<http://www.smartcells.com/smart-cells-services/cord-tissue-stem-cell-storage>



### 3- Red Blood Cell Depletion

**What are the cord blood bank's practices regarding red blood cell depletion? More specifically, what percentage of red blood cells will be removed from your baby's cord blood during processing?**

It is important to remove as many red blood cells (RBCs) as possible from the cord blood before the unit is cryogenically preserved without dramatically affecting the nucleated cells' recovery. Try to find the bank that provides both high depletion and recovery rates.

Transplant physicians do prefer stem cell units that are RBC depleted (as much as possible) as this will reduce the risks for the recipient and expand its use to other family members (in an allograft, this reduces the potential for ABO/RH incompatibility). In addition, red-cell depletion prior to cryopreservation is essential to improve the storage conditions of all cord blood units and to avoid any harmful processing prior to transplant. According to latest reports and warnings, delayed red-cell depletion (after thawing) has a dramatic negative impact on cell viability and recovery (loss of almost 25%).

**Why SCI:** *SCI has been a leader in processing cord blood according to the latest recommendations of all peer bone marrow transplant centers and NHS guidelines. RBC-depletion and nucleated cells' recovery rate have exceeded 80% in all stored units. Therefore, and in accordance with NMDP (National Marrow Donor Program) and CIBM-T (Center for International Blood and Marrow Transplant) most recent guidelines, SCI uses a state-of-the-art RBC-depletion technique known as Sepax.*

NMDP BB-IND #755J Safety Report August 31, 2009

<http://cordbloodreviews.wordpress.com/2009/06/09/the-center-for->

#### 4- Successful Storage and Release of Stem Cells

**Does the cord blood bank have a proven track record of storing and releasing stem cells for transplant? In other words, how many units have been banked and how many have been successfully released for both autologous and allogenic transplants?**

If units have been released for transplant, find out whether a unit has ever been rejected due to poor viability or low cell count or non-RBC-depletion or other causes.

**Why SCI:** *To date, SCI has collected and stored more than 50.000 cord blood units and has released several to successfully treat patients in Europe, America and Asia suffering from Cerebral Palsy, Leukemia and Thalassemia.*

#### 5- Storage eligibility

**Does the bank follow any criteria to classify a processed sample as successful and eligible to be stored (such as CD34+ and/or total nucleate cells' count)?**

When stem cells are needed for therapeutic use, treating physicians evaluate transplant success based on two factors: HLA compatibility and stem cell count. Researchers determined that, following a transplant, the number of cells received by the patient (cell dose) was the one factor that directly affected the rate of recovery and the probability of transplant-related mortality.



**Why SCI:** *As a worldwide leader, the NHS is known to have developed the world's first ever bone marrow registry in 1974. In accordance with international peer transplant centers and the NHS recommendations, SCI has adopted several classification guidelines and standards to accept or reject the storage of all processed cords collected around the world. The latest recommendation adopted by SCI for accepting to store a unit has set the cut-off at  $1.5 \times 10^9$  Total Nucleated Cells.*

[http://www.nhsbt.nhs.uk/pdf/uk\\_stem\\_cell\\_strategic\\_forum\\_report.pdf](http://www.nhsbt.nhs.uk/pdf/uk_stem_cell_strategic_forum_report.pdf)

Heimfeld S. (2003). Bone marrow transplantation: how important is CD34+ cell dose in HLA-identical stem cell transplantation? *Leukemia* (17) 856-858.

Wagner JE, Barker JN, DeFor TE, Baker KS, Blazar BR, Eide C, Goldman A, Kersey J, Krivit W, MacMillan ML, Orchard PJ, Peters C, Weisdorf DJ, Ramsay NKC, Davies SM. (2002). Transplantation of unrelated donor umbilical cord blood in 102 patients with malignant and nonmalignant diseases: influence of CD34+ cell dose and HLA disparity on treatment-related mortality. *Blood* (100) 1611-1618.

## 6- Financial Stability & Longevity

**Is the cord blood bank financially stable? And for how many years has the bank been around?**

You should seek out a bank with a strong track record and a good reputation. Also, while the cord blood banking industry is relatively new, it is still important to look for a company that has been around for a number of years (ten or more years). Other good signs are seen by looking at the bank's board of directory.

**Why SCI:** *SCI was founded in 2001 and has had a remarkable reputation since then. Throughout all these years SCI's team has been working hard to reach the highest levels of professionalism and perfection. Lately, SCI was granted the London's Life Sciences' Exporter Award for the year 2010.*



*This success was partially achieved due to the advisory board's instructions. The eminent members of the advisory board issue directives and guidelines to help local and international offices in their mission of spreading awareness among patients.*

<http://www.smartcells.com/about-smart-cells/our-advisory-board>



## 7- Transplantation Shipping Process

**If the stored stem cells are called upon for transplant, will the unit be shipped via a commercial delivery service or via a specialized medical courier to ensure safe transit?**

A preferred transport method uses liquid nitrogen dry shippers, which are designed to safely transport stem cell units at cryogenic temperatures and will maintain the stem cell unit(s) at -190 degrees Celsius for 14 days.

**Why SCI:** Those shipping containers are exclusively used by SCI to ensure a safe transport for the released units. The successful transplants are partially due to this unique technology adopted several years ago by SCI scientific and medical team. In addition, SCI will not charge you the shipping fees as it is clearly mentioned in the so-called agreement you sign.

## 8- Back-Up Facilities

**Does the cord blood bank have a backup storage facility to be used in case of an emergency? Are the facilities owned by the bank or contracted through a third-party?** Back-up storage facilities provide extra security for your banked cord blood. In addition, there is greater assurance that your cord blood will be handled properly if the bank owns the storage facility and plays a dedicated role throughout processing and storage.

**Why SCI:** Not only SCI owns and fully operates its new state-of-the-art facility, but also SCI has signed a contingency storage agreement with another UK-based and accredited cord blood bank under the HTA sponsorship. It has also signed an agreement with a third bank located on another continent to be used as a safety back-up off-site in the event of a natural disaster. In that case, cords collected during the disaster period shall be dispatched to the secured facility from all collection centers around the world.

### 9- Pricing Options & Guarantees

**Does the bank offer a range of pricing options for enrollment and long-term storage so you can pick a plan that fits best within your budget?**

One should carefully examine the company's agreement and pricing options. A good bank is the one offering pricing options fitting every parent's budget. Neither hidden cost nor extra fees should there be after paying the processing and storage price. In addition, a refund policy regarding storage fees in cases of withdrawal for therapeutic use is important to look at.

**Why SCI:** With SCI's adopted technology, stem cells are viable and stable for lifetime. SCI is among the rare banks around the world to offer expectant parents a wide range of pricing options that fit their budget. Agreements are signed for a limited period of 15, 20, 25 or 30 years according to the parent's choice. The prices are all-inclusive and cover all expenses from enrollment to storage for the period agreed upon in the so-called agreement with no extra or hidden costs. This storage agreement is renewable after expiry of the period agreed upon by a simple notification six months prior to that date and payment of the extension fees.

In case of withdrawal of the unit for therapeutic use, a refund policy has been adopted by SCI and is clearly detailed in the agreement.

## Not all stem cell storage companies are the same.

- Confirm the cost of the service with the possibility of renewal and that cords are all processed and not stored as whole blood.
- Check how close is the laboratory to the airport.
- See if they own their highly secured and state-of-the-art laboratory.
- Make sure cord units are processed in a particle-free atmosphere and in a clean-room environment.
- Confirm they use “Red Cell Depletion” technique and that they do not store cords as they are.
- Ask about the success criteria used for storing, in terms of cell count and viability.
- Verify if a detailed certificate showing all processing results is issued and delivered to you after the blood is received.
- Check for the possibility of storing both cord blood and cord tissue.
- Ask if the company arranges for the cord blood unit to be sent to any transplant center around the world.
- Ask about the reimbursment plan if the unit is ever released for treatment.
- What accreditation and regulation does the storage facility have.
- Check about the number of successful transplants that have been achieved with samples processed and stored at the bank.



Who should store my baby's stem cells?

## Storing the Stem Cells of Life

Contact us:



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Offices in | Bulgaria | Dubai | Hong Kong | Italy | Kuwait | Lebanon | London | Malta | Egypt | South Africa | Spain | Syria