Lifeline - The First Cells and Tissue Bank Established in Europe

Lifeline was established in the UK, in 1994, and has been operating in Cyprus as a regional umbilical cord blood and tissue bank since 2002. The family bank provides its services to expectant families in Cyprus, European countries, the Middle East, North Africa and the Gulf region.

Services:

- **Umbilical Cord Blood Service (UCB):** Automated cell separation technology
- **Umbilical Cord Tissue Service (UCT):** LifeCord, awarded and innovative methodology

**Lifeline - Umbilical Cord Blood and Tissue Family Bank**

- First Bank to be established in Europe
- Granted International AABB Accreditation
- Reception of units seven days a week

**Pioneering worldwide with:**

- LifeCord - Innovative methodology for the cryopreservation of umbilical cord tissue
- LifeKit - Technologically advanced collection and transportation Kit

Accredited

winner CYPRUS innovation award

Gold Chain Global Forum EXCELLENCE AWARDS

LifeCord Patented Methodology
AABB Accredited Based on International Quality and Safety Standards

Lifeline’s cord blood operations and services are accredited by the AABB organization and comply with AABB International Standards For Cellular Therapy Product Services.

The AABB standards are developed by expert scientists, researchers and physicians in the field and aim towards the implementation of good medical practices, the safety of the donors and the effective treatment of the recipient patients.

Lifeline is one of the few banks, in Europe, that bears this accreditation, which places Lifeline among the leading cord blood and tissue banks.

The AABB accreditation ensures the high quality of services already offered to tens of thousands of parents that have trusted Lifeline.
Lifeline's International Scientific Advisory Board
Renowned professors of international calibre constitute Lifeline’s Scientific Advisory Board which gives direction to Lifeline’s scientific activities.

Education, Technology and Science
Lifeline continuously invests in professional development by actively participating in international conferences and seminars where scientific developments are presented. Lifeline’s Research and Development team, in collaboration with educational institutions, conducts in-house research which is regularly presented at international meetings, contributing towards the improvement of cryopreservation services internationally.

Lifeline’s Accreditations
The following accreditation and quality assessment programs, which Lifeline has voluntarily adopted, demonstrate Lifeline’s long term commitment in offering the highest possible quality of service:

- The Cellular Therapy Products Laboratory bears a CYS EN ISO 15189:2012 accreditation for a specified scope that covers all laboratory tests performed
- AABB International Accreditation of the comprehensive Quality Management System
Blood Processing Protocol
The processing, testing and cryopreservation of cells are all performed by state of the art, approved automated methods, applying good laboratory practice and accredited procedures. Isolation of cells is achieved using the Biosafe Sepax 2 cell separation technology.

Tissue Processing Protocol
The LifeCord innovative methodology offers considerable advantages compared to other methods. LifeCord procedure enables the banking of TWO distinct cellular therapy products, under a single service, with each product containing a different cell type. The method is an awarded innovation with a granted International patent. Lifeline has licensed the rights of the LifeCord methodology to an equivalent facility and the service is already being offered by a respective organisation in the United States of America.

Family Banking or Public Donation
Lifeline encourages future parents who do not opt for family banking services, to donate the graft to a public bank. Informing parents early enough during the pregnancy contributes towards the preserving of more cord blood units and grafts, already used in tens of thousands of therapeutic applications.

Professional Indemnity Insurance
A leading insurance provider covers Lifeline’s services with professional indemnity insurance amounting to one million Euros per case; this is a clear recognition of Lifeline’s professionalism and quality of the service offered.

Lifeline’s Webpage
Lifeline’s webpage offers detailed information about the services, the stem cells and the transplantation science to future parents.

Code of Ethics
The briefing is governed by a code of ethics and the parents are presented with objective information based on scientific facts, in a simple and easy to understand language.
Collection Procedure - Simple and Painless

- Performed by gynaecologists / obstetricians
- Procurement is performed without any contact with the newborn
- Lasts few minutes

Cord Blood and Tissue procurement is performed using the consumables contained in the LifeKit which is provided upon registration. On the delivery day, the collection Kit is handed over to the medical staff who are responsible for the collection of the blood and tissue.

LifeKit – Kit for the Collection and Transportation to the Bank

The quality of the banked cellular therapy products is defined, among other, by the number of viable cells they contain. Apoptosis, or the countdown to cell death, starts when cells are removed from the body and the viable cell numbers decrease with time. Scientific research has shown that, biological samples are compromised when exposed to temperatures below 4°C and above 26°C. Evidence suggests that the shipment at constantly low temperatures results in the preservation of the cells integrity.

The new LifeKit is a groundbreaking innovation in the transportation of biological samples. The LifeKit maintains its contents at a constantly low temperature, irrespective of any external temperature variations, ensuring that the quality of the units under shipment is maintained.

The LifeKit device is the first of its kind that provides the appropriate conditions during the shipment of biological products and as such, it has been filed for International Patent.

The LifeKit has been submitted for the Excellence Awards at the Cold Chain Global Forum, in USA, where pharmaceutical and other multinational organisations, involved in the shipment of temperature sensitive products, actively participate. The LifeKit was ranked by panel of judges as one of the 4 best submissions in the category: Best Temperature Controlled Global Logistics Project.
LifeKit Advantages

- Enables the cryopreservation of more viable cells
- Maintains its content to constantly low temperature
- Continuous electronic recording of the contents temperature
- Constructed of stainless steel offering enhanced physical protection
- Bears a unique identification number linking parents and newborn to all procedures that will follow

The LifeKit, provides the best means for maintaining cell viability at the clinic, when the labour takes place at night.

Lifekit Vs. Standard Cord Blood Devices

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EXTERNAL TRANSIT TEMPERATURE

STANDARD CORD BLOOD DEVICES

LifeKit
UMBILICAL CORD BLOOD (UCB)
Haematopoietic Stem Cells Banking Service

UCB and Stem Cells
During the embryonic development, the haematopoietic stem cells are formed in the liver and spleen. Towards the final stage of gestation, these cells start to migrate towards the bone cavities through the bloodstream for the formation of the bone marrow. Blood that is entrapped in the umbilical cord just after birth is therefore rich in stem cells. The collection of this blood gives the opportunity to harvest the stem cells it contains and cryopreserve them for possible future need.

Haematopoietic progenitor cells are responsible for the production of blood components:
- The red blood cells that carry oxygen to the body
- The white blood cells that constitute the immune system
- The platelets involved in the clotting of blood

Uses of UCB
One out of three patients in need of a transplant is unable to find a suitable donor with a compatible graft. Full compatibility between donor and recipient is usually essential when the graft is obtained from the bone marrow or peripheral blood. UCB is considered as an alternative graft and may be applied in therapies even with partial compatibility. Cryopreserved UCB has already been tested and thus is readily available for an application to a family member should the need arise. Only the donor family has access to this graft.

Advantages of UCB:
- full compatibility with the donor child
- immediate availability at the early stages of a disease
- increased chances for compatibility with siblings
- possibility of application to other family members
**Possible applications**

Haemotopoietic Stem Cell Transplantation could be an option for the treatment of the conditions listed below. Each case is evaluated considering the type of disease, the patient’s needs and the source of the graft: either bone marrow, peripheral blood or umbilical cord blood. Transplantation may be autologous, meaning the use of the patient’s own cells, or allogeneic, using cells from a donor.

The criteria applied to evaluate transplantation needs are constantly changing, along with the experience gained through some 50 thousand or so haematopoietic stem cell transplants that take place worldwide every year.

The number of transplantations using UCB is rising every year. Since 2005, allogeneic UCB transplants in children, outnumber, those of bone marrow grafts.

**UCB Current Applications:**

- Different types of malignancies, Leukaemia and Lymphoma
- Severe Aplastic Anaemia and other marrow failure conditions
- Myelodysplastic Disorders or upnormalities in bone marrow cell production

Stem cells deriving from persons with congenital (inherited) condition cannot be used. However, inherited conditions (like the ones listed below) may be treated using stem cells from a healthy individual such as a sibling.

- Haemoglobinopathies like inherited types of anaemia
- Inherited Immune System Disorders
- Inherited metabolic disorders

There is 25% possibility of a perfect match between siblings. However, UCB may be used with reduced compatibility increasing the possibility of a match between siblings. Grafts deriving from siblings are preferred as they have increased possibilities for successful engraftment.
2. Endothelial Progenitor Cells

Endothelial cells are the second type of cells isolated from the UCT and specifically from the vascular system, with the use of the LifeCord method. These cells have been shown to be involved in angiogenesis (creation of new blood vessels) and the regeneration of cardiac tissue, brain tissue and skin.
Advantages of LifeCord methodology

The LifeCord innovative method, achieves the dissociation of the cord tissue into cells, allowing the banking of individual cells rather than segmented tissue. Cryopreservation of individual cells is a proven practice already used for the long term banking of cord blood stem cells. According to valid scientific evidence, the banking of cord tissue segments results in severely reduced viable cell numbers at thawing of the segments.¹

LifeCord Method Achieves:

1. The dissociation of the tissue into individual cells, thus attainment of more efficient cryopreservation.

2. No additives used for tissue dissociation. The use of additives employed by other methods may alter the biological properties of the banked cells.

3. Banking of TWO cord tissue units, each one containing different cell type, allowing the distinct application of either unit in the future, a choice provided only by the LifeCord methodology.

The pioneering LifeCord method has been awarded as innovative in 2010 and patented in 2014. (United States Patent Office US8900863B2).

¹ Chatzistamatiou TK, et al. (2014), Optimizing isolation culture and freezing methods to preserve Wharton’s jelly’s mesenchymal stem cell (MSC) properties: an MSC banking protocol validation for the Hellenic Cord Blood Bank: TRANSFUSION, 54, p. 3108-3120
Possible Future Applications of Stem Cells

The positive outcome from CB and CT stem cell research and applications has led to clinical trials for the treatment of other serious conditions.

Researchers and scientists believe that future therapies will involve the use of stem cells from various sources, including cord blood and tissue. Such research is ongoing at numerous organisations for the therapy of:

- Cerebral palsy/paralysis following hypoxia
- Multiple Sclerosis
- Diabetes types I and II
- Nerve restoration following spinal cord injuries
- Gene therapies for inherited diseases
- Heart conditions and restoration of heart vessels
- Restoration or improvement of vision and hearing
- Restoration of brain damage following stroke
- Parkinson’s Disease
- Alzheimer’s Disease

Potential applications in regenerative medicine and tissue engineering using Mesenchymal Stromal and Endothelial Progenitor Cells:

- Bone reconstruction after fracture or damage
- Tissue engineering of skin and connective tissue for applications in plastic surgery

Furthermore, research and clinical trials concerning the laboratory proliferation and expansion of UCB stem cell population has advanced significantly. This is the effort to increase the cell numbers of the graft and the transplanted dosage which significantly increases the potential of UCB graft applications; since higher stem cell numbers reduces dosage limitations and provides:

- Increased possibilities of successful engraftment
- Increased possibilities of applications in adults
- Increased number of patients who would potentially benefit from a transplant
Accredited Services according to International Standards

Traceability
Upon receiving the biological samples, the identity of the donor and parents is verified. All data are kept in the donor’s file, which will be constantly updated with data from all the procedures that will follow.

Cord Blood Stem Cells Separation
The cell separation procedures are performed under strict sterile conditions in a closed system. Cells are separated using the Biosafe Sepax 2 technology, the first automated method for the separation of haematopoietic progenitor cells to conform with the strict European Union and FDA standards. The cost of the Biosafe Sepax 2 method is significantly higher compared to traditional manual methods of cell separation, however it offers additional safety and superior quality of product. Already more than 11 thousand units processed worldwide by this method, have been successfully transplanted to patients.

Cryopreservation
Separation is followed by the airtight sealing of the blood in a double compartment cryobag which, is then placed in a predefined slot in liquid nitrogen banks for long term storage. Lifeline cryopreserves all units in a 3rd generation cryobanks, the MVE High Efficiency/Vapour Series, whereby all units are preserved in Liquid Nitrogen vapour at -196°C rather than immersed in liquid. This enables temperature stability, especially during accessing the banks for the deposition of additional new units. Temperature readings are recorded electronically at 15 minute intervals for quality control purposes and these data form part of every unit’s records.

Accredited Methods for the Testing of Cord Blood and Tissue
Lifeline’s Cellular Therapy Products laboratory bears accreditation from TWO international acclaimed bodies which cover all the necessary clinical tests for the suitability of the units. Furthermore, Nucleic Acid Testing by the method of PCR is performed for HIV (Aids), Hepatitis B and Hepatitis C are performed by an Accredited Reference Laboratory.

Independent External Quality Control Monitoring
All laboratory procedures are regularly monitored by the UKNEQAS (United Kingdom National External Quality Assessment Service) as well as the Finnish organisation LabQuality for their accuracy.

Quality Management System
Lifeline’s accredited Quality Management System defines the minimum quality and safety criteria for the banking of blood units therefore, a number of units may be rejected and not banked if they do not meet these criteria. However, successful banking does not necessarily guarantee future use; transplant centres will evaluate each available unit prior to use and the decision for using a blood unit will depend on several parameters, including, the compatibility with the patient, the nature of the disease, the weight of the patient and the number of cells in the banked unit. AABB Accreditation offers the quality assurance as an additional parameter that facilitates the transplant specialists in their decision for the medical application of cord blood.
Lifeline Receives Units on a Daily Basis
Lifeline receives biological samples seven days a week, 365 days a year.

LifeKit for More Viable Cells
The pioneering collection and transportation package, the LifeKit, ensures the banking of more viable cells.

Proven Banking Methodology for Cord Blood
Each unit is processed using a fully automated technology, approved by International Bodies.

LifeCord Pioneering Processing Protocol
Award winning-pioneering and patented processing and banking protocol. TWO independent cellular therapy products obtained from UCT with no extra charge for the second product which contains Vascular cells.

Quality Assurance
Clinical testing of all units is performed at Lifeline’s state of art laboratories.

Lifeline - An International Bank
Directed by an International Scientific Board and established in Cyprus, the Bank serves parents from European countries, the Middle East, North Africa and the Gulf region.

Direct Communication
Real opportunity of visits, personal briefing and touring of the facilities.

The umbilical cord or, the lifeline, connects the infant to the mother for 9 months of pregnancy. Family cord blood banking extends this lifeline to the rest of the family members.

It’s better to have them and never need them, rather than need them and not have them.
For further information please contact Lifeline on the following National number:

**7777 2000**

C.B.B. Lifeline Biotech Ltd: 9 Vyzantiou STR. 2064 – Strovolos, P.O.Box 28987, 2084 – Nicosia, Cyprus

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www.lifelinecordblood.com
The current brochure – information package has been approved by the state authorities in line with the relevant legislation regarding the standards of quality and safety of human tissues and cells.