Lifeline Romania

NEW LifeKit

BBB Accredited

Lifeline Cord Blood Bank

Banca de celule stem din sangele si tesutul cordonului ombilical
Umbilical Cord Blood and Tissue Family Bank

Lifeline

Prima banca de celule si tesut infiintata pe teritoriul Europei

Lifeline a fost infiintata in Regatul Unit al Marii Britanii in 1994 si functioneaza ca banca regionala in Cipru din 2002. Banca ofera servicii de stocare a celulelor stem viitorilor parinti din Cipru, Europa, Orientul Mijlociu, Africa de Nord si din regiunea Golfului.

Servicii:

- Stocarea Celulelor Stem din Sangele Cordonului Ombilical (CB): Separarea automata la nivel celular a celulelor.
- Stocarea Celulelor Stem din Tesutul Cordonului Ombilical (CT): protocol unic de separare, premiat si brevetat in SUA, US8900863B2.

Lifeline – Banca familiei tale

- Prima Banca infiintata in Europa
- Detinem Acreditarea Internationala AABB
- Receptionarea probelor 7/7 zile

Pionieri la nivel global in:

- LifeCord – metodologie unica de stocare a celulelor din tesutul cordonului ombilical
- LifeKit – Kit inovator prin tehnologia avansata de colectare si transportare a probelor

AABB Accredited

winner CYPRUS innovation award SERVICES SECTOR 2010

Cold Chain Global Forum EXCELLENCE AWARDS

LifeCord
Patented Methodology

European Business Awards RSM National Champion 2013/14

Lifeline este acreditata AABB, respectand Standardele Internationale de Calitate si Siguranta

Serviciile de procesare si stocare a sangelui ombilical se supun acreditarii AABB si sunt in conformitate cu Standardele Internationale pentru Produsele de Terapie Celulara. Standardele AABB sunt intocmite de experti stiintifici, cercetatori si cadre medicale din domeniu si urmaresc punerea in aplicare a codurilor de buna practica, siguranta donatorilor si eficacitatea tratamentelor efectuate.

Lifeline se numara printre putinele banci din Europa acreditate AABB, acest lucru plasandu-ne in elita bancilor de sange si tesut.
Acreditarea AABB reprezinta o garantie a calitatii serviciilor oferite de Lifeline miilor de parinti care au ales sa ne incredinteze probele bebelusilor lor.

aaBB Accreditation

CBB Lifeline Biotech LTD, Cypris

having been assessed by AABB, has been found to meet the requirements of applicable standards of this organization and therefore is granted this

CERTIFICATE OF ACCREDITATION

for the following activities:

Cell Therapy Activity: Cord Blood – process/store/distribute

In Witness whereof the undersigned, being duly authorized, have caused this Certificate to be issued and the AABB Corporate Seal to be affixed.

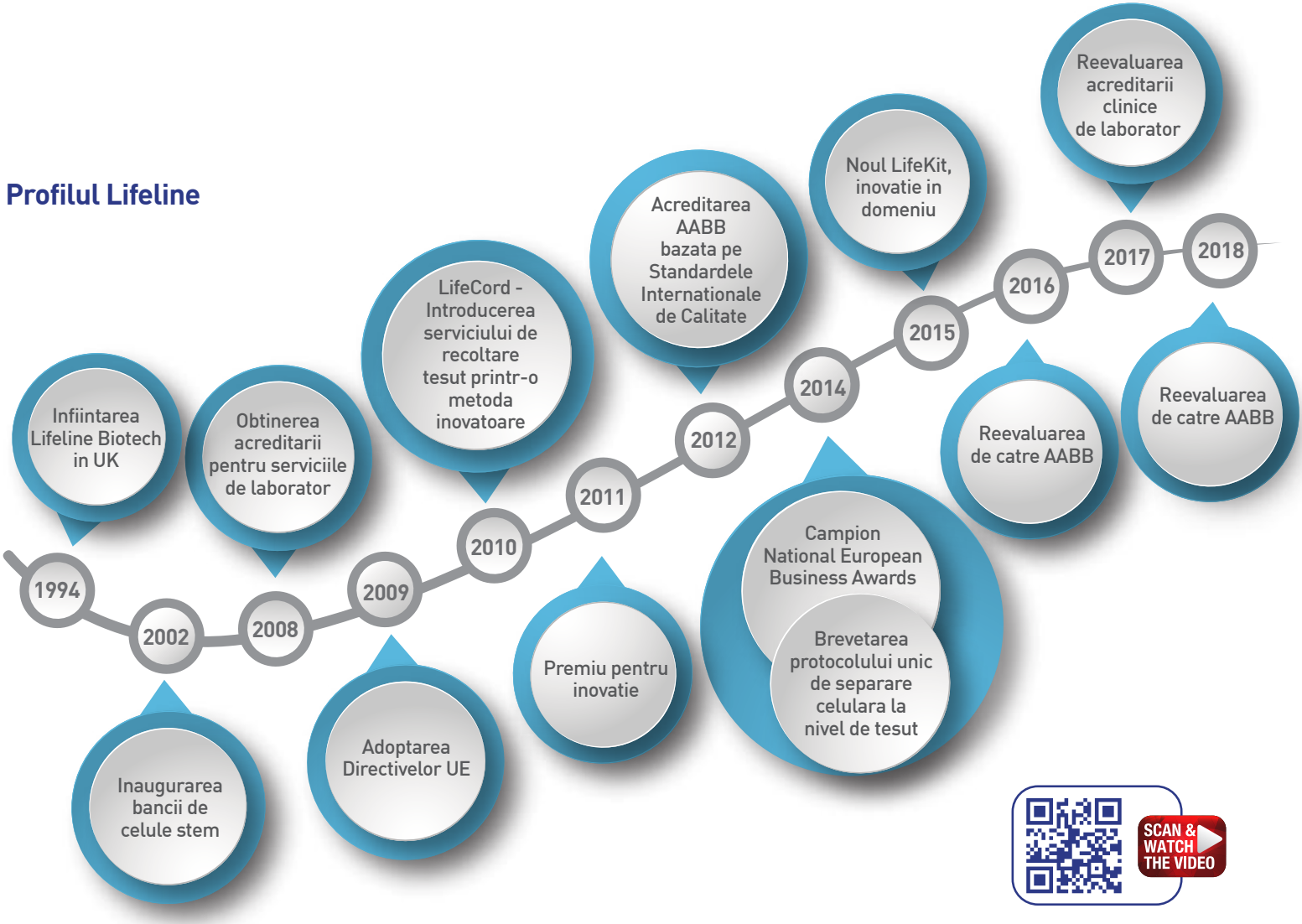
Effective Dates

October 01, 2018 - September 30, 2020

President, AABB

Chair, Accreditation Program Committee

Profilul Lifeline



SCAN & WATCH THE VIDEO

Consiliul stiintific international al Lifeline

Consiliul stiintific Lifeline este alcatuit din specialisti renumiti la nivel international, medici geneticieni, transplantologi, oncologi care dirijeaza intreaga activitate stiintifica a bancii.

Educatie, Stiinta si Tehnologie

Investim in continua dezvoltare profesionala prin participarea activa la conferinte si seminarii de profil in care se prezinta si se dezbat rezultate stiintifice din domeniu.

Echipa de Cercetare-Dezvoltare Lifeline, in colaborare cu renumite Institutii Educationale, deruleaza programe proprii de cercetare, ale caror rezultate sunt prezentate periodic in cadrul reuniunilor internationale, contribuind astfel la imbunatatirea serviciilor de crioprezervare la nivel global, stabilind criterii de baza in stocarea probelor de catre bancile de celule stem.

Pagina Web a Lifeline

Site-ul Lifeline pune la dispozitie viitorilor parinti informatii detaliate despre serviciile oferite, despre celulele stem si ultimele noutati din domeniul transplanturilor.

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Cod de Etica

Informarea parintilor se face sub reglementarile unui cod de etica, toate informatiile furnizate clientilor se bazeaza pe date stiintifice si sunt comunicate intr-un limbaj accesibil si pe intelesul acestora.

Protocolul de procesare a celulelor stem din sangele ombilical

Procesarea, testarea si stocarea celulelor stem sunt efectuate prin proceduri automatizate de ultima ora, cu practici stricte de laborator, folosind cea mai noua tehnologie de separare celulara automata, Biosafe SEPAX 2.

Protocolul Lifeline de procesare a celulelor din cordonul ombilical

Metodologia inovatoare LifeCord ofera avantaje considerabile, superioare altor metode de procesare. Metoda unica de procesare a celulelor din tesutul cordonului ombilical rezulta in stocarea a doua produse distincte de terapie celulara, oferite in cadrul unui singur serviciu, fiecare produs continand un tip diferit de celule. Metodologia LifeCord a castigat Premiul pentru Inovatie si a fost brevetata international. LifeCord reprezinta un criteriu de baza pentru calitatea probelor stocate de bancile de celule stem, fiind deja utilizata sub licenta de o banca din SUA.

Acreditari

Urmatoarele programe de acreditare si evaluare a calitatii la care ne supunem demonstreaza angajamentul Lifeline pe termen lung de a oferi servicii de cea mai inalta calitate:

• Laboratorul de produse de terapie celulara este acreditat CYS EN ISO 15189:2012, acreditare specifica conditiilor de calitate si siguranta ale probelor ce urmeaza a fi stocate.

• Acreditarea Internationala AABB ce vizeaza intregul sistem de Management al Calitatii.

Asigurarea de risc profesional

Lifeline este asigurata profesional de catre o companie de top in domeniul riscului profesional, asigurare care se ridica la valoarea de 1 milion de euro/caz. Acest lucru constituie recunoasterea clara a profesionalismului si a calitatii serviciilor oferite de catre banca noastra de celule stem.

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Procedura de recoltare - simpla si nedureroasa

- Se realizeaza de catre medicii ginecologi / obstetricieni
- Procedura nu implica vreun contact cu nou-nascutul
- Dureaza mai putin de 10 minute

Recoltarea sangelui si tesutului de cordon ombilical se realizeaza cu ajutorul LifeKit-ului, oferit viitorilor parinti la semnarea contractului.
In ziua nasterii, kitul este inmanat echipei medicale responsabila pentru recoltare.

LIFE-KIT: Kitul pentru recoltarea si transportul probelor la Banca

Calitatea produsului de terapie celulara stocat depinde de numarul de celule stem viabile continut de acesta. Apoptoza, sau moartea celulara programata, incepe in momentul imediat urmator indepartarii celulelor din organism, avand ca rezultat scaderea numarului de celule viabile odata cu trecerea timpului. Studiile stiintifice arata ca probele sunt compromise cand sunt expuse la temperaturi mai mici de 4 grade Celsius si mai mari de 26 de grade Celsius. Dovezile sugereaza ca transportul probelor la temperaturi scazute constante rezulta in mentinerea integritatii celulelor, asigurand maximum de viabilitate in timpul transportului probei pana la banca.
Noul LifeKit reprezinta o inovatie revolutionara in transportul probelor biologice. LifeKit-ul mentine o temperatura scazuta constanta pe toata perioada transportului, indiferent de orice variatii externe de temperatura, asigurand astfel calitatea probei pe toata perioada, de la recoltare si pana la procesare.
LifeKitul este unic in domeniu, reprezentand o inovatie in domeniul transportului de probe biologice si, ca atare, am inaintat cererea de inregistrare internationala a Patentului.

SCAN & WATCH THE VIDEO

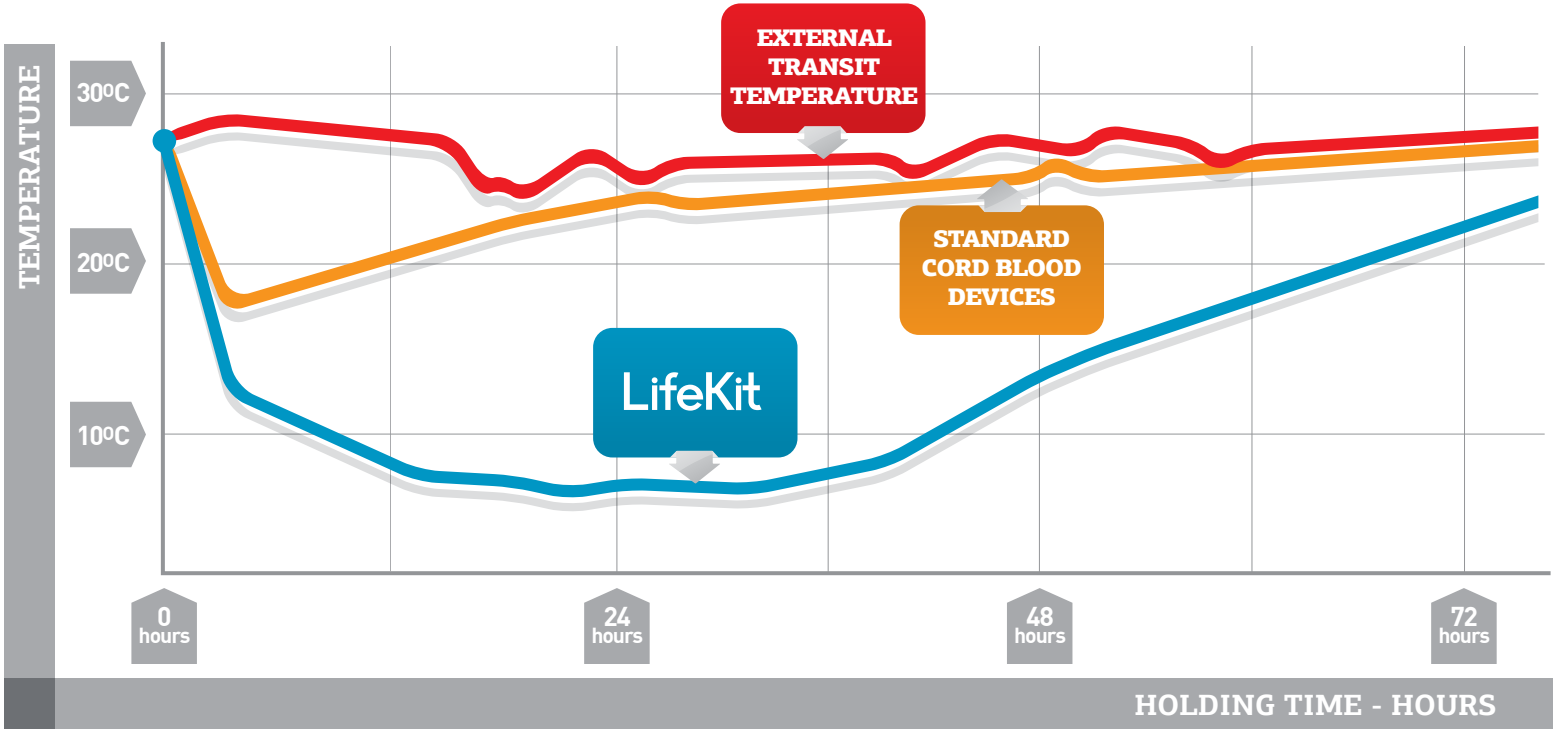
LifeKitul este inscris in cursa pentru Premiile de Excelenta din cadrul Cold Chain Global Forum, in SUA, eveniment anual la care participa companii farmaceutice si multinationale implicate in transportul produselor sensibile la temperatura. LifeKit-ul a fost clasat de catre juriu intre primele 4 cele mai bune inscrieri din categoria sa.

Beneficiile LifeKit-ului

- Asigura crioprezervarea unui numar mai mare de celule viabile
- Mentine constant o temperatura scazuta, optima pastrarii integritatii probelor si ofera izolare termica
- Monitorizeaza si inregistreaza continuu temperatura in timpul transportului.
- Fabricat din otel inoxidabil, ofera o protectie fizica sporita
- Trasabilitatea este asigurata printr-un numar unic de identificare

Life-Kitul a fost conceput pentru a oferi cea mai buna metoda de recoltare si transport a probelor biologice. Folosirea Life-Kitului contribuie la pastrarea in conditii de siguranta a sangelui si tesutului de cordon ombilical, asigurand viabilitatea celulara a probelor, chiar si in cazul in care nasterea are loc noaptea.

LifeKit vs Kiturile clasice



Sangele din cordonul ombilical (SCO)

Stocarea celulelor stem hematopoietice din sangele ombilical

SCO si Celulele Stem

Pe parcursul dezvoltarii embrionare, celulele stem hematopoietice iau nastere in ficat si splina. Aproape de momentul nasterii, aceste celule migreaza catre cavitatile osoase prin fluxul sangvin, pentru a forma maduva osoasa.
Astfel, sangele continut de cordonul ombilical dupa nastere este bogat in celule stem.
Colectarea acestui sange ofera posibilitatea de a recolta celulele stem si de a le stoca pentru o posibila viitoare utilizare.

Celulele progenitoare hematopoietice sunt responsabile pentru producerea componentelor sangelui:

- Celulele rosii, ce transporta oxigen catre organism
- Celulele albe, ce constituie sistemul imun
- Plachetele implicate in coagularea sangelui

Utilizarea SCO

Unul din trei pacienti ce are nevoie de un transplant se gaseste in imposibilitatea de a gasi un donator cu o grefa compatibila. Compatibilitatea completa intre donator si primitor este esentiala cand grefa este obtinuta din maduva osoasa sau sangele periferic. Sangele din cordonul ombilical, bogat in celule stem hematopoietice, este considerat o grefa alternativa si poate fi folosit chiar si in conditii de compatibilitate partiala.
Sangele din cordonul ombilical este deja pregatit pentru utilizare in caz de transplant, fiind testat si procesat in vederea crioprezervarii. In sistem privat doar familia donatorului are acces la grefa.

Avantajele SCO

- Compatibilitate completa cu copilul donator
- Disponibilitate imediata in timpul stadiilor incipiente ale bolii
- Sanse crescute de compatibilitate cu fratii
- Cresterea posibilitatilor de a trata restul membrilor familiei

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Tratamente posibile

Transplantul cu celule stem hematopoietice constituie o optiune terapeutica pentru afectiunile listate mai jos. Fiecare caz este evaluat individual, in functie de tipul bolii, de nevoile pacientului si de sursa grefei: maduva osoasa, sange periferic sau sange ombilical pentru a se alege tipul de transplant, fie el autolog (cu celulele proprii ale pacientului) sau alogenic (celule de la un alt donator). Criteriille folosite in evaluarea transplantului se schimba constant, odata cu experienta crescanda data de cele aproximativ 50.000 de transplanturi efectuate anual in intreaga lume.
Numarul de transplanturi cu celule stem hematopoietice din sangele cordonului ombilical cunoaste o crestere continua de la an la an. Din 2005, transplanturile alogenice cu celule din cordonul ombilical realizate la copii le-au depasit ca numar pe cele cu grefe din maduva osoasa.

Terapii curente cu SCO

- Diferite tipuri de malignitati, leucemii si limfoame
- Anemie aplastica severa si alte insuficiente medulare
- Afectiuni mielodisplazice sau disfunctii in producerea de celule de catre maduva osoasa

Celulele stem provenite de la o persoana cu afectiune congenitala (din nastere) nu pot fi folosite in transplant. Totusi, afectiunile congenitale (asemenea cu cele mentionate mai jos) se pot trata folosind celule stem de la o persoana sanatoasa, ca de exemplu un frate. Exista 25% sanse de compatibilitate perfecta intre frati. Insa, celulele din cordonul ombilical pot fi folosite chiar si in conditii de compatibilitate redusa, crescand astfel sansele unui transplant reusit. Grefele provenind de la frati sunt preferate datorita sanselor mai mari de reusita a tratamentului.

- Hemoglobinopatii, precum diverse tipuri de anemii mostenite
- Tulburari ale sistemului imunitar mostenite
- Tulburări metabolice ereditare

winner CYPRUS innovation award SERVICES SECTOR 2010

TESUTUL CORDONULUI OMBILICAL (CT)

LifeCord, stocarea a DOUA tipuri de celule stem din tesutul cordonului ombilical

Tesutul cordonului ombilical contine diverse tipuri de celule, cu diferite proprietati. Lifeline a dezvoltat LifeCord, metoda unica de separare celulara la nivelul tesutului, prin care se extrag si se stocheaza individual doua tipuri de celule stem: Mezenchimale si Endoteliale.

1. Celulele stem Mezenchimale

Celulele Mezenchimale reprezinta o categorie unica de celule stem datorita celor 2 proprietati importante pe care le detin:

- Abilitatea de a tine sub control si de a reduce inflamatiile (actiune imunomodulatoare complexa si antiinflamatoare)
- Stimuleaza si accelereaza regenerarea tesuturilor

Celulele mezenchimale sunt deja utilizate in terapii celulare avansate (conform listei de mai jos) care implica afectiuni grave. In plus, aceste celule pot fi co-infuzate in transplanturi alaturi de alte produse de terapie celulara, conducand la o stabilizare a grefei in organism mult mai rapida si la cresterea sanselor de reusita a transplantului.
Avand in vedere progresul stiintific si tehnologic, precum si rezultatele imbucuratoare obtinute in studiile clinice efectuate pentru o gama larga de afectiuni medicale, este de asteptat ca lista terapiilor cu celule stem mezenchimale sa creasca de la un an la altul.

Studii clinice in derulare privind utilizarea celulelor din tesutul cordonului ombilical:

- Afectiuni ortopedice si boli ale oaselor, muchilor si articulatiilor
- Afectiuni gastrointestinale
- Complicatii transplant
- Afectiuni oculare de suprafata
- Boli autoimune si inflamatorii
- Cancere
- Afectiuni neurologice
- Boli ischemice
- Afectiuni cardiovasculare
- Diabet
- Arsuri si ulcere de piele

2. Celule progenitoare Endoteliale

Celulele Endoteliale sunt cel de-al doilea tip de celule pe care le izolam din tesutul cordonului ombilical prin metoda LifeCord, mai precis din vene si artere, sistemul vascular al tesutului.
Aceste celule joaca un rol important in angiogeneza (formarea de noi vase de sange) si in regenerarea tesutului cardiac, cerebral si cutanat (al pielii).

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Beneficiile LifeCord, metoda unica Lifeline de separare si stocare a celulelor stem din cordonul ombilical

Metoda inovatoare LifeCord presupune disocierea celulelor din tesut, permitand stocarea individuala a acestora si nu crioprezervarea tesutului sectionat sub forma de bucati.
Separarea celulara si crioprezervarea celulelor individuale reprezinta metoda recomandata si utilizata pentru stocarea pe termen lung a celulelor stem din tesutul cordonului ombilical. Conform studiilor* din domeniu, tesutul crioprezervat sub forma de bucati contine un numar foarte mic de celule viabile la momentul dezghetarii, din acest motiv, celulele trebuie extrase si crioprezervate individual.

Metoda LifeCord implica:

1. Separarea celulara prin metoda disocierii tesutului, obtinand astfel viabilitate celulara maxima prin crioprezervarea eficienta a probelor.

2. Celulele sunt disociate din tesut fara a se folosi aditivi care sa modifice proprietatile lor biologice.

3. Stocarea a DOUA produse de terapie celulara, fiecare continand cate un tip diferit de celule, care pot fi utilizate individual in viitoare aplicatii terapeutice, in functie de nevoile fiecarui pacient.

Metoda inovatoare LifeCord a primit Premiul pentru Inovatie in 2010 si a fost brevetata in SUA in 2014
(Oficiul de Patente al SUA US8900863B2).

*Chatzistamatiou TK i colab. (2014), Optimizarea izolarii culturilor celulare si a crioprezervarii celulelor stem mezenchimale din Gelatina Wharton pentru mentinerea proprietatilor acestora: validare protocol de stocare a MSC pentru Hellenic Cord Blood Bank: TRANSFUZII, 54, p. 3108-3120

AABB Accredited

Aplicatii potentiale ale Celulelor Stem

Rezultatele pozitive ale cercetarilor si aplicatiilor medicale cu celule stem din sangele si tesutul cordonului ombilical au condus la noi studii clinice pentru tratamentul unor afectiuni medicale foarte grave. Cercetatorii si oamenii de stiinta considera ca multe din terapiile viitoare vor fi bazate pe celule stem din surse variate, precum sangele si tesutul cordonului ombilical. Cercetarile sunt in desfasurare in numeroase centre pentru tratamentul urmatoarelor afectiuni:

- Paralizie cerebrala in urma hipoxiei
- Scleroza multipla
- Diabet de tip I si II
- Repararea nervilor dupa leziuni ale coloanei vertebrale
- Terapie genica pentru afectiuni ereditare
- Afectiuni cardiace si repararea vaselor de sange
- Repararea si imbunatatirea vazului si a auzului
- Repararea creierului dupa accidente vasculare
- Parkinson
- Alzheimer

Aplicatii potentiale in medicina regenerativa folosind celule Stromale Mezenchimale si Endoteliale Progenitoare:

- Reconstructie osoasa dupa fracturi sau traume
- Inginerie tisulara a pielii si a tesutului conjunctiv in chirurgia plastica
- Regenerarea muschiului cardiac dupa infarctul de miocard
- Leziuni cerebrale si boli neurodegenerative, de ex. Parkinson, scleroza multipla
- Restaurarea functiei ficatului dupa insuficienta hepatica
- Tratamentul diabetului de tip I si II
- Ingineria tisulara a traheei si a tesutului pulmonar

Cercetarile suplimentare si studiile clinice in derulare privind proliferarea si expansiunea in laborator a celulelor stem din cordonul ombilical au avansat in mod considerabil, intr-un efort de a creste numarul de celule stem continute de grefa. Un numar mai mare de celule stem inseamna:

- Cresterea sansei de succes a transplantului
- Cresterea sansei de tratare a adultilor
- Cresterea numarului de pacienti care sa beneficieze de un asemenea transplant

Servicii acreditate conform standardelor Internationale

Trasabilitate

La primirea probelor biologice se verifica identitatea donatorului si a parintilor.
Toate datele sunt centralizate in dosarul donatorului, dosar ce va fi actualizat pe masura derularii tuturor procedurilor.

Separarea celulelor stem din sangele ombilical

Procedurile de separare celulara se realizeaza in conditii stricte de sterilitate, in sistem inchis. Celulele sunt separate utilizand tehnologia de ultima generatie Biosafe Sepax 2, metoda automata de separare a celulelor hematopoietice progenitoare, in conformitate cu standardele Uniunii Europene si FDA.
Costurile de procesare cu Biosafe Sepax 2 sunt considerabil mai ridicate comparativ cu metodele manuale traditionale de separare celulara, oferind o siguranta suplimentara si o calitate superioara produsului.
In prezent, peste 11000 de probe procesate cu Biosafe Sepax au fost transplantate cu succes la nivel global.

Crioprezervarea

Separarea este urmata de sigilarea prin vidare a probei, intr-un recipient cu doua compartimente de stocare. Recipientul este ulterior stocat pe termen lung in vapori de azot lichid. Lifeline utilizeaza tancuri de stocare de ultima generatie, seria de inalta eficienta MVE / Serie Vapori, probele fiind stocate in vapori de azot lichid, la o temperatura de -196 grade Celsius, nu scufundate in lichid.
Astfel se mentine o temperatura constanta, evitand variatiile care pot aparea, in special in timpul accesarii tancurilor pentru depunerea de noi unitati, suplimentare.
Temperatura este monitorizata in permanenta, inregistrarile electronice actualizandu-se la fiecare 15 minute in scop de control al calitatii, aceste date facand parte din fisa de inregistrare a fiecarei unitati stocate.

Metode acreditate de testare a sangelui si tesutului ombilical

Laboratorul Lifeline din domeniul produselor de terapie celulara este acreditat de DOUA organisme internationale si acopera toate testarile clinice necesare in procesarea probelor. Testarea acizilor nucleici se realizeaza prin metoda PCR pentru depistarea HIV (SIDA), Hepatita B si Hepatita C.

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Programe externe de control al calitatii

Toate procedurile de laborator sunt verificate periodic de UKNEQAS (United Kingdom National External Quality Assessment Service) si de catre organizatia finladeza LabQuality.

Sistemul de management al Calitatii

Sistemul acreditat de management al Calitatii Lifeline defineste criteriile de calitate si siguranta pentru stocarea celulelor stem din sangele si tesutul ombilical, prin urmare exista posibilitatea respingerii anumitor probe pentru stocare daca acestea nu indeplinesc criteriile de eligibilitate. Stocarea cu succes a probelor nu garanteaza utilizarea acestora in viitor, centrele de transplant vor evalua fiecare unitate inainte de utilizare si vor lua decizia in functie de anumiti parametri, incluzand compatibilitatea cu pacientul, tipul afectiunii, greutatea pacientului si numarul de celule din proba stocata. Acreditarea AABB este o garantie a calitatii probelor si reprezinta un factor suplimentar luat in considerare de centrele de transplant in decizia de efectuare a transplantului.

Lifeline
o alegere pentru Calitate

Lifeline - primirea probelor 7/7zile
Lifeline receptioneaza probele biologice sapte zile pe saptamana, 365 de zile pe an, cu scopul de a atinge un nivel ridicat de calitate al probelor stocate.

LIFE-KIT inovator pentru mai multe celule viabile
Kit-ul inovator de colectare si transport, LIFE-KIT, asigura stocarea mai multor celule viabile.

Metoda dovedita pentru stocarea celulelor stem din sangele ombilical
Toate probele sunt procesate si stocate cu ajutorul celei mai inalte tehnologii automatizate, Biosafe SEPAX 2, aprobata de organismele internationale.

LifeCord, protocol unic de procesare a celulelor din cordon
Protocolul unic patentat Lifeline pentru procesarea si stocarea a DOUA produse individuale de terapie celulara (mezenchimale si endoteliale), obtinute din cordonul ombilical, fara taxe suplimentare pentru cel de-al doilea produs.

Asigurarea Calitatii
Testarile clinice ale probelor se efectueaza in laboratoarele Lifeline, laboratoare de ultima generatie.

Lifeline- Banca Internationala a familiei tale
Guvernata de Consiliul Stiintific International si stabilita in Cipru, respectand regulamentele si standardele internationale in domeniu, banca deserveste parintii din Europa, tarile din Orientul Mijlociu, Africa de Nord si regiunea Golfului.

Comunicare directa si transparenta
Posibilitate de vizitare a bancii si a laboratorului, informare personala periodica si suport permanent.
Cordonul ombilical, sau linia vietii, reprezinta legatura dintre mama si bebelus pe parcursul celor 9 luni de sarcina. Stocarea celulelor stem in sistem privat reprezinta o sansa la viata si extinde aceasta legatura si cu restul familei.

Este mai bine sa le avem si sa nu le folosim niciodata, decat sa avem nevoie si sa nu dispunem de ele.

AABB Accredited

In Romania, serviciile C.B.B Lifeline Biotech Ltd. (Lifeline - Banca de celule stem din sangele si tesutul cordonului ombilical) sunt reprezentate de SC Lifeline Services S.R.L. : www.lifelinecelulestem.ro
Pentru mai multe informatii, va rugam sa ne contactati la urmatorul numar:

021.222.16.51

info@lifeline.com.ro

In Romania the services of C.B.B. Lifeline Biotech Ltd. (Lifeline Cord Blood and Tissue Bank) are distributed by SC Lifeline Services S.R.L.: www.lifelinecelulestem.ro
For further information please contact Lifeline on the following National number:

021.222.16.51

info@lifeline.com.ro

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
  United States Patent: US8900863B2

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

AABB Accredited

winner CYPRUS innovation award SERVICES SECTOR 2010

Cold Chain Global Forum EXCELLENCE AWARDS

LifeCord
Patented Methodology

European Business Awards
RSM
National Champion 2013/14

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.

CBB Lifeline Biotech LTD, Cypris

having been assessed by AABB, has been found to meet the requirements of applicable standards of this organization and therefore is granted this

CERTIFICATE OF ACCREDITATION

for the following activities:

Cell Therapy Activity: Cord Blood – process/store/distribute

In Witness whereof the undersigned, being duly authorized, have caused this Certificate to be issued and the AABB Corporate Seal to be affixed.

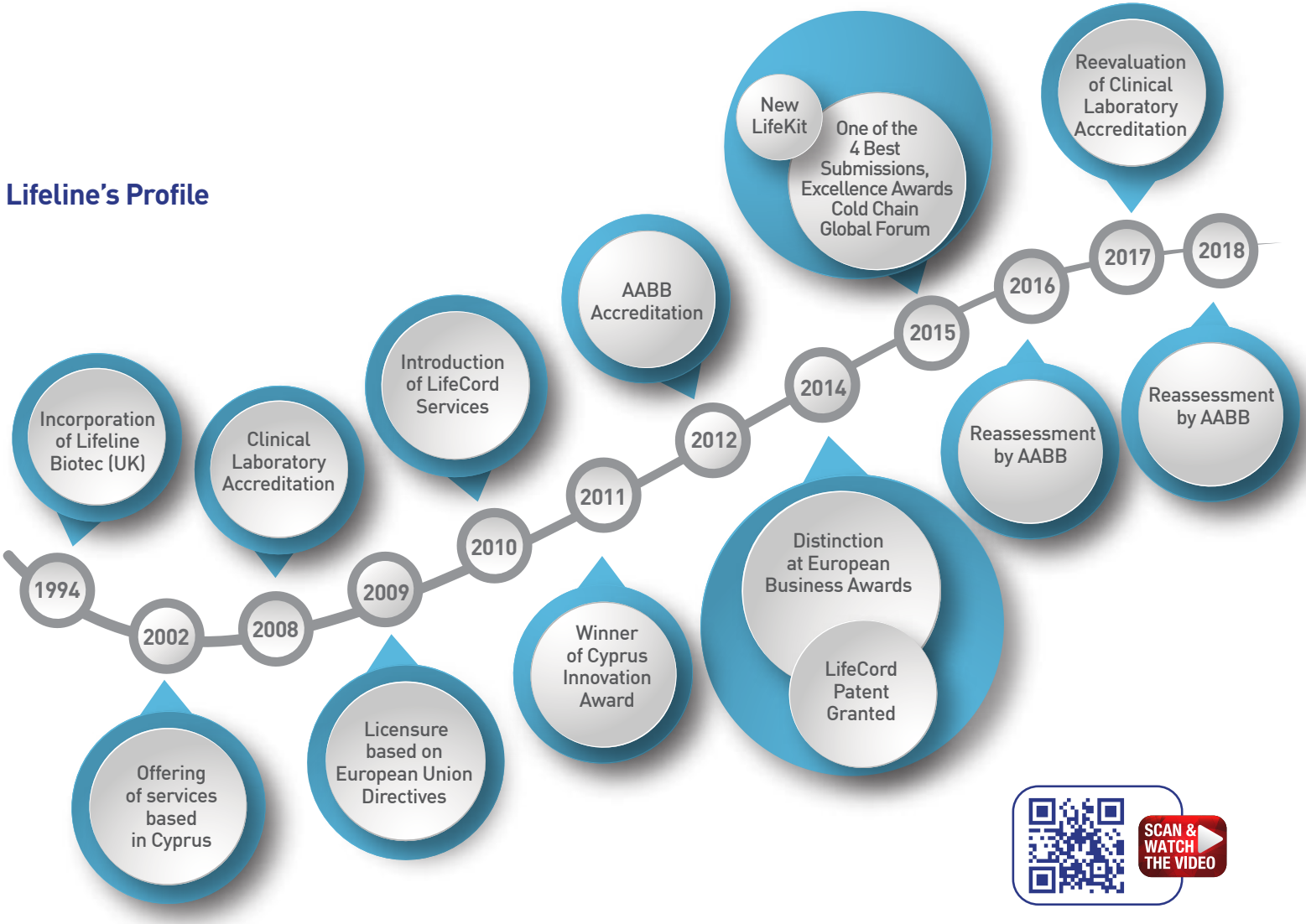
Effective Dates

October 01, 2018 - September 30, 2020

President, AABB

Chair, Accreditation Program Committee

Lifeline's Profile



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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

BB Accredited

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.

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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 4ºC and above 26ºC. 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.

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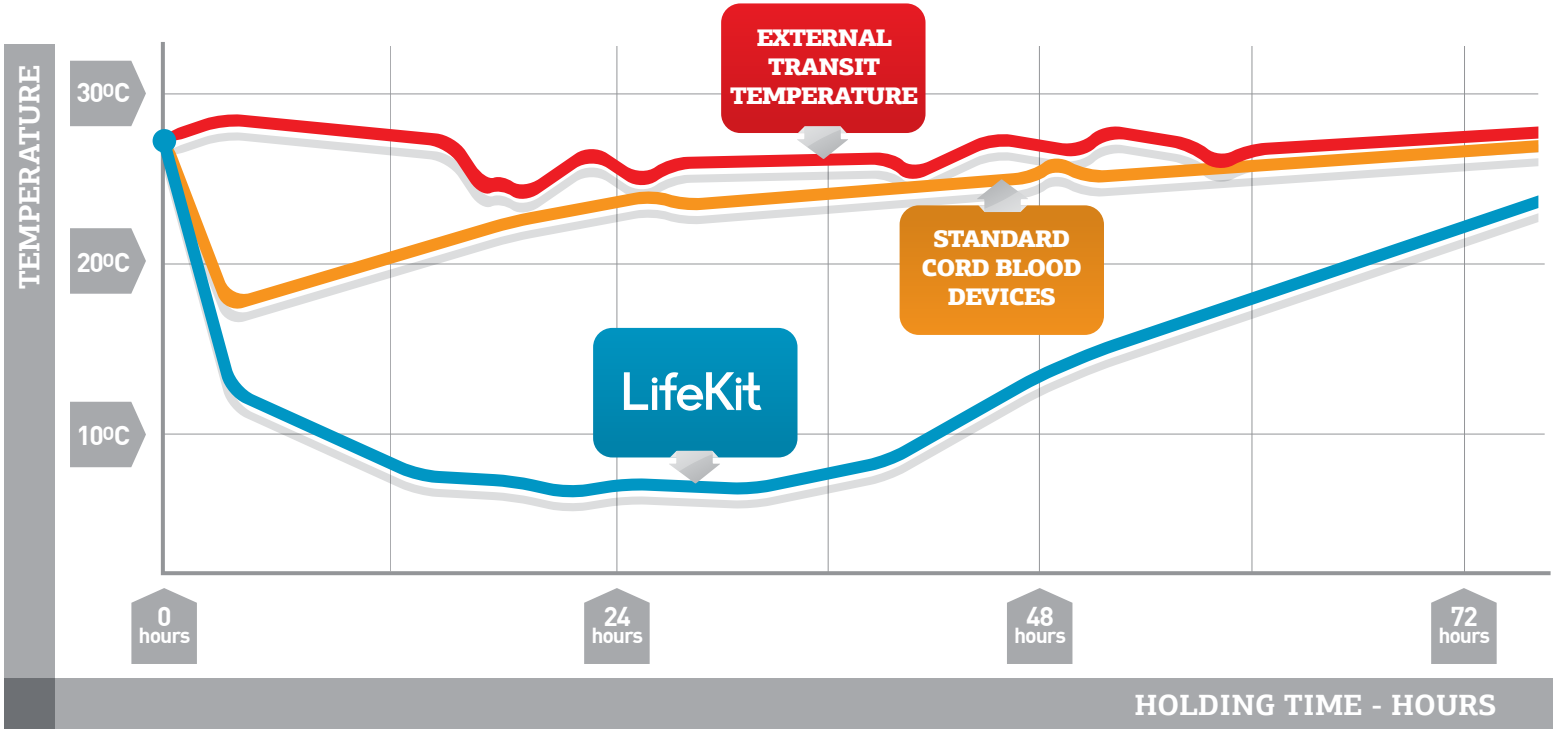
The LifeKit has been submitted for the Excellence Awards at the Cold Chain Global Forum, in USA, where pharmaceutical and other multinational organisations, involved in the shipment of temperature sensitive products, actively participate. The LifeKit was ranked by panel of judges as one of the 4 best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



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 blood stream 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

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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.

winner CYPRUS innovation award SERVICES SECTOR 2010

UMBILICAL CORD TISSUE SERVICES (UCT)

LifeCord Services provide the cryopreservation of TWO units from the Cord Tissue

The Umbilical Cord Tissue contains different types of cells, which have different properties. Lifeline has developed the novel LifeCord methodology during which two units of cells, the Mesenchymal stem cells and the Endothelial stem cells, are extracted and banked separately.

1. Mesenchymal stem cells

The Mesenchymal stem cells are considered as a unique category of stem cell by researchers, since they have two important properties:

- The ability to control and confine inflammation (immunoregulatory and anti-inflammatory action)
- Stimulate and enhance tissue regeneration

Such cells are already applied in advanced cellular therapies (as per table below) involving serious conditions. Additionally, these cells may be co-infused in transplants, assisting in the speedy and effective engraftment of the transplanted grafts. With the advancements of technology and the positive results obtained in clinical trials focusing on a wide range of conditions, it is expected that the clinical applications of UCT cells will increase.

Conditions where clinical trials are being conducted involving umbilical cord tissue cells:

- Orthopaedic applications and bone disease
- Gastrointestinal conditions
- Transplantation complications
- Optical surface conditions
- Autoimmune and inflammatory disease
- Cancer
- Neurological conditions
- Ischaemic disease
- Cardiovascular conditions
- Diabetes
- Burns and skin ulcers

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.

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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

The United States of America

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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
- Cardiac muscle regeneration after myocardial infarction
- Brain damage & neurodegenerative diseases e.g. Parkinson's, MS
- Restoration of liver function following liver failure
- Treatment of diabetes types I and II
- Tissue engineering of trachea (wind pipe) and sections of lung tissue

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 -196ºC 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.

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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
a Choice for Quality

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.

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Lifeline

C.B.B Lifeline Biotech Ltd. – Banca acreditata AABB, licentiata si autorizata in procesarea, testarea si depozitarea celulelor si tesutului.

SEDIUL CENTRAL

C.B.B. Lifeline Biotech Ltd:
Propontidos Str. nr. 5,
2033, Strovolos, Nicosia, Cipru
O.P. Box 28987, 2084 Nicosia, Cipru

C.B.B. Lifeline Biotech Ltd. - An AABB Accredited Cord Blood Bank, is a licensed and authorised cells and tissue establishment with processing, testing and banking facilities at the address:

HEAD OFFICE

C.B.B. Lifeline Biotech Ltd:
5 Propontidos Str.,
2033, Strovolos, Nicosia, Cyprus
P.O. Box 28987, 2084 Nicosia, Cyprus

In Romania, serviciile C.B.B Lifeline Biotech Ltd. (Lifeline - Banca de celule stem din sangele si tesutul cordonului ombilical) sunt reprezentate de SC Lifeline Services S.R.L.: www.lifelinecelulestem.ro
Pentru mai multe informatii, va rugam sa ne contactati la urmatorul numar:

021.222.16.51
info@lifeline.com.ro

In Romania the services of C.B.B. Lifeline Biotech Ltd. (Lifeline Cord Blood and Tissue Bank) are distributed by SC Lifeline Services S.R.L.: www.lifelinecelulestem.ro
For further information please contact Lifeline on the following National number:

021.222.16.51
info@lifeline.com.ro

Bucharest, Romania
SC Lifeline Services S.R.L.
Virtutii Business Center,
19 D, Virtutii St,
Bucharest 060783,
6th District, Romania

Tel: + 40 21 222 16 51
Fax:+ 40 21 222 16 88

Lifeline

Nicosia, Cyprus

C.B.B. Lifeline Biotech Ltd
5 Propontidos Str.
2033, Strovolos,
Nicosia, Cyprus
P.O. Box 28987,
2084 Nicosia, Cyprus
Tel: +(357) 22 817222
Fax: +(357) 22 817230

Bucharest, Romania

SC Lifeline Services S.R.L.
Virtutii Business Center,
19 D, Virtutii St,
Bucharest 060783,
6th District, Romania

Tel: + 40 21 2221651
Fax: +40 21 2221688

Beirut, Lebanon

Lifeline Services
Lebanon S.A.L. Sfeir Bldg.
4th Fl, Phoenicia Street,
Ain El Mraysseh,
2034 - 7304, Beirut

Tel/Fax: +961 1 364074
Tel/Fax: + 961 1 364075

Amman, Jordan

Regional Scientific
Supplies RSS
Obada Ben Alsamet
Str., Build No 14,
Office B101

Tel: +962 65 66 4490
Fax: +962 65 66 4491

Malta Office

Associated Drug Co.
Ltd Triq L-Esportaturi,
Mriehel BKR3000,
Malta

Tel: +356 2277 8000

Issue 9RO, July 2015

The current brochure – information package has been approved by the Republic of Cyprus Competent Authority in accordance with the relevant legislation regarding the standards of quality and safety of human tissue and cells.

Publicata 9RO, Iulie 2015

Brosura curenta – informatiile prezentate au fost aprobate de Autoritatile Competente ale Republicii Cipru, in conformitate cu legislatia relevanta privind standardele de calitate si siguranta a tesuturilor si celulelor umane.

Lifeline

021.222.16.51

www.lifelinecelulestem.ro