Technologies under development

Jointly with industry

This section details on products which have an industrial partner and the joint development efforts are ongoing

Coronary Stent - Drug eluting and drug free

Need identified:

Re-canalization and scaffolding of coronary blood vessel

Classification

Class III

Intended application:

Stents for treating coronary artery blockages and stenosis, for sizes from 2.5mm to 6mm diameter

Product description

Cobalt chromium alloy L605 stent material, biocompatible and blood compatible. Thin strut size for reduction in blood contacting surface, enhanced properties such as flexibility, low foreshortening and stability.

Novelty of the product:

Patented design with novel features.Titanium nitride coating for better haemo-compatibilty and optional drug for reduction of restenosis.

Development stage:

Prototyped 200 numbers manufactured for four sizes.

Future work:

Pre-clinical in vitro and in vivo evaluation, Technology transfer to the industry partner already identified, clinical evaluation

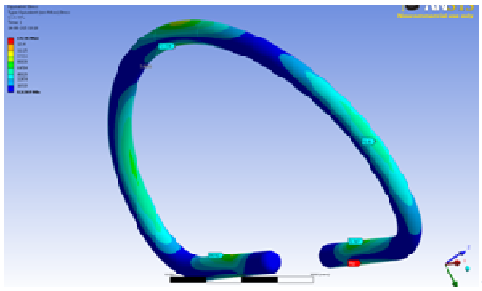
Technology Readiness Level

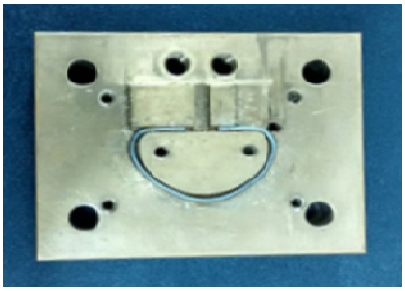
TRL 2

Industry Partner:

TTK Healthcare Ltd

Annuloplasty ring for correction of Mitral Regurgitation



4 

Classification

Class II

Mitral valve repair has become a generally accepted alternative to prosthetic replacement for surgical treatment of Mitral regurgitation. The advantages of mitral valvuloplasty parallel the disadvantages of prosthetic valve replacement. Valvuloplasty does not require lifelong anticoagulation especially in patients who have no other reason for anticoagulation, such as the presence of atrial fibrillation. Currently India has no indigenously developed Annuloplasty ring and in the last 3 years India had imported Annuloplasty Rings worth USD 2,180,952.

Product description & Salient features

An Annuloplasty ring is a rigid or flexible ring implanted around the mitral annulus for surgical treatment of Mitral regurgitation. The normal function of the mitral valve results from synchronised movement of all its components: the annulus, the leaflets, the commissures, the chordae tendineae, and the papillary muscles. Together these components are known as the mitral apparatus and a dysfunction in any of them can lead to mitral regurgitation. The Annuloplasty ring restores the shape of the mitral annulus thus ensuring good coaptation of leaflets during systole while preserving the natural movement of the annulus thus ensuring good hemodynamics during diastole.

Industry Partner:

TTK Healthcare Ltd

Paediatric and Neonatal Membrane Oxygenator for Extracorporeal cardiopulmonary bypass

Need Identified

The need for the product was identified in collaboration with the Industrial partner, SIDD Lifesciences pvt. Ltd., Maramalai nagar, Chennai and this project was initiated as an industrial sponsored project. The product is an artificial lung, required for short term cardiopulmonary bypass management of paediatric patients undergoing open heart surgery; the requirement of the product in India is currently met by 100% imports.

Product description and Salient features

Oxygenator's major component is hollow fiber gas exchange module with extra luminal blood and intra luminal gas flow. Oxygen transfer efficiency with low priming volume and minimal cell morphology damage is the challenge, with given membrane permeability, gas concentrations, achieved through flow pattern, pressure drop and contact time of blood on fibre and across entire module. A heat exchanger for warming/ cooling of patient during the surgery is an integral component of the device, which is based on a tube and shell design with anodised aluminium tubes.

Novelty of the project

Blood flow pattern in the device is optimized through designs tools including Computational Fluid Dynamics and extensive experimentation studies to achieve maximum efficiency at minimum blood damage levels and to ensure a simplified manufacturing process.

Development stage

The product has reached a prototype stage, where the performance characteristics like Oxygen transfer rate are being evaluated in in-vitro experiments.

Future work

Mould development and pre clinical animal evaluation will be following the current stage of development.

Technology Readiness Level

TRL4

Industry Partner identified:

SIDD Lifesciences Ltd

Anti-snake venom egg yolk immunoglobulins (ASV-IgY)

Need Identified

Snake bite associated mortality and morbidity is a major public health problem in tropical countries. Most commonly, 4 snakes cause bite envenomation in India. Only a single anti snake venom (ASV) product is used for all snake bites. The product isolated from immunized horse blood. The purity and potency are IgG is compromised to distribute affordable product to commonly affected rural public. There is a need to develop an affordable ASV with improved potency, and safety.

Product description & Salient features

The division has developed a technology to purify immunoglobulins from the egg yolk (IgY) of hens immunized with native venom (s). The antibodies purified with an easy 2-step process has been shown to have better potency to reverse the toxic effect of envenomation as compared to commercially available IgG using rabbits. Lack of Fc region in IgY eliminate cell-based immune response in the host receiving this therapeutic protein infusion.

Novelty of the product

Instead of a single polyclonal product used currently for all snake bites, the IgY developed has options for treating victims with hemotoxic symptoms and neurotoxic symptoms with separate venom-specific IgY. Purification is relatively easier and makes the product affordable to the most affected common public.

- Patent granted: Anti snake venom immunoglobulins obtained from chicken egg yolk; Patent No: 223121
- Patent filed: A process for the preparation of anti-snake venom antibodies; Patent no: 190889

Future work

Mammalian IgG is a widely accepted life-saving therapeutic protein. However, there is no precedence of IgY infusion for any indication. Therefore, tests recommended for new

class of therapeutic antibody such as new monoclonal antibodies need to be carried out to prove the safety of IgY for human infusion. The efficacy against each of 5 venoms by either one of the two products shall be established as WHO guideline for quality control of new therapeutic antibodies. Once the safety and efficacy in animal models is established, limited clinical trial may be carried as a step for clinical translation of the product.

Technology Readiness Level

TRL4

Industry Partner :

New Medicon Pharma Ltd

Infant warming wrapper/bassinet

Need identified:

Premature babies born with low birth weight are subjected to high temperature loss and may even die if the ambient temperature is not maintained at the core body temperature requirement of 370C. Hence such new born babies are kept in a warm environment to compensate for temperature loss and improve weight gain. Present technologies for warming infants can be used only on a specialty care centre in a hospital under the strict supervision of a technician. The radiant warmers require few hundreds of watts of electrical power and uses intense radiation, which may damage skin and eyes of baby. They are bulky, designed primarily for hospital NICUs and have limited portability. The accessibility of common man to a warmer is limited due to its high cost and unavailability in small hospitals. Also these warmers are not transportable and operatable in home conditions.

According to the World Health Report (Life in the 21st century: A vision for all, 1998) over 4 million infants die within a month of birth world-wide every year. Of this number, 3.9 million belong to the developing world. 25% of the deaths (about 1 million infants per year) are caused due to complications of prematurity, most often heat and water loss. Those have access to hospitals and can afford the treatment are cared with modern techniques and devices to save the affected infant.

Thus a light weight portable infant warmer, which can be used at home conditions, will be of high requirement for poor people.

Intended application:

Non contact warming of premature born babies having low birth weight using infrared energy while at hospital/home or during transportation.

Product description & Salient Features

A transportable, light weight, battery operated, infant warmer is developed which consists of a bassinet to keep the baby and a retractable warming pad on the top. The

warming pad consists of a cluster of infrared light emitting diodes which emits infrared rays in the wavelength suitable for warming a baby. The thermal energy released by the cluster of IR diodes raise the temperature of the environment surrounding the baby to physiological condition. Since the warming pad is kept near to the baby's body, only very little thermal energy of order of few tens of watts is required to keep the baby warm. A power controller with battery pack attached to the bassinet receives feedback signal from a set of temperature sensors distributed throughout the warming pad and controls the same. The power controller is equipped with temperature display over temperature alarm and other safety features.

Novelty of the product:

- Non contact warming using infrared radiations.
- Low electrical power requirement
- No Eye injury
- Uniform warming through distributed infrared radiations.
- Portable.
- Light weight
- Battery operated.
- Can be operated at bedside.
- Operatable in home conditions/primary health centres.

Development stage :

Prototype

Technology Readiness Level

TRL2

Techology partner identified:

HLL Lifecare Ltd

Blood and IV Fluid Warming System

Need Identified

Even though Hypothermia is most common in patients who are exposed to a cold environment, it can develop secondary toxin exposure, metabolic derangements, infections, and dysfunction of the central nervous and endocrine systems Fluid warming is a method of raising the temperature of fluids administered to a patient to maintain normal body temperature and prevent hypothermia.

Classification

Class II

Intended application

Blood & IV fluid transfusion

Product description & Salient features

A blood and IV fluids warming system suitable for slow as well as massive transfusion using infrared radiations emitted from distributed low power IR LEDs is developed. The system consists of a blood bag warming chamber and an inline IV tube warming cartridge having infrared light emitting diodes distributed throughout the inner surface and connected to a power controller. For massive transfusion, blood bag can be placed inside the bag warming chamber and the IV tube is passed through the small cartridge before connecting to the patient. The infrared radiations emitted by the LEDs warm the blood or IV fluid inside the bag to raise the temperature from refrigerated condition (4°C) to 37 °C in a few minutes. The cartridge compensates for any temperature loss occurred during traveling from bag to the patient. For slow transfusion (flow rate < 5ml/min) the cartridge alone can be used.

The product consists of the following features:

- Radiant warming using infrared radiations emitted from distributed low power LEDs
- Bulk warming of blood inside blood bag for massive transfusion
- IV tube fluid warming for slow transfusion

- Re usable, compact and portable
- Non contact warming of blood & IV fluids
- Uniform temperature distribution
- Warming independent of transfusion flow rate
- Inline IV tube warming for temperature compensation during massive transfusion
- Simultaneous or independent mode of operation of bag warmer and tube
- warming cartridge
- Light weight
- Redundant LED operation
- Warming efficiency >70%
- Blood bag warmer spec:
- Power consumption < 50W
- Warm up time (40C to 370C)
- Rate of temperature rise – 1.120C/min
- IV tube warmer cartridge spec:
- Power consumption < 20W
- Warm up time (250C to 370C) at 3ml/min <5min
- Battery operation

Novelty of the product

Indian Patent filed (6648/CHE/2014)

A system and a method for non-contact warming of bag containing blood and intravenous fluids with infrared heating from refrigerator condition to physiological condition for massive transfusion

Development stage

Prototype developed

Future work

Commercialization

Technology Readiness Level

TRL2

Industry Partner :

HLL Lifecare Ltd

Fibrin-Amnion-Hyaluronic acid skin Substitute

Need Identified

Deep and chronic wounds in diabetic subjects and burn victims often become a big health problem leading to morbidity and mortality. Most of the currently available bioactive skin substitute faces mainly two important draw backs. (1) Suturing is required for retaining the scaffold at the wound site; (2) most of them induce healing the tissue with fibrosis because the material is either allogenic or xenogenic and causes adverse immune response.

Product description & Salient features

Guided skin tissue regeneration is the strategy adopted in this product. Processed, decellularized and dried amniotic membrane and formed fibrin clot are the active components. Amnion is very thin and is difficult to handle/apply in surgical setting. Therefore, it is embedded in a suitable composition of fibrin clot and lyophilized.

The fibrin permits maintenance of amnion shape and dimension and also allows hemostatic adhesion to the wound site. Thus suture-less application of amnion at the wound site can be done easily.

Novelty of the product

Amniotic membrane originating from ectoderm having features similar to human skin, retain all the biological characteristics in dried form as that of a fresh membrane, is rich in regenerative growth factors and cytokines having angiogenic, anti-inflammatory, anti-fibrotic, anti-scaring, anti-microbial properties and low immunogenicity which can resolve many problems associated with wound regeneration. It provides a natural wound healing scaffold due to the presence of pre-formed fibrin strands and is a completely human product.

Future work

In vitro cell culture experiments are required to prove improved cell growth and extra cellular matrix synthesis to demonstrate potential in wound regeneration. Animal experiments are required to prove efficacy when wounds (size 4x4 cm2) in diabetic rabbits and burnt porcine are treated with this novel matrix. Later get clearance from Drug Controller for limited clinical trial.

Technology Readiness Level

TRL2

Industry Partner identified: Co-developer identified

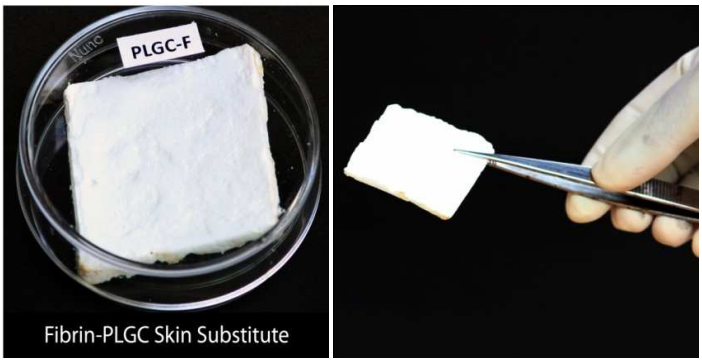
Hybrid Fibrin-degradable polymer skin Substitute

Need Identified

Deep and chronic wounds in diabetic subjects and burn victims often become a big health problem leading to morbidity and mortality. Currently autologous skin grafting is the Golden Standard to treat such wounds; but skin harvest produces another morbid site in diabetic subject and in burn victims, normal unburnt skin is often not available to treat large area. No affordable bioactive skin substitutes are available in Indian scenario.

Product description & Salient features

The purpose of this invention is to transplant the degradable, bioactive and biomimetic scaffold at full thickness skin injury for guiding in vivo tissue regeneration. It comprises optimum density of fibrin network coated on biodegradable electrospunter polymer. The polymer is in-house synthesized form FDA approved monomer L-Lactide, L-Galactide and poly €-caprolactone to obtain PLGC. Monomer composition is fine-tuned to to achieve in vivo degradation of PLGC with 3 month. The polymer is electro-spun to obtain mat compliant and mechanically similar to native skin. Fibrinogen and thrombin concentrations are adjusted to induce hemostasis in the debrided skin wound where it is to be implanted.



Novelty of the product

Guided skin tissue regeneration is the strategy adopted in this product. The implant promotes haemostasis and so suture-less application is possible. It provides a natural wound healing scaffold due to the presence of pre-formed fibrin strands, and a porous 3-dimensional structure coated with fibrin prevents excessive wound contraction and promotes fibroblast and other skin cell penetration to promote natural tissue regeneration.

Future work

The efficacy of the product is proven for healing of 1cm diameter size circular wounds. Animal experiments are ongoing to prove efficacy when wound size as big as 4x4 cm2 in diabetic rabbits and burnt porcine wounds. Need to get clearance from Drug Controller for limited clinical trial.

Technology Readiness Level

TRL4

Industry Partner

Co-developed with HLL Life care, Trivandrum