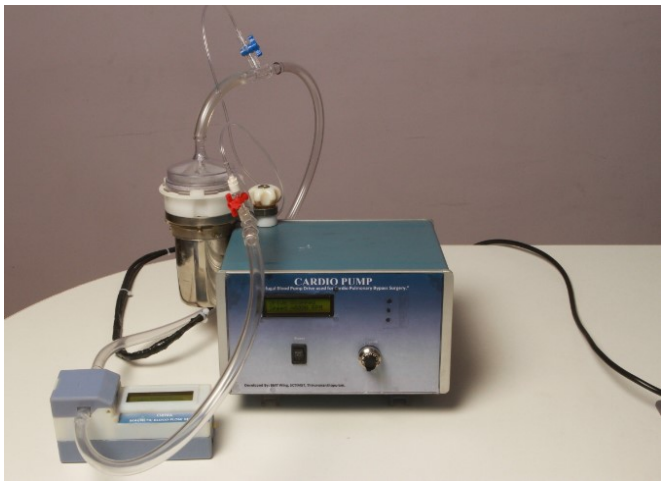
TECHNOLOGIES IN THE DEVELOPMENT STAGE

This section is on technologies that are in the development stage

Centrifugal Blood Pump



Device Classification:

Class C Cardiovascular Device

Intended Application

Supporting blood circulation during surgical procedure of Extracorporeal cardiopulmonary bypass.

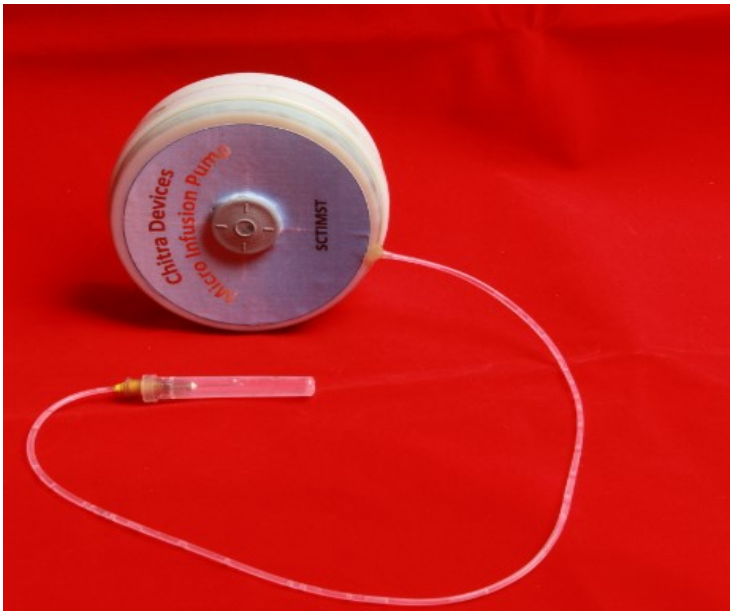
Product Description:

Extracorporeal Cardiopulmonary Bypass is a technique used during open heart surgery to maintain oxygenated blood supply to the vital organs of the body. Conventionally, roller pumps are used for this purpose, which causes excessive blood damage (haemolysis). Centrifugal blood pump is an effective alternative with substantially low blood damage. The device consists of a disposable pump head, a drive unit and a flow meter. The drive unit provides mechanical energy to rotate the magnetically coupled pump head and precisely adjusts its speed. The independent flow meter measures the rate of flow of blood in the circuit.

Novelty of the product:

Magnetically coupled, detachable pump head with less haemolysis and priming volume, an alternative for roller blood pump. Detachable motor assembly from drive unit for low priming volume circuits.

Implantable Micro infusion Pump



Device Classification:
Class D

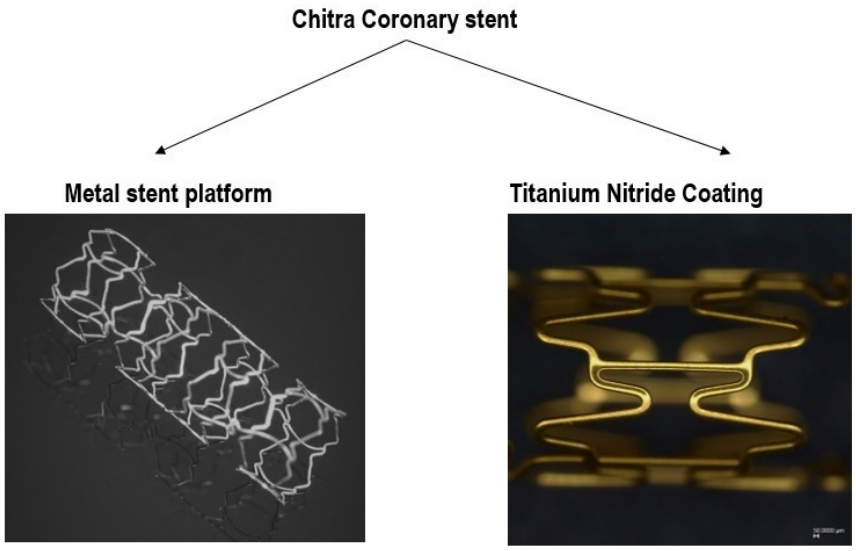
Intended Application:
Implantable device for delivering drugs to specific regions inside the body

Product Description:
An implantable micro infusion pump can deliver drugs such as baclofen/morphine to the region of interest such as peritoneal cavity, spinal cord in a controlled manner for a long period of time. The battery operated device has a drug reservoir with a capacity of 25ml and a miniature drive mechanism for delivering the drug through a catheter. Refilling of drug can be achieved by injecting through a specific port. The device is powered by a battery which can be recharged by transcutaneous energy transfer system (TETS) thereby avoiding percutaneous wires and associated infections. The device can provide basal as well bolus dosage of the drug for two to three months as per the set flowrate and can be programmed by a smart phone based mobile App.

Novelty of the product:

- Transcutaneous energy transfer system for powering the device and recharging battery
- Very low flowrate
- Mobile app based operation

TiN coated coronary stent system



Device Classification:

Class D

Intended Application:

The Cobalt-Chromium-Nickel-Tungsten alloy L605 based, Titanium Nitride coated "bare metal" coronary stent system is indicated for improving coronary luminal diameter in patients with native coronary lesion length < 50 mm, and reference vessel diameter (D Ref Vessel) ranging from 2.0 mm < D Ref Vessel < 4.50 mm.

Product Description:

The Chitra coronary stent consists of the following components:

1. L605 based Metal Stent platform
2. Titanium Nitride Ceramic coating

Development stage

Design and choice of materials completed. 12 TiN coated coronary stent are prototyped.

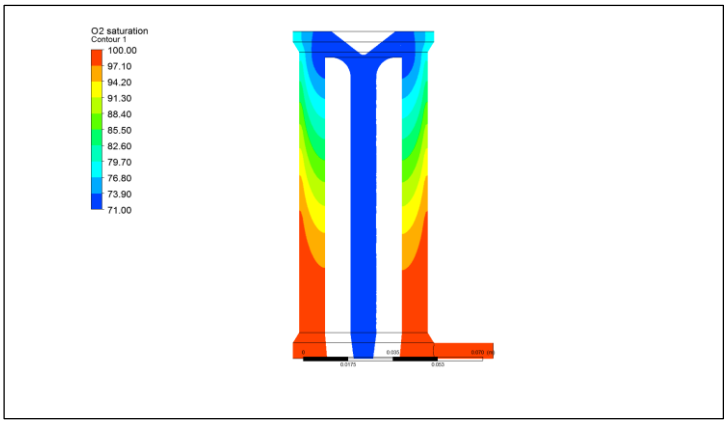
Design Verification: The safety and performance of the design has been assessed in vitro and in silico by:

Stent diameter to balloon expansion characterization as per ASTM 2081-06 (2017)
Dimensional verification as per ASTM F2081-06 (Reapproved 2017)
Recoil study as per ASTM F2079, ISO 25539-2
Foreshortening study as per ASTM 2081-06 (2017)
Percent solid area study as per ASTM 2081-06 (2017)
Computational structural analysis (ASTM F2514-08 Reapproved 2014)
Fatigue & durability- computational analysis (ASTM F2514)
Flexibility of stent as per ASTM F2606-08 (Reapproved 2014)
Flexibility of stent system as per ASTM F2606-08 (Reapproved 2014)
Dogboning studies as per ISO/DIS 25539-2:2019(E)
Deflation time at labeled RBP as per ISO/DIS 25539-2:2019(E)

Deflation time corresponding to deployed diameter as per ISO/DIS 25539-2:2019(E)
TiN coating thickness measurement as per ISO/DIS 25539-2:2019(E)
TiN coating surface roughness as per ISO/DIS 25539-2:2019(E)
TiN coating integrity as per ISO/DIS 25539-2:2019(E)
TiN coating trace element analysis as per ISO/DIS 25539-2:2019(E)
DFSS based robustness (z) assessment: Critical to Quality parameters, vendor evaluation of raw materials and manufacturing process.
POC Animal studies- Completed animal studies of 3 Chitra stents
The safety and performance indicators showed that the Chitra Stent is safe.

Novelty of the product:
Patent granted, 357096 dated 29/01/2021

Extracorporeal Membrane Oxygenator



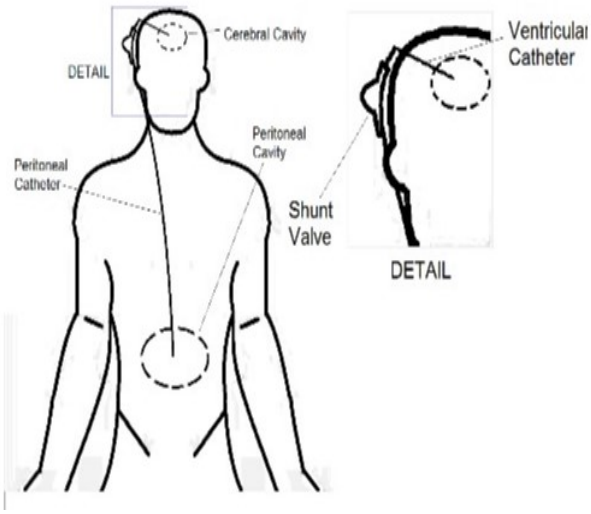
Device Classification: Class D

Intended Application: for oxygenating blood and carbon dioxide removal from blood when the natural lungs of the patient are not properly functioning due to various disease conditions.

Product Description: Essential component of the system is a gas exchanger unit made up of hollow fiber membrane packed inside a shell. Oxygen- air mixture flows inside the lumen of the membrane and blood flows outside. Oxygen and Carbon dioxide exchange takes place across the membrane.

Novelty of the product: The device uses active methods to enhance gas transfer in the device thereby achieving sufficient gas transfer rate with lower fiber area and lower priming volume.

Programmable Hydrocephalus Shunt



Device Classification:
Class D Implantable Neurological Device

Intended Application:
For draining intracranial fluid with programmable flow controller

Product Description:
Hydrocephalus is a condition in which the cerebrospinal fluid (CSF) accumulates in the brain cavities, increasing intracranial pressure. It may result in significant intellectual, developmental and physical disabilities. A CSF diversion device or shunt offers primary therapy for this condition. The shunt diverts CSF to another part of the body, often the peritonial gravity. The advanced version of the device offers a programmable pressure valve which can be adjusted from outside to control the CSF drainage rate to ensure proper intracranial pressure.

Spinal Fixation System for Thoracolumbar Stabilization

Device Classification:
Class C - Implantable Device

Intended Application:
For solid fusion of damaged vertebrae in thoracolumbar region of spine

Product Description:
Spinal Fixation devices (Implants) are non-cervical spinal fixation devices intended for fusion of spine in the following indications: degenerative disc, spondylolisthesis, trauma, deformities or curvatures, tumor, stenosis, pseudoarthrosis and/or failed previous fusion. Implants are single use only & intended to provide temporary stabilization during development of a solid fusion of the spine. The implant system is intended to be removed after solid fusion has occurred. Spinal fixation system also includes instrumentation for insertion, securing and removal of implants

Novelty of the product: Enhanced biomechanical and bio-integration properties

Bioceramic Beads with Graded Porosity for Drug Delivery in Bone

Device Classification: **Class** D

Intended Application: Neurosurgery/Orthopaedic

Product Description: Ceramic beads with hierarchical porosity designed for *in situ* loading of antibiotics.

Novelty of the product: Infections (osteomyelitis) associated with orthopedic surgery remain is a persistent complication. System antibiotic infusion results in poor local availability. Current delivery systems utilize drug – loaded PMMA cement that necessitates surgical removal after delivery. This technology obviates removal by providing a resorbable matrix.

Bioprosthetic heart valve

Device Classification: Class D

Area of Application: Cardiovascular

TRL TRL4

Technology

The proposed Bioprosthetic heart valve is made using glutaraldehyde processed Heparin-Mg immobilizedbovine pericardium which has anti-mineralization and thrombo-resistance properties.

Clinical relevance

This device is meant for replacement of diseased, damaged or malfunctioning native or prosthetic heart valve.

Product

Artificial heart valves ensure the normal unidirectional flow of blood in the heart when the natural valve is defective and malfunctions.There are two classes of valves: mechanical and biological. The biological heart valve is derived from animal tissue, porcine aortic or bovine pericardium. Biological valve is known for its natural central blood flow, less blood damage and clotting tendency compared to the mechanical valve. Hence it is recommended for pregnant women and elderly. However, it can cause calcification and early failure in young patients.

This bio prosthetic heart valve is made using Glutaraldehyde cross-linked,

TECHNOLOGIES IN THE DEVELOPMENT STAGE

Indian Patent filed –

Product Patent: Arising

Process Patent:Application no. 201741038920, Prevention of in vivo calcification in glutaraldehyde cross-linked pericardium through Magnesium chelation.

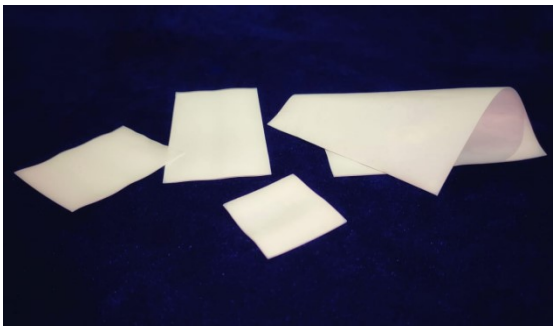
Design Registration:

A. Stent and insert for internally mounted surgical bio prosthetic valves.
B. Stent for surgically implantable externally mounted valve

Scope

The industry is expected to associate for technology transfer; carry out the clinical trials and further commercialization.

Dural substitute



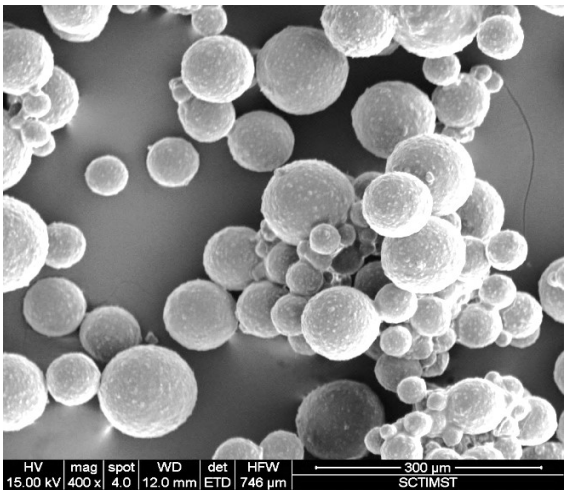
Device Classification: Class D

Intended Application: Dura mater substitute

Product Description: Dural defect reconstruction is a significant problem in many cases of decompressed craniotomy and also following skull base endoscopic surgeries. These defects are associated with a wide variety of lesions requiring neurosurgical interventions in order to obtain the re- establishment of the atomic barrier and to prevent the CSF leakage. CSF leakage is a complication associated with other possible serious complications like meningitis, and often requires re-operation. Dura substitution is indicated for use as a temporary or permanent prosthesis for repair of duramater. Electro spun polycarbonate urethane is developed as a synthetic non-degradable dura substitute.

Novelty of the product: Superior bio stability and biocompatibility

Radiopaque Polymeric Microspheres for Embolization Therapy



Device Classification:

Class D injectable vascular device

Intended Application:

Embolotherapy is a clinical procedure employed to prevent blood supply to vascular abnormalities such as tumours, arteriovenous malformation, gastrointestinal bleeding, aneurysm, etc. by blocking the vessels. Microspheres are widely used for this procedure.

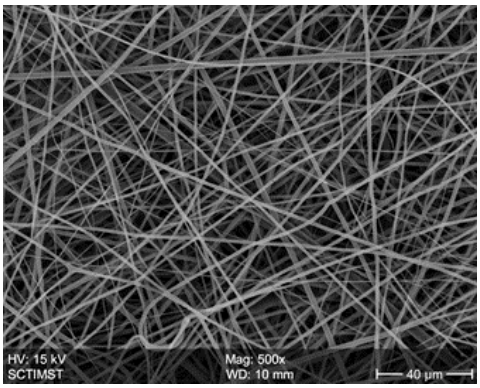
Product Description:

Microspheres were produced from a commercially available synthetic polymer. This polymer was modified by chemical process and made them radiopaque through a grafting procedure. Iodine was used as radiopacifier in his reaction. The grafted polymer was converted into microspheres through a special process. Radiopaque microspheres are available over a range of sizes. Most widely used sizes are in the range 150 – 300 microns.

Novelty of the product:

Commercially available microspheres are not radiopaque. During embolization procedure, in order to see the location of microspheres during fluoroscopic procedures, radiologist injects it along with contrast agent. Advantage of radiopaque microspheres is that they would be visible during injection and subsequent post implantation assessment under fluoroscopic conditions.

An electrospun silk fibroin based matrix for wound healing and tissue engineering applications



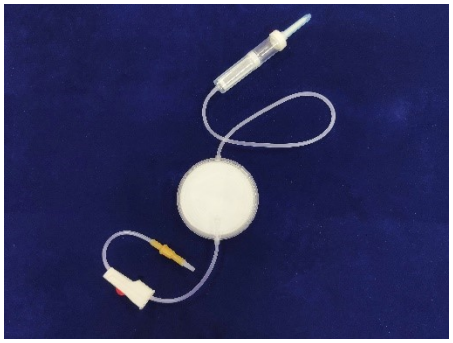
Device Classification: A/ B/ C

Intended Application: Plastic Surgery (Wound Healing)

Product Description: Wound healing is a complex phenomenon that amalgamates the interplay of many cell lineages, extracellular matrix remodeling and an array of signaling molecules. Although cellular and molecular events in the wound healing phenomenon is highly investigated and well established, wound repair still remain a major unmet clinical need. Since the introduction of a supporting matrix is inevitable in critical size wound management, biomaterials have become the central focus of wound healing and repair. The technology package developed here at SCTIMST Trivandrum offers the industrial partners an indigenously developed silk fibroin based electrospun nanofibrous matrix as a biocompatible biomaterial for wound management.

Novelty of the product: The product is the first of its kind non-woven nanofibrous matrix derived from silk fibroin – which is a natural protein polymer. The package includes know-how on purification of silk fibroin protein and a process for fabrication of the scaffold by electrospinning. One Indian patent on "Device with a clip-on scaffold for engineering co-cultured tissue constructs and methods of use and applications thereof" is filed.

Leukocyte reduction filter



Device Classification: Class C

Intended Application: For removal of white blood cells from whole blood and RBC concentrates

Product Description:

Blood transfusion is the process of infusing blood or blood products intravenously. Though a life-saving intervention, it raises some serious concerns such as infection transmission, decreased immune defense, transfusion related acute lung injury transfusion related immune suppression - most of them caused due to presence of White Blood Cells (WBC or leukocytes) in donor's blood. Leuko-reduction device filters leukocytes from the blood or blood components, thus enhancing the safety of blood transfusion. The device employs special membranes which traps WBC by adhesion as blood passes through it.

Novelty of the product: Improved housing design for better fluid distribution, reduced pressure drop during filtration.

3D bioprinted skin tissue constructs

Intended end use
For research applications

Product description
Epidermal dermal construct with fibroblast and keratinocytes. Construct can be printed of different sizes with different layers of fibroblast and keratinocytes.

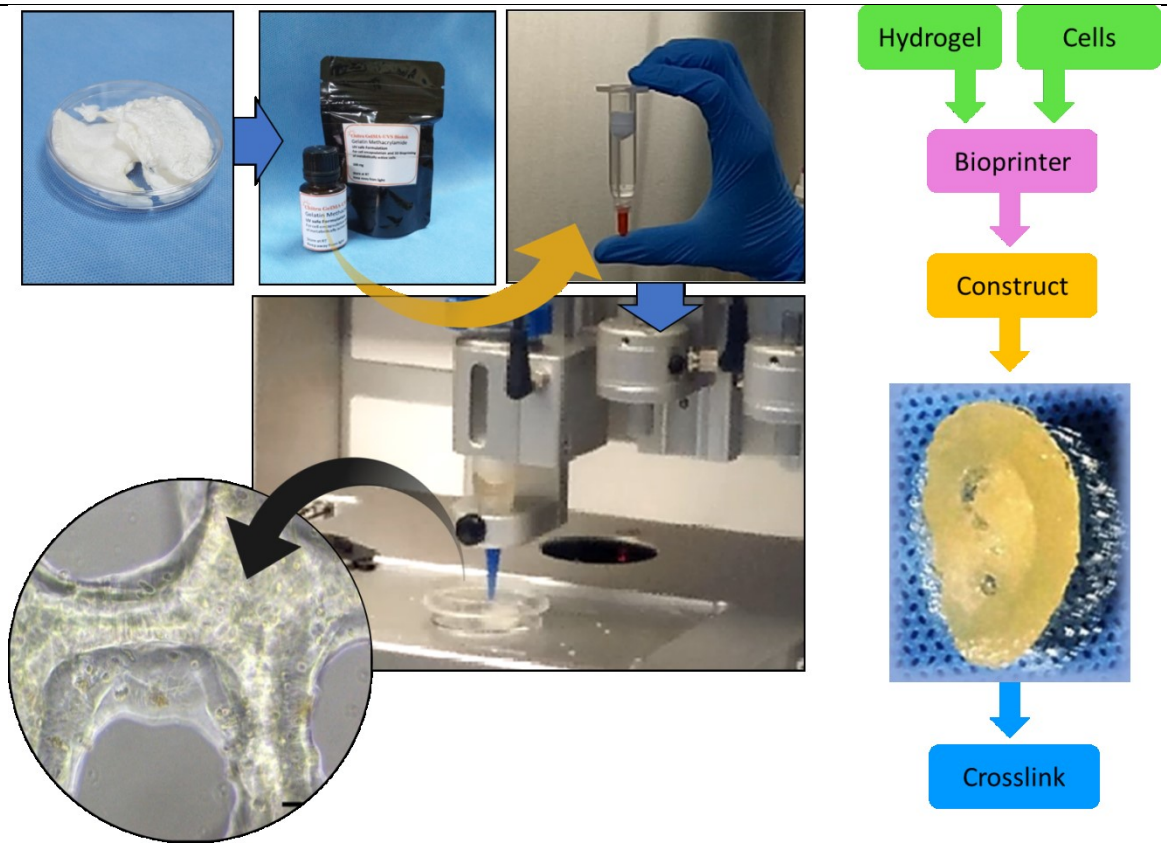
Novelty
Two patent applications filed

Current Development stage/ Evaluations done
Bioink formulation was optimized and characterized. Seeding density, media composition culture conditions were optimized for skin construct. Construct can be printed in any shapes (square, circle, rectangle, triangle)
Preliminary study on 24 rats were done

Industry responsibility
- Safety evaluation/toxicological evaluation
- Absorb the technology and deliver to the researchers

Deliverables from Institute
- Technology Transfer document with details on materials & consumables, equipment & utilities, SOPs / detailed procedures. Quality assurance, handling properties
- Training on the manufacture of the product
- Data on the evaluations done

Bioink for 3D Bioprinting



Intended end use	An optimized formulation of bioink prepolymer that has been modified with UV protective biomolecules standardized for 3D bioprinting applications
Product description	A hydrogel formulation with following properties ✓ Cell friendly ✓ Easily soluble ✓ Photo crosslinkable ✓ Novel UV safe formulation ✓ 3D printable ✓ Adjustable fluidity ✓ Consistent performance ✓ Porous ✓ Biodegradable ✓ Enzyme digestible ✓ Storage : 25°C ± 2°C

	Batch size: 200 g per month with 60% yield (lab level)
Novelty	One Indian patent application filed Three publications

Blood Plasma Derived Products

Device Classification:

Drug (IP/UP/USP)

Intended Application:

Albumin and immunoglobulin for therapeutic use in cases of blood loss, burn/liver/neurological diseases, cancer etc.

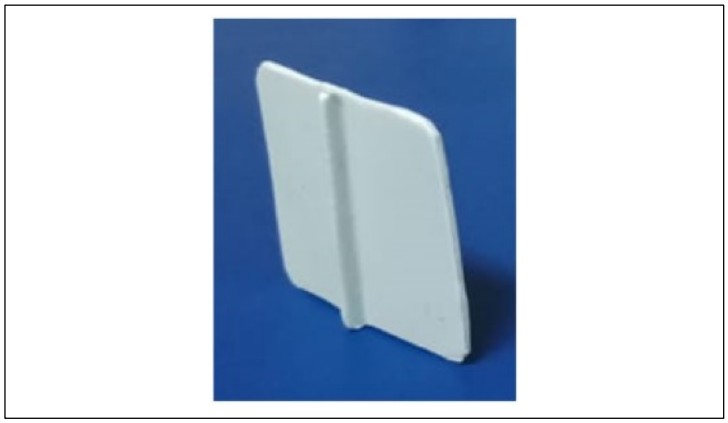
Product Description:

Both plasma products have been isolated using chromatographic processing steps to the level of purity as specified in IP/EP/USP.

Novelty of the product:

Cryo poor plasma is the starting material. Chromatographic process standardized ensues high level of purity. Both products are purified sequentially from the same starting material.

Skull Base buttress Device



Device Classification:

Intended Application: The Skull base buttress (SBB) device is intended for the closure of skull base defects formed during the surgical removal of pituitary adenomas in endoscopic transphenoidal neurosurgery.

Product Description: The product is composite sheet made of biopolymers and bioactive fillers having the capacity to integrate with cranial bone.

Novelty of the product: SBB device is flexible and have bend-recovery properties that allows the device to fold and insert through the narrow nasal cavity. The bend-recovery properties allow the device to regain its original shape from the folded conformation when the material is deployed at skull base defect site. A Projection given on the surface of SBB device allows the surgeon to hold the device using microsurgical tools, and precisely position it at the defect site of the skull base bone. Prior to deployment, the surgeon can cut and shape the device in situ at the operation site in order to fit the profile of the device to that of the defect estimated from endoscopic images. The radiopaque properties of the device allow visualizing the position of the device through X-ray imaging during post-surgical recovery.

Chitosan based antioxidant polymeric wound dressings for controlled antibiotic delivery

Device Classification:
Class C

Area of Application:
Chronic infectious wound

TRL:
TRL5

Technology
Wound dressing with antioxidant properties for in situ application of antibiotics aimed at chronic non healing wounds.

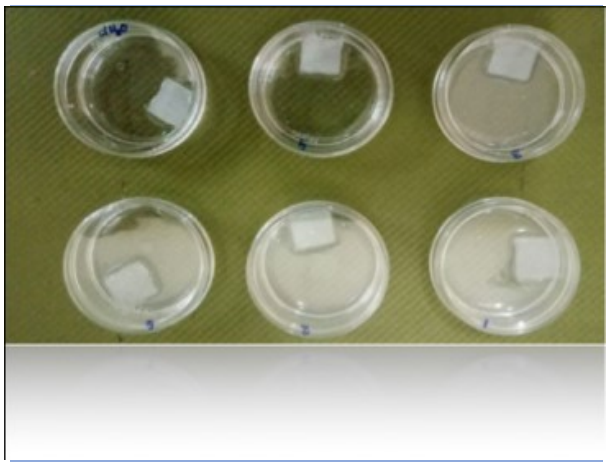
Clinical relevance
Healing of chronic wounds is a major problem of concern especially in cases of diabetic and pressure ulcers. Systemic delivery of antibiotics may not be effective in these cases. For delivery of antibiotics at the wound site an ideal dressing is required which can deliver the antibiotics in a controlled but effective manner at the wound site.

Product
The product is an advanced wound care material (primary dressing) meant for managing chronic non-healing wounds with the following features:

- Able to absorb the wound exudate
- Facilitates moist environment
- Promotes water vapour transmission
- Ability to scavenge excess reactive oxygen species in the non-healing wound bed
- Antibiotic to be delivered at wound site
- Antibiotic can be loaded by the doctor as per the need by a simple mechanism
- Can be made into different size sheets

IPR
Indian patent filed
Patent application number: 201941009511, dated 12/03/2019
Title: Antioxidant polymeric sponges for wound healing applications

Alginate scaffold with recombinant growth factors for enhanced wound healing



Device Classification:	Class B
Area of Application:	Wound healing
TRL	TRL4

Technology

Growth factors are substances secreted by the body that stimulate the growth of the cells involved in wound healing and inflammation. The novel concept allows for enhanced wound healing by incorporating growth factors.

Clinical relevance

Wound healing without scar formation is one of the major challenges. Growth factors, especially epidermal growth factors like EGF or TGFalpha are found to enhance cell proliferation. VEGF is another essential growth factor for growth of blood vessels into the wound area so that healing process is enhanced. Our approach is to incorporate both VEGF and TGFalpha for faster healing.

Product

We developed a product combination of recombinant growth factors VEGF and TGFalpha along with in-situ polymerization of alginate in difficult to heal wounds. This product will be of high value for treating chronic wounds.

Indian Patent filed –

IPMOM119.Y18 - Recombinant transforming growth factor alpha (tgfα) for various wound healing applications and the process thereof.

Scope

The industry can associate for technology transfer; carry out the field trials and further commercialization.

Automated trolley- e Drive

Medical Device Classification	Class B
Technology Readiness Level	TRL 3
Intended end use	The automated trolley e- Drive is a universal electric trolley puller/ pusher designed to be attached to any type of patient trolley so as to convert it to an electrically powered trolley. It is also provided with a patient monitoring system which makes the transport of patients safer.
Product description	The Automated trolley e Drive runs on a motor powered by a rechargeable battery. Provided with multiple clamps that can attach to any type of patient trolley, it also has a driving unit that allows for controlled acceleration and braking. A patient monitoring system is also incorporated into this unit.

TECHNOLOGIES IN THE DEVELOPMENT STAGE

Novelty	Patent Application Number: 202341002949, 14th Jan 2023 Design Application Number: No.377054-001, 09th Jan 2023 Jointly by SCTIMST and Govt. Engineering College Barton Hill.
Current Development stage/ Evaluations done	Patent filed, design registration done and initial working prototype made..
Industry responsibility	Prototype making, further testing according to industry standards and making a viable product for market.
Deliverables from Institute	Product design, technical and clinical inputs.

HRIDAY : PORTABLE LOW COST DISPOSABLE DEFIBRILLATOR FOR CARDIAC ARREST MANAGEMENT

Intended end use

HRIDAY defibrillator is low cost portable disposable defibrillator for the management of cardiac arrest victims for both Paediatric (50 joules) and Adult (150 joules)..It is mainly aiming to readily available in low cost via Ambulances,Taxis,small nursing homes, clinics, pharmacy for use.

Product description

HRIDAY portable defibrillator is an external portable defibrillator for both Pediatric and Adult. Train of shocks can be delivered with the stored energy. The casing will have a facility to view the heart rhythm rhythm via small display. User need only to switch on the device and system will monitor the ECG of the patient connected via 3 lead ECG cables. User can select either Pediatric (50 Joule) or Adult (150 Joule) option by individual switches at a time Train of 6 shocks can be delivered and after each shocks system monitor the ECG and if patient revert back it can simply stop the shock process.

Technical Details:

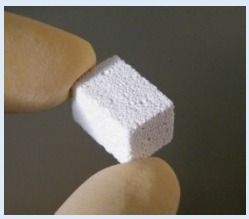
- Biphasic Paediatric and Adult shock delivering through user friendly switching operations
- 2.4 TFT display for ECG monitoring.
- Charging time for 150 joules – Less than 7 seconds
- Biphasic wave of 10 milliseconds long
- Output voltage of 1700 V and 35 Ampere for 50 ohm body impedance.
- Portable, Pre-programmed with intelligence.
- Voice assisted shock delivery.
- Delivers a Train of 6 shock of 50/150 Biphasic joules once start Sense the cardiac rhythm after each shock. If reverted stops the remaining shocks.
- DC operated-Chargeable through keyed external adapter(Can be charged at recharging centre)
- Battery – 12.5 V, 1800 mAh

- Disposable paddles

Hydroxyapatite bone graft substitute

Porous granules
(Size 2mm-3mm)

Porous blocks
(10mm cubes with 200 µm porosity)



Device Classification:	**Class D**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL9**

Technology

This technology consists of synthetic bone graft substitute based on hydroxyapatite, the bone mineral. The material is prepared through chemical reaction in implantable grade purity and converted to porous form through ceramic processing. This could be shaped into different sizes and geometries. The know-how has been developed indigenously and tested as per International standards. The intellectual property rights of the production process are protected.

Clinical relevance

The need for bone graft arises quite often in orthopaedics and spine surgeries, which is conventionally managed by autologous bone (patient's own bone harvested from other sites). Synthetic bone grafts becomes helpful in augmenting the inadequacies in grafting or to replace the autologous bone and to avoid additional surgeries. Hydroxyapatite, being similar to bone mineral, is well accepted by the body without any adverse reaction. Synthetic bone grafts with hydroxyapatite porous ceramics integrate with host bone and helps in the natural healing process to regain the normal anatomy. The material is available off-the-shelf in any quantity.

Product

The product is basically hydroxyaptite ceramic bodies of 60-70% porosity with interconnected pores in the size 150-300µm. These correspond to the mineral part of cancellous bone. This can be supplied as granules (3-5 mm size) and blocks (up to 10mm cube).

This has undergone testing cycle based on ISO 10993 and completed clinical trials.

Hydroxyapatite dense spacers

Device Classification:	**Class D**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL9**

Technology

This is a specific synthetic bone graft substitute design based on hydroxyapatite, the bone mineral. Highly dense and strong hydroxyapatite ceramic is prepared in wedge shape to provide support to the expanded vertebra in laminoplasty surgery. The material is prepared through chemical reaction in implantable grade purity.

The know-how has been developed indigenously and tested as per International standards. The intellectual property rights of the production process are protected.

Clinical relevance

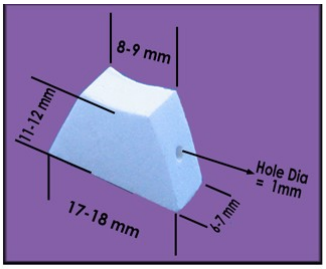
Laminoplasty is performed to treat spinal stenosis in the neck or low back. The lamina of the vertebra is carefully cut and expanded to create more space in the spinal canal, which relieves pressure from the spinal cord and nerve roots. Small wedges or pieces of bone are placed so that the enlarged spinal canal will remain in place.

This product acts as strong biocompatible wedge which will integrate with bone.

Product

This is a dense hydroxyapatite ceramic body shaped as a wedge, compatible with the sizes of the vertebrae.

The product has undergone testing cycle based on ISO 10993 and completed clinical trials.



Hydroxyapatite based cranial burr hole closure device

Device Classification:	**Class D**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL9**

Technology

The product is a mushroom-like plug of hydroxyapatite material, applicable for the closure of cranial burr-holes remaining after brain surgery. The button has a special bi-layer structure with a dense upper layer and a porous lower layer, designed as monolithic piece using a special slip-cast technique. This mimics the cranial bone and proven to integrate with human bone.

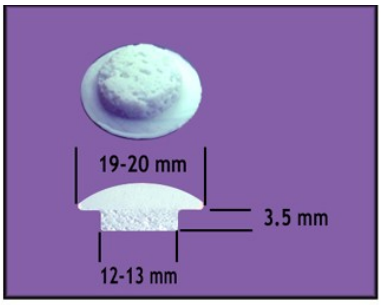
The know-how has been developed indigenously and tested for clinical efficacy. The intellectual property rights of the production process are protected.

Clinical relevance

Burr hole trephination is a safe and effective surgical option to treat patients with chronic subdural hematoma (CSDH). However, it often results in a small but undesirable scalp depression from burr-hole defect. This is a bothersome cosmetic problem and also functional handicaps to the patients especially during hairdressing or combing. Covering the burr-hole with a synthetic bone graft material is the ideal option to solve this problem.

Product

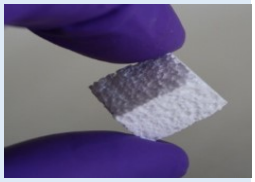
The product is made out of hydroxyapatite with a unique bi-layer structure with differing porosities, corresponding to the cortico-cancellous structure of the cranial bone. The sizes are compatible with the surgical defects.



Calcium-phospho-silicate bone graft substitute

Granules (size range 3-5 mm)

Blocks (10mm cubes)



Device Classification:	**Class D**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL9**

Technology

This technology consists of synthetic bone graft substitute based on calcium-phospho-silicate composite, which has high bioactivity. The material is prepared through chemical reaction in implantable grade purity and converted to porous form through thermal processing. This could be shaped into different sizes and geometries.

The know-how has been developed indigenously and tested as per International standards. The intellectual property rights of the production process are protected

Clinical relevance

The need for bone graft arises quite often in orthopaedics and spine surgeries, which is conventionally managed by autologous bone (patient's own bone harvested from other sites). Synthetic bone grafts becomes helpful in augmenting the inadequacies in grafting or to replace the autologous bone and to avoid additional surgeries. Hydroxyapatite, the ceramic of bone mineral, is conventionally used. Silicate containing calcium and phosphorous ions (better known as 'bioglass'), is considered as next generation bone graft compared to hydroxyapatite. It performs better, considering resorption and healing and helps to regain the normal anatomy faster . The material is available off-the-shelf in any quantity.

Product

The product is a glassy composite containing calcium-phospho-silicate phases. The porosity level is 60-70% with interconnected pores in the size 150-300µm. This can be supplied as granules (3-5 mm size) and blocks (up to 10mm cube).

This has undergone testing cycle based on ISO 10993 and completed clinical trials.

Scope

The know-how for the calcium-phospho-silicate graft substitute has been licensed. Multiple technology transfer is envisaged.

All the documents are available to obtain the production license and marketing approval.

Calcium-phospho-silicate composite periodontal graft material

Device Classification:	**Class C**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL9**

Technology

This technology consists of fine granules of bioactive material based on calcium-phospho-silicate composite. It is prepared through chemical reaction in implantable grade purity and converted to porous form through thermal processing and graded in fine particulate size. It is useful for filling periodontal bone defects in dentistry.

The know-how has been developed indigenously and tested as per International standards. The intellectual property rights of the production process are protected.

Clinical relevance

Periodontal defects and periapical cysts are common problems observed in dentistry. Fine granules or chips of bone graft materials are needed for the defect healing. Hydroxyapatite ceramics is less preferred because of slow resorption. Calcium-phospho-silicate bioactive composites enable faster healing of the defects in periodontal bone.

Product

The material contains nano level composite of hydroxyapatite, tricalcium phosphate and calcium silicate, manufactured through solid phase reaction between hydroxyapatite powder and bioactive glass powder (having calcium, phosphate and silica). It is converted to composite ceramic form and crushed and graded to obtain granules of 300-700 microns size. The material is found to be bioactive and fast resorbing compared to bare hydroxyapatite ceramics.

The product is useful for filling periodontal defects, extraction sites and ridge augmentation. Also useful in filling peri-apical cysts.

Scope

The know-how for the calcium-phospho-silicate composite periodontal graft material has been licensed and the product is available in the market. Multiple technology transfers are envisaged. All the documents are available to obtain the production license and marketing approval.

Calcium phosphate bone cement

Device Classification:	**Class C**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL9**

Technology

Calcium phosphate cements are new-generation bone filler materials, combining mouldability, resorbability and bioactivity. They are designed as powder-liquid combination, which upon mixing, gives a self setting putty. Upon setting, it will get converted to hydroxyapatite. This technology has been indigenously developed and translated to clinical application. The intellectual property rights of the production process are protected.

Clinical relevance

Bone fillers are in regular use in day-to-day orthopedics and dentistry to cover the additional gaps of implant or graft placement. Calcium salts are preferred rather than ceramic material for bone filling purpose. The advent of calcium phosphate cement was a significant development because it gave a mouldable, resorbable and bioactive material for filling applications. This cement helps in the management of bone defects in bone, spine and maxillofacial structures.

Product

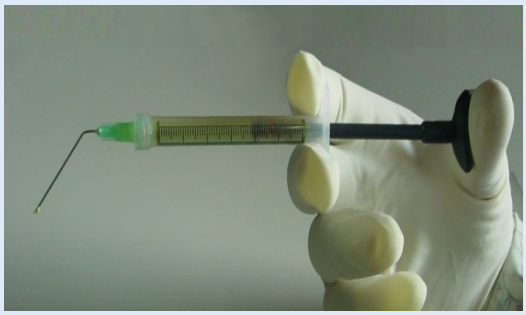
The calcium phosphate cement product comes as powder-liquid combination. Mixing the powder with the liquid in the prescribed ration will give a self-setting putty. The setting time will be 12-16 minutes and after setting the mass will develop

a strength of 10-12 MPa, comparable to spongy bone. This will get resorbed in vivo and get replaced with bone in a period of 6-9 months.

Scope

The know-how for the calcium phosphate cement has been licensed and the product is available in the market. after DCGI approval. Multiple technology transfers are envisaged. All the documents are available to obtain the production license and marketing approval.

Hydroxyapatite nanogel paste for root canal filling



Device Classification:	**Class C**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL6**

Technology

This is a nano-gel formulation of hydroxyapatite intended for the filling of root canals after pulpotomy. This satisfies most of the ideal features of a root canal filler, i.e. easily administratable, conformally filling, non-shrinking, biocompatible and completely sealing.

The know-how has been developed indigenously and tested as per International standards. The intellectual property rights of the production process are protected.

Clinical relevance

Root canal filling pastes are frequently used endodontic surgery to seal the root canal of pulp-infected tooth and to save it from extraction. An ideal root filling material should be able to administrate easily into the canal, should provide perfect sealing of the canal laterally as well as apically and should not shrink after application. Biocompatibility is an additional requirement. None of the present materials qualify these criteria. The nano-gel formulation of hydroxyapatite has proven to possess most of the characteristics. This has been particularly designed for deciduous teeth in pediatric cases where a biocompatible material is inevitable.

Product

The product consists of a special nano-gel of hydroxyapatite developed through a systematic development process. It comes as a pre-loaded injectable package convenient to transfer to root canals. It has passed the in vitro criteria prescribed by ISO/ANSI standards.

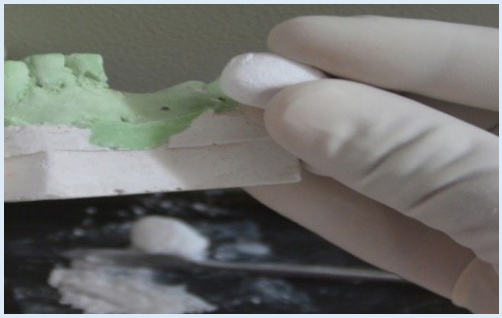
Scope

In vitro studies are completed.

Industry can associate to take forward with clinical evaluations.

TECHNOLOGIES IN THE DEVELOPMENT STAGE

Bioactive calcium sulfate cement



Device Classification:	**Class D**
Area of application	**Orthopaedic**
Technology Readiness Level	**TRL6**

Technology

Calcium sulfate cement comes as an alternative to its phosphate counterpart, retaining the properties like mouldability, resorbability and bioactivity. Major advantage is the simplicity and affordability of the material. It is a bioactive formulation of low-dimensional calcium sulfate intended for bone defect repair in orthopedic, spine and maxillofacial surgeries. It designed as powder, which upon mixing with water gives a self-setting putty. Pure calcium sulfate is made in-house and is modified with hydrogen orthophosphate ions so as to impart better biocompatibility and slower resorption.

This technology has been indigenously developed and translated to clinical application. The intellectual property rights of the production process are protected.

Clinical relevance

Bone defect repair in orthopedic, spine and maxillofacial surgeries calls for a mouldable bioactive cement material which will be helpful in grafting inaccessible sites and to build contours. This new bioactive calcium sulfate cement is a highly affordable option for bone filling. It sets by mixing with water and integrate with bone in vivo during 6-9 months.

Product

This is simple and affordable bone filler cement based on calcium sulfate, setting in water medium. The setting time will be 12-16 minutes and after setting the mass will develop strength of 10-12 MPa, comparable to spongy bone.

Scope

Pre-clinical studies completed. Clinical trials in progress.

Technology is transferred. Multiple transfers are envisaged.

TECHNOLOGIES IN THE DEVELOPMENT STAGE