Technologies in Development stage

This section is on technologies that are in the development stage

Looking for Industrial partners

Classification of technologies

The technologies under development are classified broadly under different categories based on the application of the products. Various new processes are also developed that shall find application in biomedical field.

PRODUCTS

- Cardiovascular
- Dental & Orthopaedic
- Drug, Blood and blood products
- General & plastic surgery
- In vitro Kits
- Processes

Cardiovascular

Electromagnetic Blood Flow Meter

Need Identified

The measurement and analysis of any conductive fluid, more particularly the measurement of flow of blood and other priming fluids in an extracorporeal circuit during cardiac bypass surgeries is essential. A compact device that would have high immunity to external noises and drift and eliminate the DC offset due to polarization was a major focus.

Classification

Class II

Intended application

Extracorporeal blood flow measurement

Product description & Salient features

An electromagnetic flow meter to measure the velocity and flow rate of blood and other conductive fluids used in bypass surgeries and dialysis in a cost effective way is developed. The flow meter consist of a handy probe and a signal processing system having a novel signal processing technique which enables the measurement to have better sensitivity, accuracy and stability to environmental changes.

Experimental analysis on prototype developed shows a higher sensitivity in flow variation and accuracy higher than 95%.Salient features include

- Low cost design, Handy flow probe
- Novel magnetic design for enhanced flux density near blood stream
- Improved mechanical design for reducing signal drift
- Microprocessor based flow measurement
- Advanced analogue and digital filtering for noise elimination
- Novel and improved signal extraction technique

- Signal sensitivity >80mV/1pm, Accuracy better than 95%
- Low signal variation for Ambient condition changes, Fluid connectivity variations,
- Fluid temperature variation

Novelty of the product:

Indian patent filed: High sensitive current controlled electromagnetic blood flowmeter, 2894/CHE/2013

Development stage:

Prototype developed

Future work:

Commercialization

Technology Readiness Level

TRL 3

Industry Partner identified

No

Portable Battery Operated Blood Flow Meter

Need Identified

The availability of a portable and battery operated blood flow meter would make the measurements of blood flow without constraints of switch and plug.

Intended application:

Extracorporeal blood flow measurement

Product description & Salient features:

A blood flow meter using a novel rotating permanent magnet excitation scheme is developed. A rotating disc fitted with high intensity permanent magnets in an alternate fashion provide intense sinusoidal magnetic field in the fluid stream to induce high quality signal which is processed to get the flow rates using less expensive electronic circuitry. The use of rotating permanent magnets consumes very less electrical energy and induces a smoothly varying signal without any kind of noises common in conventional systems. This novel battery powered technique enable the portability of measurement probe available in the device, light weight, less power consumption and less expensive than conventional systems. Enhanced magnetic field and low power battery operation provide enhanced patient safety, better sensitivity, accuracy and stability to environmental changes. Salient features include:

- Portable flow probe with integrated signal processing and flow display
- N ovel magnetic design for increased flux density near blood stream
- Enhanced patient safety
- Microprocessor based flow measurement
- Advanced analogues and digital filtering of noisy elimination
- Less expensive signal processing
- Power dissipation < 2W
- Low power battery operation
- Signal sensitivity > 250mV/1 pm
- Accuracy better than 95%
- Low signal variation for
- Ambient condition changes
- Fluid connectivity variations
- Fluid temperature variation

Novelty of the product:

Indian patent filed: A battery operated hand held portable blood or conducting fluid flow measuring device exhibiting high sensitivity, zero warm up time, minimum signal drift, lower heat dissipation and power losses, 19/CHE/2014

Development stage:

Prototype developed

Future work:

Commercialization

Technology Readiness Level

TRL 3

Industry Partner identified

No

DENTAL & ORTHOPAEDIC DEVICES

Mandibular Advancement Device

Need Identified

Sleep apnea is a sleep disorder characterized by pauses in breathing during sleep. Cessation of air flow for 20 to 30 sec. Each episode lasts long enough so that one or more breaths are missed. Such episodes occur repeatedly throughout sleep. About 14% of Indian population has sleep apnea. Currently used devices are expensive.

Classification

Class II

Intended application:

For the treatment of Obstructive Sleep Apnea

Product description & Salient features:

A silicone based oral device that can be worn during sleep. The device is reusable and sterilizable by putting it in boiling water.

Novelty of the product:

Not patented

Development stage:

Prototype

Future work:

Improve upon the design so that the device offers better retention in the mouth.

Technology Readiness Level

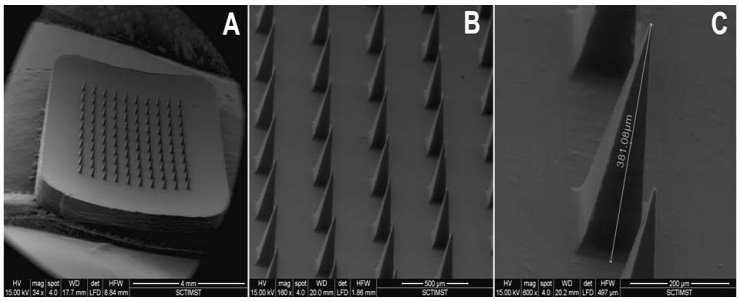
TRL 1

Industry Partner identified

No

Drugs , Blood and Biologicals

Polymeric microneedles



Need identified:

Controlled delivery of drugs, vaccines and biomolecules transdermally.

Intended application:

The micro-needle (MN) patch is aimed at delivering drugs/biomolecules in a controlled fashion. This technique can also be used for delivering vaccines painlessly. The microneedle patch could also be used for mechanical anchoring of skin grafts/substitutes in plastic surgery.

Product description:

A micro-needle (MN) patch of polymeric materials, which consists of a micro-needle array and a plate where the micro-needles are standing and aligned on, wherein the micro-needles are 100-300 µm in length, can convert from hard solid state to hydrogel state by absorbing water for controlled drug/bioactive agent delivery.

The MN patch is capable of controlled delivery of drugs/biomolecules and vaccines painlessly. Some drugs are already tested for controlled release

Novelty of the product:

Chemistry, Polymer composition and Process for fabrication

Development stage:

Process for preparing a batch of 10 numbers available.

Future work:

Controlled drug delivery of a variety of drugs to be optimized. Assessment of pain score on delivery to be done.

Technology Readiness Level

TRL2

Thrombin enriched collagen haemostat

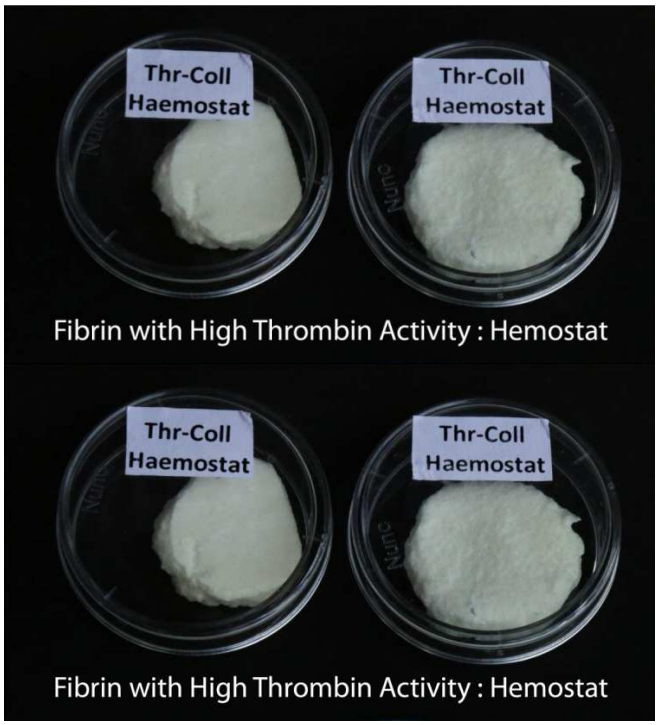
Need Identified

Accidents and war-front injuries cause major bleeding incidences leading to blood loss and death. Availability of off-the shelf hemostats can save many lives. Currently available hemostats are not efficient enough to prevent profuse bleeding. Most of the products available in the market are based on natural proteins and are expected to induce activation of clotting mechanism. Once activated the coagulation cascade produces thrombin to promote clotting of patients own blood.

Product description & Salient features

Thrombin is the most natural catalyst that induce blood clotting but it cannot be applied in liquid form because it can produce intravascular clots if even traces of thrombin enters the

blood stream. Collagen mats available in the market for wound healing applications can be used as carrier of thrombin in dried and safe form



Technology Readiness Level

TRL4

Thrombin enriched fibrin hemostat

Need Identified

Surgical bleeding often causes excessive blood loss needing several units of blood transfusion. Most of the hemostats available currently are not capable of inducing hemostasis at major internal surgical sites with high bleeding tendency. Also most of them need to be removed before suturing as these materials do not have long term biocompatibility or biodegradability. If the hemostat is removed bleeding may recur and often need re-surgery to arrest bleeding. So there is a need to develop hemostats with high efficiency to arrest bleeding, which is resorbed by body's natural absorption mechanism so that it can be left while closing the surgical wound.

Product description & Salient features

Clotted fibrin is produced with an optimum concentration of fibrin which gives porous mat for penetration of blood into the 3-D matrix so that patient's blood can clot by the action of high concentration of thrombin which is immobilized and dried..

Novelty of the product

The lyophilized fibrin and thrombin can be an off the shelf product which has >2 year shelf life. The degradation and clearance of fibrin within 30 days of use as hemostat applied on rabbit liver tissue has been demonstrated. There is fibrotic reaction in the liver tissue which assures safety of the product.

Future work

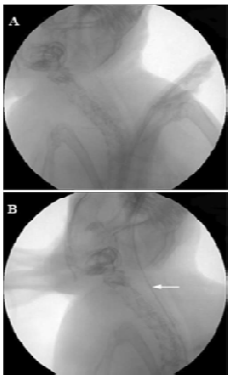
Obtain approval from drug controller for limited clinical trial. Fibrin mat is fragile and therefore, appropriate packing material has to be developed by the Industry

Technology Readiness Level

TRL5

General & Plastic Surgery Devices

X Ray opaque polyurethanes



Intended application:

Fabrication of radiopaque medical devices (e.g., catheters, tubings, etc), Radiopaque coatings for medical or non-medical devices, X-ray shielding devices.

Product description & Salient Features

This has both medical and non-medical applications wherever X-ray shielding is important. Polyurethane materials with iodine in the polymer chain. They are produced by iodinating diols and incorporating them in the polymer chain during the polymerization process.

Novelty of the product:

These are light weight polymeric materials with in-built X-ray opacity. No radiopaque additives are added in the polymer.

Patent applications filed:

Development stage

Laboratory scale

Future work:

Develop radiation shielding devices using the product

Technology Readiness Level

TRL2

Titanium (Grade 2, CP) as Reference material for bone implantation studies

Intended application:

Biological evaluation of materials based on ISO 10993

Product description & Salient Features

In the biological evaluation of biomaterials the results of experiments are always ensured

with the use of negative or positive control materials. Control material with characterized / assigned property values traceable to international standards in an established quality system platform ensures reproducible results. Such control materials can be considered as reference materials (RM) in the field of biological evaluations.

Future work:

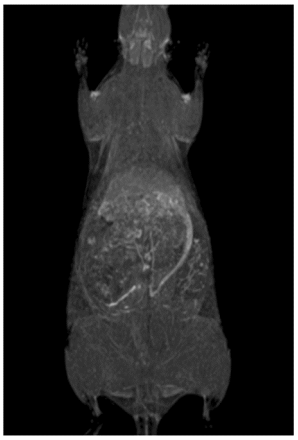
Inter laboratory comparison can be performed

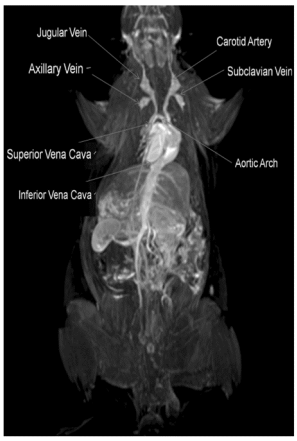
Iron nanoparticle based positive MR contrast agents

Intended application: As MRI contrast for angiograms and tumour imaging

Product description & Salient Features

Zerovalent iron based MRI contrast with longer circulation time was developed.Exhibited nontoxicity and good relaxivity properties which is comparable with that of commercially available gadolinium chelates, which has got adverse toxic effects.





As the developed zerovalent iron nanoparticles have size below 10nm it shows paramagnetic propertywith longitudinal relaxivity with an applied 1.5T magnetic field. The saturation magnetizationof the zerovalent iron nanoparticles was also comparable with that of the gadolinium contrastagent. These principles make theses material a novel one as positive contrast agent for Magnetic Resonance Imaging and for MR angiogram.

Development stage

Preclinical

Technology Readiness Level

TRL2

Iron oxide nanoparticle based negative MR contrast agents

Intended application An MRI contrast for atherosclerosis, lymph node imaging and liver imaging

Product description & Salient Features

MRI contrast agents are a group of contrast media used to improve the visibility of internalbody structures in Magnetic Resonance Imaging (MRI). The current contrast is a stable,biocompatible and size tuned iron oxide nanoparticles with highest saturation magnetizationand transverse relaxivity for 12 weighted MRI.

Novelty of the product:

Even though many contrast agents in thiscontext are available there exist only one material in this category which has got similarsurface modification compared to our material. This particular material has very less magnetic property and transverse relaxivity property compared to ours, which makes our material abetter choice for MR imaging, with better visual contrast compared to the already existing one.

Technology Readiness Level: TRL 2 Prototype

Metallic nanoclusters for brain imaging and drug delivery

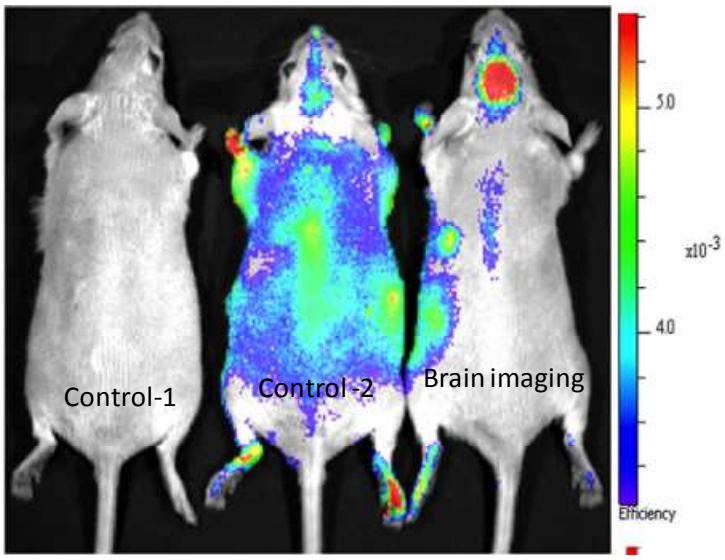
Intended application

Early stage diagnosis and drug delivery to brain at very early stages of disease when theblood brain barrier is intact

Product description & Salient Features

Blood brain barrier is served as a natural gate keeper outside the brain to protect it from theentry of unwanted things into the brain. We have developed a L doped conjugated goldcluster for theranostic applications. Drug delivery can be facilitated by attaching the drug tothis nanoconstruct.

Moreover the fluorescing property of the nanosystem enables an opticalimaging and hence can be used for diagnosis also. In vitro and preclinical studies clearlydemonstrated the efficacy of the developed system for brain imaging and treatment.



Brain imaging efficacy of gold cluster based nano probe

Novelty of the product:

Patent application filed

Technology Readiness Level: TRL 2 ,Prototype

Nano Biosensor for urea detection from whole blood

Intended application

To detect urea from whole blood (W/O separating to serum and plasma) and milk

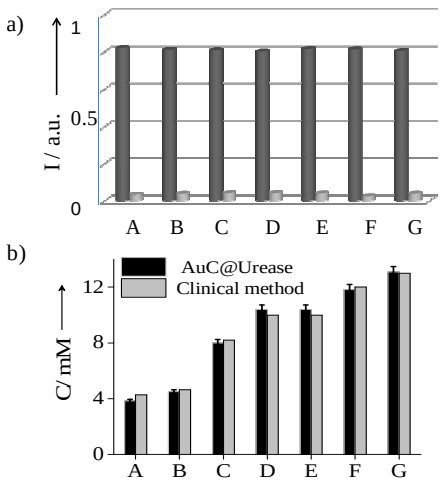
Product description & Salient Features

In severe nephritis or other disorders leading to renal failure the concentration of blood ureawill increase. Therefore urea is an important marker for evaluating uremic toxin levels and kidney functioning.

This is a novel technique to detect blood urea from the whole blood withhigh selectivity and sensitivity. The base material for this is gold cluster, a nanostructurecomprising few atoms of gold and has got fluoresecence emissions in the NIR regions andsize less than 2nm.

Novelty of the product:

The urease enzyme attached to this detects the presence of urea specifically to design thenanosensor for the blood urea detection. None of the currently available techniques couldbe used for the detection of blood urea directly from the blood with very high selectivity,sensitivity and accuracy.The nanosensor has a high potential to come out with a unique blood urea detection. Noneof the methods available in the market as such can be utilized for the detection of blood ureadirectly from the blood without separating into serum or plasma.



Patented

Selectivity of the sensor in the presence of different analytes; (A) Sensor alone (black) and after addition of urea (grey); (B-G) Sensor in presence of creatinine, albumin, glucose, uric acid, cysteine, and NaCl (black) and after addition of urea (grey). (b) Validation of the nanosensor method with the currently practiced clinical method. (A-G) serum samples spiked with different concentrations of urea

Technology Readiness Level: TRL2

IN VITRO KITS

In Vitro Pyrogen Test Kit

Need Identified

The rabbit pyrogen test which has served for drug/device safety control for more than fifty years measure the fever reaction following the injection of the sample and/extract of medical devices to the animals. Most biological especially blood derived drugs, the rabbit animal experiment is the only choice. For new therapies such as recombinant proteins or cellular therapeutics the rabbit pyrogen test is not applicable because in many cases false positive results are shown due to the species specificity of immunological recognition of these agents.

The in vitro LAL (Limulus Amebocyte Lysate) test detects only one class of pyrogen endotoxin from gram negative bacterial leaving the patients at risk from undetected non endotoxin pyrogens such as gram positive bacterial toxins, viruses and fungi. So the development of an in vitro pyrogen test system which will detect all types of pyrogens will be of great benefit to the healthcare community.

Intended application

The in vitro pyrogenicity using human whole blood assay is suitable for evaluating the biomaterials, medical devices, pharmaceuticals and blood derived products and to a wide spectrum of applications to measure the undetected non endotoxin pyrogens such as pyrogens of any chemical nature.

Product description & Salient features

A kit with a method is derived by measuring the sensitivity of the developed assay to detect low concentration pyrogenic challenges from gram negative bacterial endotoxin. The in vitro pyrogen test has the potential to replace all animal based in vivo studies in evaluation of pyrogenic response against all classes of biological and chemicals.

Novelty of the product

Indian patent filed

Development stage

Proof of Concept established

Future work

Validation pending

PROCESS

Process of detection and removal of Endosulfan from water sources using nanotechnological approach

Intended application:

To detect the deadly pesticide of endosulfan with femtomolar sensitivity from ground water and to remove it by purifying the water

Process description:

Endosulfan sensor was developed using citrate capped Cadmium selenium quantum dot for selective detection and quantification of this harmful pesticide. On addition of endosulfdan concentration dependent fluoresecence enhancement of quantum dot is observed due to the replacement of citrate from the quantum dot by endosulfan as the concentration increases.

This process results in the fluorescence enhancement of the quantum dot due the energy exchange between cadmium selenium and endosulfan. This is a convenient metod to quantify endosulfan in ground water, blood and milk.

As the endosulfan bound over surface of the quantum dot the water or milk can be purified by separating the bound pesticide by centrifugation.

Development stage:

Proof of Concept

Future work:

Scale up

Diamond like carbon based protective coating (RAXACOAT®) for metallic implants

Need Identified

Matallic components in implantable dveices require coatings that are biocompatible, imprevios and adherent to avoid in vivo corrosion. Diamond like carbon has shown to prevent leaching of metallic ions into the body. The coating finds application in dental, orthopaedic and cardio vascular implants, where protection of the metal surface is required

Intended application

For the protection of orthopaedic and dental implants

Salient features:

The Diamond Like Carbon (DLC) coating has been developed in house (with Trademark RAXACOAT R), which is biocompatible, wear resistant and corrosion resistant. The coating forms a protective layer on metallic implant surface avoiding corrosion and metal ion elution.

Novelty of the process

Protected by Indian Patent

Development stage:

Proof of Concept/Prototype

Future work:

Bone implantation studies, clinical trials

Diamond like carbon based low-friction, low wear coating (RAXACOAT®) for articulating joint prostheses

Intended application:

To minimize friction and wear in hip and knee joint prosthesis and enhance the longevity of the implant.

Salient features:

The Diamond Like Carbon (DLC) coating has been developed in house (with Trademark RAXACOAT R), which is biocompatible, wear resistant and having low friction. The coating provides a tribological layer for the articulating prostheses parts of hip implant and knee implant. It reduces the friction and wear, and add to the longevity of the implant and patient comfort.

Novelty of the process:

Protected by Indian patent

Development stage:

Proof of Concept/ Prototype

Future work:

Mechanical simulation studies, pre-clinical and clinical trials

Diamond like carbon based non reflective coating for tools and instruments used in micro surgeries

Intended application:

For reducing the reflection of microscope illumination form tools and instruments during micro surgery procedures

Salient features:

The micro surgery procedures are done by viewing under microscope with intense illumination. Metallic surfaces of tools and instruments create glare and reduce the visibility of the site. Also it causes strain to the eye of the surgeon. Diamond like Carbon based coating will reduce the reflection of from the surfaces. The coating is highly biocompatible and durable.

Development stage:

Ready to market. This is not a notified product.

Future work:

Pre-clinical and clinical trials

System for vapour polishing of plastic components, inside a metallic vessel

Need Identified

Surface finish of a plastic component can be improved by vapor polishing, where the plastic material is exposed to the vapor of a suitable solvent; the process smoothens out the irregularities on the material surface improving surface finish.

Intended application:

Polishing of plastic components

Process description

In this system the component to be polished is placed inside a temperature controlled chamber for vapor polishing and a measured quantity of solvent is delivered into the chamber; the exposure time is adjusted to achieve the required surface finish. The design of the chamber ensures complete vaporization of the fluid without droplet formation. By using a controlled quantity of solvent and varying the exposure time (without increasing the exposure volume) effective polishing is achieved on the plastic component with minimum quantity solvent and minimum environmental hazard.

- Polymers like polycarbonate can be polished without crazing
- Only a measured quantity of solvent is required
- Exposure time can be increased without increasing the exposure quantity
- Less environmental hazard
- Controlled temperature and exposure time
- Ease of operation

Novelty of the process:

Indian patent filed

Development stage:

Prototype

Future work:

Commercialization

Silver nitrate coating for infection resistant catheters – Urinary catheters, endotracheal tubes etc

Intended application:

Prevent/retard development of infections when catheters like urinary catheters, endotracheal tubes are used in health care delivery

Process description:

Urinary tract infection (UTI) caused by catheterization (CAUTI) is one of the leading cause of Nosocominal infections. Silver as an antimicrobial agent has many advantages like its broad spectrum antimicrobial activity, low toxicity to the human body and long lasting biocidal activity with high thermal stability.Urinary catheter commercially available were swollen by immersing in an organic solvent like toluene, then placed in a solution of silver nitrate in diethyl acetamide/ formamide. The solution was heated to 70 to 80OC for incorporation of AgO. Further the catheters were washed in excess of water to remove the diethyl acteamide / formamide and dried in vacuum. Polar solvents such as water or solvents like ethanol can be used with light modifications in the process, for the reaction to be carried out in cold, This is very simple and cost effective method for development of active anti-microbial catheters. The same technology can be used for endotracheal tubes also.

Development stage

For urinary catheters prototyping and efficacy proving done

Future work:

Need to take it further with industrial partner

Validation of Ethylene Oxide / Steam Sterilization equipment/process

Intended application:

Healthcare facilities with EO/steam sterilization systems

Process description:

Sterilization need to be carried out in healthcare facilities, industrial environments and laboratories regularly. Use of super heated steam and ethylene oxide for healthcare facilities and industrial sterilization are established procedures. In order to build confidence in the process of sterilization following need to be carried out:

- Selection and installation of a suitable sterilization equipment/system which will perform the sterilization with repeatability in process parameters and performance
- Selection of a sterilization method which is suitable to the requirements ie, which is suitable to the type of load that will ensure the required levels of microbial survivor index(MSI)
- Development and qualification of the sterilization system, including the process.
- The validation of the process used for the sterilization is an important step in assuring repeatable and reliable sterilization. During the validation, sterilization process must demonstrate to deliver required sterility assurance level, so that the load meets the end use requirements. This know how package describes the validation of steam and EO based sterilization equipment and / processes.

Development stage

Ready to market

Future work:

NA