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SIRIM Link

BEST PARTNER FOR INNOVATION

PROPELLING THE MEDICAL DEVICE INDUSTRY TO GREATER HEIGHTS
– Dr. Kartini Noorsal

INSPIRING BETTER IMPLANT TECHNOLOGY
– Dr. Rosdi Ibrahim

REDEFINING THE BONE GRAFT INDUSTRY
– Faizura Mohd Nor Arjamli

MALAYSIA'S MEDICAL DEVICE INDUSTRY

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Foreword

The global medical device industry has been growing at an exponential rate and is expected to reach an estimated RM1,716.75 billion (US$409.5 billion) by 2023. Malaysia has a firm footing on this burgeoning pie, achieving breakthrough export sales exceeding RM20 billion just last year.*

* Source: FinancialNewsMedia.com

With our diverse competencies, SIRIM is ready to help the country to reinforce its position in the global arena and establish itself as a prominent regional medical device hub. For one, we play an integral role in assisting the nation's regulators in the implementation and upholding of the related regulations, including the initial development of the Medical Device Act 2012. We are also constantly pushing the frontiers of technological advancements to provide a wide range of innovative offerings, which are set, not only to benefit the healthcare sector, but also to facilitate the growth of our small and medium enterprises (SMEs) involved in the industry. But that's just the beginning.

The potential and capabilities are there. Now, we just have to work together with the respective authorities, agencies and industry players to leverage our key strengths for the benefit of our SMEs, industry and economy.

The future is **BRIGHT** *for the* **MEDICAL DEVICE INDUSTRY**

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For further information on the articles featured in this magazine, please contact:
Corporate Affairs Section
SIRIM Berhad
1, Persiaran Dato' Menteri
Section 2, 40700 Shah Alam, Selangor

Tel: 03-5544 6772
Fax: 03-5544 6745

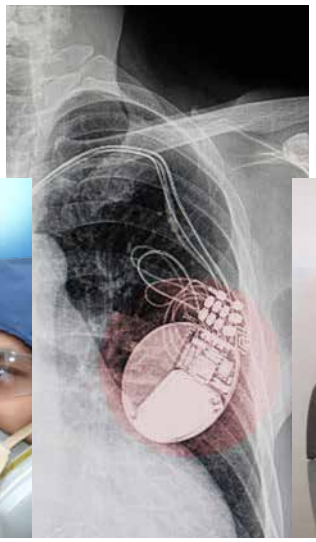
E-mail: publications@sirim.my

The current boom in Malaysia's medical device industry bodes well for industry players. To tap into the potential of this high-growth sector and stay competitive, innovation, productivity and best industry practices should be prioritised.

CONTENTS

With the proper ecosystem in place, the country is well-poised to take our medical device industry to the next level.






PROPELLING *the* MEDICAL DEVICE INDUSTRY *to greater heights*

DID YOU KNOW?

Malaysia is the world's largest producer and supplier of medical gloves (examination and surgical gloves), contributing 63% of the global supply.

Source: Malaysian Rubber Glove Manufacturers Association

Equipped with the right expertise and infrastructure, and surrounded by the right industry players – the potential is definitely there for SIRIM Kulim to transform itself into a Manufacturing Innovation Centre for Medical Devices.

The medical device industry is a burgeoning one. As one of the '3+2' high-growth subsectors under the 11th Malaysia Plan, the industry has been identified as an integral growth area in the country's economy. With over 200 manufacturers and implemented investments valued at over RM14 billion, Malaysia is definitely on its way as an up-and-coming global medical device manufacturing hub.

Nevertheless, the industry still has a long road ahead. One of the major concerns is the level of technological prowess of local players. "We are in the midst of the fourth industrial revolution, but the research and development capabilities of our medical device manufacturers remain low presently," shared Dr. Kartini Noorsal, Director of the Industrial Centre of Innovation in Biomedical at SIRIM Industrial Research.

According to her, this can be attributed to several factors, including a low focus on technological advancements and product innovation. For one, the small and medium enterprises (SMEs) tend to have a smaller budget allocation for research and development. "Typically, less than six percent of the company's total spending is directed to research and development," she said.

Many of these companies are not yet ready to invest in high technology. As high technology requires a higher investment and possibly longer waiting period for returns, the companies will keep to simpler, more generic products or acquire the technology and expertise they need from abroad. "The companies do not have the ability to develop their own technology. As a result, we have very minimal home-grown technology," lamented Dr. Kartini.

A Catalyst for the Medical Device Industry

To address this issue, SIRIM is looking into establishing Manufacturing Innovation Centres (MICs) for medical devices. With a mission of developing the nation's medical device industry as a whole to enhance our competitiveness, the MIC aims to assist in building capabilities to address manufacturing gaps and market regulations as well as growing the product innovation capabilities of medical device manufacturers in the country.

With over half a century of experience and expertise under its belt along with state-of-the-art equipment and facilities, SIRIM has plenty to offer. "SIRIM is a well-established name in the industry, and we offer a wide range of services that include bio-modelling and prototyping, industrial research and product innovation, technology commercialisation, accredited testing, certifications, training and consultation," elaborated Dr. Kartini.

Supported by its industrial research centres and subsidiaries, SIRIM has an extensive range of capabilities, from research and development to commercialisation, that industry players can tap into to facilitate market access.

"We can offer market access programmes to help companies meet the necessary requirements, or even business strategy programmes for those who might need help in this area," said Dr. Kartini.

> *SIRIM is a well-established name in the industry, and we offer a wide range of services that include bio-modelling and prototyping, industrial research and product innovation, technology commercialisation, accredited testing, certifications, training and consultation.*

THE EPICENTRE OF THE MEDICAL DEVICE ECOSYSTEM

SIRIM Kulim began life as the Advanced Materials Research Centre (AMREC), which was set up in 1996 in the Kulim Hi-tech Park with a focus on material research and testing. Today, it is home to numerous industrial centres of innovation, and has evolved its focus to market-driven research to better serve the needs of industries.

SIRIM Kulim has a strategic advantage in facilitating the nation's aspirations to become a medical device hub. For one, its location in the Kulim Hi-tech Park within the northern region means that it is within close proximity to diverse industry players, big and small. Internally, it is equipped with state-of-the-art facilities and helmed by highly trained professionals with insights into all facets of the entire value chain, making it an ideal one-stop venue to serve the needs of industry players.

Understanding that finances can be a huge deterrent, especially for start-ups and SMEs, she further suggested that SIRIM could employ a business incubator concept, renting out its facilities to this category of industry players for them to enhance their technology and innovation.

Three-way Partnership

To ensure the success of the MICs, all parties involved, such as the government, industry and research institutes, have to work closely together. "We need institutional support from the government, including funding, infrastructure and regulatory support. For example, countries like Korea and Taiwan have policies in place that prioritise the use of local medical devices. Perhaps the government could help the local medical device industry by doing something similar," suggested Dr. Kartini.

> *We can offer market access programmes to help companies meet the necessary requirements, or even business strategy programmes for those who might need help in this area.*

Industry players could also collaborate with research institutes to develop more innovations. "Industry players have cited lack of research and development capability as one of their stumbling blocks. Why not work with research institutes? We need to develop the necessary talent and attain a certain level of skill to catalyse innovation," she continued.

Acknowledging that industries, even multinational companies, will be hard-pressed to do everything by themselves, Dr. Kartini sees collaborations to be the way forward, especially during this era of Industry 4.0. "Whether the collaborations are between industries and research institutes or among industry players themselves, this means that they will not have to take on every manufacturing aspect themselves. This could happen during the marketing stage or production line stage. The larger companies could also outsource some of the tasks to the smaller vendors."

Essentially, the establishment of a solid platform will allow all industry players to move forward together for the benefit of both industry and the nation, and ensure that nobody is left behind.

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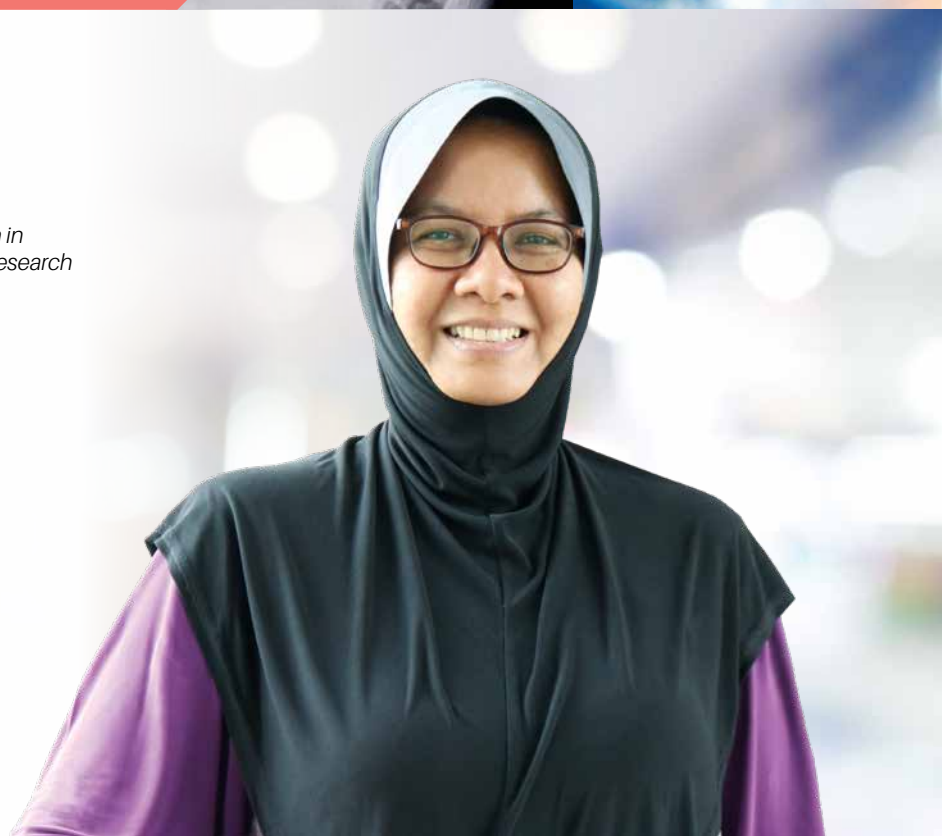
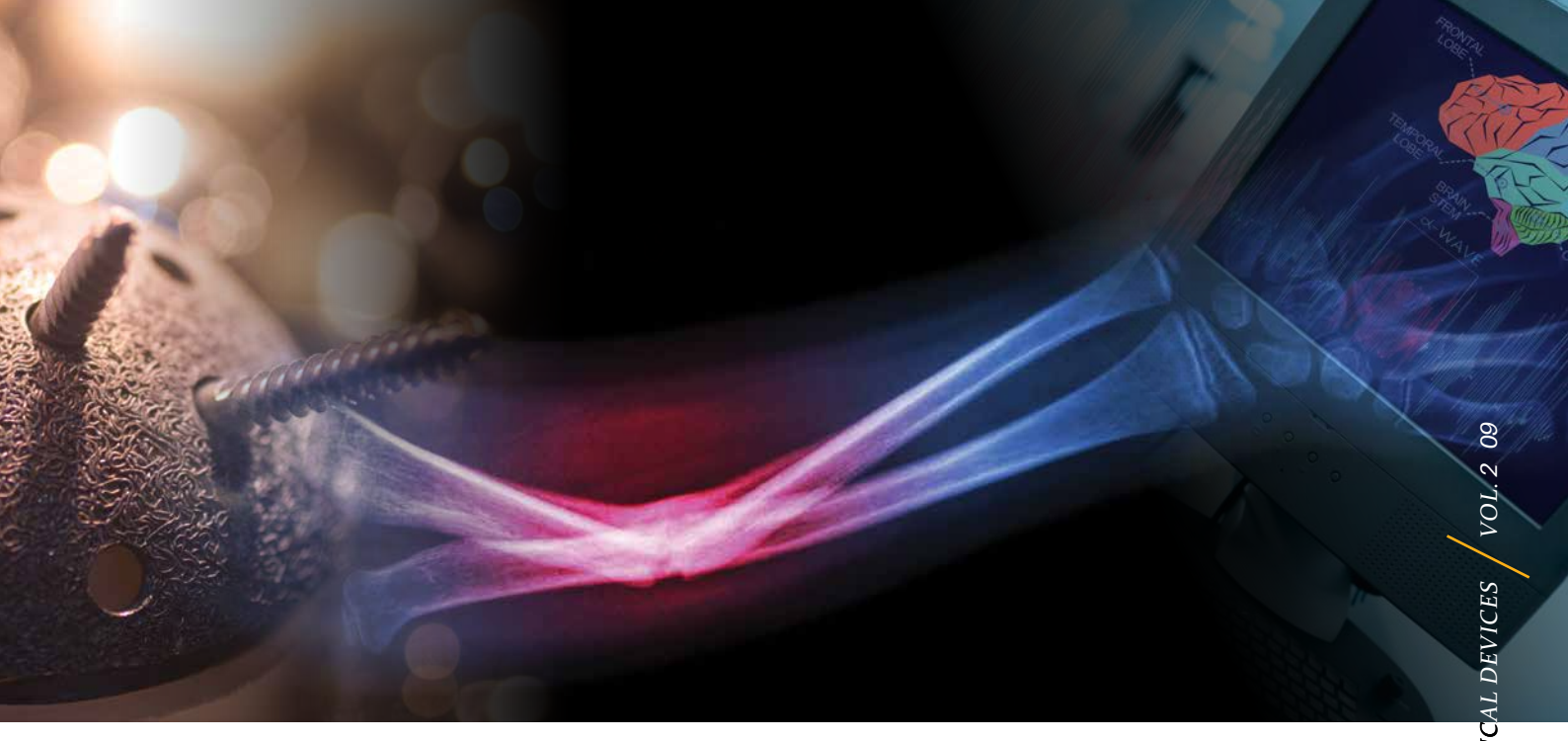


Dr. Kartini Noorsal,
Director,
Industrial Centre of Innovation in Biomedical, SIRIM Industrial Research



Upholding MALAYSIA'S MEDICAL DEVICE INDUSTRY

The medical device industry is full of extensive rules and policies, and rightfully so. Puan Salbiah Yaakop, Senior Principal Assistant Director of the Medical Device Authority, shares with SIRIMLink *the finer points of this highly regulated industry.*

DID YOU KNOW?

According to the World Health Organization, "medical device" refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended to be used, alone or in combination, for human beings for specific medical purposes.

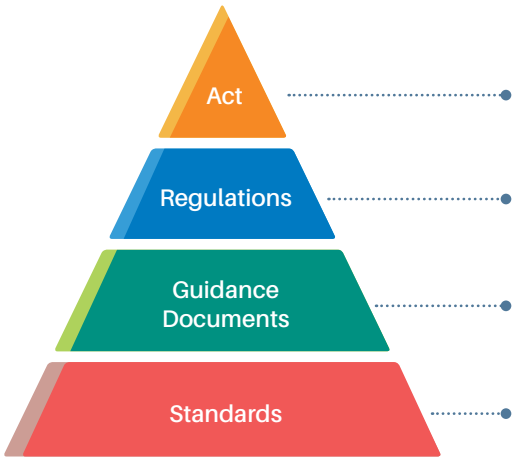
When it comes to medical devices, human health and safety are often on the line. As such, it comes as no surprise that industry players would have to abide by a myriad of stringent requirements. "It's a regulated industry!" declared Puan Salbiah Yaakop, the Senior Principal Assistant Director of the Medical Device Authority (MDA). "Most countries around the world have regulations in place to control medical devices."

MDA looks into the regulatory aspects of the industry in Malaysia, focusing on the safety and performance of the devices. Among others, it manages the registration of devices and licence applications from medical device companies. For the former, the registration validity period is normally five years, after which the device will need to be reregistered.

As the full enforcement effective date for registration of medical devices was on 1 July 2018, in accordance with the Medical Device Act 2012, there has been a sharp upswing in the number of registrations. However, Puan Salbiah expects the numbers to stabilise and decline slowly in coming years. "Even after the existing devices have been registered, new devices (whether being manufactured or imported) still kept coming into the market at a steady phase and new registrations are still taking place," she explained.

The regulatory control extends to the post-market period; even after the devices have been sold, it is still necessary to monitor the status of the devices to ensure their safety and performance. In this circumstance, both the regulator and the industry play collaborative roles. The regulator would have to make sure that the proper system is being implemented, while the necessary establishments need to monitor for safety issues or other adverse events that could happen wherever the devices have been placed.

Defining the Terms



- Act — Tells that the device needs to be safe
- Regulations — Tells how to make the device safe
- Guidance Documents — Provides further explanations on the requirements of the regulations
- Standards — Used to support/demonstrate compliance with the regulatory requirements

A Stringent Process

First and foremost, in order for the companies to conduct their business, whether it is manufacturing, distributing, importing or exporting medical devices, they will have to get their establishments licensed. To do so, they need to adhere to the respective quality management systems, such as the ISO 13485 for manufacturers or the Good Distribution Practice for Medical Device (GDPMD) for distributors, authorised representatives and importers. Certifications for these can be obtained through Conformity Assessment Bodies (CAB), after which the company will be able to apply for its licence from MDA.

To place a medical device in the marketplace or to import a medical device, on the other hand, the company will have to look into four conformity assessment elements before they are able to register the device. These are:

a) Quality management system (QMS);
b) Post-market surveillance system;
c) Technical documentation; and
d) Declaration of conformity

The medical device regulations in Malaysia are not developed from scratch. Rather, they are based on the World Health Organization (WHO) framework and in accordance with international practices. "We adapt to the local scenarios where needed, but the adaptations will be in line with international practices," clarified Puan Salbiah.

There are specific risk classification rules and standards for different types of devices to adhere to, depending on which class they fall under, for example. This is based on the devices' intended purpose and indication for use. As a rule of thumb, medical devices can be classified as Class A (low risk), Class B (low to moderate risk), Class C (moderate to high risk) and Class D (highest risk). "These are standard risk classification rules that most countries follow, so if in Malaysia, the device is a Class A device, most of the time it will also be Class A in other countries."

> *We are looking at new developments every day; hence there will constantly be new issues cropping up, especially since the Medical Device Act is still relatively new.*
>
> E

ABOUT THE MEDICAL DEVICE AUTHORITY

The Medical Device Authority was established as a federal statutory agency under the Ministry of Health Malaysia. The agency is entrusted to serve Malaysia's medical device industry by implementing and enforcing the Medical Device Act 2012.

The main functions of the Medical Device Authority include:

- Registration of medical devices
- Registration of Conformity Assessment Bodies (CAB)
- Issuance of establishment licences
- Audits and inspections of CAB, establishments and healthcare facilities
- Post-market surveillance and vigilance
- Issuance of Free Sales Certificate and Manufacturing Certificate
- Compliance monitoring and enforcement activities
- Training and awareness

> *We adapt to the local scenarios where needed, but the adaptations will be in line with international practices. These are standard risk classification rules that most countries follow, so if in Malaysia, the device is a Class A device, most of the time it will also be Class A in other countries.*
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> E

Puan Salbiah Yaakop,
Senior Principal Assistant Director,
Medical Device Authority (MDA)

International Medical Device Conference (IMDC) & Malaysia Medical Device Expo (MyMEDEX)

expo2019

15 – 17 OCT.2019

IMDC & MyMEDEX are very good platforms for local players to meet and network with international players.

SAFETY FIRST

The safety and performance aspects of the medical devices are very important. As such, a manufacturer has to ensure that its devices are able to do what they are intended to do. In this respect, the Essential Principles for Safety and Performance (EPSP) of medical devices, which was published by the GHTF (now known as the International Medical Device Regulators Forum, IMDRF), is being adopted across the world. According to one of the elements of the EPSP, the devices will have to undergo risk management to demonstrate that any risks stemming from the use of the devices are minimised.

These regulations may evolve according to current issues and needs. To revise existing regulations and requirements is an extensive process that has to be vetted by committees and approved by the Health Minister. If a change in law requirements is necessary, the Attorney-General would be involved as well. "We are looking at new developments every day; hence there will constantly be new issues cropping up, especially since the Medical Device Act is still relatively new," explained Puan Salbiah.

Some of the new policies that have been developed recently are regarding labelling requirements, authorised representatives and ownership changes. Additionally, MDA is looking at coming up with more post-market regulations, including advertising requirements. MDA also introduced several exemptions such as for devices made for demonstrations and clinical trials as well as export-only devices. As the latter would be regulated in the countries to which they are being exported, MDA does not see any need for double control and recognises that the policy would promote the export industry.

Working Hand-in-Hand

MDA works very closely with SIRIM in ensuring that the medical device industry is properly regulated. "SIRIM has always been supportive of the medical device regulatory systems and MDA in general," said Puan Salbiah. "In fact, the Medical Device Act was conceived after Ministry of Health personnel checked with SIRIM on relevant standards to support medical devices, and SIRIM was an active contributor to the development of the Act."

Among others, MDA has chaired committees managed by SIRIM to develop standards for medical devices as well. The former also works closely with SIRIM QAS International, which is registered as a CAB with MDA. "They are like our right arm, scrutinising evidences, providing ISO 13485 certifications and conducting product conformity assessments. SIRIM holds a lot of responsibilities in supporting the control of the medical device industry," shared Puan Salbiah.

Reaching Out

As a regulatory body, one of the responsibilities of MDA is to relay the information to all stakeholders. "We have conducted many awareness programmes throughout the entire country – from the north to the south, right to East Malaysia. Now, we also give customised consultations and trainings for specific industry requests. We are always open for the public to just walk in and ask about anything," commented Puan Salbiah. The agency has even reached out to hospitals to make sure that they purchase safe products that have been properly registered.

MDA is hosting the International Medical Device Conference (IMDC) and the Malaysia Medical Device Expo 2019 (MyMEDEX) from 15-17 October 2019. The conference-cum-exhibition event brings together industry leaders, researchers, service providers, medical practitioners, regulators, investors, distributors, start-ups and key players, showcasing the latest technologies and innovations in the global medical device industry. "IMDC and MyMEDEX are very good platforms for local players to meet and network with international players," said Puan Salbiah.

To find out more or register for the event, contact the Secretariat at +603 8230 0300/0211 or visit www.mymedex.com.my

Seafood waste is often replete with chitin, which has healing properties. SIRIM taps into this potential to introduce a range of wound management products.

Championing **CHITOSAN**

> *Our intention is to give our patients, such as burn victims or those with other skin injuries, a new lease of life.*
>
> *It is like using bandages. You just use one, then dispose of it and replace with a new one.*

One of SIRIM's most successful innovations is Chitosan, a range of biomedical-grade products derived from water-soluble chitosan, which is a polysaccharide made of chitin. Chitin can be found in the cell walls of fungi and the exoskeletons of crustaceans like prawns and crabs. Thanks to its antioxidative, anti-microbial and hemostatic properties, chitosan can help to staunch bleeding while also discouraging the growth of keloids.

According to Dr. Kartini Noorsal, Director of the Industrial Centre of Innovation in Biomedical in SIRIM, "Our intention is to give our patients, such as burn victims or those with other skin injuries, a new lease of life."

Among others, SIRIM is working on a bilayer product, comprising a sponge layer and dense layer, to facilitate tissue regeneration in third-degree burn patients (i.e. those who have lost their epidermis, dermis and subcutaneous tissue). After the affected tissue has been removed, a scaffold, called the Chyto Skin Regeneration Template (SRT), will be placed in the wound, acting like a framework to promote new skin growth. After approximately one month, the scaffold will degrade and is expected to be replaced by the skin.

Another promising product is the Chyto Sponge. WIth its high fluid absorption capacity, it is ideal for high exudate wounds. Additionally, its porosity allows oxygen permeability and controls dehydration, while its naturally occurring anti-bacterial properties helps to impede infections.

The Chyto Sponge is applied to the wound every few days. "It is like using bandages. You just use one, then dispose of it and replace with a new one," explained Dr. Kartini. Improvements can usually be observed within one to two weeks.

"We've done a lot of work on this, including completing the pre-clinical study in Australia," she added. The clinical trial phase of the product was recently completed at Universiti Sains Malaysia in Kubang Kerian (USM Kubang Kerian), Kelantan. "We are now in the process of transferring the technology to a company; as such we are also looking into obtaining the ISO 13485 certification to facilitate the company's marketing endeavours," she shared.

HEALING HEROES

Researchers in SIRIM's Industrial Biotechnology Research Centre have developed numerous wound healing products in its Chitosan range. These include:

- Chitosan hydrogel - for hydrating wound surfaces
- Chitosan gel - for cavity wounds
- A semi-permeable Chitosan film dressing - for shallow wounds

A Medical Perspective

Associate Professor (Dr.) Wan Azman Wan Sulaiman from the School of Medical Sciences at USM Kubang Kerian, who was involved in the clinical trial for the Chyto Sponge, weighed in on the product's performance, sharing his experience in treating Rohani, who was one of the participants of the trial.

According to him, there are various types of wounds that are referred to them for management and treatment, such as acute, chronic, infected, diabetic and vascular wounds. Most of the time, these wounds do not heal normally. Consequently, the wound management would depend on the severity of the wound.

PROPER PROTOCOL

A randomised controlled trial was conducted to research the efficacy of using the Chyto Sponge compared to current commercially available products. For this purpose, the trial followed the normal protocol for wound management, whereby the wound was cleaned before the Chyto Sponge dressing was applied, with no other form of treatment given. Regular wound inspections were conducted thereafter.

> *We've done a lot of work on this, including completing the pre-clinical study in Australia. We are now in the process of transferring the technology to a company; as such we are also looking into obtaining the ISO 13485 certification to facilitate the company's marketing endeavours.*

Pathological Wound Care Management

Infection is a major concern when it comes to open wounds. This will usually occur after two weeks. Rohani came to Dr. Wan Azman with a small traumatic wound on her heel pad. "As Rohani's wound was approximately 10mm in size, we estimated that the wound would be able to contract and heal in just a week," he said.

As such, it was decided that the wound could be allowed to heal normally. "This meant she would not have to go through a skin graft. All that was needed was the dressing. We applied the Chyto Sponge dressing and allowed the wound to contract and heal by itself," he added.

This is termed as secondary wound healing, where nothing else is actively pursued. Nevertheless, it was important that the dressing would be able to promote granulation and contraction as that would mean that the wound was showing signs of healing.

"In Rohani's case, after the first wound inspection, we could already see the granulation tissue. As such, we continued the dressing protocol until the wound had properly contracted and healed," said Dr. Wan Azman.

The same observations were made in other cases as well. "When we used the Chyto Sponge, the wound would show the formation of healthy granulation tissue after one or two dressings," he divulged.

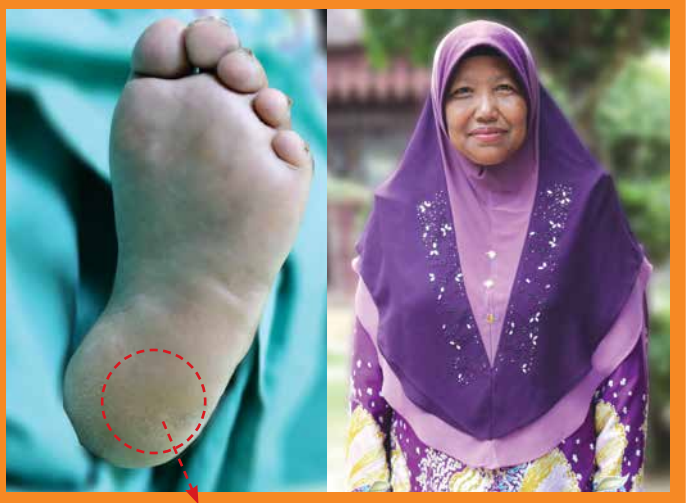
The Chyto Sponge is usually applied for a maximum of one month for wounds that have been determined to be managed via secondary contraction. Rohani's wound was healed after two weeks.

DID YOU KNOW?

The rate of contraction for the skin is around 1mm per day.

"In Rohani's case, after the first wound inspection, we could already see the granulation tissue. As such, we continued the dressing protocol until the wound had properly contracted and healed."

"When we used the Chyto Sponge, the wound would show the formation of healthy granulation tissue after one or two dressings."



After applying the Chyto Sponge dressing, Rohani's wound healed within two weeks

Comparable Alternative

According to Dr. Wan Azman, the Chyto Sponge is on par with other products that are commercially available internationally in terms of clinical benefits. In fact, the Chyto Sponge has been proven to perform better in some cases, particularly when it comes to the granulation tissue formation rate.

Moreover, it also features other benefits. "As it is locally produced, the product is also more cost-effective and easily available. In fact, it is extracted from chitin, which is a waste product! Before, this would have been thrown away. Now, we have discovered a use for it that is comparable to internationally available products," enthused Dr. Wan Azman.

Additionally, it moulds well with the wound surface. "The Chyto Sponge is easy to apply on the wound, and offers good contact, even when it comes to irregular wound surfaces," he noted. "In terms of tissue reaction, as it is a biological product, there were some expectations of hypersensitivity to the product, but that has not been the case," he added.

Dr. Wan Azman perceives that there is still room to expand and enhance the capabilities of the Chyto Sponge, but foresees a bright future for the product. "The market for dressing materials is big, so the demand is always there. The commercially available dressing materials available now are almost always imported. Subsequently, with the Chyto Sponge, there's a potential for Malaysia to save on foreign currency exchange. It's a multimillion dollar business, after all!"

IMPROVING QUALITY OF LIFE

"I was involved in an accident when I was young. Through the years, complications arose and I had difficulty walking properly because of a wound on my heel pad that could not heal properly. I recently underwent a wound management treatment using the Chyto Sponge. During this time, my wound was cleaned and the Chyto Sponge dressing was replaced frequently. Within two weeks, the wound had healed completely!"

- Rohani Husin, age 57

> *As it is locally produced, the product is also more cost-effective and easily available. In fact, it is extracted from chitin, which is a waste product! Before, this would have thrown away. Now, we have discovered a use for it that is comparable to internationally available products.*

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Associate Professor (Dr.) Wan Azman Wan Sulaiman,
School of Medical Sciences, USM Kubang Kerian

BIOMEDICAL COATING *for* ORTHOPAEDIC IMPLANTS

ABOUT HYDROXYAPATITE

Hydroxyapatite (HA) coating is well-known to promote bone integration between the bone and various medical implants. HA largely consists of calcium and phosphorus elements. This composition enables HA coating on medical implants to structurally and functionally connect with the human bone.

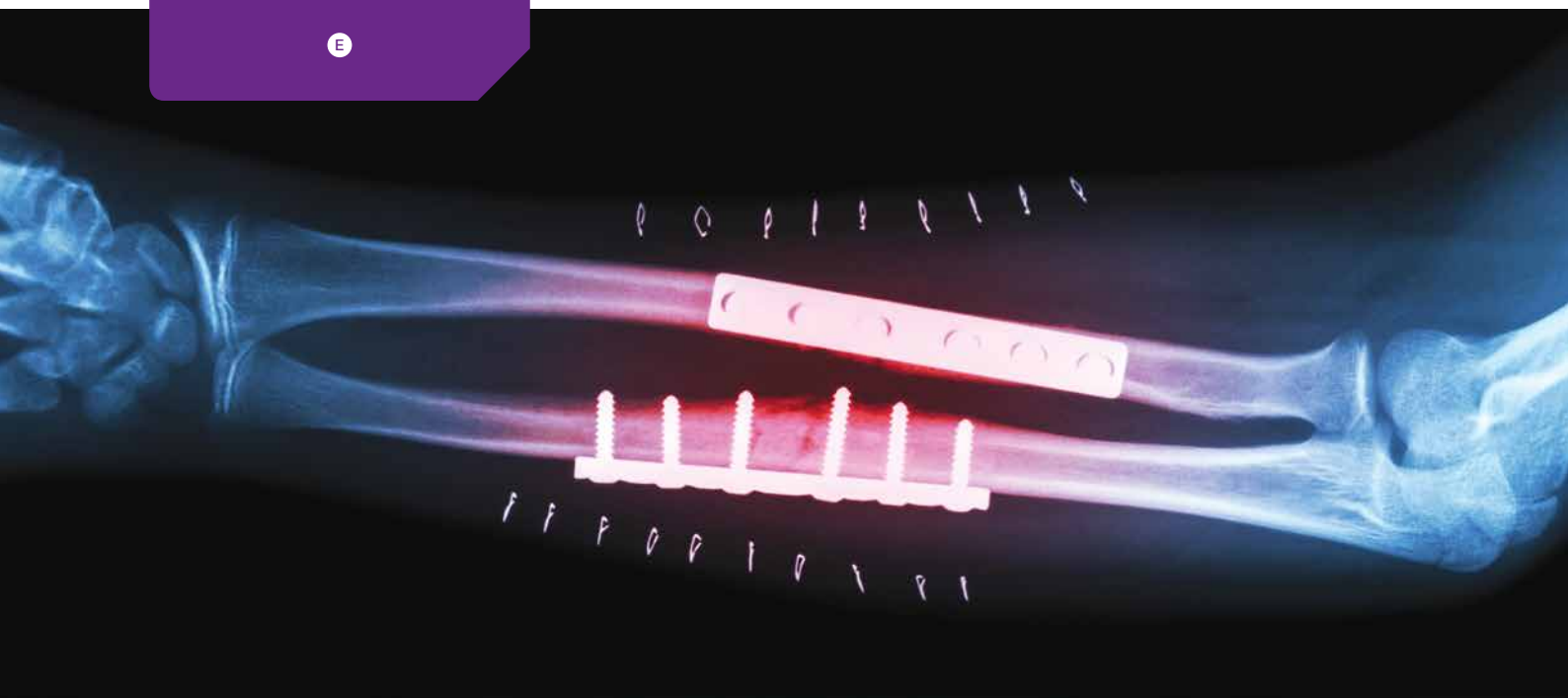
Metallic orthopaedic implants are a commonly used medical device. SIRIM has found a way to facilitate bonding between the implant and the patient's bone.

> *HA is known as a bio-active material because of its capability to forge bonds with the bone tissue. The HA coating in cement-less implant fixation promotes bone in-growth, which then results in the anchorage of the implants with bone.*

Orthopaedic implants have become necessary to replace diseased bones or joints. The implant evolution has resulted in procedures such as hip, knee and shoulder replacements. Typically, metals such as titanium alloys and stainless steel materials are used for this purpose. The smooth surface of metal implants is biologically inert. This can cause non-adherent capsule formation without bonding with the bone. When that happens, over time, daily wear and tear can cause aseptic loosening, creating a gap between the bone and the implant.

To counter this issue, hydroxyapatite (HA), which is a bio-active material, has been identified as an ideal coating that is used in cement-less implant fixations. It is mainly used as a coating for hip, knee and even dental implants. The bio-active HA coating will accelerate bone formation around the metallic implant.

"HA is known as a bio-active material because of its capability to forge bonds with the bone tissue. The HA coating in cement-less implant fixation promotes bone in-growth, which then results in the anchorage of the implants with bone," explained Dr. Jamuna Thevi Kalitheertha Thevar, a Senior Researcher at SIRIM's Industrial Centre of Innovation in Biomedical. "Because of this, it is ideal for patients who are suffering from bone diseases or traumatic injuries, as well as the elderly population."

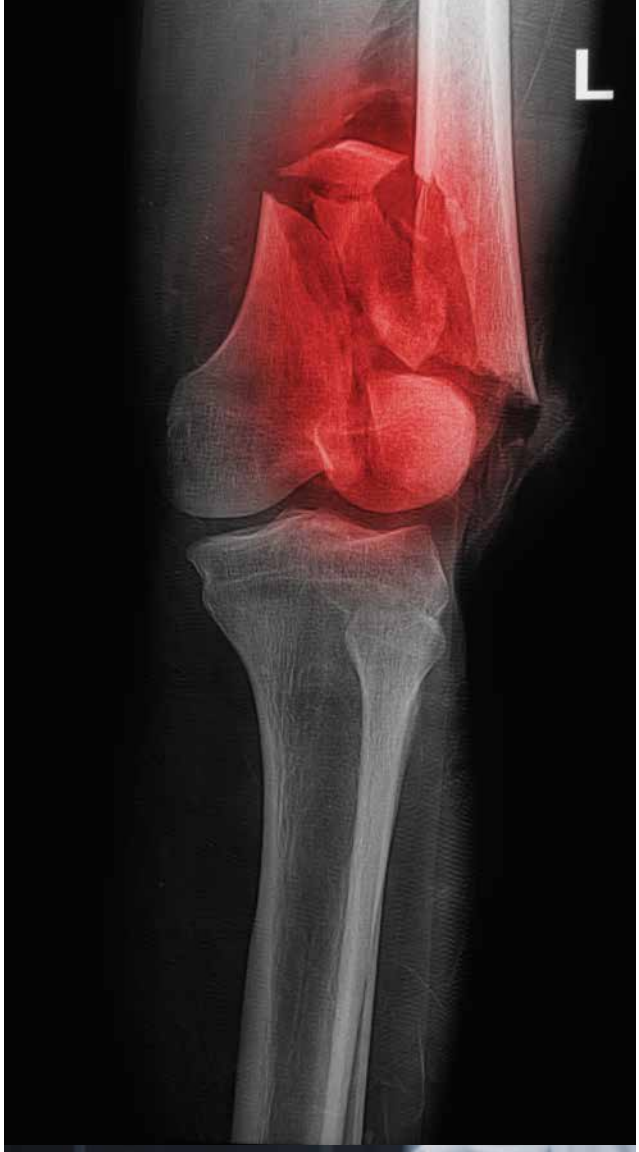


The HA as a raw material is used in powder form for coating applications using an atmospheric plasma spray system at a high temperature to enable it to adhere to the metal implant. To ensure that the coatings are acceptable for medical applications, properties such as roughness, crystallinity and thickness are evaluated according to ISO standard specification (ISO 13779).

Bright Future

Although the HA coating is still currently in the research and development stage, it has already attracted the attention of local medical device manufacturers. During a recent technology audit programme, SIRIM encountered a company looking for a service provider offering coating services. "This has been a great window of opportunity for SIRIM, and we look forward to taking this innovation further as it goes into the clinical trial phase before being commercialised," said Dr. Jamuna enthusiastically.

Dr. Jamuna is confident that the HA coating service will contribute to the medical device industry, consequently elevating Malaysia's position as a premier medical device hub in the region. With the HA coating service, local medical implant manufacturers will be able to add value to their products by producing finished products. This coating service has also caught the eye of local dental implant manufacturers. "This service will enhance Malaysia's capability in producing high-end finished medical products for the world market," she declared.



> *This has been a great window of opportunity for SIRIM, and we look forward to taking this innovation further as it goes into the clinical trial phase before being commercialised.*

> *This service will enhance Malaysia's capability in producing high-end finished medical products for the world market.*

Moving toward Commercialisation

According to Dr. Jamuna, there is a transition gap from research and development to commercial production. "For one, the company must have the ability to do large-scale production efficiently. Hence, the coating properties are currently being enhanced according to the manufacturer's standard requirements. Meanwhile, it also needs to be able to improve production capability, achieve low production cost and deliver coated implants of unparalleled quality." Furthermore, as medical devices, the implants would have to fulfil stringent medical standards requirements. All these can take time.

However, Dr. Jamuna sees the potential for further growth in this area. "We are actually surrounded by medical device manufacturers in the northern region, and our market-driven research approach has created market solutions for potential users or buyers through value chain product innovation," she said.

With research and development being a central pillar of SIRIM's strengths, Dr. Jamuna is confident that they are capable of providing innovative solutions to the country's medical device industry. Citing the current collaboration with the medical implant manufacturer as an example, she noted that the manufacturer was unable to find a coating service provider locally before approaching SIRIM.

"Nevertheless, we still have to constantly improve and grow in the medical sector so that we can remain competitive globally," she added. "We have to be able to persist in enhancing technological innovations according to global trends."

We are actually surrounded by medical device manufacturers in the northern region, and our market-driven research approach has created market solutions for potential users or buyers through value chain product innovation.

We have to be able to persist in enhancing technological innovations according to global trends.

Dr. Jamuna Thevi Kalitheertha Thevar,
Senior Researcher,
Industrial Centre of Innovation in Biomedical,
SIRIM Industrial Research

Inspiring better IMPLANT TECHNOLOGY

> *In the injection moulding process, the metal is in powder form instead of rods. This decreases the wastage and increases its affordability.*

> *Thermoplastics have been a common binder material used in metal injection moulding. However, we are trying to steer away from plastic-based materials in line with the government's efforts to ban plastics.*

When it comes to oral-maxillofacial implants, thermoplastic materials are typically used as a binder. SIRIM has come up with a better alternative.

According to statistics provided by the Malaysian Institute of Road Safety Research (MIROS), road accidents have been on an increase, with 2016 recording over half a million accidents. What's more, it has been revealed that the facial area is often most vulnerable in an accident.

Noting this, SIRIM, in collaboration with industry and academia, has come up with a patent-pending binder system for preparing maxillofacial implants via injection moulding of metal powders. Heading the team is Dr. Rosdi Ibrahim, Principal Researcher of the Industrial Centre of Innovation in Biomedical in SIRIM. Other members include Prof. Dato' Ir. Dr. Mohammed Rafiq Datuk Abdul Kadir from Universiti Teknologi Malaysia, Prof. Dato' Dr. Zainal Ariff Abdul Rahman from Universiti Malaya and Azri Ariffin from Best Impulse Sdn Bhd.

According to Dr. Rosdi, employing metal injection moulding technology for this purpose is more cost-effective. "In the injection moulding process, the metal is in powder form instead of rods. This decreases the wastage and increases its affordability."

The lower price tag will put the implants within the reach of middle-income earners, thus increasing its reach as a medical device. With the metal injection moulding process, fine metal powder is mixed with binder material. The injection moulding machine will then be used to de-bind the binder system, leaving behind the implant or desired part.

> *Our pre-clinical trials have been successful, and various testing procedures have been conducted in both non-accredited and accredited laboratories. The results we have obtained have been encouraging.*

BENEFITS OF PALM OIL STEARIN AS A BINDER SYSTEM:

- Environmentally friendly
- Non-toxic
- Suitable for all types of powders and fulfils criteria as binder
- Avoids losing shape of the parts during de-binding process
- Reduces up to 90% of cost of manufacturing parts
- A new high technology that increases the prominence of agriculture industries

In employing metal injection moulding technology, this innovative project utilises palm oil stearin in the binder system. The function of the binder in the process is temporary. Upon getting the desired shape, the binder is then rescinded.

"Thermoplastics have been a common binder material used in metal injection moulding. However, we are trying to steer away from plastic-based materials in line with the government's efforts to ban plastics. As such, we decided to turn to palm oil stearin, which is a plant-based material," explained Dr. Rosdi.

Natural Advantage

Significant properties of palm oil stearin, such as strength, density and porosity, are comparable to those of thermoplastics; as a plus, it facilitates faster attachment cell growth. "Of course, as a plant-based material, palm oil stearin is also a healthier alternative that is non-toxic and environmentally friendly," added Dr. Rosdi.

An important trait required for binders is differing melting points that allow the binder system to slowly de-bind. Thermoplastic achieves this as it typically has three to four types of polymers that each has its own melting point. Coincidentally, palm stearin contains several kinds of acids with different melting points as well. As such, the implant part will be able to retain its shape smoothly.

Dr. Rosdi Ibrahim,
Principal Researcher,
Industrial Centre of Innovation in Biomedical,
SIRIM

AWARDS

The Binder System for Preparing Maxillofacial Implants via Injection Moulding of Metal Powders project has won numerous awards. These include:

International Invention, Innovation & Technology Exhibition (ITEX) 2012:

- Gold Award
- Best Invention *(Research Institutes & Education Institutes Category)*
- Best Green Invention *(Research Institutes & Education Institutes Category)*

International Federation of Inventors' Associations (IFIA) Laureate for Excellent Invention

Malaysia Technology Expo (MTE)

- The Best Award
- Gold Medal

Expansion Opportunities

To date, the project has performed well. "Our pre-clinical trials have been successful, and various testing procedures have been conducted in both non-accredited and accredited laboratories. The results we have obtained have been encouraging," enthused Dr. Rosdi.

The project is currently at the first phase of clinical trials, which is targeted to be completed within a year. After this stage, it will be ready for commercialisation, and the second to fourth phases will be conducted subsequently.

Types of Clinical Trials

phase I	phase II	phase III	phase IV
20 - 80 Participants	*100 - 300* Participants	*1,000 - 3,000* Participants	*Thousands* of Participants
Up to several months	Up to two (2) years	One (1) - four (4) years	One (1) year +
Studies the safety of medication/treatment	Studies the efficacy	Studies the safety, efficacy and dosing	Studies the long-term effectiveness and cost-effectiveness
70% success rate	*33%* success rate	*25 - 30%* success rate	*70 - 90%* success rate

> *We can apply the same process and materials for other implants, including dental and upper and lower extremities. In fact, this technology can cater for almost all implants in the body!*

In addition to maxillofacial implants, there is potential to expand the application to include other parts of the body. "We can apply the same process and materials for other implants, including dental and upper and lower extremities. In fact, this technology can cater for almost all implants in the body!" exclaimed Dr. Rosdi.

The best of **RAMBUTAN RIND** *from* **IDEA** *to* **SHELF**

> *We decided to move forward with the rambutan rind as it is easily available locally. A bonus is that the extract is derived from fruit waste!*

From waste to award-winning product, the rambutan rind has proved its mettle in the cosmeceutical scene. The team behind this innovation shares with SIRIMLink *its journey from research to commercialisation and beyond.*

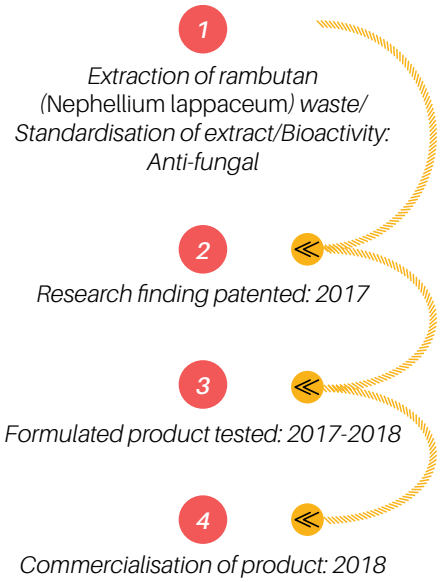
One of SIRIM's innovations, a natural bioactive dermatocide anti-fungal cream formulated with rambutan rind extract, recently won the Gold Medal and Best Invention Award at the International Innovation & Technology Exhibition (ITEX) 2019. This cream is the first of its kind to use natural resources as active ingredients.

After carrying out aqueous and solvent extractions using various herbal waste materials, the team at SIRIM came across several extracts with very good antioxidant properties and anti-fungal activity. One of them was rambutan rind. "We decided to move forward with the rambutan rind as it is easily available locally," explained Thavamanithevi Subramaniam, a Senior Researcher at the Cosmetics and Natural Products Section of SIRIM's Industrial Biotechnology Research Centre, who led the team working on this. "A bonus is that the extract is derived from fruit waste!"

Buoyed by positive results, the team decided to proceed with the formulation of the anti-fungal cream in-house, utilising SIRIM's Good Manufacturing Practice (GMP) certified facilities. "All the tests were conducted according to the Organisation for Economic Co-operation and Development (OECD) guidelines and ISO 17025," chimed in Senior Researcher and fellow teammate Dr. Theanmalar Masilamani.

To date, the product is registered with the National Pharmaceutical Regulatory Agency (NPRA) and Cosmetic Notification (NOT). It was patented in 2017 and has since been commercialised to a company, which is currently conducting external market validation studies.

From Research to Commercialisation



> *Most commercial products are steroid compounds that only work on certain fungi. This has a broader range with synergistic effects, and is non-toxic. It also has anti-inflammatory properties and is good for itchiness and insect bites.*

> *The product has also been tried for eczema and seems to work well, reducing redness and dryness.*

NATURAL GOODNESS

The anti-fungal cream:

- has antioxidant, multi-spectrum anti-fungal and anti-inflammatory properties with negligible side effects or toxicity
- is non-toxic, safe and non-irritant
- can be used to moisturise, increase smoothness, and reduce itchiness and redness of skin
- is formulated with high-antioxidant natural plant extract to nourish and strengthen nails
- is free from chemical pollutants

Fruitful Benefits

Right from the start, the rambutan rind extract has shown itself to be chock full of beneficial properties, with preliminary in-house efficacy studies obtaining good feedback, particularly for athlete's foot, scaly and infected nails and insect bites. A distinct feature of the product is its multi-spectrum activity against skin fungal and yeast (Candida albicans) infections. This means that just this one extract can target various dermatophytes that cause skin issues.

According to Dr. Theanmalar, "Most commercial products are steroid compounds that only work on certain fungi. This has a broader range with synergistic effects, and is non-toxic. It also has anti-inflammatory properties and is good for itchiness and insect bites."

"The product has also been tried for eczema and seems to work well, reducing redness and dryness," added Adida Zuraida Mohamad, a Microbiologist at SIRIM's Industrial Biotechnology Centre.

As the extract is derived from a natural resource, the product is safe, even for children to use. "In fact, parents like to use this for their young children who have eczema as, unlike most eczema products, it doesn't cause irritation to their loved ones' skin," she elaborated.

The anti-fungal cream has been well-received since being introduced. "When we were conducting in-house efficacy studies, many of our colleagues claimed that this product worked well for them and kept coming back for more," shared Thavamanithevi. "Since then, the company that has taken up the product has also reported that they get repeat buyers."

Inspired by the positive response garnered and the awards received, SIRIM is geared up to upgrade the product and widen its reach further. Among others, the agency has already applied to obtain an MAL 'Traditional Medicine' registration number from NPRA, which will enable the product to be placed in clinics as well.

On Par with the World

Thavamanithevi, Dr. Theanmalar and Adida agree that Malaysia's capabilities are comparable with the rest of the world. "SIRIM was the first to delve into the potential of rambutan rind in 2006 when we embarked on anti-diabetic studies. Based on our patent for that, countries like Australia, Canada and Vietnam have since been exploring the use of rambutan rind for cosmetic products," divulged Dr. Theanmalar.

Consequently, there is a vast potential for further growth in this area. "Malaysian research institutions and universities have vast capabilities in research and development. We have an abundance of natural resources and should be able to produce outstanding scientific output with good collaboration with our fellow researchers. There is genuine cooperation among researchers and private companies to provide high value products," said Thavamanithevi.

DID YOU KNOW

It is a requirement for all medicinal products in Malaysia, including those that are imported, to be registered with the Ministry of Health Malaysia before they can be sold. A valid registration number begins with "MAL", followed by eight digits, and ends with an alphabet to indicate their registration category. These are:

A for controlled medicines

X for over-the-counter medicines

T for traditional medicines

N for supplements

Source: Ministry of Health Malaysia

> *SIRIM was the first to delve into the potential of rambutan rind in 2006 when we embarked on anti-diabetic studies. Based on our patent for that, countries like Australia, Canada and Vietnam have since been exploring the use of rambutan rind for cosmetic products.*

Venturing into the Marketplace

The commercialisation process of the anti-fungal cream is being conducted by SIRIM Tech Venture Sdn Bhd (STV), a wholly-owned subsidiary of SIRIM. Today, the product has been successfully marketed under the name "Procell".

According to Ajmain Kasim, the Chief Executive Officer of STV, the process has been relatively smooth-sailing to date, as the formulation was already available. The company taking up this technology is part of the Malaysian Technology Development Corporation's (MTDC) Symbiosis Programme, a comprehensive graduate entrepreneurship programme aimed at training selected graduates to become technopreneurs.

(far right) ***Dr. Theanmalar Masilamani,*** *Senior Researcher*
(second from right) ***Thavamanithevi Subramaniam,*** *Senior Researcher*
(third from left) ***Adida Zuraida Mohamad,*** *Microbiologist*

SIRIM Industrial Biotechnology Research Centre

Presently, the first stage of market validation has been completed, and both STV and the company are gearing up for full commercialisation. "The product is already in hand. It has been tested and accepted in the market. In fact, they often sell out at exhibitions!" declared Ajmain.

While the company is preparing to set up its own factory, SIRIM is helping them in the production of limited quantities in its pilot plant. But there is still a lot to be done in building up the company. "For example, the owner needs to review the company's vision and mission, engage staff, set up its production line and start to do its production planning," explained Ajmain.

In the commercialisation process, STV is on hand to advise the company on all aspects of the business, from understanding the technology and manufacturing process to packaging and requirements from the regulatory bodies. "We are not like a regular company that just sells the products. We help the purchaser to achieve commercial success. We grow with the company indirectly!"

DID YOU KNOW

According to STV, there are three central elements in determining the success of a commercialisation process. These are:

Technology Readiness Level that measures the technological maturity of a particular technology on a scale of one to nine to determine when the commercialisation of the product can begin

Manufacturing Readiness Level whereby the company has to ensure it has the right resources, such as the materials, equipment and labour

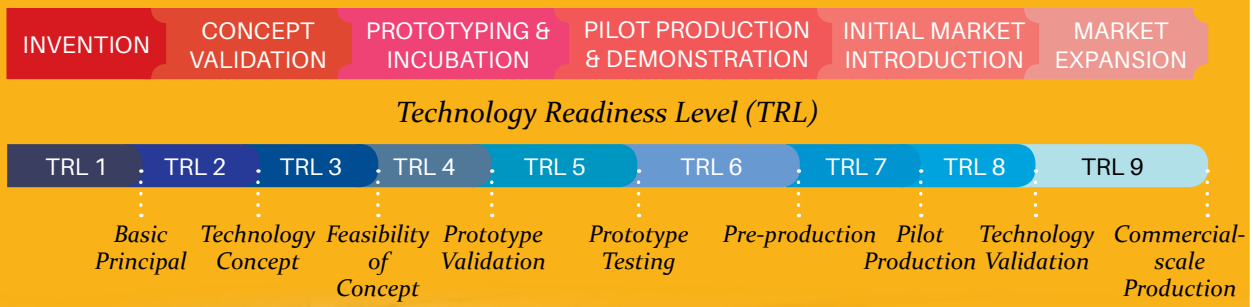
Business Readiness Level in possessing the entrepreneurial skill to determine the vision and mission of the company, creating a pathway for it to progress

Accelerating Business Commercialisation

SIRIM Tech Venture (STV) was established in 2014 as the commercialisation arm of SIRIM. The company identifies itself as a special vehicle to accelerate technological innovations to business commercialisation, in addition to facilitating technology and knowledge transfer to generate economic and social benefits, and establish collaborations with partners for long-term sustainability. STV assesses technology readiness via the Technology Readiness Level (TRL) criteria. TRL is a methodology of estimating technology maturity during the acquisition process.

STV's clients come from diverse backgrounds such as industries, agencies, start-ups and institutes of higher learning.

STV looks forward to opportunities to engage with the public and share what it can do with them. Among others, it hosts CEO Breakfast sessions, during which decision-makers are invited to network and discover STV's offerings. Interested parties are welcome to visit sirimtechventure.my to find out more about STV and sign up for its next CEO Breakfast session.



Technology Readiness Level (TRL)

Ajmain Kasim,
Chief Executive Officer,
SIRIM Tech Venture Sdn Bhd

REDEFINING *the* BONE GRAFT *industry*

DID YOU KNOW?

There are four common types of bone grafts:

- Autograft - comes from a bone inside the patient's own body
- Allograft - uses bone from a deceased donor/cadaver
- Xenograft - comes from a bone belonging to animal species
- Alloplastic - Chemically processed from synthetic material bone

OVER A DECADE OF EXCELLENCE

GranuLab (M) Sdn Bhd is the first medical device manufacturer and distributor of synthetic bone grafts in Malaysia and the ASEAN region. In line with its commitment to ensuring that its products meet the most stringent industry standards, GranuLab has GMP ISO 13485:2016 and CE Mark products, certified by BSI Netherland.

As a leading name in research and development, SIRIM is no stranger to pioneering innovations. Among these are GranuMaS® and Synthetic Bone Construct (SBC), first-of-their-kind offerings that are changing the bone graft scene.

A bone graft is a surgical procedure involving a bone tissue transplant to fix bone defects. The bone graft provides a scaffold for new bone growth and is typically obtained from another part of the patient's body or a donor. GranuLab (M) Sdn Bhd (GranuLab), a subsidiary of SIRIM, offers an unparalleled alternative with its 100% synthetic GranuMaS® and Synthetic Bone Construct (SBC) bone graft product lines that are making waves in the medical industry.

FACILITATING BONE GROWTH

Hydroxyapatite is known for its bioactive and osteoconductive properties. It acts as a scaffold in a bone void or bone loss situation to enhance bone growth and bridging and promote bone healing.

GranuMaS® is a synthetic calcium phosphate, non-animal bioceramic-based bone graft material which is chemically known as hydroxyapatite (HA). With a composition that is 99% similar to that of the human bone mineral, it is widely used in the country's hospitals for orthopaedic, dental and maxillofacial applications. It comes in spherical, cube, pin and chip formats.

SBC, on the other hand, is comprised of a combination of Tri-calcium phosphate and Tetra-calcium phosphate materials called Osteopaste™. The SBC can be shaped into solids of various shapes and sizes and, hence, can be custom-made based on surgeons' requirements for specific applications. It is usually used to treat segmental bone defects or injuries due to trauma, non-union cases or diseased bones.

> *Compared to other bone graft materials that include porcine, bovine and human cadavers, our products are a great option. In fact, GranuMaS® has even obtained Halal certification from the Department of Islamic Development Malaysia (JAKIM), providing an added assurance for our Muslim patients who might be concerned about what is being placed in their bodies.*


Chip


Pin


Cube


Spherical

Distinct Advantage

As the first and only manufacturer of 100% synthetic bone graft materials in the world, GranuLab has a significant competitive edge in terms of its product offerings. For one, as the materials are not derived from animal parts, they are a plausible option for patients with religious concerns. According to Faizura Mohd Nor Arjamli, the Marketing Manager of GranuLab, "Compared to other bone graft materials that include porcine, bovine and human cadavers, our products are a great option. In fact, GranuMaS® has even obtained Halal certification from the Department of Islamic Development Malaysia (JAKIM), providing an added assurance for our Muslim patients who might be concerned about what is being placed in their bodies."

ADHERENCE TO STRINGENT STANDARDS

In addition to possessing Halal certification by JAKIM, GranuMaS® is manufactured under GMP ISO 13485:2016 and is European CE Mark-certified by BSI Netherlands. It also conforms to the ASTM F1185-88 and ISO 13779 standards, and is registered in the Approved Product Purchase List (APPL) for KKM contract purchase.

A DENTAL SOLUTION

After a tooth is extracted, the bone will begin to recede, leading to numerous issues that could include aesthetic impairments, hygiene problems and/or articulation difficulties. With GranuMaS®, patients will be able to enjoy benefits that include:

- Maintenance of bone stability, providing flexibility of time for subsequent treatments
- Maintenance of gum condition, ensuring the aesthetics of the patient's smile are preserved
- Ease of subsequent treatments, allowing time and cost savings in the long term
- Timely preventive measure to avoid complicated procedures in the future

PRODUCT FEATURES/ BENEFITS

Product features of GranuMaS® and SBC include:

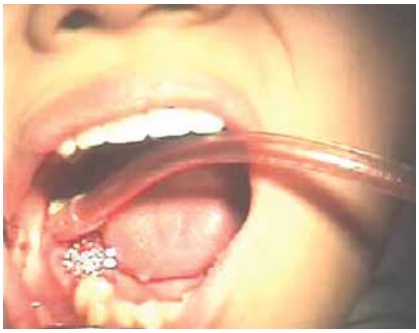
- Easy usage & handling
- 99% similar to natural bone minerals
- Highly effective
- Exceptionally high quality alternative to human bone graft materials
- Competitive pricing
- Halal-certified

Furthermore, GranuMaS® is an excellent alternative material that can be used in addition to an autograft. Mixed with the autograft, it can be used as a bone graft expander to increase the bone graft volume. The use of GranuMaS® alone for treatments also reduces the need for a second site-surgery to harvest the patient's own bone. "By avoiding a second surgery, the cost of surgery is reduced, as are the trauma, morbidity, length of hospital stay and risk of infection," continued Faizura.

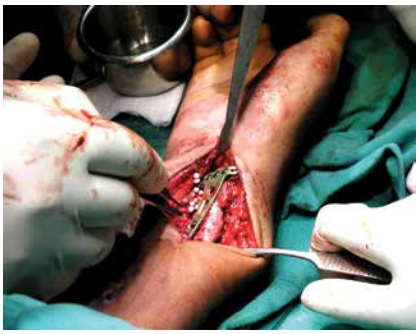
It is also a good option for those with low bone regenerative properties such as diabetes, osteoporosis and hypertension sufferers as well as geriatric patients. With its low resorption rate, it is able to provide bone volume and strength - especially for osteoporotic patients.

> *"As SBC is made to order, it can be moulded according to what the patient needs. We can also incorporate antibiotics in the mixture if required. We are the only bone graft manufacturer that is able to provide this customised service!*
>
> E

The SBC is custom-made



Dental & maxillofacial applications – insertion of GranuMaS®



Orthopaedics application

The SBC has an added advantage in terms of flexibility. It is prepared in powder form and can be shaped into solids of various shapes, sizes and thicknesses to fill any segmental bone loss or defects. "As it is made to order, it can be moulded according to what the patient needs. We can also incorporate antibiotics in the mixture if required. We are the only bone graft manufacturer that is able to provide this customised service!" exclaimed Faizura.

As the SBC is custom-made, a specific mould is used to produce the bone construct for each case. It is sterilised using gamma irradiation at 25KGy. Pre-clinical in-vitro evaluations of SBC are based on the ISO 10993 and ASTM F2721-09 standards and conducted under GLP conditions at accredited laboratories of TUV, SUD PSB.

Positive Reception

Both GranuMaS® and SBC have garnered good market feedback. Approximately 50 hospitals and more than 500 patients have used GranuMaS® to date, and the numbers are climbing. Similarly, the demand for SBC has been increasing.

In its endeavours to heighten awareness of its bone graft products, GranuLab aims to consistently engage with its stakeholders. These include conducting continuous medical and dental education sessions at both government and private hospitals and participating in local and international exhibitions. "We just got back from the MediPharm Expo in Vietnam, where we encountered some potential prospects for licensing and distribution opportunities," revealed Faizura.

Among its efforts to reach out to the general public is by setting up booths in hospitals. "We are currently doing this at KPJ hospitals," explained Faizura. "This allows us to get the attention of patients on site so they know that they have options."

As it holds the market monopoly in offering custom-made bone graft materials, GranuLab hopes to delve deeper into the global halal bone graft industry. "We have already penetrated the Indonesian market, but we are still looking at venturing into other Asian countries, including Brunei, Vietnam, the Philippines and Singapore," said Faizura.

She believes that with its strengths, GranuLab will be able to go far. "We have the Halal status, meet stringent requirements and offer competitive pricing. Now we need to forge more partnerships internationally."

> *"We have already penetrated the Indonesian market, but we are still looking at venturing into other Asian countries, including Brunei, Vietnam, the Philippines and Singapore."*
>
> *"We have the Halal status, meet stringent requirements and offer competitive pricing. Now we need to forge more partnerships internationally."*

Faizura Mohd Nor Arjamli,
Marketing Manager,
Granulab Sdn Bhd

HALAL BONE GRAFT

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