



**KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)
IN
ASSOCIATION WITH**



**INSTITUTE OF COOPERATIVE MANAGEMENT (ICM),
TRIVANDRUM**

**10TH
STAKEHOLDERS CONNECT MEET (SCM) JULY 2024**

**SEMINAR HALL
INSTITUTE OF COOPERATIVE MANAGEMENT, TRIVANDRUM**

19TH JULY 2024

**POST-MEET REPORT
25TH JULY 2024**

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1. BRIEF SUMMARY OF THE MEET

INAUGURAL SESSION

The Inaugural Session of KMTC 10th Stakeholders Connect Meet (SCM) started off around 10 AM, a little bit later than scheduled, and the following dignitaries were involved in the session, that aimed at setting the context for the whole day of sessions and panel discussions.

- Welcome Address – Mr Sasikumar M. V., Director, Institute of Cooperative Management (ICM)
- Opening Address – Mr C Padmakumar, Special Officer, Kerala Medical Technology Consortium (KMTC)
- Inaugural Address – Mr A P M Mohammed Hanish IAS, Principal Secretary (Industries), Govt of Kerala
- Special Address – Dr Joseph Benaven, President, Indian Medical Association (IMA) – Kerala Chapter
- Special Address – Mr Santhosh Kumar, Executive Director, Harrisons Malayalam Limited (HML)
- Felicitations – Advocate Sony Sebastian, Chairman, Kerala State Cooperative Marketing Federation
- Vote Of Thanks – Dr Jayamohan Nair, Deputy Director, Institute of Cooperative Management (ICM)

Mr Sasikumar M.V extended a warm welcome to all dignitaries and delegates, emphasising the crucial role cooperatives can play in transforming the industrial landscape, particularly within the MSME sector in the state. He highlighted ICM's dedicated focus on this initiative and expressed gratitude to KMTC for their support in exploring opportunities within this sector.

Mr C Padmakumar articulated KMTC's vision of positioning Kerala as the Medical Devices Hub of India within the next decade, underscoring ongoing efforts including collaborations with SCTIMST, MG University, the Rubber Research Institute, and Kerala Rubber Limited over the past two years. He elaborated on why Kerala is well-suited to spearhead advancements in medical devices using natural rubber, citing two key reasons: first, the UNDP's SHiPP initiative in which India is one of the first 10 countries that have signed on; and second, the potential for greater value addition that medical devices made from natural rubber offers to farmers compared to the current applications of natural rubber.

Mr A P M Mohammed Hanish commended KMTC for their initiatives in harnessing the potential of the cooperative sector to enhance the utilisation of natural rubber in MedTech. He emphasised the necessity of inter-departmental coordination to ensure the successful execution of such projects and highlighted KMTC's role in facilitating collaboration among various stakeholders to advance MedTech initiatives. The Industries Department reaffirmed its commitment to establishing Medical Devices as a sunrise sector in the state and pledged

full support towards endeavours involving natural rubber-based medical devices.

Dr Joseph Benaven emphasised the crucial role of doctors in the development of medical devices, underscoring their involvement from the initial design stages. He praised recent collaborative efforts between KMTC, IMA, and the Department of Health, GOK, in establishing IEDCs (Innovation and Entrepreneurship Development Cells) in Medical Colleges. These initiatives will empower practising clinicians to identify critical problem statements, essential for the ongoing advancement of medical devices. Dr. Benaven assured full support from IMA for this initiative and anticipated further awareness sessions and training programs in the future.

Mr Santhosh Kumar presented Harrisons Malayalam Limited, a company involved in Tea and Rubber Plantations, established in 1844 and acquired by RPG in 1989. It is the largest plantation company in south India with 25,000 hectares of land, producing 13,000 MT Rubber, 15,000 MT Tea, and 25,000 MT Pineapple annually. The company is known for its quality tea and rubber worldwide, with ISO certifications and a focus on sustainable plantation business. The company is a major employer in Kerala, particularly for women, and has a strong focus on research and development. Harrisons Malayalam Ltd is involved in innovative product development, such as nitrosamine-free latex and low-ammonia rubber, catering to various industries like footwear and healthcare. He stressed the commitment from HML in supporting the cause of Medical Devices from Natural Rubber as the company sees a bright future for medical devices made from sustainable materials like natural rubber.

Advocate Sony Sebastian expressed enthusiasm on behalf of the rubber cooperatives to participate in the initiative for Medical Devices. He emphasised that all advancements in this sector should ultimately benefit the farmers.

Dr Jayamohan Nair delivered the Vote of Thanks to end the Inaugural Ceremony.

SESSION BY EXPERTS

RUBBER IN MEDICAL DEVICES

SESSION BY **DR GIJO RAJ**, SCIENTIST - C, DIVISION OF POLYMERIC MEDICAL DEVICES, BIOMEDICAL TECHNOLOGY (BMT) WING, FROM SREE CHITRA TIRUNAL INSTITUTE OF MEDICAL SCIENCES & TECHNOLOGY (SCTIMST)

Dr Gijo Raj discussed the use of natural rubber in medical devices, particularly focusing on products made from latex and compounded rubber sheets. He mentioned the use of kaolin clay to improve mechanical strength and classified surgical and medical examination gloves under Medical Device Rules. The International Standard ISO 11193-1 outlines specifications for rubber gloves used in medical procedures. The compounding of dry rubber, compression moulding, and radiation shielding materials are also mentioned, along with potential applications like latex endoscope tube covers and geriatric protective materials. Challenges include latex allergies and the tackiness of natural rubber.

SESSION BY **DR ROY JOSEPH**, SCIENTIST-G & DEAN (ACADEMIC AFFAIRS) ,
FROM SREE CHITRA TIRUNAL INSTITUTE OF MEDICAL SCIENCES &
TECHNOLOGY (SCTIMST)

Dr Roy Joseph discussed the use of rubber in medical devices, focusing on products made from natural rubber, challenges with latex products, Biocompatibility and safety concerns arising from allergenic potential and toxicity of curing additives in latex products., non-toxic latex formulations. Advancements in technology include innovations in medical gloves, catheters, tubing, curing technology, and the use of isocyanate-cured latex rubber for medical devices. The Regulatory process in India involves steps to be followed for preclinical testing, obtaining manufacturing licences, and complying with biocompatibility and performance standards. He also highlighted the classification of medical devices, the regulatory roadmap in India, and the pre-clinical phase requirements for rubber-based products.

HARRISONS MALAYALAM LIMITED'S JOURNEY INTO RUBBER BASED MEDICAL DEVICES

SESSION BY **MR BIJINESH B**, MANAGER, RESEARCH & DEVELOPMENT,
HARRISONS MALAYALAM LIMITED (HML)

Mr Bijinesh said that Harrisons Malayalam Limited (HML) is a leading plantation company in south India, producing natural rubber, tea, and pineapple. With a workforce of over 10,000 employees, HML impacts the lives of thousands through housing, healthcare, and education initiatives. The company emphasises sustainability practices and maintains certifications from various environmental organisations. The company focuses on market expansion, international presence, new product development, sustainability, and strategic diversification. HML invests in innovation to diversify its product portfolio and meet emerging consumer trends. The company has a strong presence in the Indian market and exports products internationally to countries such as the Middle East, Europe, and North America. HML has ventured into producing rubber-based medical devices, aligning with the growing global healthcare demand and leveraging its expertise in rubber production. Product Portfolio Types of rubber-based medical devices under development are Endoscope protective sheath for ultrasound probes and X-ray radiation protective sheets for thyroid collar.

KERALA RUBBER LIMITED – PROMOTION OF NATURAL RUBBER BASED INDUSTRIES IN THE STATE WITH FOCUS ON MSME SECTOR

SESSION BY **MR TOMS JOSEPH**, SENIOR RESOURCE PERSON, KERALA RUBBER LIMITED (KRL)

Mr Toms Joseph discussed that Kerala Rubber Limited (KRL) plays a crucial role in promoting rubber-based value addition in Kerala, focusing on latex and dry rubber products. Examples of latex based products:- Gloves, Mittens, Mitts and Aprons; Finger/Toe Cots/Stalls; Finger Caps; Foam and Mattresses; Thread and Cord; Catheters and other

Medical Devices; Orthodontic Elastics, Adhesives; Band; Condoms; Nipples; Balloons and other Inflatable Articles; Toys; Other dipped products.

Examples of dry rubber based products:- Tyres/Inner Tubes of Cycles, Cars, Trucks and other Vehicles; Aero Tyres; Tyre Flaps and other Automotive Components; Tubes, Hoses and Pipes; Retreads; Hospital Sheeting; Belts and Beltings; Plates and Sheets; Strips, Blocks, Rings, Gaskets, Rods, Plugs, Washers and Seals; Caps, Lids, Seals, Stoppers and other Closures; Rollers; Elbows, Bushes and Flanges; Blankets and Cushions; Hot Water Bags; Mats; Erasers; Footwear; Toys Annual value of output of world rubber products manufacturing industry – USD 800 Billion. KRL aims to develop world-class infrastructure, promote natural rubber-based industrialization, and generate employment opportunities through public-private partnerships. The organisation is in the process of establishing a Rubber Industrial Complex to support NR-based industries, offering services such as research & development, technical consultancy, training, marketing assistance, and common facilities for entrepreneurs. The project is set to be completed in two phases with a total cost of Rs. 253.56 crores.

RUBBER – AN IMPORTANT CONSTITUENT OF MEDICAL PRODUCTS AND RELATED APPLICATIONS

SESSION BY **DR SIBY VARGHESE**, FORMER JOINT DIRECTOR, RUBBER RESEARCH INSTITUTE OF INDIA (RRII)

Dr Siby Varghese highlighted various aspects during his discussion, focusing on the types of rubber utilised in medical product manufacturing, particularly latex-based items. He addressed production and consumption trends in rubber products, as well as different latex production technologies. Major latex products highlighted included baby products, anaesthesia breathing bags, Foley catheters, urine drainage condoms, sheetings, and rubber caps/tabs. Dr. Varghese emphasised the promising future of natural rubber-based medical products, suggesting that Kerala Rubber Limited is poised to provide comprehensive technical support to potential investors in this sector.

EXPERT PANEL DISCUSSION – I

OPPORTUNITIES IN MEDICAL GRADE RUBBER & RUBBER BASED MEDICAL DEVICES

An interactive session with expert speakers was conducted to discuss Opportunities in Medical Grade Rubber & Rubber Based Medical Devices and to answer pertinent queries from delegates / participants. The discussion was moderated by Dr Roy Joseph, Scientist-G & Dean (Academic Affairs), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST). The Following Experts were the expert panellists in the discussion:

- Dr Gijo Raj, Scientist - C, Division of Polymeric Medical Devices, Biomedical Technology (BMT) Wing

- Mr Bijinesh B, Manager, Research & Development, Harrisons Malayalam Limited (HML)
- Mr Toms Joseph, Senior Resource Person, Kerala Rubber Limited (KRL)
- Dr Siby Varghese, Former Joint Director, Rubber Research Institute of India (RRII)

The key points covered in the discussion are:

- What kind of support is available from research institutions?
 - Availability of project reports from Rubber Research Institute at a reasonable cost.
 - RRI can offer end to end project implementation support.
- What different testing facilities are available?
 - Comprehensive testing facilities are available with RRI And Sri Chitra
 - Incubator facilities are offered at RRI
- What are the various funding supports?
 - KRL provides comprehensive support which includes funding for the natural rubber manufacturing sector.

INNOVATION IN LATEX TECHNOLOGY AND LATEX PRODUCTS

SESSION BY **DR ABI SANTHOSH APREM**, ASSOCIATE VICE PRESIDENT, TECHNICAL & OPERATIONS, HLL LIFECARE LIMITED

Dr Abi Santhosh highlighted that Natural rubber latex is a stable colloidal dispersion of rubber particles in an aqueous medium, produced through a complex biological synthesis process. From latex concentrates, a variety of products like surgical gloves, catheters, dental dams, exercise bands, latex flowers, and more are manufactured for healthcare, textile, industrial, and crafting applications. Additionally, innovations in latex technology have led to the development of NRL products for biomedical and biotechnological applications, including wound healing, drug delivery, and bone regeneration. HLL Lifecare Ltd has introduced innovative NRL products like cervical spacer, uterine balloon, urinary bag condom, and rubber moulds for explosive treatment, showcasing the diverse applications of NRL in various industries.

DEVELOPMENT AND MANUFACTURING OF RUBBER BASED MEDICAL DEVICES

SESSION BY **MR ALEX G KODI**, MANAGING DIRECTOR, KODI HEALTHCARE

Mr Kodi presented a list of medical products offered by Kodi Healthcare. Foley Balloon Catheters, a range of male urinary devices, endoscopic variceal ligation bands, and various Vasti kits including Uro Guard Ultra, Uro Guard, EVL Bands, Spit Bag, Multi Band Ligator, Kodi Standard Vasti Kits, Kodi Anuvasana Vasti Kits, Kodi Niruha Vasti Kits, and Kodi Rub Urine Bag. The products cater to different medical needs such as urinary drainage, endoscopic procedures, and enema administration. Kodi Rub Urine Bag is designed for urine collection and disposal. Foley Balloon Catheters aim to provide comprehensive solutions for urological and gastrointestinal procedures. The company's product range reflects a focus on innovation and meeting the diverse needs of healthcare professionals.

RUBBER INDUSTRY: AN OVERVIEW

SESSION BY **MR KARIMPUZHA RAMAN** , DIRECTOR, PRIMUS GLOVES

Mr Karimpuzha Raman, Director of Primus Gloves Pvt Ltd, provided an insightful overview of the natural rubber industry, highlighting its global and Indian production landscapes dominated by Thailand, Indonesia, Vietnam, and Kerala. The unique properties of natural rubber drive its high demand over synthetic alternatives, particularly in major sectors like automotive, consumer goods, and healthcare. In the medical domain, natural rubber finds extensive use in manufacturing gloves, catheters, condoms, and other devices. He emphasised the critical steps involved in establishing medical glove production, from market research and infrastructure setup to rigorous regulatory compliance with standards such as ISO 13485 and EU MDR. Innovations such as antimicrobial formulations and eco-friendly manufacturing processes are key to meeting evolving market needs. Economic opportunities are underscored by pandemic readiness efforts, government healthcare initiatives like "Make in India," and increasing demand for sustainable products, projecting a robust growth trajectory with an estimated CAGR of 5.4% until 2033.

EXPERT PANEL DISCUSSION – II

OPPORTUNITIES & CHALLENGES IN MANUFACTURING OF RUBBER-BASED MEDTECH / MEDICAL DEVICES

An interactive session with expert speakers was conducted to discuss opportunities & challenges in manufacturing of rubber-based medtech / medical devices and to answer pertinent queries from delegates / participants. The discussion was moderated by Mr Rejeesh G R, General Manager (Marketing), Kerala Medical Technology Consortium (KMTC). The following Experts were the expert panellists in the discussion:

- Mr Karimpuzha Raman , Director, Primus Gloves
- Dr Abi Santhosh Aprem, Associate Vice President, Technical & Operations, HLL Lifecare
- Mr Alex G Kodi, Managing Director, Kodi Healthcare

The key points covered in the discussions are:

- Ensuring end-to-end quality in the supply chain ensures MedTech product quality.
- Mr. Karimpuzha Raman shared his experience of receiving support from various government institutions including funding from KSIDC and KFC for his business in Kerala.
- Mr. Alex Kodi mentioned that, unlike 30 years ago, it is now easy to access technical information, which is available from institutes such as RRI and SCTIMST.
- How do cooperatives compete with big companies?
 - There are enough and more markets which are untapped in India.
 - Make use of the export and domestic markets.
 - Cooperative societies can form a consortium to pool resources and compete in the market.

DEVELOPING RUBBER-BASED MEDICAL DEVICES IN KERALA: SUPPORT BY KMTC

SESSION BY **MR REJEESH G R**, GENERAL MANAGER (MARKETING) , KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)

Mr. Rejeesh provided an overview of the global medical device industry, detailing the lifecycle of medical device development. He also outlined the organisational structure of KMTC, along with its vision and mission. Mr. Rajeesh described the components of the Kerala MedTech ecosystem, encompassing research, technology, manufacturing, and skills development. He emphasised the importance of medical device industry enablers and discussed KMTC's medtech roadmap. Additionally, he covered Kerala's medical devices sector, underscoring the significance of rubber. Mr. Rajeesh touched upon SHipp (Sustainable Health in Procurement Projects), the support available from KMTC, and highlighted the investment pipeline.

INSIGHTS & TAKEAWAYS

I. OPPORTUNITIES

Immense opportunities include:

1. Products- Medical Grade Rubber as a) raw materials, components and intermediaries and b) finished products ie. Medical Devices
2. Untapped potential of agencies such as KRL
3. Technology and technical support from Research institutions in the state
4. Funding agencies
5. Market- export and domestic
6. Pool of experts and talent in the state
7. Incentives under the New Industrial policy, 2023 of Kerala
8. Demand created by transition of sustainable materials
9. Circular economy products from natural rubber/latex processing
10. High Value addition of medical devices(40 times) vs conventional products like tyres(9 times)
11. Suitable for MSMEs
12. Regenerative Medicine application
13. Geriatric assistive/ protective material
14. Technology advancement in biocompatible materials with advanced coatings, materials with antimicrobial properties, nano technology in rubber latex production, smart latex materials and bioengineering latex rubber properties.

II. CHALLENGES

1. Policy challenges: support price, import duties, classification as Industry and not agriculture
2. Seasonal labour dependence
3. Challenges from synthetic rubber
4. Funding for the sector
5. Regulatory process - lack of awareness

III. FOLLOW UPS

- This segment is one for the future – but needs more awareness & training sessions to get the stakeholders interested.
- In the cooperative sector, one cooperative on its own may find it difficult to compete. Forming consortia could be an option.
- ICM can take this up as a project – identify potential candidates for Consortium formation and then get them on board for implementation of specific projects where agencies like KRL, KMTC can hand hold them .
- More Gemba is required – need to understand basic ground realities to have effective solutions suggested.
- A total list of product profiles /portfolios to be prepared assessing market situations – KRL can prepare the list with support from KMTC.
- Policy Decisions may be required – for eg. Moving rubber from under Industries to Agriculture.
- Follow-Up KMTC Stakeholders Connect Meeting (SCM), deep-diving into producing high quality Medical Grade Rubber and / or manufacturing specific Rubber-based Medical Devices before the end of October 2024. The Meet can be organised in Kottayam or Velloor.
- Visit with interested members from Rubber Cooperatives to :
 - a. Rubber Research Institute of India (RRII), including their incubator / accelerator.
 - b. Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), including TIMed.
 - c. Rubber Park of KRL
- Form a Rubber Consortium to focus on MedTech products from natural rubber where KMTC, KRL and RRI should play crucial roles. Help / support interested parties amongst these Cooperatives, with Institute of Cooperative Management (ICM) and Kerala Rubber Ltd (KRL), in structuring and forming a collective / consortium in exploring developing and manufacturing in Kerala:
 - a. High quality Medical grade Rubber

- b. Components, Sub-assemblies, Intermediates for Medical Devices
- c. Specific Rubber-based Medical Devices

2. ATTENDANCE & PARTICIPATION

A total of 70 representatives participated in the SCM, with representation from all stakeholder groups. The Meet was successful in getting participants to interact with each other and discuss critical issues on the theme / topic. The List of Resource Persons, Speakers and Participants are attached in Annexure.

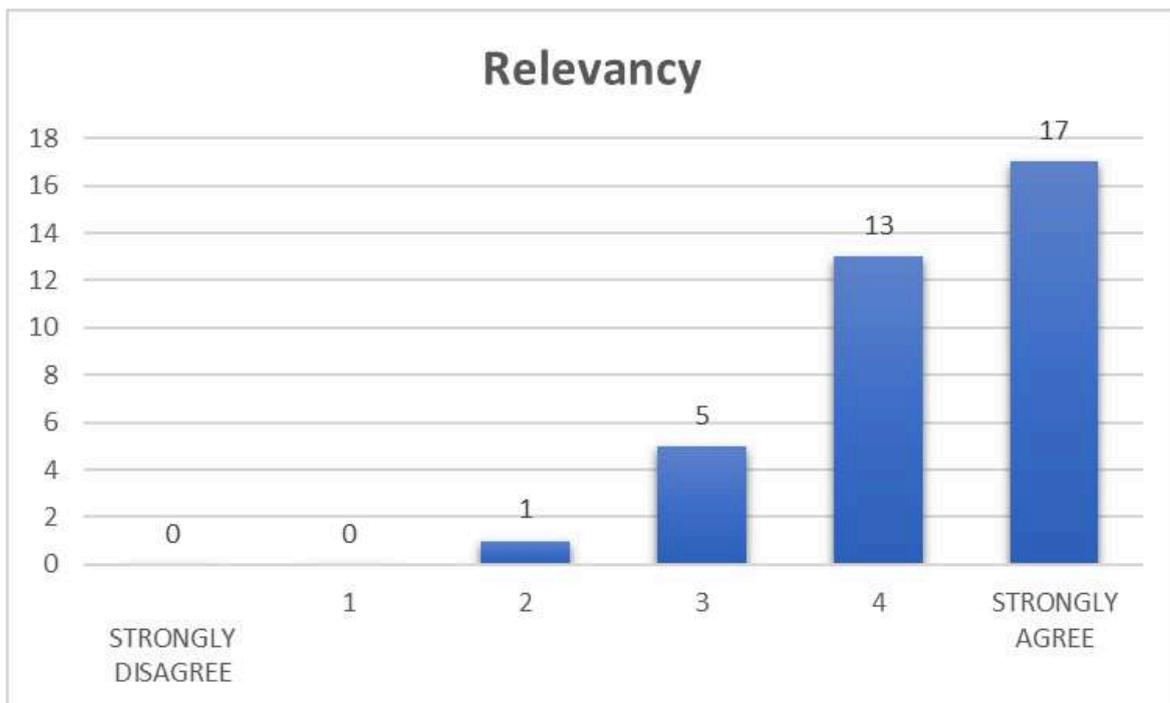
3. MEET FEEDBACK FROM DELEGATES

Feedback was collected from participants via an online form, towards the end of the Meet with a few questions for quantitative measure of the relevance, quality and the overall event and some for qualitative feedback and suggestions.

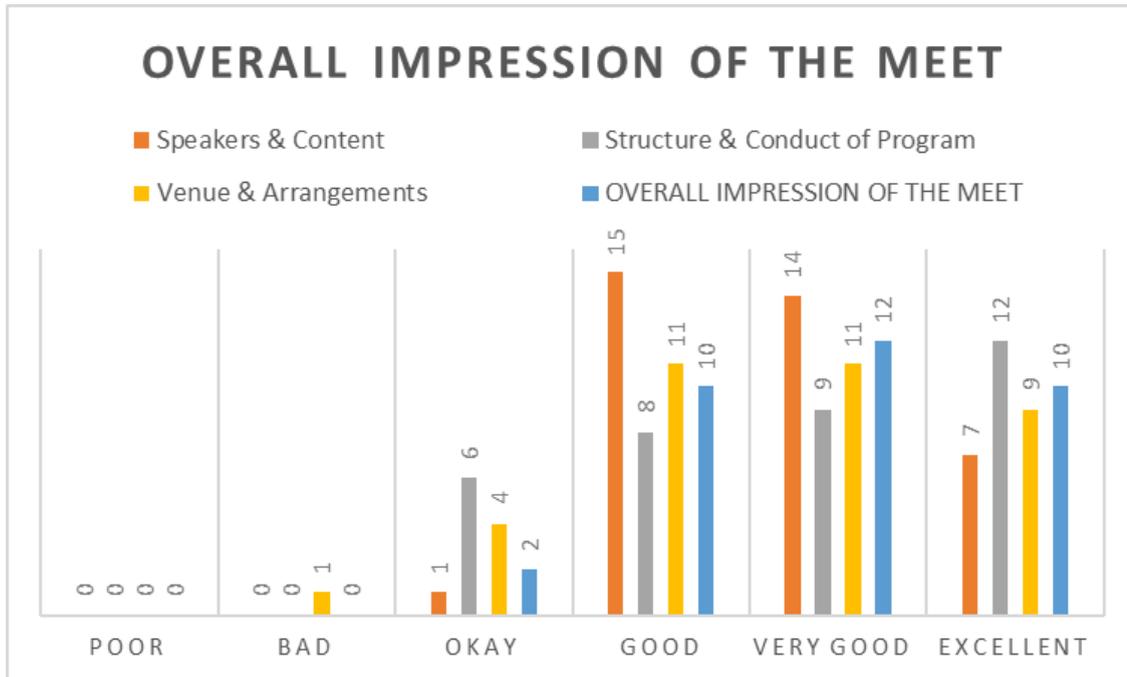
OBJECTIVE FEEDBACK

Here are the graph visualisations for the quantitative feedback collected from participants. Out of a total of 70 participants, 37 individuals provided responses to the feedback survey.

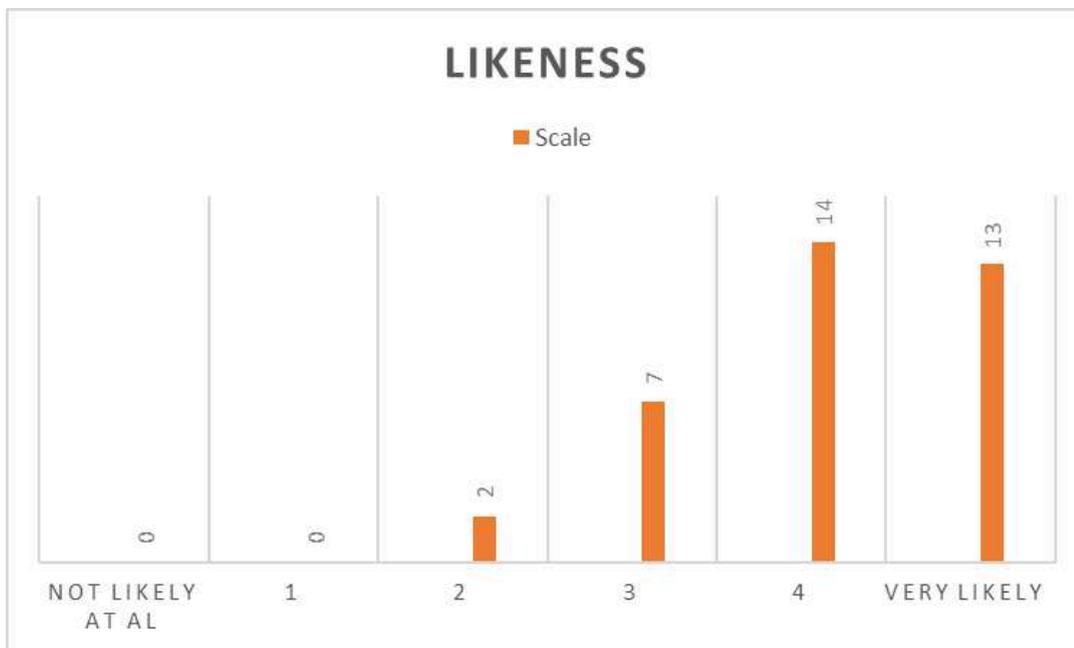
Relevancy of the Meet and the overall theme and content.



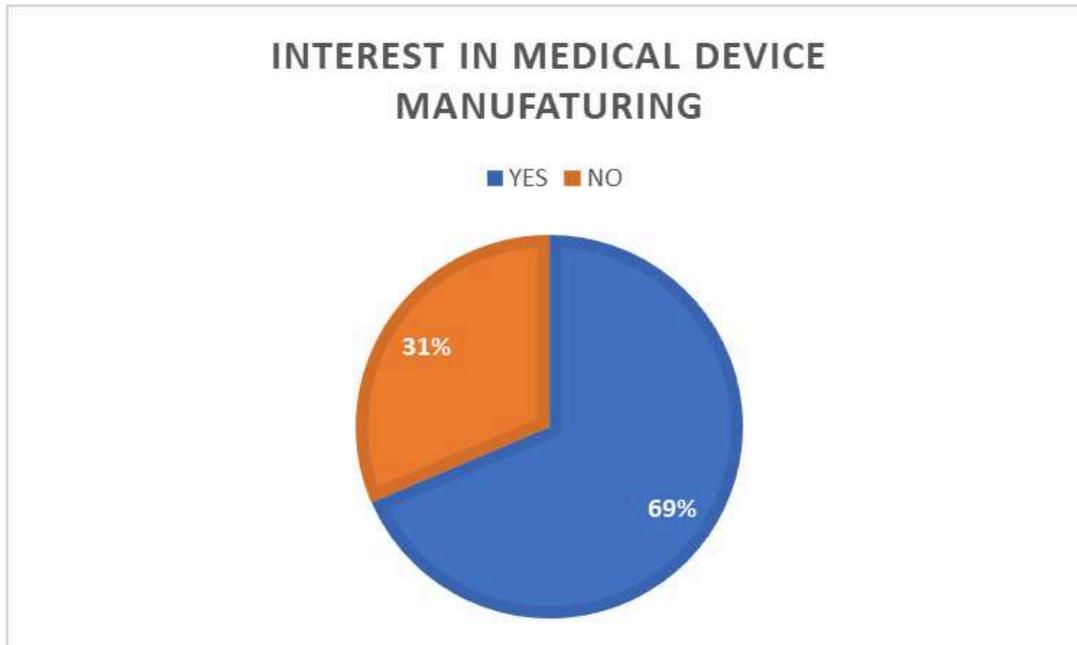
Overall Impression of the KMTTC 10th Stakeholders Connect Meet (SCM)



Likeness to recommend to others



Interest in Medical Devices Manufacturing



SUBJECTIVE FEEDBACK

After analysing the qualitative feedback from the participants, the major areas and sentiments expressed can be summarised as follows, prioritising the most repeated ones:

1. Improve Scheduling and Content Relevance:

Participants found sessions informative but expressed concerns over time management and the need for more tailored content.

2. Enhance Practical Insights:

Attendees suggested increasing interactive discussions with entrepreneurs

3. Address Financial and Regulatory Aspects:

There's a demand for sessions covering startup investment, capital requirements, and governmental support, particularly focusing on raw materials and marketing strategies.

4. Expand Regional Outreach:

To reach a wider audience, workshops should be conducted in various regions of Kerala, ensuring broader participation and relevance.

5. Strengthen Industry Collaboration and Support:

Highlight the importance of cooperative efforts and funding support for successful ventures in the field of rubber-based medical devices.

4. ANNEXURE

4.1 PROGRAM INVITE



INVITATION TO THE
10TH KMTTC STAKEHOLDERS CONNECT MEET (SCM)
ON FRIDAY, 19TH JULY 2024
AT INSTITUTE OF COOPERATIVE MANAGEMENT (ICM),
THIRUVANANTHAPURAM

We are thrilled to extend our warm invitation to you as a valued stakeholder in the Kerala MedTech ecosystem to the 10th KMTTC Stakeholders Connect Meet (SCM), organised by the Kerala Medical Technology Consortium (KMTTC) in association with the Institute of Cooperative Management (ICM). KMTTC's periodic one-day SCM has quickly become a highly anticipated interactive meet in the Kerala MedTech ecosystem. The theme for this Meet is 'Transforming Rubber: From Plantations to Medical Frontiers', spotlighting the immense opportunities in the innovation, development and manufacturing of Rubber-based Medical Devices and how cooperative farmer / planter groups can leverage this to unlock long-term value from their rubber plantations.

DATE	FRIDAY 19 TH JULY 2024 9:30 AM – 4:00 PM*
VENUE	INSTITUTE OF COOPERATIVE MANAGEMENT, TRIVANDRUM (GOOGLE MAPS)
THEME	TRANSFORMING RUBBER: FROM PLANTATIONS TO MEDICAL FRONTIERS

*PLEASE NOTE THAT REGISTRATION WILL START AT 9:00 AM AT THE VENUE

The theme underscores the immense potential of Kerala's rubber industry to innovate and diversify into the high-value domain of medical technology. By harnessing the collective strength of cooperative societies, this event aims to explore forward integration opportunities that can transform raw rubber into specialised medical-grade materials and cutting-edge medical devices. This shift not only promises enhanced economic returns for rubber farmers but also positions Kerala as a leader in the MedTech sector, driving both local and global advancements in healthcare.

HURRY! LIMITED SEATS AVAILABLE!

Since the Meet is envisioned and targeted towards leaders and professionals in the rubber plantation and marketing sectors, the first priority for attendance is given to them. Consequently, only a few seats are available for other interested participants. We recommend registering immediately to secure your spot at this important event.

[CLICK HERE TO REGISTER NOW](#)

[LIMITED SEATS – SECURE YOUR SPOT TODAY!](#)

KMTC SCMs provide an exceptional platform for stakeholders in the Kerala MedTech ecosystem to come together, exchange insights, and contribute towards the advancement of MedTech / Medical Devices development in Kerala. Here's what you can expect from this engaging event:

1. **Enlightening Presentations:** Renowned experts in the field of assistive technology innovation and device development will share their knowledge and experiences, shedding light on the innovative processes behind developing practical and accessible devices. They will explore how strategic collaborations and advancements in technology enhance the functionality and usability of assistive devices, directly impacting the quality of life for individuals with disabilities. Attendees will gain critical insights into emerging trends, best practices, and regulatory frameworks that govern the assistive technology sector..
2. **Panel Discussions and Interactive Sessions:** Panel Discussions and Interactive Sessions: Engage in stimulating panel discussions with industry leaders, researchers, and professionals, fostering dynamic exchanges of ideas and experiences. Participate in interactive sessions to discuss challenges, opportunities, and collaborative approaches to advancing medical device development in Kerala.
3. **Networking Opportunities:** Connect and network with like-minded stakeholders from across the Kerala MedTech ecosystem, including researchers, clinicians, entrepreneurs, industry representatives, healthcare professionals, and policymakers. Forge new partnerships,

strengthen existing collaborations, and build a robust network of professionals passionate about transforming lives through innovative assistive technologies.

4. Showcasing Institutions and Innovators: Get to know about the diverse cutting-edge projects and ongoing applied research in assistive and other medical devices and technological advancements by local research institutions, academia, companies, startups and innovators. Stay ahead of the curve with strategic insights from the who's who of the Kerala MedTech ecosystem.

Whether you are a startup, an established company, a researcher, or a regulator, this event will provide valuable insights and networking opportunities to help you successfully navigate innovation and development of AT / MedTech products. Don't miss this opportunity to connect with fellow stakeholders and learn from the best in the field!

The Government of Kerala is committed to transitioning the state's economy into a high value, knowledge-based economy. This is in alignment with Kerala's inherent advantages over other parts of the country, taking into consideration the rich natural resources, skilled talent, and some ground-breaking research institutions. The Govt recognizes the immense potential that Kerala has in an industry like Medical Devices, Medical Technology, which is an R&D intensive domain requiring specialised expertise and knowledge and has designated it a priority sunrise sector.

Kerala Medical Technology Consortium (KMTC) is a flagship endeavour of the Govt of Kerala, initiated in June 2022, to establish Kerala as the Top Medical Devices / Medical Technology Hub of India in the next decade. One of the key strategies identified early on to achieve this ambitious goal, is to bring together the existing ecosystem of industry, researchers, academia, startups, hospitals, regulators, policymakers, suppliers, distributors and Govt agencies, to meaningfully interact and exchange ideas and information, and to catalyse close clusters of partnerships & collaborations.

The KMTC Stakeholder Connect Meet (SCM) is a periodic ecosystem-building platform that is designed to bring all stakeholders in the Kerala MedTech Ecosystem together and is especially focused on connecting academia and research with industry. The KMTC SCM is a great opportunity for stakeholders to keep themselves updated on the latest developments in the ecosystem, find strategic partners and explore growth opportunities.

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Visit KMTC website: www.kmtc.in

4.2 PROGRAM AGENDA



10TH KMTTC STAKEHOLDERS CONNECT MEET – JULY 2024

A UNIQUE INTERACTIVE EVENT THAT BRINGS TOGETHER ALL THE STAKEHOLDERS IN THE MEDICAL TECHNOLOGY / MEDICAL DEVICES SPACE, INCLUDING THE INDUSTRY; RESEARCH INSTITUTIONS AND ORGANISATIONS; HEALTHCARE PROFESSIONALS, HEALTHCARE PROVIDERS AND INSTITUTIONS; ENTREPRENEURS AND STARTUPS; INCUBATION & ACCELERATION AGENCIES; UNIVERSITIES & COLLEGES AND THE GOVERNMENT TO PROMOTE COLLABORATION, RESEARCH, DEVELOPMENT AND INNOVATION IN MEDICAL DEVICES AND TECHNOLOGY.

PROGRAM AGENDA

DATE	FRIDAY 19TH JULY 2024 9:00 AM – 4:00 PM
VENUE	SEMINAR HALL INSTITUTE OF COOPERATIVE MANAGEMENT, TRIVANDRUM (GOOGLE MAPS)

THEME	TRANSFORMING RUBBER: FROM PLANTATIONS TO MEDICAL FRONTIERS
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TIME		PROGRAM / ACTIVITY
1.	9:00 – 9:30 AM	ARRIVAL OF PARTICIPANTS & REGISTRATION

TIME		PROGRAM / ACTIVITY
2	9:30 – 10:20 AM [50 MINS]	<p>INAUGURAL SESSION</p> <ul style="list-style-type: none"> WELCOME ADDRESS – MR SASIKUMAR M. V., DIRECTOR, INSTITUTE OF COOPERATIVE MANAGEMENT (ICM) OPENING ADDRESS – MR C PADMAKUMAR, SPECIAL OFFICER, KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC) INAUGURAL ADDRESS – MR A P M MOHAMMED HANISH IAS, PRINCIPAL SECRETARY (INDUSTRIES), GOVT OF KERALA SPECIAL ADDRESS – DR JOSEPH BENAVENT, PRESIDENT, INDIAN MEDICAL ASSOCIATION (IMA) – KERALA CHAPTER SPECIAL ADDRESS – MR SANTHOSH KUMAR, EXECUTIVE DIRECTOR, HARRISONS MALAYALAM LIMITED (HML) FELICITATIONS – ADVOCATE SONY SEBASTIAN, CHAIRMAN, KERALA STATE COOPERATIVE MARKETING FEDERATION VOTE OF THANKS – DR JAYAMOHAN NAIR, DEPUTY DIRECTOR, INSTITUTE OF COOPERATIVE MANAGEMENT (ICM)
3	10:20 – 10:35 AM [15 MINS]	NETWORKING TEA & REFRESHMENTS BREAK
4	10:35 – 11:15 PM [40 MINS]	<p>RUBBER IN MEDICAL DEVICES</p> <p>SESSION BY EXPERTS FROM SREE CHITRA TIRUNAL INSTITUTE OF MEDICAL SCIENCES & TECHNOLOGY (SCTIMST)</p> <ol style="list-style-type: none"> DR ROY JOSEPH, SCIENTIST-G & DEAN (ACADEMIC AFFAIRS) DR GIJO RAJ, SCIENTIST - C, DIVISION OF POLYMERIC MEDICAL DEVICES, BIOMEDICAL TECHNOLOGY (BMT) WING
5	11:15 – 11:35 AM [20 MINS]	<p>HARRISONS MALAYALAM LIMITED’S JOURNEY INTO RUBBER BASED MEDICAL DEVICES</p> <p>SESSION BY MR BIJINESH B, MANAGER, RESEARCH & DEVELOPMENT, HARRISONS MALAYALAM LIMITED (HML)</p>
6	11:35 – 11:55 AM [20 MINS]	<p>KERALA RUBBER LIMITED – PROMOTION OF NATURAL RUBBER BASED INDUSTRIES IN THE STATE WITH FOCUS ON MSME SECTOR</p> <p>SESSION BY MR TOMS JOSEPH, SENIOR RESOURCE PERSON, KERALA RUBBER LIMITED (KRL)</p>
7	11:55 AM – 12:25 PM [30 MINS]	<p>RUBBER – AN IMPORTANT CONSTITUENT OF MEDICAL PRODUCTS AND RELATED APPLICATIONS</p> <p>SESSION BY DR SIBY VARGHESE, FORMER JOINT DIRECTOR, RUBBER RESEARCH INSTITUTE OF INDIA (RRII)</p>

TIME		PROGRAM / ACTIVITY
8	12:25 – 1:10 PM [45 MINS]	<p>EXPERT PANEL DISCUSSION – I OPPORTUNITIES IN MEDICAL GRADE RUBBER & RUBBER BASED MEDICAL DEVICES INTERACTIVE SESSION WITH EXPERT SPEAKERS – ALSO ANSWERING QUERIES FROM DELEGATES / PARTICIPANTS MODERATED BY DR ROY JOSEPH, SCIENTIST-G & DEAN (ACADEMIC AFFAIRS), SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY (SCTIMST)</p> <ul style="list-style-type: none"> • DR GIJO RAJ, SCIENTIST - C, DIVISION OF POLYMERIC MEDICAL DEVICES, BIOMEDICAL TECHNOLOGY (BMT) WING • MR BIJINESH B, MANAGER, RESEARCH & DEVELOPMENT, HARRISONS MALAYALAM LIMITED (HML) • MR TOMS JOSEPH, SENIOR RESOURCE PERSON, KERALA RUBBER LIMITED (KRL) • DR SIBY VARGHESE, FORMER JOINT DIRECTOR, RUBBER RESEARCH INSTITUTE OF INDIA (RRII)
9	1:10 – 1:55 PM [45 MINS]	NETWORKING LUNCH BREAK
10	1:55 – 2:10 PM [15 MINS]	<p>INNOVATION IN LATEX TECHNOLOGY AND LATEX PRODUCTS SESSION BY DR ABI SANTHOSH APREM, ASSOCIATE VICE PRESIDENT, TECHNICAL & OPERATIONS, HLL LIFECARE LIMITED</p>
11	2:10 – 2:25 PM [15 MINS]	<p>DEVELOPMENT AND MANUFACTURING OF RUBBER BASED MEDICAL DEVICES SESSION BY MR ALEX G KODI, MANAGING DIRECTOR, KODI HEALTHCARE</p>
12	2:25 – 2:40 PM [15 MINS]	<p>RUBBER INDUSTRY: AN OVERVIEW SESSION BY MR KARIMPUZHA RAMAN , DIRECTOR, PRIMUS GLOVES</p>
13	2:40 – 3:25 PM [45 MINS]	<p>EXPERT PANEL DISCUSSION – II OPPORTUNITIES & CHALLENGES IN MANUFACTURING OF RUBBER-BASED MEDTECH / MEDICAL DEVICES INTERACTIVE SESSION WITH EXPERT SPEAKERS – ALSO ANSWERING QUERIES FROM DELEGATES / PARTICIPANTS MODERATED BY MR REJEESH G R, GENERAL MANAGER (MARKETING) , KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)</p> <ul style="list-style-type: none"> • MR KARIMPUZHA RAMAN , DIRECTOR, PRIMUS GLOVES • DR ABI SANTHOSH APREM, ASSOCIATE VICE PRESIDENT, TECHNICAL & OPERATIONS, HLL LIFECARE • MR ALEX G KODI, MANAGING DIRECTOR, KODI HEALTHCARE
14	3:25 – 3:40 PM [15 MINS]	<p>DEVELOPING RUBBER-BASED MEDICAL DEVICES IN KERALA: SUPPORT BY KMTC SESSION BY MR REJEESH G R, GENERAL MANAGER (MARKETING) , KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)</p>
15	3:40 – 3:50 PM [10 MINS]	PARTICIPANTS FEEDBACK COLLECTION – THROUGH PEN & PAPER FORM

TIME		PROGRAM / ACTIVITY
16	3:50 – 4:05 PM [15 MINS]	SUMMARISING & WRAPPING UP THE MEET KEY TAKEAWAYS OF THE DAY – INSTITUTE OF COOPERATIVE MANAGEMENT (ICM)
	4:05 PM ONWARDS	NETWORKING TEA & REFRESHMENTS

4.3 LIST OF SPEAKERS AND PARTICIPANTS

Speakers and Resource Persons:

Name	Designation	Organisation
Dr Roy Joseph	Scientist G & Dean (Academic Affairs)	Sree Chitra Tirunal Institute for Medical Sciences and Technology
Dr Gijo Raj	Scientist C , Division of Polymeric Medical Devices, BMT Wing	Sree Chitra Tirunal Institute for Medical Sciences and Technology
Mr Bijinesh	Manager, Research and Development	Harrisons Malayalam Limited
Mr Toms Joseph	Senior Resource Person	Kerala Rubber Limited (KRL)
Dr Siby Varghese	Former Joint Director	Rubber Research Institute of India (RRII), Rubber Board
Dr Abi Santhosh Aprem	Associate Vice President, Technical and Operations	HLL Lifecare Limited
Mr Alex G Kodi	Managing Director	Kodi Healthcare
Mr Karimpuzha Raman	Director	Primus Gloves

Participants:

#	NAME	DESIGNATION	ORGANIZATION
1	Vishnupriya CB	Intern-KRL	Kerala Rubber Limited (KRL)
2	Reshma Vijay V.J.	Business Development	Kerala Rubber Limited (KRL)

		Officer cum EA to CMD	
3	Haritha Vijayan	Intern-KRL	Kerala Rubber Limited (KRL)
4	Dr. Shera Mathew	Scientist C(OIC of Technical Consultancy Division, RRII)	Rubber Research Institute of India (RRII), Rubber Board
5	Parvathy S. Kumar	Scientific Assistant	Rubber Research Institute of India (RRII), Rubber Board
6	Shaheen Mohammad	Scientific Assistant	Rubber Research Institute of India (RRII), Rubber Board
7	V M Pradeep	Director	Kerala State Rubber Co-operative Limited
8	Sunil U	Factory Manager	Kerala State Rubber Co-operative Limited
9	Anoop Thottakara	Production Quality Engineer	Rubco, Coir Mattress Division Pambady, Kottayam
10	Haimohan M	Mechanical Maintenance Engineer	Rubco Kannur
11	Sheeja K V	Shift in Charge	Kerala State Rubber Co-operative Limited, Kannur
12	P Sasidharan	President	Mathil Service Cooperative Bank, Kannur
13	E janardhanan	President	Chuzali Service Cooperative Bank, Kannur
14	B Vijayan	President	Kottarakkara Taluk Cashews & Rubber Owners Processing and Marketing
15	Sunny Augustine	President	Pala Marketing, Co-operative Society, Chithimattom
16	R. D. Prakash	President	Kunnathoor General Marketing & Processing Cooperative Society
17	E.T Mohammed	Director Marketing	P.C.C Marketing Society, Kondotty
18	Sunil Bhaskar	Factory Manager	Rubbermark Intermix Factory, Kadumthuruthy
19	Leo T Oomman	Junior Clerk	Rubber Growers Processing & Marketing Cooperative Society , Kadaikode
20	Sandhya Rani R	Secretary	The Quilon Processing & Marketing Cooperative Society, Kadappakkad, Kollam
21	Navakumaran Nair S	Foreman	Rubber Mark, Kochi, The Kerala State Marketing Federation Ltd.

22	Sarath Krishnan	Clerk	Rubber and General Marketing Cooperative Society, Chadayamangalam
23	Basheer A	Member	Trivandrum District Rubber Marketing Society, Nedumangad
24	Ajaykumar A	Board Member	Kerala State Cooperative Marketing Federation, Cochin
25	J. Anilkumar	Director	Kerala State Cooperative Marketing Federation, Cochin
26	Sureshkumar Kalarikkal	President	Malappuram Rubber Growers Cooperative Marketing Society, Nilamboor
27	K R V Sahajan	President	Marketing Cooperative Society Kadappakada, Kollam
28	S Suresh Babu	President	Trivandrum District Rubber Marketing Society, Nedumangad
29	Adv. Joseph Mandapathil	Director	Marketing Fed, Kadavanthra , kochi
30	P J Thomas	President	Agri-Cooperative Marketing Society, Perambra
31	Appanna B S	Secretary	The Kasargod Agricultural Cooperative Marketing Society Ltd.
32	V P Raghavan	Director	The Ranni Marketing Cooperative Society
33	Latha M	Secretary	The Kotachery Co-operative Society Ltd., Kotachery
34	P K Vinodkumar	Secretary	KCMP Society, Kasargod
35	Renju Radhakrishnan	Secretary	The Ranni Marketing Cooperative Society
36	M Maniyan Pillai	Director	Venjaramood Cooperative Rubber Marketing Society Limited
37	Devapriya P A	Secretary	Alakode Rubber Marketing Cooperative Society Ltd, Kannur
38	B Rajeev	Director	RUBCO, Kannur
39	Toney M Varghese	Production Manager	Kerala State Rubber Cooperative Ltd., RCM Kottayam
40	Sumesh S N	Assistant Managing Director	Venjaramood Cooperative Rubber Marketing Society Limited
41	E. Shamshudeen	President	Rubber Marketing Society, Venjaramoodu, Trivandrum

42	M S Shaji	Director	Venjaramood Cooperative Rubber Marketing Society Limited
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4.4 LIST OF RUBBER BASED MEDICAL DEVICES

1	Surgical and exam gloves
2	Catheters and other tubing
3	Blood pressure cuffs
4	Latex endoscope tube cover
5	X-ray radiation shielding sheet
6	Ultrasound probe covers
7	Anaesthesia breathing bag
8	NR baby teats
9	Urine drainage condoms
10	Rubber bulb syringes
11	Rubber bladders
12	Douche bags
13	Breast pump
14	Pessary rubber ring
15	Menstrual cups
16	Ear ulcer syringes
17	Elastic bandages and wraps
18	Medicine vials
19	Tourniquet
20	Hot water Bottles

4.5 PRESENTATIONS

Inaugural Session PPT: **Mr Santhosh Kumar**, Executive Director, Harrison's Malayalam Limited (HML)



HARRISONS MALAYALAM LTD

✓ In the business of Tea and Rubber Plantations



Santosh Kumar
Executive director
Harrisons Malayalam Limited
Cochin .



History and Heritage

- ❑ Harrisons and Cross fields- Oldest company in South India established in 1844.
- ❑ Acquired by RPG in 1989.
- ❑ Started operation as 2 separate business units in 2011
- ❑ Largest Employer (especially Women) in Kerala

Vision

Lead a sustainable Plantation business delivering cost efficient and differentiated products





Snapshot of our company



Harrisons Malayalam Limited



- ❑ Largest plantation company based in south India
- ❑ 25000 hectares of land under its fold –
 - Tea : 15,000 hectares
 - Rubber : 10,000 hectares
- ❑ Largest Natural Rubber producer in India, 2nd largest Tea producer in south India.
- ❑ Spread over 24 Estates, 5 rubber factories and 12 tea factories
- ❑ Production of about 13000 MT Rubber, 15,000 MT Tea and 25,000 MT pineapple
- ❑ One of the Biggest producers of Pineapple (25000 Mt)
- ❑ Known for Quality Tea and Rubber Worldwide .

3

HML & RUBBER- A. LONG ASSOCIATION

- ❑ HMLs Rubber operation started in 1900 when the Mooply Valley estates were planted .
- ❑ HML has 2 premium latex processing units at Mooply and Kumbazha Respectively
- ❑ Our HML –KA and HML –MY are Registered Quality Trade Marks In the Industry that Command a premium in the Market .





OUR STRENGTHS

- ❑ **Captive Production.**
(More than 5000 Mt of own production)
- ❑ **Large captive processing space.**
(More than 140000 Mt of NR)
- ❑ **Separate QC delinked from Production.**
- ❑ **Separate R& D.**



HML Factories are all ISO 9001 ,14001 Certified .



OUR SPACE

- ❑ **Almost 90% of our production is in the Latex space**
- ❑ **One of the most important feature is the production of Specialised grades of Centrifuged latex based on Industry Requirement.**
- ❑ **Of the 2 factories one is complexly into dedicated Manufacturing for Niche Industries and specialized applications .**





Rubber

Grades	%
Cenex	79
PLC	5
SKIM	8
ISNR	8



Current marketing portfolio :

	%
Direct to End User	48
Through Agents	52

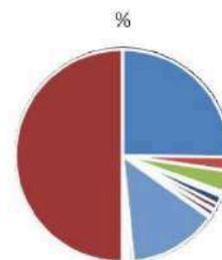


HML IS THE ONE STOP GRADE FOR ALL NATURAL RUBBER GRADES



OUR SHARE IN PRODUCT SEGMENT

PRODUCT SEGMENT	%
ADHESIVES	50.38
AGGARBATHI MANUFACTURER	4.15
BALLOONS	6.49
CARPETS	0.91
CHEMICALS	0.01
CONDOM	0.57
CONVEYOR BELTS	2.62
FOOTWEAR	1.82
GLOVES	0.45
HOSPITAL ITEMS	1.74
LATXS IVE	0.10
MATRESS	0.52
OTHERS	26.95
RUBBER MOULDED COMPONENTS	1.20
SPORTS GOODS	0.48
TAPES	0.52
TEXTILE INDUSTRY	0.32
EXPORT	0.59
PROCESSOR	0.15
Grand Total	100.00





REPOSITIONING RUBBER

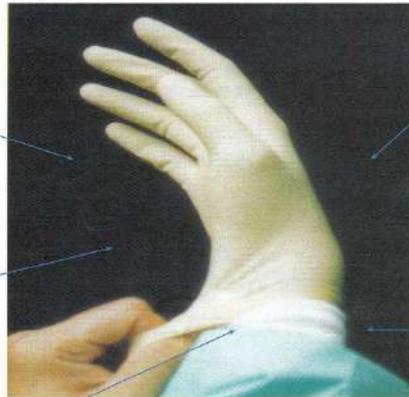


PRE-REQUISITES OF A BARRIER MATERIAL(e.g. glove)

Soft and conform to contour of hand

Mechanically strong (stretchable) and elastic (non-deformable)

Good grip for working surface



Continuous (impervious) film for protection against pathogens and microbes

Donnable as a glove: low surface friction against skin



SUBSTITUTION BY VINYL, NITRYL AND CHLOROPRENE

EFFECTIVE DEPROTEINISATION STRATEGIES



DEPROTEINISATION

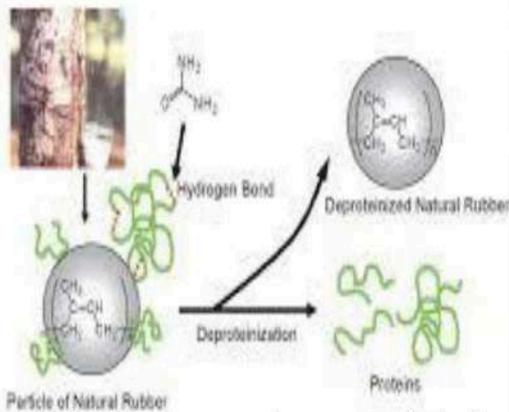
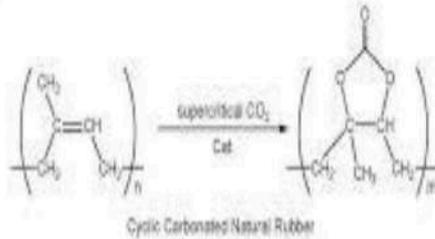


Table 2. Property	Treated NRL	Standard NRL
Dry Rubber Content, % (m/m)	60.03	60.08
Total Solids Content % (m/m)	60.94	61.21
Non Rubber Solids, % (m/m)	0.91	1.13
pH	10.05	10.55
Alkalinity (as NH3), % (m/m)	0.60	0.62
Volatile Fatty Acid Number (VFA)	0.02	0.03
KOH Number	0.45	0.6
Mechanical Stability (MST) seconds	960	650
Extractable Protein content PPM	20	600 PPM
Coagulum content(m/m)	0.002	

Treated NRL shows superior property in terms of stability and also reduction in NRS

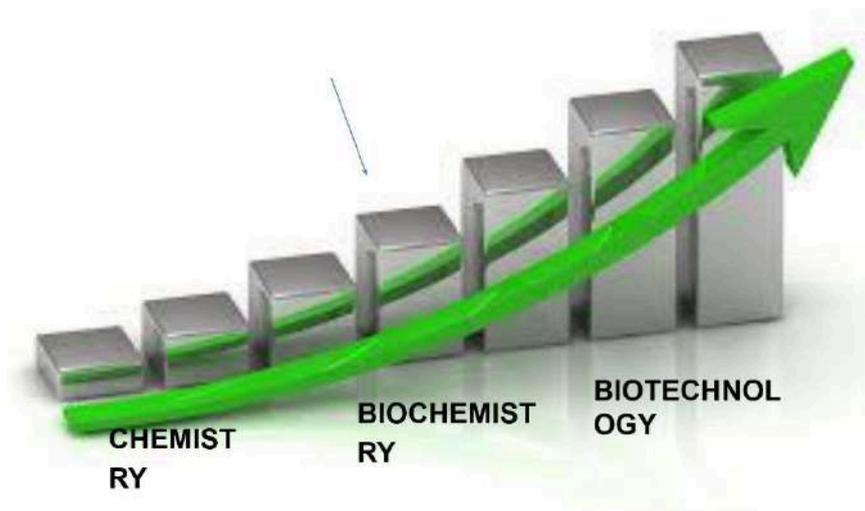


NITROSAMINE FREE RUBBER

- ❑ Nitrosamines are chemical compounds that are produced by reactions of nitrites with amines or amides. They can be found in rubber products, health, beauty care products, baby products and food products.
- ❑ Nitrosamines are carcinogens, that can potentially cause cancer. Hence, manufacturers need to monitor the presence of nitrosamines in their products, so as to ensure safety, quality and compliance with regulations.



TOWARDS GREENER TECHNOLOGIES





LOW AMMONIA LATEX

- HIGH AMMONIA
- LOW AMMONIA
- ULTRA LOW AMMONIA
- LOW AMMONIA



Rubber product development

- Pressure sensitive adhesives.
- De- proteinised rubber.
- Nitrosamine free Latex
- Footwear Industry
- Condoms and health care



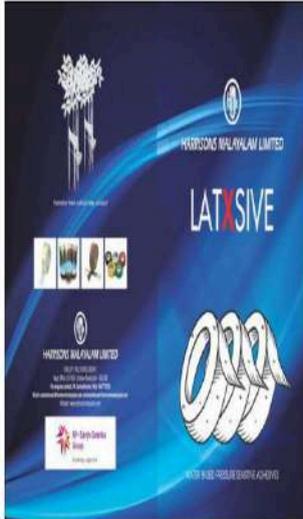


NEW PRODUCT –PSA

HML was the first to have developed the technology of Latex based PSAs

This Innovative product

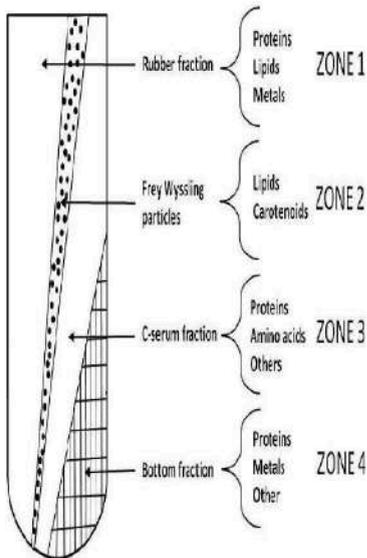
- Is water Borne PSA (Solvent Free).
- No fire Hazard and health hazards.
- Varies Kinds Of Specialty Adhesive Tapes And Adhesive Coated Products for Diversified End Applications.
- For a Variety of Substrate like Plastic Films, Paper, Metal Foil, Fabric's, Foams etc.
- This adhesive exhibits , a very good balance of peel adhesion , holding power (Shear Strength), Rolling Ball tack, and good ageing resistance.



FUTURE AREAS



EXTRACTION OF USEFUL MOLECULES



No.	Zone	Major Components	Function
1	Rubber Particle	cis-1,4-polyisoprene Phospholipids	Elastomer
2	Frey Wyssling particles	Clusters of carotenoids and luteoids	affects viscosity, yellow color of latex
3	Clear serum	water soluble proteins, free amino acids, quebrachitol, potassium and phosphate ions, carbohydrates	<input type="checkbox"/> protein hydrolysis for stabilization, <input type="checkbox"/> buffers pH for stabilization, bioactive components for micro-organism consumptions
4	Bottom fraction	water soluble lipids, choline compounds, ash, inorganic constituents	<input type="checkbox"/> degrade on storage to form high fatty acids for stabilization, vulcanization accelerators, and natural anti-oxidants <input type="checkbox"/> forms sludge and removed during centrifugation, oxidizes rubber particles

Fractions of Natural Rubber Latex after Centrifugation¹¹



PRODUCT MANUFACTURING



High quality Printed and Party Balloon Manufacture



Our Forey Into Bio Medical devises



Collaboration with SCIMSAT – Journey has just begun.....



Dr Gijo Raj, Scientist C , Division of Polymeric Medical Devices, BMT Wing,
Sree Chitra Tirunal Institute for Medical Sciences and Technology

Medical Devices using Natural Rubber



Dr. Gijo Raj
Scientist C

Division of Polymeric Medical Devices
Department of Medical Devices Engineering
Biomedical Technology Wing
SCTIMST

19/07/2024

Hevea brasiliensis

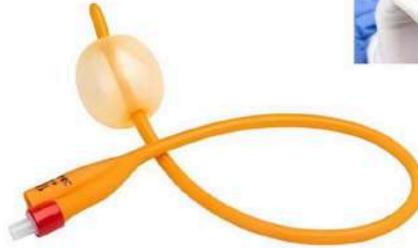
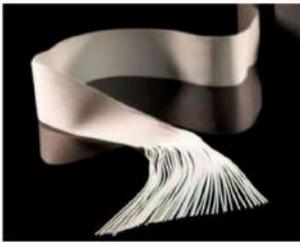


Products by dipping in latex



Products using compounded
rubber sheets

Medical devices using Latex



Kaolin clay is used with latex to improve mechanical strength

<https://www.rubfila.com/rubber-threads-for-medical-applications>

Surgical and Medical examination gloves



secure | pharmabiz.com/NewsDetails.aspx?aid=158290&sid=1

you can get e-magazine links on WhatsApp. [Click here](#)

Medical Equipment + Font Resize -

Retail prices of gloves shoot up by almost 40% due to longer testing time at CDSCO designated lab in Chennai

Shardul Nautiyal, Mumbai
Thursday, May 25, 2023, 08:00 Hrs [IST]

As per Medical Device Rules 2017, Surgical gloves (latex and non-latex) and Medical examination gloves (latex and non-latex) falls under Medical devices and are classified under Class B, and Class A respectively.

International Standard ISO 11193-1

Single-use Medical Examination Gloves

Part 1: Specification for gloves made from rubber latex or rubber solution.

Scope of ISO 1193-1 :

- Specifies requirements for packaged sterile, or bulked non-sterile, rubber gloves intended for use in medical examinations and diagnostic or therapeutic procedures to protect the patient and the user from cross-contamination.
- It also covers rubber gloves intended for use in handling contaminated medical materials and gloves with smooth surfaces or with textured surfaces over all or part of the glove.
- This document is intended as a reference for the performance and safety of rubber examination gloves.
- It does not cover the safe and proper usage of examination gloves and sterilization procedures with subsequent handling, packaging and storage procedures.

International Standard ISO 11193-1

Clause 6 : Sampling

Table 1 — Inspection levels and AQLs

Characteristic	Inspection level	AQL
Physical dimensions (width, length, thickness)	S-2	4,0
Water tightness	G-I	2,5
Force at break and elongation at break (before and after accelerated ageing)	S-2	4,0

Lot Size	General Inspection Levels			Special Inspection Levels			
	I	II	III	S1	S2	S3	S4
2 to 8	A	A	B	A	A	A	A
9 to 15	A	B	C	A	A	A	A
16 to 25	B	C	D	A	A	B	B
26 to 50	C	D	E	A	B	B	C
51 to 90	C	E	F	B	B	C	C
91 to 150	D	F	G	B	B	C	D
151 to 280	E	G	H	B	C	D	D
281 to 500	F	H	J	B	C	D	E
501 to 1200	G	J	K	C	C	E	E
1201 to 3200	H	K	L	C	D	E	E
3201 to 10000	J	L	M	C	D	F	F
10001 to 35000	K	M	N	C	D	F	F
35001 to 150000	L	N	P	D	E	G	G
150001 to 500000	M	P	Q	D	E	G	G
500000 and more	N	Q	R	D	E	G	H

Letter code	Acceptance Quality Limit (AQL) - Normal Inspection																							
	0.4		0.65		1		1.5		2.5		4		6.5		10		15		25		50			
	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re		
A	2																							
B	3																							
C	5																							
D	8																							
E	13																							
F	20																							
G	32	0	1																					
H	50																							
J	80																							
K	125	1	2	2	3	3	4	5	6	7	8	10	11	14	15									
L	200	2	3	3	4	5	6	7	8	10	11	14	15	21	22									
M	315	3	4	5	6	7	8	10	11	14	15	21	22											
N	500	5	6	7	8	10	11	14	15	21	22													
P	800	7	8	10	11	14	15	21	22															
Q	1250	10	11	14	15	21	22																	
R	2000	14	15	21	22																			

Re: Rejection number Ac: Acceptance number
 ↓: Use first sampling below arrow ↑: Use first sampling above arrow

International Standard ISO 11193-1

Clause 7 : Requirements

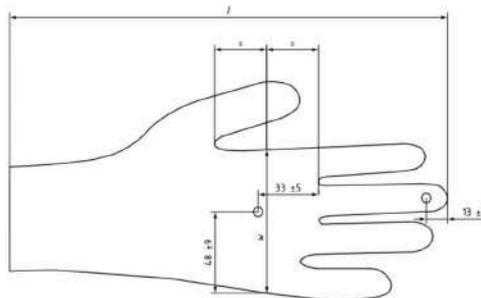
Sl. No.	Name of the test/process
1.	Dimensions (clause 7.1)
2.	Water tightness (clause 7.2)
2.	Sample preparation for Tensile properties (clause 7.3.1)
3.	Force at break and elongation at break* before accelerated aging (clause 7.3.2)
4.	Accelerated aging
5.	Force at break and elongation at break* after accelerated aging (clause 7.3.3)

International Standard ISO 11193-1

Clause 7.1 : Dimensions

Table 2 — Dimensions and tolerances

Size code	Width corresponding to size code (dimension w , Figure 1) mm	Descriptive size	Width corresponding to descriptive size (dimension w , Figure 1) mm	Minimum length (dimension l , Figure 1) mm	Minimum thickness (at locations shown in Figure 1) mm	Maximum thickness (at approximate centre of palm) mm
6 and below	≤ 82	Extra small (X-S)	≤ 80	220	Smooth area: 0,08 Textured area: 0,11	Smooth area: 2,00 Textured area: 2,03
6 1/2	83 ± 5	Small (S)	80 ± 10	220		
7	89 ± 5	Medium (M)	95 ± 10	230		
7 1/2	95 ± 5			230		
8	102 ± 6	Large (L)	110 ± 10	230		
8 1/2	109 ± 6			230		
9 and above	≥ 110	Extra large (X-L)	≥ 110	230		



International Standard ISO 11193-1

Clause 7.2 : Water tightness

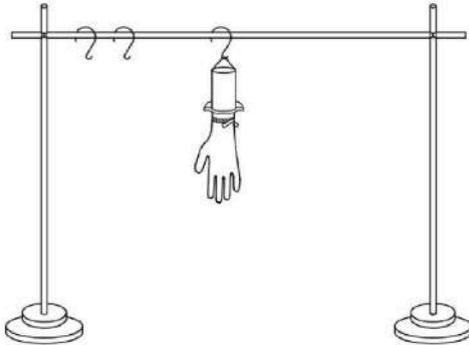


Figure A.2 — Holding device



Table 1 — Inspection levels and AQLs

Characteristic	Inspection level	AQL
Physical dimensions (width, length, thickness)	S-2	4,0
Water tightness	G-I	2,5
Force at break and elongation at break (before and after accelerated ageing)	S-2	4,0

International Standard ISO 11193-1

Clause 7.3 : Tensile properties

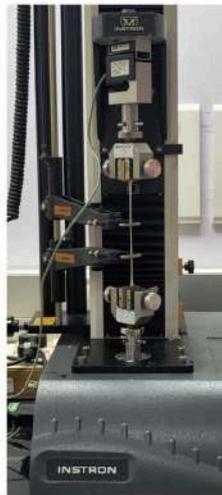


Table 3 — Tensile properties

Property	Requirement	
	Type 1 glove	Type 2 glove
Minimum force at break before accelerated ageing, N	7,0	7,0
Minimum elongation at break before accelerated ageing, %	650	500
Minimum force at break after accelerated ageing, N	6,0	6,0
Minimum elongation at break after accelerated ageing, %	500	400

Compounding of dry rubber

Brabender plastograph



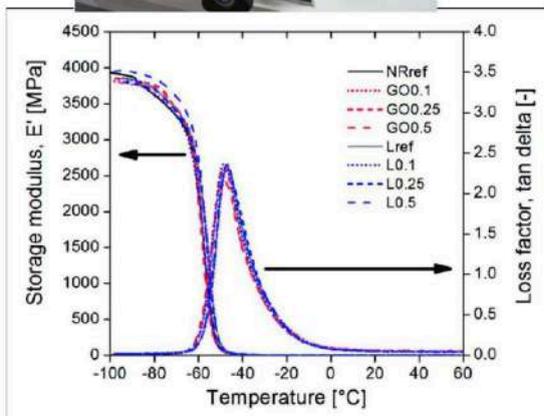
Rubber + functional ingredients

Compression moulding



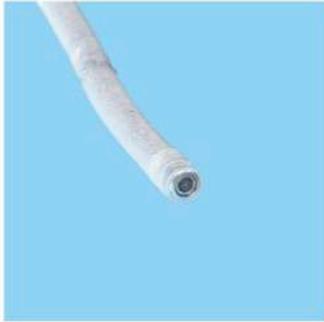
Radiation shielding material

Dynamic Mechanical Analysis (DMA)



https://www.researchgate.net/figure/Storage-modulus-E-0-vs-temperature-a-and-mechanical-loss-factor-tan-d-vs_fig4_313460547

Prospective application of Latex products for Medical use



Latex endoscope tube covers



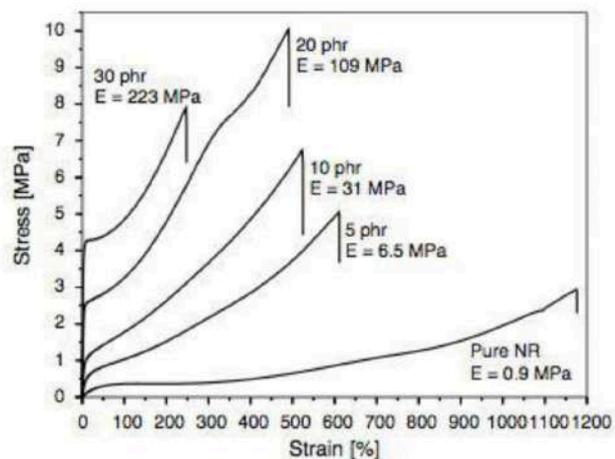
X-ray Radiation shielding sheet



Jaipur foot uses Microcellular Rubber
(Image: IEEE, www.embs.org)

Geriatric assistive/protective materials from Natural rubber

Objective: To make use of Energy absorption property of Natural Rubber to protect old age population from fractures due to falls.



Galembeck, Fernando & Abreu Filho, Pompeu. (2017). Perspectives for Biomass Production and Use in Brazil. Revista Virtual de Química. 9. 274-293. 10.21577/1984-6835.20170018.

Image from: <https://www.decathlon.in>

Challenges of developing Medical devices using latex formulations.

Constituent	% by weight of latex
Rubber particles	30-40
Protein	2-3
Lipids	0.1-0.5
Sugars	1-2
Ash	0.5-1.0
Others	1.5-3.5
Water	55-65



- Proteins present in the latex may induce allergic reactions in some people.
- Tackiness of Natural rubber
- Innovations succeed with Proactive support and collaborations with Rubber Industry and Stakeholders

Nahhar, Alkhaledi & Khoo, Kok Siong. (2019). Study on natural rubber absorption of selected actinides. IOP Conference Series: Materials Science and Engineering. 555. 012015.



<https://www.industrialrubbergoods.com/medical-rubber-products.html>



<https://www.rubfila.com/products/rubber-thread-for-catheter-making>

THANK
YOU

Session PPT: **Dr Roy Joseph**, Scientist G & Dean (Academic Affairs), Sree Chitra Tirunal Institute for Medical Sciences and Technology



RUBBER IN MEDICAL DEVICES



Dr. Roy Joseph
Scientist, SCTIMST, Trivandrum

19 July 2024

10TH KMTc STAKEHOLDERS CONNECT MEET – JULY 2024

Medical Products Made from Natural Rubber

- **Surgical Gloves:** Provide barrier protection without compromising tactile sensitivity.
- **Medical Tubing:** Flexible and resilient, used for IV lines, catheters, etc.
- **Elastic Bandages:** Supports joints and wounds with controlled compression.
- **Seals and Gaskets:** Ensures hygiene and safety in medical equipment.

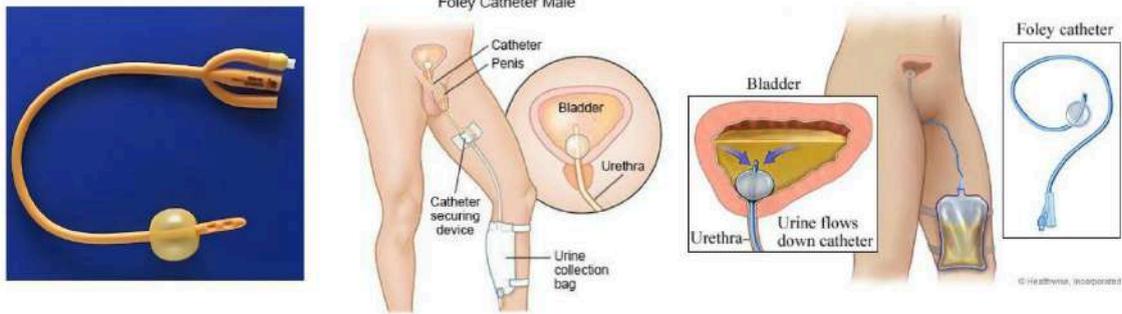


Infusion bleeding regular size are 5x7mm or 6x9mm



Products Made from Natural Rubber

Foleys Catheter



Products Made from Natural Rubber

Ultrasound probe covers



Unique Properties of Latex Rubber

- Natural product and degradable
- Elasticity
- Can be formulated to make them biocompatible
- Durability
- Conformable fit
- Effective barrier properties
- Flexible and minimizes discomfort during procedures
- Sterilization Compatibility: Can withstand various sterilization methods (e.g., autoclaving, gamma irradiation).

Latex Products - Challenges

- **Challenges:**
 - Traditional NRL contains allergenic proteins.
 - Chemical Additives: Traditional accelerators and vulcanizing agents are toxic.
- **Requirement:** Develop formulations with reduced allergenicity and toxicity.
 - Protein Reduction: Methods to lower allergenic proteins in NRL.
 - Use Low-toxicity accelerators and vulcanizing agents.
 - Quality Standards: Compliance with global safety regulations (e.g., ASTM, ISO).
- **Benefits:** Enhance safety for consumers, workers, and the environment.

Biocompatibility and Safety

- **Allergenic Potential:** Allergic reactions
 - Estimated 1-6% in general population, higher in healthcare workers.
- **Toxicity from curing additives**



Accelerators used in latex curing

1. **Zinc Diethyldithiocarbamate (ZDC)** – Highly toxic
2. **Zinc Dimethyldithiocarbamate (ZDMC)** - Less toxic
3. **Tetramethylthiuram Disulfide (TMTD)** - Highly toxic
4. **Diphenylguanidine (DPG):** DPG is a secondary accelerator that can be used in combination with primary accelerators like TMTD or ZDMC to achieve the desired vulcanization properties in latex products.
5. **Thiazoles:** Compounds like 2-Mercaptobenzothiazole (MBT) and Benzothiazole disulfide (MBTS) are thiazole-based accelerators that can serve as alternatives to ZDC in latex formulations.
6. **Thiurams:** Accelerators such as Tetraethylthiuram disulfide (TETD) and Tetraethylthiuram monosulfide (TETM) are thiuram-based alternatives that can be used effectively in place of ZDC.
7. **Guanylthioureas:** Guanylthiourea derivatives like Dicyclohexyl-2-thiopseudourea (DTU) can also act as accelerators in latex formulations, offering an alternative to ZDC

Non-Toxic Latex Formulations

Challenges and Considerations

- **Technical Hurdles:** Balancing allergen reduction with material performance.
- **Cost Implications:** Investment in research and development.
- **Education:** Awareness among stakeholders about benefits and usage.

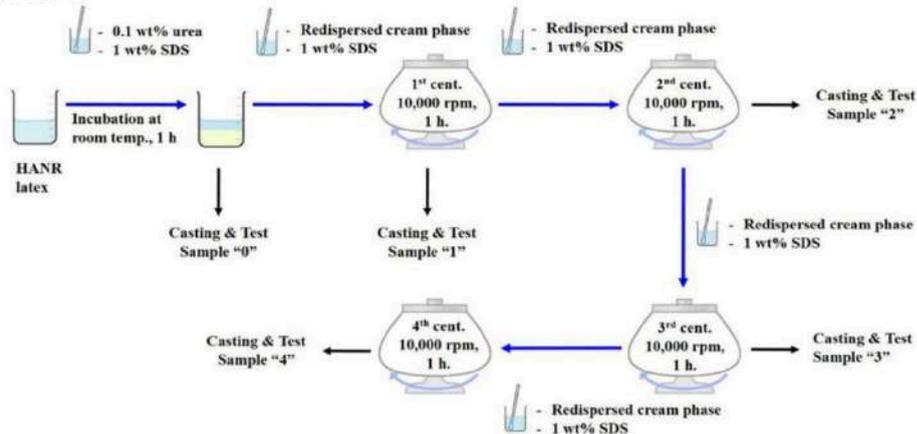
Non-Toxic Latex Formulations

Approaches to Reduce Allergenicity

- **Protein Removal:** Purification techniques to extract allergenic proteins.
- **Protein Modification:** Chemical treatments to alter protein structure.
- **Work with academia for solutions**

Low Protein Latex - Process

- Sodium dodecyl sulphate (SDS) in deproteinized natural rubber latex (DPNRL)
- SDS effectively facilitated the removal of 20 – 80% proteins during the deproteinisation process



Components of Non-Toxic NRL Formulations

1. Low levels of latex protein

- Reduced Content: Purification to lower allergenic proteins (e.g., Hev b proteins).
- Modification: Chemical treatments to alter protein structure.

2. Non-toxic Vulcanizing Agents:

- Traditional Concerns: Use of toxic accelerators (e.g., thiurams, carbamates).
- Safer Options: Low-toxicity alternatives (e.g., thioureas, zinc oxide).

Technology Advancements

Advancements in Medical Gloves

- Thinner Designs: Maintaining tactile sensitivity without compromising protection.
- Antimicrobial Properties: Incorporating agents to reduce infection risk.
- Longer Wear Time: Enhanced durability for extended procedures.

Innovations in Catheters and Tubing

- Biocompatible Materials: Natural rubber latex variants with reduced allergenicity.
- Advanced Coatings: Non-stick coatings to minimize friction and irritation.
- Customizable Features: Tailored designs for specific medical procedures.

Advancements in Medical Tubings and Catheters

Antimicrobial Coatings

Purpose: Reduce microbial colonization and infection risk.

Benefits: Enhance safety, extend tubing lifespan, and improve patient outcomes.

Techniques: Incorporation of antimicrobial agents onto tubing surfaces.

Innovations in Curing Technology

Medical Devices From Isocyanate Cured Latex Rubber

- Isocyanate cured latex rubber is a specialized material used in the manufacturing of medical devices.
- It offers unique properties that make it suitable for various medical applications.

Properties of Isocyanate Cured Latex Rubber

- **Biocompatibility:** Isocyanate cured latex rubber exhibits excellent biocompatibility, making it safe for use in contact with human tissues.
- **Elasticity:** The material provides elasticity and flexibility, crucial for medical devices requiring stretchability.
- **Chemical Resistance:** Isocyanate cured latex rubber is resistant to many chemicals, ensuring durability in medical settings.

Applications of Medical Devices Made of Isocyanate Cured Latex Rubber

1. **Medical Gloves:** Isocyanate cured latex rubber is commonly used in the production of medical gloves due to its elasticity and chemical resistance.
2. **Catheters and Tubing:** The material is also utilized in catheters and tubing for its flexibility and biocompatibility.
3. **Wound Dressings:** Isocyanate cured latex rubber can be found in wound dressings for its conformability and durability.

Advantages of Using Isocyanate Cured Latex Rubber

- **Superior Biocompatibility:** Ensures minimal adverse reactions when in contact with the human body.
- **Enhanced Durability:** Offers long-lasting performance even under challenging conditions.
- **Cost-Effective Manufacturing:** The production process of isocyanate cured latex rubber devices can be efficient and cost-effective.

Emerging Technologies for Latex Rubber

- 1. Nanotechnology in Latex Rubber Production:** Nanotechnology has been increasingly integrated into latex rubber production to enhance its mechanical properties, durability, and performance. **Nanoparticles such as silica, carbon nanotubes, and graphene are being incorporated into latex rubber formulations to improve strength, elasticity, and wear resistance.**
- 2. Smart Latex Rubber Materials:** The development of smart materials in latex rubber involves **incorporating sensors or responsive components that can react to external stimuli like temperature, pressure, or pH.** These smart latex rubber materials have applications in fields such as healthcare (smart gloves for monitoring vital signs), robotics (flexible sensors), and wearable technology (smart clothing).
- 3. Bioengineering Latex Rubber Properties:** Advancements in bioengineering techniques are being applied to **modify the properties of latex rubber at a molecular level. By genetically engineering rubber-producing plants or microorganisms, researchers can tailor the composition of latex to exhibit specific characteristics such as increased strength, elongation, or chemical resistance.**



Medical Device -The Definition



"All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which **does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means**, but which may assist in its intended function by such means for one or more of the specific purposes of —

- (i) diagnosis, prevention, monitoring, **treatment or alleviation of any disease or disorder;**
- (ii) diagnosis, monitoring, **treatment, alleviation or assistance for, any injury or disability;**
- (iii) investigation, **replacement or modification or support of the anatomy or of a physiological process;**
- (iv) supporting or **sustaining life;**
- (v) **disinfection of medical devices;** and
- (vi) **control of conception"**

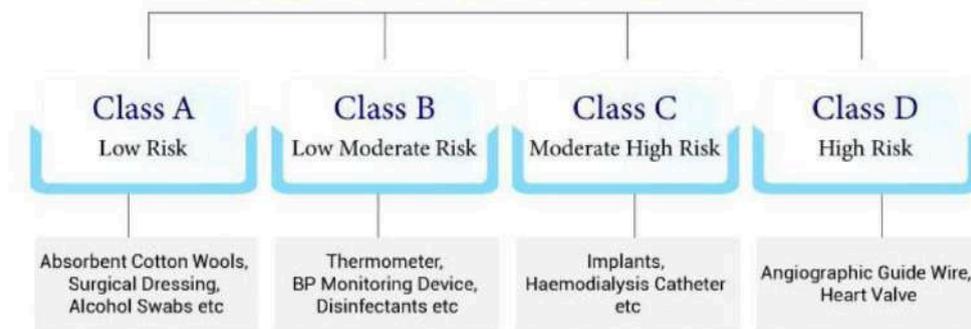
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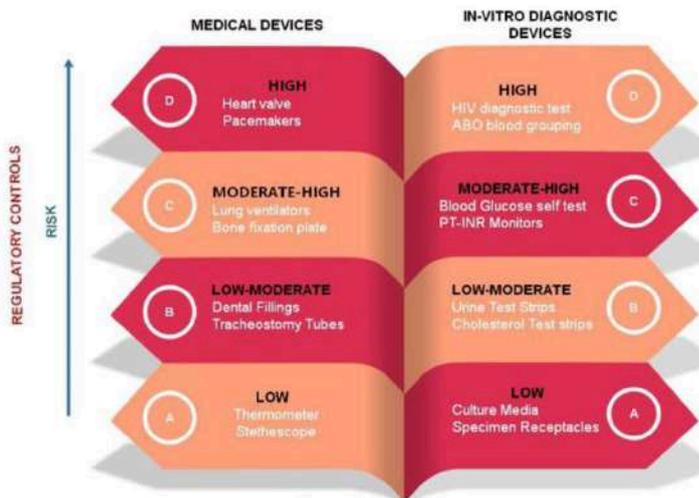
Medical Devices Risk-Based Classifications



Identify the risk Class of the Device

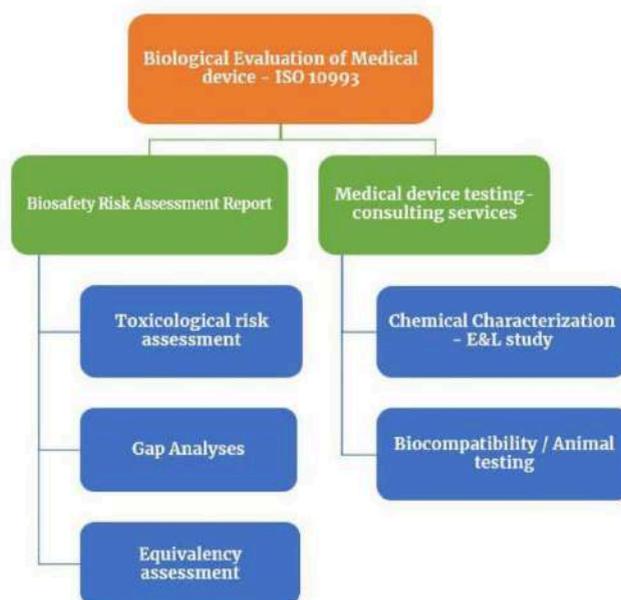
• The major factors considered for **Medical device** classification

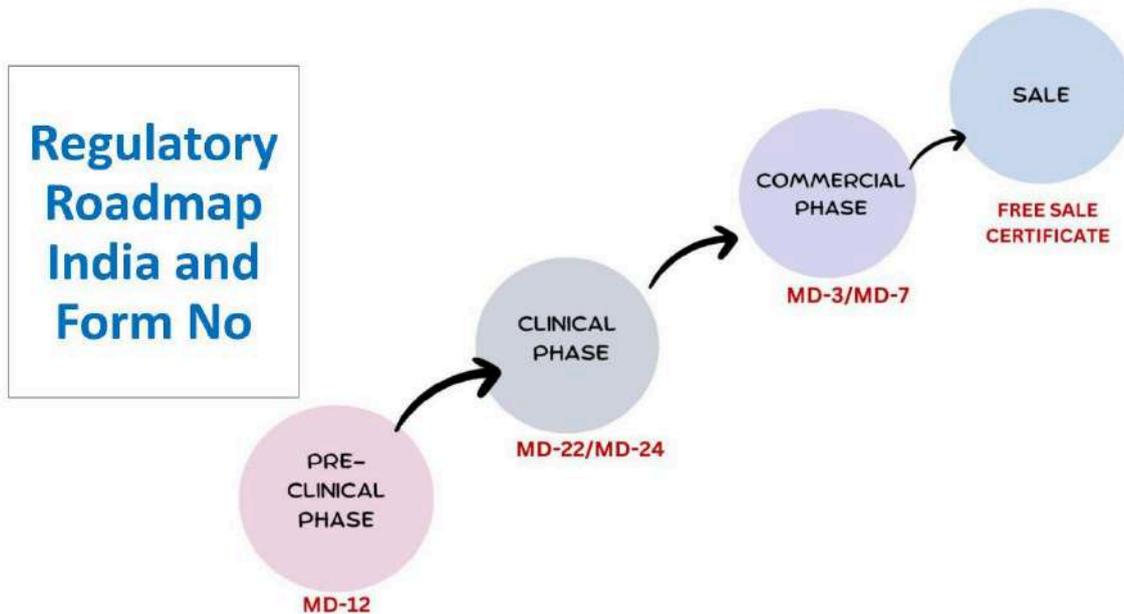
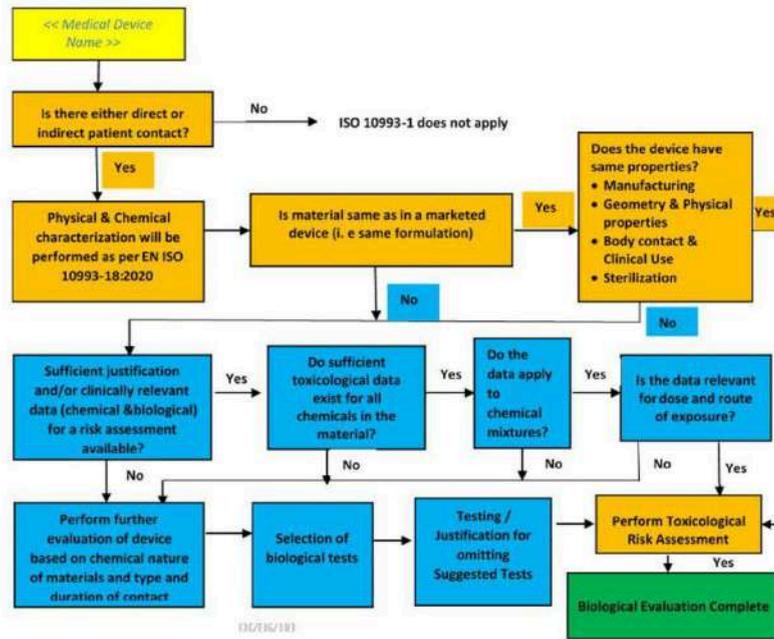
- **The duration of contact of the device** with the body
- The **degree of, and site of, invasiveness** into the body
- Whether the device **deliver medicines / energy**
- Is intended **to have a biological effect on the body**
- **Combinational device.**
- **Intended action** on the human body
- **Local versus systemic effects**
- Whether **comes into contact with injured skin.**
- **Single Use/re-use**



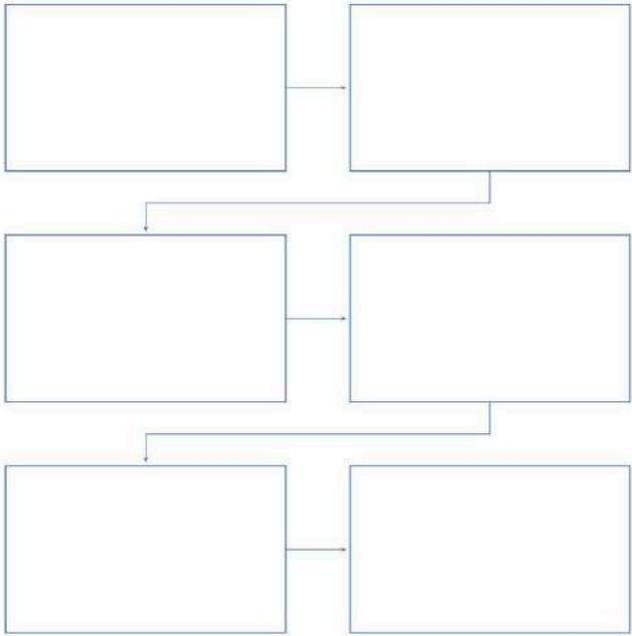
Ref: IMDR 2017, Schedule 1

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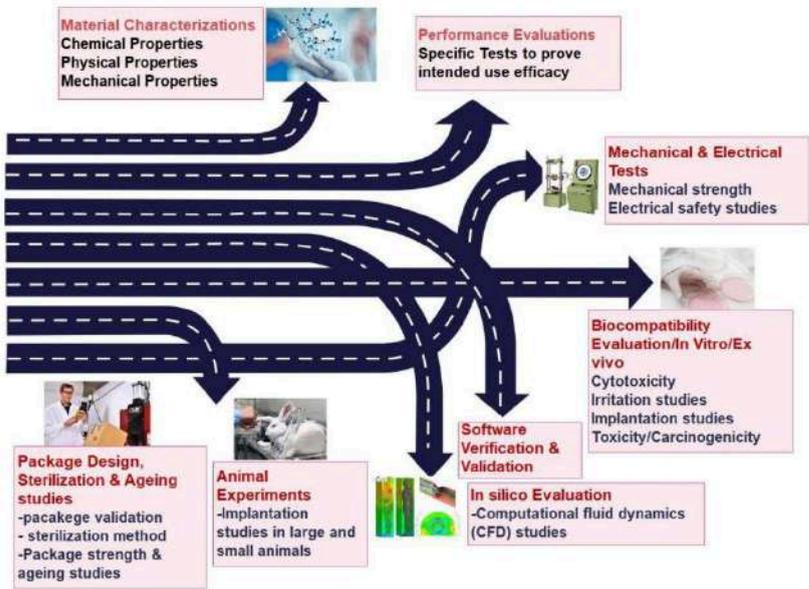


General steps to be followed



Preclinical Phase

Test Manufacturing License MD13



Minimum Pre-clinical Data for Rubber Based products

- Biocompatibility –Depends on ISO 10993 Class
- Physico-Chemical-Chemical characterization & Extractable and Leachable Studies
- Mechanical Characterization
- Degradation Studies
- Performance studies to prove Intended use
- Shelf life

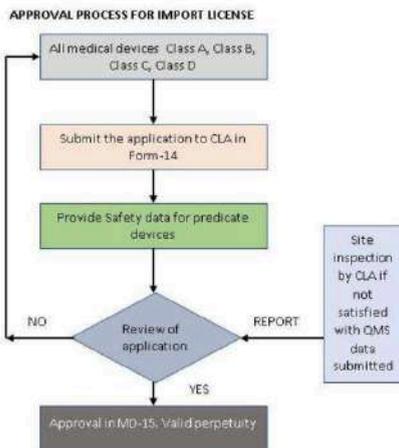
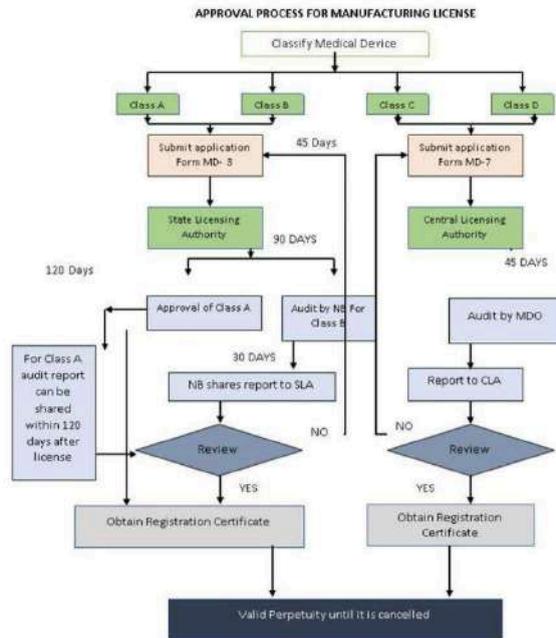
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Device Class	Class A	Class B	Class C	Class D
Activity				
IMPORT	CLA	CLA	CLA	CLA
MANUFACTURE	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
SALE	SLA			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA
*Note: Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.				

Regulatory Authorities & Duties

- State Licensing Authority (SLA)-State DCs
- Central Licensing Authority (CLA)-DCGI

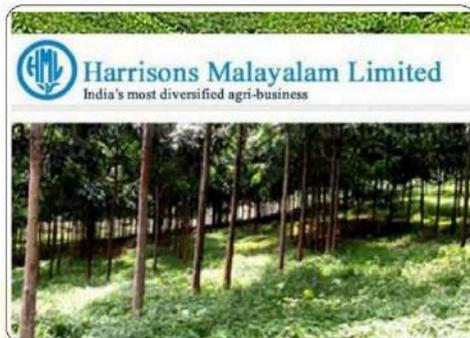
28



Mr Bijinesh, Manager, Research and Development, Harrisons Malayalam Limited



02



About Us



Harrisons Malayalam Limited (HML) is one



of the oldest and largest plantation company based in south India

25000 hectares of land under its fold –

-Tea : 15,000 hectares

-Rubber : 10,000 hectares

03



About Us

Largest Natural Rubber producer in India, 2nd largest Tea producer in south India.



Spread over 24 Estates, 5 rubber factories and 12 tea factories.

Production of about 8,000 MT Rubber, 15,000 MT Tea and 25,000 MT pineapple

04

Workforce



•Employees: The company employs over 10,000 people, including a significant number of women.

•Community Impact: HML provides housing, healthcare, and educational facilities to its employees and their families, impacting the lives of thousands of individuals.

Market Expansion

05

Domestic Growth

HML has a strong presence in the Indian market, supplying rubber and tea to various industries and consumers.

International Expansion

The company exports its products to several countries, establishing a robust international presence. HML's tea is particularly popular in markets such as the Middle East, Europe, and North America.

New Product Development

HML invests in innovation to diversify our product portfolio and meet emerging consumer trends. Collaborating with experts, we create products that offer unique and environment friendly

06






Quality Certifications: HML's products meet various national and international quality standards, ensuring high-quality output.

Sustainability Practices: The company emphasizes sustainable agricultural practices, maintaining certifications from various environmental and sustainability organizations.

Strategic Diversification

De-proteinised Centrifuged Natural rubber Latex

- De-proteinisation of natural rubber latex using proteolytic enzymes
- Contains very low amount of non-rubbers
- Very low extractable proteins and Nitrogen content.
- Developed to cater for the production of dipped articles like Health care products, Gloves, Condoms etc.



07

Nitrosamine Safe Centrifuged latex

Nitrosamines (“NAs”) are receiving special negative attention within the rubber industry because they possess high mutagenic and carcinogenic potential.

Nitrosamine safe Centrifuged latex as a significant step towards moving away from “NAs” due to safety concerns and evolved safer technology's and systems.



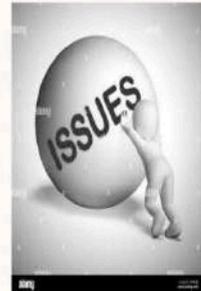
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CONCERNS

Nitrosamines has become a major concern in products coming in contact with Human Body.

□ Industries in which NAs are typically found are Rubber, Food, Metal, Leather, and chemicals.

□ Rubber products with major NA concerns are baby teats (nipples) and soothers (pacifiers), potable water components, pharmaceutical articles, condoms, carpet backing compounds and gloves.



9

Other products

Ultra Low Ammonia Centrifuged Latex

- Ammonia Content : <0.15%
- Nitrosamine safe preservative system
- Less Hazardous and Safe workplace
- Environmentally superior and green initiative

Zero Ammonia Nitrosamine Free centrifuged Latex

- Environmentally superior and green initiative
- Ammonia has been completely replaced by an alternative preservative



09

Rubber-Based Medical Devices:

- As part of its strategic diversification, HML has ventured into the production of rubber-based medical devices, expanding its product portfolio and market reach.

- This extensive size and reach position HML as a leader in the plantation industry, with significant contributions to both the economy and the communities it operates in.



10

Reasons for diversification

1. Market Potential: The global healthcare demand is increasing, leading to a growing need for high-quality, reliable rubber-based medical devices. These devices are valued for their durability, flexibility, and biocompatibility.

2. Opportunity for Growth: The expanding market presents a lucrative opportunity for the company to leverage its expertise in rubber production and enter a high-growth industry.

3. Alignment with Vision and Mission: This move supports Harrison Malayalam Limited's goals of sustainable growth and innovation, utilizing their established resources and knowledge in rubber processing to produce medical devices that meet stringent quality standards.

11



Key Partnerships and Collaborations

HML is in collaboration with Sri Chitra Medical Science, Trivandrum, & the Kerala Medical Technology Consortium.



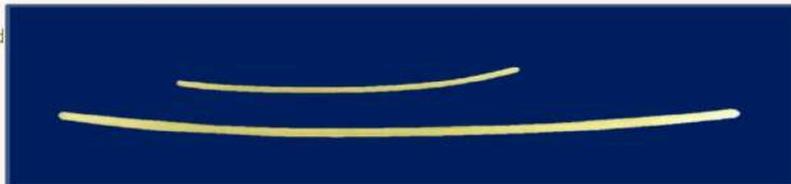
Product Portfolio

Types of rubber-based medical devices under development

1. Endoscope protective sheath for ultrasound probes

Advantages:

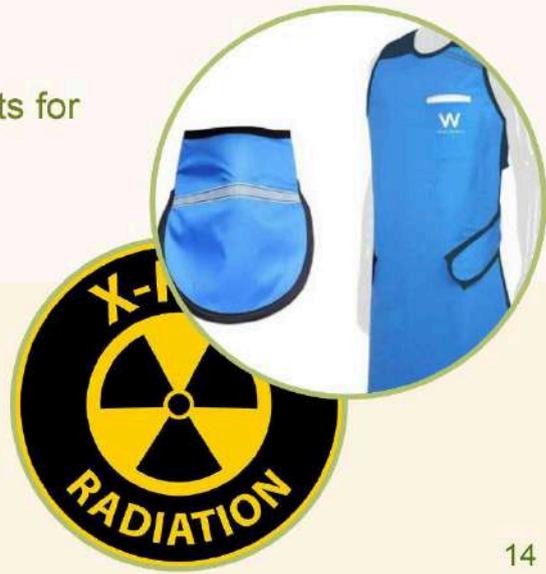
- Eliminate the risk of human immunodeficiency virus and other infectious agents, being transmitted from patients to patients
- Protection of endoscopic equipment
- Use in card





X-ray radiation protective sheets for thyroid collar

- Radiation shielding apparels are heavy and weights 3 to 7 kg'
- Thyroid apparels are heavy 0.6 Kg, worn tight around neck



14

Thank You!



Mr Toms Joseph, Senior Resource Person, Kerala Rubber Limited (KRL)



Kerala Rubber Limited

Role of Kerala Rubber Ltd (KRL) in promoting rubber based value addition in Kerala in the context of the emerging trends in rubber based industrialisation

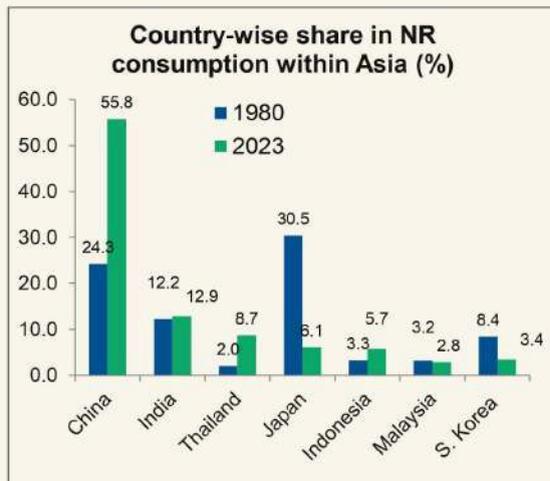
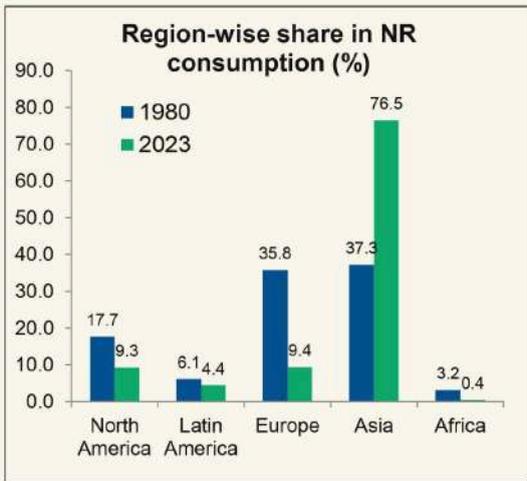
Examples of latex based products:-

Gloves, Mittens, Mitts and Aprons; Finger/Toe Cots/Stalls; Finger Caps; Foam and Mattresses; Thread and Cord; Catheters and other Medical Devices; Orthodontic Elastics, Adhesives; Band; Condoms; Nipples; Balloons and other Inflatable Articles; Toys; Other dipped products

Examples of dry rubber based products:-

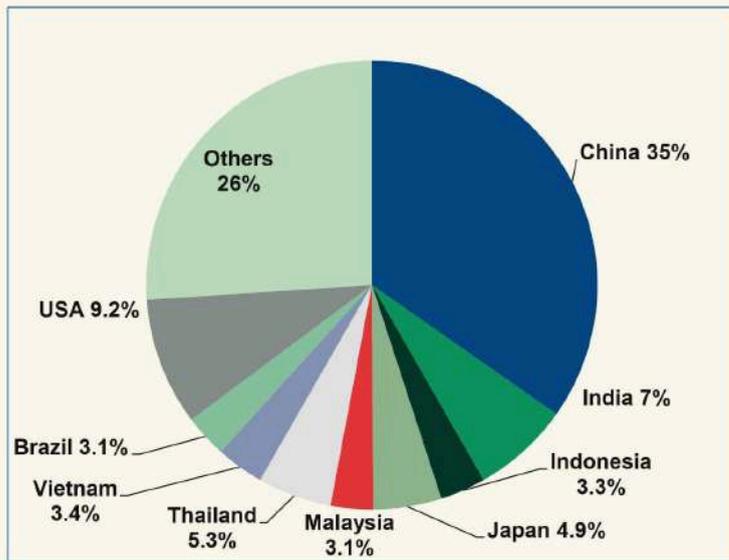
Tyres/Inner Tubes of Cycles, Cars, Trucks and other Vehicles; Aero Tyres; Tyre Flaps and other Automotive Components; Tubes, Hoses and Pipes; Retreads; Hospital Sheeting; Belts and Beltings; Plates and Sheets; Strips, Blocks, Rings, Gaskets, Rods, Plugs, Washers and Seals; Caps, Lids, Seals, Stoppers and other Closures; Rollers; Elbows, Bushes and Flanges; Blankets and Cushions; Hot Water Bags; Mats; Erasers; Footwear; Toys

❑ Annual value of output of world rubber products manufacturing industry – USD 800 Billion



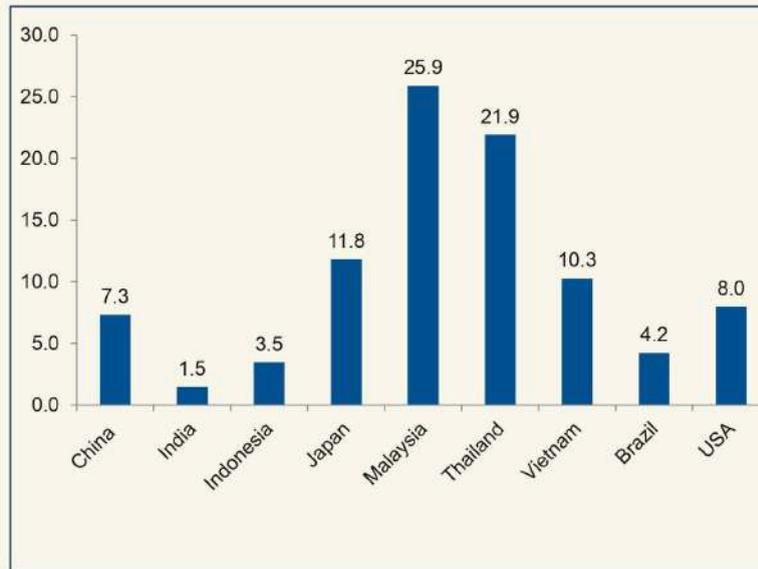
World NR consumption increased from 3.7 million tonne in 1980 to 14.3 million tonne in 2023

NR and SR Consumption in 2023 (million tonne)
 NR – 14.3
 SR – 15.4
 NR : SR Ratio
 48 : 52



Per capita
consumption
of rubber

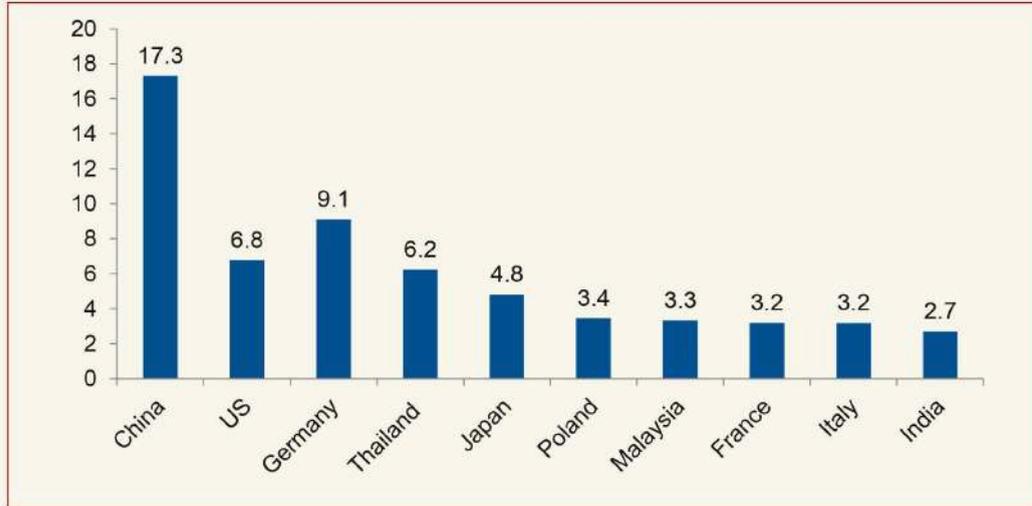
World
average : 3.7
kg per person



World export in rubber products

Product category	USD Million
New tyres, used/retreaded tyres, inner tubes etc	95296
Hygienic/pharmaceutical articles	1312
Articles of apparel and clothing accessories covering different types of gloves	10855
Tubes, pipes and hoses	11536
Plates, sheets, profile shapes etc	5050
Other rubber products	46951
Total	171000

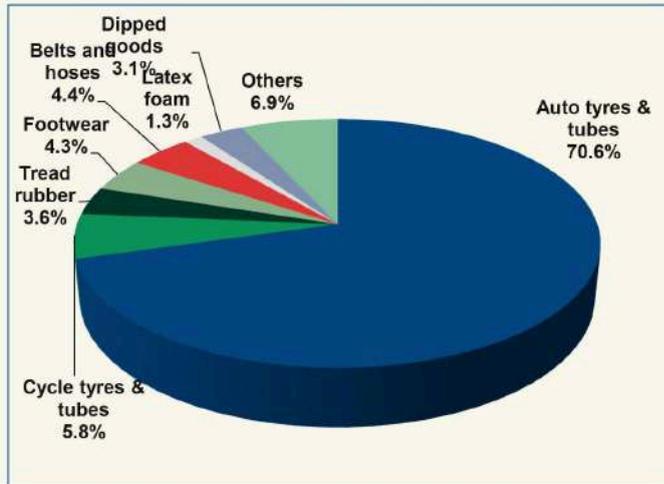
Relative shares in rubber product exports (%)



Rubber products manufacturing sector in India

NR consumption	14.16 Lakh tonne
SR consumption	7.84 lakh tonne
RR consumption	1.54 lakh tonne
Total rubber consumption	23.54 lakh tonne
NR : SR ratio	64 : 36
No of manufacturing units	4000 approx.
Value of output	Rs 132,781 Crore
Export	Rs 36,129 Crore
Import	Rs 15,300 Crore

End product wise consumption of rubber



Large and growing market

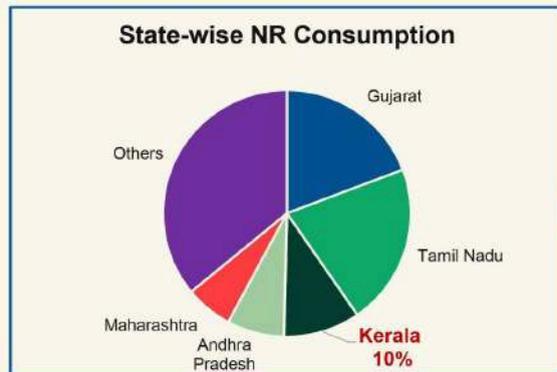
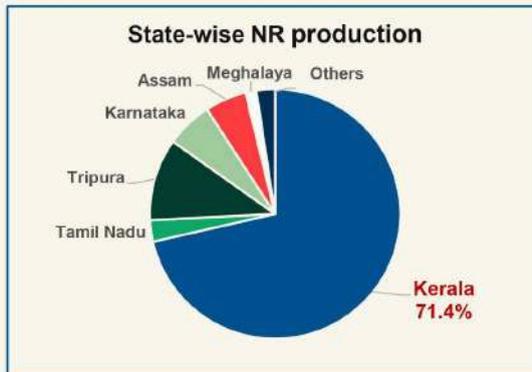
- 144 Crore population
- Fifth-largest economy with a GDP of USD 3.95 trillion
- USD 650 billion foreign exchange reserves
- Large and growing domestic market approx. Rs 111,952 Crore

Rubber products manufacturing sector in Kerala

NR consumption	141500 tonne
SR consumption	65000 tonne
RR consumption	18500 tonne
Total rubber consumption	225000 tonne
No of units	Around 700

- ❑ Kottayam district accounts for 42.1% of NR consuming units followed Ernakulam (17.8%), Thrissur (12.5%), and Alappuzha (7.4%).
- ❑ Around 40% of the units have licensed capacity below 25 tonne/year.
- ❑ Only around 8% of the units have licensed capacity above 500 tonne.
- ❑ Dry rubber products account for around 95% of the licensed capacity.

Context



- ❖ Kerala Rubber Ltd incorporated in June 2019 by Government of Kerala
- ❖ A dedicated agency to promote rubber based value addition in the State

Vision

Develop world-class infrastructure to promote value addition in natural rubber through public-private investment in the sector, thereby creating a stable market for natural rubber, ensuring consistent returns to natural rubber growers, and contributing to the state's economic development

Mission

- ✓ Promotion of NR based industrialisation in Kerala with initial focus on MSME sector.
- ✓ Develop seamless linkages with NR growers' groups, co-operatives, producer companies etc.
- ✓ Promote public-private partnerships and generate employment through creation of direct and indirect job opportunities.
- ✓ Serve as an umbrella organisation providing services to NR based and allied industries in the state.
- ✓ Act as a link between existing NR industry promotion agencies at the state and national level and with entrepreneurs/investors

Business Model

- ✓ KRL is in the process of setting up a Rubber Industrial Complex to promote investment and common facilities for NR based industries.
 - Services from common facilities available for units within/outside the Complex.
 - Land developed will be allotted to prospective entrepreneurs.
- ✓ In KRL
 - Shareholding by government and private investors
- ✓ Industrial Complex
 - 100% investment by entrepreneurs
 - Major share holding by entrepreneurs and minor shareholding by Government of Kerala/organisations

Strategies and Initiatives

- ❖ Research & Development
- ❖ Technical Consultancy
- ❖ Testing Facilities
- ❖ Training and Skill Development
- ❖ Product/ Process Innovation



- Research and Development Centre
- Testing and Quality Control Centre
- Business Incubation Centre
- Training and Information Centre

- ❖ Marketing & Export Assistance



- Rubber Products Exhibition Centre
- Databank on market and export information

Strategies and Initiatives

❖ Common Facilities



- Raw material Bank and Warehouses for raw materials and products
- Common Effluent Treatment Plant (CETP)
- Engineering assistance and tool room facility
- Rubber Products Sterilisation Centre

❖ Service cum income sources



- Tyre Testing and Research Centre
- Rubber Products Recycling Centre

Single Window Clearances and Approvals



Project to be completed in two phases

- ✓ Phase I - 62.5 Acres
- ✓ Phase II - 100 acres

Project cost – Rs. 253.56 crores

Thank you

Contact Us



admin.krl@kerala.gov.in



9633444645



krl.kerala.gov.in

Dr Siby Varghese, Former Joint Director, Rubber Research Institute of India (RRII), Rubber Board

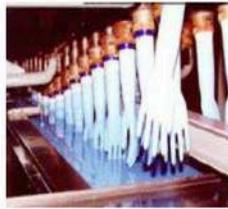


Rubber: An Important Constituent of Medical Devices & Related Applications

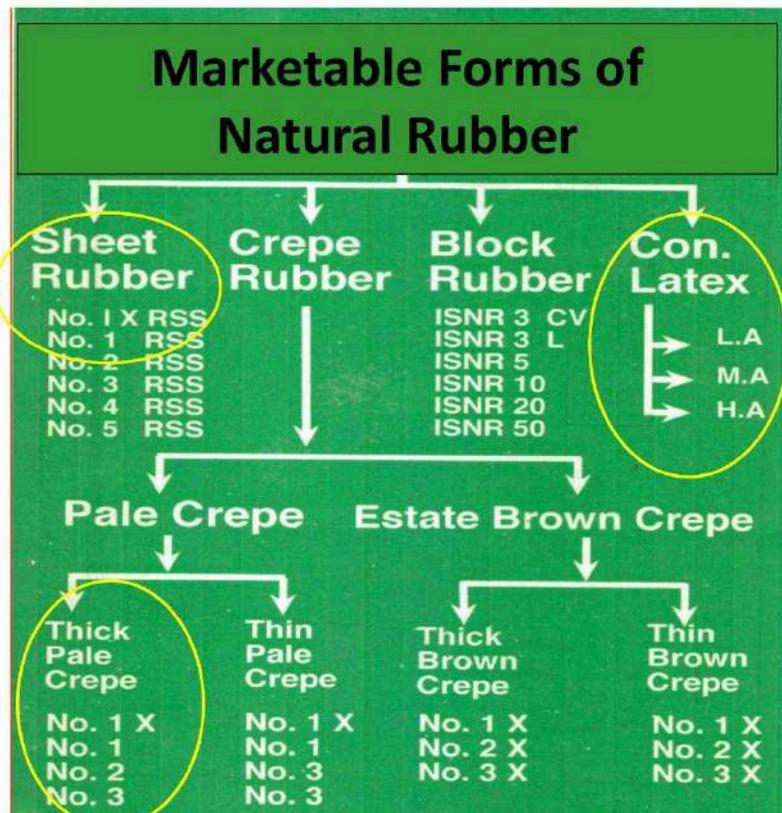
Dr.Siby Varghese
Resource Person
Kerala Rubber Limited

Types of rubber used in making medical products

- Natural Rubber
- Butadiene Rubber (BR)
- Butyl Rubber (IIR)
- Ethylene Propylene Diene Monomer (EPM, EPDM)
- Fluoroelastomers (FKM)/Viton
- Isoprene Rubber (IR)
- Nitrile Rubber (NBR)
- Silicone Rubber (SiR)
- Styrene Butadiene Rubber



Latex Based Products

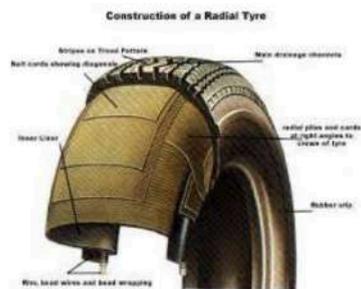


Latex Based Industries

- Less capital requirement
 - Lower power consumption
 - Simple technology (Easy to shape)
 - Reasonable marketability.
 - Regional advantage
-

Higher value addition

Dry rubber product



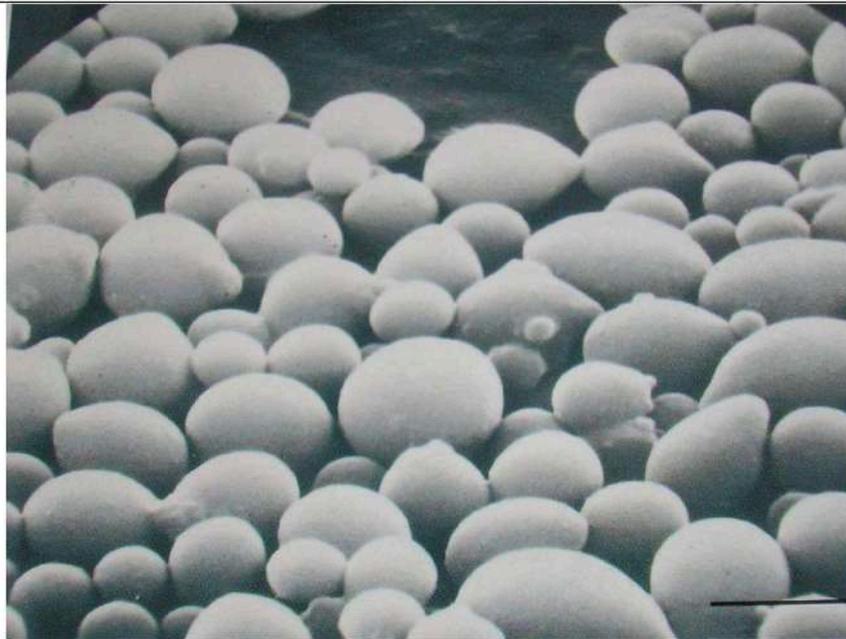
Value addition 9 times

Latex rubber product

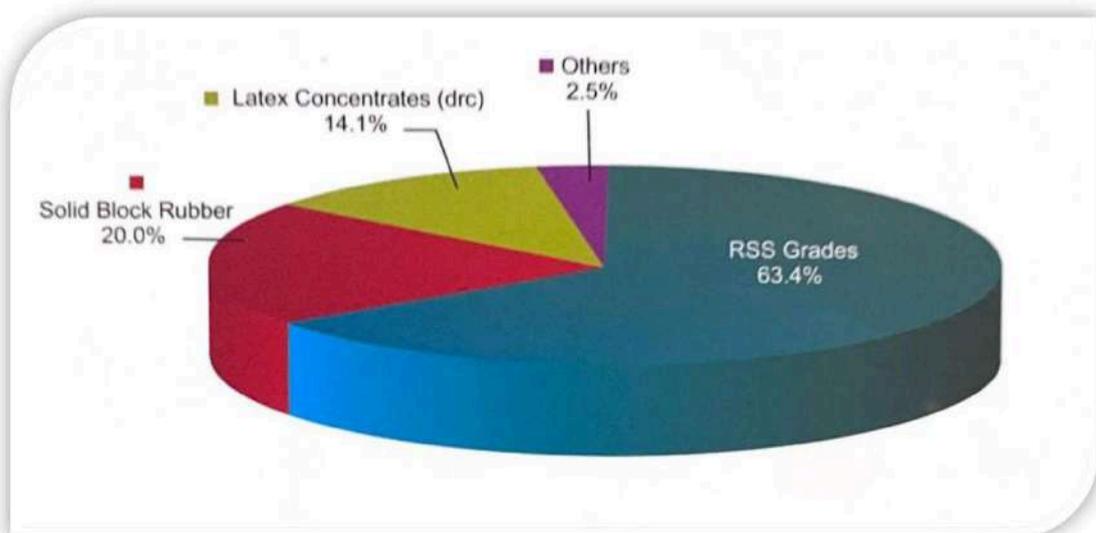


Value addition 40 times

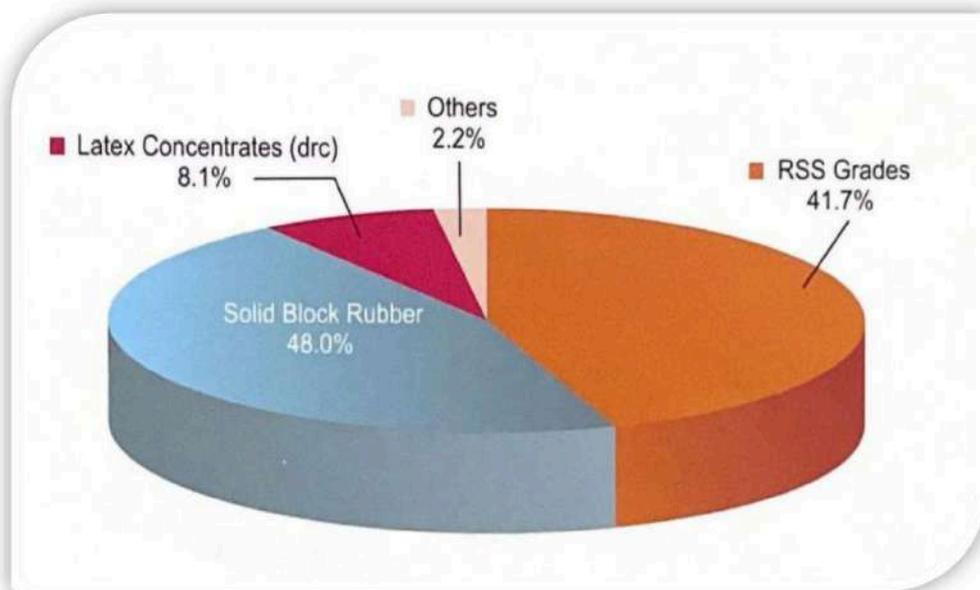
Rubber Particles in NR latex



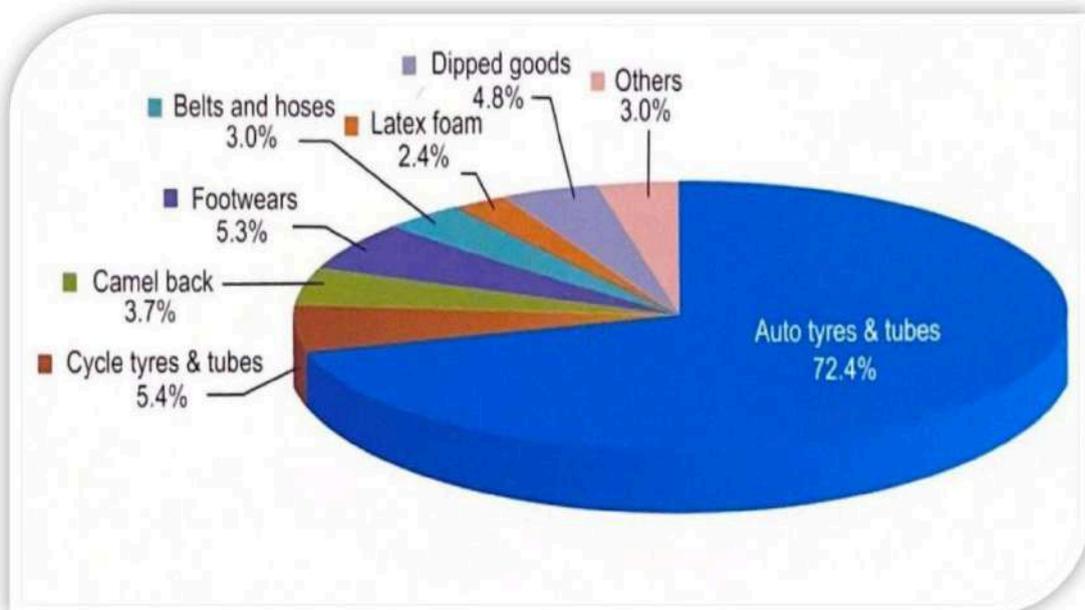
Production of Different Forms of Natural Rubber 2021-22



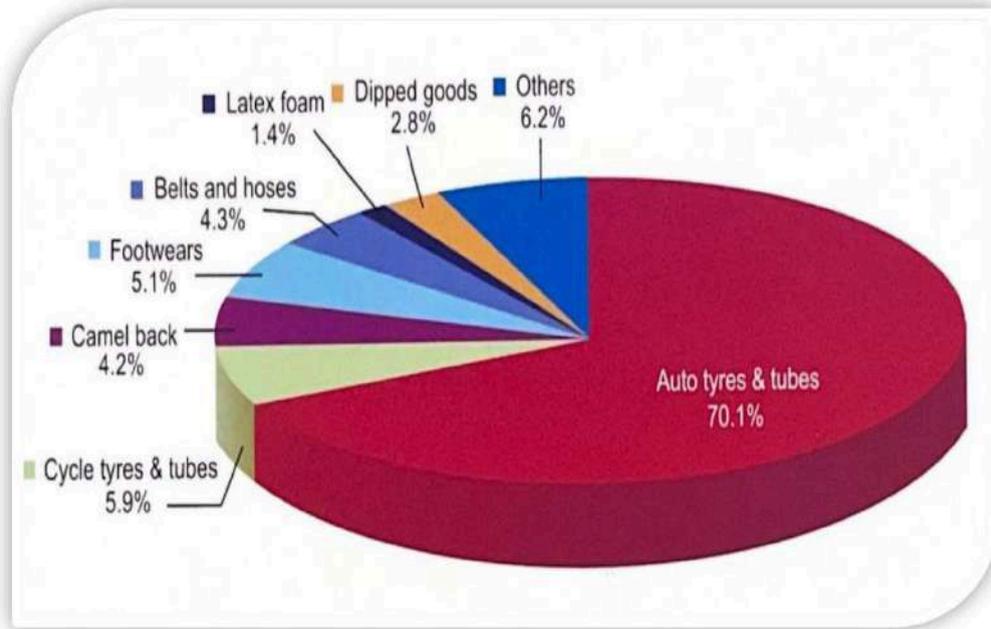
Consumption of Different Forms of Natural Rubber 2021-22



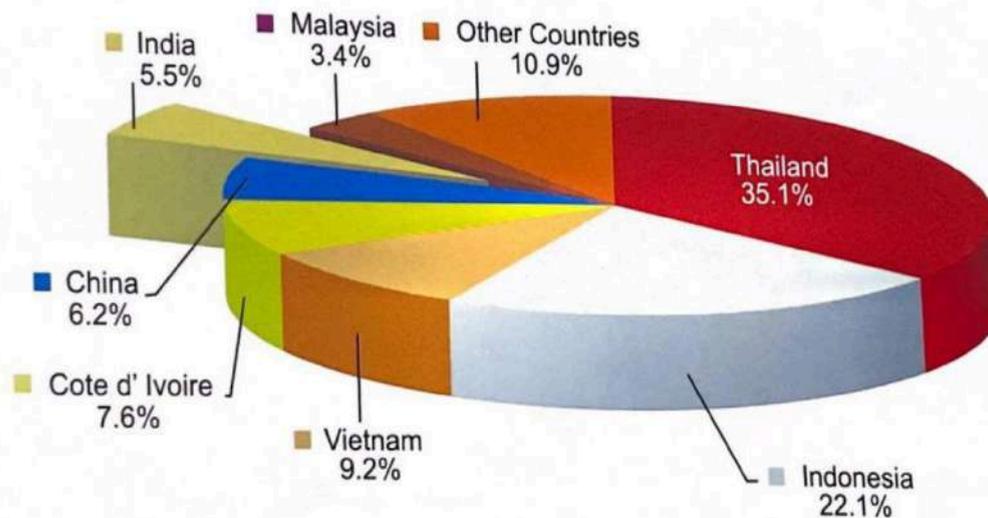
Consumption of Natural Rubber According to End Products 2021-22



Consumption of All kinds of Rubber According to End Products 2021-22

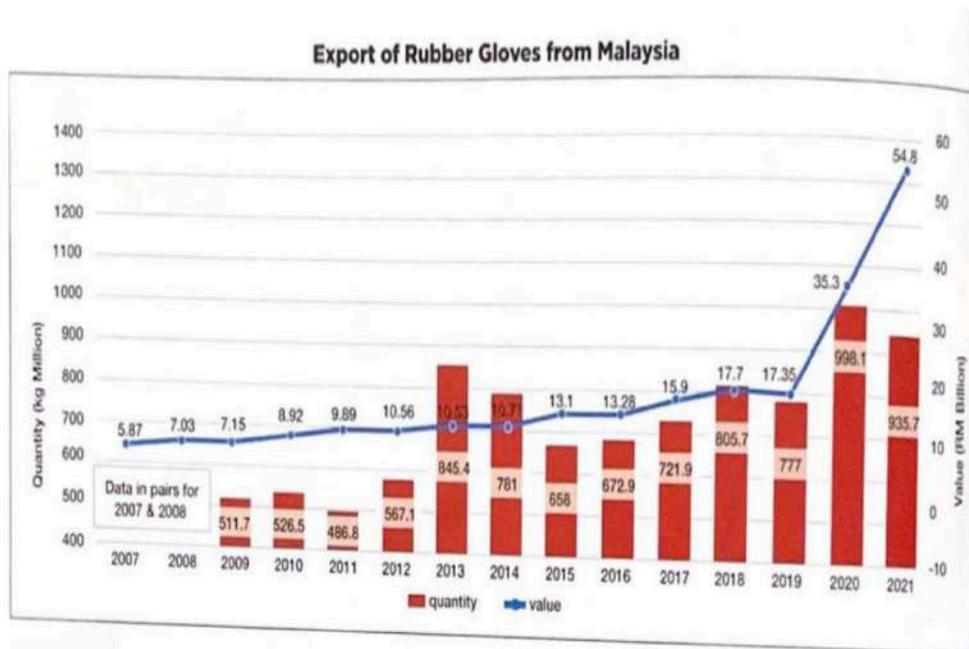


SHARE OF MAJOR PRODUCING COUNTRIES IN WORLD PRODUCTION OF NR - 2021

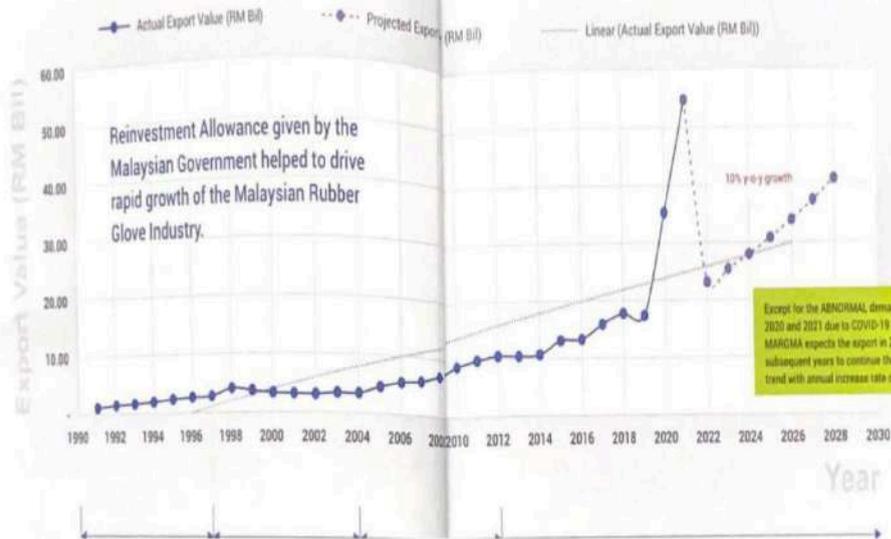


Ever Increasing Applications of Natural Rubber Gloves

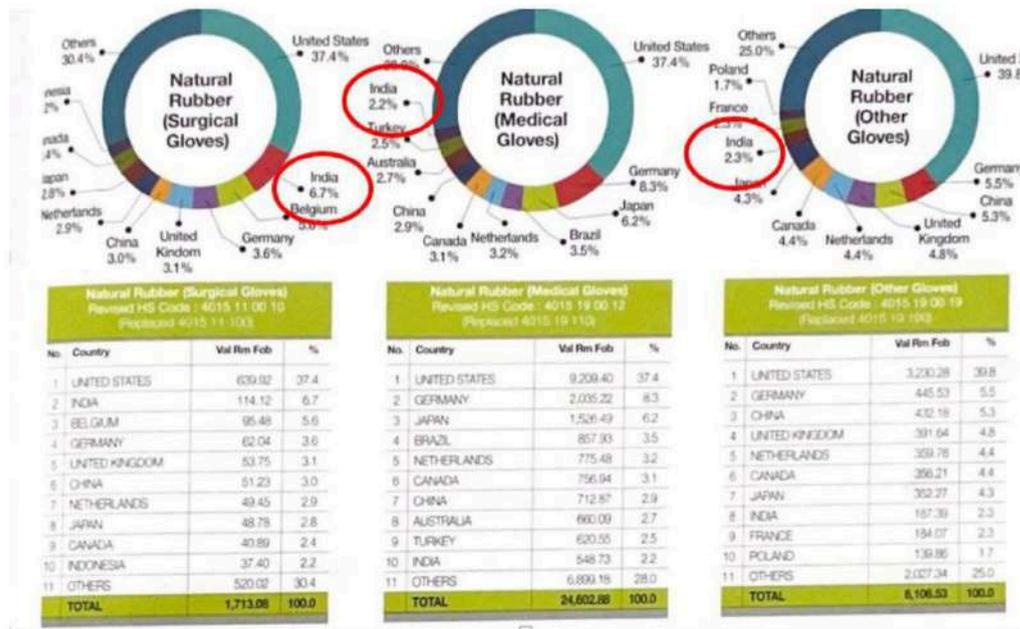
Estimated global demand	399,000,000,000
	399 billion gloves
Usage every second	12,622
Malaysian production	259 billion
Estimated growth	10-12%
Indian production	> 2 %



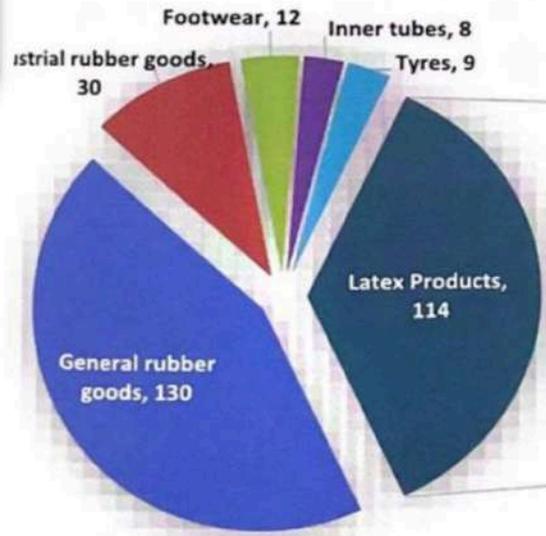
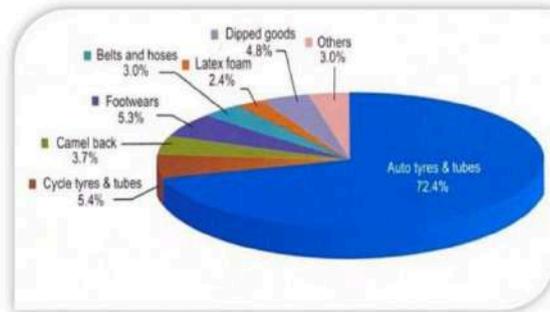
STATISTICS Rubber Gloves Export from Malaysia (1991 to 2028)



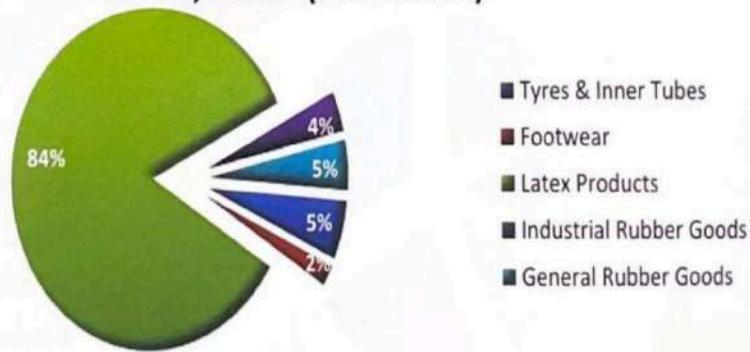
Top ten destinations of Malaysian Glove Export



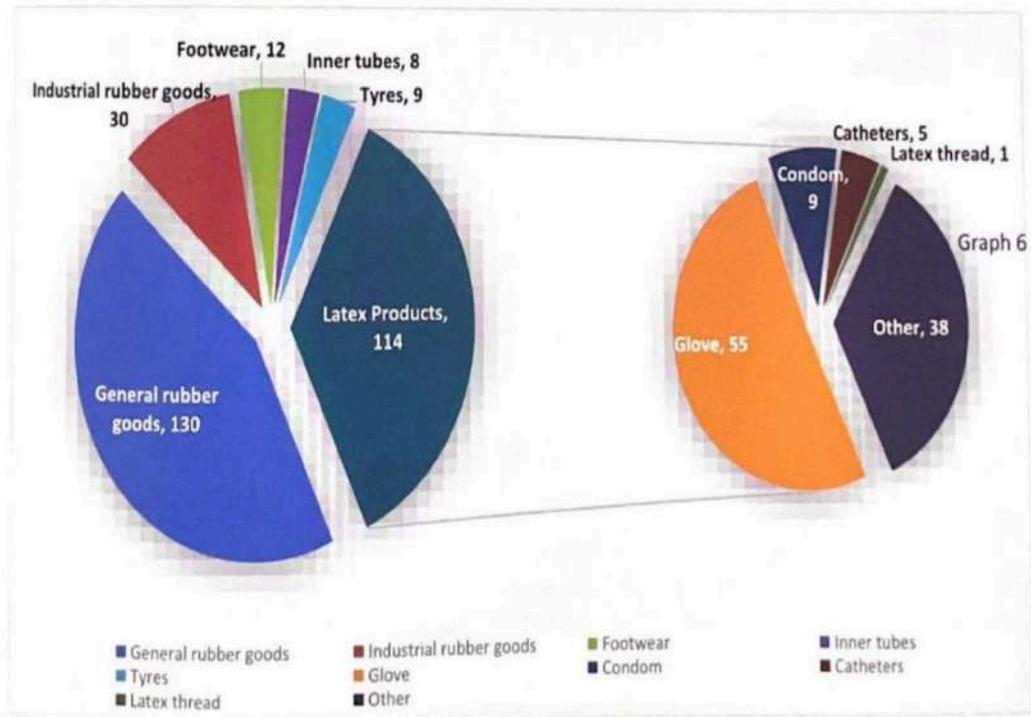
Consumption of Natural Rubber According to End Products 2021-22



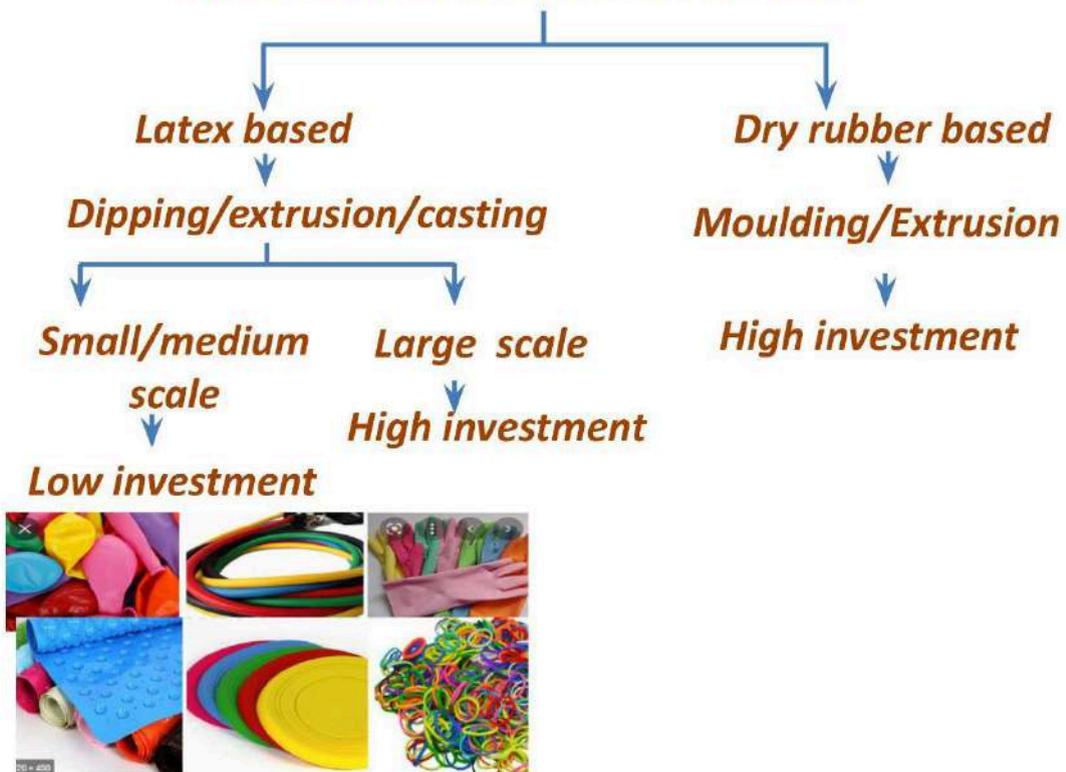
Malaysia's Export of Rubber Products by Product Sector, 2020* (RM Million)



Total : RM 6,225.87 Million



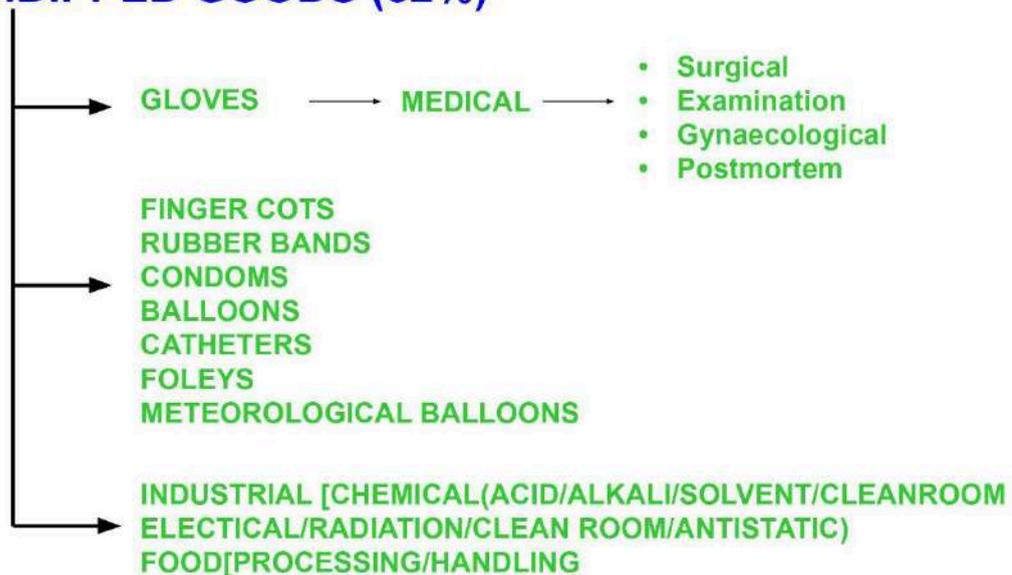
Value Addition of Natural Rubber



LATEX PRODUCTS GROUPS ACCORDING TO PROCESS OF MANUFACTURE

1 DIPPED GOODS	- 52 %
2 EXTRUDED GOODS	-11 %
3 LATEX FOAM PRODUCTS	- 6 %
4 SPREADS AND BACKINGS	-10 %
5 CAST PRODUCTS	- 4 %
6 ADHESIVES	-7 %
7 OTHERS –SHEETINGS/LININGS	-3 %

1.DIPPED GOODS (52%)



Types of gloves – 80 grades

- Chemotherapy Gloves
- Cleanroom Gloves
- Examination Gloves (Natural Rubber)/Latex Gloves
- Examination Gloves (Nitrile)/Nitrile Gloves
- Surgical gloves (Natural)
- Surgical Gloves (Synthetic)
- Gynaecology Gloves
- High Risk Gloves
- Radiation Gloves
- Sterile Gloves

LATEX PRODUCTION TECHNOLOGIES

Surgical gloves

- Suitable for all medical and surgical use
- Sterile
- Gamma irradiation and gassing ethylene oxide
- Usually 290mm long



- ASTM D3577
- MS 1291
- EN 455-1
- ISO 10282
- EN 455-2

Characteristics

- Thickness
- Coating
- Powder Free Or Powdered
- High Or Low Protein
- Textured Or Smooth
- Beaded Or Beadless

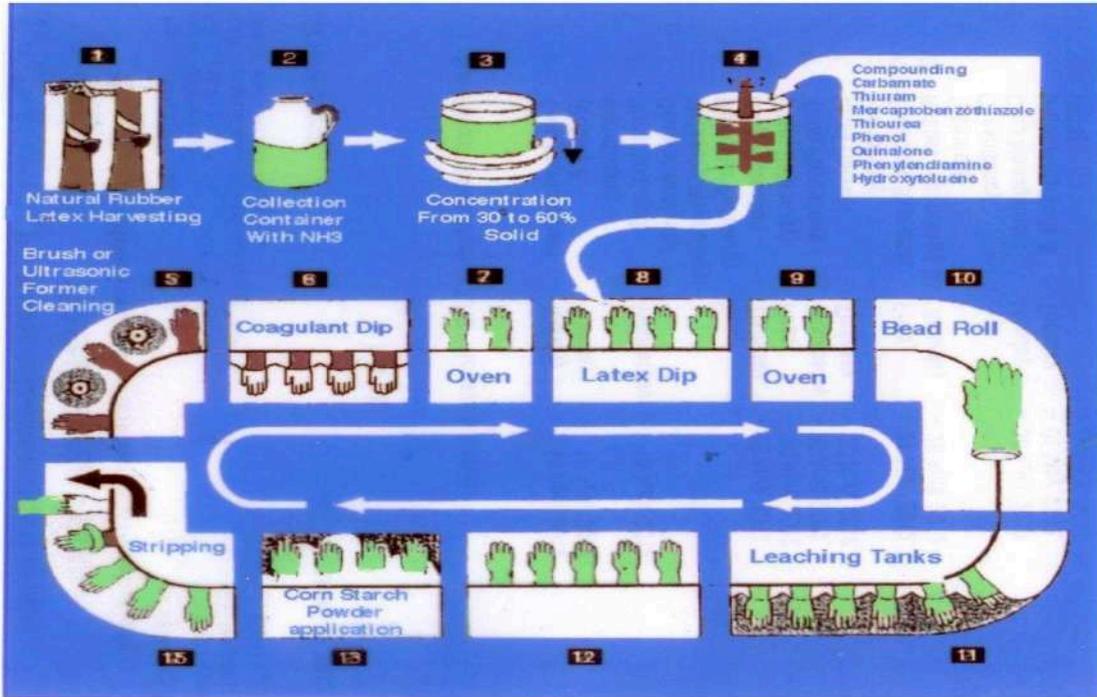


Differentiate them in performance, functionality, and cost in meeting individual needs and requirements.

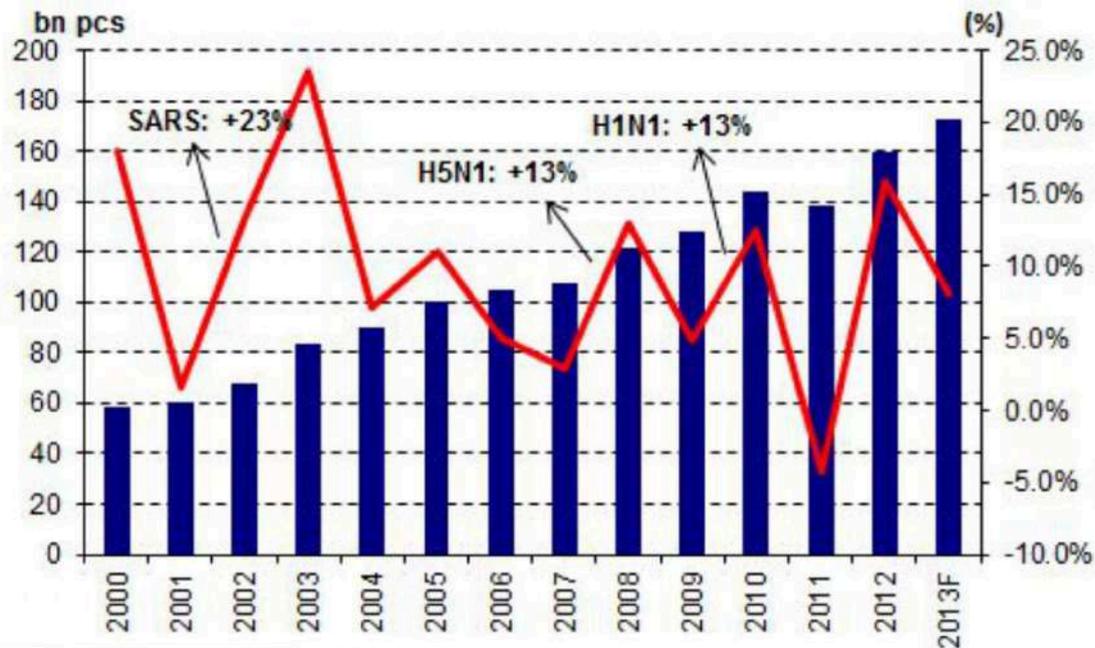
General packing specification :

- A Pair of L/R per wallet/pouch
- 60 Pouch/Dispenser
- 6 Dispensers/Carton
- 527 Carton/20' Container Load





Global demand (LHS) and growth (RHS)



PRODUCTION TECHNOLOGIES

EXAMINATION GLOVE

- ASTM D3578
- ASTM D5151
- ASTM D5250
- ASTM D6319
- SMG 2ND EDITION
- AS/NZS 4011
- ISO 11193-1
- EN 455 PART 1 AND 2

EXAMINATION GLOVES

- Suitable for all medical and non-medical applications.
- They are ambidextrous, i.e. they fit on either left or right hand when wearing
- Usually 240mm long

Characteristics

- Color
- Thickness
- Coating
- Powder Free Or Powdered
- High or Low Protein
- Textured Or Smooth
- Beaded Or Beadless

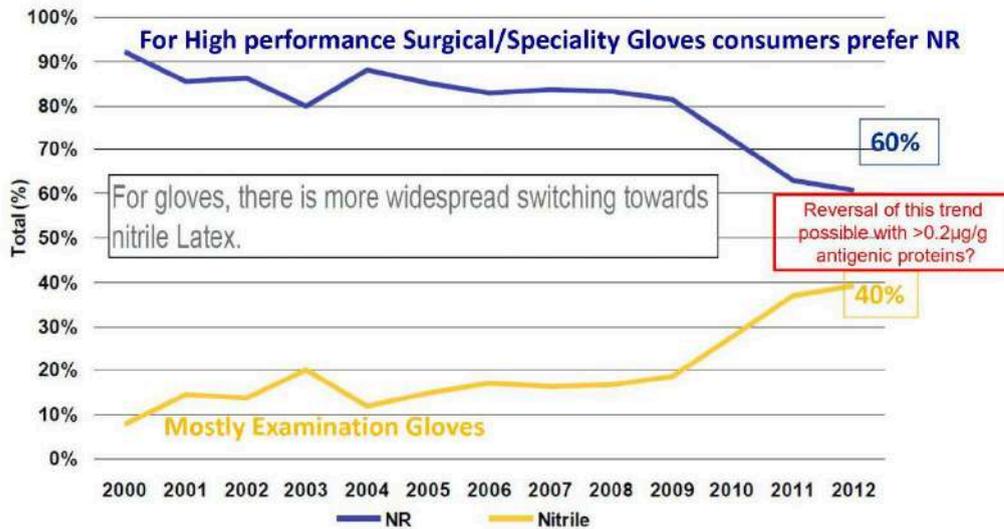


Performance, functionality, and cost in meeting individual needs & requirements

GENERAL PACKING SPECIFICATION :

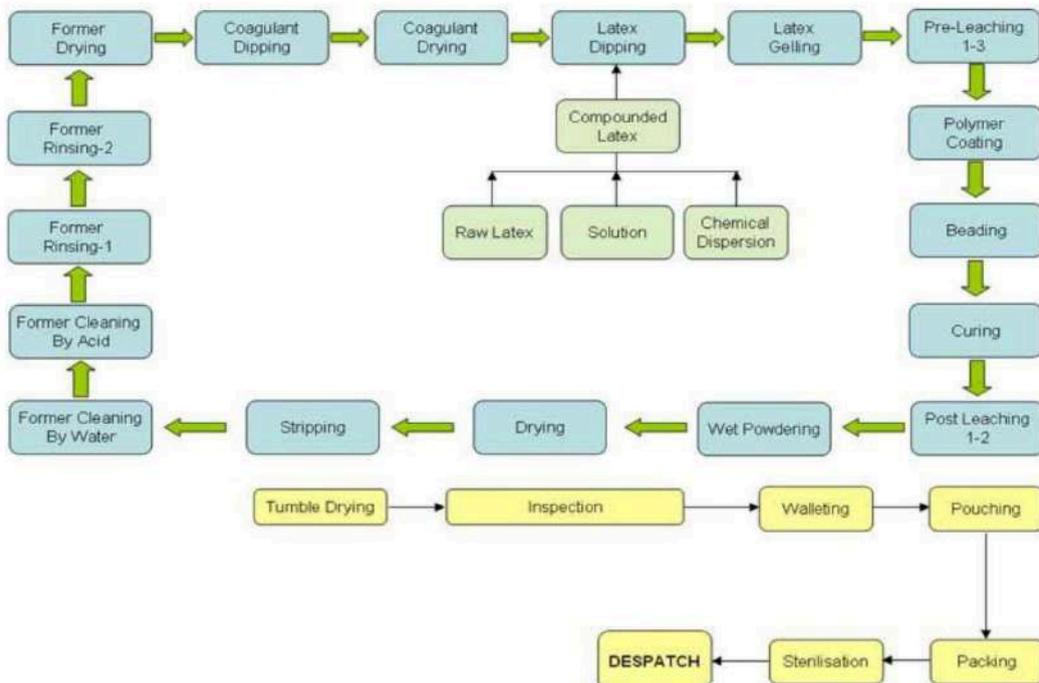
- 100 Gloves To A Dispenser Box
- 10 Dispenser Boxes to a Carton

IMPACT OF THE PROTEIN ALLERGY ISSUE ON THE USE OF NATURAL RUBBER GLOVES
NITRILE ENCROACHES INTO THE NR GLOVES MARKET



2
9

Flow-chart of latex gloves



PRODUCTION TECHNOLOGIES

HOUSEHOLD GLOVES

- Re-useable gloves suitable for household, gardening and janitorial applications.
- They are usually hand specific
- Usually 290mm long

Characteristics

- Color
- Thickness,
- Coating
- Flocked Or Unflocked
- Supported
- High Or Low Protein
- Textured Or Smooth And Type Of Texture
- Beaded Or Beadless

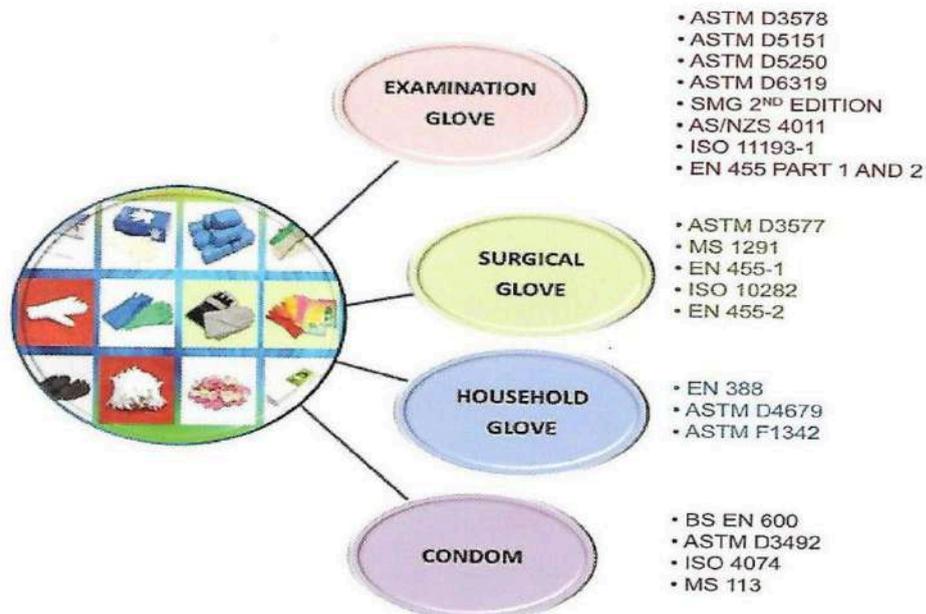


- EN 388
- ASTM D4679
- ASTM F1342

Differentiate them in performance, functionality, and cost in meeting individual needs and requirements

GENERAL PACKING SPECIFICATION

- 12 Pe Polybag/Master Polybag
- 12 Master Polybag/Carton
- 980 Ctn /20' Container Load



PRODUCTION TECHNOLOGIES

CLEAN ROOM GLOVES

These gloves are processed and specially washed and packed in clean environments to ensure low traces of chemical extractable content. Industries where clean room operations are common include

- Semi-conductor industry,
- Wafer fabs,
- Pharmaceutical labs
- High technology biotech labs.

They may also be sterile.

Usually 300mm long,

Characteristics

Thickness

Textured Or Smooth

Beaded Or Beadless

GENERAL PACKING SPECIFICATION

100 Gloves In A Polythene Bag/Double Bagged

10 Polythene Bags To A Carton

Comparison of glove cleanliness of various types of glove finishes

▪ Powdered glove	:18,000 to 28,000
▪ Powderfree On line chlorinated	:9,000 to 15,000
▪ Powderfree polymercoated	: 7,000 to 13,000
▪ Powderfree double chlorinated	: 5,000 to 7,000
▪ Cleanroom ISO Class 8	: < 3,800
▪ Cleanroom ISO Class 4	: < 1,200

WHY USE CLEANROOM GLOVES?

- Contamination control in electronic industry
- Prevention of circuit disasters
- Ensure internal medicines/vaccines are free from contaminants.
- To ensure print free surfaces
- Unblemished metal finishings
- To mitigate Type IV allergy

Various types of rubbers are widely used in the manufacture of different types of IV sets

Due to their unique physical and chemical properties



Natural rubber
Silicone rubber
Isoprene rubber



Durability.
Flexibility and elasticity
Spontaneous resealing of punctures
Chemical resistance
Protective barrier

Latex products in medical applications



Baby products

- Natural rubber latex products have an yellow colour
- Natural rubber film is hygroscopic and loses its transparency on water leaching/boiling



Suggestions

- Remove the non-rubbers from the NR latex
- Use of sub micron dispersions
- Low ammonia/no ammonia preservation
- Addition of water soluble polymers



Anaesthesia breathing bags



- NR latex or from synthetic latex material in compliance with ISO regulations
- Breathing bags are available either as disposable or reusable
- Anaesthesia machinery and breathing circuit markets

Static electricity in such bags needs to be addressed

- Conductive carbon black
- Addition of graphene

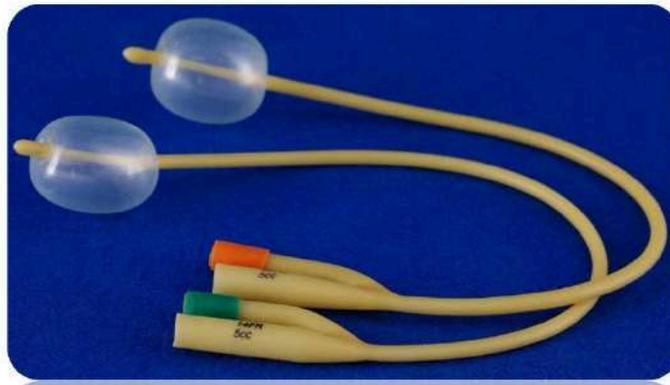
Foley Catheter

A Foley catheter is a flexible tube having two separated channels running down its length.

One channel is open at both ends and allow urine to drain out into a collection bag. T

The other Channel has a valve on the outside end and connects to a balloon at the tip.

The balloon is inflated with sterile water when it lies inside the bladder in order to stop it from slipping out.



P. 39

Urine drainage condoms

- Urine drainage condoms: For bedridden male patients.
- Condom with a tube that is connected to a urinary drainage bag.



Sheetings



REVERTEX (MALAYSIA) SDN BHD

NR Latex Foam

- Soft to touch.
- Open cell structure.
- High resilience.
- Good load bearing characteristic.
- Good fatigue resistance.
- Can be moulded into shapes.

Footweares for diabetic leprosy patients

- Work completed:
- Developed the sole as per specifications
- Successfully completed the trials at CMC Vellore

Specifications

No	Specification parameter	Specified value	Actual
1	Split tear strength	2-3	2.5
2	Compression set, %	< 20	10
3	Hardness, Shore A	< 20	14
4	Material	100 % NR	100 % NR
5	Relative Density, g/cc	-	0.406
6	Cost, Rs	Rs.20/pair	Rs.14/pair



Status : Completed, commercial production started

M/s. Pran Medisystems

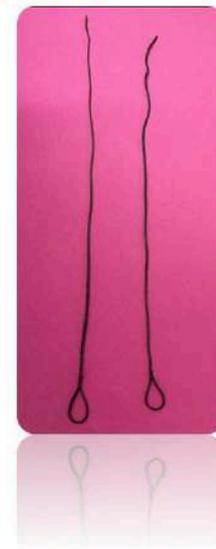
Vessel loops : Flagging the nerves, artery and vein during surgery

□ Work completed

- Designed the prototype of the product
- Hospital trails are progressing

□ Action plan

- Get the feedback & Completed the work
- Bulk production to be initiated





Rubber Caps/Tabs for Medical use:

Rubber Tubes for Infusion and Transfusion Set:

Birth Control Products:

Surgical Gloves

Rubber Medical Masks

Rubber Catheters

Rubber Bulb Syringe

Rubber bladders

Rubber Caps/Tabs for Medical use:

- Rubber caps are specially designed for medical purposes. These are caps on T-piece as the main adjunct which provides pass and injection port for infusion and transfusion sets. They are made of natural rubber and polychloroprene rubber.
- **Xray Penrose tubings:** Which helps to identify any implants in human body which is wrapped in pen rose tubings while taking Xray photographs.



Innovations

- No ammonia preservation
- Sulphur free crosslinking
- Highly transparent NR latex products
- Polar NR latex
- Grafted latex



Highlights

Natural rubber based medical products have good future:

- European Union Deforestation Regulation- EUDR
- Products complying to REACH regulations
- Urge for natural products and sustainability
- Global warming protocols

Kerala Rubber Limited can extend all possible technical support to the investors

Thanks

Dr Abi Santhosh Aprem, Associate Vice President, Technical and Operations,
HLL Lifecare Limited



INNOVATION IN LATEX TECHNOLOGY AND PRODUCTS



Abi Santhosh Aprem, Ph.D
General Manager (R&D)
HLL Lifecare Ltd



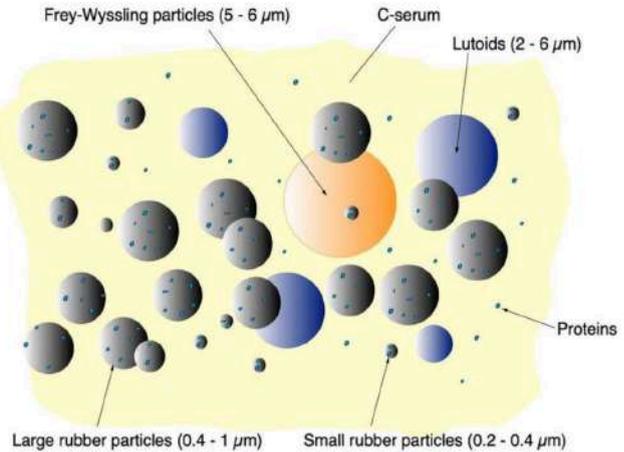
Natural Rubber Latex

- What is natural rubber latex?
 - a stable colloidal dispersion of natural rubber (cis-1,4 poly isoprene) particles in an aqueous medium
 - Think of milk; milk is a stable colloidal dispersion of fat particles in an aqueous medium



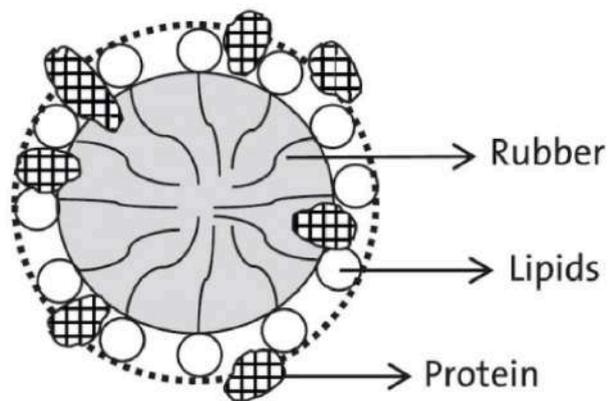
Natural Rubber Latex

- The rubber exists as small, generally spherical particles surrounded by a protective shell of surfactants, proteins etc.
- The size is typically around $1\ \mu\text{m}$ ($0.001\ \text{mm}$)



The NR latex particle

- The non-rubbers on the surface of the latex particle are typically phospholipids and proteins.
- It is believed that the phospholipids are closely associated with the rubber particle surface and bind the proteins to the particle
- Carboxylic anions derived from hydrolyzed proteins give the particle a negative electric charge.

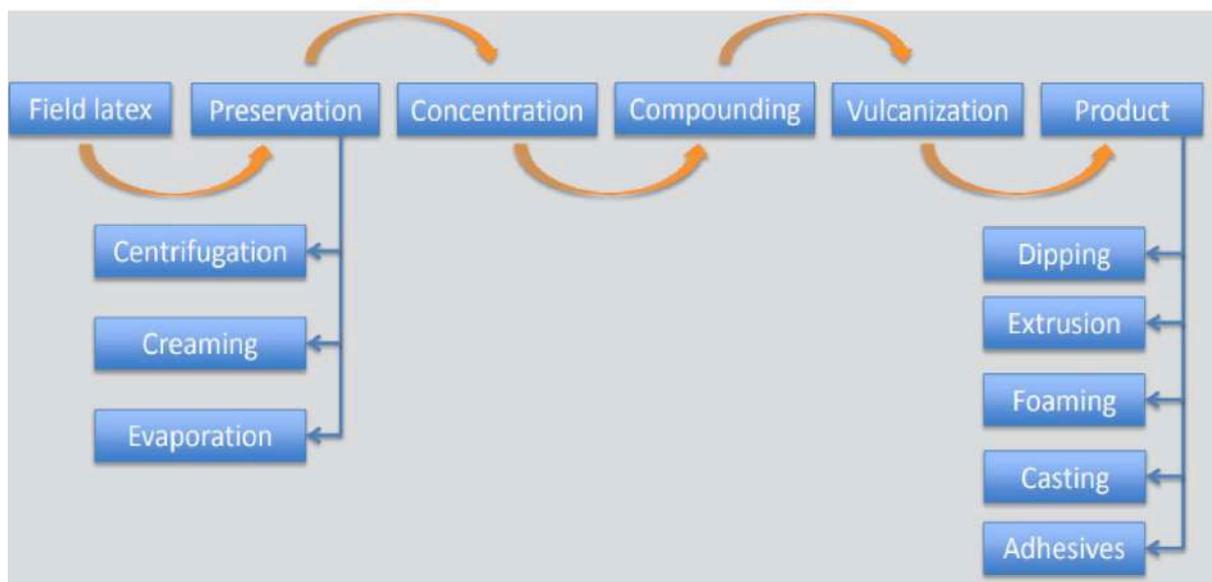


Biosynthesis of NR

- Natural rubber latex is produced by a complex and multistep biological synthesis
- Carbohydrates are converted by many steps to a complex of acetate ion with a co-enzyme
- Further reactions of the acetate/co-enzyme complex with acetate ions gives a 3-hydroxy-3-methyl-glutaryl complex
- This complex leads to the formation of mevalonic acid and then isopentenyl pyrophosphate.
- Polyisoprene is formed by the condensation polymerization of the isopentenyl pyrophosphate.



From Latex to Products





Products from latex concentrate

Dipped Goods	Gloves, condoms, balloons, catheters
Foam Products	Mattresses, seating, pillow
Extruded products	Latex Thread
Other Products	Adhesives, carpet backing Toys



NATURAL RUBBER IN HEALTHCARE

Hospital Rubber Products



<ol style="list-style-type: none"> 1. Surgical and exam gloves 2. Catheters and other tubing 3. Blood pressure cuffs 4. Tourniquets (bands used to stop or slow blood flow) 5. Stethoscopes (used to listen to your heart beat and breathing) 6. Grips on crutches and crutch tips 7. Bed sheet protectors 8. Elastic bandages and wraps 9. Wheelchair tires and cushions 10. Medicine vials 11. Ear, Ulcer Syringes 12. Pessary rubber ring 13. Rectal, Infant Syringe 14. Stomach Tube 15. Tourniquet 16. Hot water Bottles 17. Breast Pump 	 <p>Asepto & Enema Syringe</p>	 <p>Breast Pump</p>	 <p>Ear Ulcer Syringe</p>	 <p>Pipette Filler</p>
	 <p>Hot Water Bottle</p>	 <p>Invalid Air Cushions</p>	 <p>Ice Bag</p>	 <p>Rubber Sheeting</p>
	 <p>ECG Bulb</p>	 <p>Vaginal Douche Spray</p>	 <p>Kellys Douche Pad</p>	 <p>Rubber Bladders</p>
	 <p>Rubber Catheter</p>	 <p>Rubber Tubing</p>	 <p>Tourniquet</p>	 <p>Pessaries Ring</p>

NRL products in market

Surgical Gloves



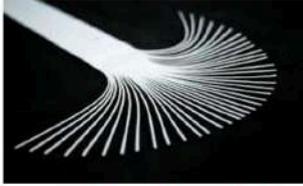
- A barrier against blood, body fluids, and other potentially infectious materials.
- Gloves can be made from various polymers, but NRL based gloves are commonly preferred
- Different types available

- ✓ **Comfort**
- ✓ **Tactile Sensitivity**
- ✓ **Barrier Protection**
- ✓ **Cost-effectiveness**
- ✓ **Biodegradability**

Catheters



<ul style="list-style-type: none">• consists of a soft plastic or rubber sheath, tubing, and a collection bag for the urine.	<ul style="list-style-type: none">• used when the catheter is to be inserted and removed immediately	<ul style="list-style-type: none">• known as Foley catheter, is left inside the bladder to provide continuous urine drainage.
Condom catheter 	Straight Catheter 	Indwelling Catheter 
<ul style="list-style-type: none">• is a type of indwelling catheter. It is inserted to irrigate the bladder to prevent obstruction (i.e. bleeding)	<ul style="list-style-type: none">• inserted into the bladder through a surgical incision made in the abdominal wall, right above the pubic bone.	
3-Way Catheter for continuous bladder irrigation (CBI) 	Suprapubic Catheter 	



Latex Rubber Thread



- **Medical Applications:** Elastic bandages, compression garments, and surgical support products.
- **Textile Industry:** In garments, to provide elasticity and shape retention.
- **Home Furnishings:** Bedsheets, fitted covers, and upholstery due to its stretchability.
- **Industrial Applications:** Conveyor belts, elastic ropes, and bungee cords, owing to their robustness and elasticity.
- **Crafting:** In various creative projects like jewelry-making, weaving, and fabric manipulation.

Dental Dams & Rings



- To isolate the operative site from the rest of the mouth
- To prevent saliva interfering with the dental work
- The dental dam market is estimated to be valued at USD 149.95 Mn in 2024 and is expected to reach USD 248.78 Mn in 2031 with a CAGR of 7.5%
- Latex dental dams occupies 45 %
- Asia-Pacific region fastest growing market





Latex flowers

- The global artificial flowers market size was valued at USD 1.64 billion in 2023 and is projected to be worth USD 1.70 billion in 2024 and reach USD 2.56 billion by 2032, exhibiting a CAGR of 5.24%
- Europe dominated the artificial flowers market share of 28.66% in 2023



Exercise Bands



- Exercise Bands Market size was valued at over USD 1.2 billion in 2023 and it is anticipated to reach around USD 4.3 billion by 2033 with a CAGR of 12.5%

Interesting Latex Products



NR LATEX PRODUCTS FROM HLL

NRL Contraceptive barriers



- A condom is a barrier device most commonly used during sexual intercourse to reduce the probability of pregnancy and spreading sexually transmitted diseases
- Quality condoms should be
 - ✓ Free from holes
 - ✓ Adequate physical strength
 - ✓ Correctly packaged to protect them during storage
 - ✓ Correctly labeled
- Available in market in designs, colours, odours

Condom Market



The key players holding the market are

- Reckitt Benckiser Group PLC [<https://www.reckitt.com/>]
- Church & Dwight Co. Inc. [<https://www.churchdwight.com/>]
- Okamoto Industries Inc. [<https://www.okamoto-inc.jp/en/>]
- HLL Lifecare Ltd [<http://www.lifecarehll.com/>]
- Karex Berhad [<https://www.karex.com.my/>]
- Humanwell Group [<http://en.humanwell.com.cn/>]

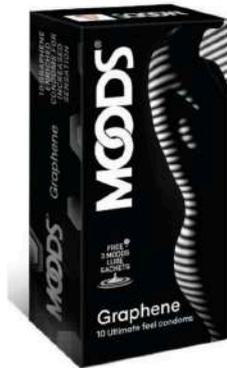




Moods – Male Condom launched in 1987



VELVET –NRL Female condom launched in 2012



Moods Graphene – Male Condom launched in 2023

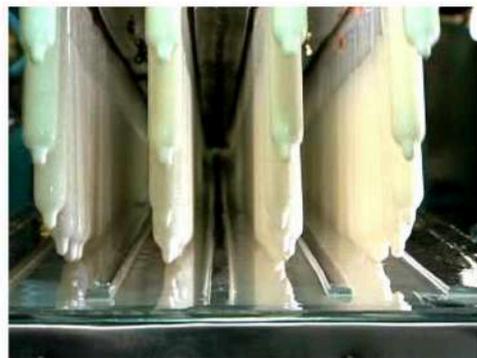
Male Condom- Technology



Technical collaboration -
Okamoto, Japan

Installed capacity
1.24 billion condoms per year

24 Product Variants:
Plain, Dotted, Ribbed, Coloured,
Delayed, Flavoured, Scented,
Skin Thin, 3 in 1 etc





Female Condom- Technology



Technical collaboration: Own patented technology

Installed capacity:
25 million condoms per year

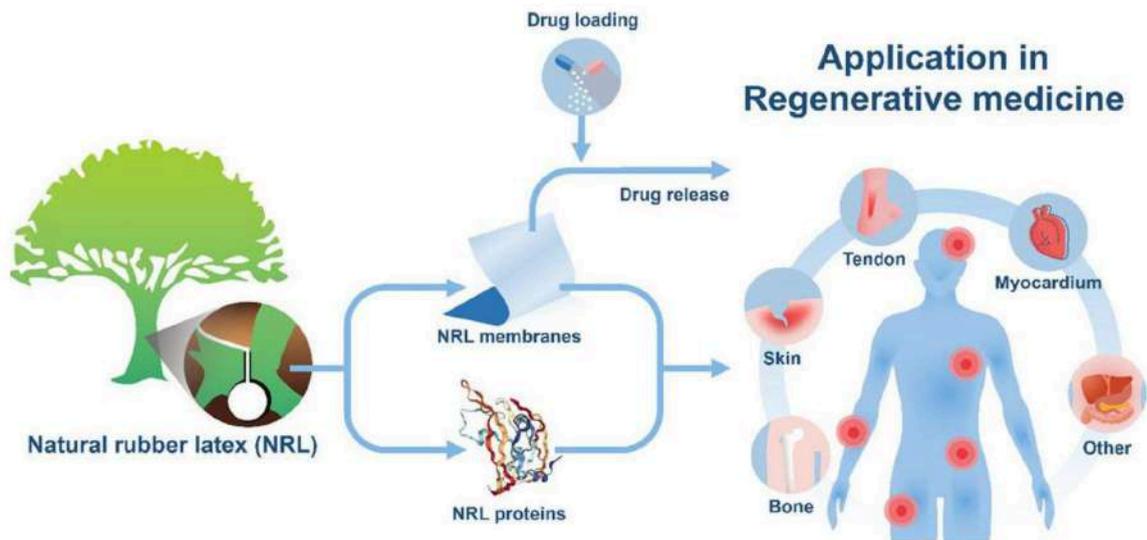
Holds Indian Patent (Patent No. 338697) and International patents



Biomedical applications of NRL

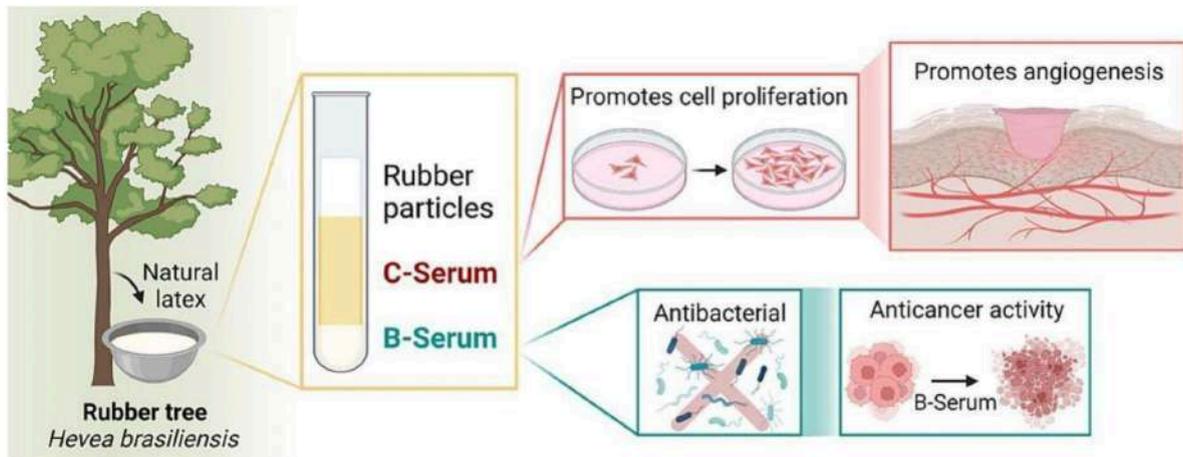
- NRL is a biocompatible polymer capable of stimulating the repair of adjacent tissues.
- NRL membranes can be applied to dermal wounds, helping with healing.
- NRL can also be used as an occlusive membrane for GBR applications.
- NRL serum has angiogenic, anti-inflammatory, antimicrobial and osteogenic properties.
- NRL matrix-based biomedical devices can be used to release bioactive compounds.

<https://doi.org/10.1016/j.msec.2021.112126>



[Materials Science and Engineering: C Volume 126, July 2021, 112126](#)

Possibilities of NRL





Natural Rubber Latex Gloves with Curcumin for Torn Glove Detection

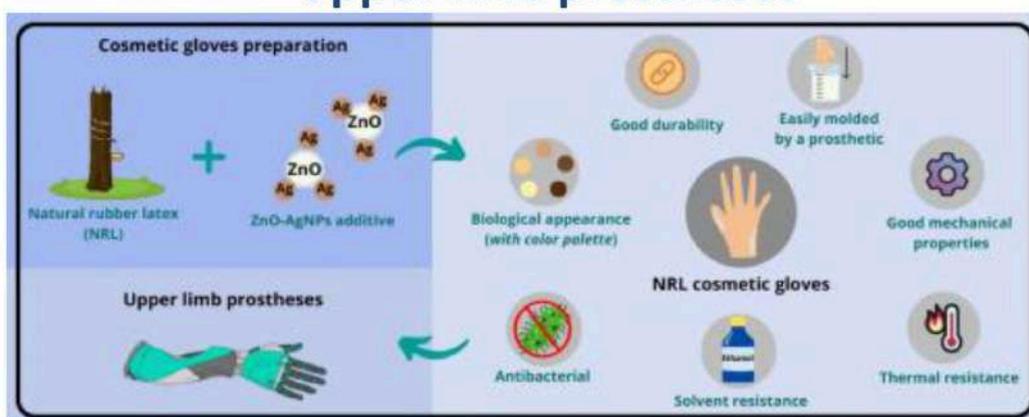
Development of a torn glove fluorescence-based sensor can assist in detecting any perforation damage to the glove when exposed to these UV light.



Cuts in the NRL film are clearly visible when examined under UV light

Sarih, N.M. et.al., 2022 *Polymers*
<https://doi.org/10.3390/polym14153048>

Cosmetic gloves from natural rubber latex for upper limb prostheses



Contents lists available at ScienceDirect
Biomedical Engineering Advances
journal homepage: www.journals.elsevier.com/biomedical-engineering-advances



Cosmetic gloves from natural rubber latex for upper limb prostheses: Preparation and physicochemical, mechanical and biological characterization

Danielle Restelatto^a, Jordana Bortoluz^a, Paula Sartori^{b,c,d}, Nayrim B. Guerra^e, Cristiani C. P. Cid^f, Robinson C.D. Cruz^g, Noel M. Gately^h, Declan M. Devine^h, Marcelo Giovanelaⁱ, Mariana Roesch-Ely^j, Janaina S. Crespo^{k,l,m}

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^b Área de Conhecimento de Ciências da Vida, Instituto de Biotecnologia, Universidade de Caxias do Sul, Rua Francisco Gastão Vargas, 1130, Caxias do Sul, RS 95070-500, Brazil
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^e Instituto Hercílio Pires, Caxias do Sul, RS 95140-000, Brazil
^f Applied Polymer Technology Gateway, Technological University of the Shannon: Midlands Midwest, Athlone Campus, University Road, Athlone N37 FEM66, Ireland
^g PRISM Research Institute, Technological University of the Shannon: Midlands Midwest, Athlone Campus, University Road, Athlone N37 FEM66, Ireland



Incorporation of nanosilica can efficiently reduce the residual proteins in latex gloves

International Journal of Science & Technology
www.ijst.co.in

ISSN (online): 2250-141X
Vol. 2 Issue 2, April 2012

Study on the properties of NR latex-Nanosilica composite for surgical gloves

JOSE PAUL MELETH^{1*}, K E GEORGE², G MADHU³, RANI JOSEPH⁴

¹ Primus Gloves Pvt Ltd, Plot no: 14-A, Cochin special economic zone, Kakkanad, Cochin, Kerala, 682037- India.

^{2,4} Department of PS & RT, Cochin University of Science & Technology, Cochin, Kerala, India

³ Department of safety and fire, Cochin University of Science and Technology, Cochin, Kerala, India

Antibacterial surgical gloves in order to minimize the microorganisms in the gloves

Plasma Chem Plasma Process (2012) 32:1275–1292
DOI 10.1007/s11090-012-9405-9

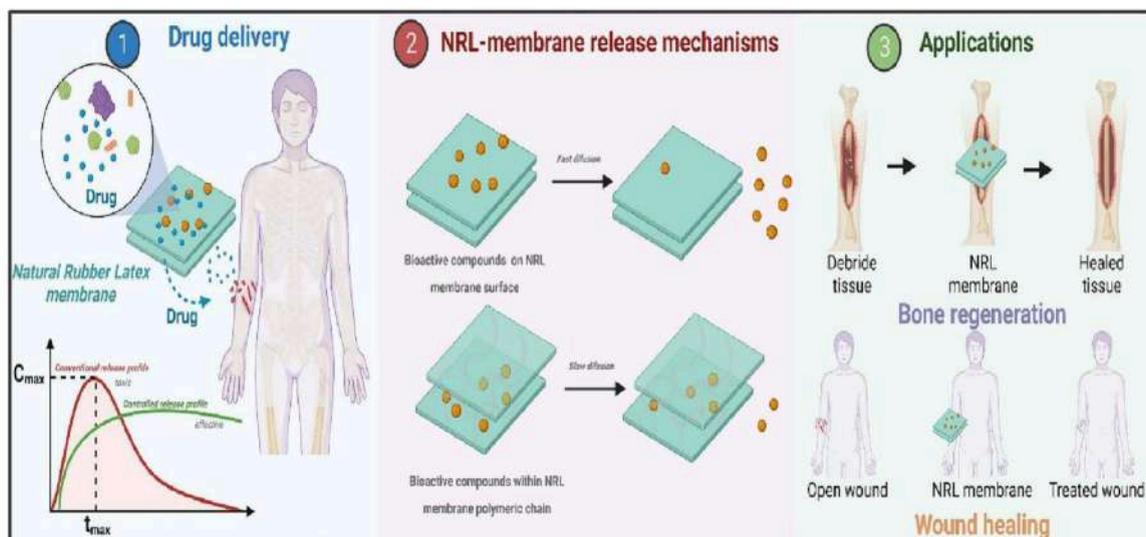
ORIGINAL PAPER

Preparation and Characterization of Chitosan-Coated DBD Plasma-Treated Natural Rubber Latex Medical Surgical Gloves with Antibacterial Activities

Sakkawet Yorsaeng · Orathai Pornsunthorntawe · Ratana Rujiravanit



Role of NRL in biomedical and biotechnological applications

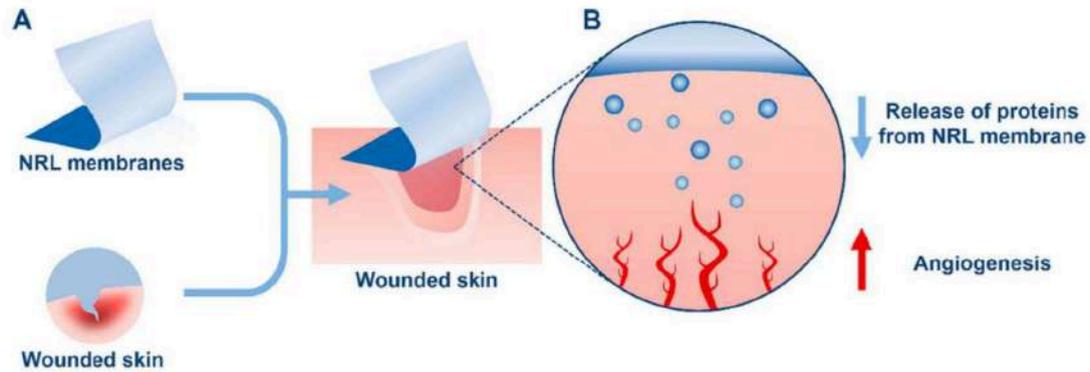


Floriano et.al., 2024 Int. J of biological macromolecules
<https://doi.org/10.1016/j.ijbiomac.2024.131666>

Wound-Healing



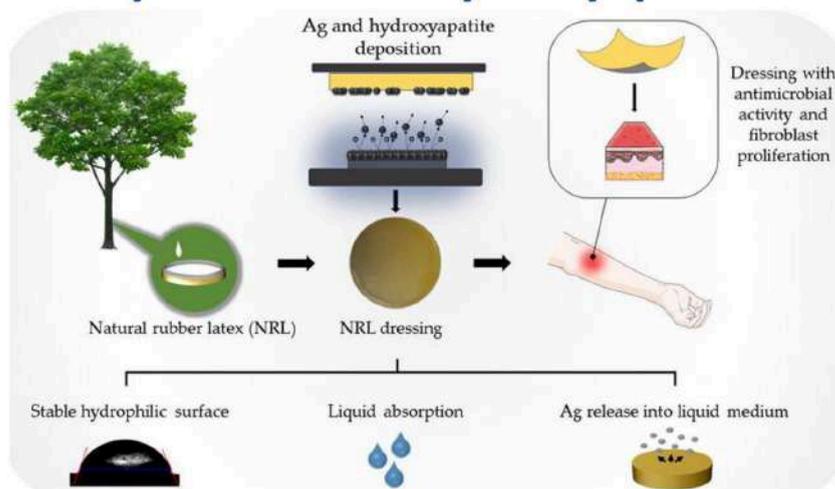
Wound healing is the biological process by which the body repairs damaged tissue after injury or trauma.



NRL dressings, after being sterilized, can be directly applied to the wounded skin

Guerra et.al., 2021 Materials science & engineering C
<https://doi.org/10.1016/j.msec.2021.112126>

Wound dressing composed of NRL, silver nano particles and hydroxyapatite

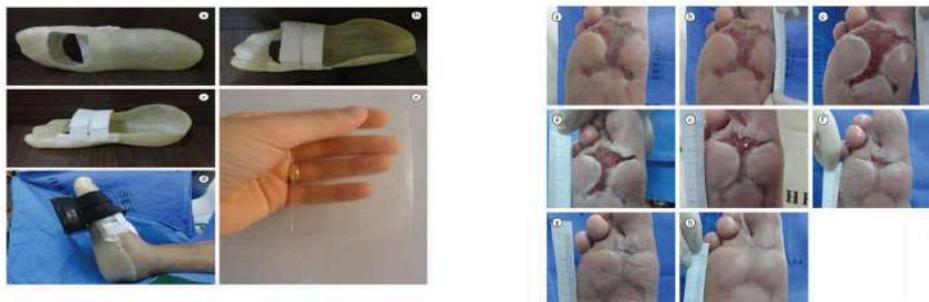


Latex induces the formation of blood vessels, silver in nanoparticulate form is bactericidal and HA is responsible for fibroblast proliferation.

Crespo et al., 2022 Reactive and functional polymers
<https://doi.org/10.1016/j.reactfunctpolym.2022.105316>



A novel system comprising a sheet of NRL and a matrix of light emitting diodes (LED) aimed at facilitating the healing of diabetic foot ulcers.



RESEARCH ON
**BIOMEDICAL
ENGINEERING**
rbejournal.org

Volume 32, Number 1, p. 3-13, 2016

Original Article

DOI: <http://dx.doi.org/10.1590/2446-4740.0744>

A system for treatment of diabetic foot ulcers using led irradiation and natural latex

Gustavo Adolfo Marcelino de Almeida Nunes*, Maria do Carmo dos Reis, Mário Fabricio Fleury Rosa, Luciana Roberta Tenório Peixoto, Adson Ferreira da Rocha, Suélia de Siqueira Rodrigues Fleury Rosa



The impact of NR membrane combined with aqueous propolis extract (P) on wound healing

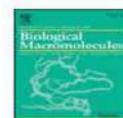
International Journal of Biological Macromolecules 131 (2019) 980–988



Contents lists available at ScienceDirect

International Journal of Biological Macromolecules

journal homepage: <http://www.elsevier.com/locate/ijbiomac>



NATURAL RUBBER – PROPOLIS MEMBRANE IMPROVES WOUND HEALING IN SECOND-DEGREE BURNING MODEL



Tamires Krupp^a, Bruna Daniele dos Santos^a, Loyane Almeida Gama^b, Josmary Rodrigues Silva^c, Wagner Welber Arrais-Silva^d, Nara Cristina de Souza^c, Madileine Francely Américo^b, Paula Cristina de Souza Souto^{a,*}

^a Laboratório de Biologia Vascular e Histopatologia, Instituto de Ciências Biológicas e da Saúde, Universidade Federal de Mato Grosso/UFMT, Barra do Garças, Mato Grosso, Brazil

^b Laboratório de Fisiologia de Sistemas e Toxicologia Reprodutiva, Instituto de Ciências Biológicas e da Saúde, Universidade Federal de Mato Grosso/UFMT, Barra do Garças, Mato Grosso, Brazil

^c Grupo de Materiais Nanoestruturados, Instituto de Ciências Exatas e da Terra, Universidade Federal de Mato Grosso/UFMT, Barra do Garças, Mato Grosso, Brazil

^d Laboratório de Parasitologia, Departamento de Morfologia, Centro de Ciências Biológicas e da Saúde, Universidade Federal de Sergipe, São Cristóvão, Sergipe, Brazil

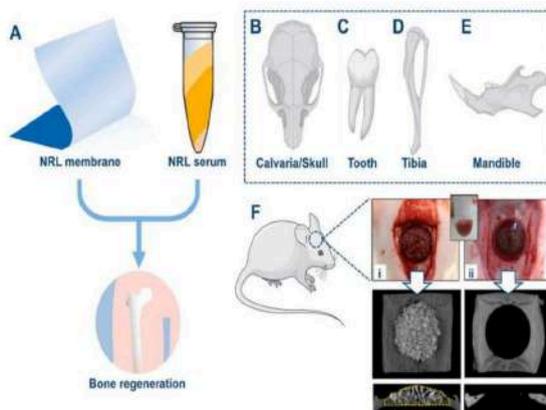
Drug Delivery

- **Natural rubber latex foam loaded with metronidazole.** Adv Mater Res 844:490–493, Issarayungyuen et al., 2014
- **Ciprofloxacin release using natural rubber latex membranes as carrier.** Int J Biomater , Murbatch et al., 2014
- **Natural rubber latex: study of a novel carrier for Casearia sylvestris Swartz delivery.** Int Sch Res Not, Borges et al., 2014
- **Evaluation of sodium diclofenac release using natural rubber latex as carrier.** Mater Res 17:146–152, Aiello et al., 2014
- **Diclofenac potassium transdermal patches using natural rubber latex biomembranes as carrier.** J Mater 2015:1–7, Barros et al., 2015
- **Oxytocin sustained release using natural rubber latex membranes.** Int J Pept Res Ther 22:435–444, Barros et al., 2016

Regeneration of bones



- Bone loss due to congenital defects, traumas, surgery procedures or cancers.
- Bone reconstruction has relied on bone grafts or implants .
- NR membranes, known for their high osteogenic potential, are suitable candidate for this application.



A) The NRL can be used as simple membranes or as its protein serum for bone regeneration.

B–E) Calvaria, tooth, tibia, and mandible.

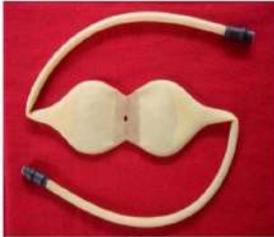
F) Defect region (rat skull) filled with the biomaterial, deproteinized bovine bone and porous biphasic calcium phosphate with or without protein fraction (i) and filled with a blood clot, control group (ii)

Guerra et al., 2021 Materials science & engineering C
<https://doi.org/10.1016/j.msec.2021.112126>

CERVICAL SPACER



- A Natural rubber latex device to reduce radiation dose to critical organs surrounding Uterine Cervix during Brachytherapy radiation treatment of cervical cancer treatment
- Existing method: wet cotton gauze packing
- Clinically proved- effective in reducing radiation dosage on critical organs
- Received National award for Technology Innovation
- Technology ready for transfer



Winner of National award for technology innovation in 2017



Winner of Lockheed Martin India innovation Growth Award in 2016



Indian Patent was awarded for the spacer balloon device, Patent No. 379287



UTERINE BALLOON

- A Natural Rubber latex device used to reduce Uterine Bleeding (Post Partum Hemorrhage)
- The uterine balloon can be inserted inside the uterus, and inflated with air/fluid to compress the bleeding vessels to stop bleeding
- It could withstand around 300 to 500ml in uterine balloon and 150 to 250 ml in vaginal balloon for a minimum period of 24 hrs
- Clinical trials in progress



Inflated Balloon



URINARY BAG CONDOM (HLL U-DRAIN)

- External condom catheters are not useful for patients who have insufficient anatomy to fix the urinary condom tightly.
- Useful for men whose bladders are able to drain urine but who have trouble controlling when it's released.
- Special type of molds and natural rubber latex formulations were designed for the development of the device.





Rubber molds for explosive treatment

- For Terminal Ballistics Research Laboratory (Defence Research Development Organisation)
- Casing for pressing the explosive material in a furnace at specific temperature and pressure.
- The mould should not undergo charring and should withstand high temperature and pressure when used for the purpose
- Technology developed and transferred



Conclusion

- Large scope exists in natural latex utilization for different products
- New opportunities coming out in the biomedical area needs to be tapped
- To exploit the innovation in utilising latex serum
- Utilization of NRL is critical to the state economy
- Alliance between the stake holders

Mr Alex G Kodi, Managing Director, Kodi Healthcare



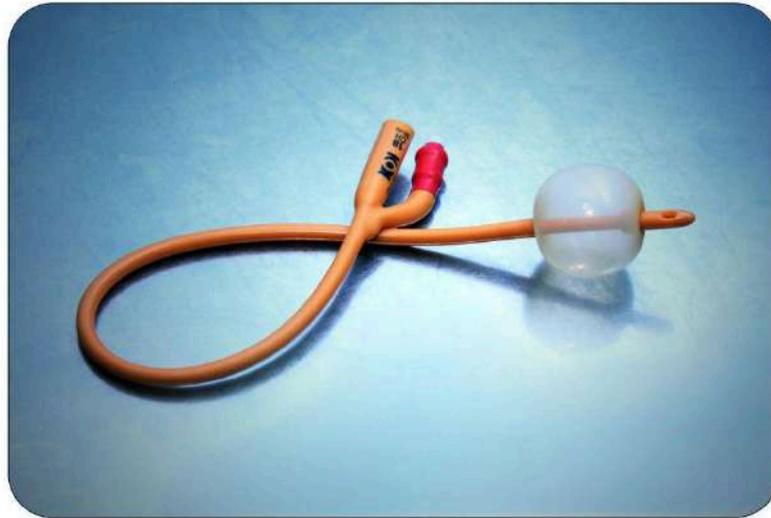
Kodi Healthcare Pvt Ltd

PRESENTED BY
ALEX GEORGE
MANAGING DIRECTOR

LIST OF PRODUCTS

- ◆ FOLEY BALLON CATHETERS
- ◆ URO GUARD ULTRA – MALE URINARY DEVICE
- ◆ URO GUARD – MALE URINARY DEVICE
- ◆ SPIT BAG
- ◆ EVL BANDS- ENDOSCOPIC VARICEAL LIGATION
- ◆ MULTI BAND LIGATOR
- ◆ KODI STANDARD VASTI KITS
- ◆ KODI ANUVASANA VASTI KITS
- ◆ KODI NIRUHA VASTI KITS
- ◆ KODI RUB URINE BAG

FOLEY BALLON CATHETERS



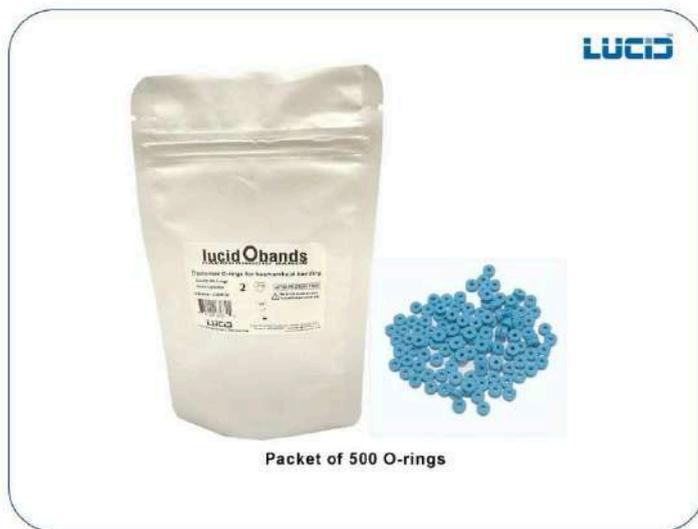
URO GUARD ULTRA – MALE URINARY DEVICE



URO GUARD – MALE URINARY DEVICE



EVL BANDS- ENDOSCOPIC VARICEAL LIGATION

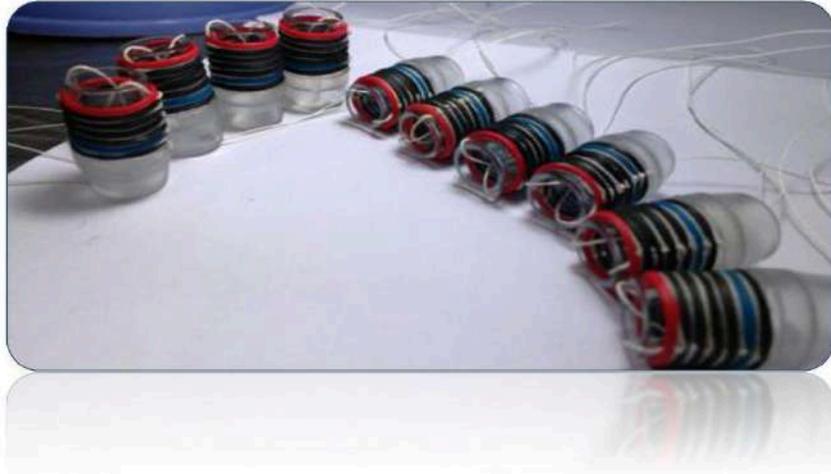


SPIT BAG



MULTI BAND LIGATOR





KODI STANDARD VASTI KITS



KODI ANUVASANA VASTI KITS



KODI NIRUHA VASTI KITS



KODI RUB URINE BAG





Thank You

AN ISO 9001:2000 COMPANY



Kodi Healthcare Pvt Ltd

Mr Karimpuzha Raman, Director, Primus Gloves



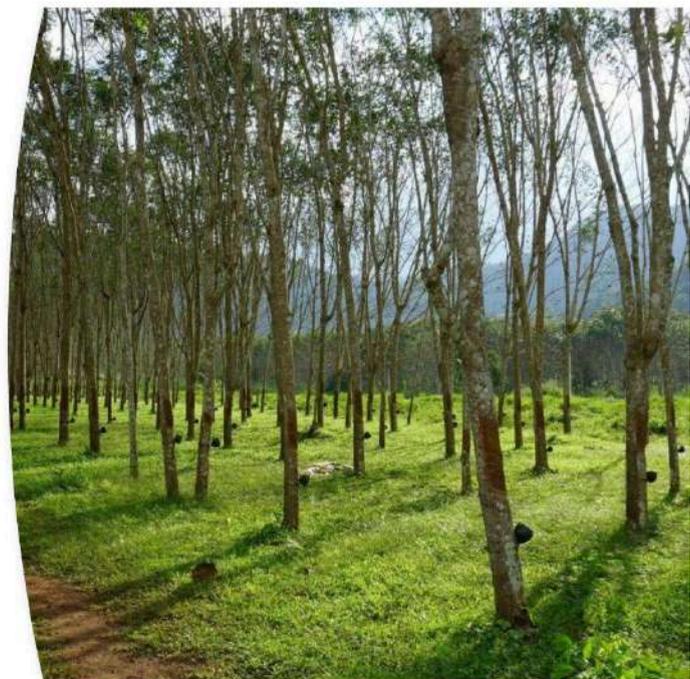
Transforming Rubber: From Plantations to Medical Frontiers

“Rubber Industry: An Overview”

By
Karimpuzha Raman
Director, Primus Gloves Pvt Ltd

Natural Rubber – Global Scenario

- Natural Rubber(NR) – Hevea Brasiliensis Trees



Natural Rubber – Global Scenario

- Natural Rubber(NR) – Hevea Brasiliensis Trees
- Global Production – **14.3** million MT



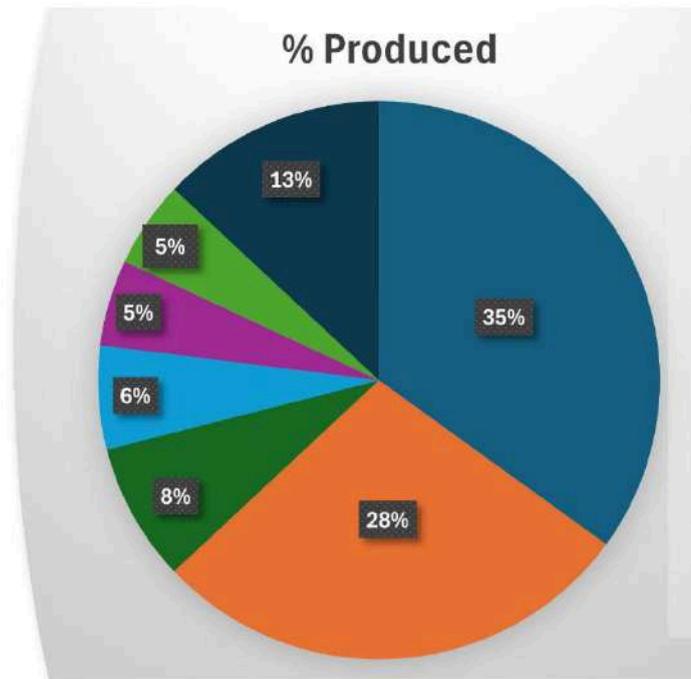
Natural Rubber – Global Scenario

- Natural Rubber(NR) – Hevea Brasiliensis Trees
- Global Production – **14.3** million MT
- Unique property of NR results in High Demand over Synthetic Rubber



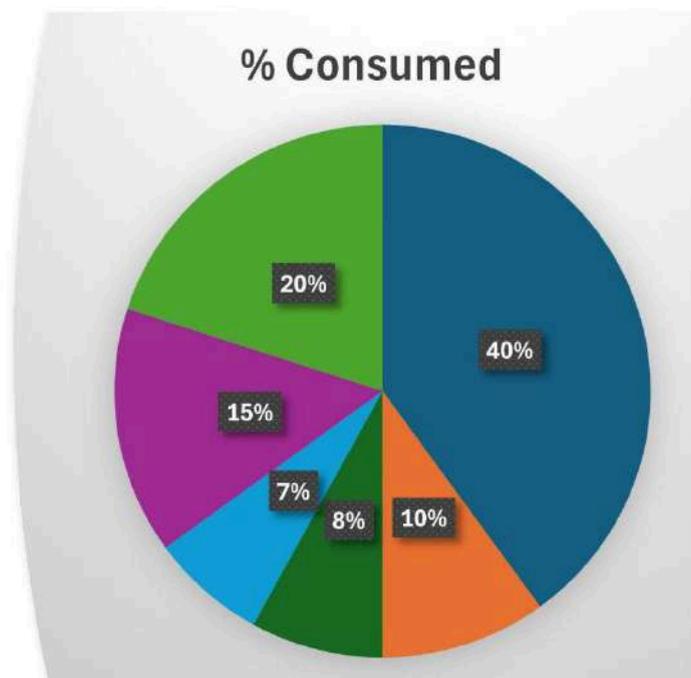
Global Scenario – Major Producers

- Thailand – 35%
- Indonesia – 28%
- Vietnam – 8%
- India – 6%
- China – 5%
- Malaysia – 5%
- Others – 13%



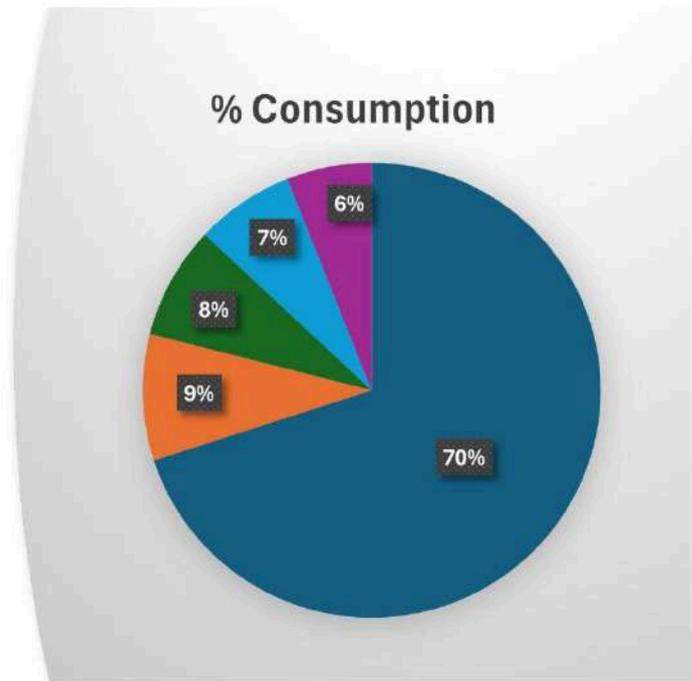
Global Scenario – Major Consumers

- China – 40%
- India – 10%
- USA – 8%
- Japan – 7%
- EU – 15%
- Others – 20%



Global Scenario – Major Industries

- Automotive – 70%
- Consumer Goods – 9%
- Footwear – 8%
- Industrial Goods – 7%
- Healthcare – 6%

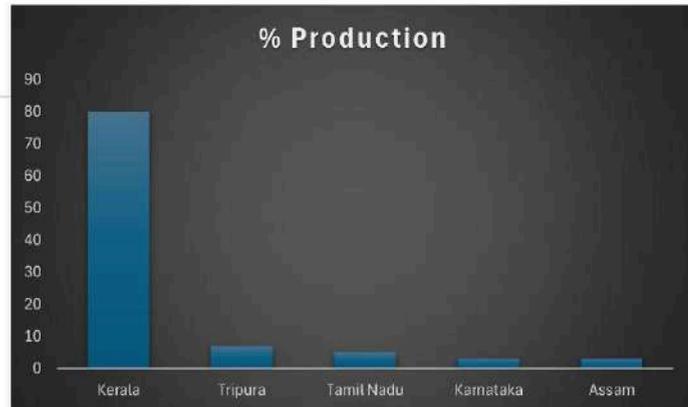


Indian Scenario



Indian Scenario – Major Producers

- Kerala – 78~80%
- Tripura – 7~10%
- Tamil Nadu – 5~7%
- Karnataka – 3~4%
- Assam – 3~4%



Indian Scenario – Major Industries

- Automotive – 65~70%
- Healthcare – 10~15%
- Industrial Goods – 5~10%
- Footwear – 5~10%
- Consumer Goods – 3~5%



Natural Rubber – Medical Devices

- Medical Gloves
- Catheters
- Condoms
- Medical Tubing
- Diaphragms
- Respiratory Masks
- Dental Dams
- Etc



Medical Gloves: Surgical & Examination

Getting Started

- Market Research
- Location
- Infrastructure and Machinery
 - 15 ~ 20 Cr
- Statutory:
 - Pollution Control Board
 - Factories and Boilers License
 - Fire License
 - Electrical Inspectorate



R&D and Quality Assurance

- Implement a comprehensive quality management system to ensure product consistency and compliance with regulatory standards such as Indian Standards (IS), ASTM (American Society for Testing and Materials) and EN (European Norm) standards.
- Well Equipped Lab for product testing and product development.



Regulatory Compliance

- Central Drugs Standard Control Organization (CDSCO) Manufacturing License
- IMDR 2017 (Indian Medical Device Rules)
- EU MDR 2017/745 (European Union Medical Device Regulation)
- ISO 13485: 2016 (International Organization for Standardization)
- ICMED Issue 2 (Indian Certificate for Medical Devices)
- FDA (US Food and Drug Administration)
- TGA (Australia Therapeutic Goods Administration)
- MDSAP (Medical Device Single Audit Program) accepted by USA, Canada, Brazil, Japan and Australia.



Innovations

- Development of new techs like Antimicrobial, Enhanced Biodegradability, Hypoallergenic formulations etc.
- Development of new varieties which is more user specific e.g. Pharmaceutical, Orthopaedic, Gynaecology etc.
- Eco – Friendly Manufacturing Processes.
- Nanotechnology Integration
- Implementation of Advanced Automation and AI to ensure quality



Economic Potential

- Pandemic Preparedness and control.
- Increased focus of Government on Healthcare which increased the consumption of Medical Gloves.
- "Make in India" initiatives which promote local manufacturers.
- Growing demand on Eco-friendly and sustainable products.
- Estimated Growth until 2033 – 5.4% (CAGR)



Thank You



Mr Rejeesh G R, General Manager (Marketing) , Kerala Medical Technology Consortium (KMTC)

DEVELOPING RUBBER-BASED MEDICAL DEVICES IN KERALA SUPPORT BY KMTC

Rejeesh G R , KMTC
10th KMTC , Stake Holder Connect Meet

World Medical Devices Industry



High cost of Medical Devices and Health Care in US, EU & Japan | Low Growth in these markets

Source : KPMG



Indian Medical Devices Industry

Indian Medical Devices Market

US \$ 12.00 Billion
in 2023

Forecast for 2040

US \$ 50 Billion



Small but rapidly growing
Medical Device Industry



**High Quality Scientific
Engineering and Medical talent**

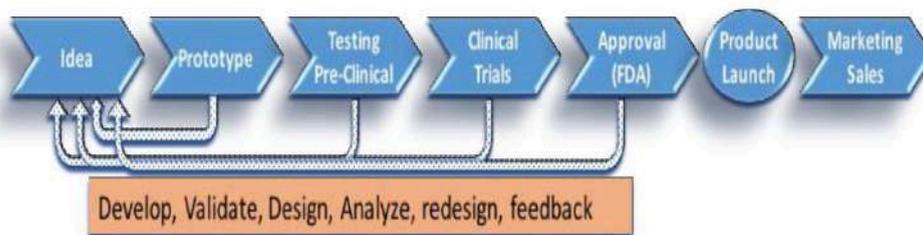
Poor quality
Medical Devices

75% imports



Medical Device Development Life Cycle

The long pathway of medical device development from discovery, ideation, product launch and post market monitoring



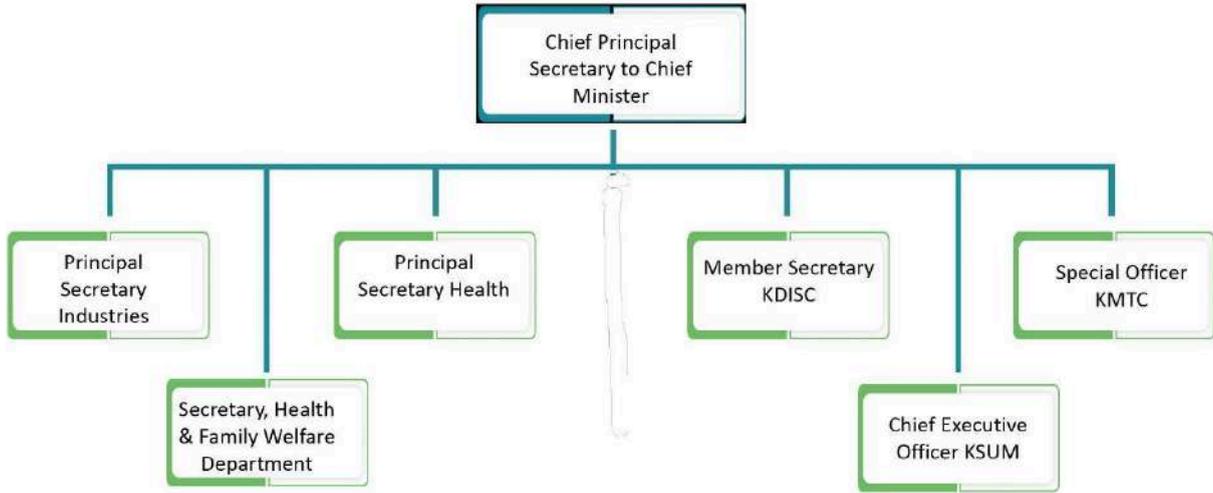
This process often takes 2 to 10 years, with several potential Valleys of Death

The regulatory process affects a significant portion of the device development pathway

It is difficult for any one entity or organization to undertake all aspects of the technology development

The KMTC envisions creating services that support entrepreneurs in each area of the lifecycle

KMTC Co ordination Committee (Organogram)



KERALA MEDICAL TECHNOLOGY CONSORTIUM (KMTC)

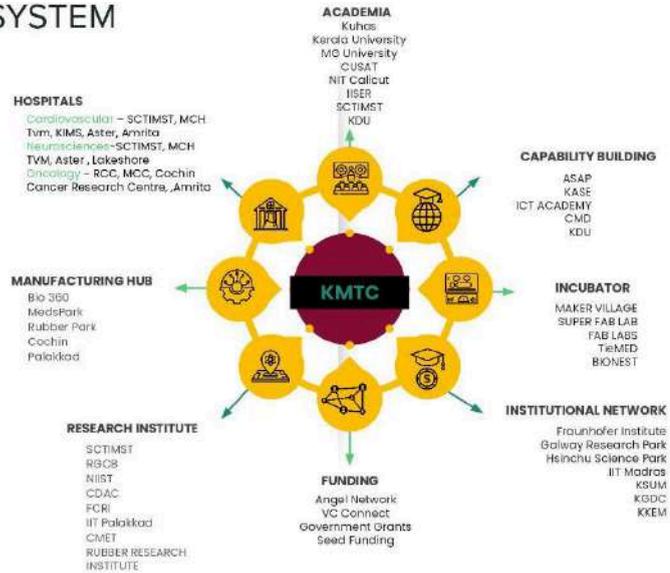
Vision :

Establish Kerala as the TOP Medical Technology / Medical Devices Hub in the country by 2032, and to aspire to be counted in the Top 20 MedTech Ecosystems in the World

Mission :

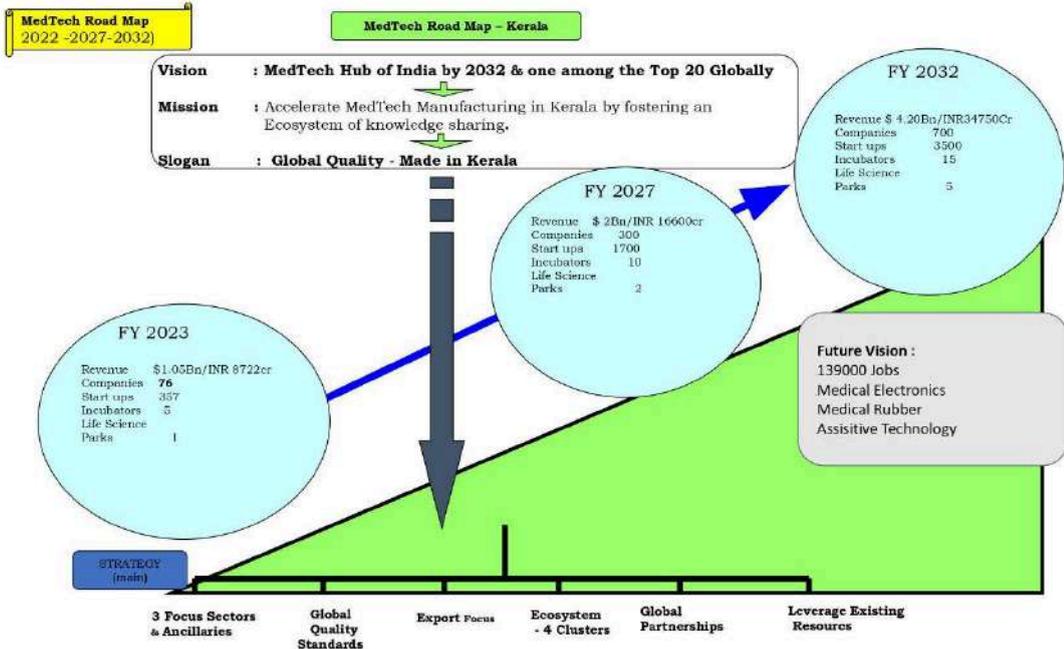
To accelerate Medical Device manufacturing and technology in Kerala by fostering an ecosystem of knowledge sharing between Research Organizations, Academic Institutions, Industry, Healthcare Institutions and Government

KERALA MEDTECH ECOSYSTEM

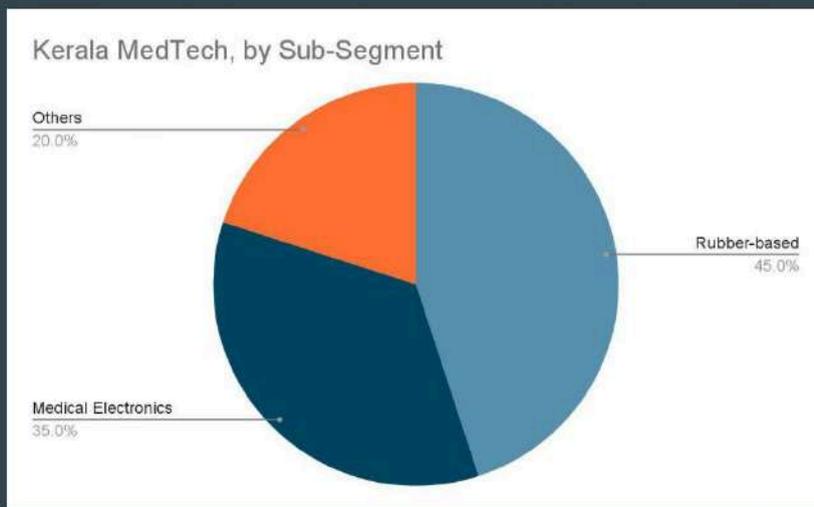


MEDICAL DEVICE INDUSTRY ENABLERS

Sl. No	Industry Enablers	Kerala Status
1.	MedTech Research Institutions	✓
2.	Multidisciplinary skilled Manpower	✓
3.	High Quality Healthcare	✓
4.	Entrepreneurship & Innovation	✓
5.	MSME Focus	✓
6.	Presence of Clusters	✓

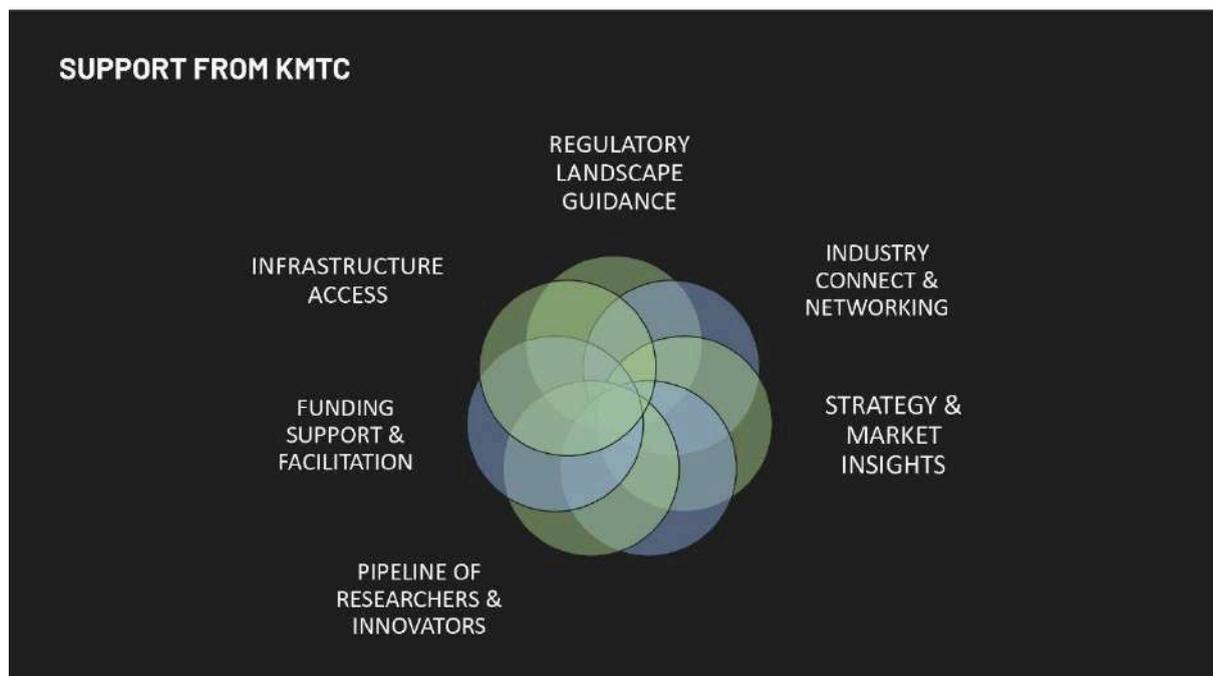


Medical Devices Industry // KERALA- Why Focus on Rubber ?

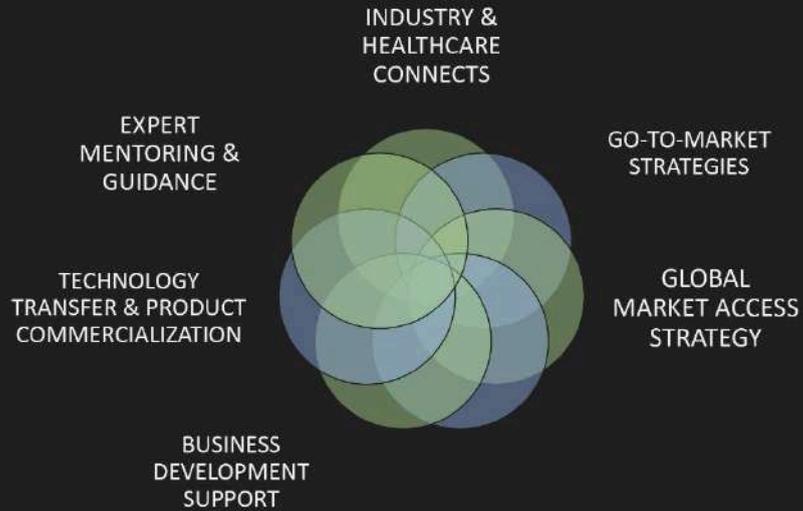


SHIPP: SUSTAINABLE HEALTH IN PROCUREMENT PROJECTS

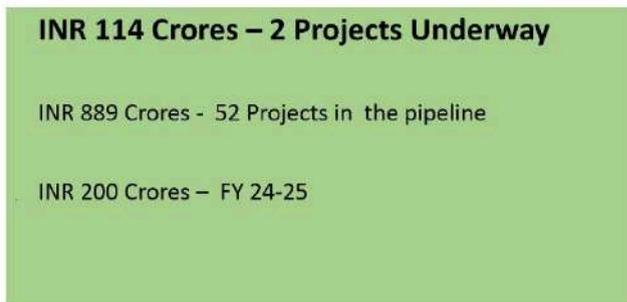
- **Health sector comprising 10% of the global economy.**
- UNDP Project aimed at Promoting Sustainability in Healthcare.
- Develop Universally applicable Criteria for sustainable manufacturing, distribution & content of products procured by Health Sector
- Strengthen capacity for sustainable production, supply, and disposal of health care products.
- 10 countries including India have signed up for the Project .



SUPPORT FROM KMTC



KMTC RESULTS: INVESTMENTS PIPELINE



KMTC HIGHLIGHTS: 2022-2024



KMTC FOCUS ON QUALITY

Policy Representations -

Parliamentary Standing Committee
National Medical Devices Promotion Council
Association of Indian Medical Device Manufacturers

New Industrial Policy 2023-2028, GOK

IEDCs in Medical Institutions



VISIT OUR
WEBSITE
WWW.KMTC.IN

