

FREUDENBERG medical

Advancing medical technology

Innovating together for
the future of healthcare

EDITORIAL
INFORMATION

Published by

Freudenberg Medical LLC
40 Sam Fonzo Drive
Beverly, MA 01915 USA

Editorial staff

Laura Kirstein
laura.kirstein@
freudenbergmedical.com

Freudenberg Medical LLC
40 Sam Fonzo Drive
Beverly, MA 01915 USA

Contributors

Laura Kirstein, Martina
Muschelknautz, Maura Leahy,
Holly Bruning

Photos, graphics, illustrations

Paul Lehane (1, 6–7 top and
bottom, 24), Marco Schilling
(2, 6–7), Christian Heyse/Profil-
werkstatt (2, 16–17), Martina
Regan (3, 10–11), mattbadal/
Adobe Stock (3, 14–15), 00one/
iStock (3, 22–23), Gerald Schilling/
Freudenberg Medical (4–5), Anke
Rabbeau/Profilwerkstatt (13),
Bambi Medical (18), Signifier
Medical Technologies (19),
Freudenberg Medical (20, 23)

Design & concept

Profilwerkstatt GmbH,
Darmstadt

Print

Germany (ABT Print und
Medien GmbH, Weinheim) and
USA (Tepel Brothers, Troy, MI)

Print run

1,000 English

We use gender-neutral terms as
personal identifiers wherever
possible. At a few points, we
dispense with the simultaneous
use of different descriptions –
solely to improve readability. In
all cases, however, we are en-
compassing all genders – male,
female and other (m, f, x).



06

**“The patient always
comes first”**

Dr. Mark Ostwald, CEO of
Freudenberg Medical, on
how the company partners
with its customers to
provide patients with life-
saving medical devices.

16

**Digital tech-
nologies for
the healthcare
of the future**

Addressing un-
met needs with
the digitization
of smart medical
devices.





10

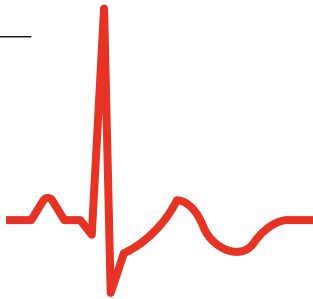
Growing in the heart of MedTech

1,000 employees manufacture more than 16 million complex catheters annually in Ireland. Galway celebrated a recent site expansion.

14

In the right rhythm

Pulsed field ablation – a game changer for treating atrial fibrillation.



22

Quickly and reliably, from idea to market

The Center of Excellence for Automation and Robotics enables innovation with configured automation solutions.

Contents

04

The eye-catcher

06

“The patient always comes first”

10

Growing in the heart of MedTech

13

How I fixed it ...

14

In the right rhythm

16

Digital technologies for the healthcare of the future

20

4 questions for ... Lars Gerding, VP Technology

22

Quickly and reliably, from idea to market



Delve deeper into the world of Freudenberg Medical. Join the conversation on LinkedIn.

The eye-catcher

They promote the healing process, and follow-up surgeries are needed far less often: Drug-coated balloon catheters from Freudenberg Medical are making a huge difference in improving patient outcomes.





View more in the video on
LinkedIn.

Medical technology is a relatively new field across Freudenberg's 175 year history. It started with the acquisition of a manufacturer of silicone components in the United States in 2004. Today, after nearly two decades of organic growth, acquisitions, joint ventures and newly established locations, Freudenberg Medical is one of the company's fastest growing Business Groups.



→ A market for the future: medical technology

**“The patient
always
comes first”**

DR. MARK OSTWALD,
CEO, FREUDENBERG
MEDICAL

A PhD industrial engineer, Ostwald has held a number of positions at Freudenberg Medical over the past 15 years. Since becoming CEO in April 2022, he has been strategically developing the company from its headquarters in Beverly, Massachusetts.

Dr. Ostwald, what accounts for Freudenberg Medical's success?

The No. 1 factor is our highly motivated team. Based on conversations with colleagues at our facilities worldwide, it is clear that we always put the patient first. Human lives depend on the care and diligence with which we manufacture our products. In the worst case, if we are unable to deliver, patients do not receive the treatment that they urgently need. We're all aware of this, and we take on the responsibility together. That's why we are fully committed every day.

Another important factor is that our range of products and services has steadily expanded over the past few years and continues to grow. Our devices are used in a wide variety of therapeutic areas. Among others, our portfolio consists of injection-molded components and tubing made of silicone and thermoplastics. We also offer minimally invasive catheter solutions and our own medical devices such as voice prostheses.

We produce many finished medical devices that play an important role in the portfolios of our customers – devices that we develop, manufacture and package in-house. Our customers handle sales and distribution to hospitals and medical practices. Given the world's aging population, we are doing business in the very definition of a growth market.

“Minimally invasive procedures with vascular catheters put significantly less strain on patients.”

How does medical care need to be positioned to meet future demands?

Let's take cardiology as an example: Open-heart surgery used to take several hours and required a seven day hospital stay, taking up to eight weeks recovery. Due to the severity of the procedure, these operations were not considered for older or seriously ill patients. Today, a much better result can be achieved with a vascular catheter – usually in less than an hour. These minimally invasive procedures place significantly less stress on patients. Since the complication rate is low and the patients recover quickly from the procedures, they usually go home the following day, resuming normal activities immediately. —>

“From development to manufacturing all the way to large-scale production – our customers can take their product from idea to market-ability with us.”

Advances in the miniaturization of medical devices are another trend. We and our customers face a challenge: The individual components have to be smaller and smaller to combine more functions into a single product. For example, diagnosis and treatment should take place in a single procedure. This offers many advantages: Patients are treated less frequently and for shorter periods, and they recover more quickly. That further reduces the strain on patients while conserving valuable healthcare resources. There are also benefits for sustainability if more can be achieved with less material.

What other trends are you seeing?

Digitalization is making it possible for surgical robots to assist surgeons. The physician controls specialized instruments using a control panel and gets an enlarged 3D view of the operation area. Thanks to the improved precision, only relatively small incisions are needed. Patients benefit from less trauma to their tissue and faster recoveries.

Technological advances and expansion of robotic systems will lead to broader availability and even more precise execution of surgeries. For example, for certain operations, specialists will no longer need to be in the same hospital as the patient during the procedure. This decentralization is enabling the best possible patient care over long distances.



What was the impact of the COVID-19 pandemic?

Minimally invasive products were in less demand because elective surgeries were postponed. On the other hand, we were able to increase sales in the thermoplastic and silicone injection-molding and extrusion business. We were thus able to help ensure that COVID-19 vaccines could be produced and packaged, so they could reach as many people as possible worldwide. The test cartridges we produced for in vitro diagnostic (IVD) tests made it possible to detect COVID-19. Besides infectious agents such as viruses, bacteria and parasites, IVD tests are also used to detect cancer and to diagnose and monitor cardiovascular disease. Interrupted supply chains, material shortages and overloaded logistic systems have been a major issue. The after-effects still impact but are declining. That’s why our customers today are clearly focused on on-time delivery and reliability.



How has Freudenberg Medical responded to this trend?

With 11 production facilities in medical industry hubs in the United States, Costa Rica, Ireland, Germany and China, along with sales offices in Southeast Asia and India, we are close to our customers. Most of our facilities have at least one sister site with the same material expertise and manufacturing technology. We have also continued to strengthen our relationships with raw material suppliers and machine manufacturers.

Our customers consider us a preferred partner with whom they can take a product from the initial idea to regulatory approval and market launch, from product design and development to efficient production processes with lean methods, and finally to volume production. When medical device companies outsource development and production to us, either wholly or in part, they benefit in two ways: They are adding resources to strengthen their teams, and they have access to extra competencies, such as capabilities and technologies that they lack themselves. This makes it possible for them to bring products to the market faster. With Freudenberg, they know they have a partner who always puts the patient first. —



Following the principle of vertical integration, Freudenberg Medical is introducing technologies and expertise for process steps into their own manufacturing operations that previously had to be handled by third parties. This reduces the risk for customers since supply chains are simplified.



Tubing reinforced with fiber braiding withstands high pressures during the bottling of pharmaceuticals. In addition, it is both robust and flexible when employed in catheter shafts used in heart surgery.



Vice President and General Manager of Freudenberg Medical's Galway facility, Steven Langan, with team member Mertie Halili, holding coated hypotubes.

→ Freudenberg Medical in Ireland

Growing in the heart of MedTech



Ireland is an internationally recognized hub for medical technology with eight of the world's top 10 MedTech companies having a physical presence. The Freudenberg Medical site in Galway recently celebrated its expansion.

"I joined in 2018. Since then, our sales turnover has tripled and our workforce has gone from 100 to close to 300 so you could definitely say I was in the right place at the right time," says Brandon Hobbs, a native of South Africa who moved to Ireland in search of better professional and educational opportunities for himself, his wife and children. "I could see on our arrival here the importance of the MedTech industry in Galway. I applied to Freudenberg Medical for an entry-level role as a Production Operator. Later I was promoted to Group Lead, managing people on the production line, then Senior Group Lead, Production Coordinator, and to my current role, Production Unit Leader."

Over the next few months, Hobbs will get another 100 colleagues. The new team members will further strengthen engineering, research and development, manufacturing operations, quality and support services. The additional jobs were announced during the celebration of the official opening of the expanded facility in Galway. The existing manufacturing footprint was increased by 50%. The expansion is a strategic move to meet soaring global demand for hypotubes that are critical metal components used in catheters for minimally invasive surgery.



A hypotube is a long thin metal tube, typically over 1 meter in length. Its name derives from a combination of the terms "hypodermic needle" reflecting its diameter and a "metal tube" reflecting its material and cylindrical nature. In minimally invasive surgery, the best patient outcome begins with navigating the vasculature safely and smoothly. The core characteristic of a hypotube is that it needs to be thin-walled to maximize the inner diameter while keeping the outer diameter small enough to proceed through small openings, navigate complex vasculatures, and reach hard-to-access parts of the body. For balloon catheters utilizing a metal shaft construction, good design begins with a high-performing hypotube.

"The continued success and accelerated growth of our Galway operations is a testament to the dedication of our talented teams for high-quality, innovative products and excellent customer service. We look forward to deepening our partnerships with customers as we add new capacity, capability, and talent in Galway," said Vice President and General Manager of Freudenberg Medical's Galway facility, Steven Langan. —>

GLOBAL LOCATIONS

Freudenberg Medical operates 11 production sites and 2 sales offices in key industry hubs across the US, Europe, Asia and Costa Rica. Manufacturing capabilities range from molding and extrusion to complex catheters, coatings and conductive materials.



Dr. Mark Ostwald, CEO of Freudenberg Medical, said the opening of the expanded facility was a major milestone for the company's Irish operations: "Ireland is of strategic significance within our global network. The country is renowned worldwide as a leader in the life sciences sector and stands as an epitome of excellence and innovation for medical devices. With the investment in our newly expanded facility and plans to further increase our team, we look forward to building on our 25-year history as we strengthen our presence in Ireland."

Freudenberg Medical employs more than 1,000 people in Ireland, operating from a combined 200,000 sq ft manufacturing footprint at facilities in Galway and Co. Leitrim. Its Irish facilities were originally established as joint venture partnerships with the former Cambus Medical and VistaMed operations which have now transitioned into Freudenberg Medical. Together, its Irish operations manufacture more than 16 million complex catheters each year, serving a global customer base.



Steven Langan, Vice President and General Manager Freudenberg Medical Galway, Dr. Mark Ostwald, CEO Freudenberg Medical, Dr. Mohsen Sohi, CEO Freudenberg Group and Barry Comerford, Advisory Board Member to Freudenberg Medical, (from left to right) officially cut the ribbon in the expanded facility in Galway, Ireland.

→ Hydrophilic foam for wound cleansing

How I fixed it ...

Cleansing a wound requires know-how and the right materials. But which ones are easy to handle, clean wounds painlessly and offer cost advantages? Freudenberg Performance Materials (FPM) took a pragmatic approach in its search for the best-possible material. In workshops, FPM made an assortment of Freudenberg products available to experienced nurses and caregivers, including nonwovens, fabrics and sponges. “There are no standardized tests for wound-cleansing products,” explains Dr. Birthe Lang, R&D Manager Foam at FPM. “But what could be better than to talk directly to wound specialists?” To make the situation as realistic as possible, the team recreated wounds on simulated skin. In the end, a soft, large-pored foam prevailed. The material has generated interest in the market, and the product is now being developed to maturity. —



DR. BIRTHE LANG,
R&D MANAGER AT FPM

Before joining FPM, she worked on the product in her previous position at Freudenberg Technology Innovation. She now leads a team there that is responsible for the foam's further development.



More information
on the material can
be found here.



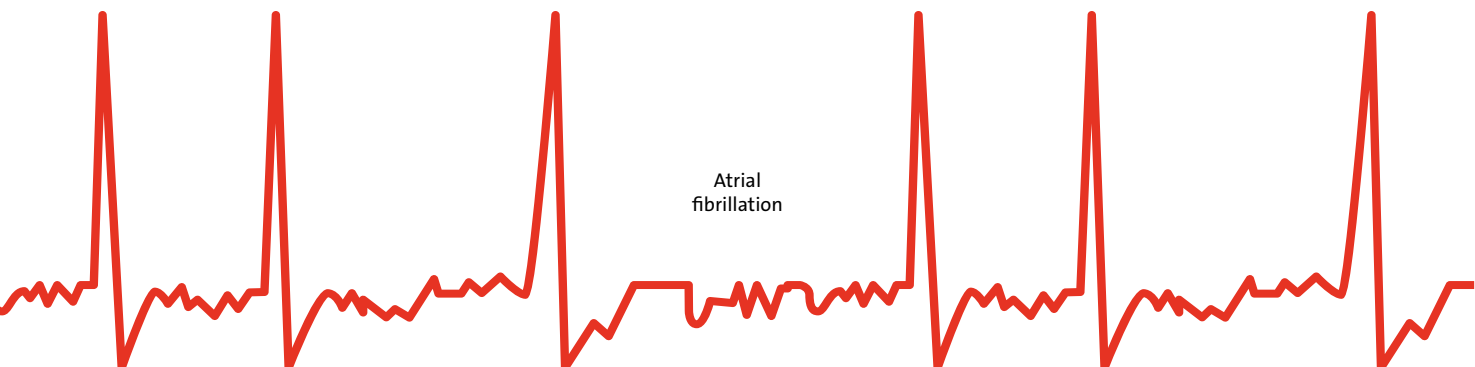
In the right rhythm

About 46 million people live with atrial fibrillation worldwide. This condition increases the risk of stroke fivefold.

Working with leading medical technology companies, Freudenberg Medical is developing catheters for a new treatment method called pulsed field ablation.

The heart suddenly falters, and a strong pressure develops inside the rib cage. The world starts to spin. That's how patients describe the typical symptoms of cardiac arrhythmias. Their hearts beat too fast – and at an irregular pace. The solution is pulsed field ablation (PFA), a novel catheter ablation technique.

“The new technology is a turning point and will change the global market long-term. It is now conquering Europe, and it will continue its success in the United States next year,” said Miroslav Secerov, VP Business Development at Freudenberg Medical.



Knowing what is achievable

Freudenberg Medical is working on the design, development and production of access, visualization and ablation catheters, cooperating with market leaders in **electrophysiology**.

Catheters are produced at five Freudenberg Medical facilities around the world, including industry clusters focusing on medical technology in the U.S. state of Minnesota and in Ireland.

“The global electrophysiology market, which is valued at about US \$8 billion, is at a turning point with doctors quickly adopting PFA to treat patients with atrial fibrillation,” said Maura Leahy, Global Product Marketing Manager for minimally invasive solutions at Freudenberg Medical. “We understand the needs of our customers and are longtime partners dealing with the innovative product development and production of catheter-



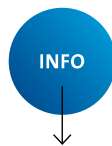
Electrophysiology is a subcategory of neurophysiology that deals with the transmission of electrochemical signals in cells and tissue.

based devices. Our strengths are fast execution, experienced teams of engineers and developers with an understanding of the technology, and the knowledge of what is achievable.”

New technology is fast and safe

Catheter ablation is a minimally invasive intervention. A long flexible tube, or catheter, is inserted through a small incision into the body’s vascular system at the groin to ultimately reach the heart. Short electrical impulses are generated through the catheter. When the diseased cells die, the interference signals are halted and adjacent tissue and organs are not damaged.

Catheter ablations are traditionally carried out with the use of heat or cold. But these methods pose the risk of complications in part due to the physician’s lack of control of the thermal energy. “The new method is much safer and more precise with equally good results.” Leahy said. “Plus, what would normally take one to two hours with traditional catheter techniques can be performed in just 30 minutes, allowing hospitals to treat more patients from a steadily growing global population.”



Atrial fibrillation: About 46 million people live with atrial fibrillation worldwide. The incidence of the disease has increased 33 percent in the past 20 years. Atrial fibrillation is considered an age-related ailment in which the nodes that regulate the heart’s rhythm start to function erratically. The heart’s chambers no longer beat synchronously because chaotic electrical signals are transmitted to them. To this point, the patient’s heartbeat has been regulated with medication or catheter ablations to bring it back to normal.

Normal
sinus rhythm



Dr. Kai Opendwinkel (left) and Daniel Kaltbeitzel with the “Bambi Belt”: Wide-ranging experience in injection molding was essential for the development of the silicone belt.

→ Smart medical devices

At Freudenberg Medical, material expertise and anticipating trends in the medical sector come together. Drawing on their know-how, its experts are helping to digitalize medical devices.

Digital technologies for the healthcare of the future

“Freudenberg Medical has years of manufacturing experience in the field of biocompatible silicone as well as strong expertise in electrical functionalization.”

DR. KAI OPDENWINKEL,
GENERAL MANAGER OF FREUDENBERG MEDICAL EUROPE

Digital technologies are increasingly having an impact on healthcare and individual health behavior. In the field of medical technology, the digitalization of medical devices is a global trend, mirroring other segments of the economy.

Reliable and long-lasting

Working with its customers, Freudenberg Medical is developing smart medical devices. Among other substances, they are made of medical silicone, which insulates electronic components and can be made into an electrically conductive part.

How does it work? Electric current is conducted through the combination of silicone and a conductive filler, enabling the stimulation of targeted areas of the body. The applications include neurostimulation to treat pain or the targeted training of muscle groups. Silicone also insulates electronic com-

ponents and sensors in medical products and protects them from dirt, water and perspiration. This enables devices to operate reliably over long periods. The modification and processing of these materials requires medical knowledge as well as a high level of expertise in materials development and tools.

“Freudenberg Medical has years of manufacturing experience in the field of biocompatible silicone as well as strong expertise in electrical functionalization,” explains Dr. Kai Opdenwinkel, General Manager of Freudenberg Medical in Kaiserslautern, Germany.

Thanks to its technical expertise in injection molding, the company can encapsulate particular electronic components with silicone. Freudenberg Medical is using these solutions to overcome medical challenges and to drive the digitalization of medical technology. —>

“We took advantage of our knowledge to meet the customer’s requirements with specially fabricated tools.”

DANIEL KALTBEITZEL,
HEAD OF ENGINEERING, FREUDENBERG MEDICAL EUROPE

Reliable monitoring without constraints


One special medical challenge is the reliable monitoring of premature infants without negative consequences for their health or development. The Dutch startup Bambi Medical has developed the Bambi Belt, an innovative monitoring system for these infants.

The Bambi Belt replaces cumbersome monitoring with electrodes and wires, substituting

a silicone belt that is kind to the infant’s skin. It consists of a flexible strip conductor encased in various silicones. The sensors are built-in. This especially soft belt can be put on and taken off painlessly. The sensors inside capture the vital functions of the preemie through the skin. Thanks to its wire-free design, the skin-to-skin contact between the parents and the baby is no longer a problem. Studies show that this contact promotes the infant’s psychological and physical development. The Bambi Belt is made from an extremely soft biocompatible material. It adheres to the skin yet can be easily removed.

Freudenberg Medical tapped into its knowledge of materials and processes to help Bambi Medical with the belt’s development and production. Platinum-cured, biocompatible silicone in various degrees of hardness, along with other materials and sensors, are used in the Bambi Belt. In-depth material analysis and numerous tests were performed to ensure that the various materials are compatible with one another and achieve the desired physical characteristics.

“The processing of the materials stood out as the major challenge,” explains Daniel Kaltbeitzel, Head of Engineering at Freudenberg Medical in Kaiserslautern. “To make the belt as comfortable as possible for a baby we have to process very soft materials and have a well-thought-out design, which requires extensive experience.”



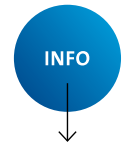
Thanks to the Bambi Belt, premature infants can enjoy skin-to-skin contact without complications.



In this video, see how Freudenberg Medical teamed up with Bambi Medical to develop and manufacture the Bambi Belt passionately and enthusiastically to address an unmet need.



The material developed by Freudenberg Medical guarantees wearing comfort in the oral cavity.



Sleep apnea: Around the world, about 900 million people suffer from sleep apnea, a condition in which breathing stops for short periods during sleep. Aside from snoring and reduced sleep quality, the disruption in breathing poses other risks, such as high blood pressure. One of the most common causes is slack tissue in the nose and throat.

For a good, healthy sleep

London-based Signifier Medical Technologies took on the challenge of developing a device to treat sleep apnea. Freudenberg made a significant contribution to its success.

Working with Freudenberg Medical, Signifier Medical Technologies developed a neuromuscular tongue training device. Controlled with a smartphone app, it is used 20 minutes a day in the oral cavity to stimulate the tongue muscle with slight electric pulses. The device's mouthpiece was manufactured by Freudenberg Medical in Kaiserslautern. Its material consists of electrically conductive silicone that Freudenberg improved specifically for Signifier Medical Technologies.

In addition, Freudenberg Medical developed all of the tools for the mouthpiece's manufacture. "Unlike standard materials, platinum-interlaced, electrically conductive silicone is not flowable and is therefore hard to process.

Regular production processes and tools are not optimized for its special needs and can have a negative effect on conductivity. We took advantage of our knowledge of automation and process technology to meet the customer's requirements with specially fabricated tools," Kaltbeitzel says. "The material that we developed is medically approved," adds Opdenwinkel. "It guarantees wearing comfort inside the oral cavity, contributing to patients' well-being and helping to maintain their health." —



4 questions for ...

→ Innovation in Medical Technology

LARS GERDING
VP TECHNOLOGY AND GENERAL MANAGER
OF THE GLOBAL BUSINESS UNIT SILICONES

Working with and for his customers, Lars drives innovations at Freudenberg Medical that improve the lives of patients worldwide.

01

What is Freudenberg Medical's approach to research and development (R&D)?

To identify the right R&D topics, we consider industry trends, opportunities for growth and our current positioning. Our Centers of Excellence have the lead role for new, groundbreaking technologies, consolidating internal expertise and coordinating cross-facility cooperation. We apply Freudenberg's core competencies such as expertise in materials and processing to the highly regulated medical technology market and make them available to customers and patients.

02

How do you make sure the company can meet customers' requirements now and in the future?

Industry events and customer surveys help us anticipate the needs of the market. Unlike product innovations, which involve the development of new products or services, we focus on how they can be manufactured, supplied and improved. We drive process innovations with technology transfers from other industries. In addition, we not only understand the technology but the clinical application as well.

03

What is the impact of digitalization as a megatrend?

Digitalization has an impact on many levels: For example, medical products such as insulin pumps and catheters are increasingly equipped with sensors. New solutions are needed, and they will pose a challenge to manufacturers since designs are simultaneously being miniaturized. On one hand, we are addressing these trends with materials that have been rendered electrically conductive, and, on the other, with adjustments in our processes. Cooperation with customers is becoming more digital and thus more efficient. We are increasingly turning to virtual reality to train our production staff.

04

What role does cooperation with startups play at Freudenberg Medical?

Startups and creators are frequently the source of excellent ideas that reveal needs in the medical field that have not been addressed. They come to us with a sketch since they lack the design resources and manufacturing know-how that they would otherwise need. With our expertise in **“design for manufacturing,”** we help them realize their ideas. This creates added value for both sides, and it is commonplace for groundbreaking innovations to move quickly into volume production if they are picked up by one of the major medical technology players, even if we start with small volumes during the collaboration.

Design for manufacturing means designing products so that they can be produced efficiently.

→ Automation in medical technology

Quickly and reliably, from idea to market

There is no shortage of ideas for medical devices. But only a small portion becomes a reality. Why is that? The requirements for their approval and manufacture are stringent – after all, human lives are at stake. Automation could be a solution.

Freudenberg Medical is offering its customers configurable automation solutions that can minimize time to market for newly developed medical devices while ensuring the highest quality standards. “Automation makes it possible to adhere to strict quality standards while guaranteeing product safety and reliability. By reducing process variations, we benefit from improved reproducibility as well,” said Michael McGee, Chief Operating Officer at Freudenberg Medical. “Automated processes also promote greater production efficiency and help to reduce waste, which mitigates the effect of rising raw material and labor costs.”

Automation enables innovation

The tight regulations and approval processes for medical devices are a major challenge. “By ruling out human error, automation makes it possible to manufacture, assemble and guarantee the quality of important components for medical devices whose production would otherwise

be difficult or even impossible,” said Tom Diaz, Director of Engineering at Freudenberg Medical in Baldwin Park, in the U.S. state of California.

Focus on patients and customers

Freudenberg Medical has established a Center of Excellence for Automation and Robotics to promote global, cross-functional cooperation and the development of new, ground-breaking technologies. “Our experts are working closely with our customers to achieve the optimal level of automation – from the automation of individual process steps to comprehensive, end-to-end automation,” McGee added. “Together we are constantly pushing the boundaries of what is possible to boost efficiency, precision and quality – for our customers and above all for patients whose health depends on the availability of these devices.”



**MICHAEL MCGEE,
CHIEF OPERATING
OFFICER AT
FREUDENBERG
MEDICAL**

He began his career in the medical technology sector more than 25 years ago and has been loyal to it ever since. McGee joined the management board of Freudenberg Medical in August 2022.

“With configurable automation solutions, we are boosting efficiency, precision and quality in the production of medical devices.”

MICHAEL MCGEE, CHIEF OPERATING OFFICER FREUDENBERG MEDICAL

Virtual reality ...



**SÉAMUS MAGUIRE,
VICE PRESIDENT OF GROWTH
AND LEAN SYSTEMS**

... is only for video games? Far from it! At Freudenberg Medical, operators learn how to manufacture high-precision catheters using VR, hitting takt time 5 times faster and eliminating raw material waste. "Introducing new employees to production is a challenge," says Séamus Maguire. "This new approach now gives our colleagues the opportunity to learn at an individual pace in a virtual environment that mimics every aspect of the process to manufacture this life-saving medical product." VR training builds muscle memory for trainees and educates on materials and equipment terminology.



Scan to read the full article or visit
www.freudenbergmedical.com