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MEDICAL PLASTICS NEWS
— ADVANCING MEDICAL PLASTICS —

Moulder Denroy Group responds to medical face mask needs

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Michael Butler, key accounts manager, Medical, Branson Welding and Assembly at Emerson, shares the story on how the company teamed up with Denroy to create PPE during the pandemic.

Quality Technician Lisa McBride (right) demonstrates Denroy products to Economy Minister Diane Dodds (left) and Health Minister Robin Swann (second left), Chief Executive of Invest NI Kevin Holland and Chief Executive Officer of Denroy Group Kevin McNamee.

At the outbreak of the COVID-19 pandemic, governments, military establishments and healthcare systems everywhere were scrambling to locate suppliers of personal protective equipment (PPE) after demand skyrocketed in spring 2020.

In Northern Ireland, the situation was no different, as Health and Social Care Northern Ireland (HSCNI) confronted the critical shortage. Northern Ireland's health minister, Robin Swann, said: "The demand for PPE in the first surge of the pandemic placed tremendous strain on the health service. We had to urgently consider how best to meet the challenge of protecting our health and social care staff while safely treating COVID-19 patients." To fill the supply gap, HSCNI turned to the region's manufacturers.

At about the same time, Denroy Group, based in Bangor, Northern Ireland, a major designer and producer of injection-moulded products for aerospace, medical, automotive and hair-care products, experienced a significant contraction in its aerospace business due to the pandemic. Seeking ways to redeploy unused engineering and production capacity, Denroy responded to HSCNI's request and obtained approval to rapidly tool up, produce and deliver more than 1 million medical face shields to HSCNI for use by front-line medical workers. During the summer and fall of 2020, the company also decided to develop, produce and market a consumer-focused face mask, called the Bubl. Made of clear, moulded plastic, this washable, reusable mask features two circular filter ports that contain prefabricated filter elements made of layered, nonwoven fibres. The design allows users to replace the filter elements with new elements every few days.

In late 2020, when HSCNI sought to establish a reliable indigenous supply of high-grade medical face masks, Denroy responded with another innovative design, this time aimed at protecting medical and social-care personnel treating high-risk COVID-19 patients. HSCNI officials responded positively, asking Denroy to participate in meetings with medical and clinical personnel to gain insight into and feedback on the face mask design before completing the product's design. HSCNI also agreed to purchase the new face masks in quantity, offering an initial £19.5 million contract to Denroy on the condition that the new masks be certified to BSI and Conformité Européenne (CE) requirements and produced quickly.

A rapidly evolving product design

Medical and clinical personnel in contact with COVID-19 patients require a greater degree of protection than typical surgical masks provide. Such protection is provided by medical-grade face masks that combine a leak-resistant face seal and highly effective filtration of airborne droplets and particles. CE standards define two types: FFP2 face masks (sometimes called respirators) provide a minimum

of 94% particle/droplet filtration with maximum outside air leakage of 8% (comparable to U.S. National Institute for Occupational Safety and Health [NIOSH] N95 masks), while FFP3 masks provide a minimum of 99% particle filtration and maximum leakage of just 2%.

“Designing a high-grade medical face mask is all about balance,” explains Denroy’s CEO Kevin McNamee. “To attain BSI and CE approval, the mask must pass strict testing criteria on filtration, breathability and internal CO2 levels. In addition, it must also provide the highest possible level of comfort and visibility and be simple to fit and remove. Of course, balancing these factors is challenging, since a minor change to improve on one requirement can have a significant effect on others.” He credits medical and clinical experts, together with HSCNI procurement experts, for the “invaluable” advice that helped Denroy finalise the design of the Denpro FFP3 medical face mask.

Instead of the typical FFP3 mask designs that rely on a heat-formed shell made of filter material, the Denpro mask is built around a lightweight, injection-moulded frame that includes holders for four user-adjustable elastic straps. A soft filter “cup” made of four nonwoven fabric layers is bonded onto one side of the frame, while a comfortable, face-hugging thermoplastic elastomer (TPE) foam seal is bonded to the other. The combination gives the Denpro mask a great fit, all-day wearer comfort and plenty of high-performance filtration capacity.

The Denpro mask (left) is built around a lightweight, injection-moulded frame that includes holders for four user-adjustable elastic straps, providing a comfortable, face-hugging fit for all-day use.

Manufacturing challenges

Because of the COVID-19 emergency and the urgent need for PPE, McNamee says that the timelines for every aspect of the Denpro mask development were dramatically compressed, often running concurrently. So, even as engineers sought experts' design input, others were sourcing materials, developing information for CE and BSI certification, and evaluating assembly methods. Meanwhile, a cross-functional product development, manufacturing engineering, and production team was already working to staff, equip and open a new high-volume medical mask manufacturing plant by summer 2021.

"We literally started with a blank screen in terms of production process design, machinery specification and factory layout," McNamee notes. He adds that just as the mask's design relied on advice from medical professionals, its successful production required significant assistance from assembly technology experts. The expertise was essential to helping a Denroy team skilled in injection moulding to learn an unfamiliar technology — ultrasonic plastic welding — then rely on it for rapid, automated assembly of diverse plastics into high-performance PPE.

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For this, Denroy turned to HTE Engineering Services (Dunboyne, Ireland), a company with experience in mask manufacturing, a specialty in assembly systems that utilise plastic welding and, since 2018, an Emerson subsidiary. “Denroy came to us with a prototype product consisting of a filter attached to an injection-moulded frame with an elastomeric face seal. Both the frame and face seal were designed and moulded by Denroy. They asked us to help them develop automated processes and tooling for assembling these parts into finished masks using ultrasonic welding,” says Patrick Wood, HTE managing director. Wood’s first decision was to expand his own team, reaching out to Emerson’s Branson plastic welding and process automation experts based in Europe. While HTE and Branson automation experts worked with Denroy manufacturing engineers to design assembly machinery, Branson welding experts would assist Denroy’s product developers in evaluating and selecting materials and welding processes essential for volume assembly.

“In daily meetings over a period of weeks, and through a series of iterations from Denroy, we kept developing and evaluating weld solutions, weld tooling and equipment configurations as the design and materials evolved,” Wood explained. “The difficulty and pressure of the project were considerable, so it was a roller-coaster ride for everyone. There were a great many questions and issues to be

resolved before decisions about the design of production equipment could be made."

For example, the frame-based medical mask design offered excellent filtration and breathability, since its cup shape allowed for a large surface area of filtering material. But process and machinery designers had to decide how to form the material into a cup shape, how many welds would be required to bond the filter materials together, and whether the same welds would hold the filter to the frame. Similarly, the selection of moulded TPE foam for the face seal ensured outstanding fit and comfort for wearers. However, developing an ultrasonic weld to repeatably bond this soft part to the rounded plastic frame, which includes a tight horseshoe bend around the nose, required intensive weld programming and tooling effort.

Over a period of months, the concurrent product development and assembly efforts yielded results. Low-volume production began with a process that had individual operators making a succession of ultrasonic welds manually, using Branson 2000 Xc ultrasonic welding systems. Then, a first-generation production machine was developed. After further optimisation, a second-generation assembly machine was created, which produces masks with the help of four integrated Branson 2000 Xc ultrasonic welding power supplies and customised weld tooling.

Finished masks are placed on a conveyor and moved to final packing stations. At present, four of these second-generation machines are now in production. Because the company anticipates additional longer-term orders, Wood says that HTE is continuing to consult with Denroy on a third generation of production equipment that will automate part feeding into fully automated production cells.

According to McNamee, "The FFP3 medical mask development, CE approval, tooling, production equipment design and establishment of an entirely new production facility were all conducted at a rapid pace, with the product moving from concept to production in five months. The FFP3 factory, which employs 150 people, is now fully operational with an annual capacity of over 10 million Denpro masks."

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