

New device invented on an attic sewing machine will improve lives of those with stoma bags

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A new device invented on an attic sewing machine is set to revolutionize

the lives of thousands living with stoma bags as well as saving the NHS considerable time and expense following an injection of specialist support from the Medical Device Manufacturing Centre at Heriot-Watt University.

In the UK alone, one in every 400 people undergoing a surgical procedure have a stoma bag to create an opening in the body to discharge waste. The technique is used to treat and manage a range of medical conditions including several cancers, Crohn's disease and bowel incontinence.

While individuals are encouraged to lead a normal life, leaks from bags are common leading to embarrassment and a loss of confidence and dignity.

Stoma bag leaks cost the NHS significant time and money. For in-patients, changing a soiled bed is a 38-step process that can happen multiple times in a day while an operation must be halted to sterilize the area and equipment. Elderly patients cannot be discharged if their bag leaks; this can make unavailable much-needed hospital beds. Skin management is also an ongoing issue.

Now, a woman from South Lanarkshire is set to transform lives with an invention that contains stoma bag leaks, drawing it away from the skin and allowing people time to change their bag without embarrassment.

Working with Heriot-Watt University to have the device listed on prescription, thousands look set to benefit.

Anne Inch and her husband Iain both wear stoma bags. She explains: "Iain was in hospital and in a single day, his bag leaked nine times. Changing hospital sheets has a huge impact on nursing time and Iain was understandably distressed. I went home and designed ConfiPlus using a

disposable bedsheet.

"Because ConfiPlus is so absorbent, the user has time to go and change even if their bag does leak as the waste is absorbed. When I brought my design into the hospital the next day, the nurses couldn't believe how effective it was."

Lisa Crombie helped Anne set up Confidence Plus Ltd, the company behind ConfiPlus.

Lisa added "There hasn't been a shake-up of the products on the market in years and there is little investment going back into design and development. Current accessories try to stop leaks happening in the first place with sticky dressings. However, this means people don't know they've leaked until it's too late, and skin irritation occurs quickly. We want to bring the device to everyone who needs it by making it available on prescription and in care homes but, for a small company like ours, it is a difficult process to navigate the pathways to have the device adopted by the NHS. That is why we have enlisted specialist support from Heriot-Watt University."

Professor Marc Desmulliez, Medical Device Manufacturing Centre (MDMC), Heriot-Watt University said: "We recognize the incredibly life changing potential of this device for both patients and healthcare practitioners, so we are supporting ConfiPlus by helping them to introduce the product into [clinical settings](#) as quickly as possible. Navigating the process of clinical evaluation is difficult and tortuous for new companies. The NHS regulatory landscape is necessarily complex to protect patients, but it also slows down the introduction of products that could save significant money for the NHS, reduce nurse intervention and free hospital beds.

"The MDMC was set up to help people like Anne and Lisa to navigate

the challenging path of medical device regulation and prepare product cases to help new items to become available on prescription. Our support is free to SMEs as a way of supporting innovation in Scotland and beyond. While ConfiPlus is currently available over the counter, we strongly believe that everyone should be able to wear their stoma bag with dignity and it shouldn't be down to financial ability to pay for a product of this type.

"Usually when you make a medical [device](#) for a hospital, you can benchmark it with similar products, but this product is unique. Putting together a clinical evaluation is very difficult for an SME so this is where the MDMC can step in, find the right experts to advise the company, find the right hospital for trials and maximize the chance of adoption quickly. ConfiPlus is the first company to use in Scotland the new tool developed by NICE in order to prepare an effective healthcare technology assessment document."

ConfiPlus is available now to buy confiplus.com.

Provided by Heriot-Watt University

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