

Manufacturer Focus

NeedleCalm improves needle patient experience

Lauren Barber, CEO of NeedleCalm, tells *Manufacturers' Monthly* how she set about developing and commercialising an Australian made medical technology that could drastically reduce the discomfort in patients who experience severe anxiety during needle procedures.



NeedleCalm's Needle Desensitising Device is used to improve the patient experience for those with severe anxiety during needle procedures, such as immunisation.

LAUREN Barber has been a registered nurse for around 12 years, originally trained at the Sydney Adventist Hospital in Wahroonga, NSW. Upon studying cosmetic dermatology and beginning work for a dermatologist in Sydney, she received a needlestick injury during a procedure on a young patient, which required surgery. This was the catalyst for the development of a medical device that could reduce the discomfort associated with needles.

"I started thinking about a lot of the patients that I looked after in the

past and noticed a strong correlation between healthcare avoidance and chronic comorbidities that they had," Barber said. "These patients have often had a poor experience when they were younger with needle procedures that can range from being held down and restrained, having lumbar puncture, watching siblings go through lots of procedures or having type one diabetic parents inject insulin. In my mind, there was a strong view that something needed to be done that was quick and easy for clinicians to use."

Headquartered in Melbourne, the

medical device company NeedleCalm Pty Ltd was set up in 2016 with the intention to develop and commercialise a technology to treat patients that experienced needle-related fear and anxiety.

A clinical trial was conducted with an early 3D printing prototype and Barber joined a medical start up incubator program with a nine-month intensive course. Following the research and development stage and receiving funding from the federal government's Industry Growth Centres Initiative (MTPConnect) and NSW government's Minimum Viable

Product Grant program, NeedleCalm enlisted a local manufacturing company called PMG Engineering to begin production of its first product, which was released onto the Australian market in March 2021.

Needle Desensitising Device

The company's signature product, the Needle Desensitising Device, is a Class One Medical Device approved by the Australian Therapeutic Goods Administration (TGA), which is disposable but retains a long shelf life. It is designed to be used in over 60 per cent of Australia's



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needle procedures carried out each year, including injections, immunisations, venepuncture, and intra venous catheterisations.

The concept behind the device is known as gate control theory, which modulates the perception of pain. By stimulating the skin near the site, the flow of pain signals to the brain are blocked. The key is administering the Needle Desensitising Device in quick succession to ensure the patient registers a cooling, pressurised sensation instead of the needle.

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During the research and development stage, gate control theory was originally implemented in the NeedleCalm product through an all-natural liquid that produced a sensation similar to the pain relief product, Deep Heat rub. The liquid was inserted into a small capsule and once the product was applied to the patient, the pressure would break the capsule and distribute the liquid to the area.

However, Barber found that this design was not feasible.

"When I looked into the manufacturing process to make this, it was just a huge headache regarding the back end, with the tooling that would have been required," she said.

"Another barrier we faced when

we started testing it on a couple of quite young people, they were getting more distressed about the heat sensation staying on the skin instead of the needle. It was just something that we couldn't deactivate, like the effects of Tiger Balm or Dencorub where you can't get it off quickly."

This led to the final product, which harnessed a cooling effect rather than heated.

"We started looking at a more cooling aspect of NeedleCalm and put it in the fridge, put it in the freezer, experimented with different layers and different thicknesses," Barber said. "After that, we found the materials and appropriate tooling to get the final version of NeedleCalm ready for large scale manufacturing."

As undertaken by PMG Engineering, the manufacturing process for the final version of the Needle Desensitising Device – while not automated – is quite simple.

"It's all done by hand and PMG Engineering already had all the tooling in their factory. It's an injection moulded kind of process," Barber said. "There's two layers: first, they make the inner layer and then the over mould, and they can do that quite quickly. Then it's all put together by hand with the tape and then heat is sealed in the little packet and then packed. The whole process needed to be simple."

Target market

During its first year in the medical technology market, Barber has found that NeedleCalm has most benefitted teenagers between 14 and 19 years of age. However, there have been many



NeedleCalm CEO, Lauren Barber.

adults and people from all walks of life who have expressed interest in using the product.

"It's so variable; I'd say teenagers are definitely a big patient cohort, although I've had a surprising number of adults and older gentleman get in touch to use NeedleCalm," Barber said. "In saying that, most people who are over 65 years old have already had so much exposure to different procedures and operations and there's really no benefit for them and they find a needle procedure to be tolerable."

"But when dealing with issues like dementia and Alzheimer's, you do often get a heightened sensitivity for pain, and they usually need to have anti-coagulation injections in hospital; in that case it's beneficial

for them. Even people who have tattoos, who you wouldn't guess would have a needle phobia – I've done a bit of research into that recently and it's a different type of pain for them. That whole process is more of a kind of therapy for them."

As there are many main procedures where the NeedleCalm device can be applied, it can even be used alongside highly sterilised procedures such as epidurals for women in labour.

Case studies

There have been several successful cases where NeedleCalm has been able to facilitate procedures for people with severe needle phobias. One 23-year-old female suffered from such a phobia and exhibited

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adverse responses including anxiety, fainting, sweating, nausea, and physical resistance. This had a negative impact on her general health as she was not able to receive regular blood tests to monitor health conditions and had not received several immunisations.

"This girl was just suffering – a common theme with a lot of our patients recently is that they've lost their job or been asked to stay on annual leave because they can't get the COVID vaccinations," Barber said. "We had a few discussions with her and sometimes with her parents. The decision is usually made by the patient to make the next step of going to get their procedure done and their GPs are well aware of their problem. But with patients like her, it just takes a little bit of time for them to kind of wrap their head around it, see the product, and then we'll train the nurse or doctor to use it."

With NeedleCalm's help, the patient attended her GP for a vaccination in October 2021 and a registered nurse administered the device during the procedure, in which she reported feeling no pain. Since then, she has been able to have further vaccinations and blood tests with the device's aid. She now provides guidance to other patients as part of a support group.

Another 19-year-old patient had not received any immunisations since she was 6 years old.



"She was 19 at the time when we helped her, and we helped her with her COVID vaccination," Barber said. "She just did so well. It was such a great thing for her because she met these nurses that were so experienced and they do a lot of vaccinations day-in, day-out and she felt comfortable enough to have her vaccination using NeedleCalm."

The patient's positive experience supplied her with the confidence to book her next appointment for the second COVID vaccination and subsequent catch-up vaccinations.

"She changed as soon as she went back out into the waiting room, she

was a different person beforehand," Barber said. "She was really down, kind of apathetic, I'd say possibly a little bit depressed. Then she was just on a complete high afterwards, smiling and telling everyone what had happened, and everyone was so proud of her."

Examples of how NeedleCalm has had a positive impact on improving patient experience has been one of the biggest highlights for Barber throughout the process of producing the Needle Desensitising Device.

"It's been a tough journey and I've learned a lot throughout the process," she said. "I think speaking to patients, explaining to them how NeedleCalm works and getting them in for treatment has been the biggest gift following the launch."

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Good Design Award winner

In October 2021, NeedleCalm won a prestigious international Good Design Award in the Product Design Category that recognised the Needle Desensitising Device's outstanding design and innovation.

The Good Design Awards jury commented: "Given about one in 10 people are afraid of needles, this is a positive approach to overcoming a common problem. The discreet

aesthetics of the device and its similarity to a sticky plaster may assist in uptake; and the technique of activating alternate pain receptor pathways is clever too."

More recently, NeedleCalm was awarded a judge commendation at the Consumer Healthcare Products (CHP) Australia 2021 Diamond Awards for Outstanding and Innovative New Consumer Healthcare Product.

The company has also been recognised as a finalist in various other awards for its innovative concepts, such as the Local Business Awards and Medtronic Eureka Pitch in 2020, and the MTAA Women in Med Tech in 2019.

The future of NeedleCalm

Barber is also aiming to release three new products by the end of 2022, to further enhance the patient experience. NeedleCalm also has exciting plans to launch internationally.

"I've got my next two products 80 per cent ready to go, which are more aimed at children," she said. "And then we have a third product which we will need a bit more income for and the necessary manufacturing tools. We're also going overseas into the US and the UK next!"

There are also plans for more in-depth research around how NeedleCalm works in different parts of the body and into how it can be used alongside procedures which require port-a-caths. With a vast range of needle procedures that are performed each year, both in Australia and worldwide, there are many avenues that NeedleCalm could take as a business in the future. **M**



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