

Press release

Monitoring premature babies without causing discomfort

- **Freudenberg Medical manufactures innovative silicone monitoring belt Bambi Belt for premature babies**
- **Initial studies in hospitals a success**

Weinheim, November 16, 2021. November 17 is World Prematurity Day. A World Health Organization report states that worldwide roughly 15 million babies are born pre-term each year. Oftentimes, they spend up to 42 days in a neonatal intensive care unit where their vital signs can be kept under strict medical observation. Since monitoring electrodes and a separation from the mother can lead to discomfort and stress, half of all pre-terms go on to develop concentration problems and cognitive impairments. In 2008, pediatrician and neonatologist, Sidarto Bambang Oetomo, came up with an idea for a skin-friendly monitoring belt. Today, he runs the Bambi Belt enterprise in Eindhoven, the Netherlands, with his son, Fabio Bambang Oetomo, and 13 employees. “It’s been a long journey. But a product that improves the lives of so many premature babies is worth every effort,” says Fabio Bambang Oetomo. To create the first prototypes, the Freudenberg Medical team were on hand to support in the belt’s manufacture with material expertise as well as medical technology process and product knowledge. Small series and large quantities are also planned.

Being cable-free, the innovative Bambi belt allows parents to remove their premature baby from an incubator without causing injury to their baby’s skin. The belt itself is formed from a narrow band placed around the baby’s chest. Sensors send signals to a

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portable monitor. For premature babies weighing a mere 500 or 600 grams whose skin is still too sensitive for adhesive electrodes, the band makes it possible to easily monitor the heart muscle's electrical activity and measures respiration activity. Prior to this, in the absence of adhesive-free electrodes on the market or electrodes specifically developed for sensitive skin, a patch on the baby's foot had to be used to monitor the heart rate and oxygen content in the blood of such babies while in hospital – often leading to injury or infection.

Freudenberg supports with process and material knowhow

“The belt is made of skin-friendly silicone and uses dry electrodes. Developing the product was a challenge, since when it comes to materials, process technology and production, medical technology product specifications are demanding. The Freudenberg Medical team in Kaiserslautern supported us with ideas, material knowhow and modern production technology,” says Bambang Oetomo. “Teamwork enabled us to achieve our goal.” Development took several months. “When it came to the prototypes and first samples, we built special tools for the belts and tested different silicones which we can produce in four sizes. A special manual production process is used in their manufacture,” says Rudolf Dering, Project Engineer Molding at Freudenberg Medical in Kaiserslautern, Germany, referring to the collaboration.

A long journey from idea to product

Thirteen years passed from the initial idea for a skin-friendly monitoring belt in 2008 to the present day. During this time, the enterprise was founded in 2016, Fabio Bambang Oetomo who, as a young family man, had left his job at a large company, joined the enterprise, several years of development work were undertaken, employees were hired, and the first clinical studies and the search for manufacturing partners conducted. Along the way, there were also setbacks. Potential partners backed out, employees didn't

always receive their salaries and developments were delayed. But father and son continued to believe in their idea, as did financially strong private investors and the European Union that co-financed the project through the Horizon 2020 SME program. At the prototype's presentation, parents, hospital staff and clinics were thrilled. After two successful trials, the product is expected to be launched next year, and certification is awaited.

The Bambi Belt has been tested in two studies in Dutch hospitals, including at Amsterdam University Hospital. The study monitored premature babies simultaneously using the current monitoring device with conventional adhesive electrodes and the wireless Bambi Belt. The results were very good: Less stress for the premature babies and reliable monitoring.

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