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ASX Announcement

FDA clearance for NovoSorb MTX

PolyNovo is excited to announce it has received FDA 510(k) clearance for NovoSorb® MTX (“MTX”), a major new product innovation for soft tissue regeneration for the management of complex wounds.

MTX leverages the technology platform underpinning the clinical success of BTM, but without a sealing membrane. The product was developed to satisfy clinician demand for a product for use in indications where the sealing membrane is not required. MTX is complimentary to BTM and expands PolyNovo’s advanced wound care portfolio for the treatment of soft tissue deficits. BTM and MTX are complementary, and it is expected that clinicians will use both products.

Development of MTX was informed by clinical experience with NovoSorb BTM, where early removal of the sealing membrane is followed by rapid formation of granulation tissue and wound closure. With MTX, the wound can be closed either with a skin graft or allowed to heal by contraction and formation of an epithelial layer. This can simplify wound management and presents wider applications for common wound healing problems.

MTX is indicated for use in partial and full thickness wounds, pressure ulcers, venous ulcers, chronic and vascular ulcers, diabetic ulcers, and surgical and trauma wounds, offering clinicians greater versatility in wound management. The MTX product portfolio expands PolyNovo’s addressable market in the U.S. by an estimated \$AU500M.

Associate Professor Marcus Wagstaff, PolyNovo Medical Director, and Plastic Surgeon, said, “*MTX is a synthetic dermal substitute comprised of NovoSorb foam providing a scaffold for wound healing across deep, complex structures such as bone and tendon. For wounds that do not require temporising or protection from contraction, there is a clear clinical need for MTX. It is best suited in cases where wound contraction and reduced time to healing are preferred, such as diabetic and venous ulcers, and smaller traumatic or post-surgical wounds (for example after excision of skin cancer). MTX promises clinicians ease of use and simplicity as a one-step procedure.*”

Chief Executive Officer, Swami Raote said “*The creation of MTX is an exciting example of surgeon led product development that opens a significant new market for us. We are proud to bring MTX to U.S. surgeons and patients, and believe a product specifically designed for use in a single-stage procedure will leverage and expand our penetration of the advanced wound care space. We expect clinicians to carry BTM and MTX and provide them a richer tool kit for patient care. We aim to quickly put MTX in the hands of Key Opinion Leader surgeons.*”

This announcement has been authorised by PolyNovo Company Secretary Jan-Marcel Gielen.

About NovoSorb® MTX

NovoSorb MTX utilizes PolyNovo's NovoSorb platform technology that has been shown to support the rapid in-growth and deposition of healthy vascularized tissue. The unique NovoSorb technology is protected with over 40 patents, and clinical efficacy in the management of complex wounds demonstrated in over 65 investigative, peer-reviewed, and published articles. This new FDA 510(k) clearance distinguishes PolyNovo as the synthetic skin substitute leader by increasing the versatility of its advanced wound care product offerings.

The initial NovoSorb MTX offering comprises an engineered 2-mm thick synthetic dermal scaffold **without** a sealing membrane. It is designed to support the rapid in-growth and deposition of vascularized tissue and allow for wound closure by either applying a skin graft or allowing to heal by contraction and formation of an epithelial layer. This provides clinicians expanded options in managing complex wounds to definitive closure.

About PolyNovo®

PolyNovo is a disruptive medical device company, focused on Advanced Wound Care. PolyNovo is an Australian based medical device company that designs, develops, and manufactures dermal regeneration solutions (NovoSorb BTM) using its patented NovoSorb biodegradable polymer technology. Our development program covers Breast Sling, Hernia, and Orthopedic applications. For further information and market presentations see www.polynovo.com

About NovoSorb®

NovoSorb® is a novel range of bio-resorbable polymers that can be produced in many formats including, film, fiber, foam, and coatings. NovoSorb's unique properties provide excellent biocompatibility, control over physical properties, and programmable bio-resorption profile. NovoSorb® BTM is a dermal scaffold for the regeneration of the dermis when lost through extensive surgery or burn.