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FDA clearance for PolyNovo's wound care innovation

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The US regulator approves Australia's PolyNovo's NovoSorb MTX



Australia's PolyNovo has received US FDA 510(k) clearance for NovoSorb 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 US by an estimated $AU500M.