

19 March 2025

ASX Announcement

FDA 510k Clearance for NovoSorb MTX (up to 6 mm)

TGA and India CDSCO Clearance for NovoSorb MTX (2 mm)

PolyNovo Limited (**PolyNovo** or the **Company**) is pleased to announce three key commercial milestones for the NovoSorb MTX product portfolio.

NovoSorb MTX (up to 6 mm) has received FDA 510k clearance with the addition of new indications for tunneled/undermined wounds. This approval will offer healthcare professionals greater versatility in management of deep soft tissue defects and expand the use of NovoSorb MTX into plastic and reconstructive surgery applications. The Company will work towards a market release to introduce the product to the U.S., leveraging the successful model first used for NovoSorb MTX (2 mm).

In addition, NovoSorb MTX with a 2 mm thickness has now been approved in Australia after inclusion in the Australian Register for Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA) and can now be marketed and sold in Australia.

Clearance for importation of NovoSorb MTX with a 2 mm thickness has also been received from the India CDSCO (Central Drugs Standard Control Organisation).

NovoSorb MTX leverages the technology platform underpinning the clinical success of NovoSorb 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.

Chairman, David Williams said: "The availability of the product in Australia and elsewhere will be welcome news to Plastic Surgeons, amongst others."

This announcement has been authorised by PolyNovo General Counsel & Company Secretary, Lior Harel.

About PolyNovo®

PolyNovo is a disruptive ASX 200 medical technology company, based out of Melbourne, Australia. Its products simplify management of acute complex wounds, redefining healing with meaningfully differentiated patient outcomes across multiple wound etiologies. After treating 67,000+ patients across 46 countries, the company is investing for growth via new products, indications, and markets. For more information see polynovo.com.

About NovoSorb®

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