

Changing lives

The future of synthetic biodegradable medical devices



Regenerating tissue. Changing lives.

Biodegradable technology

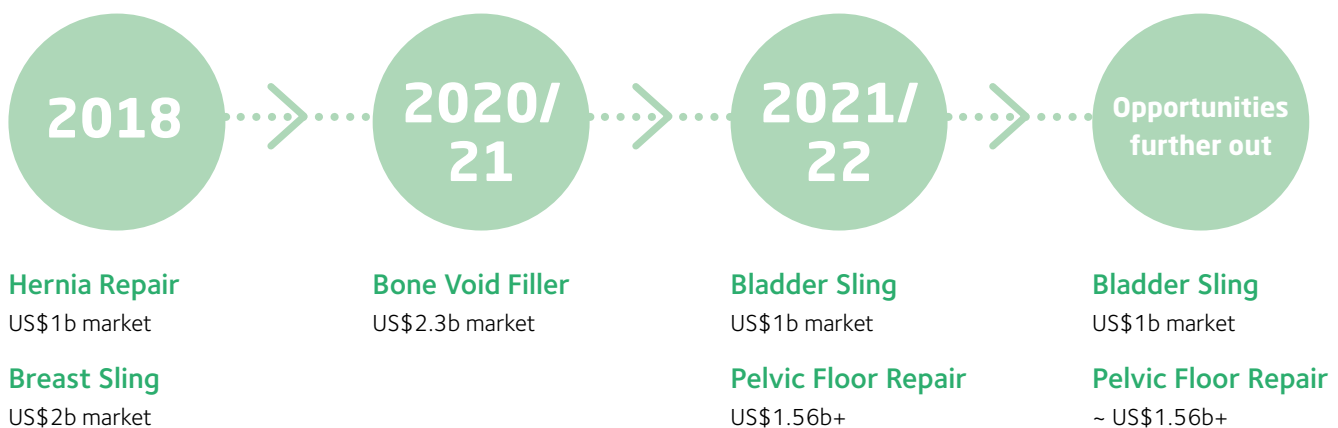
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These synthetic polymers were commonly adapted for medical devices from other areas of science often leading to less than optimum performance.

By the 1990s researchers at the Australian Commonwealth Scientific & Industrial Research Organization (CSIRO) were focusing on shifting the emphasis from forming permanent synthetic polymer implants to developing devices that would assist the body in using its own mechanisms to repair damaged tissue. It would take them over four years to develop a family of safe biodegradable polyurethanes for use in biomedical applications that had only previously been addressed with less than ideal synthetics or limited collagen applications.

Going forward



A portrait of a middle-aged man with short, dark hair, a beard, and glasses. He is wearing a dark blue button-down shirt with a subtle geometric pattern. He is standing outdoors with green foliage in the background. The image is framed with rounded corners and has a dark blue shape in the top right and a teal shape in the bottom left.

“After my surgery I can now
get on with living instead
of just surviving.”

John – NovoSorb BTM recipient

PolyNovo takes the lead

The team at PolyNovo was charged with the responsibility of building on the radical NovoSorb technology and turning it into game changing medical devices.

They started by developing NovoPore™, a wound interface used in the advanced wound healing process known as Negative Pressure Wound Therapy, this was followed by NovoSorb BTM a Biodegradable Temporizing Matrix that has been designed to improve cosmetic and functional outcomes associated with large, deep surgical wounds.

These two developments have been the main recipients of time invested by the Executive team so far. This investment, coupled with extensive market research, has resulted in the identification of numerous applications for the NovoSorb technology. These new applications for NovoSorb will address a strong demand for product innovation in biodegradable tissue scaffolding from within the medical profession.

Expansive production development and successful regulatory approval applications put PolyNovo in an ideal situation to benefit from this demand for an innovative and lateral approach that will match the pace of medical advancement.

2004

PolyNovo incorporated
(ex-CSIRO)

2006

NovoSkin feasibility
study

2008

New research and production
facility established

2015

New CEO appointed
Commercial Scientist appointed
Addition of regulatory staff
Factory expansion
BTM CE Mark trials commence
Royal Adelaide Hospital trial – patient
enrollment concluded BRDA
Contract to conduct 5-year
clinical program with BTM. This will
lead to a PMA filing with US FDA.
Achieved US FDA 510(k) approval
for BTM use in Surgical Wounds

2014

NovoPore receives 510(k)
and CE Mark approvals
Royal Adelaide Hospital BTM
burn trial commences

2013

First BTM human study
(Royal Adelaide Hospital)

2011

Feasibility study in NovoPore™
(NPWT)

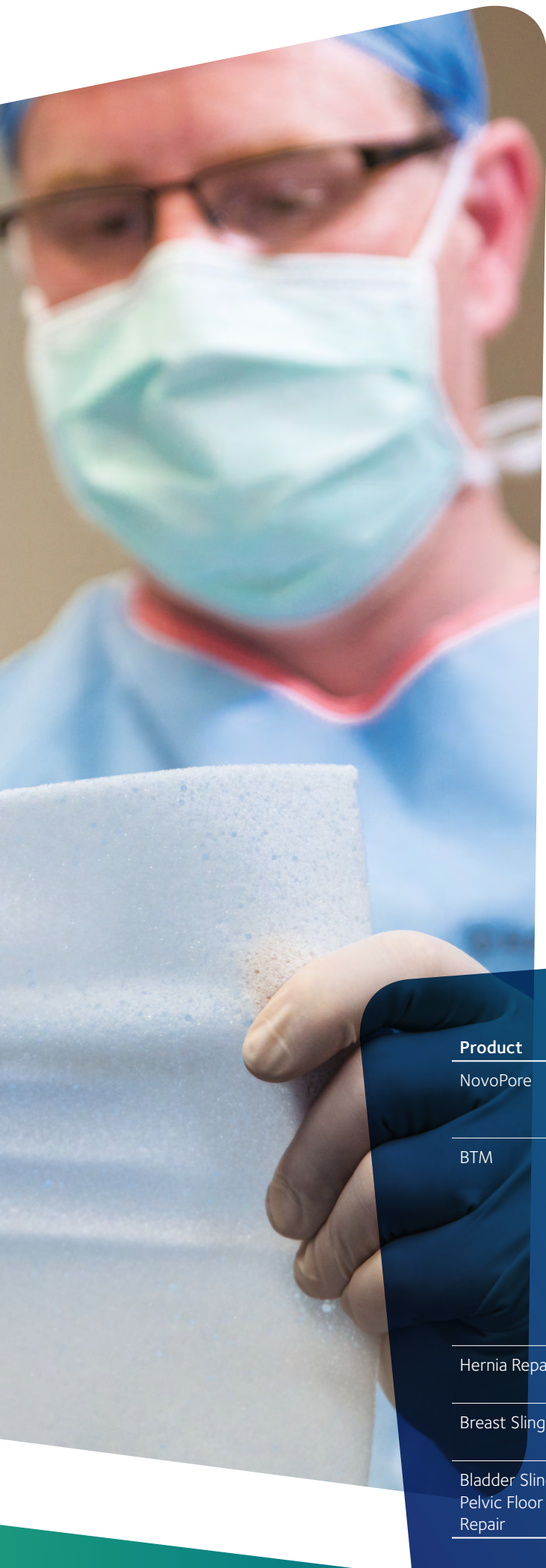
2010

NovoSkin is incorporated

BTM - Innovates the standard

Note the lack of scar/contracture and topography.





NovoSorb changes the rules

Unique and versatile

NovoSorb is a biodegradable polymer like no other. Unlike current polymers filling the space of Tissue Scaffolds (TS), NovoSorb technology has moved at a much advanced pace. For the first time in the history of TS we have the capacity to reformulate our polymer to the specific needs of each application providing various degradation rates. Combine this amazing leap forward in technology with the added benefit of a low risk of sensitization and a material that has been designed to be fully degrading and you have changed the game.

NovoSorb has a broad range of potential biomedical applications, particularly in vascular disease treatment, healing bone fractures and damaged cartilage, tissue engineering, wound care and drug delivery.

Product formats for NovoSorb are varied and cover foams, laminates, thermoplastics, injection molding, filament extrusion to spray-on or dipping applications in other implantable devices. All forms of NovoSorb are patented as Eluting Polymers.

Development trajectory

PolyNovo is heavily focused on product development and delivering those products to growing markets in both the US and Europe as well as the Asia Pacific region. The patented NovoSorb technology offers significant opportunities with a scalable production process and difficult to reverse engineer.

An extensive amount of product development is in the PolyNovo pipeline with an intense amount of commercial activity planned over the next few years (See Table 1). We will be targeting markets currently valued in excess of US\$7.6b.

Product	Market Size	Commercial Activities
NovoPore	~ \$450m – foam and gauze component	Discussions with multinationals building their business case, agreement anticipated 2016.
BTM	~ \$800m Surgical wounds ~ \$80m Full thickness burns	In discussion with interested parties for the US/Canada rights – first sales for Surgical wounds application in 2016. Acquiring CE Mark (expected end 2017) with sales in 2018. EU commercial rights negotiations throughout 2016.
Hernia Repair	~ \$1b	Refining design, working with Key Opinion Leaders.
Breast Sling	~ \$2b	Refining design, working with Key Opinion Leaders.
Bladder Sling/ Pelvic Floor Repair	~ \$1.56b+	Early design specifications with multinational collaboration

Clinical and regulatory activities

FDA and CE Mark registration status

Current, regulatory registrations cover NovoPore (a Negative Pressure Wound Therapy dressing) and NovoSorb BTM for application in surgical wounds. FDA and CE Mark registrations for broader applications are pending (See table 2). New applications expected to be lodged will cover NovoSorb product developments in the areas of hernia repair, breast slings, bladder slings, and pelvic floor repair (see pipeline details on back page). Premarket Approval Application (PMA) funding for the use of NovoSorb BTM in full thickness burns has been secured and the required clinical trials to meet FDA PMA requirements are underway.

Table 2

Product	Market Size	Commercial Activities
NovoPore™	Negative Pressure Wound Therapy	Acquired CE Mark & FDA 510(k)
BTM	Surgical Wounds	Acquired FDA 510(k) Seeking CE Mark (eta end 2017)
BTM	Full Thickness Burns	Seeking CE Mark (eta 2017/18) Seeking FDA PMA (eta 2022)
Hernia Repair	Surgical Repair of Hernias	Planned application FDA 510(k) pathway ~ 2018 Planned application CE Mark clinical ~ 2018
Bladder Sling/Pelvic Floor Repair	Incontinence and Pelvic Floor Repair	Planned application FDA 510(k) 2021/22 Planned application CE Mark 2021/22

BTM Clinical Studies so far...

Studies undertaken at the Royal Adelaide Hospital conclude that, when implanted in the human body, NovoSorb BTM successfully facilitates neovascularization and integration¹, minimal longterm scarring, and delivers superior cosmetic outcomes².

Patients in the studies required free flap reconstruction creating anterolateral thigh flap, fibular osseocutaneous flap, or radial/ulnar forearm (RF/UF) flap donor sites. Reconstruction was a 2-stage procedure using NovoSorb BTM to form a neodermis, followed by definitive closure with an autologous split-skin graft. Integration was complete and uncomplicated in every case (See Table 3) including the well timed delamination which occurred in one piece and in one action². Integrated BTM sustained successful graft-take in all patients¹ with improved long-term scar outcome². Split-skin over-grafting was successful and uncomplicated with no infection and degradation was complete within 12 months².

Conclusion: NovoSorb BTM integrates well in humans providing a strong neo-vascular bed and appears resilient in the presence of infection. The split-skin over-grafting¹ takes quickly and provides an improved long-term scar result with minimum contracture².

Table 3. Patient age, flap type, complications, BTM integration, day of grafting, graft take and degree of wound contracture at the last reading (days post-implantation).

Patient	Age (Year)	Flap	Complications	% BTM Integration	Graft Day	% Wound Area at Grafting	% Take	% Initial Wound Are at Last Reading (Days)
1	63	FOC	Nil	100	34	103.3	100	102.36 (367)
2	62	RF	Nil	100	34	103.94	100	69.08 (424)
3	65	FOC	Nil	100	40	130.60	100	103.56 (391)
4	62	RF	Lost to follow-up after day 86	100	43	93.13	100	70.45 (86)
5	51	RF	Died of carotid blow-out after day 12					
6	61	RF	Nil	100	33	114.58	100	70.31 (378)
7	48	RF	Nil	100	36	100	100	73.10 (364)
8	50	RF	Died of local recurrence after day 236	100	29	88.15	100	61.67 (236)
9	55	RF	Nil	100	36	96.86	100	70.16 (362)
10	68	RF	Died of local recurrence after day 224	100	34	96.41	100	63.59 (224)

BTM indicates biodegradable temporizing matrix; FOC, fibular osseocutaneous, and RF, radial forearm.

The people of PolyNovo

PolyNovo Board

Chairman

David Williams

An experienced Director and Investment Banker, David possesses over 25 years' experience working with and advising ASX listed companies in the food, medical device and pharmaceutical sectors. He specializes in mergers and acquisitions, capital raising and has an impressive record in business development and strategy.

Non-Executive Director

Dr David McQuillan

David's expertise covers technical, medical, scientific, regulatory knowledge, merger and acquisition. He has held positions as Vice-President for R&D, Senior Vice President of Advanced Research & Technology (KCI), and Chief Science Officer (TELA Bio). He currently serves as an Operating Partner of 1315 Capital.

Non-Executive Director

Max Johnston

Max held the position of President and Chief Executive Officer (Johnson & Johnson Pacific), and prior to that Director of Research (Johnson & Johnson) as well as senior roles with Diageo and Unilever in Europe. Max's extensive experience spans both Western and Central-Eastern Europe, Africa as well as Asia-Pacific.

Non-Executive Director

Bruce Rathie

As Senior In-house Counsel (Bell Resources Limited) and Head of the Industrial Franchise Group (SalomonSmith Barney) Bruce has extensive legal experience. Currently Chairman of Eftpos Payments Australia Limited, Bruce has held Executive Chairman and Non-Executive Director roles in the finance and medical device space for over 15 years.

Non-Executive Director

Philip Powell

Philip spent 10 years in senior financial roles at OAMPS Ltd, a former ASX listed financial services group and 10 years in audit with Arthur Andersen & Co. in Melbourne, Sydney and Los Angeles. He has been involved in numerous IPO engagements, valuations and venture capital related raisings.

Non-Executive Director

Leon Hoare

Leon's career spans 24 years in senior roles with Smith & Nephew ANZ & APAC. His roles with this medical devices multinational included Managing Director (Smith & Nephew ANZ), Regional President (Smith & Nephew APAC, Advanced Wound Management). Leon also held the position of Vice-Chair (MTAA), Australia's peak medical device body.

PolyNovo Senior Executives

Chief Executive Officer

Paul Brennan

Paul holds a Masters of Business Administration (MBA) and a Bachelor of Science (Nursing) degree. He has directed the marketing, global strategy, new product development and regulatory processes for a number of leading medical products and devices organizations in the Asia-Pacific region. Paul also has an intimate knowledge of the manufacturing/production processes. His most recent role, prior to joining PolyNovo in February 2015, was as Marketing Director, Australia & New Zealand (Smith & Nephew) this also carried the responsibility of Sales Director, New Zealand.

CFO and Company Secretary

Ms Andrea Goldie CPA

Andrea is a Chartered Accountant, Chartered Tax Adviser and holds a Bachelors of Economics, Finance and a MBA. She has over 13 year's corporate governance experience with multinational companies within the Pharmaceutical and Health-care industries located in a number of geographic regions including Europe, Middle East, Africa, Asia Pacific and North America. Andrea was appointed Company Secretary and Chief Financial Officer (CFO) of PolyNovo in October 2015.

Operational Team and Capabilities

PolyNovo operates with a strong technical team headed up by Dr Tim Moore, Principal Scientist.

Tim is co-inventor of some of the variants of NovoSorb and also developed a novel range of biodegradable chain extenders now included in a number of PolyNovo patents. Tim has been with PolyNovo since it was established he holds the responsibility for the maintenance of the extensive intellectual property portfolio held by PolyNovo.

Paul comes with an impressive record, spanning over 30 years, heading up highly successful research and development teams. His ability to transition newly developed products into large scale production places Paul in a very select group of research scientists and puts PolyNovo in a great position to benefit from this rare level of expertise. Paul's focus is to scale up production and drive efficiencies within production processes.

The operational team's capabilities include:

- 3 full-time Regulatory Managers
- 2 full-time Development Scientists
- 2 Clinical Managers
- 1 full-time USA-based Project Manager, overseeing the BARDA/PMA program
- 1 full-time Quality Manager

Our team is expanding as we invest in the resources required to fully commercialize our product pipeline.



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References

1. Wagstaff MJD, Schmitt BJ, Coghlan P, Finkemeyer PJ, Caplash Y, and Greenwood JE. A Biodegradable Polyurethane Dermal Matrix in Reconstruction of Free Flap Donor Sites: A Pilot Study. *ePlasty*..2015 2. Wagstaff MJD, Schmitt BJ, Caplash Y, and Greenwood JE. Free Flap Donor Site Reconstruction: A Prospective Case Series Using an Optimized Polyurethane Biodegradable Temporizing Matrix. *ePlasty*..2015

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Trading

Share registry

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Auditors

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Securities Exchange

PolyNovo shares are
quoted on ASX Limited
(ASX Code: PNV)

For more detail about the company's governance and financial results please visit our website at www.polynovo.com.au and click through to Investor Centre.