South Australian Policy Advisory Committee on Technology (SAPACT)

Health Technology Assessment (HTA) Decision Summary

Government of South Australia

SA Health

NovoSorb® Biodegradable Temporising Matrix (BTM) for Treating Burns and Complex Wounds

SAPACT MEETING DATES	35th and 18th SAPACT Meetings (29 November 2024 and 7 June 2019)
APPLICATION #	1919
TECHNOLOGY	NovoSorb® BTM (PolyNovo Biomaterials Pty Ltd, Melbourne, Australia) *The primary function of the NovoSorb BTM is to 'temporise' wounds by affording physiological closure through reduction of trans-epidermal water loss.*
TECHNOLOGY CLASSIFICATION	TGA class III high-risk
PATIENT INDICATION (TGA)	NovoSorb BTM for use wherever the skin dermis is lost, regardless of (1) causes e.g. trauma, surgical removal, wounds or burns and (2) severity.

SAPACT DECISION

☒ Recommended for clinical use with no further need for assessment.

Background

Since the applicant's last clinical outcomes report in January 2022, SAPACT has recommended ongoing monitoring of the technology to collect more robust data and further assess its efficacy. The applicant has now committed to providing clinical outcome results from South Australian patients and pertinent international evidence. This will be delivered alongside SAPACT's five-year evidence update (2019-2024).

2024 SAPACT Advisory Recommendations

Following a thorough review of both local and international evidence, SAPACT recommends that Novosorb BTM can be integrated into routine clinical practice for treating burns and complex wounds within SA Health. SAPACT recognizes Novosorb BTM's demonstrated positive outcomes in complex wound and burn care, offering a safe and effective solution for complex cases. The Committee also recognized the challenges in conducting RCTs and comparative studies in this patient cohort due to ethical, logistical, and clinical factors.

2024 SAPACT Evidence Review Conclusion

Novosorb BTM is supported by a fast-growing international evidence base, expanding from 35 patients in 8 studies (2019) to over thousands of patients in about 100 studies (2024). While comparative studies and RCTs are lacking, a large number of case-series and case reports across the world have consistently demonstrated positive safety and clinical outcomes, including high integration rates, low infection and complication rates, as well as successful grafting and improved scar quality. The international evidence has also described expanded clinical indications across diverse patient groups and wound types, including acute, chronic and high-risk wounds and in immunocompromised patients and those with comorbidities. Current evidence gaps included limited data for paediatric populations, extensive burns (>50% total body surface area (TBSA)), and lack of reported long-term outcomes beyond 12 months.

2019 SAPACT Advisory Recommendations

Burns and complex wounds represent a challenging and important area of patient care and BTM has the potential to improve patient outcomes. Based on the evaluation of safety, clinical-effectiveness, cost-effectiveness and budget impact, SAPACT recommends the conditional approval of the NovoSorb BTM for 25 patients (10 burns patients and 15 complex wounds patients) for the first 12 months at CALHN. The applicant should report clinical outcomes of the patients in a 12-month follow-up report to SAPACT. Any other updated published evidence, including the results (available end of 2019) from the BARDA Feasibility Burn Study and the Australian case-series study (ACTRN12615000405516) should be submitted to SAPACT for review. SAPACT notes that the NovoSorb BTM is price equivalent to the Integra dermal template (a bovine collagen I base substitute) per square centimetre. For procurement efficiencies in SA Health, SAPACT recommends that SA Health Procurement considers a price negotiation process for the NovoSorb BTM in comparison with the Integra and any other alternatives.

2019 SAPACT Evidence Review

Emerging low level descriptive evidence for NovoSorb BTM found favourable and safe short-term device and clinical performance in majority of the limited number of patients across few clinical indications. However, the study designs did not allow for the validation of the clinical effectiveness of NovoSorb BTM. There remained uncertainty around long term benefits and risks to patients. High quality controlled clinical trials are recommended to establish the comparative safety, clinical-effectiveness and cost-effectiveness of this technology.

REGULATORY APPROVALS

☒ **ARTG**: 14/08/2018	☒ **US FDA**: 8/11/2017 Note: FDA-approved only for clinical indications (i.e. surgical wounds) outside of full thickness burns.	☒ **EU CE mark**: 13/12/2019 UK, Ireland and EU

ARTG ID: 308217 PolyNovo Biomaterials Pty Ltd - NovoSorb BTM - Dressing, absorbable

ARTG functional description: The device is a sterile, fully synthetic biodegradable temporary skin substitute intended to temporize dermal injuries, where the dermis has been lost, and to facilitate dermal repair and generate a neodermis. The device is implanted and stapled/ sutured into a debrided wound bed and integrates through vascular and cellular infiltration. The device biodegrades through hydrolysis and is eventually fully resorbed in the body. The physician removes the sealing membrane for appropriate intervention.

Sizes (cm): 20x40; 10x20; 10x10

QUALITY OF EVIDENCE

Quality of Evidence	Local consultations and inputs with the Chief Applicant also informed the SAPACT Advisory Recommendations.

	For the 2024 evidence update, the search strategy and study screening were performed using the same 33 databases as in 2019. A review of bibliographic references was also conducted. No RCTs and comparative studies (NHMRC Level I-III evidence) were identified. Most studies remain descriptive (case-series and case reports) and a few observational single-arm cohort studies (NHMRC Level V and IV respectively), reflecting inherent challenges in conducting comparative trials in complex wounds and burns care. Since the 2019 SAPACT evaluation, the evidence base has expanded with two new systematic reviews—Fruergaard 2025 and Lane 2024. These reviews encompassed larger patient cohorts and a wide range of wound types including acute, chronic, and high-risk wounds. These reviews and one published paper were prioritized for SAPACT's review: • **Fruergaard 2025** – A Denmark-based systematic review of 69 case-series and reports (n=880) on both wounds and burns using Novosorb BTM. Median duration of patient follow-up is 8 months (1 month to 36 months). This review, mostly concerned with burns management, has evidence included till April 2024, with no conflicts of interest declared. • **Lane 2024** – A UK-based systematic review and meta-analysis of 26 observational and case series studies (n=1153) on both wounds and burns. Only case-series and above evidence level with n=5 and adults only were included, with evidence included till July 2024. No conflicts of interest was declared. • **Zhang 2023** – A US-based literature review comparing Novosorb BTM with Integra in the context of burn infections. <u>Evidence gaps:</u> • Limited data exist for paediatric populations, extensive burns (>50% TBSA), and long-term outcomes beyond 12 months. • Lack of comparative studies or RCTs <u>2019</u> Comprehensive searches were conducted in eight published scientific databases and 25 grey literature sources. No HTA reports, Systematic Reviews of RCTs or RCTs comparing NovoSorb BTM with Integra in human studies were identified. Eight studies (comprising of 35 humans + 20 mice) were included in the SAPACT Evidence Review; seven studies were NHMRC level IV evidence and the mice study was level V evidence. Out of the 35 humans in the studies, 6 had significant burns and the remaining 29 had complex wounds. The included studies were critically appraised to be of moderate methodological quality. Clinical evidence on the safety and clinical-effectiveness of the NovoSorb BTM were limited to four small case-series (total n=32), three case reports (n=3) and one mice study (n=20) comparing NovoSorb BTM and Integra dressing. Conflicts of interest were present for most papers.
CLINICAL NEED	
Burden of Illness	Australia experiences approximately 5,430 hospitalizations for burn injuries annually, with 16% classified as life-threatening. One in five patients with burns covering >20% TBSA succumbs to complications, underscoring the critical need for advanced wound care technologies. Although specific Australian data on chronic wounds remain sparse, these wounds, including diabetic ulcers and pressure sores, represent a significant healthcare burden due to prolonged healing times, recurrent infections, and high treatment costs. Lane 2024 emphasised the importance of addressing chronic wounds, which frequently require multiple interventions and extensive care resources. Chronic wounds and burns result in extended hospital stays, increased need for surgical interventions, and long-term rehabilitation, placing a considerable financial burden on healthcare systems.
Need	NovoSorb BTM addresses key challenges in managing complex wounds, including temporary physiological closure of wounds, reducing trans-epidermal water loss, as well as robust scaffold support for vascular and cellular infiltration, promoting neodermis formation. Compared to bovine collagen-based alternatives like Integra (Life Sciences Corp., New Jersey, US), NovoSorb BTM offers a fully synthetic, biodegradable option with reduced antigenicity and infection rates (Fruergaard 2025). Its utility across diverse wound types, including high-risk and hostile environments, enhances its applicability. Patients with contraindications to bovine-derived products (e.g, allergies or infected wounds) benefit from NovoSorb BTM's synthetic composition. Evidence supports its use in previously challenging scenarios, such as wounds with exposed bone or tendon.
CLINICAL BENEFIT	
Safety	There were no reports of severe or systemic adverse events directly attributable to NovoSorb BTM. This aligns with findings in earlier studies reviewed by SAPACT in 2019. The evidence highlighted a low incidence of adverse events, including infections, haematomas, and device non-integration. Fruergaard 2025 noted a significant reduction in infection-related complications compared to the comparator Integra, possibly due to the synthetic nature of NovoSorb BTM. **Non-integration or failure of BTM** > Failure rates ranged from 2.4% to 11.4% across studies in Lane 2024's analysis, depending on wound type and bed condition. Common reasons for failure included inadequate vascularisation, contamination, and patient comorbidities (e.g, diabetes, ischemia). > Fruergaard 2025 noted higher risks of failure in specific anatomical sites, such as areas with minimal soft tissue or exposed bone, which may require prolonged integration times or adjunct treatments. **Adverse events** > Haematomas: Lane 2024 reported a low incidence, with most cases resolved through drainage without affecting BTM integration. For example: • Austin 2023 reported 2 haematomas in 79 wounds, which were successfully managed without device removal. • Li 2021 observed 1 haematoma in 35 wounds, caused by patient trauma. > Tenolysis: Concannon 2023 in Lane 2024 documented 2 cases needing tenolysis in 21 wound beds where the templates were used to reconsutrct defects with exposed tendon. **Scar-related complications**

	> Scar contractures or delayed healing were infrequent and primarily occurred in wounds with a history of significant contamination or delayed integration. Greenwood 2017 in Lane 2024 reported 3 contracture cases in 5 patients treated with BTM. **Low infection rates** Infection rates associated with BTM were low, even in high-risk scenarios (e.g., diabetic ulcers, necrotising fasciitis). Sensitivity analysis showed no statistically significant differences in infection rates between high-risk and general populations, demonstrating BTM's robustness in complex wound beds. > Lane 2024 reported a low infection rate of 12.6% across 21 studies (n=577 wounds). Infections were defined as cases involving erythema, purulence, pain, or microbial confirmation via swabs. > Lane 2024 showed that high-risk wounds (e.g., diabetic ulcers, wounds post-debridement of necrotising fasciitis, pressure ulcers) showed infection rates comparable to the general wound population. This was supported by sensitivity analysis, which found no statistically significant difference (odds ratio: 0.951, p=0.931). > Fruergaard 2025 recorded a low infection rate of 10%, observed similar rates. > Fruergaard 2025 noted that the synthetic composition of BTM likely contributes to its reduced antigenicity and infection risk. > Most device-related complications, including infections and haematomas, were effectively managed without necessitating complete BTM removal. For example, Lane 2024 documented that partial seal removal to address infections often allowed continued integration of the BTM. > Zhang 2023 offered a different perspective with its review – in severe burns patients, Integra was shown to be a more effective method compared to Novosorb BTM and has resulted in lower infection rates. <u>2019</u> **Safety outcomes in burns group** > Faecal contamination BTM thigh w failure of BTM integration over shoulders (2% removed) > 4% infected BTM upper abdomen with Stenotrophomonas > 5 haematomas under BTM whilst heparinised for dialysis (8% removed) > Pseudomonas aeruginosa under BTM seal both arms (0% removed) **Failure to integrate** > 7% total of 122% TBSA (5 burns) > Failure to integrate over lower limbs (1 burn) > Failure to integrate over devitalised muscle (1 complex wound) and seroma (1 complex wound) **SSG take** > Failure over malleolus > Failure over area where BTM has failed to integrate (2 complex wound patients) **Infection** Data from case series of 10 reconstructed free flap donor sites. Localised infection in 4/10 > One: muscle necrosis (BTM failed to adhere) > One: UTI and incontinence onto BTM – 37% BTM removed (resolved non-operatively) > Two: partial removal of seal allowed turbid fluid escape, integration continued without removal of BTM Subsequent series of 10 patients had no infection, all integrated and successfully grafted. No self-reported adverse events were reported from the Sponsor and there was no adverse event reports for the NovoSorb BTM and the Integra received by the TGA since 1 July 2012 based on the TGA Database of Adverse Event Notifications for Medical Devices.
Effectiveness	**High integration rates** > Lane 2024 reported a mean integration rate of 92.7% (95% CI: 88.57–96.87) across 1153 wounds included in 26 studies. This reflects the proportion of wounds where the BTM successfully integrated into the host tissue, as evidenced by clinical signs such as uniform pink colour and blanching on pressure. Subgroup analysis: • Wounds with exposed bone showed slightly slower integration times (mean: 40.7 days) compared to other wound bed types (mean: 34.05 days), indicating the need for longer treatment durations in these cases. • Integration rates were consistently high across various wound types, including burns, diabetic ulcers, pressure ulcers, and wounds post-debridement for necrotising fasciitis. > Fruergaard 2025 did not report on this indicator. **High graft take over integrated BTM** > Both Lane 2024 and Fruergaard 2025 reported high graft take success rates following BTM integration. Lane 2024 observed a mean graft take rate of 98.9% (n=511 wounds), with minimal graft failure. > Cases of graft failure were primarily attributed to prior BTM non-integration. Fruergaard 202 5highlighted that in such instances, clinical interventions (e.g. additional debridement or reapplication) often led to successful outcomes. **Wound types treated** > Lane 2024 emphasised the versatility of NovoSorb BTM in managing a broad spectrum of wounds, including: • Burns: Deep and full-thickness burns demonstrated high integration rates, making BTM an effective alternative to traditional grafting techniques. • Diabetic foot ulcers: Sensitivity analyses showed no significant increase in infection or integration failure rates in diabetic patients, underscoring BTM's utility in this high-risk population.

	• Trauma and post-infective wounds: Wounds with exposed critical structures (e.g., bone, tendon) showed favorable outcomes, with BTM providing a reliable scaffold for reconstruction. **Favourable scar outcomes**: Scar quality improved with BTM use. Lane 2024 noted statistically significant improvements in patient and observer-rated scales, with scars demonstrating normal pliability and pigmentation in most cases. > Lane 2024 reported consistently favorable scar outcomes using validated tools, including the Patient and Observer Scar Assessment Scale (POSAS) and Matching Assessment of Scars and Photographs (MAPS). These tools demonstrated improvements in pigmentation, pliability, and overall scar aesthetics over time. > Fruergaard 2025 highlighted reduced scar contractures and improved long-term scar quality compared to untreated or poorly grafted wounds. For example, in Lane 2024, Lo 2021 reported a statistically significant reduction in Vancouver Scar Scale scores from 5.6 (95% CI: 4.7–6.6) at 3 months to 3.0 (95% CI: 2.6–3.5) at 12 months, demonstrating progress in scar maturation and appearance. <u>2019</u> > The BTM' 'take' rate was mostly complete and uneventful without complications, however, a few patients experienced failed BTM integration in certain body areas with remedies undertaken. > The split skin graft (SSG) that followed BTM integration took and healed well in most patients, with some reports of no graft loss. In most patients, the graft take was complete and had a robust and aesthetically pleasing appearance. In cases which graft take was marred, there was adequate clinical management with successful regrafting. > The timings of delamination and definite grafting post BTM implantation were recorded in most studies and were described well; however, there are no yardsticks for comparison. > Scar outcomes evaluated using the Patient and Observer Scar Assessment Scale (POSAS) and Matching Assessment of Scars and Photographs (MAPS) found good scar characteristics and were mostly favourable to both patient and observer. > For studies that reported other patient-related outcomes, these patients recovered their functions, movements, cosmetically acceptable appearance and had regained their normal lifestyle, which are the aims of wound closure. > In two studies evaluating NovoSorb BTM for the reconstruction of free flap donor sites, localised infection was found in 40% of the patients. Subsequently, the NovoSorb BTM was improved and in the second study, no patient reported any infection. > In the laboratory mice study, the authors found that the fully synthetic NovoSorb BTM could provide wound closure, and its short-term (2 weeks) performance demonstrated its potential as an effective dermal template performing similar to the animal-derived Integra.
SUITABILITY OF PATIENT GROUP	
Suitability of Patient Group	The international evidence has described expanded clinical indications across diverse patient groups and wound types, including: • Acute wounds (e.g. burns, trauma). • Chronic wounds (e.g. diabetic ulcers, venous ulcers, and pressure ulcers). • High-risk wounds with exposed bone or tendon and wounds from necrotising fasciitis. • Immunocompromised patients and those with comorbidities (e.g. diabetes) showed outcomes comparable to healthier populations. Clinical evidence continues to be limited to mainly adult populations. Lane 2024 identified promising results for elderly patients, but evidence for paediatric populations or patients with >50% TBSA burns remains insufficient. <u>2019</u> SAPACT members noted that given the lack of comparative trials for burns and wounds indications, the FDA only approved the NovoSorb BTM for clinical indications (i.e. surgical wounds) outside of full thickness burns. The BARDA Feasibility Burn trial currently running (Nov 2016 - 2019) to assess BTM in full-thickness burns (open label single arm). TGA has approved Novosorb BTM for use wherever the skin dermis is lost, regardless of (1) cause and (2) severity. Published clinical evidence is only present for adults between 30 to 88 years old. In significant burns, patients with more than 50% TBSA burns have not been trialed (except for 1 patient in Greenwood 2016 case report) due to higher risk of morbidity and mortality. Within the approved TGA indications, there may also be a potential consideration for NovoSorb BTM in patients who are contraindicated to Integra, for example, patients who are allergic to bovine collagen or who have infected wounds.
FINANCIAL CONSIDERATION	
Device costs	NovoSorb BTM continues to be priced [redacted] to Integra dermal template (a bovine collagen I-based substitute) per square centimeter. 2024 Prices [redacted]: Novosorb BTM 1010 (Size 10x10cm): [redacted] vs comparator, Integra (size 10x12.5cm): [redacted] Novosorb BTM 1020 (Size 10x20cm): [redacted] vs no corresponding size from Integra. Novosorb BTM 2040 (Size 20x40cm): [redacted] vs Integra (size 20x25cm): [redacted]
Value for Money	No published studies on costing or economic evaluations were found. The high integration rates (92.7%), graft take (98.9%), and favorable scar outcomes reported by Lane 2024 suggested fewer complications and a reduced need for secondary interventions, leading to potential cost savings. NovoSorb BTM remains comparable in price to Integra per square centimetre, but it offers possible cost benefits by reducing infection rates and complications (Fruergaard 2025).

	Its lower antigenicity and synthetic composition make NovoSorb a more sustainable option for long-term use. A local SAPACT cost-effectiveness analysis was attempted in 2019 but could not be completed due to insufficient evidence from the sponsor and applicant, hindering the ability to assess the validity of the underlying claims.
Australian Funding Approvals	The NovoSorb BTM has not been systematically evaluated for scientific evidence and clinical outcomes by any other international HTA and government agencies for the purposes of public funding, reimbursement, policy or consideration for uptake in routine clinical practice. The Commonwealth Medical Services Advisory Committee (MSAC) and Prostheses List Advisory Committee (PLAC) have not, at this time, approved NovoSorb BTM for funding. No other interstate health technology committees have reported evaluation on this technology.
FEASIBILITY OF ADOPTION	
Organizational Feasibility	The expertise at the Burns Unit, Royal Adelaide Hospital is recognized and SAPACT understands that the procedures will be carried out and followed-up appropriately.
Credentialing and Competency	The applicants have written that clinicians will ensure that patient training and support are provided. The Clinician(s) should be appropriately credentialed and approved by the SA Health Credentialing and Scope of Practice Committee to implant the NovoSorb BTM (refer to paragraph 3.4.3 New Clinical Procedures, Technologies and Treatments of the SA Health Credentialing Policy Directive).
CONSISTENCY WITH EXPECTED SOCIETAL/ ETHICAL/ LEGAL VALUES	
Values	Consistent with expected societal, ethical and legal values at this time.
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