Executive Summary

Novoglan: Building a Clinical Evidence Base for a First-Line Non-Surgical Treatment of Adult Phimosis

The integrated evidence package demonstrates the evolution of Novoglan from a novel tissue-expansion device into one of the most extensively studied non-surgical interventions for adult phimosis. Across peer-reviewed clinical trials, post-marketing surveillance studies, conference presentations, literature reviews, and updated outcome analyses, the data consistently support Novoglan as a safe, effective, and well-tolerated alternative to circumcision.

Importantly, the evidence extends beyond anatomical improvement to include measurable benefits in sexual function, psychological wellbeing, quality of life, and patient satisfaction—areas increasingly recognised as critical treatment outcomes in adult phimosis management.

Evolution of the Evidence

Phase 1: Initial Clinical Validation

The NOVOGLAN-01 clinical trial was conducted across Macquarie University Hospital and Princess Alexandra Hospital in Australia and registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12621000924853).

The original prospective open-label study enrolled 20 adult males with phimosis who underwent twice-daily Novoglan treatment over a 4–8 week period. The trial was designed to evaluate efficacy, safety, tolerability, and quality-of-life outcomes.

Key findings included:

- Improvement in foreskin retraction in 90% of participants.
- Full foreskin retraction achieved in all participants following treatment.
- 95% reduction in phimosis-related anxiety.
- More than 60% reduction in pain and discomfort.
- 95% patient satisfaction and willingness to recommend treatment.
- No adverse events reported.
- Minor side effects reported by only 10–15% of participants.

These findings established proof-of-concept that controlled foreskin tissue expansion could provide a clinically meaningful alternative to surgery while maintaining an excellent safety profile.

Phase 2: Independent Peer-Reviewed Publication

The NOVOGLAN-01 results were subsequently published in *Translational Andrology and Urology* (2023), providing independent peer-reviewed validation of the study outcomes.

The publication highlighted several clinically significant findings:

- Strong efficacy across all grades of phimosis.

- Particularly notable outcomes in severe phimosis (Grades 1–3), where all patients achieved substantial improvement.
- Significant reductions in anxiety, sexual discomfort, and quality-of-life impairment.
- No serious treatment-related complications.
- High treatment adherence and usability.

The authors concluded that Novoglan demonstrated significant potential as a conservative first-line treatment for adult phimosis and warranted larger follow-up studies.

Phase 3: Real-World Post-Market Surveillance

To determine whether clinical outcomes translated into routine patient use, extensive post-marketing surveillance was conducted.

Questionnaires were distributed to approximately 9,700 Novoglan customers, generating over 800 completed responses, with 461 patients using the current-generation device included in detailed analysis.

Results demonstrated remarkable consistency with the clinical trial findings:

Outcome	Post-Market Surveillance
Treatment effectiveness	93.5%
Easy to use	91.8%
Treatment tolerability	96.3%
Would recommend to others	98.1%
Improved mental wellbeing	88.8%
Significant side effects	0%

The close alignment between clinical and real-world outcomes substantially strengthens confidence in the reliability and reproducibility of the Novoglan treatment model.

Phase 4: Comparative Clinical vs Real-World Analysis

A dedicated comparative analysis was undertaken to evaluate concordance between the clinical trial and post-marketing surveillance datasets.

The comparison demonstrated:

Outcome	Clinical Trial	Post-Market Study
Efficacy/Satisfaction	100%	93%
Significant Side Effects	0%	0%
Device Usability	90%	92%
Reduced Anxiety	95%	85%

The findings showed that patient-reported outcomes in routine practice closely mirrored outcomes observed in controlled clinical settings.

This represents a particularly important milestone because many medical devices perform well in clinical environments but fail to achieve similar outcomes in real-world use.

Phase 5: Psychosexual Impact Research

A recurring theme throughout the evidence package is the substantial psychosexual burden associated with adult phimosis.

Across studies:

- 81–98% of participants reported negative psychological impacts associated with their condition.
- Up to 97.7% reported that phimosis adversely affected mental wellbeing.
- Up to 90% reported discomfort during sexual activity before treatment.

Novoglan treatment consistently produced meaningful improvements:

- Anxiety reductions of between 71% and 95%.
- Significant reductions in sexual discomfort.
- Improved confidence and quality of life.
- Reduced interference with daily activities and relationships.

These findings reposition Novoglan from being solely an anatomical intervention to a treatment that addresses both physical and psychosocial consequences of phimosis.

Phase 6: Updated Clinical Outcomes and Larger Cohorts

More recent analyses expanded the evidence base beyond the original 20-patient trial.

An updated cohort of 42 adult males demonstrated:

- Improvement in prepuce retractability in 78.6% of all participants.
- 79.4% of patients with more severe phimosis achieving full retraction.
- Reduction in general pain/discomfort from 33% pre-treatment to 12% post-treatment.
- Reduction in sexual discomfort from 90% to 27%.
- Anxiety/depression prevalence reduced from 81% to 16%.
- Marked reductions in interference with normal daily activities.

These larger-cohort findings reinforce the original trial outcomes and provide stronger evidence of reproducibility.

Position Within the Treatment Landscape

The evidence package also includes contemporary literature reviews examining prepuce-preserving alternatives to circumcision.

The reviews identify Novoglan as part of a growing movement toward conservative management strategies that preserve foreskin function while avoiding surgical risks.

Key advantages identified include:

- Non-invasive treatment.
- Self-administered home use.
- Preservation of foreskin anatomy.
- High patient satisfaction.
- Strong safety profile.
- Applicability across a wide range of phimosis severity levels.

The literature positions Novoglan alongside emerging conservative therapies while noting that the device currently possesses one of the most developed clinical evidence bases among foreskin-preserving treatment options.

Overall Conclusion

Taken collectively, the evidence package presents a coherent and progressively strengthening body of clinical validation.

Across clinical trials, peer-reviewed publication, post-market surveillance, comparative analyses, psychosexual outcome studies, and larger follow-up cohorts, Novoglan consistently demonstrates:

- High efficacy (approximately 79–100% depending on endpoint and population).
- Exceptional safety with no significant adverse events reported.
- Strong patient satisfaction and usability.
- Meaningful improvements in sexual function and quality of life.
- Significant reductions in anxiety and psychological distress.
- Reproducible outcomes in both controlled and real-world settings.

The accumulated evidence supports Novoglan's positioning as a credible first-line conservative treatment option for adult phimosis and provides a foundation for future guideline consideration and broader clinical adoption.