

# novoglan<sup>®</sup>

## ADULT PHIMOSIS TREATMENT FORESKIN TISSUE EXPANDER

### OVER 55,000 MEN TREATED

- ✓ INDEPENDENTLY CLINICALLY PROVEN\*
- ✓ EFFECTIVE FIRST - LINE TREATMENT OPTION
- ✓ ALL GRADES OF PHIMOSIS
- ✓ EXCELLENT LONG-TERM EFFICACY<sup>^</sup>

**0%** SURGICAL  
INTERVENTIONS

**2** YEARS  
FOLLOW-UP



SCAN ME

\*TAU: Novoglan device for treatment of adult phimosis: Novoglan-01 open-label clinical trial on safety, efficacy and tolerability. D. Gillatt, E Chung, D. Polikarpov

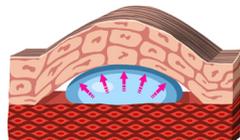
<sup>^</sup>USANZ: Two-Year Follow-Up of NOVOGLAN-01 Open Label Multicentre Clinical Trial: Efficacy and Safety of Novoglan for Adult Phimosis. D. Polikarpov, E. Chung, D. Gillatt

## FORESKIN TISSUE EXPANDER

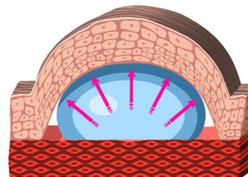
FDA, CE, MHRA, TGA LISTED CLASS 1 MEDICAL DEVICE



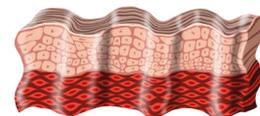
1. PRE TREATMENT



2. EARLY TREATMENT



3. PROGRESSIVE TREATMENT



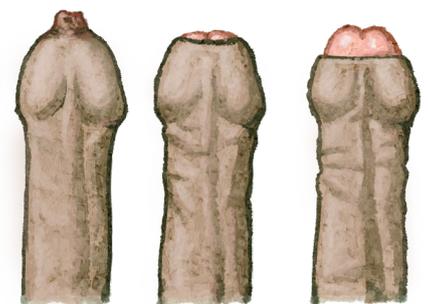
4. POST TREATMENT

## FIRST LINE TREATMENT OPTION

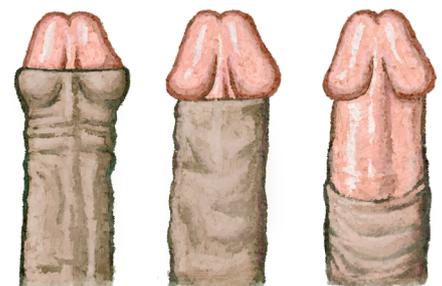
30 MINUTES A DAY FOR 6 WEEKS

### PHIMOSIS PATIENT SELECTION CRITERIA

- ✓ **PHYSIOLOGICAL**
  - All Grades
- ✓ **PATHOLOGICAL**
  - Balanitis (post antimicrobial tx)
  - Non-Circumferential BXO
- ✓ **NOT SUITABLE CANDIDATE FOR SURGERY**
- ✓ **MOTIVATED TO KEEP FORESKIN INTACT**
- ✓ **LOW-COST TREATMENT PREFERENCE**
- ✓ **LONG WAIT-LIST TIME FOR SURGERY**



1. EXTREME 2. SEVERE 3. MODERATE



4. MILD 5. RETRACTILE FREE

# novoglan<sup>®</sup>

## ADULT PHIMOSIS TREATMENT FORESKIN TISSUE EXPANDER

FDA, CE, MHRA, TGA LISTED CLASS 1 MEDICAL DEVICE



- ✓ 90% TREATMENT EFFICACY AT 6 WEEKS<sup>^</sup>
- ✓ REDUCED PAIN IN SEXUAL ACTIVITY<sup>^</sup>
- ✓ EXCELLENT SAFETY & TOLERABILITY<sup>#</sup>
- ✓ IMPROVED QUALITY OF LIFE<sup>#</sup>
- ✓ LONG-TERM OUTCOMES<sup>+</sup>



**0%** SURGICAL INTERVENTIONS      **2** YEARS FOLLOW-UP

<sup>#</sup> n=461 Clinical Trial and Real-World data of Novoglan use for conservative treatment of adult phimosis. D. Polikarpov, E Chung, D. Gillatt

<sup>^</sup> TAU: Novoglan device for treatment of adult phimosis: Novoglan-01 open-label clinical trial on safety, efficacy and tolerability. D. Gillatt, E Chung, D. Polikarpov

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PROFESSOR  
**ERIC CHUNG**  
Independent Investigator



**UROLOGICAL SOCIETY  
OF AUSTRALIA  
AND NEW ZEALAND**

## Efficacy and Safety of Novoglan for Adult Phimosis

E. Chung<sup>1</sup>, D. Polikarpov<sup>2</sup>, H. Mazure<sup>3</sup>, A. James<sup>4</sup>, H. Doosti<sup>5</sup>, D. Campbell<sup>6</sup>, D. Gillatt<sup>7</sup>

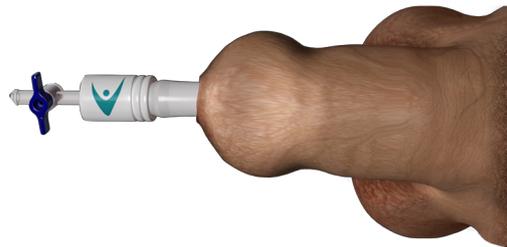
### AIM

Conventional definitive treatment for adult phimosis is circumcision. Novoglan device is a potential non-surgical alternative through the application of custom-moulded balloons for gradual skin remodelling and prepuce dilation. Initial results of the NOVOGLAN-01 open-label clinical trial demonstrated promising outcomes. This follow-up abstract presents the two-year results, aimed at establishing long-term efficacy, safety, and tolerability.



### TRIAL REGISTRATION

The NOVOGLAN-01 study is registered with the Australia and New Zealand Clinical Trial Registry under reference ACTRN 1262 10009 24853, dated 15 July 2021



### METHODS

A prospective, open-label trial was conducted on the first 20 adult patients with phimosis at Macquarie University Hospital and Princess Alexandra Hospital. Following eligibility screening, patients underwent Novoglan treatment involving twice-daily 10-minute applications for 4-8 weeks. Efficacy was measured by the degree of phimosis before and after treatment, with follow-ups at 6-8 weeks and two years. Each patient served as their own control. Safety and tolerability were assessed using questionnaires.

### RESULTS

Two-year follow-up data revealed that 19 of the first 20 patients (95%) maintained successful outcomes with full normal retraction. Among these 19 patients, 100% reported no new symptoms and did not require further intervention or circumcision. The statistical analysis supports that these results are likely attributable to the Novoglan treatment rather than chance, given the consistent improvement across individual cases and sustained efficacy over two years.

### CONCLUSIONS

The NOVOGLAN-01 trial's two-year follow-up data underscore the long-term efficacy and safety of Novoglan for treating adult phimosis. Each patient serving as their own control further strengthens the validity of these results. The high success rate, absence of new symptoms, and lack of need for further surgical intervention highlight the potential of Novoglan as a viable nonsurgical alternative to circumcision.

## Title: Efficacy, tolerability, and safety of two generations of Novoglan device designed for conservative treatment of adult phimosis

Dmitry Polikarpov, Eric Chung, Hubert Mazure, Andrew James, Hassan Doosti, Douglas Campbell, David Gillatt (Australia)

### PURPOSE

Novoglan is a non-surgical phimosis treatment using an inflatable balloon under the foreskin. Initially the device was controlled by an air plunger, but later updated with a bulb, stopcock, and a medical-grade silicone balloon. A post-marketing survey compared both generations, assessing efficacy, usability, tolerability, safety, and mental wellbeing impact.

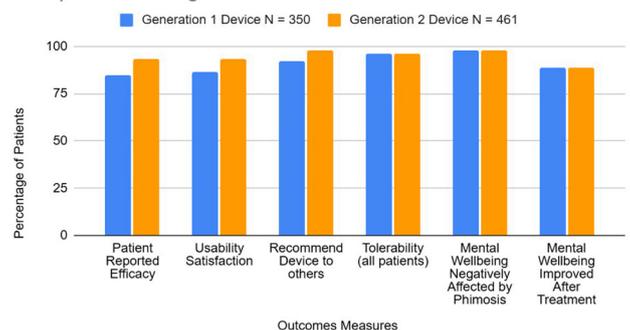
### METHODS

Questionnaires were emailed to 9,700 Novoglan customers, with 811 complete responses analyzed.

### RESULTS

The updated design improved patient-reported efficacy, usability, and satisfaction. No significant side effects were reported, and most patients tolerated treatment well. Mental wellbeing also improved post-treatment.

Comparison Novoglan Generation 1 and Generation 2 Devices



### CONCLUSION

The study confirmed that the updated Novoglan design improved efficacy, usability, and safety, further supporting its role in non-surgical adult phimosis management.

### Ethical Approvals:

Macquarie University HREC (Ref: 520193 3799 8816, 11 June 2019; 52020 3799 21701, 16 October 2020) and Royal Alexandra Hospital (Queensland Health Metro South HREC Ref: HREC/2020/QMS/66682, 17 November 2020).