novoglan®

For Healthcare Professionals

Clinical Education

ADULT PHIMOSIS

A foreskin-preserving approach to management, for clinicians assessing conservative treatment options.

Adult phimosis can affect **urinary function, sexual function, comfort and psychological well-being.**

Clinical assessment of **foreskin retractability, tissue characteristics, symptoms and patient goals** can help guide appropriate management and identify patients who may be suitable for foreskin-preserving approaches.

Patient-centric care starts with understanding the condition.

1 ASSESS SEVERITY → 2 IDENTIFY TISSUE CHARACTERISTICS → 3 UNDERSTAND PATIENT GOALS → 4 CONSIDER TREATMENT OPTIONS

INSIDE THIS GUIDE

SELECTING THE RIGHT PATIENT

Management of adult phimosis should begin with a structured clinical assessment. Clinical assessment should consider:

Degree of foreskin narrowing and retractability
Assess the extent of preputial retraction and the degree to which the glans and meatus can be exposed.

Scarring and fibrosis
Examine the foreskin for visible scarring, fibrotic tissue, cracking, whitening or other changes that may indicate pathological disease.

History of balanitis or recurrent infection
Consider previous episodes of inflammation, balanitis, infection or other associated symptoms.

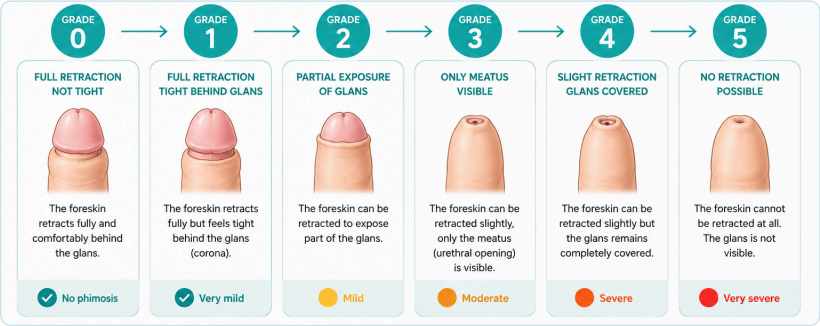
Pain, discomfort and functional symptoms
Assess symptoms during urination, erection, sexual activity and everyday function.

Patient treatment goals and preferences
Discuss the patient's priorities, including whether preservation of the foreskin is an important treatment goal.

Ability to follow a structured protocol
Conservative approaches require appropriate patient selection, education, adherence and follow-up.

Kikiros Classification of Phimosis

A CLINICAL FRAMEWORK FOR ASSESSING FORESKIN RETRACTABILITY



Adapted from the Kikiros and Woodward classification of foreskin retractability.

PATIENT SELECTION IS CRITICAL

! Conservative management may not be appropriate for all patients. Clinical assessment should identify the underlying tissue characteristics and exclude conditions requiring alternative management or specialist evaluation.

THE SCIENCE BEHIND TISSUE EXPANSION

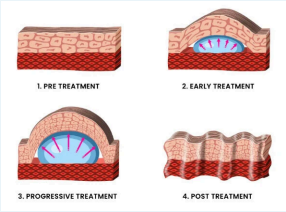
CONTROLLED TENSION

TISSUE ADAPTATION & REMODELLING

GRADUAL EXPANSION

Living tissue has the capacity to adapt to **controlled, progressive mechanical loading.** Tissue expansion applies a gradual mechanical force to tissue over time. With repeated, appropriately controlled loading, tissue can undergo biological adaptation and remodelling, allowing progressive changes in tissue dimensions and mechanical properties.

In foreskin-preserving treatment, the principle is to apply **controlled expansion to the preputial opening** rather than surgically removing the foreskin.



WHY THIS MATTERS IN PHIMOSIS

Phimosis is characterised by narrowing of the preputial opening that can limit foreskin retractability. A progressive tissue-expansion approach aims to increase the diameter and flexibility of the preputial opening, potentially improving foreskin retractability while preserving the prepuce.

Tissue response to controlled tension: pre-treatment → early → progressive → post-treatment.

Preserve → **Load** → **Adapt** → **Expand**

FROM MECHANICAL LOADING TO CLINICAL FUNCTION

CONTROLLED MECHANICAL TENSION
Applies progressive force to the constricted tissue.

BIOLOGICAL ADAPTATION
Living tissue responds to sustained mechanical loading through structural and cellular processes.

TISSUE REMODELLING
Repeated loading may result in changes to tissue structure and mechanical properties.

PROGRESSIVE EXPANSION
Over time, the preputial opening may increase in diameter and flexibility.

IMPROVED RETRACTABILITY
The intended clinical outcome is greater functional foreskin mobility while retaining the foreskin.

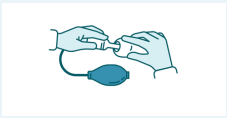
SCIENTIFIC CONTEXT & KEY REFERENCES

1. Kikiros CS, Woodward AP. Classification of phimosis severity.
2. Chung E, et al. Novoglan device for treatment of adult phimosis: Novoglan-01 open-label clinical trial on safety, efficacy and tolerability. *Transl Androl Urol.* 2023.
3. George A, et al. Prepuce-Preserving Management of Phimosis: Therapeutic Options, Evidence and Clinical Relevance for Urologists. *Trends Urol Men's Health.* 2025.

HOW TO USE NOVOGLAN

Clear demonstration, patient education, and follow-up can support correct use and adherence. Using Novoglan is a simple three-step process:

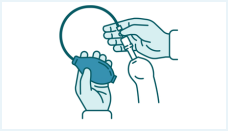
1



PLACE

Position the device as demonstrated by your healthcare professional.

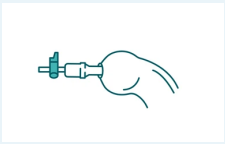
2



INFLATE

Gently inflate using the bulb until a controlled, comfortable tension is felt.

3



WAIT

Hold for the prescribed duration, then deflate and remove as instructed.

! GUIDED DEMONSTRATION MATTERS

As with any structured treatment protocol, outcomes are best supported by clear demonstration, patient education and scheduled follow-up — not by the device alone.

15–30 MIN DAILY

Follow the applicable IFU. Current treatment instructions recommend daily treatment for 15–30 minutes per session; a healthcare professional may recommend an alternative twice-daily 15-minute regimen with at least 8 hours between sessions.

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NOVOGLAN CONSERVATIVE PATHWAY

A DECISION FRAMEWORK FOR ADULT PHIMOSIS

FOR UROLOGISTS & ANDROLOGISTS

1 SPECIALIST ASSESSMENT

Evaluate foreskin retractability (Kikiros grade), tissue quality, symptoms and patient goals.

2 SCARRING, BALANITIS OR ACTIVE INFECTION PRESENT?

Assess for lichen sclerosus / BXO, active infection, or significant scarring of the foreskin.

YES

IF YES — REQUIRES FURTHER ASSESSMENT

2A. INFECTION RESOLVED, NO BXO, ADEQUATE TISSUE REMAINING?

Active infection must be treated first; suspected BXO or significant scarring requires specialist assessment and may be unsuitable for Novoglan.

NO

NOVOGLAN NOT RECOMMENDED

Manage the underlying condition; consider surgical referral (circumcision / preputioplasty).

YES

NOVOGLAN MAY BE CONSIDERED

Individualised assessment only, once infection is resolved and BXO / significant scarring is excluded.

NO

3 CONSERVATIVE TREATMENT OPTIONS

Conservative options may include topical corticosteroids and tissue-expansion approaches. Treatment selection should be based on clinical assessment, tissue characteristics, patient preference and applicable guidance.

TOPICAL CORTICOSTEROIDS

Applied per standard course; reviewed for response and tolerability.

NOVOGLAN TISSUE EXPANSION

Guided use per the applicable IFU: 15–30 min daily, or twice-daily 15 min if clinician-directed.

4 IMPROVED RETRACTABILITY / SYMPTOMS AT REVIEW?

Reassess at the end of the treatment course.

YES

CONTINUE / MONITOR

Maintain gains with routine follow-up; taper as appropriate.

NO

CONSIDER ALTERNATIVE OR SURGICAL REFERRAL

Trial the alternative conservative option if not yet used, or discuss circumcision / preputioplasty.

For use by urologists and andrologists. Novoglan is one conservative option within a broader phimosis management pathway and does not replace individualised specialist clinical judgement.

EXPLORE THE CLINICAL EVIDENCE

What does the evidence tell us about foreskin-preserving tissue expansion for adult phimosis? Explore clinical research, real-world data and the scientific literature supporting conservative approaches to phimosis management.

Novoglan-01 Clinical Trial

A prospective, open-label trial evaluated the safety, efficacy and tolerability of a tissue-expansion device in 20 adults with phimosis. Participants underwent a structured protocol involving 10-minute applications twice daily for 4–8 weeks, with clinical assessment before and after treatment. No adverse events were observed; minor side effects were reported by a subset of participants.

90%	100%	95%	60%+	95%
IMPROVED FORESKIN RETRACTION	ACHIEVED FULL RETRACTION	REDUCED ANXIETY	REDUCED PAIN / DISCOMFORT	MODERATELY–VERY SATISFIED

19/20 (95%) maintained successful outcomes with full normal retraction at **two-year follow-up.**

811 patient-reported PMS responses analysed in a real-world post-market surveillance programme.

Scientific literature — Contemporary literature recognises a range of foreskin-preserving approaches to phimosis management, with treatment selection dependent on disease severity, tissue characteristics, symptoms, underlying pathology and patient preference. Recent review literature highlights the growing clinical relevance of prepuce-preserving management and patient-centred treatment decisions.

Scan to Explore the Evidence

CLINICAL EVIDENCE →

Access clinical studies, published evidence and supporting scientific literature.

INDEPENDENT INVESTIGATORS

PROFESSOR DAVID GILLATT
Independent Principal Investigator

PROFESSOR ERIC CHUNG
Independent Investigator

Novoglan® Foreskin Tissue Expander is an FDA, CE, MHRA, and TGA Listed Class I Medical Device*, supported by independent clinical trial and real-world evidence.

*The manufacturer is Platigo Solutions Pty Ltd. Medical Device Regulations: AUS ARTG# 168962 / CE Marketing Approval / UK MHRA# CAO15054 / US FDA# 00860009967205

Evidence should be interpreted in the context of study design, patient population, treatment protocol and individual clinical circumstances.
Novoglan® is a medical device. Please consult the applicable Instructions for Use and local regulatory information before recommending or using the device.