World-first clinical trial of Australian conservative treatment for adult phimosis

I am conducting an independent Investigator Instigated clinical trial to assess the efficacy, safety and patient satisfaction of the Novoglan Foreskin Tissue Expander in the treatment of phimosis in adults. Novoglan is listed on the ARTG as a class 1 non-sterile procedure pack.

The Novoglan product presents an attractive alternative to circumcision in the current climate of curtailed elective surgeries related to the COVID-19 pandemic.

The trial started recruiting subjects on 2nd September 2019 and will run for approximately 18 months. This clinical trial has been approved by the Macquarie University Ethics Committee and meets the Australian and international standards for Good Clinical Practice.

The main inclusion criteria are:

- Subject 18 or older referred to the urology clinic
- Symptoms of adult phimosis, inability to fully retract the foreskin
- Subject reporting pain or discomfort.
- Subjects with BXO or prior frenuloplasty are acceptable

The main exclusion criteria are:

- Any known latex or silicone allergy
- Any bleeding, ulcer or active infection of the penis
- Any prior prepuce surgery, except for frenuloplasty
- Any hypospadia
- Any history of penile cancer
- Any severe scarring of the glans or foreskin

Participants to this study will need to visit the Macquarie University Hospital Urology Clinic and will need to be referred to me for an initial assessment. There will be no out of pocket charges for the participants and transport costs to the Urology Clinic will be covered.

To refer a patient to me for this study, please fill in the attached Novoglan-01 GP Referral Request form attached to this letter.

For further information or inquiry, please contact me directly on my mobile number 0415 368 405 or contact my assistant Maizie Barakat on 9812 3031.

Professor David Gillatt
Novoglan-01 clinical study
GP Referral Request Form

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Prof David Gillatt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Sponsor</td>
<td>Macquarie University</td>
</tr>
<tr>
<td>Study Site</td>
<td>Macquarie University Hospital</td>
</tr>
</tbody>
</table>

From General Practitioner

<table>
<thead>
<tr>
<th>Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Number</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Phone number</td>
<td></td>
</tr>
</tbody>
</table>

To Professor Gillatt
Head of Urology and Gynaecology Clinical Discipline
Director of Medical and Surgical Services, Macquarie University Hospital
Suite 304, Level 3, 2 Technology Place, Macquarie University NSW 2109, Australia
T: +61 (2) 9812 3838 | M: + 61 415 368 405
E: david.gillatt@mq.edu.au | mqhealth.org.au

Dear Professor Gillatt,
Thank you for seeing my patient ...........................................................................................................
for his possible participation in the Novoglan-01 Clinical Trial for adult phimosis.

General Practitioner’s signature

..................................................................................................................................................

Date: ................................................................................................

Please remind your patient to bring this signed referral letter to his first appointment.