

REGROW BIOSCIENCES PVT. LTD.

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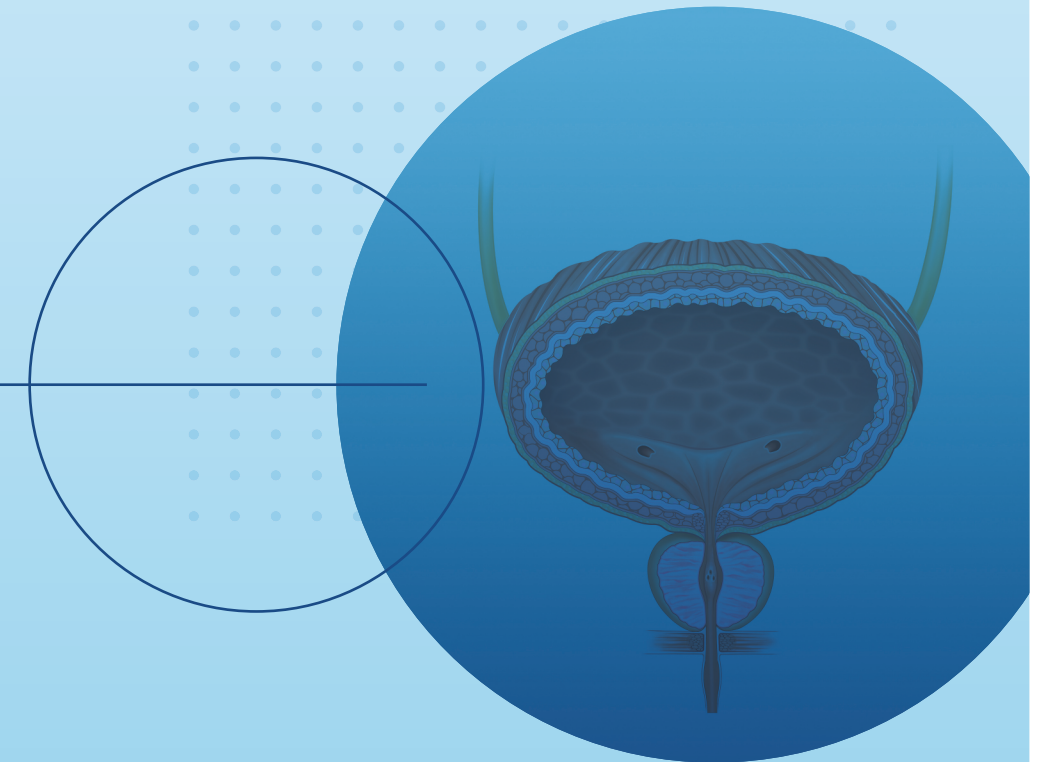
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UREGROW®

IMPLANTATION MANUAL



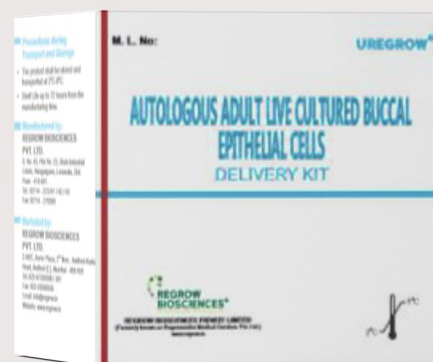
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Contents of the Product Box



DELIVERY KIT



1ML SYRINGE (10 NOS)

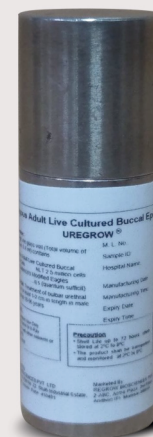


20 GAUGE NEEDLE (10 NOS)

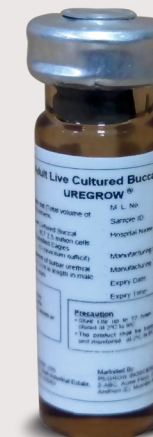


18 GAUGE NEEDLE (5 NOS)

Contents of the Delivery Kit



Outer Vial (Non-sterile) (Metal Canister)

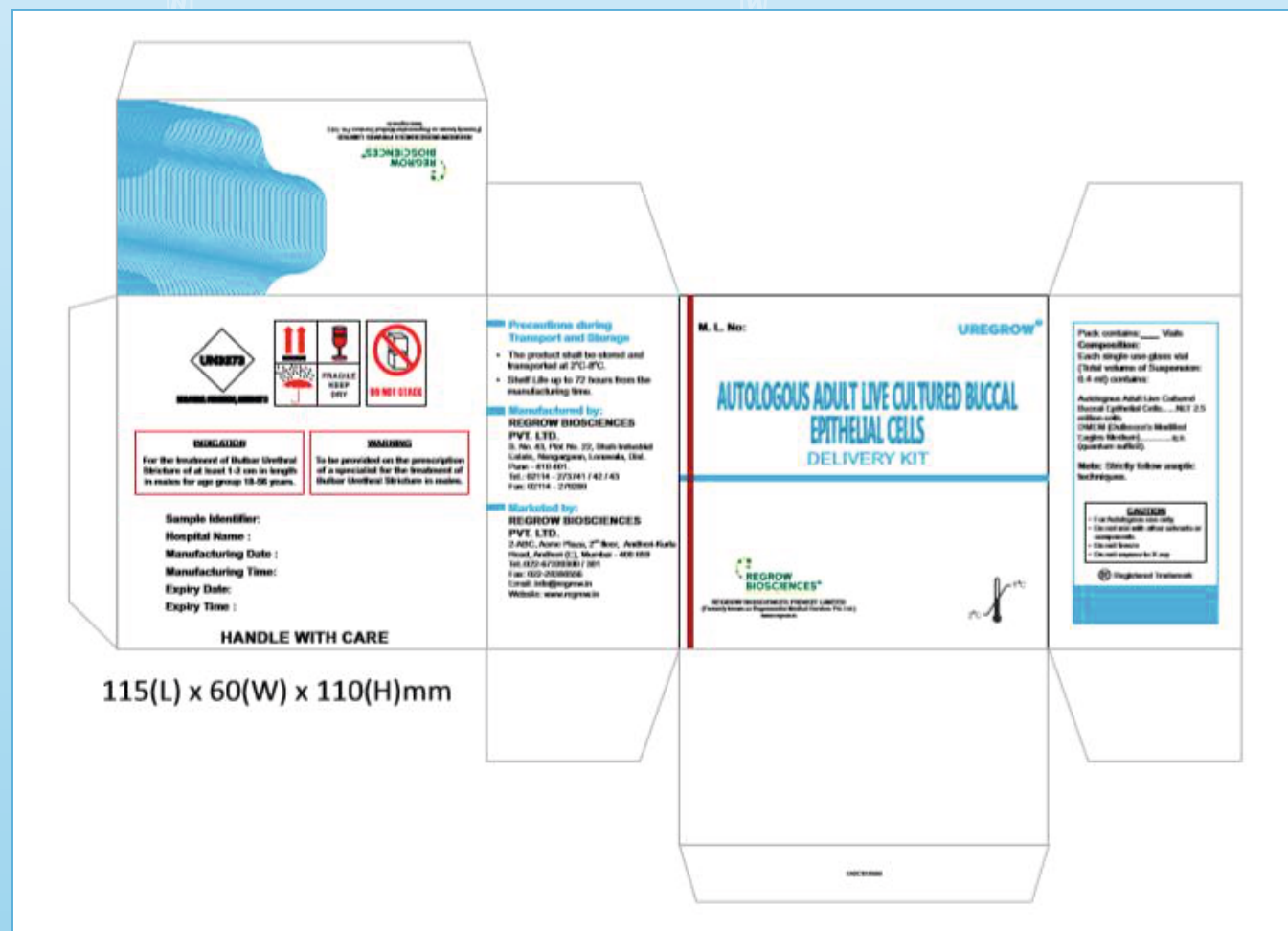


**Inner Glass Vial containing
final product (Sterile) [Min. 02 vials]**

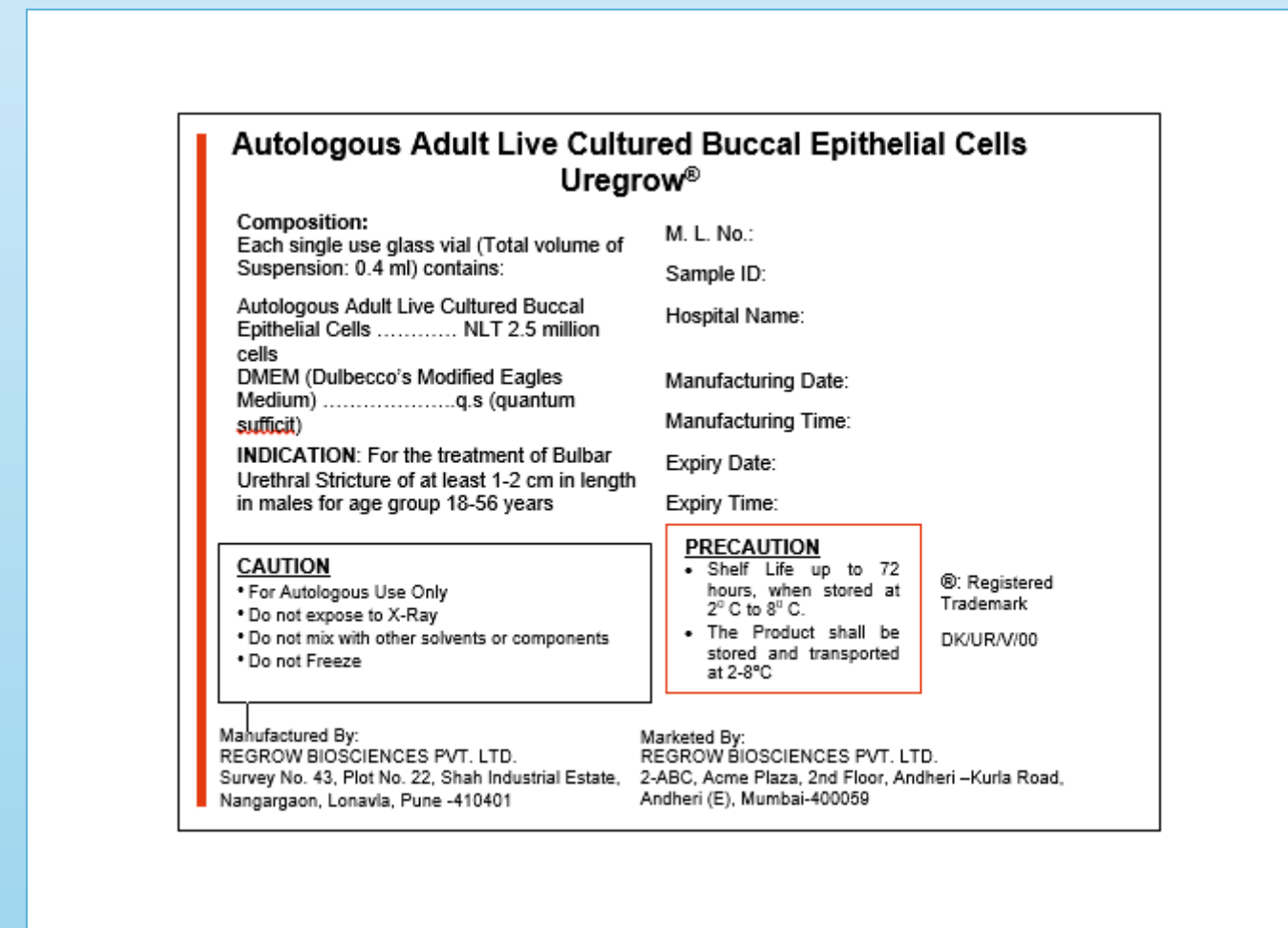
FINAL PRODUCT:

Over 2.5 million Autologous Adult Live Cultured Buccal Epithelial Cells (Uregrow®) in 0.4 ml DMEM solution

Delivery Kit Carton



Inner vial (Primary packaging) label



Outer vial (Secondary packaging) label

Autologous Adult Live Cultured Buccal Epithelial Cells Uregrow®	
Composition: Each single use glass vial (Total volume of Suspension: 0.4 ml) contains: Autologous Adult Live Cultured Buccal Epithelial Cells NLT 2.5 million cells DMEM (Dulbecco's Modified Eagles Medium).....q.s (quantum sufficit)	M. L. No.: Sample ID: Hospital Name: Manufacturing Date: Manufacturing Time: Expiry Date: Expiry Time:
INDICATION: For the Treatment of Bulbar Urethral Stricture of at least 1-2 cm in length in males for age group 18-56 years	
CAUTION <ul style="list-style-type: none"> • For Autologous Use Only • Do not expose to X-Ray • Do not mix with other solvents or components • Do not Freeze 	PRECAUTIONS <ul style="list-style-type: none"> • Shelf Life up to 72 hours when stored at 2° C to 8° C. • The Product shall be stored and transported at 2-8°C
Manufactured By: REGROW BIOSCIENCES PVT. LTD. Survey No. 43, Plot No. 22, Shah Industrial Estate, Nangargaon, Lonavla, Pune -410401	Marketed By: REGROW BIOSCIENCES PVT. LTD. 2-ABC, Acme Plaza, 2nd Floor, Andheri -Kurla Road, Andheri (E), Mumbai-400059
	®: Registered Trademark DK/UR/CN/00

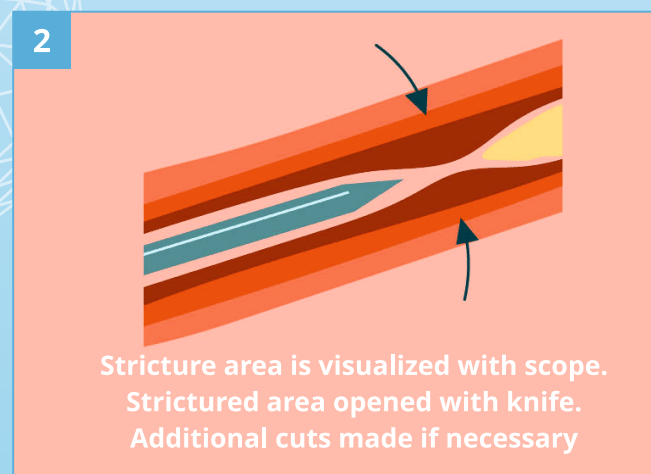
Precautions before Implantation

- Check the expiry date & time of the product implant of patient. It should be before completion of 72 hours from the time of manufacture
- Just before implantation, place the Delivery Kit on non sterile trolley. Remove the stainless steel canister(s) from the carton and place it on the same trolley
- Take out the Inner Glass Vial(s) and with the help of sterile gauze piece. Wipe the Inner Glass Vial(s) containing final product on sterile trolley
- If media of inner vial is cloudy or showing any foreign particles/microbial growth, do not use the vial, instead use new vial
- Do not use the vial if there is visible change of color of medium from pink to yellow or brown
- If any vial in the Delivery Kit is damaged or has caused leakage or mislabeling on vial(s), do not use the vial, instead use new vial

The Implantation Procedure

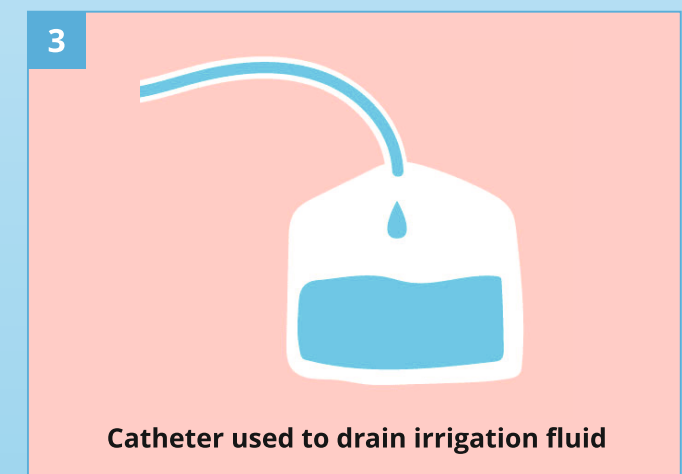
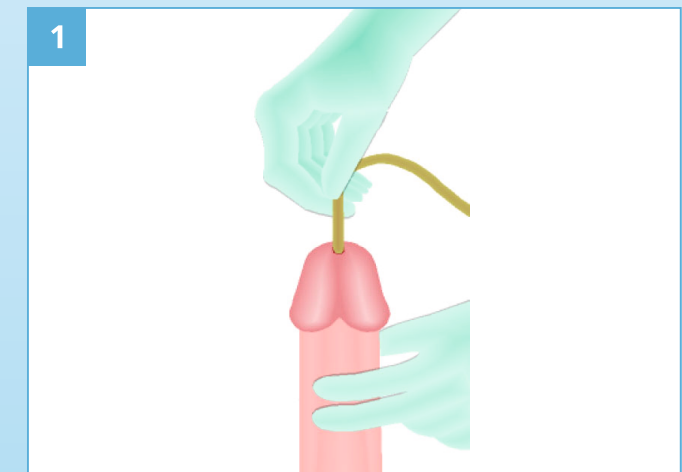
Spinal or general anaesthesia or local anaesthesia is given to the patient to relieve pain.

Urethotomy is conducted (to open or widen the stricture area) to relieve the complete urethral stricture using an internal cystoscopic knife mainly at 12 O'clock position.



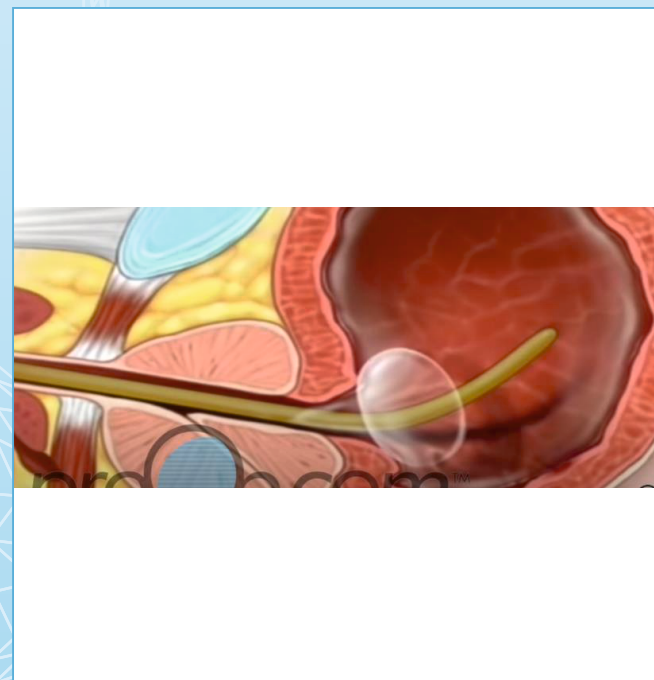
Step 1

Foley's catheter of 12-14 French is passed through urethra and Foley catheter balloon is inflated.



Step 2

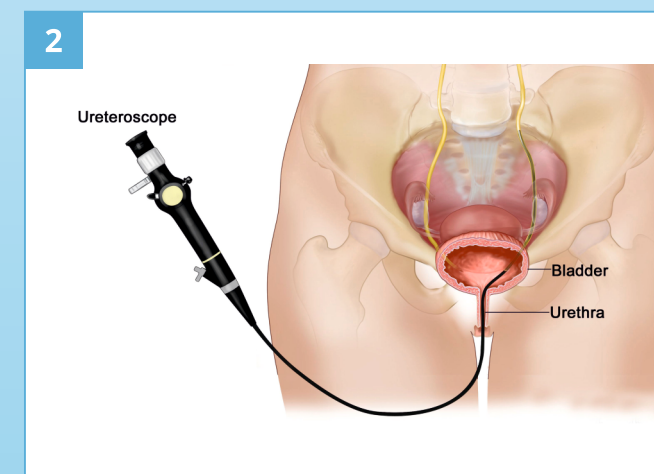
Minimal traction of Foley catheter is given, and saline flow is stopped.



Insertion of catheter with continuous flow of saline

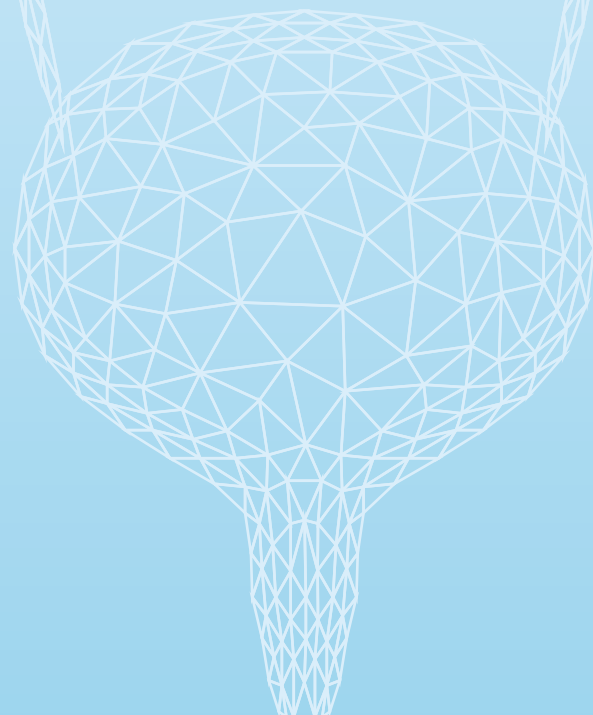
Step 3

6 French Ureteroscope is passed through urethra and stricture area is visualized.



Step 4

Keeping 6 French scope in urethra,
5 French special instruments is passed.

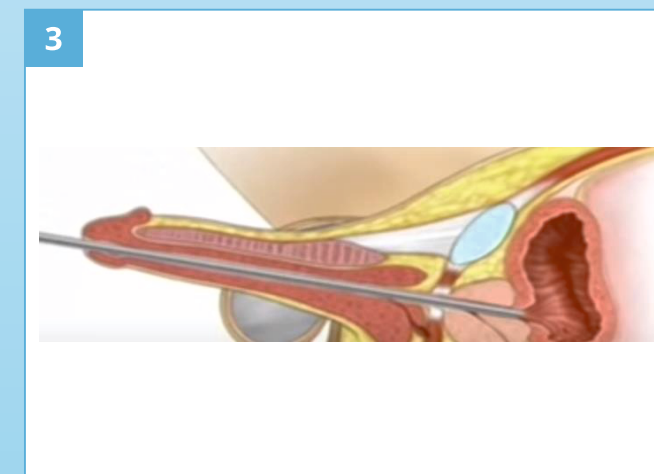
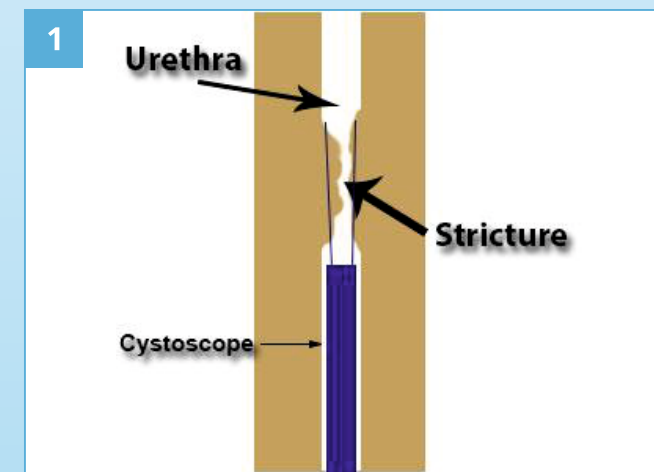


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Step 5

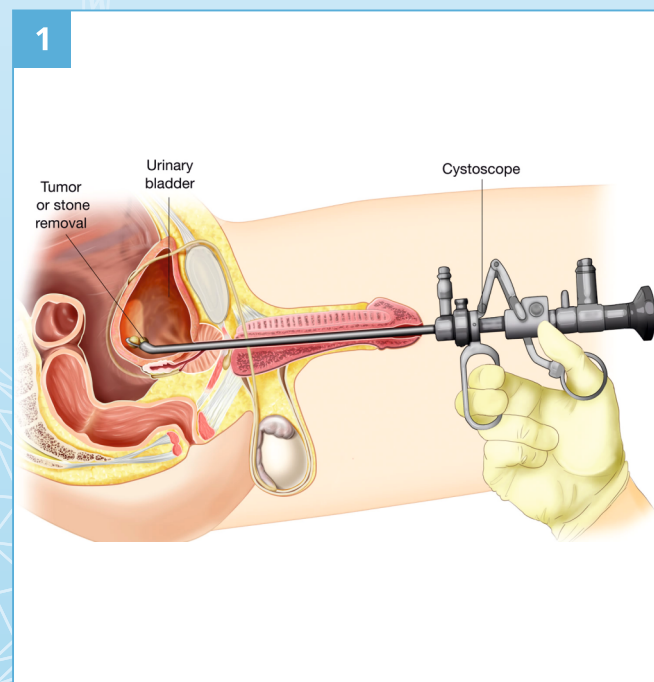
With same cystoscopy, stricture area is visualized, and tip of special instrument is visualized and directed towards the stricture area at starting of the stricture at bladder side.

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Step 6

Buccal mucosa epithelial cells are implanted at the stricture area with the help of biological scaffold through special instrument at stricture area. Special instrument is little withdrawn till another end of stricture.

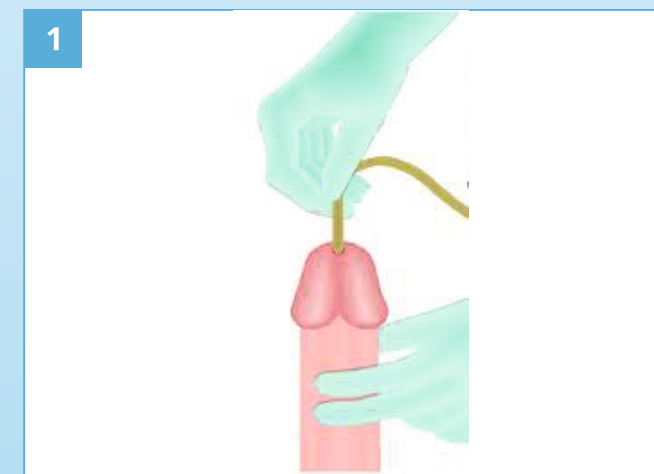


Connect Duploject syringe to the cystoscope and slowly inject the buccal mucosa epithelial cells with biological scaffold at the stricture area using cystoscope.



Step 7

Biological scaffold is surrounded by Foleys catheter and covers stricture area in a cylindrical form.



Urine bag is attached to the Foley's catheter



Step 8

Wait for 6 to 7 minutes, holding penis in vertical position and maintain minimal traction on Foley's catheter.

