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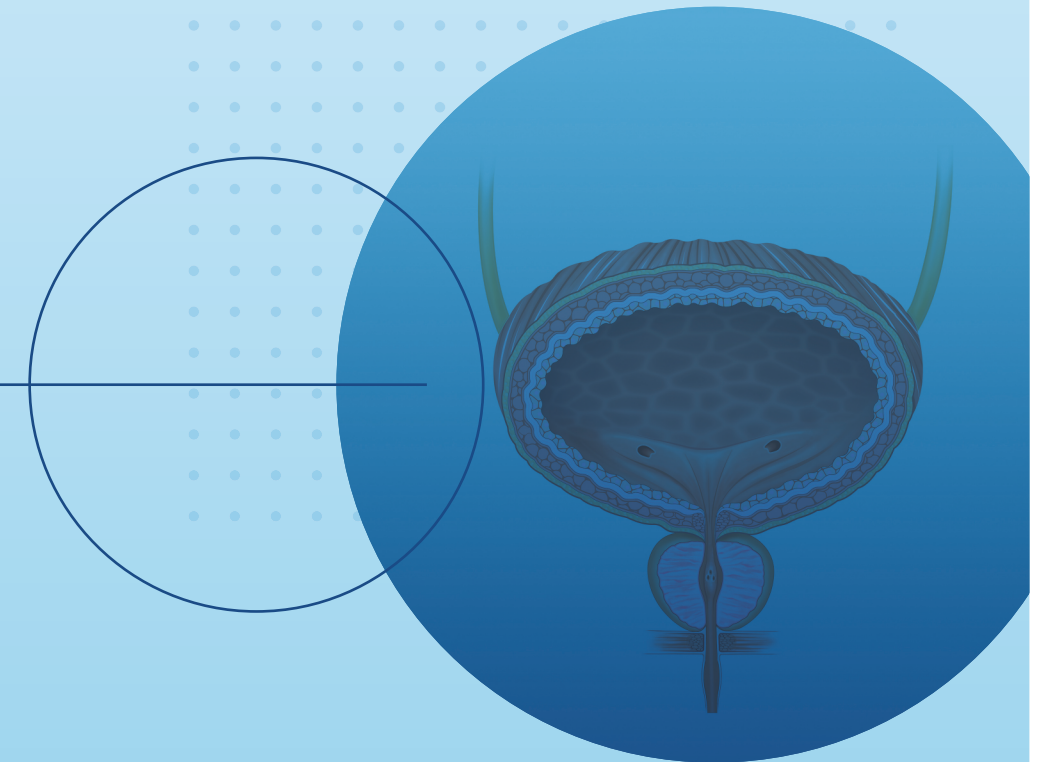
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# UREGROW®

## TISSUE HARVEST MANUAL



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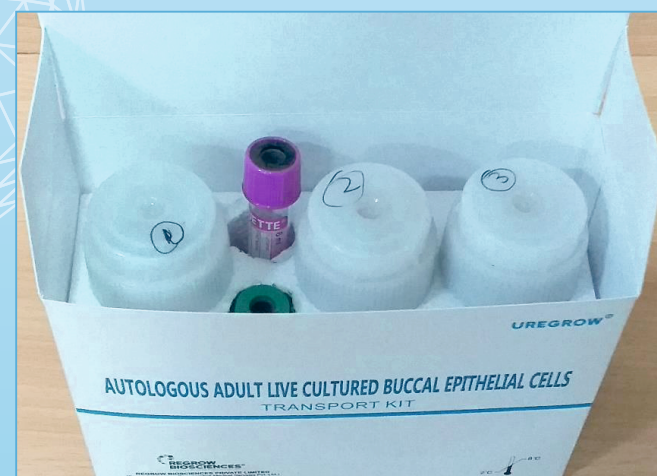
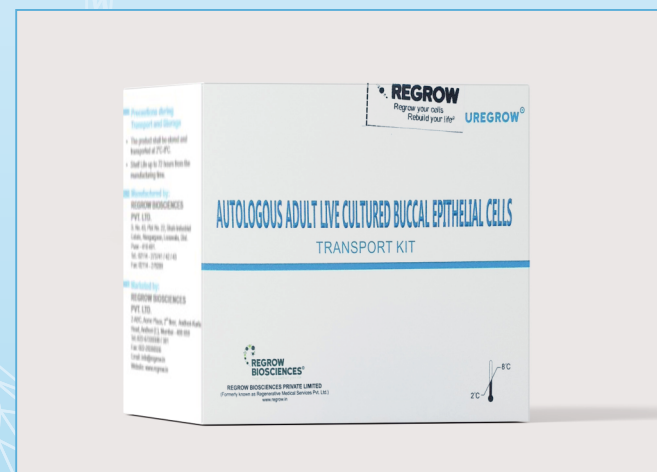


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## Contents of Uregrow® Transport Kit

- ✓ One vial of washing buffer I (WB-I)
- ✓ One vial of washing buffer II (WB-II)
- ✓ One vial of sterile transport nutrient medium
- ✓ One Heparin vacutainer (green color) for Karyotypic Analysis, and one EDTA vacutainer (purple color) for Infectious Disease Testing. Minimum 3 ml patient's peripheral blood is to be collected in each tube.



## Contents of Uregrow® Transport Kit

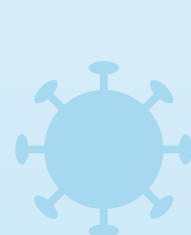
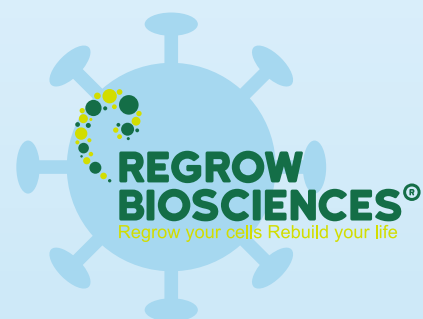


**Washing Buffer - I  
(WB-I) - Vial 1**

**Washing Buffer - II  
(WB-II) - Vial 2**

**Sterile transport  
nutrient Medium -  
vial 3**

**Inner Vial (universal  
container) with 15 ml  
sterile transport  
nutrient medium [1 No.]**



## Instructions to be followed during Covid-19 pandemic

**During Covid-19 pandemic adhere to following instructions before collection of buccal mucosa tissue:**

- Patient having negative medical report for Covid-19, collect both buccal mucosa tissue and patient's peripheral blood
- Patient with declaration for negative report of Covid-19, collect only buccal mucosa tissue, don't collect patient's blood



## Patient selection

- ➔ The product is indicated for the male patients having bulbar urethral stricture of at least 1-2 cm in length for age group 18-56 years
- ➔ The clinical trial studies included both types of patients i.e. patients who had previously underwent and who had not undergone any surgical procedure like dilatation and any surgical care such as Visual Internal Urethrotomy etc.





## Visual inspection of Transport Kit

✓ WHEN TO USE TRANSPORT KIT	✗ WHEN NOT TO USE TRANSPORT KIT
Medium is pink/red	Medium is yellow or brown
Medium not showing any foreign particles or suspended matter other than cells	Medium showing any foreign particles or suspended matter other than cells
Medium is clear and not showing microbial growth in the form of turbidity	Showing microbial growth in the form of turbidity
No Leakage of the vial contents	Not sealed
Within shelf life	Exceeding the shelf life of 72 hrs. from the time of manufacturing
Non tampered	Integrity is broken
Correct labelling details	Incorrect labeling details
Medium consistency is liquid without bubbles	Change in medium consistency with bubbles

## Pre-operative evaluation and preparation of patient

**Before planning to harvest the buccal mucosa from the cheek of the patient should be fully evaluated to check the extension of the mouth opening, the size of available tissue on both cheeks and the presence of scars due to chronic cheek biting or previous surgeries. The following groups of patients are not ideal candidates for oral mucosa cheek harvesting:**

- Patients who chew areca nut products like pan-masala, gutka etc. which may develop sub mucosa fibrosis resulting in a reduced ability to open a mouth.
- Patients who chew tobacco.
- Patients who currently have an infectious disease of mouth.
- Patients who have had previous surgery in the mandibular arch prohibiting a wide opening of the mouth

***Note: 3 days prior to surgery, the patient should begin using chlorhexidine mouthwash for oral cleansing twice a day.***

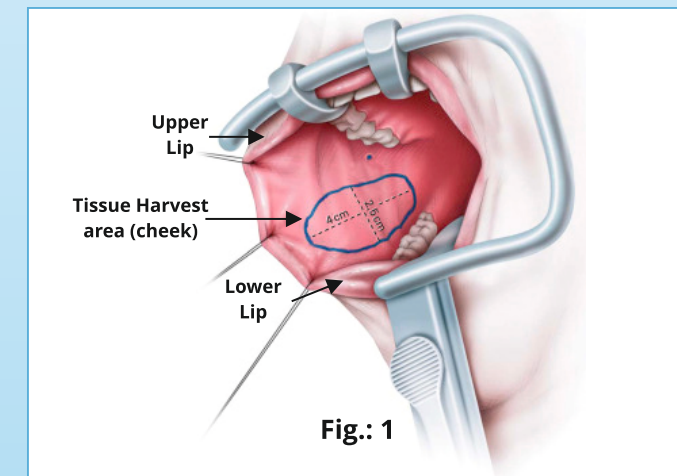
## Instruments for buccal mucosa tissue harvesting

- 1) Kilner Doughty Mouth Retractor
- 2) 10 ml syringe
- 3) Bipolar Electrocautery



## Buccal mucosa tissue harvest procedure

- 1) The external and internal mucosal surfaces of the cheek are prepared, disinfected and draped.
- 2) The Kilner Doughty mouth retractor is put in place and three stay sutures are placed along the edge of the mouth to stretch the oral mucosa. **(Fig.: 1)**
- 3) The stensen duct is identified in proximity of the second molar.
- 4) A 10 ml solution with local anesthetic agent are injected along the edges of the graft to facilitate hemostasis and dissection **(Fig.: 2)**



**Fig.: 1**



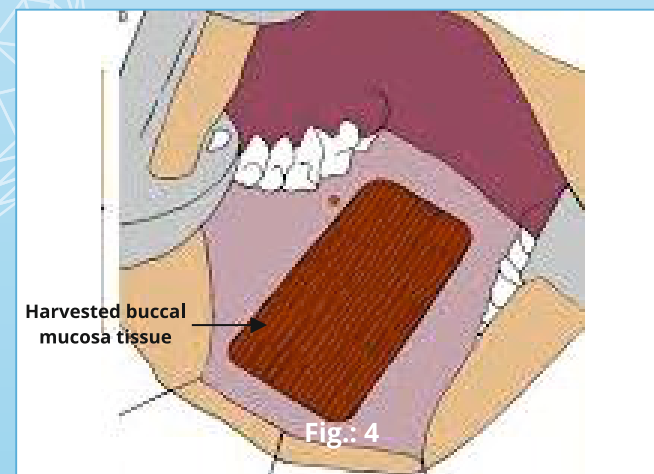
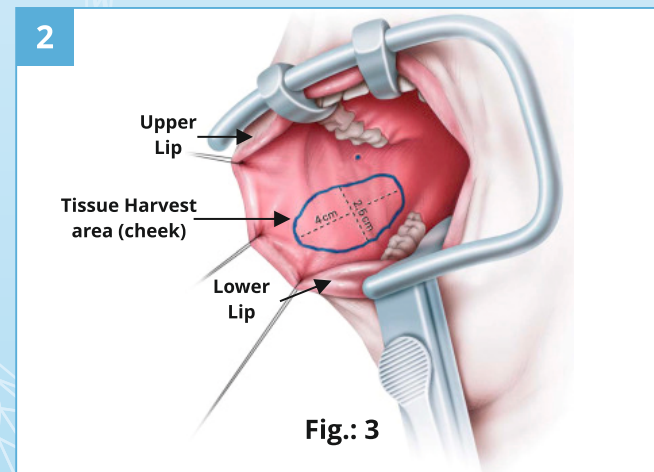
**Fig.: 2**

## Buccal mucosa tissue harvest procedure

**5)** Harvest 1.0 cm long buccal mucosal tissue from the stensen duct and 1.5 cm wide from the external edge of the cheek (total - 1.5 cm<sup>2</sup>). **(Fig.: 3)**

**6)** The buccal mucosal tissue is dissected in the plane between the mucosa and the muscle with the use of bipolar electro cautery.

**7)** Two traction stitches are passed at the distal and proximal apex of the donor site and when traction is applied to these stitches the 2 lateral margin of the donor site tend to approximate towards the midline, which makes primary closure easier and tension free with running 5- zero polyglactin sutures. **(Fig.: 4)**

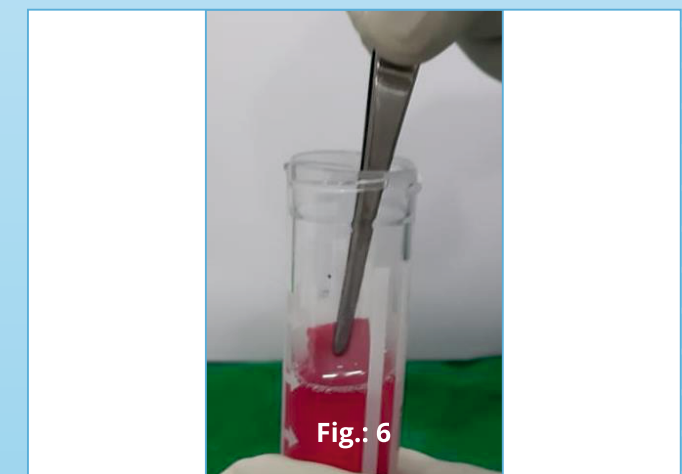
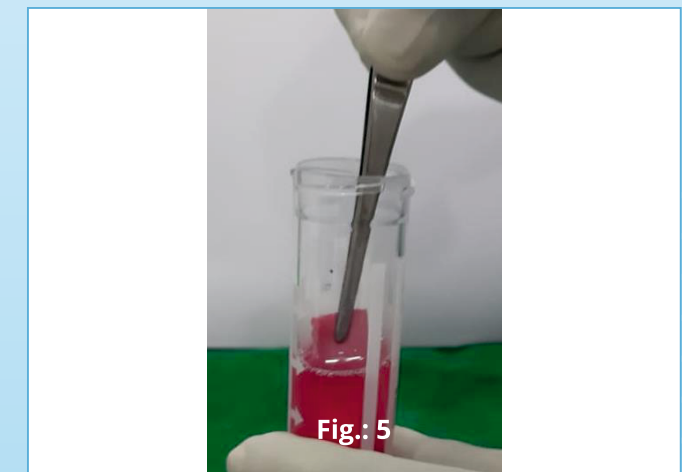


## Buccal mucosa tissue harvest procedure

**8)** The buccal mucosal tissue is stabilized on a silicone board to remove the submucosal tissue.

**9)** Suspend and wash the buccal mucosal tissue (1-2 times) aseptically with Washing buffer -I (WB-I) contained in Vial 1 with the help of sterile forceps to remove any particles attached on it. **(Fig.: 5)**

**10)** Suspend and wash the buccal mucosa tissue (3-4 times) aseptically with Washing buffer -II (WB-II) contained in vial 2 with the help of sterile forcep to remove any particles attached on it. **(Fig.: 6)**. Discard left over WB I and WB II after washing the tissue.



## Buccal mucosa tissue harvest procedure

**11)** Transfer the buccal mucosa tissue aseptically to in inner vial (universal container) containing sterile transport nutrient medium (Vial 3) with the help of sterile forcep. **(Fig.: 7)**

**12)** Capture patient ID, hospital name, sample collection date and time on the label of the inner vial (universal container) of vial 3 with the help of permanent marker. **(Fig.: 8)**

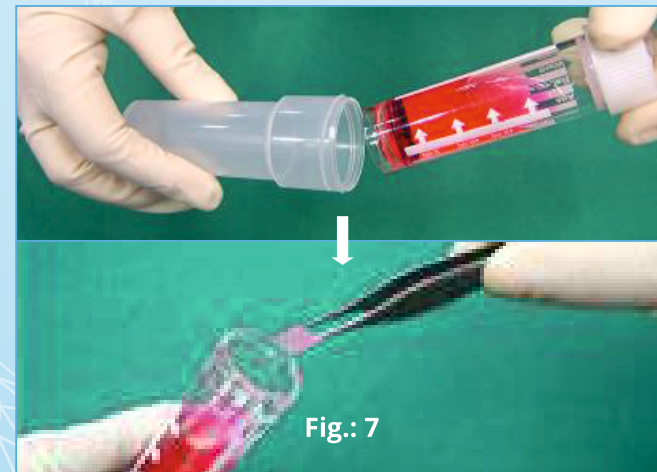


Fig.: 7

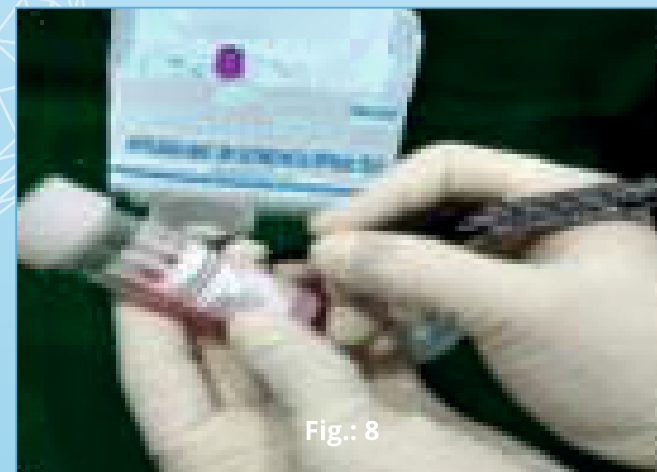


Fig.: 8

## Buccal mucosa tissue harvest procedure

**13)** Pack the inner vial (Universal container) into the outer vial (transport container) **(Fig.: 9, Fig.: 10)**

**14)** Tighten the lid of the Outer Vial (Transport container). **(Fig.: 11)**

**15)** Capture patient ID, hospital name, sample collection date and time on label of outer vial (transport container) of vial 3 wherever applicable. **(Fig.: 12)**



Fig.: 9



Fig.: 10

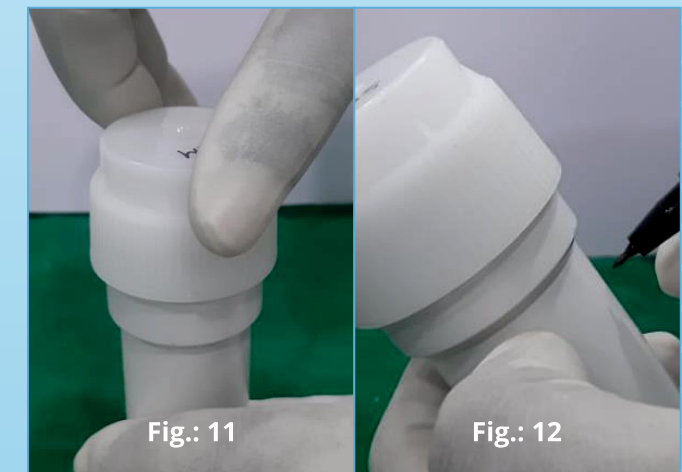


Fig.: 11



Fig.: 12



## Buccal mucosa tissue harvest procedure

**16)** Pre-conditioned shipping unit with temperature maintained at 2-8 C with data logger for monitoring of temperature during transportation.

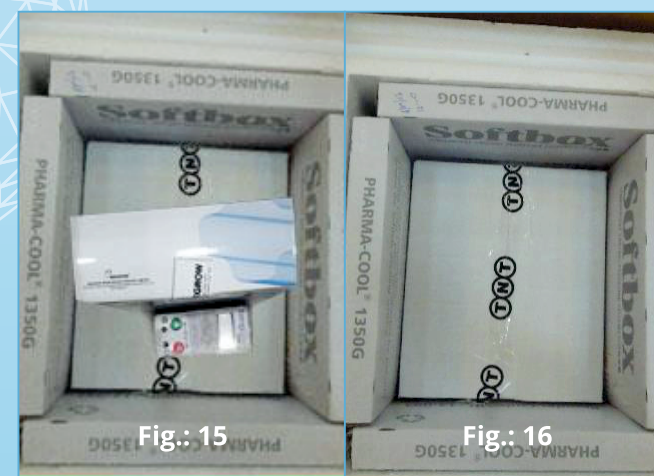
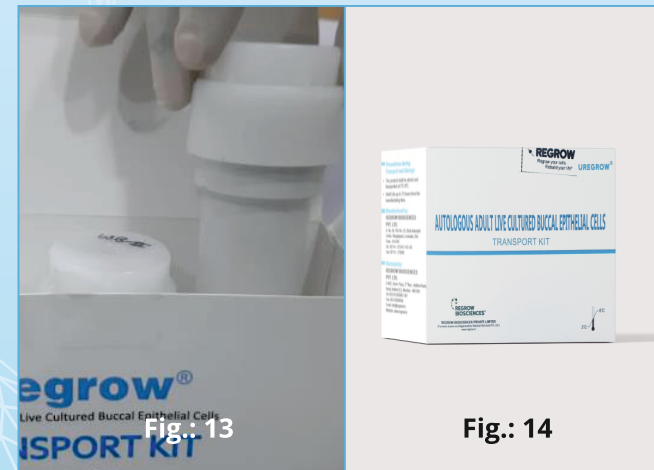
**17)** Place the transport container inside the Transport Kit. Seal the Transport Kit with seal proof/tamper proof sticker provided and capture patient ID, sample collection date and time wherever applicable.

**(Fig.: 13 & Fig.: 14)**

**18)** Keep Transport Kit in allotted space in the Product Box along with the data logger (the data logger should be in ON condition).

**(Fig.: 15)** △ Data Logger should not be in direct contact of gel packs.

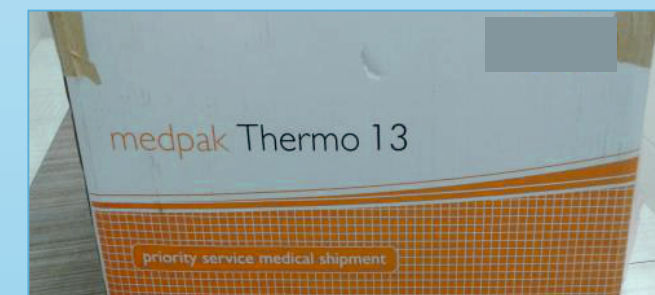
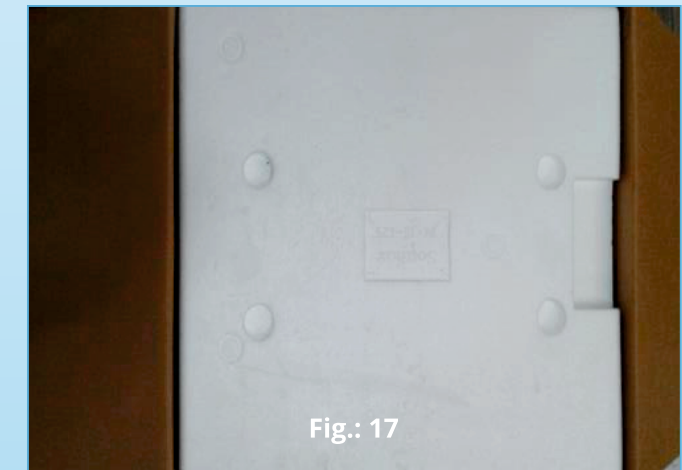
**19)** Seal the Product Box with sealing tape. **(Fig.: 16)** and Place inside Transport Box (with pre-conditioned gel packs).



## Buccal mucosa tissue harvest procedure

**20)** Store the Transport Box in upward position in custody of the hospital at room temperature away from light in dry closed area until handover to approved logistic agency for further shipment to processing laboratory. **(Fig.: 17)**

**21)** The Transport Box with patient file should be picked up by the approved logistics department or agency for shipment to Regrow lab for further processing. **(Fig.: 18)**





## Transport from hospital to GMP Lab

- By Day 07, Regrow Operations team will update the clinician about the status of the sample.
- Regrow coordinator will inform the hospital for the tentative implant date well in advance, so that patient can be informed for second step of implantation.

*Patient's sample (Buccal mucosa tissue) reach to GMP facility of Regrow, Pune within 72 hours.*



## Post-tissue harvest precautions

- Avoid spicy and hot food till specialist advice
- Do regular gargle with medicines as per specialist advice
- Avoid food which need strain while chewing
- Avoid smoking and alcohol
- In case of increase in pain or bleeding, contact to specialist
- Avoid forceful brushing on teeth for 1 week
- An ice bag is applied to the cheek for 24 hours to reduce pain and risk of haematoma formation
- The patient can consume a cold clear liquid diet on the first post-operative day before advancing to a regular diet on the next day
- If bleeding occurs after tissue harvest, apply pressure with gauze until it subsides. There may be some oozing the first- or second days following surgery
- If you observe swelling around the mouth and cheeks, contact specialist