

BIOPSY MANUAL FOR CARTIGROW®

AUTOLOGOUS ADULT LIVE CULTURED CHONDROCYTES

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CONTENTS OF PRODUCT BOX



Transport Kit [1 No.]



Cartilage Tissue Harvester [2 Nos.] (7 mm inner punch)



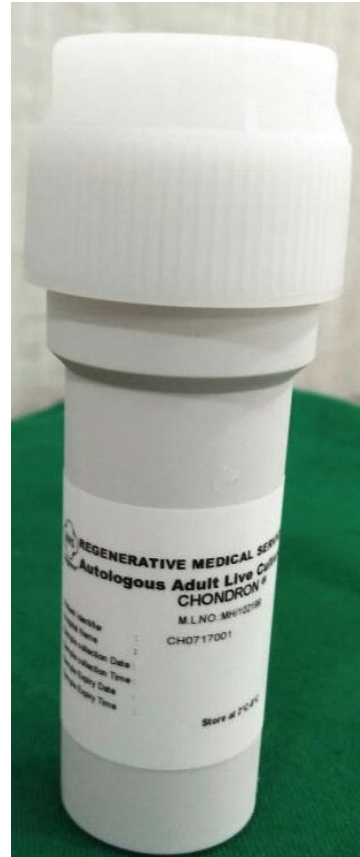
Pouch containing: 1. Heparin tube (green color) for Karyotyping Analysis, 2. EDTA tube (purple color) for Infectious Disease Testing and 3. parafilm for covering tubes.

Note: Total 6ml (3ml + 3ml) blood is to be withdrawn for Karyotyping and Infectious Disease Testing. [1 No. each]



In case of Bilateral case, use two Transport Kits.

CONTENTS OF TRANSPORT KIT



Outer Vial (Non-Sterile) [2 Nos.]



Inner Vial with 15 ml culture media (sterile) [2 Nos.]

PRECAUTIONS BEFORE SAMPLE COLLECTION



- Tissue Harvester must be sterile before use.
- Place Inner Vial(s) on separate sterile trolley for sample collection in aseptic manner.
- Color of solution should be reddish-pink, if color changed to yellow or brown of any vial, do not use the Transport Kit, instead, use new Transport Kit.
- If any vials in the Transport Kit are damaged or has caused leakage, do not use the kit, instead, use new Transport Kit.

CARTIGROW® BIOPSY PROCEDURE

1. The biopsy procedure must be performed in the operation theatre only.

2. For harvesting specimen, insert harvester into cartilage tissue of non-weight bearing area (superior aspect of medial or lateral femoral condyle, trochlea). **(Fig 1)**

3. Remove the cartilage which is attached with subchondral bone which is minimum 6 mm long with 3 mm cartilage and rotate clock-wise and anti-clock-wise 3 times rotation continuously & then pull it out. **(Fig 2)**



Fig 1

Harvester Marking

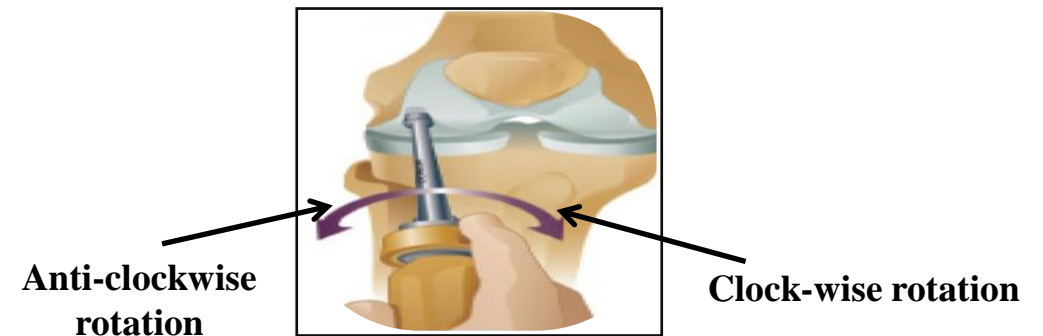


Fig 2

CARTIGROW® BIOPSY PROCEDURE

4. Visually observe the cartilage which is minimum 3 mm in length attached to subchondral bone. **(Fig 3)**

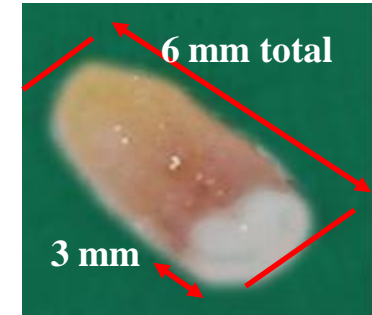


Fig 3

5. Transfer the cartilage sample aseptically to Inner Vial(s) containing sterile culture media with the help of sterile forcep. **(Fig 4)**



Fig 4

6. Capture patient ID, sample collection date and time on the sticker of the Inner Vial(s) with the help of permanent marker. **(Fig 5)**



Fig 5

CARTIGROW® BIOPSY PROCEDURE

7. Pack the Inner Vial(s) into the Outer vial(s) and capture patient ID, sample collection date and time on the sticker of the Outer Vial(s) with the help of permanent marker. **(Fig 6)**



8. Tighten the lid of the Outer Vial(s).



9. Place the Outer Vial(s) 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 7)**



Fig 6

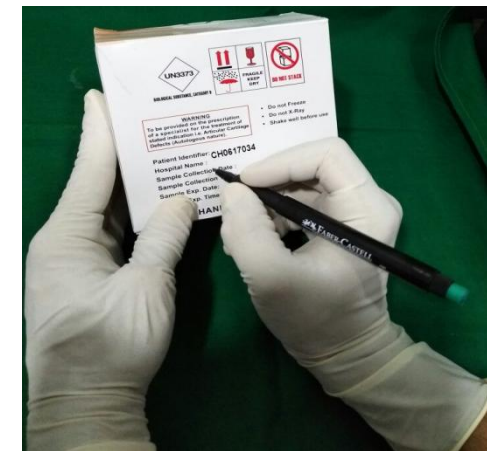


Fig 7

CARTIGROW® BIOPSY PROCEDURE

10. Keep Transport Kit in allotted space in the Product Box along with the data logger (the data logger should be in ON condition). (**Fig 8**)



Data Logger should not be in direct contact of gel packs.



11. Seal the Product Box with sealing tape. (**Fig 9**) and Place in side Transport Box (with pre-conditioned gel packs).



Fig 8



Fig 9

CARTIGROW® BIOPSY PROCEDURE

12. Store the Transport Box in upward position in custody of the hospital at room temperature away from light in dry closed area until shipment to the lab for process. **(Fig 10)**



Fig 10

13. The Transport Box should be picked up by the approved logistics department or agency for shipment to Regrow lab for further processing. **(Fig 11)**



Fig 11

APPENDIX A: Pre-conditioning of Gel Packs of Transport Kit

Softbox

TEMPERATURE CONTROL PACKAGING SYSTEMS ■■■■■

POLYBOX14-CHILLED48

+2°C TO +8°C TEMPERATURE CONTROLLED SHIPPING UNIT
ASIAN REGION DISTRIBUTION PROFILE
SUMMER PACK OUT

ITEM #	DESCRIPTION	QTY
1	CORRUGATED OUTER CARTON	1
2	EPS-47L MOULDED BOX	1
3	EPS-47L MOULDED LID	1
4	PHARMA-COOL 2400G PACK	6
3 X CHILLED 3 X FROZEN		
5	PRODUCT CARTON	1

POLYBOX14 OVERVIEW	
PRODUCT SPACE	344mm X 264mm X 153mm
PRODUCT CAPACITY	14 LITRES
EXTERNAL DIMS	564mm X 514mm X 435mm
DEAD WEIGHT	18KG
VOLUMETRIC WEIGHT	21KG

2400g
PACK

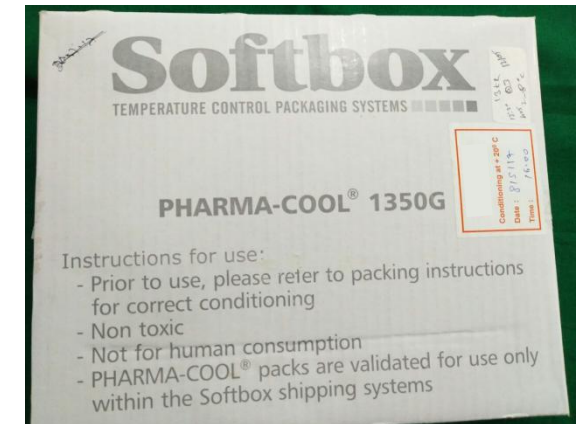
+5°C

CHILL @ +5°C FOR 72HRS (MIN)

2400g
PACK

-20°C

FREEZE @ -20°C FOR 72HRS (MIN)
PRE CONDITION @ +20°C
FOR 30MIN PRIOR TO PACKING



APPENDIX B: Functioning of Data Logger

1. Starting a data logger:

- Press and release the Start button.
- The “Sunshine” icon ☀ appears in the upper left corner of the display.
- The data logger will begin to record data after the start-up delay has been passed.

2. To mark an important event (“Date Stamp”)

- TempTale4 monitors provide an option to “Date Stamp” or mark an important event at any time during the monitoring cycle that will be visible when viewing the data. The mark is displayed as an arrow when viewing the graph and shown in italics when viewing the tabular data.
- To mark a graph while the monitor is recording, press and release the “Start” button.
- The “arrow” icon will appear temporarily in the lower left corner and the temperature history will appear on the display. Data appears as follows:
 1. Average temperature
 2. Highest temperature recorded
 3. Total time above high temperature limit
 4. Lowest temperature recorded
 5. Total time below low temperature limit



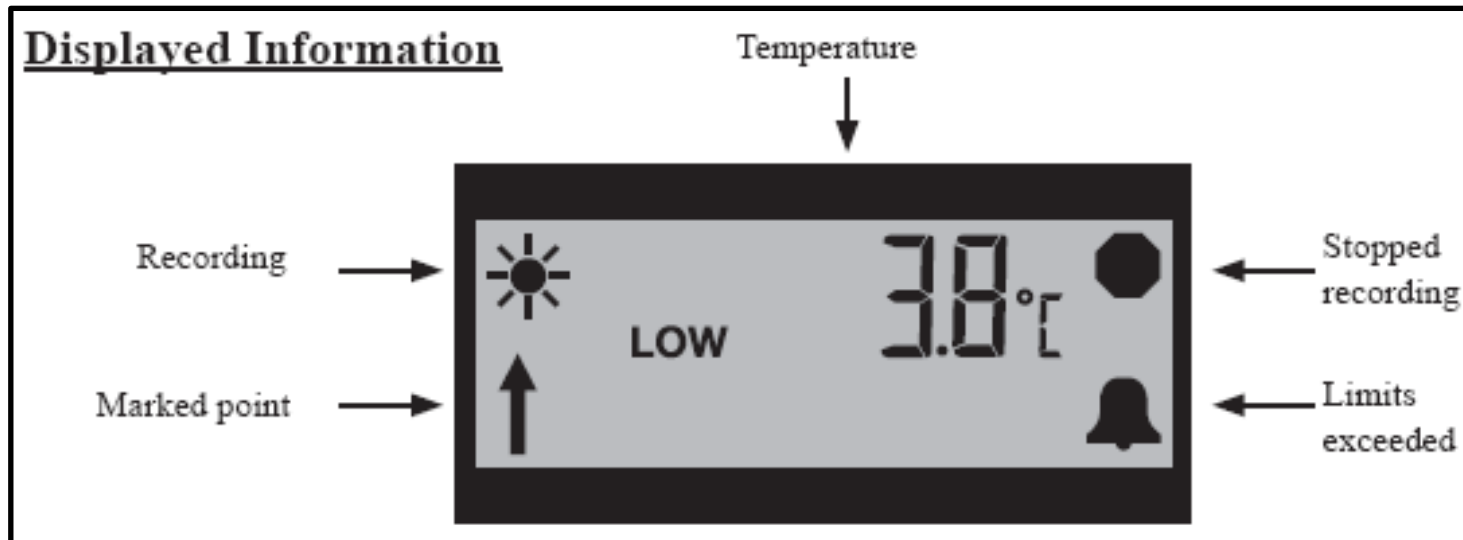
APPENDIX B: Functioning of Data Logger

3. ALARM

- When the TempTale4 is exposed to a temperature outside a pre-programmed limit and time threshold, an “Alarm bell” icon will appear in the lower right corner of the LCD display.

4. Stopping of Data Logger

- Press and hold (1 to 3 seconds) the Stop button until the “Stop button” icon appears in the upper right corner of the LCD display.



TRANSPORT FROM HOSPITAL TO GMP LAB



Cartilage biopsy reach to GMP facility of Regrow, Pune within 48 hours.



- By Day 07, we 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.

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