

SECTION: Clinical
ID NO.: CPI-9-534
PAGE: 1 of 14

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APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Policy:

Health Canada's Safety of Human Cells, Tissues and Organs for Transplantation (CTO) Regulations set out the requirements for the interior label, the package insert and the exterior labels. Additional requirements set out by the American Association of Tissue Banks (AATB) Current Standards for Tissue Banking have been incorporated into this Clinical Process Instruction (CPI).

Process:

1. This document describes the information required for the recovery agency when shipping tissue to the processor.

Interior Label

- 2. The following information shall be included on the interior container label when transporting from retrieval establishment to the source establishment (processor). See exhibits 1 3 including:
 - name of tissue and whether right or left side if applicable;
 - information capable of identifying the donor; and
 - a hazard symbol entitled "Biohazardous Infectious Material" as set out in schedule II in the Controlled Products Regulations as applicable.

Package Insert

- 3. The package insert information may include items from the interior/container label that due to space requirements, could not be included on the interior label (see exhibits 4 7) including:
 - name of tissue and whether right or left side if applicable;
 - description of the tissue;
 - information capable of identifying the donor;
 - date, time, time zone of asystole or aortic cross clamp if applicable;
 - date, time and time zone of retrieval;
 - information specific to the retrieval procedure;
 - name of storage solution if applicable;
 - name, address and telephone number of the retrieval establishment; and
 - name, address and telephone number of the source establishment (tissue bank responsible for determining donor suitability).



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: **2** of 14

ISSUE DATE: June 19, 2017
ISSUE REVISION: 1.15

REVISION DATE: July 24, 2024
APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exterior Label

- 4. The exterior transport package label (see exhibits 8 12) shall include the following information:
 - name, address and telephone number of the source establishment (tissue bank responsible for determining donor suitability);
 - name, address and telephone number of the retrival establishment (recovery facility);
 - recommended storage conditions and transport expiration date including recommended storage temperature and/or acceptable storage temperature range (if applicable);
 - type and quantity of refrigerant or other hazardous materials enclosed in the transport package;
 - a hazard symbol entitled "Biohazardous Infectious Material" as set out in schedule II in the Controlled Products Regulations, as applicableany special handling instructions or for storage during transportation;

Records:

No records

References:

- Health Canada: Safety of Human Cells, Tissues & Organs for Transplantation Regulations, June 2007
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. G3.000, G3.100, G3.120, G3.220, G3.300, G3.310



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: **3** of 14

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.15

REVISION DATE: July 24, 2024
APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 1: Recovered Bone Tissue Labels

CSF-9-194

Recovered Bone Tissue Labels L Humerus L Post. Tibialis L Femur En Bloc or ID: Oonor ID: onor ID: L Radius L Fibula L Peroneus Longus L Knee En Bloc onor ID: Oonor ID: onor ID: Date-Time: Date-Time L Ulna L Achilles w/ Calc./Talus L Peroneus Brevis L Ankle En Bloc onor ID:_ onor ID: L Fascia L Femur L Proximal Femur onor ID:_ onor ID:_ Oonor ID:_ onor ID: Date-Time: ate-Time L Gracilis L Hemi-Pelvis onor ID: onor ID: mor ID: Oonor ID: Date-Time Date-Time L Semitendinosus L Shoulder En Bloc L Ant. Tibialis L Elbow En Bloc Positive Control 1 Positive Control 2 Oonor ID: onor ID: onor ID: onor ID: Date-Time: Date-Time: Date-Time: Date-Time

R Humerus	R Tibia w/ Patellar Tendon/ Meniscus	R Post. Tibialis	R Femur En Bloc
Donor ID:	Donor ID:	Donor ID:	Donor ID:
Date-Time:	Date-Time:	Date-Time:	Date-Time:
R Radius	R Fibula	R Peroneus Longus	R Knee En Bloc
Donor ID:	Donor ID:	Donor ID:	Donor ID:
Date-Time:	Date-Time:	Date-Time:	Date-Time:
R Ulna	R Achilles w/ Calc./Talus	R Peroneus Brevis	R Ankle En Bloc
Donor ID:	Donor ID:	Donor ID:	Donor ID:
Date-Time:	Date-Time:	Date-Time:	Date-Time:
R Fascia	R Femur	L Proximal Femur	
Donor ID:	Donor ID:	Donor ID:	Donor ID:
Date-Time:	Date-Time:	Date-Time:	Date-Time:
R Gracilis	R Hemi-Pelvis		
Donor ID:	Donor ID:	Donor ID:	Donor ID:
Date-Time:	Date-Time:	Date-Time:	Date-Time:
R Semitendinosus	R Shoulder En Bloc		
Donor ID:	Donor ID:		
Date-Time:	Date-Time:		
R Ant. Tibialis	R Elbow En Bloc		
Donor ID:	Donor ID:		I
Date-Time:	Date-Time:		

June 19, 2017



SECTION: Clinical ID NO.: CPI-9-534 PAGE: 4 of 14

June 19, 2017

ISSUE DATE: ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 2: Recovered Skin Tissue Labels Recovered Skin Tissue Labels CSF-9-183 QUARANTINED HUMAN ALLOGRAFT SKIN FOR QUARANTINED HUMAN ALLOGRAFT SKIN FOR TRANSPLANT- processing still required TRANSPLANT- processing still required Storage Media Tis-U-Sol Solution Storage Media Tis-U-Sol Solution Residual amounts of chlorhexidine gluconate used in recovery may be present Residual amounts of chlorhexidine gluconate used in recovery may be presen Transport Storage Temperature Above Freezing (0°C) -10°C Transport Storage Temperature Above Freezing (0°C) -10°C Date-Time recovered: Date-Time recovered: Recovered By: Recovered By: QUARANTINED HUMAN ALLOGRAFT SKIN FOR QUARANTINED HUMAN ALLOGRAFT SKIN FOR TRANSPLANT- processing still required TRANSPLANT- processing still required Storage Media Tis-U-Sol Solution Storage Media Tis-U-Sol Solution Residual amounts of chlorhexidine gluconate used in recovery may be present Transport Storage Temperature Above Freezing (0°C) -10°C Residual amounts of chlorhexidine gluconate used in recovery may be present Transport Storage Temperature Above Freezing (0°C) -10°C Date-Time recovered: Date-Time recovered: Recovered By: Recovered By: QUARANTINED HUMAN ALLOGRAFT SKIN FOR QUARANTINED HUMAN ALLOGRAFT SKIN FOR TRANSPLANT- processing still required TRANSPLANT- processing still required Storage Media Tis-U-Sol Solution Storage Media Tis-U-Sol Solution Residual amounts of chlorhexidine gluconate used in recovery may be present Residual amounts of chlorhexidine gluconate used in recovery may be present Transport Storage Temperature Above Freezing (0°C) -10°C Transport Storage Temperature Above Freezing (0°C) -10°C Date-Time recovered: Date-Time recovered: QUARANTINED HUMAN ALLOGRAFT SKIN FOR QUARANTINED HUMAN ALLOGRAFT SKIN FOR TRANSPLANT- processing still required TRANSPLANT- processing still required Storage Media Tis-U-Sol Solution Storage Media Tis-U-Sol Solution Residual amounts of chlorhexidine gluconate used in recovery may be present Transport Storage Temperature Above Freezing (0°C) -10°C Residual amounts of chlorhexidine gluconate used in recovery may be present Transport Storage Temperature Above Freezing (0°C) -10°C Date-Time recovered: Date-Time recovered: Recovered By: Recovered By: QUARANTINED HUMAN ALLOGRAFT SKIN FOR QUARANTINED HUMAN ALLOGRAFT SKIN FOR TRANSPLANT- processing still required TRANSPLANT- processing still required Storage Media Tis-U-Sol Solution Storage Media Tis-U-Sol Solution Residual amounts of chlorhexidine gluconate used in recovery may be present Residual amounts of chlorhexidine gluconate used in recovery may be present Transport Storage Temperature Above Freezing (0°C) -10°C Transport Storage Temperature Above Freezing (0°C) -10°C TGLN #: Date-Time recovered: Date-Time recovered: Recovered By: Recovered By:



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: **5** of 14

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024

APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 3: Recovered Heart Valve Tissue Labels

	Recovered Heart	t Valve Tissue Laber	CSF-9-195
Cardiac Tissue Recovered		Cardiac Tissue Recovered	
TGLN #	Heart for valves	TGLN #	Heart for valves
Date-Time Recovered:	Pericardium	Date-Time Recovered:	Pericardium
Date-Time Rinsed:	Other	Date-Time Rinsed:	Other
Recovered by:		Recovered by:	
Cardiac Tissue Recovered		Cardiac Tissue Recovered	
TGLN #	Heart for valves	TGLN #	Heart for valves
Date-Time Recovered:		Date-Time Recovered:	Pericardium
Date-Time Rinsed:	Other	Date-Time Rinsed:	Other
Recovered by:		Recovered by:	
Cardiac Tissue Recovered		Cardiac Tissue Recovered	
TGLN #	Heart for valves	TGLN #	Heart for valves
Date-Time Recovered:	Pericardium	Date-Time Recovered:	Pericardium
Date-Time Rinsed:	Other	Date-Time Rinsed:	Other
			l — l
Recovered by:		Recovered by:	
Cardiac Tissue Recovered		Cardiac Tissue Recovered	
TGLN #	Heart for valves	TGLN #	Heart for valves
Date-Time Recovered:	Pericardium	Date-Time Recovered:	Pericardium
Date-Time Rinsed:	Other	Date-Time Rinsed:	Other
Recovered by:		Recovered by:	
Cardiac Tissue Recovered		Cardiac Tissue Recovered	
TGLN #	Heart for valves	TGLN #	Heart for valves
Date-Time Recovered:	Pericardium	Date-Time Recovered:	Pericardium
Date-Time Rinsed:	Other	Date-Time Rinsed:	Other
Recovered by:		Recovered by:	



SECTION: Clinical ID NO.: CPI-9-534 PAGE: 6 of 14

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 4: Recovered Bone Tissue Package Insert

CSF-9-149

TRILLIUM GIFT OF LIFE NETWORK
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9
Felephone (24'7): 1.877.363.8456
Facsimile: 1.866.557.6100

Recovered Bone Tissue Package Insert - NOT SUITABLE FOR TRANSPLANT IN CURRENT FORM

This box contains quarantine donated human tissue for transplant. Donor eligibility has <u>not</u> been completed.					
Recovery Information					
TGLN Donor ID# Receiving Tissue Bank Donor ID#:					
Source Establishment (
Source Establishment (NEIEVO	3111 1155	uc ball	K) IVGI	ic/Audicss/Tel.
Retrieval Establishment (Recovery Location) Name/Address/Tel:					
Death (□Asystole/□Aortic Clamping/□LSA): Date (dd/mm/yy) Time: ET					
Initial Preparation: Date	e (dd/	mm/yy)		Time: ET
					Time: ET
Last Tissue on Ice: Date	(dd/i	mm/w)		Time: ET
				ived	
Tissue Shipped	L	R	L	R	I hereby verify that I packaged the donor according to TGLN CPIs for consent,
Humerus					screening and recovery of deceased donor tissue.
Fascia					Print Name:
Gracilis					Packaged Date (DD/MM/YY):
Semitendinosus					
Tibialis, Anterior					Packaged Time: ET
Tibialis, Posterior					Courier: lb
Peroneus Longus					
Tibia □ W □ P □ D					For Receiving Tissue Bank Use ONLY: Receiving Information
Fibula □W □P □D					Date Received (dd/mm/yy):
Achilles					Shipment Opened: By Date Time
Femur 🗆 W 🗆 P 🗆 D					
☐ Hemipelvis ☐ Ilium					Was the shipment delivered before package expiration?
☐ Iliac Crest					□YES □ NO
Radius:					2. Was wet ice present upon opening?
Ulna:					UYES INO
Peroneus Brevis:					If No, Temperature of contents°C, Thermometer ID
Other:					i No, remperature of contents C, Thermometer ib
Storage Solution: Ringer's Lactate with Cefazolin and Bacitracin Other: NA Comments:			Bacitraci	n	Shipment Acceptable? (Acceptable temperatures are (≥ 0°C) to ≤ 10°C for MS tissue for up to 72 hours) YES NO Initial
For Receiving Tissue Bank Use ONLY ID Verification: The Donor ID of each tissue was verified to match the Donor ID at the top of this form. Initial Storage: Fridge / Freezer ID Shelf Date/Time Placed in Freezer Initial					

September 27, 2023 Page 1 of 1



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: 7 of 14

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 5: Recovered Skin Tissue Package Insert - Sunnybrook

Ontario Health
Trillium Gift of Life Network

TRILLIUM GIFT OF LIFE NETWORK 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9 Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100

CSF-9-156

Recovered Skin Tissue Package Insert (Sunnybrook) - NOT SUITABLE FOR TRANSPLANT IN CURRENT FORM

This box contains quarantine donated human tissue for transplant. Donor eligibility has not been completed. Recovery Information Source Establishment (Relevant Tissue Bank) Name/Address/Tel: Sunnybrook Health Sciences Centre Tissue Bank, Room B219 2075 Bayview Avenue, Toronto, ON M4N 3M5 Tel: 416-480-4050 Retrieval Establishment (Recovery Location) Name/Address/Tel: Choose an item. Death (□Asystole/□Aortic Clamping/□LSA): Date (dd/mm/yy) _____ Time: Initial Preparation: Date (dd/mm/yy)______ ___ Time: ____ ___Time: ______ ET First Incision: Date (dd/mm/yy)_ Last Tissue on Wet Ice: Date (dd/mm/yy) __ Time: Tissue Bank Use Shipping Information (TGLN Use) Received Tissue Shipped Shipped I hereby verify that I packaged the donor tissue according to TGLN CPIs for (v) consent, screening and recovery of deceased donor tissue. Posterior Skin Trunk Posterior Skin Legs Packaged Date (DD/MM/YY): _____ Anterior Skin Abdomen Packaged Time: ______ ET Weight of Wet Ice: _ Anterior Skin Legs Storage Solution: ☐ Tis-U-Sol Other: Comments: For Receiving Tissue Bank Use ONLY: Receiving Information

July 24, 2024 Page 1 of 1



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: 8 of 14

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 6: Recovered Skin Tissue Package Insert - Regen Med

Ontario Health
Trillium Gift of Life Network

TRILLIUM GIFT OF LIFE NETWORK 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9 Telephone (247): 1.877.363.8456 Facsimile: 1.866.557.6100

CSF-9-161

Recovered Skin Tissue Package Insert (RegenMed) - NOT SUITABLE FOR TRANSPLANT IN CURRENT FORM

This box contains quarantine donated human tissue for transplant. Donor eligibility has not been completed. Recovery Information ____ Receiving Tissue Bank Donor ID #: __ Source Establishment (Relevant Tissue Bank) Name/Address/Tel: RegenMed 290 Munro Street, Suite 2000, Thunder Bay, ON P7A7T1 1-807-346-2265 Retrieval Establishment (Recovery Location) Name/Address/Tel:Choose an item. Death (□Asystole/□Aortic Clamping/□LSA): Date (dd/mm/yy) ______ Time: _ Initial Preparation: Date (dd/mm/yy)______Time:_____ET First Incision: Date (dd/mm/yy) ______Time: _____ ET Last Tissue on Wet Ice: Date (dd/mm/yy) _ Tissue Shipped consent, screening and recovery of deceased donor tissue Posterior Skin Trunk Posterior Skin Legs Packaged Date (DD/MM/YY): ____ Anterior Skin Abdomen Packaged Time: _____ET Weight of Wet Ice: __ Anterior Skin Legs Storage Solution: ☐ Tis-U-Sol ☐ Other: Comments: For Receiving Tissue Bank Use ONLY: Receiving Information Date Received (dd/mm/yy): ___ ETShipment Opened By: 2. Is wet ice present upon receipt? ☐ YES ☐ NO 3. The TGLN Donor ID # on each tissue container matches the TGLN Donor ID # on all documentation? ☐ YES ☐ NO 4. Tissue jars double bagged and sealed? ☐ YES ☐ NO 5. Tis-U-Sol storage solution in jars covers skin? ☐ YES ☐ NO 6. Tissue refrigerated on receipt? ☐ YES ☐ NO

March 27, 2024 Page 1 of 1



SECTION: Clinical ID NO.: CPI-9-534 PAGE: 9 of 14

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 7: Recovered Cardiovascular Tissue Package Insert



TRILLIUM GIFT OF LIFE NETWORK 483 Bay Street South tower, 4th Floor Toronto, Ontario M5G 2C9 Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100 CSF-9-150

Recovered Cardiovascular Tissue Package Insert - NOT SUITABLE FOR TRANSPLANT IN CURRENT FORM

			Recovery Information	
TGLN Donor ID# Rece			Receiving Tissue Bank Donor ID#:	
Source Establishment (F	Relevant Tissu	e Bank) Name/	'Address/Tel:	
Retrieval Establishment (Recovery Location) Name/Address/Tel:				
Death (Asystole Aortic Clamping Asystole Aortic Clamping Asystole ET				
Initial Preparation: Date	(dd/mm/yy	r)	Time: ET	
First Incision: Date (dd/	mm/yy)		Time: ET	
Exposure to Cold Rinse	Solution: Da	te (dd/mm/yy) Time: ET	
Last Tissue on Ice: Date	(dd/mm/yy)	Time: ET	
Tissue Shipped	Shipped	Received	Shipping Information (TGLN Use) I hereby verify that I packaged the donor according to TGLN CPIs for consent,	
Heart for Valves			screening and recovery of deceased donor tissue.	
Pericardium			Print Name:	
Descending Aorta			Packaged Date (DD/MM/YY):	
Storage Solution: 0.9% Saline Other:			Packaged Time: ET Weight of Wet Ice: lb	
			For Receiving Tissue Bank Use ONLY : Receiving Information	
Comments:			Date Received (dd/mm/yy):	
			Shipment Opened: By Date Time	
			Was the shipment delivered before package expiration?	
			□YES □ NO	
			Was wet ice present upon opening? YES NO If No, Temperature of contents*C, Thermometer ID* Thermometer ID*C, Thermometer ID	
			3. Shipment Acceptable? (Acceptable temperatures are >0 to 10°C for fresh tissue for up to 72 hours)	
□YES □ NO Initial			□YES □ NO Initial	
For Receiving Tissue Bank Use ONLY				
ID Verification: The Donor ID of each tissue was verified to match the Donor ID at the top of this form. Initial				
Storage: Fridge ID Date/Time Placed in Fridge Initial				

Page 1 of 1 May 27, 2020



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: 10 of 14

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

CSF-9-153

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 8: Donated Human Tissue For Transplant - Bone (Regenmed) Exterior Transport Label

Ontario Health
Trillium Gift of Life Network

DONATED HUMAN TISSUE FOR TRANSPLANT

Quarantine: Not Suitable for Transplant in its Current Form

TGLN #:

KEEP UPRIGHT

KEEP COOL HANDLE WITH CARE

TISSUE ON WET ICE

LBS of Wet Ice Enclosed

Time-Date Packaged: _____

KEEP UPRIGHT

THIS BOX HAS BEEN VALIDATED TO MAINTAIN TEMPERATURE AT OR BELOW 10°C FOR 72 HOURS

TISSUE MUST REMAIN AT OR BELOW 10°C DURING TRANSPORT FREEZE TISSUE AT -40°C OR COLDER UPON RECEIPT

RECOVERY FACILITY	DELIVER TO
(Name/Address/Phone)	(Source Establishment)
	RegenMed
	290 Munro Street, Suite 2000
	Thunder Bay, ON P7A 7T1
	Tel: 1-807-346-2265
	Toll Free: 1-877-554-2205
	Fax: 1-807-683-1017

January 24, 2024



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: 11 of 14

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 9: Donated Human Tissue For Transplant – Bone (MSAT) Exterior Transport Label



CSF-9-152

DONATED HUMAN TISSUE FOR TRANSPLANT

EP UPRIGHT

KEEP COOL HANDLE WITH CARE

TISSUE ON WET ICE
__LBS of Wet Ice Enclosed

Time-Date Packaged: _____

THIS BOX HAS BEEN VALIDATED TO MAINTAIN TERPERATURE AT OR BELOW 10°C FOR 72 HOURS

TISSUE MUST REMIN AT OR BELOW 10°C DURING TRANSPORT FREEZE TISSUE AT -40°C OR COLDER UPON RECEIPT

RECOVERY FACILITY	DELIVER TO
(Name/Address/Phone)	(Source Establishment)
	Mount Sinai Hospital
	Mount Sinai Allograft
	Technologies
	600 University Avenue
	Room 138.05
	Tel: 416-586-4800 ext. 7929
	Fax: 416-586-4458

November 29, 2018



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: **12** of 14

ISSUE DATE: June 19, 2017

ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 10: Donated Human Tissue For Transplant – Skin (Sunnybrook) Exterior Transport Label



CSF-9-154

DONATED HUMAN TISSUE FOR TRANSPLANT

CEEP UPRIGHT

KEEP COOL HANDLE WITH CARE

TISSUE ON WET ICE LBS of Wet Ice Enclosed

Time-Date Packaged: _____

TISSUE MUST REMAIN ABOVE FREEZING (0°C) -10°C DURING TRANSPORT

RECOVERY FACILITY	DELIVER TO
(Name/Address/Phone)	(Source Establishment)
	Sunnybrook Health Sciences
	Centre
	Tissue Bank, Room B219
	2075 Bayview Avenue
	Toronto, ON M4N 3M5
	Tel: 416-480-4050
	Fax: 416-480-4185



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: 13 of 14

ISSUE DATE: June 19, 2017

ISSUE REVISION: 1.15

REVISION DATE: July 24, 2024 APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 11: Donated Human Tissue For Transplant – Heart Valve (Sick Kids) Exterior Transport Label



CSF-9-151

TRANSPLANT KEEP COOL HANDLE WITH CARE TISSUE ON WET ICE

____LBS of Wet Ice Enclosed

Time-Date Packaged: _____

THIS BOX HAS BEEN VALIDATED TO MAINTAIN TEMPERATURE >0°C to 10°C FOR 72 HOURS

TISSUE MUST REMAIN >0°C to 10°C DURING TRANSPORT

RECOVERY FACILITY	DELIVER TO
(Name/Address/Phone)	(Source Establishment)
	The Hospital for Sick Children
	Transfusion Medicine, Rm.
	3688-555 University Avenue
	Toronto, ON M5G 1X8
	Tel: 416-813-6208
	Fax: 416-813-5433



SECTION: Clinical
ID NO.: CPI-9-534
PAGE: **14** of 14

ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.15

REVISION DATE: July 24, 2024
APPROVED BY: Tissue Authority

Clinical Process Instruction Manual

Tissue and Transport Labelling Information Process Instruction

Exhibit 12: Donated Human Tissue For Transplant – Skin (RegenMed) Exterior Transport Label



TGLN #:

CSF-9-228

DONATED HUMAN TISSUE FOR TRANSPLANT

KEEP COOL HANDLE WITH CARE

TISSUE ON WET ICE

Click or tap here to enter text. Lbs of Wet Ice Enclosed

Time-Date Packaged: Click or tap here to enter text.

TISSUE MUST REMAIN ABOVE FREEZING (0°C) DURING TRANSPORT

RECOVERY FACILITY (Name/Address/Phone)

Enter name/address (including postal code)phone number here

DELIVER TO

(Source Establishment)

RegenMed

290 Munro Street, Suite 2000 Thunder Bay, ON P7A 7T1

Tel: 1-807-346-2265

Toll Free: 1-877-554-2205 Fax: 1-807-683-1017

KEEP UPRIGHT

January 24, 2024

KEEP UPRIGHT