Operational Directives	WRHA Infection Prevention & Control Program	
	Management of Critical and Semi-Critical Loaned, Shared, or Leased Medical Devices used for Surgical Procedures	**Page 1 of 4**
	Approval Signature:	**Supersedes:** November 2010
	Date of Approval: June 2, 2023	
	Review Date: June 2025	

1. PURPOSE:

1.1 Minimize patient risk and increase patient safety when using Loaned, Shared, or Leased Medical Devices.

1.2 Protect patients, healthcare providers, manufacturers, distributors, and other parties from hazards associated with contaminated Loaned Shared or Leased Medical Devices, related to scheduling issues, malfunctions, damaged, and/or missing parts.

1.3 Provide adequate time for the inspection, Decontamination, and sterilization of Loaned, Shared, or Leased Medical Devices by the Borrower.

1.4 Prevent the return of contaminated, incomplete, damaged, or malfunctioning Loaned, Shared, or Leased Medical Devices to Lender.

2. DEFINITIONS:

2.1 Borrower – Healthcare facility, vendor, or manufacturer receiving Loaned, Shared, or Leased Medical Devices from another healthcare facility, manufacturer, or vendor.

2.2 Business Hours – Monday to Friday, 0800 – 1600.

2.3 Decontamination – Cleaning, followed by inactivation of pathogenic microorganisms, to render an object safe for handling.

2.4 Emergency – An unexpected situation in which there is an immediate threat to patient life or health (e.g., multiple trauma cases where specified reprocessing of the Medical Device is not possible).

2.5 Healthcare facility - Includes, but are not limited to, acute care hospitals, emergency departments, rehabilitation hospitals, mental health hospitals, and long-term care facilities

2.6 Implantable Medical Device – A Medical Device placed into a surgically or natural formed cavity of the human body that is intended to remain there for a period of 30 days or more. Examples include but are not limited to mesh products, breast implants, grafts and orthopedic prosthesis, and plates and screws.

2.7 Lender – Healthcare facility, vendor, or manufacturer from which Medical Devices are being transferred to a Borrower.

2.8 Loaned, Shared, or Leased Medical Devices – Critical and Semi-Critical Medical Devices used at more than one Healthcare Facility, intended for use during surgical or invasive procedures. This includes, but is not limited to Medical Devices that are:

a) Physician owned and provided
b) Implantable
c) Owned by a Healthcare Facility other than the WRHA or Health Sciences Centre; or
d) Manufacturer/vendor owned.

2.9 Medical Device – as defined in the Medical Device Regulations (SOR/98-282) but non-exhaustively , any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; investigation, replacement, or modification of the anatomy or a physiological process; or control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but can be assisted in its function by such means[5.1].

Medical Devices fall into one of the following three classes:

2.9.1 Critical Medical Device - one that penetrates skin or invades normally sterile parts of the body (i.e. Medical Devices with blood contact, and/or invasive into sterile body cavities).

2.9.2 Semi-critical Medical Device – one that touches mucous membranes during use (i.e., Medical Devices with mucous membrane contact or invasive into non-sterile body cavities).

2.9.3 Non-critical Medical Device – one that does not normally contact the person receiving care or body fluids (i.e., Medical Devices with either no direct contact or intact skin contact only).

2.10 Reprocessing – Process of rendering a potentially contaminated Medical Device safe and effective for use on a patient. This includes cleaning, disinfecting, packaging, and sterilizing the Medical Device as required, and can include sharpening, repairing, re-lubricating, and recalibrating.

2.11 Sterilization - A validated process used to render a product free from viable micro-organisms.

2.12 Traceability – Ability to follow up on a report of a suspected Medical Device malfunction, manufacturer recall, or health care associated infection.

3. OPERATIONAL DIRECTIVES:

3.1 Healthcare providers involved with lending, borrowing, and Reprocessing Loaned, Shared, or Leased Medical Devices shall be knowledgeable in principles and practices of Infection Prevention and Control (IP&C), and Reprocessing, as applicable to their task(s).

3.2 All Loaned, Shared, or Leased Medical Devices shall

- 3.2.1 Be licensed according to Health Canada Medical Device Regulations SOR/98-282 (unless exempt). Verification of Medical License available at https://health-products.canada.ca/mdall-limh/index-eng.jsp;
- 3.2.2 Not exceed 10kg (22lbs) weight, including container and/or wrapping. Please notify your individual MDR department if device exceeds this weight so arrangements can be made if necessary;
- 3.2.3 Comply with WRHA Policy 110.220.060, Medical Devices - Implanted and Explanted, Management of, when containing Implantable Medical Devices;
- 3.2.4 Be reprocessed by the Borrower prior to returning to the Lender. Note: returning items that have only been decontaminated requires the Lender's permission;
- 3.2.5 Be placed in a sealed plastic dust cover, then within a rigid type container with tamper-evident tabs for transport to ensure sterility is maintained and not compromised when borrowed between sites; and
- 3.2.6 Be returned to the Lender at the earliest opportunity, and no later than stipulated in shipping documents.

3.3 Sterilized Loaned, Shared, or Leased Medical Devices borrowed between WRHA/HSC sites shall be in working condition and considered ready to use on arrival.

- 3.3.1 If medical device is malfunctioning or defective, or if it has missing parts, it shall not be Loaned or Shared until appropriate repair/replacement has occurred by the sending facility.

3.4 Loaned, Shared or Leased Medical Devices borrowed from outside WRHA/HSC sites

- 3.4.1 Shall be Reprocessed by the Borrower prior to use on/with a patient
- 3.4.2 Shall arrive to the Borrower (for example: Shipping Receiving Department) a minimum of 48 hours (72 hours preferred) prior to the ***surgical or invasive procedure***. This includes accessories and/or Implantable Medical Devices to ensure adequate time for inventory checking, verification testing, Reprocessing, IP&C assessment and Clinical Engineering safety & functionality assessment, as applicable. Contact the receiving site to help determine estimated time of arrival to reduce delays. For example: If instrumentation is required for a Monday surgical procedure at 1000, it is required at the receiving site by 1000 Thursday (48 hours in advance)

- When Medical Devices do not arrive 48 hours prior to the surgical or invasive procedure but time does allow for inventory checking, Reprocessing and Clinical Engineering safety and functionality assessment, as applicable, the incident shall be documented as a Patient Safety Event in an RL6 as an Equipment/Medical Devices Event. Capture the severity level as No Harm. The submission of a Patient Safety Event shall adhere to the direction outlined in 10.50.020, Patient Safety Event: Management and Disclosure of Occurrences, Near Misses and Critical Incidents. This incident is to be reviewed by the Operating Room (OR) Manager, MDR Manager, and Surgery Site Director. The review should identify ways to avoid similar situations in the future. Findings are then communicated more broadly.
- In an Emergency, or when Medical Devices do not arrive in time to allow for inventory checking, Reprocessing, and Clinical Engineering safety and functionality assessment, as applicable, OR staff shall complete a Patient Safety Event in RL6 as an Equipment/Medical Devices Event. The decision to use the Medical Device rests with the surgeon, provided the Medical Device has been cleaned and disinfected, assembled and sterilized. Follow-up may be initiated as deemed appropriate.
  i. Events involving medical devices are evaluated against the criteria in the following policies
     - 10.50.020, Patient Safety Event: Management and Disclosure of Occurrences, Near Misses and Critical Incidents
     - 10.50.045, Critical Occurrence Reporting and Management, and/or
     - 110.000.490, Medical Device Incident Mandatory Reporting to Health Canada, as appropriate.
- The completion of a Patient Safety Event shall be reported to
  i. Site IP&C
  ii. OR Manager
  iii. Surgery Site Director/designate
  iv. Surgery Physician Director, and
  v. MDR Manager

3.5 Any modification or alteration of a Loaned, Shared or Leased reusable medical device or it's components shall be prohibited

3.5.1 If a Loaned, Shared or Leased reusable medical device is found to be altered or modified it shall be removed from service and its manufacturer and/or owner be notified.

3.6 The Lender shall provide the following information to the Borrower for all Loaned, Shared, or Leased Medical Devices

3.6.1 Inventory list of parts, components, necessary accessories, and illustrations for identification.

3.6.2 Inventory list of parts and components known to be missing.
3.6.3 Any known existing malfunctions or breakage.
3.6.4 Instructions for use including packing and shipping instructions.
3.6.5 Manufacturer validated written instructions for Reprocessing.
3.6.6 In-servicing to the Borrower on the use and Reprocessing of the Medical Device, as applicable.
3.6.7 Keep to the mutually agreed on time lines
3.6.8 Pictures if applicable.

3.7 The Borrower shall verify the Loaned, Shared, or Leased Medical Devices
3.7.1 Are complete and in good working order.
3.7.2 Have a Health Canada License(s) if required.
3.7.3 Contain contents as listed. For Loaned, Shared, or Leased Medical Devices borrowed between Healthcare Facilities, the OR shall document missing items from instrument/sets if applicable.
3.7.4 Can be reprocessed according to the Loaned, Shared or Leased Medical Device's Manufacturer's Instruction for Use (MIFUs)
3.7.5 Any other information as requested by the Lender.
3.7.6 Have not been used on;
- Human or animal research labs/veterinary clinics
- Morgues
- Cadaver labs
- Dry labs

3.8 The Borrower, when returning Loaned, Shared, or Leased Medical Devices to the Lender shall provide the following information.
3.8.1 Any known breakage or malfunctions incurred during use.
3.8.2 Confirmation any Implantable Medical Device or consumable item used was reordered as required.
3.8.3 List of parts, components and accessories.
3.8.4 Inventory list of parts, components and necessary accessories known to be missing.
3.8.5 Any other information as requested by the Lender.

3.9 The Lender and Borrower shall maintain records including but not limited to
3.9.1 Shipping.
3.9.2 Receiving.
3.9.3 Traceability of the Shared, Loaned, or Leased Devices to a specific patient.
3.9.4 Personnel education specific to the medical device.

3.10 Records shall be kept for a minimum of seven years.

4. PROCEDURE:

4.1 See Appendix A for forms for requesting, shipping, receiving and Traceability of Shared, Loaned or Leased Medical Devices.

5. REFERENCES

5.1 Canadian Standards Association (2023). Canadian medical device reprocessing CSA-Z314-23.

5.2 Health Canada. (2006, September). Medical devices regulations SOR/98-282. Available at Department of Justice Canada https://laws.justice.gc.ca/eng/regulations/SOR-98-282/

5.3 ORNAC (2017). ORNAC Standards, Guidelines and Position Statements for Perioperative Registered Nurses.

5.4 Government of Canada, Health Canada Branch https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html

Operational Directive Contacts:
Molly Blake, Regional Lead, Medical Device Reprocessing

Appendix A

When a device is loaned, shared, or leased, the following forms are to be completed by the appropriate site.

1. Requesting/Receiving site:
    a. Complete the Borrowing/Leasing Request Form
    b. Send form to the Lending site/vendor

2. Loaning/Lending site:
    a. Complete the Loaning Facility/Company form.
    b. Send form with the item to the Requesting site

3. Transportation:
    a. Loaning/Lending site to complete the Transportation – Lender/Leaser to Borrower/Lessee form. Send with the item(s)
    b. Receiving site to complete the Transportation – Borrower/Lessee to Lender/Leaser form

4. Requesting/Receiving site:
    a. Complete Receiving (Borrower/Lessee) Facility form.
    b. Retain as per regional policies.

Loaning Facility/Company Form		
Item(s) name and/or description:		
Loan approved by	Name:	Signature:
	Company/Facility:	Date:
Copy of Borrower request received	Date:	Time:
Company name		

Suitability for Loan, Share or Lease	
Licensed or exempted by Health Canada?	Yes / No
Has the Loaned, Shared or Leased piece of equipment been altered in any way?	Yes / No ***If "yes" the item cannot be Loaned, Shared or Leased***
Has the item been used on human or animal research labs and veterinary clinics: morgues; cadaver labs; and/or dry labs	Yes / No ***If "yes" the item cannot be Loaned, Shared or Leased***
Any breakage or malfunctions?	Yes / No
If a healthcare setting owned medical device is malfunctioning or defective or if it has missing parts it shall not be loaned or shared until it has been properly repaired or replaced by the lending facility. *If the medical device is owned by the vendor/manufacturer the vendor manufacturer shall be notified in the accompanying documentation.*	
Vendor representative has current copy of MDR loaner instrument policy?	Yes / No ***If "no" contact MDR Supervisor/Manager before proceeding***

Documentation	
Are reprocessing records available for the receiving facility?	Yes / No
There is an itemized list of all parts and components accompanying the item(s). Please attach. *This should include any illustrations, identifying numbers that allow for confirmation of set contents*	Yes / No
All components accounted for and functional?	Yes / No
MIFUs accompanied with drop-off?	Yes / No

Total number of trays:					
List specific trays:					
Instrument count			**Prostheses count**		
Name of set(s)		**Total items in set**	**Container(s)**		**Total items in container**
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		

Prior to entering into an agreement, the lending and receiving (borrowing) facilities shall determine who shall be responsible for the following costs:

- Consumables _____
- Transportation including return_____
- Loss/repair /replacement for any damaged medical devices_____
- Reprocessing costs_____

Copy of this form and any required documentation sent	
Date	**Time**
Completed by	**Signature**
Role/Designation	**Facility/Company**

End of form

Borrowing/Leasing Request Form		
Name of item(s) requested and/or description:		
Requestor	Name:	Signature:
	Role/Designation:	Facility:
	Department:	
Date and time requested	Date:	Time:
Date and time required at site	Date:	Time:
Prior to entering into an agreement, the lending and receiving (borrowing) facilities shall determine who shall be responsible for the following costs • Consumables _____ • Transportation including return_____ • Loss/repair /replacement for any damaged medical devices_____ • Reprocessing costs_____		
Request sent on	Date	Time
Copy of this form and any required documentation sent		
Date		**Time**
Completed by		**Signature**
Role/Designation		**Facility/Company**

End of form

Receiving (Borrower/Lessee) Facility Form		
Name of item(s) requested and description:		
Name of Vendor/Facility Lending/Leasing		
Vendor/Facility emergency contact		
Date and Time requested	Date	Time
Date and Time received	Date	Time
Date and Time required at site (procedure date/time)	Date	Time

Loaned, shard or leased medical devices shall arrive to the Borrower (for example, Shipping/Receiving Department) a minimum of 48 hours (72 hours preferred) prior to the surgical or invasive procedure. When Medical Devices do not arrive 48 hours prior to the surgical or invasive procedure but time does allow for inventory checking, Reprocessing and Clinical Engineering safety and functionality assessment, as applicable, the incident shall be documented as a Patient Safety Event in an RL6 as an Equipment/Medical Devices Event. Capture the severity level as No Harm. This incident is to be reviewed by the Operating Room (OR) Manager, MDR Manager, and Surgery Site Director

If less than 48 hours is this an emergency situation? Yes / No

In an Emergency, or when Medical Devices do not arrive in time to allow for inventory checking, Reprocessing, and Clinical Engineering safety and functionality assessment, as applicable, OR staff shall complete a Patient Safety Event in RL6 as an Equipment/Medical Devices Event. The decision to use the Medical Device rests with the surgeon, provided the Medical Device has been cleaned and disinfected, assembled and sterilized. Follow-up may be initiated as deemed appropriate. The completion of a Patient Safety Event shall be reported to:

ii. Site IP&C
iii. OR Manager
iv. Surgery Site Director/designate
v. Surgery Physician Director, and
vi. *MDR Manager*

Documentation	
Copy of Loaning/Leasing form from Facility/Vendor received?	Yes / No
Packing and shipping instructions have been received?	Yes / No
Manufacturer's Instruction for Use (MIFUs) sent?	Yes / No
Inventory list received?	Yes / No
Reprocessing records have been made available for traceability of the item(s)?	Yes / No

Suitability for Use	
Can the receiving facility reprocess the item(s) in accordance with its MIFUs?	Yes / No
The receiving Medical Device Reprocessing area is able to provide validated reprocessing equipment and cycles?	Yes / No
All components are accounted for and functioning?	Yes / No
Has the Loaned, Shared or Leased piece of equipment been altered in any way?	Yes / No ***If "yes" the item cannot be Loaned, Shared or Leased***
Has the item been used on human or animal research labs and veterinary clinics: morgues; cadaver labs; and/or dry labs	Yes / No ***If "yes" the item cannot be Loaned, Shared or Leased***

Education	
Education on use of the device has been provided	Yes / No
If no explain:	

Reprocessing		
Reprocessed at Receiving (Borrowing/Leasing) facility on	Date	Time

Name of set(s) received		**Total items in set**	**Container(s) received**		**Total items in container**
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		

Set list matches set contents	Yes / No

Surgeon name:			
☐	Spine	☐	General
☐	Ortho	☐	Bariatric
☐	Plastic	☐	GU
☐	ENT	☐	GYNE
☐	Other:		

Return to Lender/Leaser		
Reprocessed prior to return on	Date	Time
Are reprocessing records available for Lender/Leaser?		Yes / No
Report any damaged or missing pieces here:		
Any breakage and malfunctions?		Yes / No
If yes document here:		

	Name of set(s) received	**Total items in set**		**Container(s) received**	**Total items in container**
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		

End of form

Transportation – Lender/Leaser to Borrower/Lessee			
Name of Transporting Service:			
Type of Items Transported:			
Number of Containers Received:			
Items are sealed in a plastic dust cover, then within a rigid type container with tamper-evident tabs?			Yes / No
Is the transporter aware of the manufacturer's instructions on temperature and humidity, handling requirements and restrictions (avoiding agitation, bumps etc)?			Yes / No
Have they been followed?			Yes / No
Item is physically separated from any soiled items during transportation			Yes / No
Date and Time received from Leaser/Lender	Date:	Time:	
Name of Transporter		**Signature:**	
Date and Time delivered to Borrower/Lessee	Date:	Time:	
Name of person receiving delivery		**Signature:**	
Number of containers delivered			
Is there is a discrepancy between number of containers received *If yes, explain:*			Yes / No

..... *End of form* .....

Transportation – Borrower/Lessee to Lender/Leaser		
Name of Transporting Service:		
Type of Items Transported:		
Number of Containers Received:		
Items are sealed in a plastic dust cover, then within a rigid type container with tamper-evident tabs?		Yes / No
Is the transporter aware of the manufacturer's instructions on temperature and humidity, handling requirements and restrictions (avoiding agitation, bumps etc)? **Have they been followed?**		Yes / No Yes / No
Item is physically separated from any soiled items during transportation		Yes / No
Date and Time received from Borrower/Lessee	Date:	Time:
Name of Transporter	**Signature**:	
Date and Time delivered to Lender/Leaser	Date:	Time:
Name of person from Lender/Leaser receiving Delivery	**Signature**:	
Number of containers delivered		
Is there is a discrepancy between number of containers received *If yes, explain:*		Yes / No

End of form

Loaned, Reusable Medical Device Process Flow Chart