

POLICY

Handling Patient Requests for Explanted Medical Devices, Human Tissue or Specimens

Purpose

This policy outlines the considerations and responsibilities for handling patient requests for explanted medical devices, human tissue or specimens in non-hospital facilities.

Background

The *Environmental Management Act (EMA)* sets out the requirements for the introduction of waste into the environment. The Hazardous Waste Regulation, under the *EMA*, sets out the requirements for the proper handling and disposal of hazardous waste which includes biomedical waste. However, there is no provincial or federal law which explicitly outlines whether explanted medical devices, human tissue or specimens can or cannot be given to the patient after removal.

The Non-Hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP) accreditation standard for waste management requires that health-care waste be safely and appropriately managed.

The Non-Hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP) accreditation standard for consent requires that there be a consent discussion before any health-care treatment, procedure or surgery.

Policy

Provision of explanted medical devices, human tissue or specimens requires oversight by the medical director of the facility.

Considerations

If a patient has requested the provision of explanted medical devices, human tissue or specimens several factors are to be considered and include but are not limited to:

- federal, provincial and local laws pertaining to medical devices, human tissue and specimens, biomedical waste and the declaration on the rights of Indigenous peoples
- culturally, religious, and spiritually appropriate care (i.e., Indigenous cultural safety)

- consultation with the patient's surgeon
- alternatives and/or options other than giving the explanted medical device, human tissue or specimen to the patient and may be preferred (i.e., viewing, providing a photograph)
- hazards and risks of release (i.e., infection prevention and control, handling and disposal of biomedical waste) such as:
 - human tissue or specimens required for pathology
 - human tissue or specimens that contain cytotoxic, pharmaceutical, chemical or radioactive waste
 - human tissue or specimens that may pose an infection disease risk (e.g., hepatitis B, multi-resistant bacteria)
 - medical devices which require return to the manufacturer (e.g., adverse event, recall, post-market surveillance)

Authorization

- Only the medical director is authorized to grant a patient's request for the medical device, human tissue or specimen.

Disposition

- Explanted medical devices, human tissue or specimens provided to the patient must be appropriately prepared and contained for release.
- When providing the explanted medical device, human tissue or specimen, the patient must be given written information which details their responsibilities for the explanted medical device, human tissue or specimen being provided to them (i.e., appropriate disposal) and this information must be reviewed with the patient by a regulated health professional prior to the patient receiving the explanted medical device, human tissue or specimen.

Documentation

- The medical director must document in the patient's medical record when provision of the explanted medical device, human tissue or specimen is not possible and include the reason(s).
- The details of the provision of any of explanted medical devices, human tissue or specimens to the patient must be documented in the patient's medical record and include:
 - the date it was provided
 - a description or the name/identifier of what was provided (i.e., type of implant, hardware or tissue)
 - the full legal name of who the medical device, human tissue or specimen was provided to

- how the medical device, human tissue or specimen was contained (i.e., leak-proof container) and packaged (i.e., double-wrapped, biohazard label, icepack) at time it was provided
- that written information detailing the patient's responsibilities for the explanted medical device, human tissue or specimen being provided to them was reviewed with and provided to the patient

Facility Policy and Procedures

- The medical director is responsible for ensuring that the non-hospital facility has policy and procedures in place for handling patient requests for explanted medical devices, human tissue or specimens.
- The medical director is responsible for ensuring the necessary experts have been engaged in the development of facility policy and procedures for handling patient requests for explanted medical devices, human tissue or specimens (i.e., legal counsel, infection, prevention and control, local medical health officer and/or environmental health officer, Indigenous knowledge keepers).
- The policy and procedures are required to:
 - be specific to the types of explanted medical devices, human tissue or specimens that, based on the facility's scope of accreditation (i.e., plastic surgery, orthopedic surgery, reproduction), may be requested by their patients (i.e., implants, hardware, products of conception).
 - detail the process and steps for processing patient requests for explanted medical devices, human tissue or specimens.
 - detail the factors that are to be considered when providing the explanted medical device, human tissue or specimen following a patient request.
 - explicitly state that only the medical director can authorize providing the patient with the explanted medical device, human tissue or specimen.
 - based upon the type of explanted medical devices, human tissue or specimens, detail the required disposition of the explanted medical device, human tissue or specimen.
 - identify the written instructions document to be reviewed with and given to the patient which outlines the patient's responsibilities for the explanted medical device, human tissue or specimen, such as safe handling, storage and disposal (i.e., minimum depth for burying) once the medical device, human tissue or specimen has been provided to them and the enduring option to return the medical device, human tissue or specimen to the non-hospital facility for appropriate disposal.

References

Association of periOperative Registered Nurses. Guidelines for perioperative practice 2023. Denver, CO: Association of periOperative Registered Nurses; 2023. Guideline for specimen management; p. 971-1014.

Canadian Standards Association. Handling of health care waste materials. Toronto: Canadian Standards Association; 2021. 70 p. CSA Standard: Z317.10:21.

College of Physicians and Surgeons of British Columbia, Non-Hospital Medical and Surgical Facilities Accreditation Program. Accreditation standards: Consent [Internet]. Vancouver: College of Physicians and Surgeons of British Columbia; 2025 Jan 09 [cited 2026 Feb 6]. 11 p.

College of Physicians and Surgeons of British Columbia, Non-Hospital Medical and Surgical Facilities Accreditation Program. Accreditation standards: Indigenous cultural safety, cultural humility and anti-racism [Internet]. Vancouver: College of Physicians and Surgeons of British Columbia; 2023 Jun 15 [cited 2024 Feb 26]. 7 p.

College of Physicians and Surgeons of British Columbia. Practice standard: Indigenous cultural safety, cultural humility and anti-racism [Internet]. Vancouver: College of Physicians and Surgeons of British Columbia; 2022 Feb 25 [updated 2022 May 6; [cited 2024 Feb 26]. 4 p.

Environmental management act: hazardous waste regulation [Internet]. Victoria (BC): Queen's Printer; 1988 Feb 18. [amended 2022 Mar 30; cited 2024 Feb 26].

Operating Room Nurses Association of Canada. The ORNAC standards, guidelines, and position statements for perioperative registered nurses. 16th ed. Bath (ON): Operating Room Nurses Association of Canada; 2023. 562 p.

Healthcare Insurance Reciprocal of Canada. Taking placental/fetal remains home [Internet]. Toronto (ON): Healthcare Insurance Reciprocal of Canada; [reviewed 2018 Jan; cited 2024 Feb 27].

Contact

For further information, please contact the NHMSFAP at nhmsfap@cpsbc.ca.