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Management of Medicinal Leeches from Leech Therapy

Medicinal Leeches (*Hirudo medicinalis* or *Hirudo verbana*) are laboratory raised freshwater Annelida worms intended for use as an adjunct to the graft tissue healing (when problems of venous congestion may delay healing) or to overcome the problem of venous congestion by creating prolonged localized bleeding. The use of medicinal leeches is sometimes referred to as "Hirudotherapy."

History: The use of leeches to draw blood dates back thousands of years. They were widely used as an alternative treatment to bloodletting and amputation for several thousand years. Leeches used for bloodletting usually involved the medicinal leech, *Hirudo medicinalis*.

In June 2004, the Food and Drug Administration (FDA) cleared medicinal leeches as the second living organism approved as a medical device. In 2005, an FDA panel voted to classify medicinal leeches as "non-exempt, Class II medical devices with special controls." The special control for the leeches was a guidance document stating that "discarded leeches should be treated as biohazard waste due [to] their contact with blood."

Leech Therapy: Leeches may be used in instances where skin flaps, skin grafts, or other tissues are suffering from impaired venous circulation. Leeches help to alleviate the problem of venous congestion by creating prolonged localized bleeding. Leeches produce an enzyme in their saliva called hirudin. Hirudin is a powerful anticoagulant. This enzyme prevents their host from forming a clot so that they can feast on blood more easily. When you apply a leech, the hirudin acts locally at the bite site to allow continued bleeding for 2–3 hours after the leech is removed. While attached, the leech actively removes some of the built-up blood, which eases the pressure within the tissue. After the leech is removed, the built-up venous blood will continue to drain from the site where the leech was attached, which is therapeutic for the tissue.

Leeches may be used to promote healing in an infected wound that is resistant to antibiotic therapy; reduce venous congestion following skin grafting, reattachment of body parts, or transplant surgery; and relieve engorgement after plastic or reconstructive surgery of the breast. Leeches are used as commonly as medical maggots or any other wound treatments.

Disposal of used and unused leeches: Always refer to your local and state regulations for guidance on proper use and disposal. Leeches used for a medical procedure shall not be reused (even on the same patient) and shall be destroyed immediately after use or if unused and no longer needed.

For example, the State of Hawaii's Plant Quarantine Branch (PQB), which regulates the importation of non-domestic animals (i.e., any animal not considered to be domesticated and common in Hawaii), allows medicinal leeches to be shipped into Hawaii on a case-by-case basis for use by a physician or hospital staff to treat a medical condition or emergency. The leeches MUST be under PQB oversight and always safeguarded. The medical treatment facility (MTF) must implement standard operating procedures for possession, use, and disposal of the leeches. Leeches shall be destroyed by placing the used and unused leeches (if no longer needed) in a fresh batch of 70% alcohol solution to cover the leeches for 15 minutes. The leeches must remain in the alcohol solution and be disposed of as a hazardous waste (EPA hazardous waste code D001). Personnel from the MTF may need to certify the alcohol/leech mixture as non-infectious before Disposition Services (or their disposal contractor) will take them. Do not dispose of containers with both the leeches and 70% alcohol solution as regulated medical waste (RMW).

In the absence of specific state or local regulations, follow directions above by placing the used and unused leeches (if no longer needed) in a fresh batch of 70% alcohol solution to cover the leeches for 15 minutes. If safe to do so, remove the leeches from the solution, place them in a leak-proof plastic bag and seal the bag completely. Then, place the sealed bag into a second plastic bag and seal completely. Place the bag with other pathological waste in an RMW container lined with a red RMW bag. Mark the outside of the shipping container to indicate incineration is required. The container should be turned in for disposal as soon as possible through the RMW disposal contractor. Pathological waste must be refrigerated if it will remain onsite longer than 24 hours. If frozen, pathological waste may remain in storage onsite up to 30 calendar

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days, if permissible by applicable state or local regulation. The used 70% alcohol solution should be collected separately and discarded as a hazardous waste (EPA hazardous waste code D001).

If the leeches are not removed from the 70% alcohol solution, then manage as indicated above where the entire solution (alcohol and leeches) are disposed of as a hazardous waste (EPA hazardous waste code D001) through the Disposition Services hazardous waste disposal contractor.

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