Implantable Medical Devices

Alexa Andre MD & Alex Williamson MD

Background

Implantable medical devices are placed permanently or temporarily into the human body to deliver medicine, monitor physiologic processes, or support the functioning of certain organs.

Ideally, all devices are left in place for documentation at autopsy but in practice this may not always be the case.

Quick Tips at Time of Autopsy

Clinical History

- Examine the clinical history carefully for clues as to which implantable devices may be found at autopsy (e.g. surgical history, oncologic history, cardiac pathology requiring a pacemaker or stents, history of ECMO, etc.).
- If an automated implantable cardioverter-defibrillator (AICD) is present, make sure the device has been deactivated before beginning the autopsy.

External examination

- Clues to the presence of implanted medical devices may be evident on external evaluation in the form of scarring (ex. straight vertical scar overlying the knee may indicate prosthetic joint), anatomic defects (ex. elevation of skin overlying an implanted defibrillator) or external components (ex. connector of endotracheal tube extending from oropharynx).

General Approach

- Document which devices are present including their anatomic location.
- Some medical devices will come with an individual tracking number, which may be useful in identification and should be recorded.
- Consider if the device
    - Is in the expected anatomic location
    - Has signs of infection (purulence, necrosis, vegetations)
    - Has evidence of mechanical failure (dehiscence from surrounding tissue, damage/disconnection of device components, obstruction of tubular lumens)
    - Has evidence for complications of device insertion/implantation (e.g. arterial perforation, hemorrhage, pneumothorax)
    - Has evidence for secondary systemic complications (sepsis, emboli, organ failure)

Specific Medical Devices

Arterial/venous stents and filters

- Metal-based mesh tubes placed in various arteries/veins (coronary, carotid arteries, lower extremity vessels) and expanded via balloon.
- Some are drug-eluting stents to lower the risk of re-stenosis.
- Generally, stents do not cause immediate complications, though acute coronary rupture is a risk of percutaneous angioplasty.
- In certain cases, the coronary artery can be sent to a specialized reference laboratory that can use a laser cutter to section and histologically evaluate the specimen for obstructions. Consider this in cases where there is cardiac death within 30 days after stent placement or when light does not travel through the lumen on inspection.

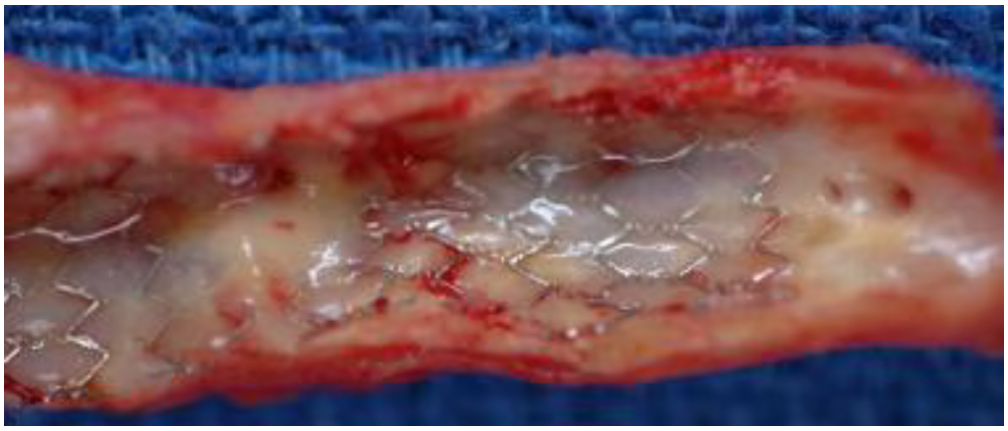


Image: coronary artery stent visualized at autopsy (Image credit: Dr. Joseph Prahlow, Medscape (login required)).

Baclofen pumps

- Pressurized drug delivery system with long catheter to deliver to desired site.
- Indication: relieve muscle spasm/cramping caused by various spinal injuries/pathologies (ex. multiple sclerosis, cerebral palsy).
- Placement: pump inserted in subcutaneous tissue of abdomen.
- Refill of baclofen: needle inserted into silicon pump access port.
- At autopsy: sepsis should always be considered.

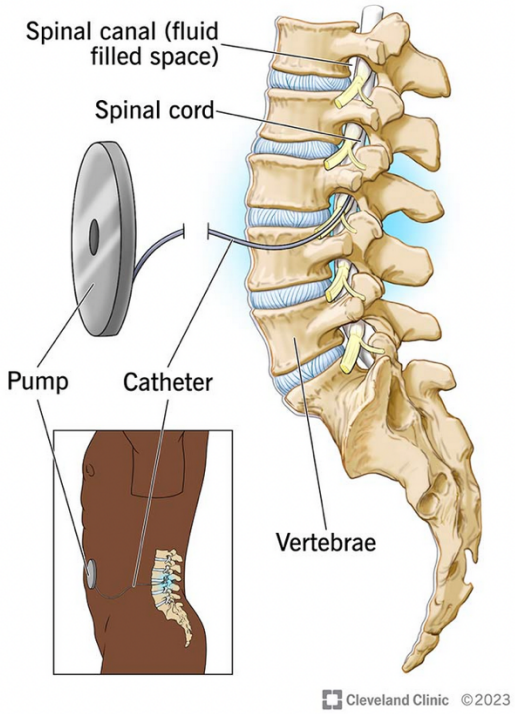


Image: Intrathecal baclofen pump diagram (Image credit: Cleveland Clinic).

Balloon pumps

- Intra-aortic circulatory assist device used to temporarily maintain blood pressure in cases of cardiac dysfunction.
- Placed in descending aorta via groin, repetitively inflated via helium.
- Potential complications (rare): aortic vessel damage, thrombosis, infection.
- At autopsy, maintain the original position of the device by cutting it flush with the skin and pushing slightly inwards.

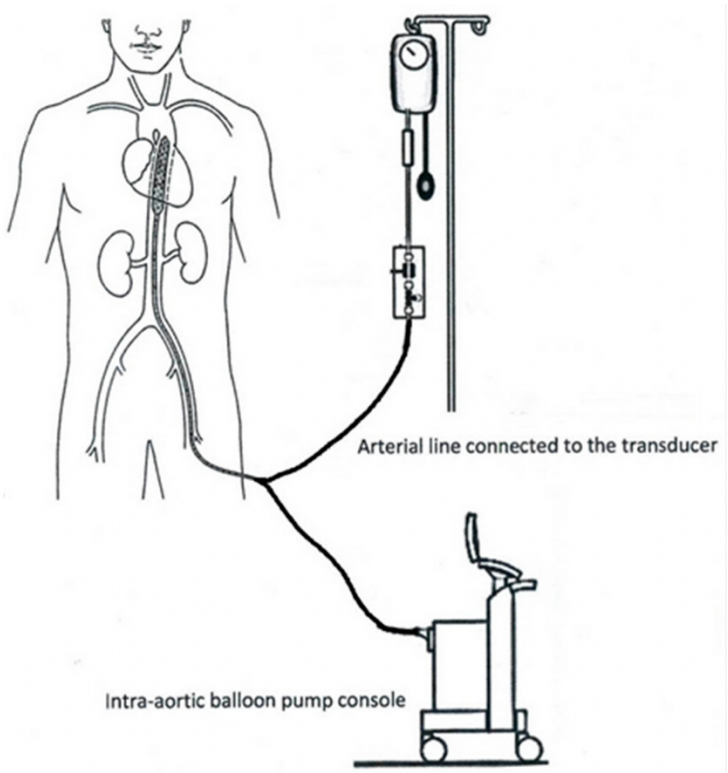


Image: Intra-aortic ballon pump mechanical setup (Image credit: Dr. Vanessa Limbert and Dr. Amir Amiri).

Bowel and urinary stents, as well as flatus tubes

- Metallic/synthetic polymer tubes used to prop open stenotic or malignant tissues.
- Most commonly inserted into the esophagus or rectum, but can also be found in the ureters and biliary tract.
- At autopsy: careful dissection should be performed to ensure stents are in the proper place and to investigate for any bleeding, infection, perforation, or blockage.

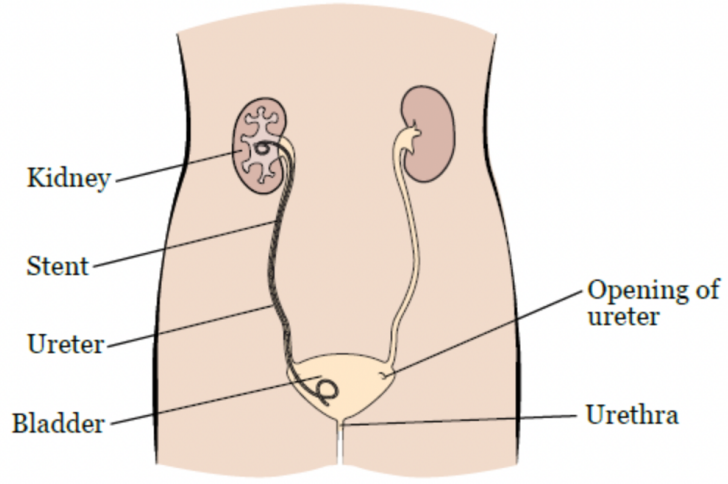


Image: Ureteral stent placement to prop open ureter (Image credit: Memorial Sloan Kettering Cancer Center).

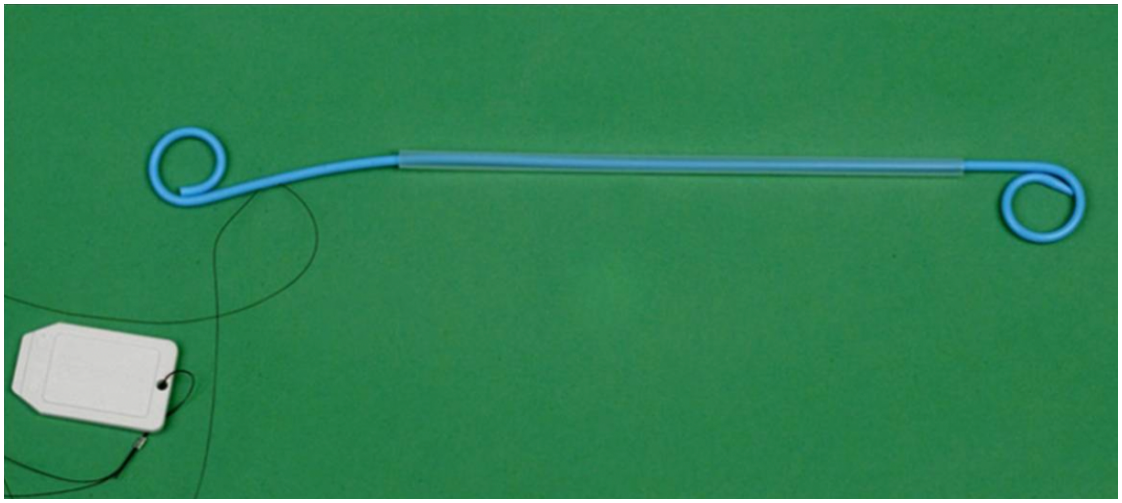
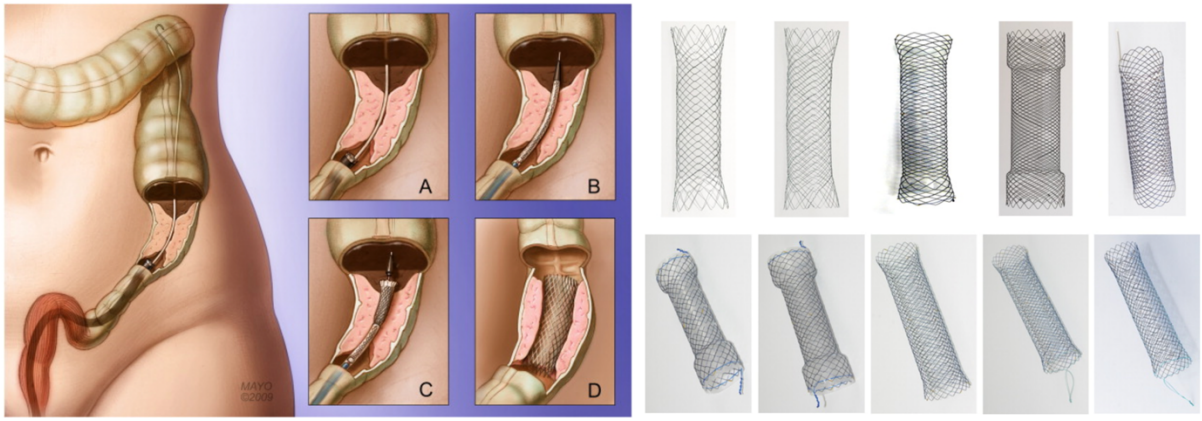


Image: Ureteral stent (Image credit: British Society of Interventional Radiology).



Images: Left - Illustration of the endoscopic placement and deployment of a colonic stent. Right – Various designs of metallic colonic stents (Image credit: Dr. Todd Baron, Elsevier).

Breast (and other) implants

- Most commonly breast implants, inserted for breast reconstruction after mastectomy or non-cancer augmentation/reconstruction.
- Other implants may be found in the penis, buttocks, or abdominal wall.
- May be composed of silicone gel or saline-filled, with a silicone shell.
- May be associated with scarring fibrosis and local nodal reaction in the event of contents leakage, and infection around implants is possible.
- Rare cases of breast implant-associated anaplastic large cell lymphoma have been reported.

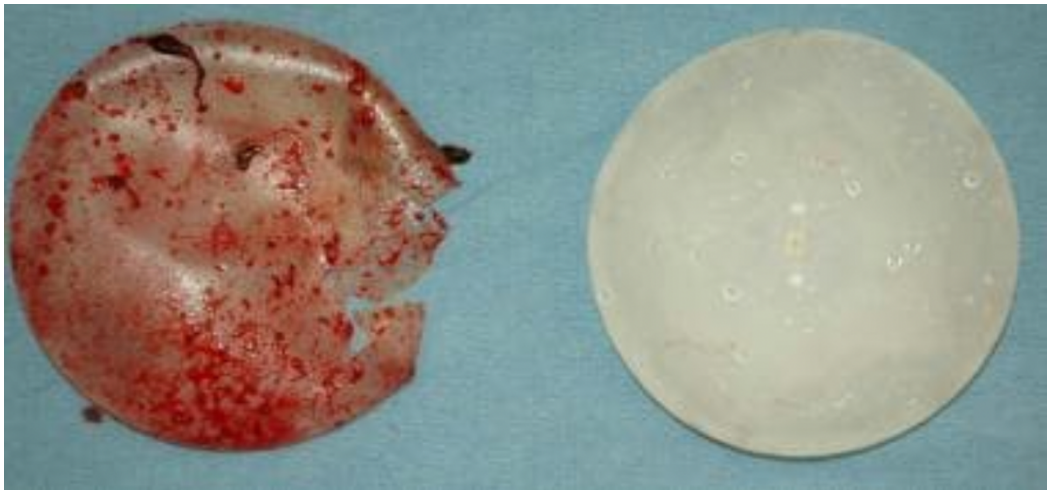


Image: Left breast implant perforated due to trauma. (Image credit: Dr. Joseph Prahlow, Medscape (login required)).

Cardiac pacemakers

- Surgically implanted to control cardiac rhythm (ex. bradycardia caused by SA node dysfunction).
- Consist of a generator (battery and electrical unit) in metal casing (typically implanted under skin of left chest) and 1-3 plastic coated leads and electrodes (enter subclavian vein and threaded into the right heart).
- Types of pacemakers:
    - Single chamber (one pacing lead, right atrium or right ventricle)
    - Dual chamber (two pacing leads, right atrium and right ventricle)
    - Biventricular (leads in both the right and left ventricle)
- An implantable cardioverter defibrillator (ICD, with or without pacemaker) can deliver an electric shock to reset an abnormal heart rhythm (ex. ventricular fibrillation).
- Must know the type device and capability of delivering a shock – essential to deactivate any defibrillation device prior to autopsy!
- Important to know clinical history requiring placement of pacemaker/ICD (ex. ischemic heart disease, heart block).
- Most pathologists cut the pacemaker leads close to the generator unit as the chest tissue is reflected, though it is possible to keep the leads attached through careful dissection or to unscrew them from the generator.
- Devices can be interrogated for performance data by the device representative or cardiology clinic (may provide information on final cardiac rhythm and accurate time of death).
- Check for lead insulation failure by searching for black/brown soft tissue discoloration.
- Investigate for local bleeding or infection at the generator implantation site (microbiology and histology tissue sampling of site).
- Correct positioning of pacemaker leads can be confirmed through small incision in the superior vena cava and then cut to facilitate removal of the heart.

- Confirm correct positioning of distal leads and electrodes by carefully opening the posterior right atrium and ventricle.
- All standard pacemakers should be removed before cremation (risk of explosion under extreme heat).
- Document removal of the pacemaker/ICD in the autopsy report.

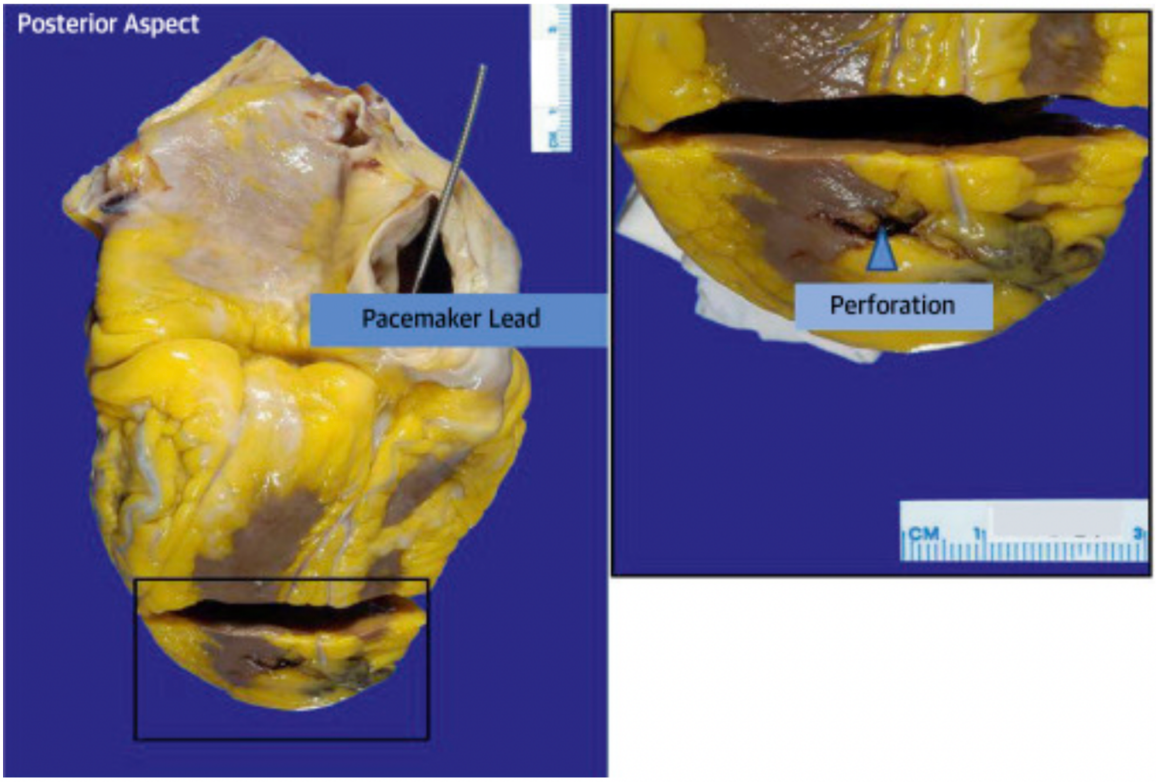


Image: Appropriate right ventricular lead placement with left ventricular perforation. (Image credit: Sinha 2016).

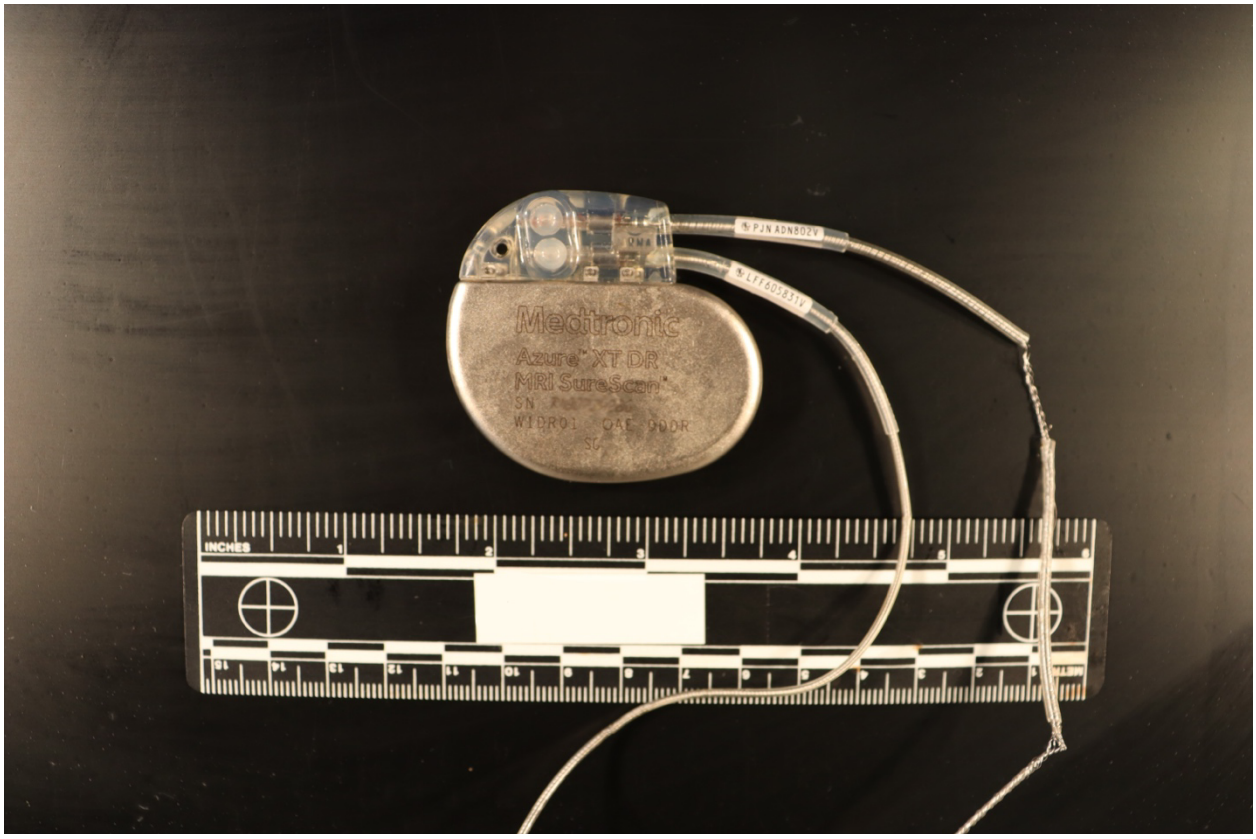


Image: Defibrillator with intact leads. Ensure device is deactivated prior to handling. (Image credit: Meagan Chambers/University of Washington)

Cardiac valves

- Two types: tissue valves and mechanical valves
    - Tissue valves: human/animal valve tissue attached to a plastic/cloth frame, generally do not require anticoagulation, degrade over time (failure after ~10 years).
    - Mechanical valves: valves composed of metal, ceramic, or polymer in various configurations (ball and cage, bi-leaflet, tilted disk), require chronic anticoagulation.
- Cardiac dissection needs to be modified so the valve is visualized in position
    - Mitral/tricuspid devices: large circumferential cut around the base of the atrium as well as the upper ventricle.
    - Aortic/pulmonary devices: the superior cut should be made transversely around the base of the aorta (maintaining view of intact coronary ostia) or pulmonary artery, and the inferior cut circumferentially along the upper ventricle.
- Investigate for misposition, thrombus, calcification, thrombosis, vegetations, leakage.

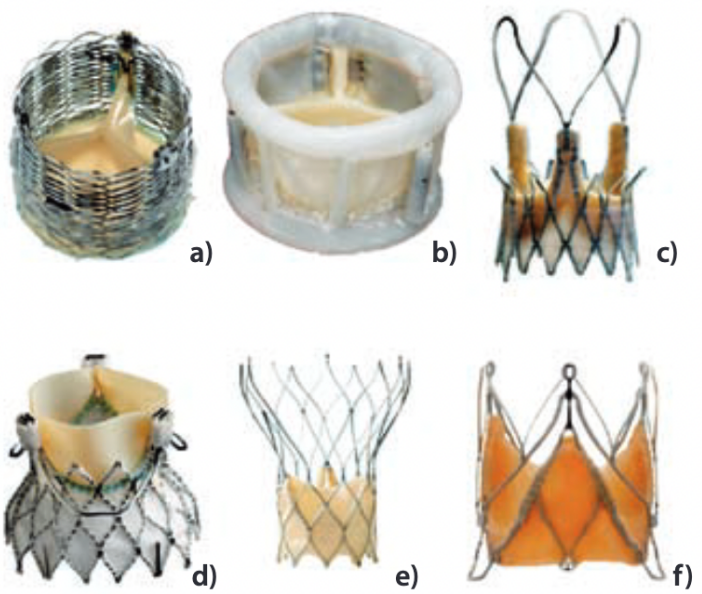


Image: Mechanical heart valves. (Image credit: Benita Kostrzewa).

Cerebrospinal fluid drainage devices

- Used to lower intracranial pressure and prevent hydrocephalus.
- Common placement: tip placed in the lateral ventricle cavity, tube passes through brain tissue, out through the skull, tunneled under the scalp, and terminates in pleural or peritoneal tissue.
- Pre-autopsy imaging can help determine the approach.
- Transection of the drain during external scalp incision and reflection is usually required, with care to not displace the tube during removal of the calvarium.
- Brain sectioning can help confirm the tip of the drain remains in the ventricle.
- Consider sepsis and obtain microbiological samples.

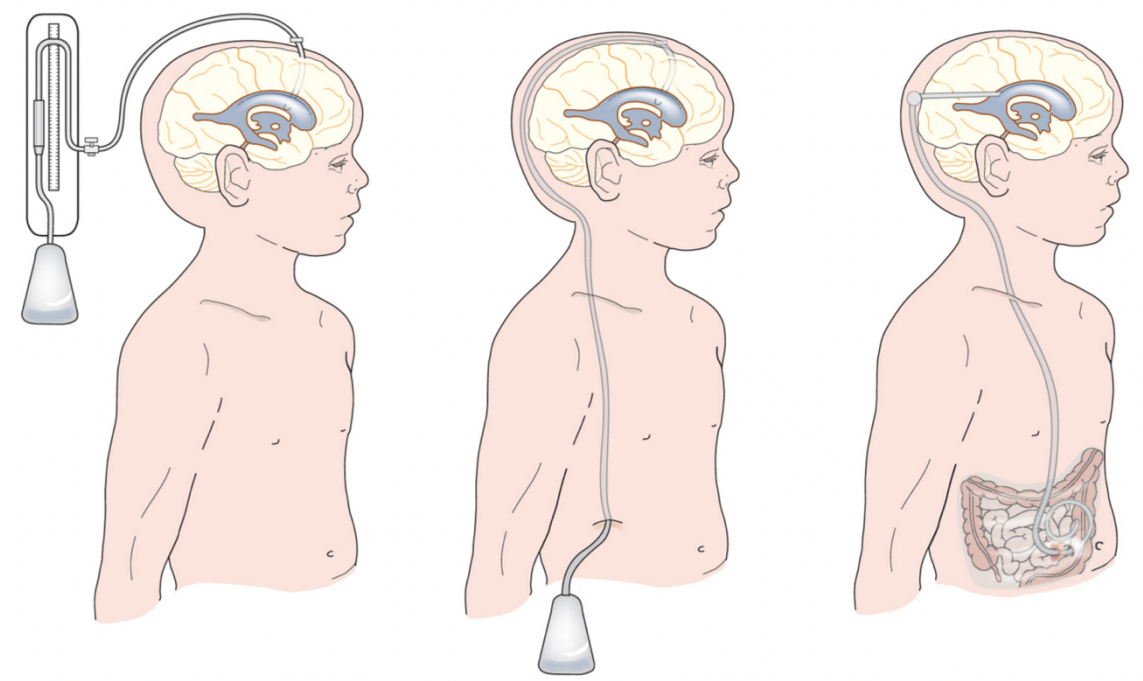


Image: Cerebrospinal fluid drainage systems. (Image credit: Copley 2021).

Closure devices

- Variety of metal, mesh, or homograft material-based devices used to treat congenital heart disease by closing septal defects or redirecting blood flow within/around the heart.
- Cardiac dissection may need to be modified to investigate potential complications (ex. infection, device failure).

Cochlear implants

- Small metal device used to improve hearing for patients with severe hearing loss.
- Often composed of platinum, ceramics, silicone, and titanium.
- Parts: transmitter and microphone (external), receiver and electrode array (internal).
- Rarely require any detailed dissection at autopsy, though rarely may be associated with infection.

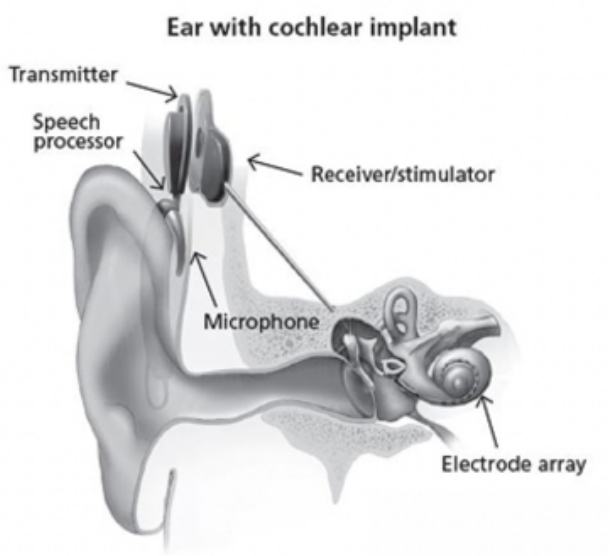


Image: Diagram of a cochlear implant. (Image credit: National Institute on Deafness and other Hearing Disorders).

Contraceptive and female genital tract devices

- Tubal ligation clips (usually silicone-lined titanium) are placed to permanently prevent pregnancy.
- Possible autopsy-relevant complications: ectopic pregnancy, pelvic inflammatory disease – histology, microbiology, and photography are recommended.
- Intrauterine contraceptive devices (copper or plastic), ring pessaries, and menstrual cups may also be found, which should be noted in the report but rarely have pathologic significance.

Implanted nerve stimulators

- Used in the treatment of poorly controlled epilepsy and Parkinson's disease.
- Similar to a pacemaker, electric pulse generator is placed under the skin of the upper chest, with lead wires extending up into the cranium connecting to electrodes implanted adjacent to targeted deep brain structures.
- The position of the device, condition of the leads, and placement of the electrodes should be reported at the time of autopsy.
- Device malfunction should be considered in determining cause of death.
- Data can be downloaded directly from the device in conjunction with specialist consultation.
- Device must be removed at autopsy due to the risk of explosion with cremation.

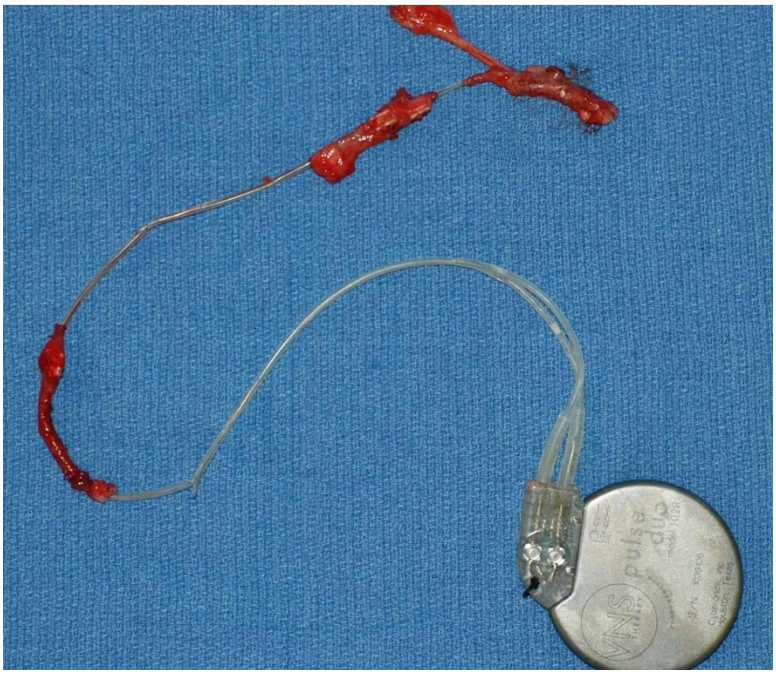


Image: Implanted nerve stimulator removed at autopsy with segments of nerve attached. (Image credit: Joseph Prahlow, Medscape).

Insulin pumps and monitoring devices

- Used to directly deliver insulin to soft tissues and blood stream in poorly controlled diabetes.
- Most common placement is the subcutaneous tissue of the abdomen.
- Complications: pump machinery vs. electrical system failure, battery failure
- Device should be kept if there is any concern for device failure.
- Photography and microbiology are important if concern for infection, must rule out sepsis.
- Toxicology and histology assessment also have a role in these cases.
- Data can be obtained from the device regarding pre-mortem glycemic control.

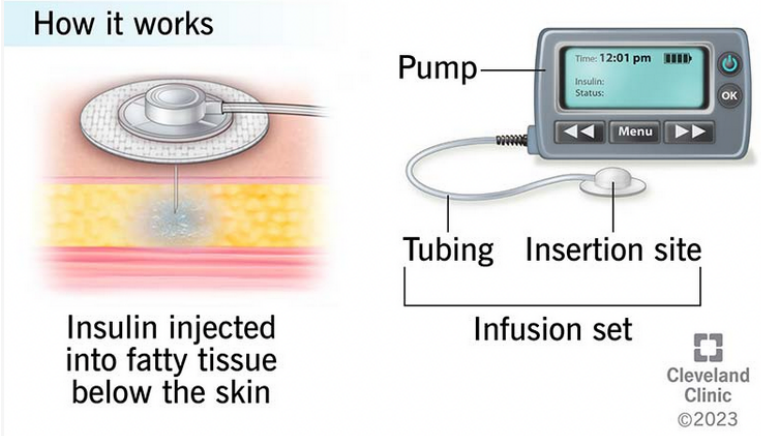


Image: Insulin pump components (Image credit: Cleveland Clinic).

Joint stabilization/replacement (orthopedic) devices

- May include rods, plates, screws, nails, or other metal/plastic implants.
- Potential complications to consider include mal-positioning, loosening/instability, structural failure, fracture of adjacent bone, leaching of metal into tissue, bleeding, and infection.
- If complications arose during the surgery to implant the device, consider fat embolization or bone cement implantation syndrome.
- If the device is likely related to the cause of death, post-mortem CT scan is especially useful.

Laryngeal masks, endotracheal tubes and tracheostomies

- Used to maintain the patient's airway, connected to ventilation devices.
- Check the positioning of the endotracheal tube to ensure there is no airway obstruction:
    - It may be necessary to cut across the tube at the mouth so it does not move during upper head/neck dissection.
    - It may be necessary to make a transverse cut along the trachea to visualize the correct positioning of the distal tube.
- Investigate for any damage to the tube.

Image: Endotracheal tube (Image credit: Dr. Aayush Dhakal).

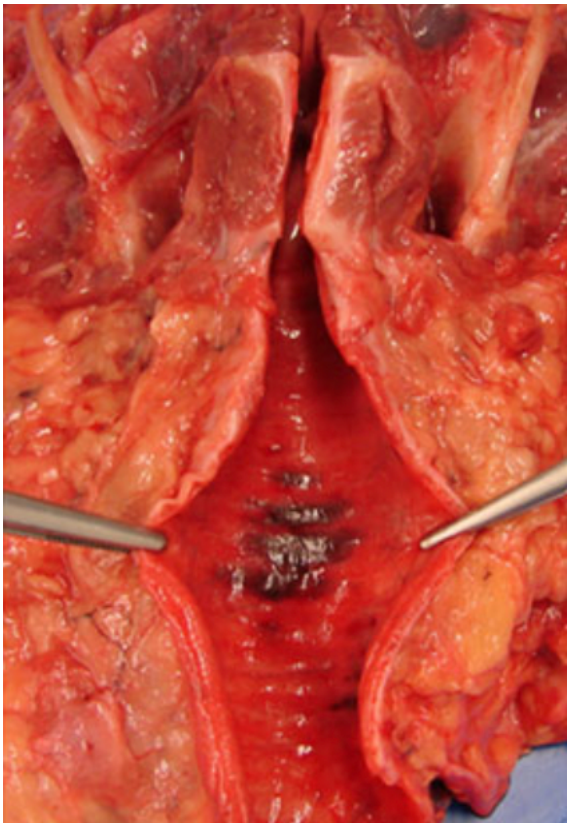


Image: Mucosal hematoma of the trachea indicates correct final position of the endotracheal tube (Image credit: Dr. Claas Buschmann).

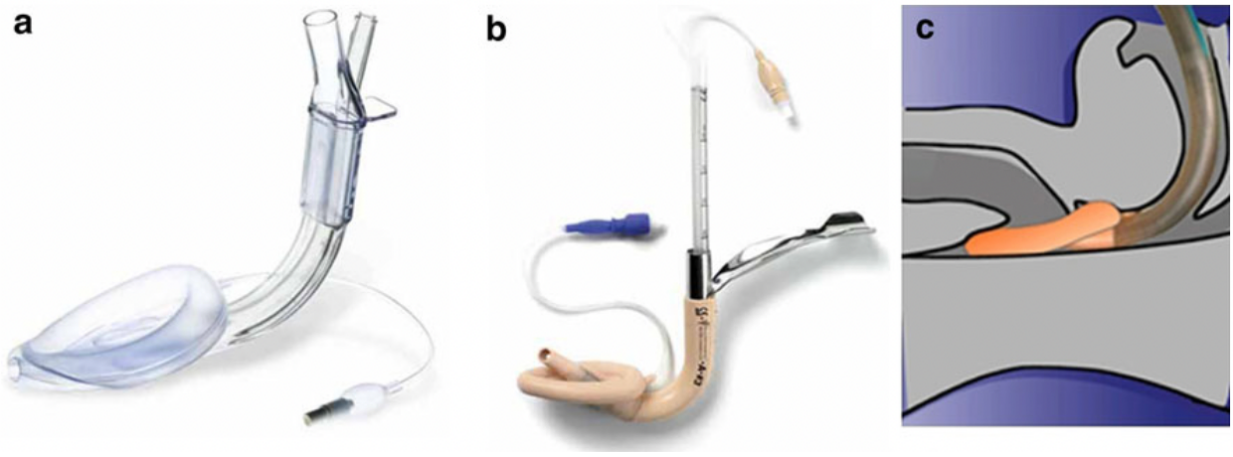


Image: Laryngeal mask airway and placement (Image credit: Dr. Claas Buschmann).

Loop recorders (implantable cardiac event monitors)

- Device to monitor cardiac electrical activity for up to 3 years.
- Small metal device (slightly thicker/longer than a matchstick) implanted subcutaneously (left chest).
- Difficult to find at autopsy without prior knowledge of implantation site.
- Data can be downloaded to provide information on pre-mortem cardiac function.

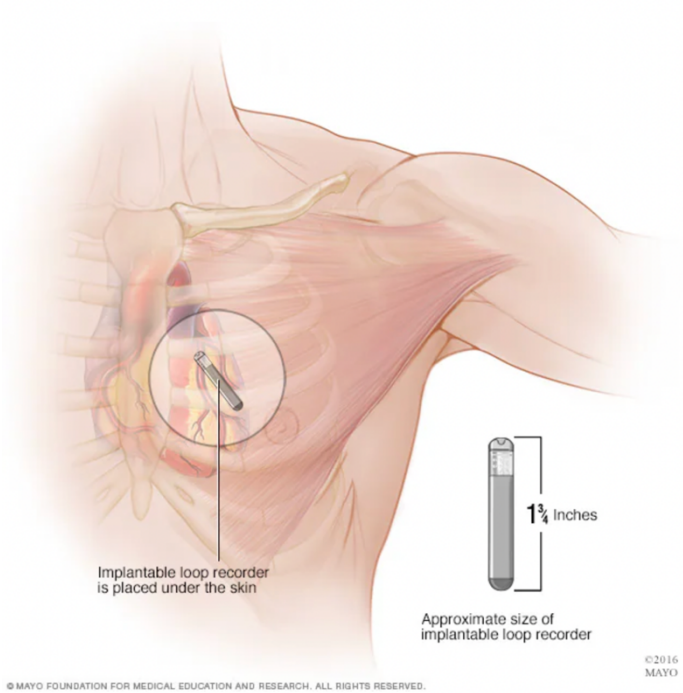


Image: Implantable loop recorder (Image credit: Mayo Clinic).

Mesh devices

- Plastic mesh sewn into areas of weakened tissues, most commonly abdominal wall hernia sites.
- The mesh and resultant fibrosis help strengthen the defect.
- If evidence of infection grossly, photographs and samples for micro should be obtained.
- Histology is rarely needed.

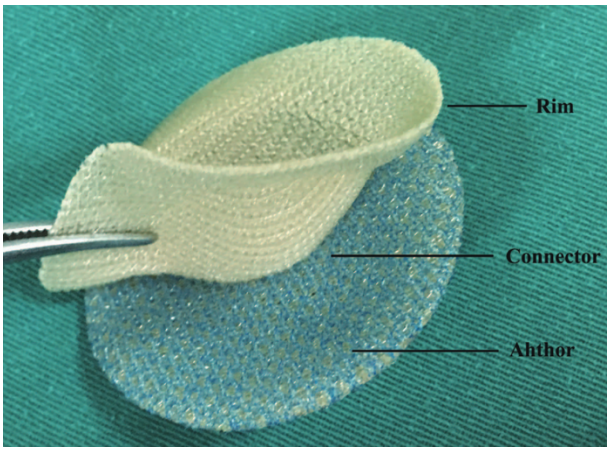


Image: Mesh device used for umbilical hernia repair (Image credit: Dr. Yanyan Xie, et al.)

Nasogastric tubes

- Used to deliver medications or nutrition, or conversely to decompress the stomach (ex. in treatment of small bowel obstruction).
- Small, flexible tube that passes through the nose (or mouth), down the esophagus, and into the stomach.
- The distal tip of the tube should be confirmed in the stomach.
    - Trauma and perforation are possible, but rare.
- The contents of any drainage bags should be examined.
    - Absent drainage could indicate a misplaced tube.

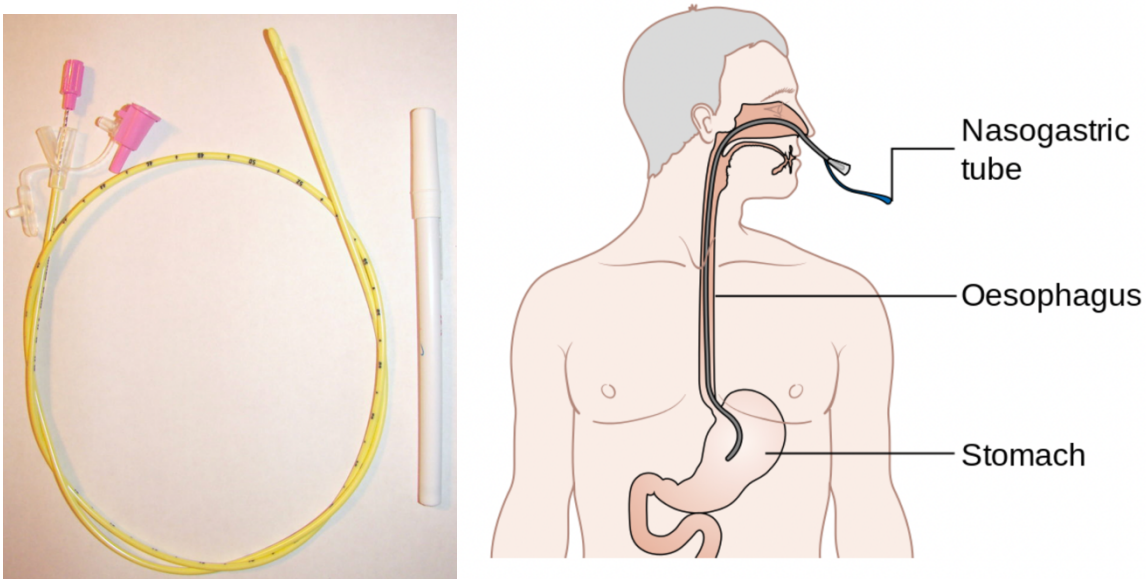


Image: Nasogastric tube and correct placement (Image credit: Oxford Medical Education).

Percutaneous and post-operative drains and tubes

- These tubes can be placed in various parts of the body to drain excess fluid, including: peritoneal cavity, chest, pericardium, gallbladder/biliary tract, renal pelvis.
- Drain patency and correct placement are important to confirm at autopsy.
- Document the reason for drain failure if present (ex. blockage, malposition).
- Look for any septic collection that requires microbiology sampling.

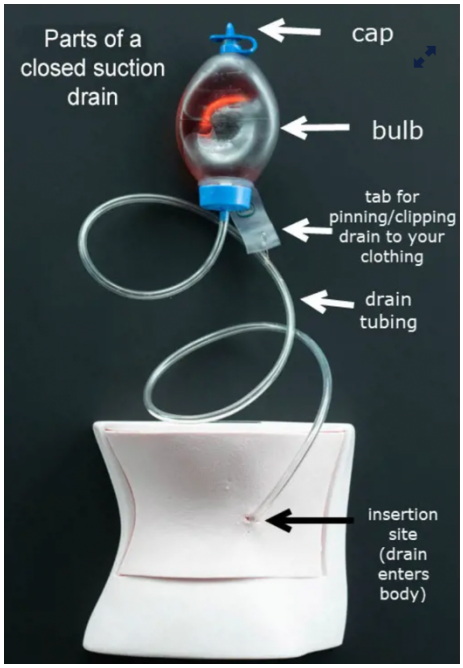


Image: Components of a closed suction surgical drain (Image credit: American College of Surgeons).

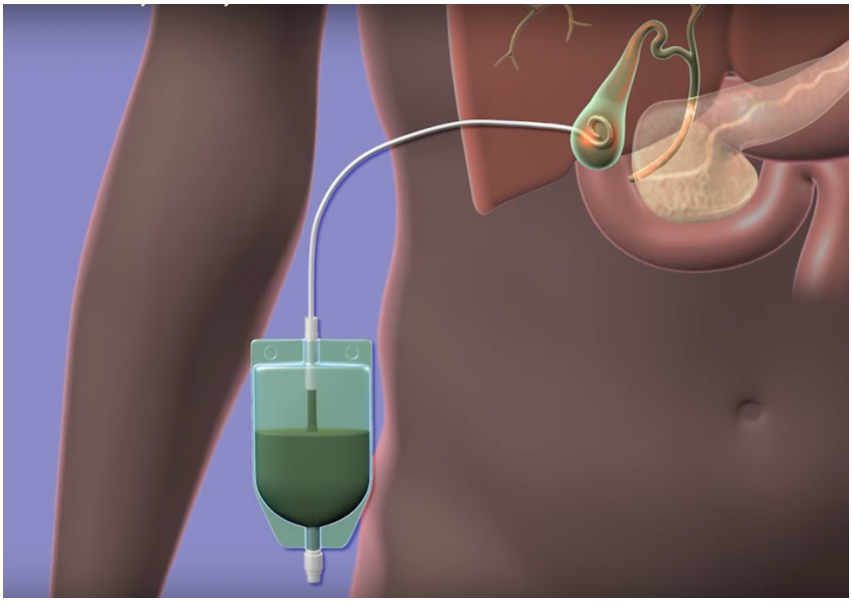


Image: Percutaneous surgical drain placement into gallbladder (Image credit: Cleveland Clinic).

Radioisotopes

- Infused or inserted within a solid device for treatment of cancer.
- Risk of radiation should be assessed prior to autopsy (know the half-life of the radioisotope used, total amount of radioisotope used).
- Needles/beads should be removed and stored in a lead-lined container.

Special devices in cardiac transplantation

- Mechanical hearts and ventricular assist devices used in patients with extremely severe cardiac failure while they await cardiac transplant.
- A modified approach to cardiac dissection is required based on the device and underlying pathology, usually these cases are performed at large transplant centers.

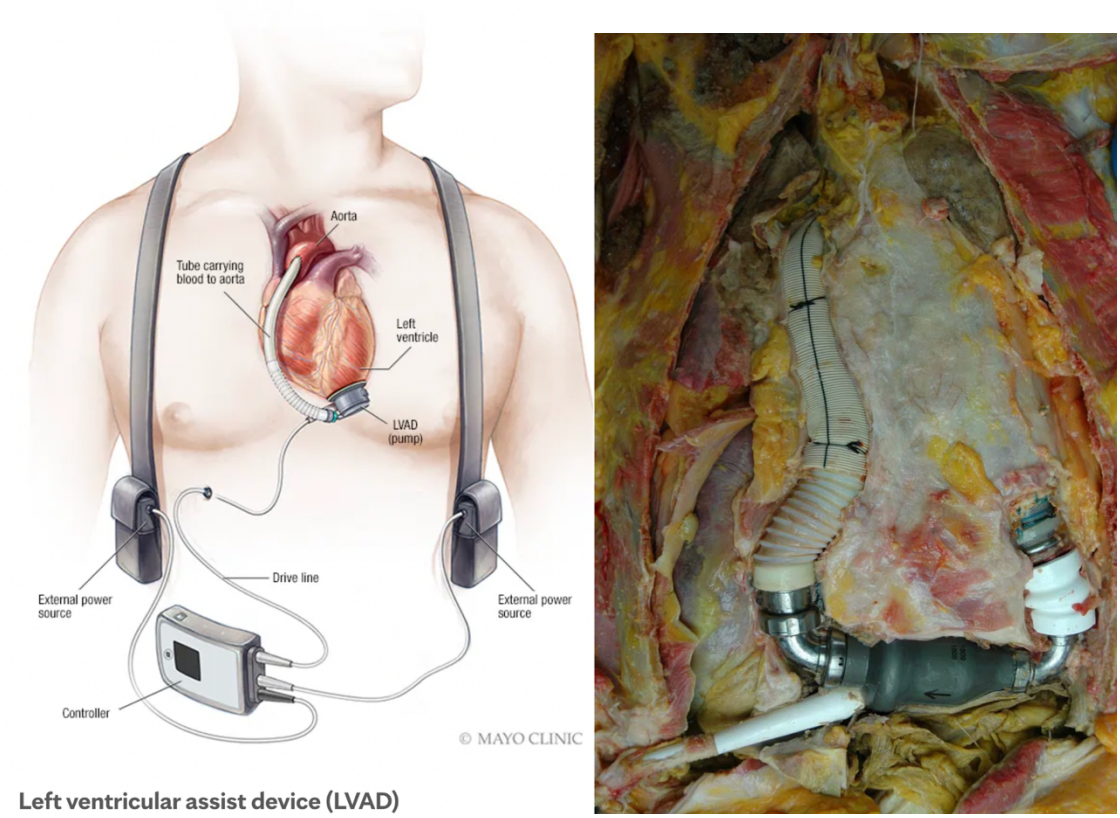


Image: diagram of a left ventricular assist device (left) and a ventricular assist device as seen in situ at autopsy (right). (Image credits: Mayo Clinic (left) and Dr. Joseph Prahlow, Medscape (right)).

Urinary catheters

- Used to help drain the bladder in patients with urologic and renal pathologies.
- Often cause minor amount of bladder wall trauma.
- Urine samples may be taken from catheter drainage bag for drug levels.
- Potential complications arise from a significant increased risk for urinary tract infections.
- Ensure proper placement of the urinary catheter; misplacement can lead to urinary retention and renal failure.

Vascular lines

- Metal or plastic tubes that are used to deliver medication, blood, or fluid.
- May be inserted into veins or arteries.

- These devices themselves are rarely implicated in cause of death, however they can often serve as a source of infection.
- Potential complications include hemorrhage around insertion site, pneumothorax (central lines), thrombosis, and insertion into the wrong site.
- If suspected, dissect and reflect the tissues along the route of the vascular line until its distal tip is exposed.

Gross examination

- As noted above, some devices will need to be left in place at the time of autopsy in order to confirm their placement. Refer to medical device section above for tips on evaluation of each specific device.
- If there is suspicion the device may have contributed to the cause of death, document findings with photography and (in some cases) retain the device.

Quick Tips at Time of Reporting

- Generally, if a medical device directly contributed to cause of death, it should be denoted in the cause of death statement.
    - Example 1:
      1a. Staphylococcus aureus bacteremia
      1b. Abscess surrounding pacemaker inserted to treat bradycardia
      2. Type 1 diabetes mellitus
    - Example 2: Complications of acute on chronic pyelonephritis, status post nephrostomy tube placement, due to urethral obstruction, due to prostatic carcinoma.

Recommended References

- Bailey, David, et al. “Guidelines on Autopsy Practice: Guidance for Pathologists Conducting Post-Mortem Examinations on Individuals with Implanted Medical Devices.” The Royal College of Pathologists, Aug. 2022, www.rcpath.org
- Johnson JA. FDA regulation of medical devices. Congressional research service, June 25, 2012. Washington, DC: Federation of American Scientists; 2013.

Additional References

- Jannati M, Attar A. Intra-aortic balloon pump postcardiac surgery: A literature review. J Res Med Sci 2019;24:6.
- Buschmann C, Schulz T, Tsokos M, Kleber C. Emergency medicine techniques and the forensic autopsy. Forensic Sci Med Pathol. 2013 Mar;9(1):48-67. doi: 10.1007/s12024-012-9366-6. Epub 2012 Aug 8. PMID: 22872361.
- Kostrzewa B, Rybak Z. Rys. History, present and future of biomaterials used for artificial heart valves. Polim Med. 2013 Jul-Sep;43(3):183-9. Polish. PMID: 24377185.

- Sinha SK, Crain B, Flickinger K, Calkins H, Rickard J, Cheng A, Berger R, Tomaselli G, Marine JE. Clinical Inferences of Cardiovascular Implantable Electronic Device Analysis at Autopsy. J Am Coll Cardiol. 2016 Sep 20;68(12):1255-64. doi: 10.1016/j.jacc.2016.06.052. PMID: 27634115
- Tseng ZH, Hayward RM, Clark NM, et al. Sudden Death in Patients With Cardiac Implantable Electronic Devices. *JAMA Intern Med.* 2015;175(8):1342–1350. doi:10.1001/jamainternmed.2015.2641