## Specimen Use Case for Explanted Medical Device

### Description

Implanted medical devices need to be removed (explanted) sometimes due malfunction or some type disease process around the device, such as an infection. Regardless of the reason for the explantation, the procedure to remove the device will generate at least one or more specimens. The medical device will be at least one or more of the specimens and relevant tissue collected at the time of explantation can also be included. For this use case, the specimen workflow that follows is identical to that of any other patient-derived clinical specimen with the exception of the data collected on the specimen(s) of the medical device. To ensure appropriate lookback studies, device recalls, and patient-device associations, device-specific information such as model and serial number must be collected in addition to the other specimen data commonly obtained. Examples of this additional data include:

1. Device identifiers (UDI, device number, serial number)
2. Any other identifiers (manufacturer name, brand name, etc.)
3. Type of device
4. Condition of device (intact, multiple fragments, leads disconnected, etc.)

These additional data are included in the UDI DAM R1 (Appendix 1: Device)

### Preconditions

A medical device has been explanted and submitted to the laboratory for gross analysis in one or more labeled containers.

### Use Case Sequence Steps

1. Container(s) containing a medical device arrive at a laboratory.
2. The device is accessioned as an anatomic pathology case, with the device submitted as at least one specimen (or multiple parts) as part of the case.
3. If present, additional tissue related to the device (either separate or removed from device) is submitted for at least gross examination.
4. Upon gross examination, information about the medical device is collected and recorded into the anatomic pathology laboratory system.
5. The additional material, if present, also has a gross examination and, if warranted, is submitted for additional testing (such as microscopic analysis).
6. At the close of the gross examination, the medical device specimen(s) and any residual tissue are returned to their respective containers and held for long-term storage.

### Post Conditions

1. If ordered, additional testing of submitted tissue related to the medical device is completed.
2. The assigned pathologist on the case completes the report, with clear reference to all identifiers on the medical device present in the report.

### Actors

Testing laboratory

### Use Case Scenario

Patient Lionel Hutz, a 45 year-old white male is seen by Dr. Homer J. Simpson for removal of a failed hip replacement. Under general anesthesia, Dr. Simpson removes the failed joint (broken in two pieces) and submits the joint fragments as “Joint Part 1 - Long” and “Joint Part 2 - Short”.

The explanted medical device is placed in a container and is accessioned as case S-17-34234 when it reaches the anatomic pathology laboratory. Upon grossing, the pathology assistant Bruce Banner identifies the two parts of the joint (long and short) and after removal of tissue from “Joint Part 1 – Long”, he is able to read and dictate the brand, model, and serial number of the joint into the report. No other material is submitted on the case, so the report is quickly finalized by Dr. Rajesh Dash as a gross-only report with the relevant device information clearly listed in the report.