Medical Device Warranty Credits –

Example Policy/Procedure Statements

### Policy

Compliant activities include:

* Returning eligible explanted devices to manufacturer for warranty credit review
* Adjusting billing when credit received is ≥50% of cost of replacement device
* Reporting discounts on annual cost report when credits are received on replacement devices
* Excluding any device charges to the patient or payer if implant device is provided free of charge

Conditions which may suggest warranty eligibility:

* Device failure or malfunction
* Recall or advisory
* Early battery depletion

In the event that return of the device to patient is authorized, explanted medical devices must not be returned to the patient prior to determination of whether a warranty credit is available.

If there is a legal hold on the explanted medical device, the legal hold must be removed prior to return of the device to the manufacturer.

### Procedure

Document reason for explant to assist in triage of devices potentially eligible for warranty credit.

Clean explanted device of gross blood and tissue by wiping and/or rinsing at procedure table (unless device requires culture).

Double bag the device inside of two sealed biohazard labeled bags with appropriate label.

For surgical devices: contact the vendor to obtain return authorization and explicitly request warranty review, device analysis report, and credit memo as applicable.

Return explant to vendor via provided return kit including any required paperwork within 30 days.

Track patient, device, and shipping information and reconcile with potential credit memos received.

Identify warranty credits meeting the 50% rule and triage to revenue cycle for billing adjustment.

Perform routine internal checks to reconcile vendor reported warranty credits vs. claim adjustments.