

Short-Term and Long-Term Loaner Set Management Procedure

PURPOSE: This document provides Ascension requirements to vendor representatives for the steps involved in managing loaner sets. Vendor representatives are required to comply with all guidelines in this document per the Ascension Vendor Access Policy.

DEFINITIONS

- **Count Sheet** This includes the correct and complete name of the instrument set, a detailed list of instrument set contents, including item quantities, size and catalog or reference numbers.
- **Holding Area** Designated space(s) for vendor representatives to securely and temporarily store short-term loaner sets and trunk stock. This space will be routinely checked by Sterile Processing or Supply Chain personnel to ensure short-term loaner sets and trunk stock is removed according to the policy.
- **Loaner Set** Instrument set owned by a vendor that can either be a short-term loaner set or a long-term loaner set.
- **Long-Term Loaner Set** Instrument set that is owned by the vendor and has been approved to remain located within the facility between cases, available for immediate use. Consigned sets are governed by a consignment agreement and the preferred form of Long-Term Loaner Sets. For Long Term Loaner Sets containing consigned implants, ownership of the implant is transferred upon use; ownership of the instruments does not change.
- **Owned Set** Instrument set owned by the facility.
- **Short-Term Loaner Set** Instrument set owned by a vendor that is brought or shipped in by the vendor for specific cases and removed by the vendor afterwards.
- **Sterile Processing Department** Area within the hospital responsible for instrument processing, decontamination, sterilization, inspection, preparation, packing and storage of instruments and medical devices needed for surgery.
- **Trunk Stock** Case-specific med / surg product that is brought in or shipped in by a vendor that is neither consigned nor owned. A similar concept to short-term loaner sets, this is terminology typically used by clinicians and supply chain for implants walked in or shipped in for a case.

1.0 Short-Term Loaner Sets: Notification Prior to Drop-off:

- 1.1 Any Ascension facility where short-term loaner sets are used, vendor representatives should notify SPD via locally-determined process with the following information at the time a surgical case is scheduled, but no earlier than seven days prior to the case,
 - Date and time of surgery
 - Physician name
 - Instrument tray name(s)
 - Date and time of drop off



- Vendor name and contact information
- Count sheets and IFU information as requested

2.0 Short-Term and Long-Term Loaner Sets: Check-In Process:

2.1 Short-term loaner sets will enter the facility no earlier than 96 hours (excluding weekends and holidays) and no later than 48 hours prior to scheduled surgery time. First-time short-term loaner instrumentation must be brought in at least 72 hours prior to a case. This allows for IFU reviews, associate in-servicing, and education of staff. Verbal/written/email exceptions may be provided on a facility basis for weekends and holidays.

Example: Required Check-In Time Frame (assumes there is no holiday)

Case Day of the Week	Arrives No Sooner Than the Prior	Checked In No Later Than the Prior	If First Time Loaner Set is in Use at the facility, Check in No Later Than The Prior
Monday	Tuesday	Thursday	Wednesday
Tuesday	Wednesday	Friday	Thursday
Wednesday	Thursday	Monday	Friday
Thursday	Friday	Tuesday	Monday
Friday	Monday	Wednesday	Tuesday

2.1.1 Short-term loaner sets may only be brought in less than 48 hours prior to a case for cases scheduled less than 48 hours in advance and, in these instances, the date the case was scheduled will be verified.

2.1.2 Verbal/written/email approval from the SPD Manager is required to bring sets less than 48 hours prior to a case.

2.1.3 Short-term loaner sets must include all required documentation as outlined in 2.3, whether personally dropping off, using courier, or shipping.

2.2 Short-term loaner sets will enter the facility either via the vendor representative in-person, via the vendor's courier, or shipping. The vendor representative or designee, i.e. courier, assumes responsibility for ensuring the loaner set is checked into decontamination with documentation outlined in 2.3 complete.

- 2.2.1 Short-term loaner sets shipped in will be placed in the designated holding area. Signatures for receipt will not imply content verification. Vendor representatives must ensure sets include the required information.
 - 2.2.2 Vendor representative or designee is responsible for transporting the loaner sets to SPD from the dock or delivery location.
 - 2.2.3 SPD is not responsible for checking in sets.
 - 2.2.4 Unless otherwise agreed to in writing by vendor representatives and either Ascension or The Resource Group, SPD accepts no responsibility for missing/damaged instrumentation.
- 2.3 Each short-term loaner set that enters the facility must be checked in with the following information regardless of whether facility maintains a electronic tracking system:
- Date and time of surgery
 - Physician name
 - Instrument tray name(s)
 - Weight of set(s)
 - Date and time of drop off
 - Vendor name and contact information
 - Count sheets, as requested
 - IFU information, as requested
- 2.3.1 At sites not equipped to electronically track short-term loaner sets, vendor representatives should use the Loaner Set Tracking Form available at check in location to submit this information.
 - 2.3.2 At sites able to electronically track short-term loaner sets, vendor representatives should use the system in place to submit this information in addition to one photo of each tray level.
 - 2.3.2.1 If a vendor representative does not yet have a CensiTrac login to access the National Ascension CensiTrac system, access can be requested using this [form](#). Access will be granted within seven calendar days.
 - 2.3.2.2 At sites where a tracking system other than CensiTrac is in place, access

should be secured through the local SPD Manager.

- 2.4 At sites not equipped to electronically track short-term loaner sets, the vendor representative will upload one photo of each tray into the [SmartSheet Form](#) - accessible through a QR code.
- 2.5 All instruments that come into the facility via short-term loaner sets are to be considered non-sterile, contaminated, and must be transported directly to decontamination for reprocessing.
 - 2.5.1 The only exception is if the product / instrument is single-use, labeled as sterile, and contained in factory-sealed sterile packaging.
- 2.6 For loaner set drop-off outside of facility's operating hours, the facility will post appropriate signage denoting hours of operations and whom to call for assistance outside of these times.
- 2.7 Vendor representatives are responsible for providing the correct number of short-term and long-term loaner sets for each scheduled case.
 - 2.7.1 Vendors are required to provide the sufficient number of instrument sets to support the facility's case load for the day that would not require an instrument set to be processed multiple times and used more than once on the same day.
 - 2.7.2 Unless otherwise agreed to in writing or via electronic correspondence by vendor representative and either Ascension or The Resource Group, loaner sets and their contents are the direct responsibility of the vendor and not the facility.
- 2.8 Vendor instrument and implant sets cannot exceed 25 lbs, or facility's maximum stated weight, after containerization or wrapping. Vendor representative is responsible for weighing sets.

3.0 Short-Term and Long-Term Loaner Sets: Pre-Case:

- 3.1 Vendor representatives are not to decontaminate any sets under any circumstances.
- 3.2 Documentation from SPD to the vendor representative will be provided if any instruments are unusable, and the facility is not liable for the cost of damaged

instruments.

3.2.1 In all scenarios, the vendor representative will be notified in writing or via electronic correspondence of missing and/or damaged instrumentation and must replace the instrument(s) or have the set processed without the identified instrument(s).

3.2.2 SPD will not replace any items from any loaner set with locally-owned inventory.

4.0 Short-Term and Long Term Loaner Sets: Post-Case

4.1 Vendor representatives will not handle contaminated instrumentation.

4.2 Post-decontamination, the vendor representative will reassemble and inventory instrument sets.

4.3 Short-term loaner sets will be removed by the vendor representative or designee no later than 48 hours post-case completion unless the loaner sets will be used again within 96 hours or an exception is provided in writing or via electronic correspondence by SPD Manager.

4.3.1 If short-term loaner sets have not been removed from the facility within the allotted time, the loaner set may be relocated outside of the SPD at the discretion of the SPD Manager.

4.3.2 Upon taking possession of short-term loaner sets post case, vendor representatives will have 48 hours to identify lost or damaged components and five additional business days to provide an invoice to SPD manager for any missing items, as compared to the validated contents of the set at the time of check-in.

4.3.3 If a short-term loaner set is being used again within 96 hours, it will need to be checked in again.

5.0 Long-Term Loaner Sets

5.1 Vendor representative and SPD Management should evaluate the utilization of specific loaner sets to determine if sets should be classified as short-term loaner sets or long-term loaner sets.

6.0 Additional Requirements

- 6.1 All vendor representatives must follow local facility policies for grooming, attire, and hygiene to avoid any issues with sterility.

- 6.2 Third Party Couriers delivering and picking up instruments or implants to sterile processing departments must notify an Associate of their presence upon entering restricted areas, and are responsible for following local facility visitor policies and requirements.