

Medical Device Reprocessing Blind Study

Overview

In collaboration with Provision, we are offering blind studies to be conducted with invasive devices that have high volume and high price points to ensure you will see an impact on savings generated by reprocessing and provide visibility to many of the surgeons who will be using these devices. Please read through the device criteria and protocol on how the blind study would be managed.

Priority of devices to be used for a blind study:

1. Carpal Tunnel Release Blades
2. Arthroscopic Shavers & Abraders
3. Ablation Wands

Blind Study Protocol

1. Collection of Devices

- **New Devices:** collect 5-10 New Devices in their original package.
- **Used Devices:** collect 5 -10 Used Devices of the same Vendor and Item Number as that of the new devices.

2. Shipment of Devices

- **Preclean Used Devices:** rinse devices to remove visible blood and bioburden.
- **Package Devices:** package all devices in a reinforced cardboard box.
- **Ship via FedEx Ground:** Provision will provide a prepaid FedEx shipping label so that you can return these devices at no cost to your facility. Affix the shipping label to the cardboard box and give the box to any FedEx Ground driver.

3. Tracking New vs. Used Devices

- **New Devices:** Provision will repackage, relabel, and re-sterilize the new devices in our standard Tyvek packaging and will identify these by a unique lot number which will be kept confidential until the blind study is complete.
- **Used Devices:** Provision will reprocess, package, label & sterilize the used devices and will assign a separate lot number to these devices which will also be kept confidential until the blind study is complete.
- **Confidentiality of Lot Numbers:** To eliminate bias, neither the Cardinal Health representative nor the facility will know which lot number applies to the new or used devices. Only representatives from Provision’s corporate office and the Administrator of the facility will know which lot number belongs to the new and used devices. These will be revealed to all parties once the observations have been documented.

4. On the Day of the Study

During a period when there will be a sufficient procedural volume to adequately evaluate these devices, a Provision Representative will randomly provide the surgeon with one of the devices for each procedure. Following each surgical case, a Provision Representative will record the lot number used and detail the surgeon’s experiences in using the device.

5. Conclusion of the Blind Study

At the end of this evaluation, Provision will consolidate all reveal all results and will identify which devices were new and which devices were reprocessed.

6. Next Steps

If the results prove that the reprocessed devices met the surgeon’s needs for quality and performance, we will ask your facility to add these devices to the mix of devices to be reprocessed.