



## REPROCESSING SERVICES LIST

Clinical Area (FDA Category)	FDA Class(es)	Notes	Manufacturers (We may not reprocess all models)	510(k) Clearance
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\*Denotes the Vanguard Medical Concepts' FDA Clearances

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### Cardiovascular

Cardiac Stabilization and Positioning Devices	I	Non-Exempt	Guidant Medtronic	K070034** K070036**
Compression Sleeves & Foot Wraps	II	Not approved for OR Direct Program	Kendall, Healthcare Service & Supply, Huntleigh Healthcare, Venodyne	K011192
			Aircast VenaFlow	K021654
			Albahealth	K024074
			KCI	K024087
			Hill-Rom Active Care (Wiz Air)	K053316
			Medline (Talley)	K060091
			Kendall SCD Express	K060049
			Hill-Rom	K051438*
			Aircast VenaFlow, Compression Therapy Concepts VasoPress, Healthcare Service & Supply ALP, Huntleigh Healthcare Flowtron, KCI Inc., Kendall SCD & ImPad, Microtek Venodyne, NuTech PlexiPulse	K012403*
			Electrophysiology Catheters & Cables	II
EP Technologies				
Daig Response	K030026			
Cordis Webster IVC Unipolar & Fixed Curve	K030109			
C.R. Bard Deflectable Tip	K030187			
Medtronic Marinr & StableMapr	K030279			
Medtronic Torqr® (2x)	K061045			
Daig Livewire (1x)	K043392			
Daig Livewire (6x)	K052603			
EPT (1x)	K043393			
EPT (6x)	K052414			
Biosense Webster Variable 2515 Lasso®	K082023**			
Daig Reflexion Spiral™	K090323**			
Bard	K012688*			
Biosense Webster	K012687*			
Biosense Webster Halo	K040751*			
Biosense Webster CS Bi-Directional	K100254			
Daig Response Supreme	K030114*			
Daig Livewire	K042074*			
EP Technologies – Explorer	K022316*			
EP Technologies – SteeroCath	K050763*			
EP Technologies – DX	K051043*			
EP Technologies – Polaris	K023180*			
Irvine Biomedical, Inc.	K081329**			
Accessory Cables	K030005*			
Reusable Ablation Catheter Cables	N/A			
Reusable Diagnostic EP Cable	N/A			
Inflation Devices	II		SCIMED Encore, Guidant 20/20 and 20/30 Indeflator, Medtronic AVE Everest and Everest 30, Intellisystem 25	K012480*
Femoral Compression (FemoStop)	II		Radi Medical Systems	K011832*
Ultrasound Catheters	II		Siemens Medical Solutions	K033436
			AcuNav Biosense Webster SoundStar	K063076** K092425**



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### Endoscopic/Laparoscopic

Unipolar Laparoscopic/Endoscopic Instruments (Babcocks, Clamps, Dissectors, Graspers/Forceps)	II	Lumened Devices Only	Auto Suture	K012603
			Ethicon Endopath	K012625
			US Surgical Auto Suture, Ethicon	K012700*
Laparoscopic Accessories (Babcocks, Clamps, Dissectors, Graspers, Scissors)	I	Exempt	ALL	N/A
Scissor Tips	I	Exempt	All	N/A
Trocars	II		Autosuture (US Surgical), Ethicon	K024015
			Ethicon	K043253*
				K062497**
				K070059**
			US Surgical Applied Medical	K100080**
				K043594*
				K063788**
Ultrasonic Scalpels/Shears	II		Ethicon Foot, Hand-Activated	K043358
			Ethicon	K043225*
			Ethicon Scissor Handle, Hand-Activated	K093702**
			Ethicon (Focus™), Hand-Activated	K100537**
			Ethicon Hand-Activated	K043315*
Suture Passer	II		Cooper Surgical (Inlet Medical, Inc.)	K053585**
Bipolar Cutting Forceps	II		Gyrus/ACMI	K052690

### Gastroenterology

Biopsy Forceps – Hot	II		Microvasive Radial Jaw, Bard Precisor	K011800*
Biopsy Forceps – Cold	I	Non-Exempt	Bard, Microvasive, Wilson Cook	K042594*

### General Surgery/OR/Respiratory

Tourniquet Cuffs	I	Exempt	ALL	N/A
Pulse Oximeter Sensors	II		Mallinckrodt Nellcor Oxisensor II	K012344*
			Masimo	K081238**
			OxiMax	K042316*
Pressure Infuser Bags	I	Exempt	Medex, Statcorp, Vital Signs	N/A

### Ophthalmology

Phacoemulsification Tips	II		Alcon	K050518
			Alcon, Allergan	K012698*
			Mackool	K060648**

### Orthopedic/Arthroscopic

Arthroscopic Shavers	II	Will not process shavers that cannot be disassembled	Linvatec	K012613
			Stryker	K012635
			Dyonics	K012611
Arthroscopic Burrs	II		Linvatec	K012630
			Stryker	K012605
			Dyonics	K012652
Arthroscopic Shavers & Burrs	II		Smith & Nephew Dyonics, Linvatec, Stryker	K012346*
Diamond Burrs	II		Linvatec, Microaire, Zimmer, Anspach, Stryker	K041978
Arthroscopic Wands (Soft Tissue Ablators)	II		ArthroCare, Mitek (Non-Suction)	K012695*
			ArthroCare, Mitek (Integrated Cables)	K043198*
Soft Tissue Ablators	II	Will not process lumened Mitek devices Will not process ORATEC/REDEL devices	ArthroCare, Mitek	K012631



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### Orthopedic/Arthroscopic (Cont'd)

External Fixation Devices	II		Stryker Trauma, Synthes (USA), Smith & Nephew	K031687*
				K051180*
			EBI	K012645
			EBI	K051616*
			EBI (Non-Sterile)	K052064
			Howmedica	K012648
			Howmedica (Non-Sterile)	K052065
			Synthes	K012623
			Synthes (Non-Sterile)	K032058
			Smith & Nephew	K012634
			Smith & Nephew (Non-Sterile)	K051554
			Orthofix	K023714
			Orthofix	K053051*
Orthofix (Non-Sterile)	K052062			
DePuy (Non-Sterile)	K052918			
Zimmer TransFx™ (Non-Sterile) (2x)	K061759**			
Cannula Sets	I	Exempt Complete sets only	ALL	N/A
Chisels	I	Exempt	ALL	N/A
Donor and Recipient Devices	I	Exempt	ALL	N/A
Drill Bits	I	Exempt Standard Quick-Disconnect	ALL	N/A
Rasps	I	Exempt	ALL	N/A
Reamers – Acetabular/ Patellar & ACL	I	Exempt Will not process ACL reamers without calibration marks	ALL	N/A
Saw Blades	I	Exempt	ALL	N/A
Taps	I	Exempt	ALL	N/A
Trocars	I	Exempt	ALL	N/A

#### GENERAL NOTES FOR ALL CATEGORIES

- Devices without manufacturer's part number will not be processed
- Devices with batteries will not be processed except for some models of Balloon Inflation Devices
- Devices with pressure cartridge will not be processed



## REPROCESSING SERVICES LIST

### Unused Devices Services

Ascent can service most of the devices in the categories listed below through our opened, but unused or expired service program. This list is not all inclusive and there may be specific devices within the categories which cannot be processed.

Arthroscopic/Orthopedic	Cardiovascular	General Surgery
Arthroscopic Shavers/Burrs Cable & Clamp Systems Cannula Sets Cartilage Knives Clamps External Fixation Devices/Kits Femoral/Tibia Nails/Hip Stems Orthopedic Prostheses Pins/Screws/K-Wires Plates/Tubes Rasps/Reamers/Taps Saws Blades/Drill Bits/Burrs Soft Tissue ablaters Tendon Spacers	Angiographic Catheters Aortic Punches Arterial & Venous Cannulae Balloon Inflation Devices Embolization Coils EP Catheters Guidewires & Glidewires Guiding Catheters OPCAB Devices Shunts Ultrasound Catheters Vascular Clamps, Clips Vascular Grafts (non-Collagen) Vein Harvesting Devices	Chest Drains Hemostatic Erasers Implanted Ports Introducers & Dilators Laser Probes/Light Pipes PICC/CV Catheter Trays Retractors, Stays Surgical Mes/Felt Mesh Tubing/Irrigation Wound Drainage
Laparoscopic/Endoscopic	Ophthalmic/ENT	Urological/Biliary/Gastro
Clip Appliers/Staplers Harmonic Scalpels Insufflation Needles Lap Chole Kits Ligation Devices Scissors, Clamps & Dissectors Specimen Pouches/Retractors Suction/Irrigation/Tubing Suture Passers Trocars	ENT Shavers Illuminators Laser Fibers Ocular Probes Phaco Needles Stapes/Piston/Torp Implants Vent Tubes Vitrectomy/Catarat Kits	Cytology Brushes Electrodes (Loop, Roller, Leep) Endoscopic Catheters Endoscopic Snares & Baskets ERCP Cannula Gastro Tubes Linear Cutters/Staplers PEG Kits Stents (Pigtail, Biliary, Enteral)

Devices which can be processed only if received in intact OEM packaging (e.g. expired product):

- Devices that contact cerebral spinal fluid (e.g. – Neurological items such as Cranial Access Kits, Neuro Burs, Neuro Shunts/Valves/Catheters and Spinal Puncture Trays)

Devices that are NOT approved for processing under the opened, but unused or expired service program include:

- Devices that are classified as Class III by the FDA (e.g. Ablation Catheters, Wall Stents)
- Devices with batteries or pressure cartridges (except some models of Balloon Inflation devices)
- Devices containing any latex components
- All gowns and woven Drapes/Sheets
- Devices with bioactive coatings (heparin, collagen, etc.)
- Devices with bio-absorbable components (e.g. staples, pins)
- Permanent Implants which have FDA required tracking (e.g. Pacemakers, Defibrillators, Heart Valves)
- Devices requiring calibration codes
- Any device supplied Non-Sterile by the OEM (except External Fixation devices)
- Cement Mixers
- Ophthalmic Knives, Dermatome Blades, Iris Retractors
- Surgical Packs
- All products that are less than \$20.00 (OEM price)