

Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services 072 '00 APR 10 A9:20
Food and Drug Administration
5630 Fischers Lane Room 1061, (HFA-305)
Rockville, MD 20852

Re: Reuse of Single Use Devices

To Whom It May Concern:

Stryker Instruments is greatly concerned with the practice of reusing single use devices. As a manufacturer of many single use devices we feel that it is important to help the FDA in making a decision regarding the regulation of third-party reproprocessors. As a manufacturer of medical devices, our primary concern is to assure superior quality of our products.

The decision to label a device as single use is based on research during product development. This entails testing of the physical characteristics to determine whether the reuse of a device would place a patient at unreasonable and substantial risk of illness or injury. Concerns of infection and contamination need to be addressed as well as the integrity of the product. A manufacturer must consider whether the device could be safely and effectively used multiple times on the same patient or different patients. Inherent in the intended use of many of our products, such as cutting accessories, is the expected use conditions. These devices are intended to contact normally sterile tissue or body spaces which, in effect, places the devices in the critical risk category.

Regulations require that all claims made of a product's performance, such as "Good or Better than New," be demonstrated by sound scientific evidence. Stryker believes that such claims are falsely represented by third party reproprocessors as we ourselves, have been unable to meet the rigor demanded to adequately demonstrate that a used cutting accessory is as safe or effective as a new one. Stryker cutting accessories are precision instruments, some designed to rotate up to 100,000 RPM, while delivering precise, clean cuts. Attempts to sharpen a used device only removes additional material and further destabilizes and depletes the device. Metal flakes and broken tips or fragments are pre-existing concerns and these are multiplied when units have been reworked. Dull, flaking or misdimensioned cutting accessories may lead to increased surgical time and/or poor surgical outcomes, accelerated handpiece wear due to the increased power needed to run the handpiece and injuries to the patient and healthcare worker. In addition, loss of cutting effectiveness leads to increased heat at the bone – device interface which may cause thermal necrosis of the bone.

Over the past four months our sales representatives, working with their hospital accounts, randomly pulled 213 reprocessed devices from various facilities across the country. A team of five highly skilled engineers inspected these devices against Device Master Record documents for any findings that would be checked prior to shipping product from our manufacturing site.

Study Results:

42.2% (90/213) Mislabeled

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38.0% (81/213) Compromised Condition

10.8% (23/213) Packaging Flaws

Description of Categories:

Labeling. Engineers examined the part number, original equipment manufacturer's name, dimensions, lot number, and extra wording that was placed on the outside of the reprocessed device. Of the 90 devices that were mislabeled, 77 labels had the wrong dimensions. Another key finding was that 20 devices had the wrong part number. In addition, the wrong original manufacturer's name was on 6 labels. Other errors included wrong device descriptions, adding phrases to the description, and not including a label, warning or instructions for use.

Device Condition. The quality of the flutes, sharpness of the blades, and device cleanliness was examined to determine the condition of the reprocessed device. A total of 81 devices were found to have flaws in their integrity. Twenty-three devices had worn, damaged flutes. It appeared that the attempted re-sharpening by the third-party reprocessor resulted in dull flutes on burs and teeth on saws. A reprocessed Mixevac (PMMA Bone Cement Mixer) had an inactivated filter due to the EtO gas used by the reprocessor. EtO gas activates the charcoal filter, soaks up the gas, and results in the inability to completely degas; thereby, inactivating the filter. Other findings included bent devices, broken devices, rusted or dirty mounts, punctured burs, cleaning residue, extra coatings on blades, and severely scratched surfaces. It should be noted that resharpener a cutting accessory will anneal the metal, decreasing the hardness. A coating is then applied by the reprocessor in an attempt to raise the hardness. This coating flakes off during use into the surgical site.

Packaging. The inner and outer packaging was assessed with a magnifying glass for pinholes and punctures. Out of 213 devices, 23 had packaging flaws. An additional finding was that all devices were repackaged in pouches when the OEM intentionally packaged some of them in blisters due to the sharpness of the device. Through validation, the OEM found pouches were not sufficient to protect the integrity of the package for some devices.

Issues Regarding Reprocessed Single Use Devices:

Labeling. The findings from our study indicate a prevalence of mislabeling. The mislabeling of a reprocessed device could cause a delay or additional surgery, misrepresentation of the OEM, and misuse of the device. The delay in surgery could increase the risk of injury or infection. If a smaller cutting accessory is packaged with a label indicating that it is larger and is used during a procedure on a patient, this may have a deleterious effect. A precision cut of a certain dimension may be required for placement of an implant. The physician may not be aware that the device was reprocessed and mislabeled by the reprocessor, not the OEM. This obvious misrepresentation of the OEM could influence a clinician's mistrust in the manufacturer's products. There are many examples one could use but in the end this is why OEM's routinely recall devices for mislabeling.

The prevalence of mislabeling on reprocessed devices is a great concern. If Stryker Instruments was responsible for the labeling issues found in our study, we would conduct a recall. It is obvious that third party reprocessors are not held accountable for labeling errors. This reflects a major discrepancy in accountability between the reprocessor and the OEM. According to QSR 820.120(d) a manufacturer should control labeling and packaging operations to prevent labeling mixups. Clearly, a third party reprocessor is not aware of the specific uses or warnings for every device or even the correct name of the device. In addition, many cutting accessories have specifications that are extremely hard to detect by visual inspection. Thus, the labeling errors detected during our study emphasize the prevalence of negligence by the third party reprocessor and the need for regulation.

Medical Device Reporting. When a device is reprocessed, the OEM (original equipment manufacturer) trademark is still on the device and therefore is held accountable for adverse events or device failures. The third party reprocessor's name is solely on the packaging material, which is typically disposed of when preparing for the procedure. If an adverse event occurs during the procedure, the only label on the device is that of the OEM. This creates a loophole in the accountability of MDRs. When an OEM receives a MDR it is virtually impossible for the OEM to know whether the device was reprocessed. Clinicians may not be aware that the device was reprocessed and therefore will report to the manufacturer whose name is on the device. In addition to the lack of traceability to the third party reprocessor, hospitals do not want to inform the OEM in fear of bad publicity that they are reusing single use devices. The third party reprocessor does not receive any information about the adverse event or device failure and the OEM processes the MDR/complaint even though the device has been reprocessed. Thus, it is not surprising that third party reproducers have few MDRs. Clearly, third-party reproducers do not have a true representation of MDRs and the OEM is held accountable for the MDRs that should be reported to the third-party reprocessor.

Traceability. Manufacturers of medical devices establish tracking systems that will enable them to promptly locate devices in commercial distribution in the event that a corrective action or notification about the device is necessary. If a single use device has been reprocessed the ability to track the device becomes extremely difficult. Third party reproducers leave the OEM's name on the device but their label does not indicate the OEM lot numbers that are used to track the devices. Thus, if the OEM needs to remove a product from the marketplace it becomes impossible and therefore a flawed device could remain in the marketplace.

Once a single use device is reprocessed the OEM should not maintain any responsibility for the product. The regulations state that third party reproducers are held accountable for Medical Device Reporting (Sections 519 (a) (b) and (c) of the Act; 21 CFR Part 803), Medical Device Tracking (Sections 519 (e) of the Act; 21 CFR Part 821), Medical Device Corrections and Removals (Section 519 (f) of the Act; 21 CFR Part 806), Quality System Regulations (Section 520 (f) of the Act; 21 CFR Part 820), and Labeling (Section 502 of the Act; 21 CFR Part 801). However, it is obvious from our study that more oversight is needed to ensure accountability by the reproducers. In the current situation, the OEM is still held responsible for the integrity and sterility of the reprocessed single use device. This makes it very difficult to prove the effects of a reused single use device. It is time to establish and implement a more rigorous regulation of third party reproducers to ensure that each patient receives the same quality of care.

If you have any questions concerning this document please call Mary Beth Novak, Stryker Instruments, at 800-800-4236 ext.3245.

Key to the Reprocessing Spreadsheet

Third-Party Reprocessors

1. Medical Instruments Technology, Inc.
2. Medical Device Services
3. Vanguard Medical Concepts
4. Alliance Medical Corporation
5. Adven
6. Anew Medical Enterprises
7. SterilMed, Inc.

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
1608-2-43	2.2 mm Drill	OK	OK	hole	1	01372-0143	
1608-2-7	1.6mm Bur	OK	OK	OK	1	01372-0121	"Osteotomy" is on label
1608-2-7	1.6mm Bur	OK	OK	OK	1	01372-0121	"Osteotomy" is on label
1608-2-49	2.3mm Drill	OK	OK	OK	1	01372-0145	QC on label
1607-2-113	1.2mm Bur	OK	OK	OK	1	01372-0133	
1607-2-107	1.6mm Bur	Mislabeled	OK	OK	1	01372-0131	1.65 on label, actually 1.6
1607-2-57	3.02mm Bur	OK	OK	OK	1	01372-0109	QC, No longer available
1608-2-13	4.7mm Bur	OK	Damaged	OK	1	01372-0113	Flutes look worn, damaged
1608-2-13	4.7mm Bur	OK	Damaged	OK	1	01372-0113	Flutes look worn, damaged
1608-2-9	2.3mm Bur	OK	Damaged	OK	1	01372-0123	Flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	Damaged	OK	1	01372-0123	Flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	Damaged	OK	1	01372-0123	Flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	Damaged	OK	1	01372-0123	Flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	Damaged	OK	1	01222-0026	Flutes look worn, osteotomy
1608-2-9	2.3mm Bur	OK	Damaged	OK	1	01372-0123	Flutes look worn, osteotomy
1608-2-13	4.7mm Bur	OK	Damaged	OK	1	01372-0113	Hole in bur,damaged
1608-2-11	3.2mm Bur	Mislabeled	Damaged	OK	1	01372-0111	3.1 on label, actually 3.2
1608-2-11	3.2mm Bur	Mislabeled	Damaged	OK	1	01372-0112	3.1 on label, actually 3.2
1608-2-13	4.7mm Bur	OK	Damaged	OK	1	01339-0100	Flutes look worn, QC
1608-2-13	4.7mm Bur	OK	Damaged	OK	1	01372-0113	Flutes look worn, QC
1608-2-13	4.7mm Bur	OK	Damaged	OK	1	01372-0113	Flutes look worn, QC
1608-2-14	4.7mm Bur	OK	Damaged	OK	1	01372-0113	Flutes look worn, QC
1607-2-17	7.0mm Bur	OK	Damaged	OK	1	01372-0105	Flutes look worn, Osteotomy
1608-2-7	1.6mm Bur	OK	OK	OK	1	01372-0121	Osteotomy
1607-2-113	1.2mm Bur	Mislabeled	Dirty	OK	1	01372-0133	Not a Stryker bur, dirt on bur
1607-2-101	2.26mm Bur	OK	OK	OK	2	221522	
1608-2-59	1.5mm Drill	OK	OK	OK	3	235349	Worn
277-10-216	1.6mm Bur	Mislabeled	OK	OK	3	237928	Not a Stryker bur
1608-2-17	7mm Bur	Mislabeled	Rusted	OK	1	01372-0117	Labeled 8 flute, actually 16. Rusted mount
1608-2-17	7mm Bur	Mislabeled	OK	OK	1	01372-0117	Labeled 8 flute, actually 16
1607-2-17	7mm Bur	OK	OK	OK	1	01372-0105	Osteotomy
1607-2-17	7mm Bur	OK	OK	OK	1	01372-0106	Osteotomy
1608-2-17	7mm Bur	Mislabeled	OK	OK	1	01372-0117	Labeled 8 flute, actually 16

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	dirty	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5; dirt in mount area
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
5100-37-113	Small tear cross cut Rasps	Mislabeled	OK	Pinholes?- Need blisters for Rasps	1	01372-0135	Label states 1675-113, actually 5100-37-113;label states 11.10mmx4.7mm, actually 11x5
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	Scratched	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	00738-0026	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01222-0023	Label states 10mm actually 5.5mm
2296-3-51	5.5mm saw blade	Mislabeled	OK	OK	1	01372-0072	Label states 10mm actually 5.5mm
2296-3-115	7mm saw blade	Mislabeled	Residue on blade	OK	1	01222-0029	Label states 10mm actually 7.0mm
2296-3-115	7mm saw blade	Mislabeled	Residue on blade	OK	1	01012-0035	Label states 10mm actually 7.0mm
2296-33-115	7mm saw blade	Mislabeled	OK	OK	1	01222-0028	Label states 10mm actually 7.0mm
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-125	9mm saw blade	Mislabeled	Residue on blade	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-125	9mm saw blade	Mislabeled	Scratched	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01506-0026	Label states 10mm actually 9.0mm;states oscillating
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01506-0026	Label states 10mm actually 9.0mm;states oscillating
2296-3-125	9mm saw blade	Mislabeled	Bent	OK	1	01372-0060	Label states 10mm actually 9.0mm;blade is bent
2296-3-125	9mm saw blade	Mislabeled	OK	OK	1	01372-0060	Label states 10mm actually 9.0mm
2296-3-206	12mm saw blade	Mislabeled	OK	OK	1	01012-0033	Label states 10mm actually 12mm
2296-3-105	9mm saw blade	Mislabeled	Scratched	OK	1	01372-0058	Label states 10mm actually 9.0mm;scratched
2296-3-105	9mm saw blade	Mislabeled	OK	OK	1	01372-0058	Label states 10mm actually 9.0mm

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2296-3-105	9mm saw blade	Mislabeled	Scratched	OK	1	01372-0058	Label states 10mm actually 9.0mm;scratched
2296-3-105	9mm saw blade	Mislabeled	Broken	OK	1	01372-0058	Label states 10mm actually 9.0mm; broken
2296-3-105	9mm saw blade	Mislabeled	OK	OK	1	01372-0058	Label states 10mm actually 9.0mm
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01372-0062	Label states 10mm actually 7.0mm
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01339-0072	Label states 10mm actually 7.0mm
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01372-0062	Label states 10mm actually 7.0mm
2296-3-103	7mm saw blade	Mislabeled	Broken	OK	1	01372-0062	Label states 10mm actually 7.0mm; broken
2296-3-103	7mm saw blade	Mislabeled	OK	OK	1	01372-0062	Label states 10mm actually 7.0mm
2296-3-104	16.4mm saw blade	OK	Residue on blade	OK	1	01012-0034	Label only states "saw blade"; residue left on blade
2296-3-104	16.4mm saw blade	OK	Residue on blade	OK	1	01012-0034	Label only states "saw blade"; residue left on blade
2296-3-103	7mm saw blade	OK	OK	OK	2	239819	Label states micro-oscillating saw blade
2108-150	Saw blade	OK	Dirty	OK	1	01012-0031	Something in package
2108-150	Saw blade	OK	OK	OK	1	01506-0022	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	Scratched	OK	1	01012-0031	Blade scratched
2108-150	Saw blade	OK	Scratched	OK	1	01012-0031	Blade scratched
2108-150	Saw blade	OK	Scratched	OK	1	01012-0031	Blade scratched
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	No insert line	OK	1	01372-0036	Blade worn; no insert line
2108-150	Saw blade	OK	Scratched	OK	1	01372-0036	Blade scratched

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2108-150	Saw blade	OK	OK	Pouch punctured	1	01012-0031	Punctures in pouch
2108-150	Saw blade	OK	Scratched	Pinholes in inner pouch	1	01012-0031	Pinholes in inner pouch
2108-145	Saw blade	OK	Residue on blade	OK	1	01339-0068	Cleaning residue on blade
2108-145	Saw blade	OK	Residue on blade	OK	1	01372-0030	Cleaning residue on blade
2108-156	Saw blade	OK	Residue on blade	OK	1	01372-0038	Cleaning residue on blade
2108-156	Saw blade	OK	Residue on blade	OK	1	01372-0038	Cleaning residue on blade
2108-156	Saw blade	OK	Residue on blade	OK	1	01372-0038	Cleaning residue on blade
5100-37-114	Large tear cross cut rasp	Mislabeled	OK	Need blister for rasps	1	01372-0137	Labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
5100-37-114	Large tear cross cut rasp	Mislabeled	Residue	Need blister for rasps	1	01372-0137	Labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7; residue near mounting
5100-37-114	Large tear cross cut rasp	Mislabeled	OK	Need blister for rasps	1	01372-0137	Labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
5100-37-114	Large tear cross cut rasp	Mislabeled	Residue	Need blister for rasps	1	01372-0137	Labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7; residue on mount
5100-37-114	Large tear cross cut rasp	Mislabeled	OK	Need blister for rasps	1	01372-0137	Labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
5100-37-114	Large tear cross cut rasp	Mislabeled	OK	Need blister for rasps	1	01372-0137	Labeled 1675-114, actually 5100-37-114; labeled 11.2x6.81 actually 14x7
1607-2-35	4mm Bur	Mislabeled	OK	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
1607-2-35	4mm Bur	Mislabeled	Flutes rounded/dull	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur; flutes rounded/dull
1608-2-35	4mm Bur	OK	Flutes rounded/dull	OK	1	01372-0119	Flutes are dull,rounded
1607-2-1	6mm Bur	OK	Flutes rounded/dull	OK	1	01372-0103	Flutes are dull,rounded
1607-2-35	4mm Bur	Mislabeled	Flutes rounded/dull	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur; flutes rounded/dull
1607-2-35	4mm Bur	Mislabeled	Flutes rounded/dull	OK	1	01372-0107	Labeled as Stryker but it is not a Stryker bur; flutes rounded/dull
1608-2-35	4mm Bur	OK	Flutes rounded/dull	OK	1	01339-0103	Flutes are dull, rounded; osteotomy
1607-2-1	6mm Bur	OK	Flutes rounded/dull	OK	1	01372-0103	Flutes are dull, rounded; osteotomy
1607-2-1	6mm Bur	OK	Flutes rounded/dull	OK	1	01372-0103	Flutes are dull, rounded; osteotomy
1608-2-1	6mm Bur	OK	Flutes rounded/dull	OK	1	01506-0029	Flutes are dull, rounded
1608-2-35	4mm Bur	OK	OK	OK	1	01372-0119	Osteotomy
1608-2-35	4mm Bur	OK	OK	OK	1	01506-0031	Osteotomy
1608-2-35	4mm Bur	OK	OK	OK	1	01506-0031	Osteotomy
1607-2-35	4mm Bur	OK	OK	OK	1	01372-0107	
1607-2-35	4mm Bur	OK	OK	OK	1	01372-0108	
1607-2-35	4mm Bur	OK	Flutes dull	OK	3	245334	Attempted to sharpen; flutes dull and residue left on them
1675-133	Saw blade	OK	Residue	OK	4	16943-0126	Residue on blade
277-10-216	1.6mm Bur	Mislabeled	Residue	OK	3	244862	Labeled as Microaire, actually Stryker; Residue on bur
2108-150	Saw blade	OK	Scratched	OK	1	01372-0036	Blade scratched;worn (opened)
2108-150	Saw blade	OK	Scratched	OK	1	01012-0031	Blade scratched;worn
2108-150	Saw blade	OK	Scratched	OK	1	01012-0031	Blade scratched;worn

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2108-150	Saw blade	OK	OK	OK	1	01012-0031	Worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	Worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	Worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	Worn
2108-150	Saw blade	OK	OK	OK	1	01372-0036	Worn
2108-150	Saw blade	OK	OK	OK	1	01372-0036	Worn
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2108-150	Saw blade	OK	Damaged	OK	1	01012-0031	Edges damaged
2108-150	Saw blade	OK	Damaged	OK	1	01372-0036	Edges damaged
2108-150	Saw blade	OK	Damaged	OK	1	01372-0036	Edges damaged and scratched
2108-150	Saw blade	OK	OK	OK	1	01012-0031	
2296-33-414	Saw blade	Mislabeled	OK	OK	1	01372-0074	Labeled 10mm actually 5.5
2296-33-414	Saw blade	Mislabeled	OK	OK	1	01372-0074	Labeled 10mm actually 5.5
2296-33-414	Saw blade	Mislabeled	OK	OK	1	01372-0074	Labeled 10mm actually 5.5
2296-33-414	Saw blade	Mislabeled	OK	OK	1	01506-0024	Labeled 10mm actually 5.5
2296-3-525	Saw blade	Mislabeled	Damaged	OK	1	01222-0032	Labeled 10mm actually 9mm;Dent near cut surface;Mount marks
2296-3-414	Saw blade	Mislabeled	Damaged	OK	1	01164-0017	Labeled 10mm actually 5.5mm, thin blade; Dent near cut surface; Mount marks
2296-33-414	Saw blade	Mislabeled	Damaged	OK	1	01372-0074	Labeled 10mm actually 5.5mm; Dent near cut surface; Mount marks

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
2296-3-525	Saw blade	Mislabeled	Damaged	OK	1	01222-0032	Labeled 10mm actually 9mm;Dent near cut surface;Mount marks
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-410	Saw blade	Mislabeled	OK	OK	1	01372-0064	Labeled 10mm actually 5.5mm
2296-3-411	Saw blade	Mislabeled	OK	Dirty	1	01372-0066	Fuzzy hair in package; Labeled as 10mm actually 9mm
2296-3-411	Saw blade	Mislabeled	OK	OK	1	01372-0066	Labeled as 10mm actually 9mm
2296-3-411	Saw blade	Mislabeled	OK	Dirty	1	01372-0066	Dirt in package; Labeled as 10mm actually 9mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm
2296-3-412	Saw blade	Mislabeled	OK	OK	1	01372-0068	Labeled as 10mm actually 5.5mm

Reprocessed Devices by Third-Party Reprocessors

Part Number	Description	Labeling	Condition	Packaging	Reprocessor	Lot Number	Comments
5305-25-123	Saw blade	OK	OK	OK	1	01372-0044	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-124	Saw blade	OK	OK	OK	1	01372-0046	
5305-25-125	Saw blade	OK	OK	OK	1	01372-0048	
5305-25-125	Saw blade	OK	OK	OK	1	01372-0048	
5305-25-125	Saw blade	OK	OK	OK	1	01372-0048	
5100-37-115	Small tear Rasp	Mislabeled	OK	Hole	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5; hole in inner pouch rightside of flutes
5100-37-115	Small tear Rasp	Mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
5100-37-115	Small tear Rasp	Mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
5100-37-115	Small tear Rasp	Mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
5100-37-115	Small tear Rasp	Mislabeled	OK	OK	1	01372-0139	Labeled as 1675-115 11.2x5.82mm actually 5100-37-115 11x5mm
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	Scratched	OK	1	01372-0030	Scratched
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	Scratched	OK	1	01372-0030	Scratched
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-302	Saw blade	OK	OK	OK	1	01012-0015	
2108-145	Saw blade	OK	OK	OK	1	01372-0030	
2108-145	Saw blade	OK	OK	OK	1	01506-0021	

Align top of FedEx PowerShip Label here.

STRYKER INSTRUMENTS
4100 EAST MILHAM
KALAMAZOO MI 490016197
(616)323-7700

SHIP DATE: 07APR00
ACCOUNT #: 131788886
ACTUAL WGT: 1 LBS

TO: DOCKET NO.00D-0053;DOCKET MGNT
BRANCH: DIV OF MGNT SYSTEMS &
POLICY. OFF OF HUMAN RECOURCE
&MGNT SERV:FDA
ROCKVILLE MD 20852

4683 5842 2121

FedEx.

4683 5842 2121

REF: 20852

PRIORITY OVERNIGHT MON

CAD# 057532 07APR00

TRK# 4683 5842 2121

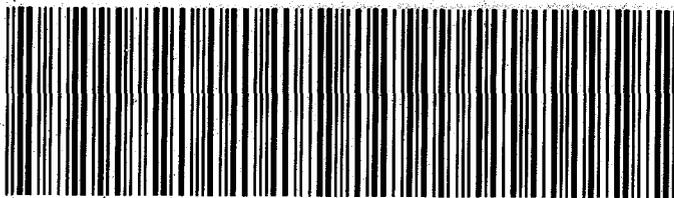
Form
201

Deliver by:
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