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Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn drive
Room 1-23
Rockville, Maryland 20857

Re: Docket 00D-0053

To Whom It May Concern:

Johnson & Johnson respectfully submits these comments, in duplicate, in response to the notice of availability of two guidance documents entitled: "Reprocessing and Reuse of Single Use Devices: Review Prioritization Scheme," (RPS) and "Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals" (Enforcement Guidance).¹

Johnson & Johnson is a member of the Association of Disposable Device Manufacturers (ADDM) and agrees with the comments submitted to this docket by ADDM. These comments, therefore, do not repeat the issues raised by ADDM, but are instead limited to a discussion of the review priority categorization under the RPS for particular categories of single use devices manufactured by Johnson & Johnson companies. The RPS contains two flowcharts intended to delineate the Food and Drug Administration's (FDA's) decision-making process in assigning a risk level to various types of reprocessed single use devices. These risk levels will then be utilized to prioritize FDA's enforcement of the premarket submission requirements as set forth in the companion Enforcement Guidance.

While Johnson & Johnson agrees with ADDM that some of the questions in the RPS flowcharts should be deleted or modified, we have attempted to apply the FDA-proposed flowcharts to various Johnson & Johnson products to assist FDA in determining the appropriate category ("high," "moderate" or "low" risk) for these device once reprocessed.

¹ 65 Fed. Reg. 7027 (Feb. 11, 2000).

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For each device type discussed, the flowchart questions are restated followed by a response for the given device type.

I. Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (no regulation), Percutaneous Transluminal Angioplasty (PTA) Catheters (no regulation), Diagnostic Intravascular Catheters (21 C.F.R. § 1200) and Guiding Catheters (21 C.F.R. § 870.1330)

A. Infection Risk

1. *Are disposable PTCA, PTA, diagnostic intravascular and guiding catheters (collectively, cardiac catheters) non-critical devices?*

No. According to the Spaulding criteria cited in the RPS, a non-critical device is one "intended to make topical contact and not penetrate intact skin."² Disposable cardiac catheters enter the vasculature and are therefore not "non-critical" devices.

2. *Does postmarket information suggest that using a reprocessed cardiac catheters may present an increased risk of infection when compared to the use of a single use device that has not been reprocessed?*

Yes. Cordis, a Johnson & Johnson subsidiary, has conducted two studies evaluating reprocessed single use catheters retrieved from hospitals. Full study reports were previously submitted to FDA by ADDM.³

The January 1999 study evaluated cleaning, sterility and endotoxin levels as well as several functional characteristics for a total of ten (10) balloon catheters, twenty (20) diagnostic catheters and ten (10) guiding catheters. Visual inspection demonstrated sterility problems with the balloon catheters in that several outer packages possessed open

² RPS at 5.

³ "Report on Refurbished Single Use Devices," an enclosure to January 27, 1999 letter from Torrente, President, ADDM to Burlington, M.D., Director, FDA, Center for Devices and Radiological Health (CDRH) and "Evaluation of Refurbished Single Use Devices," an enclosure to November 22, 1999 letter from Torrente, President, ADDM to Feigal, Jr., M.D., M.P.H., Director, FDA, CDRH.

channels which, in some cases, were large enough to allow a piece of paper through the seal. Package functional testing revealed channels in the inner and outer pouches of two samples rendering the packages non-sterile. All outer pouches failed a package challenge test to identify leaks in the seals, and all inner pouches failed a package pull test to assess seal strength. One guiding catheter package did not meet the requirements for package pull tests. In addition, reddish brown contamination on the dispenser tubes of packages was identified as proteinaceous material indicating the presence of blood.

One each balloon and diagnostic catheter were subjected to a detailed inspection of internal and external surfaces. White contamination was found trapped within the closed inflation lumen of the balloon catheter. Contaminants were identified as components of saline solution and contrast media used in the clinical setting.

The November 1999 study again focused on package integrity and visual observations as well as some functional testing. Over half of the twenty-seven (27) balloon, guiding and diagnostic catheters tested exhibited some type of seal defect, including open seal. Foreign contaminants, residual blood and blood components were also identified. Specifically, catheters failed each of the following tests: package visual inspection (59%), package seal test (63%), package pull test (26%), product visual inspection (50%).

The results of these studies collectively suggest that cardiac catheters are difficult to clean. Unlike with new catheters then, ethylene oxide (EtO) sterilization may be ineffective on reprocessed cardiac catheters.

Reprocessed cardiac catheters are therefore HIGH-RISK devices under the infection risk flowchart. Nonetheless, below are responses to the remaining questions in the flowchart which demonstrate that, even without postmarket data, reprocessed disposable cardiac catheters are high-risk devices.

3. *Do disposable cardiac catheters include features that could impede thorough cleaning and adequate sterilization/disinfection?*

Yes. Cardiac catheters are comprised of long narrow lumens which would be difficult to rinse or flush. Moreover, the catheter sheaths are opaque, not permitting visual inspection of the lumen. The balloon material in PTCA and PTA catheters may also incorporate body fluids while distended. Guiding catheters are comprised of one wire coiled around another creating many crevices for accumulation of patient material and cleaning residue. None of these devices were designed to permit verification of cleaning.

4. *Does a reusable device exist that has (a) an equivalent design and (b) the same intended use as a disposable cardiac catheters?*

We are not aware of reusable PTCA, PTA, diagnostic intravascular or guiding catheters.

5. *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the disposable cardiac catheters have been adequately cleaned and disinfected/sterilized?*

No. We are not aware of any standards for the cleaning and sterilization of disposable cardiac catheters.

6. *Is this a semi-critical device?*

No. According to the Spaulding criteria cited in the RPS,⁴ a semi-critical device is one intended "to contact intact mucous membranes and not penetrate normally sterile areas of the body." As discussed in Section I.A.1, a cardiac catheter comes in contact with normally sterile body tissues such as the vasculature and is therefore a critical device.

CONCLUSION: This is the final question in the flowchart. Under the RPS, a reprocessed disposable cardiac catheter presents a HIGH RISK of infection.

⁴ RPS at 5.

B. Inadequate Performance Risk

1. *Does postmarket information suggest that using reprocessed disposable cardiac catheters may present an increased risk of injury when compared to the use of a disposable cardiac catheter that has not been reprocessed?*

Yes. Data from both studies conducted by Cordis on these devices suggest that reprocessed cardiac catheters present an increased risk of injury over a new device.⁵ The January 1999 study tested material integrity and product functionality as well as cleaning/sterility issues for ten (10) reprocessed balloon catheters, twenty (20) reprocessed diagnostic catheters and ten (10) reprocessed guiding catheters. Packaging and labeling failures included failure to provide the size of the guidewire lumen or the pressure requirement of the catheters. For some devices, lot numbers were not provided on the catheter or on the packaging.

Functional failures specific to balloon catheters included: (1) poor trackability likely due to the unfolded condition of the balloon as it is removed from the package, (2) inability of balloons to be prepared in accordance with Instructions for Use, (3) curved innerbodies and S-shaped innerbodies in the balloon on inflation for testing, and (4) failure to withstand average burst pressure of 21 atm.

Functional failures with diagnostic and guiding catheters included (1) out of tolerance condition for shape conformance of guiding (100%) and diagnostic (66%) catheters within their packaging, (2) outer diameter measurements above their pre-established specifications on 33% of diagnostic catheters, (3) the top inner diameters below pre-established specifications on 33% of diagnostic catheters, (4) failure of diagnostic catheters (20%) in a dynamic pressure test performed to determine if the samples could withstand five injections to the pressure rating indicated on the hubs of the catheters, (5) failure of reprocessed diagnostic catheters to perform as well as new catheters in two types of torque testing, and (6) signs of material degradation post tensile overload test in guiding catheter.

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See supra note 3.

In the November 1999 study, twenty-seven (27) reprocessed cardiac catheters underwent functional testing. Catheters failed to perform adequately in the following tests: (1) 9% shape conformance (diagnostic/guiding catheter), (2) 26% visual inspection including flaking of exit marker, kinks, bends, sliced outer body and strain relief, open fuse (balloon, diagnostic and guiding catheter), (3) 100% trackability (balloon catheter), and (4) 100% balloon preparation test (balloon catheter).

The results of these two studies suggest that reprocessed cardiac catheters may not perform as anticipated by the cardiologist. These devices, when new, are in conformance with tight specifications critical to patient safety and device functionality. The failure of reprocessed cardiac catheters to meet these specifications presents an increased risk to the patient.

Reprocessed cardiac catheters are therefore HIGH-RISK devices under the performance flowchart. Nonetheless, below are responses to the remaining questions in the flowchart which demonstrate that, even without postmarket data, reprocessed disposable cardiac catheters are high-risk devices.

2. *Could failure of a reprocessed disposable cardiac catheter cause death, serious injury or permanent impairment?*

Yes. Failure of a reprocessed disposable cardiac catheter could result in serious patient injury. Breakage of the device could result in free floating debris in the vasculature which can lead to occluded blood flow and result in stroke or myocardial infarction.

3. *Do reprocessed disposable cardiac catheters contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?*

Yes. Cardiac catheters do contain materials, coatings and components which may be damaged or altered by single use or reprocessing. For instance, many of these catheters have a lubricious coating which is water soluble and is therefore removed during use. Exit markers on balloons, including crimped or glued on metal bands and radioopaque markers can be removed during use and cleaning. The balloons themselves are engineered from specialized biomaterials whose

compliance characteristics may be altered by reprocessing. Embrittlement of plastics in cardiac catheters due to accelerated aging brought about by reprocessing can result in unnecessary trauma to the vasculature. Finally, diagnostic and guiding catheters are available in a family of shapes to allow appropriate matching to the patient's coronary anatomy. These devices are unlikely to return to their original shapes after reprocessing.

4. *Are there recognized consensus standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the disposable cardiac catheters has been altered due to reprocessing or reuse?*

No. We are not aware of any standards or guidances to assess the performance of reprocessed disposable cardiac catheters.

5. *Can visual inspection determine if performance has been affected?*

No. Removal of coatings, failure of the balloon to inflate to its proper dimensions, accelerated aging of plastic components and changes in flexibility might not be determined by visual inspection.

CONCLUSION: This is the final question in the flowchart. Under the RPS, a reprocessed, disposable PTCA, PTA and diagnostic intravascular or guiding catheter presents a HIGH RISK of inadequate performance.

II. Electrophysiology Catheters (21 C.F.R. § 870.1220⁶) and Cardiac Ablation Catheters (no regulation)

A. Infection Risk

1. *Are disposable electrophysiology catheters and cardiac ablation catheters (together, EP catheters) non-critical devices?*

No. According to the Spaulding criteria cited in the RPS,⁷ a non-critical device is one "intended to make topical contact and not

⁶ The "List of Frequently Reprocessed Single Use Devices" in Appendix 2 of the RPS lists 21 C.F.R. § 870.1120 as the regulation for electrophysiology recording catheters. The correct regulation is 21 C.F.R. § 870.1220.

⁷ RPS at 5.

penetrate intact skin." EP catheters are inserted into the patient's vasculature and enter the chambers of the heart, and are therefore not "non-critical devices."

2. *Does postmarket information suggest that using a reprocessed disposable EP catheter may present an increased risk of infection when compared to the use of a single use device that has not been reprocessed?*

Yes, Biosense Webster, Inc., a Johnson & Johnson subsidiary, conducted a study on the effects of reprocessing and reuse of EP catheters.⁸

In Part One of the study, thirty-four (34) reprocessed catheters (32 in-house, 2 commercial) were tested along with thirty-nine (39) new stock catheters which were either used as control articles or were assessed after simulated reprocessing/reuse. Four different tests relevant to infection risk were conducted.

- Stock catheters were subjected to simulated reuse (repeated deflection cycles and detergent washes using same detergent used in hospitals) and ethylene oxide sterilization and examined for sterilization residuals.
- Stock catheters were tested for loss of sterility when inoculated inside the handles before sterilization.
- Reused and resterilized catheters were examined by microscopy, endotoxic, sterility, material and chemical testing.
- Contaminant residue found on reprocessed catheters was removed and tested for biological toxins.

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"R&D Report: Changes in Electrophysiology Catheters during Reprocessing and Reuse," (Oct. 15, 1999), an enclosure to November 22, 1999 letter from Torrente, President, ADDM to Feigal, Jr., M.D., M.P.H., Director, FDA, CDRH.

Significant findings include (1) a reddish brown colored sterile contaminant on the tip electrodes on over 70% of the catheters reprocessed by the hospital, (2) a distinct shaft discoloration in over 90% of the catheters reprocessed by the hospital, indicating a chemical/material possibly associated with changes in sterilizability, (3) excess sterilization residual and byproduct residual levels after 10 worst-case wash/sterilization cycles.

In Part Two of the study, thirty-three (33) reprocessed EP catheters were examined for degradation and possible risk to patient during next use. Two tests relevant to infection risk were conducted.

- Reprocessed EP catheters were microscopically examined for contaminant within the sealed package. Contaminants were tested for thrombogenicity (in vivo canine model), size and texture (SEM), and composition (EDS and FTIR).
- Catheters which were known to have undergone a large number of reuse cycles were tested for EtO residuals.

Significant findings include (1) a reddish brown colored foreign residue was found on the tip electrodes of 7 of 33 catheters examined; (2) catheters with this residue were significantly more thrombogenic than comparable new catheters; (3) a white colored foreign residue was found on 8 of 33 catheters examined.

In addition to this study, Johnson & Johnson is aware of testing performed by FDA's Office of Science & Technology which calls into question the cleanability of certain EP catheters. Devices which are not clean cannot be effectively sterilized by EtO. Therefore, reprocessed EP catheters represent an increased risk of infection over new catheters which have not come in contact with a patient and are thus clean prior to EtO.

Reprocessed EP catheters are therefore HIGH-RISK devices under the infection risk flowchart. Nevertheless, below are responses to the remaining questions which demonstrate that, even without postmarket data, reprocessed EP catheters are high-risk devices.

3. *Do disposable EP catheters include features that could impede thorough cleaning and adequate sterilization/disinfection?*

Yes. EP catheters are comprised of a long plastic closed lumen with one or more electrodes at the distal end. Each electrode-catheter interface represents an opportunity for retention of residual patient material. Repeated cleaning and use can loosen the electrodes providing even larger gaps and greater potential for transfer of residual bioburden to the next patient. The plastic sheath cannot withstand steam sterilization and EtO will not effectively sterilize this patient material.

4. *Does a reusable device exist that has (a) an equivalent design and (b) the same intended use as a disposable EP catheter?*

No. We are not aware of any reusable EP catheters.

5. *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the disposable EP catheters have been adequately cleaned and disinfected/sterilized?*

No. We are not aware of any standards for the cleaning and sterilization of disposable EP catheters.

6. *Is this a semi-critical device?*

No. According to the Spaulding criteria cited in the RPS,⁹ a semi-critical device is one intended "to contact intact mucous membranes and not penetrate normally sterile areas of the body." As stated in Section II.A.1 above, EP catheters come in contact with the sterile vasculature and are thus critical devices.

CONCLUSION: This is the final question in the flowchart. Under the RPS, a reprocessed disposable EP catheter presents a HIGH RISK of infection.

⁹ RPS at 5.

B. Inadequate Performance Risk

1. *Does postmarket information suggest that using a reprocessed disposable EP catheter may present an increased risk of injury when compared to the use of a disposable EP catheter that has not been reprocessed?*

Yes. The Biosense Webster Study discussed in Section II.A.2 above, also collected data on device performance. Part One of the study, included two test categories relevant to device performance.

- Reprocessed EP catheters were examined for mechanical, material and surface degradation by microscopy and compared to stock catheters.
- Simulated reuse stock catheters were examined for mechanical, material and electrical degradation.

Relevant findings include (1) a distinct shaft discoloration indicating a chemical/material change typically associated with changes in mechanical properties in over 90% of the hospital-reprocessed EP catheters; (2) mechanical and electrical failures occurred after as few as 260 cycles; and (3) up to 28% and 12% reductions in catheter piston force and catheter tip bending stiffness, respectively, were observed after 700 catheter deflections.

In Part Two of the study, Biosense Webster examined reprocessed EP catheters microscopically for physical damage and seal integrity defects; catheters with physical damage were studied under SEM while catheters with seal defects were pressure tested to manufacturer's specifications.

Significant findings included EP catheters which failed manufacturer's quality inspection in the following areas (1) 3 of 33 catheters with scratched and dented electrodes, (2) 2 catheters with damaged polyurethane seals around the electrodes resulting in loss of seal integrity, (3) 7 catheters with loss of curve integrity, and (4) one catheter with electrical failure resulting in a high, erratic leadwire inspection.

The results of this study suggest that reprocessed EP catheters may be physically damaged and not in conformance with their specifications. These specifications are critical for patient safety and product performance. Therefore, the failure of reprocessed EP catheters to meet these specifications presents an increased risk to patients.

Reprocessed EP catheters are therefore, HIGH-RISK devices under the performance risk flowchart. Nevertheless, below are responses to the remaining questions in that flowchart, demonstrating that, even without postmarket data, reprocessed EP catheters are high-risk devices.

2. *Could failure of a reprocessed disposable EP catheter cause death, serious injury or permanent impairment?*

Yes. The greatest potential for injury from a reprocessed EP catheter arises from formation of emboli which could result in stroke or myocardial infarction. The potential for emboli is increased when the electrode-catheter junction fails to be smooth and continuous as is the case with reprocessed EP catheters. In addition, ablation catheters are utilized to ablate areas of heart muscle that cause abnormal electrical activity. Reprocessing-induced alterations in the steerability of these devices and electrode defects could lead to accidental ablation of normal tissue. This type of medical error could result in pacemaker dependence for the patient.

3. *Do reprocessed disposable EP catheters contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?*

Yes. As demonstrated by the study results summarized in Section II.A.2, EP catheters are comprised of components and materials susceptible to damage by use and reprocessing. Specifically, reprocessing can adversely affect the electrical properties of the catheter electrodes and can damage the polyurethane seals around the electrodes. In addition, the electrodes are not attached to the catheter with sufficient strength to withstand repeated cleaning and can therefore separate from the catheter.

4. *Are there recognized consensus standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the disposable EP catheter has been altered due to reprocessing or reuse?*

No. We are not aware of any standards or guidances to assess the performance of reprocessed disposable EP catheter.

5. *Can visual inspection determine if performance has been affected?*

No. Damage to electrical components and seals of reprocessed EP catheters may not be observed by visual inspection.

CONCLUSION: This is the final question in the flowchart. Under the RPS, a reprocessed, disposable EP catheter presents a HIGH RISK of inadequate performance.

III. Disposable Trocars (21 C.F.R. §§ 870.1390, 876.5090, 884.1720, 874.4420, and/or 876.1500)

A. Infection Risk

1. *Are disposable trocars non-critical devices?*

No. According to the Spaulding criteria cited in the RPS,¹⁰ a noncritical device is one that is "intended to make topical contact and not penetrate intact skin." The disposable trocars manufactured by Johnson & Johnson companies typically contact normally sterile body tissues during use are therefore not non-critical devices.

¹⁰ RPS at 5.

2. *Does postmarket information suggest that using a reprocessed single use trocar may present an increased risk of infection when compared to the use of a single use trocar that has not been reprocessed?*

Yes. For example, Ethicon Endo-Surgery, a Johnson & Johnson subsidiary, conducted a laboratory study involving visual inspection, functional testing, and inspection after disassembly, of several reprocessed, single use devices. All devices tested for this study were retrieved from hospital stores and were in the reprocessor's package. The report from this study, "Field Quality Engineering Report Evaluation of Reprocessed Ethicon Endo-Surgery Single Patient Use (SPU) Devices," (October 1999), which was submitted to FDA by ADDM in November 1999,¹¹ shows dried blood on a reprocessed trocar housing. Dried blood can harbor bacteria and viruses able to infect subsequent patients. If not for this study, the trocar would have been used in another patient. The risk of infection evidenced by this contaminated device is not present in a new disposable device since that device was sterilized after packaging and has not yet come into contact with a patient.

Reprocessed Ethicon Endo-Surgery disposable trocars are therefore HIGH-RISK devices under the infection risk flowchart. Nonetheless, below are responses to the remaining questions in the flowchart which demonstrate that, even without postmarket data, reprocessed single use trocars are high-risk devices.

3. *Do disposable trocars include features that could impede thorough cleaning and adequate sterilization/disinfection?*

Yes. A good example is Ethicon Endo-Surgery's disposable trocar generally used for gynecologic laparoscopy. The sleeve and housing of this trocar are made of injection-molded polycarbonate. Unlike resposable trocars in which the sleeves are designed to be detachable,

¹¹ Enclosure to November 22, 1999 letter from Torrente, President, ADDM to Feigal, Jr., M.D., M.P.H., Director, FDA, CDRH.

this trocar's sleeve and housing are fastened together as one unit. During a procedure, an obturator consisting of a long narrow shaft with a molded polycarbonate sheath containing the cutting blade is inserted through the housing and sleeve. When activated, the blade penetrates the skin, then immediately, the sheath closes over the blade. The obturator is then removed to permit insufflation and introduction of surgical instruments through the housing and sleeve. On the lower portion of the housing is an insufflation gas inlet port with a rotating stopcock. Inside the housing is a mechanical valve with a silicone gasket. The entrance to the housing has another silicone gasket. The valve and gaskets allow the introduction and removal of instruments with minimum loss of insufflation.

Following penetration, blood and tissue can be drawn up into the obturator sheath upon closing to cover the blade. It is difficult, if not impossible, to access and clean all portions of the blade or the inside of the obturator sheath. In addition, during a laparoscopic procedure, the pressure of insufflation gas during the insertion and removal of instruments through the trocar can push blood and tissue up through the sleeve and gasket into the housing. Because the sealing gasket is normally closed, the inside of the housing cannot be accessed for adequate cleaning.

4. *Does a reusable device exist that has (a) an equivalent design and (b) the same intended use as a disposable trocar?*

No. (a) We are not aware of any trocars that are completely reusable. There are some reusable trocar sleeves that are used with screw-on disposable housings. Reusable trocar sleeves, however, are made of stainless steel or extremely durable plastics. Unlike the materials used in disposable trocars, these materials are designed and tested to withstand over 200 cycles of proper cleaning and sterilization.

(b) There are disposable and reusable trocar sleeves intended for the same surgical application, however, disposable and reusable trocar sleeves differ in their intended use. Specifically, disposable trocar sleeves are intended to be used on a single patient in a single procedure. Reusable trocar sleeves are designed and intended to be used on more than one patient.

5. *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the disposable trocars have been adequately cleaned and disinfected/sterilized?*

No. We are not aware of any standards for the cleaning and sterilization of disposable trocars.

6. *Is this a semi-critical device?*

No. According to the Spaulding criteria cited in the RPS, a semi-critical device is one intended "to contact mucous membranes and not penetrate normally sterile areas of the body." Trocars contact normally sterile body tissues and are therefore critical devices under the Spaulding criteria.

CONCLUSION: Under the RPS, reprocessed disposable trocars present a HIGH RISK of infection.

B. Inadequate Performance Risk

1. *Does postmarket information suggest that using a reprocessed disposable trocar may present an increased risk of injury when compared to the use of a disposable trocar that has not been reprocessed?*

Yes. For example, the October 1999 Ethicon Endo-Surgery report of reprocessed single use devices¹² shows significant physical damage to a trocar – specifically, a complex crack in the housing near the stopcock, and a chip in the leading, beveled edge of the trocar sleeve. The disinfecting solutions used in reprocessing weaken the plastic and cause it to crack at stress points. Cracks at stress points may cause the trocar to break upon reuse resulting in pieces of plastic breaking off in the patient.

¹²

See supra note 11.

Ethicon Endo-Surgery disposable trocars are therefore HIGH-RISK devices under the performance flowchart. Nonetheless, below are responses to the remaining questions which demonstrate that, even without postmarket data, reprocessed single use trocars are high-risk devices.

2. *Could failure of a reprocessed trocar cause death, serious injury or permanent impairment?*

Yes. The presence of dried blood and tissue, and the effects of reprocessing on essential moving parts of the sheath, may impede the sheath from covering the blade quickly after penetration. If the blade is not covered properly, insertion of the trocar could result in puncture damage to untargeted organs or life-sustaining blood vessels.

3. *Do reprocessed disposable trocars contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?*

Yes. A continuing Ethicon Endo-Surgery study of reprocessed devices — the report of which is expected to be completed this spring — has demonstrated that reprocessing seriously weakens the adhesive used to attach the stopcock. Stopcocks detached from ten or eleven reprocessed trocars tested against their original specifications. Failure of the stopcock would result in loss of insufflation.

Repeated exposure of the trocar to irradiation sterilization would cause the silicone gaskets to harden and lose flexibility and cause the polycarbonate to discolor. Gasket failure would also result in loss of insufflation.

Autoclaving would deform the polycarbonate plastic.

EtO sterilization would weaken the polycarbonate and cause it to become brittle. As a result, the trocar could crack or break upon insertion or manipulation of instruments through the sleeve.

Through reuse, the beveled insertion end of the sleeve may become nicked or dulled by the repeated passage of instruments.

Finally, the penetration blade will become dull with repeated use.

4. *Are there recognized consensus standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the disposable trocar has been altered due to reprocessing or reuse?*

No. We are not aware of any standards or guidances to assess the performance of reprocessed disposable trocars.

5. *Can visual inspection determine if performance has been affected?*

No, not in all cases. Visual inspection may not reveal whether the adhesive attaching the stopcock has degraded or whether the silicone gaskets have hardened as a result of disinfection and sterilization. Yellowing of the polycarbonate due to sterilization may be recognized as a sign of weakness. Nicks in the insertion edge of the sleeve could be readily apparent. While larger cracks in the housing or sleeve also would be detectable upon visual inspection, other smaller cracks may go undetected.

CONCLUSION: Reprocessed disposable trocars present a HIGH RISK of inadequate performance and should be categorized as such in the RPS.

C. General Comments

The RPS categorizes reprocessed "OB-GYN" trocars and reprocessed "Gastroenterology/Urology" trocars as low-risk devices, while other types of reprocessed "Surgery" trocars are categorized as moderate-risk devices. As demonstrated above, we disagree with these categories. Moreover, we note that one type of disposable trocar made by Ethicon Endo-Surgery has been cleared under a 510(k) for gynecologic use and under a different 510(k) for general surgical applications. In this instance, the identical device has been categorized in two different risk categories by FDA.

IV. Disposable Staplers and Clip Appliers (21 C.F.R. §§ 876.4400, 876.4540, 878.4800, 882.4190)

A. Infection Risk

1. *Are disposable staplers and clip appliers non-critical devices?*

No. Ethicon Endo-Surgery makes a variety of disposable staplers and clip appliers. These devices are "intended to contact normally sterile body tissues and spaces during use." They are therefore not non-critical devices under the Spaulding criteria cited in the RPS.¹³

2. Does postmarket information suggest that using a reprocessed disposable endoscopic stapler or clip applier may present an increased risk of infection when compared to the use of a single use device that has not been reprocessed?

Yes. For example, Ethicon Endo-Surgery's October 1999 laboratory study¹⁴ shows a mass of blood and tissue that was ejected along with a clip from a reprocessed clip applier. The deployed clip was also contaminated with blood and tissue as was the base of the clip applier jaws and the clip track. In a previous study conducted by Ethicon Endo-Surgery in 1998, "Evaluation of Reprocessed Ethicon Endo-Surgery, Inc. Single Use Medical Devices," that was also submitted to FDA by ADDM,¹⁵ small flakes of blood were found on the cartridge, handle, and inside a recessed hole near the tip of a reprocessed multiclip clip applier. In the same study, inspection of a reprocessed linear stapler revealed no externally visible blood or tissue. However, upon disassembly of the staple drivers, a flake of dried blood and tissue was observed in the groove at the tip of one of the drivers where it meets the staple. A large flake of dried blood was also found in the back of the anvil assembly of another reprocessed disposable stapler.

¹³ RPS at 5.

¹⁴ See supra note 11.

¹⁵ Enclosure to January 27, 1999 letter from Torrente, President, ADDM to Burlington, M.D., Director, FDA, CDRH.

These areas would have direct contact with patient tissue and fluids during subsequent procedures. Dried blood and tissue can harbor bacteria and viruses able to infect subsequent patients. This risk of infection is not present in a new disposable device since that device has never been used on a patient.

Ethicon Endo-Surgery disposable staplers and clip applicators are therefore HIGH-RISK devices under the infection risk flowchart. Nonetheless, below are responses to the remaining questions in this flowchart which demonstrate that, even without postmarket data, reprocessed single use staplers and clip applicators are high-risk devices.

3. *Do disposable staplers and clip applicators include features that could impede thorough cleaning and adequate sterilization/disinfection?*

Yes. Ethicon Endo-Surgery's disposable staplers and clip applicators have intricate assemblies of small moving parts. These parts contact blood and tissue during operation of the device, and blood and tissue can be drawn into the device upon operation and retraction of the moving parts. The space between these parts is very small and the devices cannot be disassembled for cleaning. In addition, many of these devices have small holes at the top of the lumen nearest the operating tip. During use in endoscopic procedures, pressure from insufflation can drive blood and tissue into the holes and up into the lumen of the device. The inside of the lumen cannot be accessed for cleaning. Moreover, the presence of blood and tissue in the moving parts and lumen will impede complete sterilization by EtO.

Furthermore, the metal parts of these devices are often not made of the same quality stainless steel as reusable devices, and will corrode and weaken upon repeated exposure to saline solutions, cleaning solutions and disinfectants.

4. *Does a reusable device exist that has (a) an equivalent design and (b) the same intended use as a disposable endoscopic stapler or clip applicator?*

No. (a) There are reusable staplers and single clip applicators, however, the designs of these devices differ significantly from the designs of single use staplers and clip applicators. Specifically, reusable staplers and clip applicators are made of higher quality metals that can withstand

repeated cleaning and sterilization. In addition, reusable staplers and clip applicators are designed to be disassembled for cleaning. In contrast, disposable staplers and clip applicators are made of materials that will corrode during reprocessing, and they cannot be disassembled for cleaning without destroying the device.

(b). There are disposable and reusable clip applicators that are intended to serve the same function, however, disposable and reusable staplers and clip applicators differ in their intended use. Reusable devices are designed and intended to be used on more than one patient with disinfecting and sterilization between patients. Disposable staplers and clip applicators have multiclip capacity and are more intricate than the reusable devices.

5. *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the disposable staplers and clip applicators have been adequately cleaned and disinfected/sterilized?*

No. We are not aware of any standards for the cleaning and sterilization of disposable staplers and clip applicators.

6. *Is this a semi-critical device?*

No. According to the Spaulding criteria cited in the RPS,¹⁶ a semi-critical device is one intended "to contact intact mucous membranes and not penetrate normally sterile areas of the body." Disposable endoscopic staplers and clip applicators come into contact with normally sterile body tissues, and are therefore critical devices.

CONCLUSION: Under the RPS, reprocessed Ethicon Endo-Surgery disposable staplers and clip applicators present a HIGH RISK of infection.

¹⁶ RPS at 5.

B. Inadequate Performance Risk

1. *Does postmarket information suggest that using a reprocessed disposable stapler or clip applicator may present an increased risk of injury when compared to the use of a disposable stapler or clip applicator that has not been reprocessed?*

Yes. Some examples: (a). The October 1999 report of Ethicon Endo-Surgery's laboratory evaluation of reprocessed single use devices¹⁷ describes the repeated misfiring of a reprocessed clip applicator and a clip that was lodged in the clip track because of blood and tissue residues.

(b). Greater force than usual was required to fire another clip applicator. Difficulty in firing a device may cause surgeons to assume there is a problem with the device.

(c). Some reprocessed non-reloadable devices had fewer than the original number of clips. This could prevent a surgeon from completing a procedure with the instrument.

(d). Ethicon Endo-Surgery's 1998 report on the evaluation of reprocessed single use devices¹⁸ describes a reprocessed reloadable linear stapler that required excessive force to turn the rotation knob. The handle snap on this reprocessed stapler also failed to engage. Rotation permits the surgeon to access wound areas in all directions. Restriction of movement may preclude the surgeon from reaching some parts of the opening to be sealed. This may occur at a critical point in the procedure, and during the time required to remove the faulty stapler from the trocar and reinsert a new stapler, the patient could bleed significantly. In addition, the snap handle is designed to provide audible feedback to assure a full firing stroke. If a full stroke is not achieved, malformed staples may result. Malformed staples may result in improper wound closure.

¹⁷ See supra note 11.

¹⁸ See supra note 15.

Therefore, Ethicon Endo-Surgery disposable staplers and clip applicators should be HIGH-RISK devices under the performance flowchart. Nonetheless, below are responses to the remaining questions which demonstrate that, even without postmarket data, reprocessed staplers and clip applicators are high-risk devices.

2. *Could failure of a reprocessed disposable stapler or clip applicator cause death, serious injury or permanent impairment?*

Yes. For example, adverse effects of reprocessing on critical moving parts and/or residual blood and tissue could impede the staple or clip deployment and "crimping" mechanism. If a staple or clip is not properly formed upon deployment, and does not achieve the proper closure or seal, it would result in lack of hemostasis. In addition, in gastroenterology procedures, improper closure will result in intestinal leakage into the abdominal cavity, significantly increasing the risk of peritonitis and sepsis. Conversely, staples and clips formed too tightly could lead to distal tissue necrosis.

3. *Do reprocessed disposable staplers and clip applicators contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?*

Yes. As noted above, the moving parts of Ethicon Endo-Surgery's disposable staplers and clip applicators are made from metals that may corrode upon exposure to saline solutions and disinfectants. Even slight corrosion can impede the proper movement of these critical parts in relation to one another. In addition, the handles of such instruments are made of plastic which may become brittle when reprocessed. As a result, the handles of reprocessed staplers or clip applicators requiring greater force to fire as a result of reprocessing could snap or crack during use. Further, the staple cartridges for use with some disposable staplers and the moving parts inside the handles are treated with sodium stearate lubricant to aid smooth deployment. This lubricant is water-soluble and is removed by reprocessing.

4. *Are there recognized consensus standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the disposable stapler or clip applier has been altered due to reprocessing or reuse?*

No. We are not aware of any standards or guidances to assess the performance of reprocessed disposable staplers and clip appliers.

5. *Can visual inspection determine if performance has been affected?*

No. Most disposable staplers and clip appliers are not designed to be taken apart and reassembled. Without disassembling these devices, it is impossible to observe the condition of internal moving parts or the presence of residual blood and tissue inside the lumen. In addition, many of these devices are loaded with a fixed number of staples or clips. After such devices are reprocessed, it is not possible to determine how many staples and clips are still available.

CONCLUSION: Under the RPS, reprocessed disposable staplers and clip appliers present a HIGH RISK of inadequate performance.

C. General Comments

The RPS identifies reprocessed, disposable "gastroenterology" staplers as low-risk, and "plastic surgery" staplers as moderate-risk. As explained above, we disagree with these categories. Both disposable "gastroenterology" staplers used internally and disposable "plastic surgery" staplers used superficially make contact with blood and tissues beneath the dermal protection layer.

V. **Disposable Electrosurgical Cutting and Coagulation Devices (21 C.F.R. § 876.4300)**

A. **Infection Risk**

1. *Are disposable electrosurgical cutting and coagulation devices non-critical devices?*

No. Ethicon Endo-Surgery makes disposable electrosurgical cutting and coagulation devices such as the UltraCision® Harmonic Scalpel®, the UltraCision® LaparoSonic® Coagulating Shears, and the RF line of electrocautery devices. These devices are “intended to contact normally sterile body tissues and spaces during use.” They are therefore not non-critical devices under the Spaulding criteria cited in the RPS.¹⁹

2. *Does postmarket information suggest that using a reprocessed electrosurgical cutting and coagulation device may present an increased risk of infection when compared to the use of a single use device that has not been reprocessed?*

Yes. For example, Ethicon Endo-Surgery’s 1998 laboratory evaluation of reprocessed single use devices²⁰ revealed visible residue both on an internal component (bushing), and between the clamp pad and clamp arm of a LaparoSonic® device. The presence of such residue could lead to an infectious or pyrogenic reaction. RF electrosurgical devices have a protective sheath around the shaft. The October 1999 study showed that residues may be left on the screw at the base of the end effector and under the sheath.²¹ These areas would have direct contact with patient tissue and fluids during subsequent procedures. Dried blood and tissue can harbor bacteria and viruses able to infect subsequent patients. This risk of infection is not present in a new disposable device since that device has never been used on a patient.

¹⁹ RPS at 5.

²⁰ See supra note 15.

²¹ See supra note 11.

Therefore, Ethicon Endo-Surgery's electrosurgical cutting and coagulation devices should be HIGH-RISK devices under the infection risk flowchart. Nonetheless, below are responses to the remaining questions in this flowchart which demonstrate that, even without postmarket data, reprocessed single use electrosurgical cutting and coagulation devices are high-risk devices.

3. *Do disposable electrosurgical cutting and coagulation devices include features that could impede thorough cleaning and adequate sterilization/disinfection?*

Yes. The cutting and coagulating tips of Ethicon Endo-Surgery's LaparoSonic® devices are attached to long shafts with narrow lumens. These devices cut and coagulate tissue by rapid vibration at a particular frequency. Vibration of the cutting blade can cause blood and tissue to migrate into the shaft. It is difficult if not impossible to clean residual blood and tissue out of the shaft. Moreover, the presence of such blood and tissue may impede complete sterilization by ethylene oxide. If fluid or residue invades the shaft during reprocessing, the contaminants may interfere with the vibrations and become hot. This could result in burns to the patient or operator.

4. *Does a reusable device exist that has (a) an equivalent design and (b) the same intended use as a disposable electrosurgical cutting and coagulation device?*

No. We are not aware of any reusable devices that have an equivalent design or the same intended use as the UltraCision® Harmonic Scalpel or LaparoSonic® Coagulating Shears.

5. *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if disposable electrosurgical cutting and coagulation devices have been adequately cleaned and disinfected/sterilized?*

No. We are not aware of any standards for the cleaning and sterilization of disposable electrosurgical cutting and coagulation devices.

6. *Is this a semi-critical device?*

No. As previously noted, electrosurgical cutting and coagulation devices are intended to contact normally sterile areas of the body. Therefore, they are critical devices under the Spaulding criteria in the RPS.²²

CONCLUSION: Under the RPS, reprocessed, Ethicon Endo-Surgery disposable UltraCision® and RF electrosurgical cutting and coagulation devices present a HIGH RISK of infection.

B. Inadequate Performance Risk

1. *Does postmarket information suggest that using a reprocessed disposable electrosurgical cutting and coagulation device may present an increased risk of injury when compared to the use of a disposable electrosurgical cutting and coagulation device that has not been reprocessed?*

Yes. For example, Ethicon Endo-Surgery's October 1999 report²³ shows reprocessed Ultrasonic® and RF devices whose shafts were bent or bowed. The report notes that although such devices are still capable of functioning, the bent shafts can impede insertion and removal through a trocar and interfere with the surgeon's ability to position the device appropriately. The protective sheath is more susceptible to damage during insertion and removal thus increasing the risk of unintended burns at or near the targeted site. The report also shows a reprocessed RF device whose protective sheath had receded. The increased area of exposure to metal would increase the risk of unintended patient burns.

²² RPS at 5.

²³ See supra note 11.

In addition, Ethicon Endo-Surgery's 1998 report²⁴ describes a reprocessed UltraCision® device which exhibited damage to the small teeth on the clamp pad used to grip tissue during cutting and coagulation. The clamp pad in this device was also partially separated from the clamp arm. Damage to clamp teeth and separation of the clamp pad from the clamp arm could impede (1) activation of the shears or (2) accurate placement and controlled use of the device resulting in suboptimal coagulation, and hence, internal bleeding. Such bleeding would not be expected with these devices and may not be immediately apparent to the surgeon. The 1998 report also shows an UltraCision® device blade that has not been uniformly sharpened. These devices must vibrate at a specific frequency to achieve their dual cutting and coagulation effect. Imperfect shaping, scratching and other surface damage to the blades of such devices will cause them to resist vibration. As a result, (1) the device may not activate in mid-procedure or (2) the device may cut, but not coagulate resulting in internal bleeding or (3) the blade may fracture during use possibly leaving fragments in the patient.

Therefore, electrosurgical cutting and coagulation devices are HIGH-RISK devices under the performance flowchart. Nonetheless, below are responses to the remaining questions which demonstrate that, even without postmarket data, reprocessed single use electrosurgical cutting and coagulation devices are high-risk devices.

2. *Could failure of a reprocessed electrosurgical cutting and coagulation device cause death, serious injury or permanent impairment?*

Yes. As noted in Section V.B.1, if the protective sheath is damaged or recedes, or reprocessing residues invade the lumen, a patient could suffer unintended burns. In addition, uneven sharpening and other surface damage to the cutting blade will cause the device to vibrate at the wrong frequency. As a result, the device may cut, but not coagulate, thus resulting in internal bleeding that would not be expected, and may go unnoticed.

3. *Do reprocessed electrosurgical cutting and coagulation devices contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and sterilization in such a way that the performance of the device may be adversely affected?*

Yes. See Section V.B.2, above.

4. *Are there recognized consensus standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of a disposable electrosurgical cutting or coagulation device has been altered due to reprocessing or reuse?*

No. We are not aware of any standards or guidances to assess the performance of reprocessed electrosurgical cutting and coagulation devices.

5. *Can visual inspection determine if performance has been affected?*

No, not in all instances. Visual inspection would reveal whether the shaft has been bent or bowed. Certain damage to the protective sheath, the cutting/coagulating blade, and the clamp teeth may also be apparent upon visible inspection. Visual inspection would not reveal whether there are residues in the shaft. It may also not be possible to detect certain blade damage upon visual inspection.

CONCLUSION: Under the RPS, reprocessed, Ethicon Endo-Surgery disposable UltraCision® and RF electrosurgical cutting and coagulation devices present a HIGH RISK of inadequate performance.

VI. Disposable Surgical Drapes (21 C.F.R. § 878.4370) and Surgical Gowns (21 C.F.R. § 878.4040)

A. Infection Risk

1. *Are disposable surgical drapes and surgical gowns non-critical devices?*

No. According to the Spaulding criteria cited in the RPS,²⁵ a non-critical device is one "intended to make topical contact and not penetrate intact skin." Disposable surgical drapes are used in close proximity to a surgical incision site and disposable surgical gowns are worn by operating room personnel working near or in the incision. As such, both disposable surgical drapes and surgical gowns may come in contact with mucous membranes and normally sterile body tissues, and are therefore not non-critical devices.

2. *Does postmarket information suggest that using a reprocessed disposable surgical drape or surgical gown may present an increased risk of infection when compared to the use of a single use device that has not been reprocessed?*

No. We are not aware of any studies performed to evaluate this risk for disposable surgical drapes or surgical gowns.

3. *Do disposable surgical drapes and surgical gowns include features that could impede thorough cleaning and adequate sterilization/disinfection?*

Yes. These devices are uniformly manufactured from porous materials which cannot be cleaned via wiping, scrubbing or brushing. While reusable surgical drapes and surgical gowns are also manufactured from porous materials, those materials are typically strong, woven fabric which can withstand laundering. Disposable surgical drapes and surgical gowns would be destroyed by laundering.

²⁵ RPS at 5.

4. *Does a reusable device exist that has (a) an equivalent design and (b) the same intended use as a disposable surgical drape or surgical gown?*

No. (a) While reusable surgical drapes and surgical gowns exist, these devices have designs that differ substantially from the designs of their single use counterparts. The reusable devices, designed to withstand laundering and reuse are made of durable woven fabrics such as cotton and/or polyester. Conversely, single use surgical drapes and surgical gowns are designed to provide barrier protection to the patient and/or the healthcare worker during a single procedure and are thus made of less durable materials and/or construction.

(b) Both single use and reusable surgical drapes and surgical gowns are intended to be used as barrier devices during surgical procedures. The disposable and reusable devices, however, have different intended uses. The former is intended for use in connection with a single patient during a single procedure, while the latter is intended to be reused. FDA's own Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes (Aug. 1993) recognizes that the intended use of a surgical gown or surgical drape must include the conditions for which such device is intended and that such conditions include "single use only, disposable and reusable."

5. *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the disposable surgical gowns or surgical drapes have been adequately cleaned and disinfected/sterilized?*

No. We are not aware of any standards for the cleaning and sterilization of disposable surgical gowns and surgical drapes. Certain standards may exist for the cleaning and sterilization of reusable surgical linens, but these cannot be applied to single use devices because of the substantial design and materials differences.

6. *Is this a semi-critical device?*

No. According to the Spaulding criteria cited in the RPS,²⁶ a semi-critical device is one intended "to contact intact mucous membranes

²⁶ RPS at 5.

and not penetrate normally sterile areas of the body.” As recognized in the RPS, a surgical drape “may come in contact with mucous membranes as well as normally sterile body tissues.”²⁷

CONCLUSION: This is the final question in the flowchart. Under the RPS, a reprocessed disposable surgical drape or surgical gown presents a HIGH RISK of infection.

B. Inadequate Performance Risk

1. *Does postmarket information suggest that using a reprocessed disposable surgical drape or surgical gown may present an increased risk of injury when compared to the use of a disposable surgical drape or surgical gown that has not been reprocessed?*

No. We are not aware of any study performed to evaluate this risk for reprocessed disposable surgical drapes and surgical gowns.

2. *Could failure of a reprocessed disposable surgical drape or surgical gown cause death, serious injury or permanent impairment?*

Yes. Failure of a reprocessed disposable surgical drape could result in microbial or viral contamination of a surgical site. Failure of a reprocessed disposable surgical gown could result in transfer of microorganisms, contaminated body fluid or particulate matter to the surgical patient or the healthcare provider. Either failure could result in transmission of a serious or life-threatening disease.

3. *Do reprocessed disposable surgical drapes and surgical gowns contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?*

Yes. Most single use surgical drapes and surgical gowns are made of nonwoven fabrics that would be destroyed upon laundering and many contain plastic components that would melt during heated drying. Seams are typically glued rather than sewn and are thus likely to pull apart upon reprocessing. Any of these failure modes would defeat the barrier properties of the devices.

Some fabrics used in disposable surgical gowns and surgical drapes are treated with a fluorocarbon liquid repellent such as Fabric-450[®], or coated with polyethylene such as Drisite[®]. Such treatments and coatings, designed to prevent bacterial penetration or render the fabric impervious, may not survive reprocessing. The barrier performance of the reprocessed device would necessarily suffer.

4. *Are there recognized consensus standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the disposable surgical drape or surgical gown has been altered due to reprocessing or reuse?*

No. We are not aware of any standards or guidances to assess the performance of reprocessed disposable surgical gowns and surgical drapes. While reusable device standards and guidances may exist, these were developed for reusable surgical gowns and drapes and are not applicable to disposable devices because of substantial design and material differences.²⁸

5. *Can visual inspection determine if performance has been affected?*

Yes. In most instances, physical damage or destruction caused by reprocessing disposable surgical drapes and surgical gowns will be evident on visual inspection.

CONCLUSION: This is the final question in the flowchart. Under the RPS, a reprocessed, disposable surgical drape or surgical gown presents a MODERATE RISK of inadequate performance.

²⁸

The RPS states that these standards "are available for testing the barrier properties of drapes" and therefore responds "Yes" to Question 5 for disposable surgical drapes. See RPS at 17. Adopting FDA's position, reprocessed disposable surgical drapes and surgical gowns present a MODERATE risk of infection.

C. General Comments

We note that the RPS lists reprocessed disposable surgical drapes as moderate risk devices and disposable surgical gowns as low risk devices.²⁹ As demonstrated above, we disagree with these categories. In addition, we fail to understand how gowns could be deemed lower risk than drapes when both devices perform similar barrier functions and are made of similar materials.

* * * * *

In closing, Johnson & Johnson appreciates the opportunity to comment on the RPS. Should you have any questions regarding these comments, please call me at 732-524-6872.

Respectfully submitted,



Robert H. O'Holla
Vice President, Regulatory Affairs
Medical Devices and Diagnostics Group

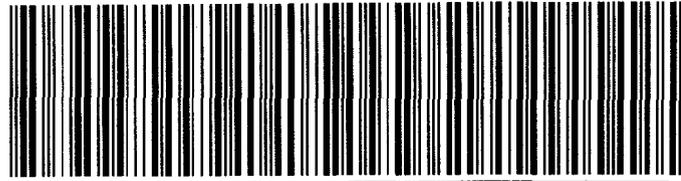
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²⁹ Please note that the RPS lists "OR drapes" as an Ophthalmic Device. These devices should instead be listed under Surgery.

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