A non-critical device is a device that is intended to make topical contact and not penetrate intact skin. A non-critical device presents a low risk of disease transmission when reprocessed and reused.

A semi-critical device is a device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body. A semi-critical device presents a greater risk of disease transmission than a non-critical device.

A critical device is a device that is intended to contact normally sterile tissue or body spaces during use and presents the greatest risk of disease transmission.

If the answer to question 1 is "Yes", then the risk of infection is low.

If "No", go to question 2.

<u>Question 2</u>: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed?

If the device were determined to be critical or semi-critical, FDA would evaluate existing postmarket data (e.g., published data, laboratory reports, reports to FDA) to determine if the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed. FDA believes that the existence of significant adverse postmarket data is a compelling reason for concern and, therefore, FDA would consider the device to be high risk.

If the answer to question 2 is "Yes", then the risk of infection is high.

If "No", go to question 3.

Question 3: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Some design features, such as narrow lumens and interlocking parts, can harbor debris that cannot be readily accessed and removed during cleaning unless the device can be disassembled or otherwise serviced and all surfaces of the devices exposed for manual cleaning. If a device cannot be adequately cleaned, terminal processing to disinfect or sterilize the device will not be successful and the SUD presents a greater risk of disease transmission. If a device does not incorporate any of these hard to clean features, then the SUD presents a low risk of disease transmission.

If the answer to question 3 is "Yes", then go to question 4.

If "No", then the risk of infection is low.

Question 4: Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

In some circumstances, there will be cleared, approved, or exempt reusable devices (including designs with problematic construction or materials features) that are equivalent to a SUD with the same intended use. In this case, the risk is diminished because it is evident that cleaning and sterilization/disinfection can be accomplished with the reprocessed SUD by using techniques directed by labeling for the reusable device.

If the answer to question 4 is "Yes," then the risk of infection is low.

If "No," then go to question 5.

Question 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 SUD has been adequately cleaned and sterilized/disinfected?

FDA has recognized numerous domestic and international consensus standards that may be used for design and performance aspects of the

reprocessed SUD. The list of FDA-recognized standards is available on FDA's website www.fda.gov/cdrh/modact/recstand.html. OEM-recommended performance tests (e.g., manufacturer-developed test, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's website www.fda.gov/cdrh/guidance.html, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 5 is "Yes", then the risk of infection is moderate.

If "No", then go to question 6.

Question 6: Is this a semi-critical device?

If the SUD is a semi-critical device, the risk of infection is moderate.

However, if a product is a critical device, the risk of infection is high.

Flowchart 2: Risk of Inadequate Performance (Appendix 1)

Another one of FDA's primary concerns is the risk of inadequate performance during reuse of a reprocessed SUD. For a reusable device, the OEM validates that the device will perform without failure for the number of times it is labeled to be reused. However, a manufacturer of a SUD validates that the SUD will perform without failure for only one use. In Flowchart 2, we evaluate the risk of inadequate performance posed by reuse of a SUD following use and reprocessing.

FDA considers all implantable SUDs to be high risk. Implantable devices are defined in 21 CFR Part 860.3(d). Flowchart 2 pertains only to non-implantable devices.

Question 1: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?

FDA evaluates existing postmarket data (e.g., published data, laboratory reports, reports to FDA) to determine if the reprocessed SUD may present an increased risk of injury when compared to the use of a SUD that has not been reprocessed. FDA believes that existence of significant adverse postmarket data is a compelling reason for concern and, therefore, would consider the device to be high risk. FDA does not consider the absence of relevant information to be either evidence of increased risk or proof of safety.

If the answer to question 1 is "Yes", then the risk of inadequate performance is high.

If "No", go to question 2.

Question 2: Could failure of the device cause death, serious injury, or permanent impairment?

For purposes of risk categorization associated with inadequate performance, Flowchart 2 distinguishes between those SUDs whose failure could cause death, serious injury, or permanent impairment and those SUDs whose failure would cause less severe harm.

If the answer to question 2 is "Yes", then go to question 3.

If "No", go to question 2a.

Question 2a: 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 performance of the SUD has been altered due to reprocessing and use?

FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may

also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 2a is "Yes", then the risk of inadequate performance is low.

If "No", then go to question 2b.

Question 2b: Can visual inspection determine if performance has been affected?

Visual, critical failure of the device may be self-evident before or during use of the device. Measures can then be implemented to correct the failure.

If the answer to question 2b is "Yes" then the risk of inadequate performance is low.

If "No", then the risk of inadequate performance is moderate.

Question 3: Does the SUD contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected?

Materials, coatings, or components may be damaged or altered by a single use or by reprocessing. For example, battery life, material strength or flexibility, lubrication, and antimicrobial coatings may be adversely affected.

If the answer to question 3 is "Yes" then go to question 4.

If "No" then go back to question 2a.

<u>Question 4</u>: 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 performance of the SUD has been altered due to reprocessing and use?

FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 4 is "Yes", then the risk of inadequate performance is moderate.

If "No", then go to question 5.

<u>Question 5</u>: Can visual inspection determine if performance has been affected?

Visual, critical failure of the device may be self-evident before or during use of the device. Measures can then be implemented to correct the failure

If the answer to question 5 is "Yes," then the risk of inadequate performance is moderate.

If "No," then the risk of inadequate performance is high.

How to Determine the Risk of a Reprocessed and Reused SUD

After determining the risk of infection from Flowchart 1 and the risk of inadequate performance from Flowchart 2, the worksheet in Appendix 1 is used to determine the overall risk presented by reprocessing the SUD. Step-by-step instructions for using the worksheet follow:

1. As noted in the introduction to each flowchart, if the device is an implant, as defined in 21 CFR Part 860.3(d), the SUD is categorized as high risk and no further evaluation is necessary.

2. Determine the risk of infection posed by reprocessing and reuse of a SUD using Flowchart 1. Based upon this flowchart, the risk of infection will be low, moderate, or high. If the risk of infection is high, the overall risk is also considered high and no further evaluation is necessary.

3. Determine the risk of inadequate performance of a reprocessed and reused SUD using Flowchart 2. Based upon this flowchart, the risk of inadequate performance will be low, moderate, or high. If the risk of inadequate performance is high, the overall risk is also considered high and no further evaluation is necessary.

4. If the SUD was assigned a moderate risk for either Flowchart 1 or Flowchart 2, then the overall risk is also considered to be moderate.

5. If a SUD was assigned a low risk for both Flowchart 1 and Flowchart 2, then the overall risk associated with reprocessing is considered to be low.

Applying the RPS: Examples

FDA is providing 3 examples of how the RPS can be used to assess the overall risk of a reprocessed SUD. The headings for the examples note the risk category, the generic type of device, and, in parentheses, the FDA classification regulation number and internal three-letter product codes assigned by FDA. The questions in the examples are paraphrased from the flowcharts.

Example 1

Example 1: Low Risk SUD: Orthopedic Drill Bit (878.4540 HTW)

Evaluation of infection risk: Flowchart 1

Question 1: Is the orthopedic drill bit a non-critical device?

The answer to Question 1 is "No" because the drill bit makes contact with a normally sterile area.

Go to Question 2.

Question 2: Does FDA have postmarket data that suggest using a reprocessed drill may present an increased risk of infection?

At this time, the FDA does not know of any postmarket data that suggest using a reprocessed drill bit may present an increased risk of infection when compared to the use of a drill bit that has not been reprocessed.

The answer to Question 2 is "No."

Go to Question 3.

Question 3: Does an orthopedic drill bit have features that may impede cleaning and disinfection or sterilization?

The answer to Question 3 is "No."

Therefore, the drill bit presents a Low Risk of infection.

Example 1

Evaluation of risk of inadequate performance: Flowchart 2

Question 1: Does FDA have postmarket data that suggest using a reprocessed drill may present increased risk of performance failure?

At this time, FDA does not know of any postmarket data that suggest a orthopedic drill bit may present an increased risk of performance failure compared to the use of a drill bit that has not been reprocessed and reused.

The answer to Question 1 is "No."

Go to Question 2.

Question 2: Will failure of an orthopedic drill bit cause death, serious injury, or permanent impairment?

The answer to Question 2 is "No."

Go to Question 2a.

Question 2a: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance that may be used to determine if the performance of the drill bit has been altered due to reprocessing and use?

The answer to question 2a is "No".

Go to Question 2b.

Example 1

<u>Question 2b</u>: Can adequate performance of all vital parameters related to safety and effectiveness be determined by visual inspection of the drill bit?

The answer to Question 2b is "Yes".

Therefore, an orthopedic drill bit has a low risk of inadequate performance

Worksheet Results

1. An orthopedic drill bit is not an implant.
2. The risk of infection according to Flowchart 1 is Low Risk.
3. The risk of inadequate performance according to Flowchart 2 is Low Risk.
4. The orthopedic drill bit resulted in Low Risk on both flow charts; therefore the device is **Low Risk**.

Example 2

Example 2: Moderate Risk: Operating Room Drapes (878.4370 KKX)

Evaluating infection risk: Flowchart 1

Question 1: Is an operating room drape a non-critical device?

The answer to this question is "No" because an operating room drape may come in contact with mucous membranes as well as normally sterile body tissues.

Go to Question 2.

Question 2: Does FDA know about any postmarket data that suggest that there is an increased risk of infection?

At this time, FDA does not know of any postmarket data on drapes that suggest using the reprocessed drape may present an increased risk of infection when compared to the use of a drape that has not been reprocessed.

The answer to Question 2 is "No."

Go to Question 3.

Question 3: Does the OR drape have any features that could impede thorough cleaning and adequate sterilization?

The answer to Question 3 is "No."

Therefore, a single-use only OR drape is considered a Low Risk device for infection when reprocessed and reused.

Example 2

Evaluation of risk of inadequate performance: Flowchart 2

Question 1: Does postmarket information suggest there is an increased risk of injury?

At this time, the FDA does not know of any postmarket data that suggest that the reprocessed drape may present an increased risk of patient injury when compared to the use of a drape that has not been reprocessed.

The answer to Question 1 is "No."

Go to Question 2.

Question 2: Could failure of the OR drape cause death, serious injury, or permanent impairment of the patient?

If the drape fails as a barrier device, it may allow transmission of disease.

The answer to Question 2 is "Yes."

Go to Question 3.

Question 3: Does the SUD contain materials that may be damaged or altered by a single use?

Some OR drapes contain materials, coating or components that may be damaged or altered by either a single-use or by reprocessing in such a way that the drape performance may be affected.

The answer to Question 3 is "Yes."

Go to Question 4.

Example 2

Question 4: Are there recognized standards that may be used to determine if performance has been altered?

The following two standards are available for testing the barrier properties of drapes: ASTM F1671-97b "Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage as a test system;" and ASTM F1670-97 "Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood."

The answer to Question 4 is "Yes."

Therefore, the OR drape presents a Moderate Risk of inadequate performance.

Worksheet Results

1. An OR drape is not an implant
2. The risk of infection according to Flowchart 1 is Low Risk.
3. The risk of inadequate performance according to Flowchart 2 is Moderate Risk.
4. The OR drape resulted in a Moderate Risk on Flowchart 2; therefore, the device is **Moderate Risk**.

Example 3

Example 3: High Risk: Cardiac Ablation Catheter (unclassified, LPB)

Evaluating infection risk: Flowchart 1

Question 1: Is the SUD a noncritical device?

Cardiac Ablation Catheters are introduced directly into the bloodstream. Therefore, they are considered critical devices.

The answer to Question 1 is "No."

Go to Question 2.

Question 2: Does postmarket information suggest that there is an increased risk of infection?

At this time, FDA does not know of any postmarket data on cardiac ablation catheters that suggest that using the reprocessed catheter may present an increased risk of infection when compared to the use of a cardiac ablation catheter that has not been reprocessed and/or reused.

The answer to Question 2 is "No."

Go to Question 3.

Question 3: Does the SUD include features that impede thorough cleaning and sterilization/disinfection?

Cardiac ablation catheters do have features that could impede thorough cleaning and adequate sterilization (e.g.,. band electrodes).

The answer to Question 3 is "Yes."

Go to Question 4.

Example 3

<u>Question 4</u>: Does a reusable device exist that has an equivalent design and the same intended use?

At this time FDA does not know of any reusable catheter that has an equivalent design (including materials) and the same intended use (including anatomical site of use) as a cardiac ablation catheter.

The answer to Question 4 is "No."

Go to Question 5.

<u>Question 5</u>: Are there recognized standards that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected?

At this time there are no recognized standards, tests recommended by the OEM, or a CDRH guidance that may be used to determine if the cardiac ablation catheter has been adequately cleaned and disinfected/sterilized.

The answer to Question 5 is "No."

Go to Question 6.

<u>Question 6</u>: Is this a semi-critical device?

No, cardiac ablation catheters are critical devices.

Therefore, cardiac ablation catheters are considered to pose a high risk of infection if reprocessed and reused.

Example 3

Evaluation of risk of inadequate performance: Flowchart 2

Question 1: Does postmarket information suggest there is an increased risk of injury?

Significant postmarket data (published literature) exists that suggest that the reprocessed cardiac ablation catheter may present an increased risk of patient injury.

The answer to Question 1 is "Yes."

Therefore, cardiac ablation catheters are considered to have a high risk of inadequate performance if reprocessed and reused.

Worksheet Results

1. Cardiac ablation catheters are not implants.
2. The risk of infection according to Flowchart 1 is High Risk.
3. The risk of inadequate performance according to Flowchart 2 is High Risk.
4. The cardiac ablation catheter resulted in a High Risk on Flowcharts 1 and/or 2; therefore, the device is **High Risk**.

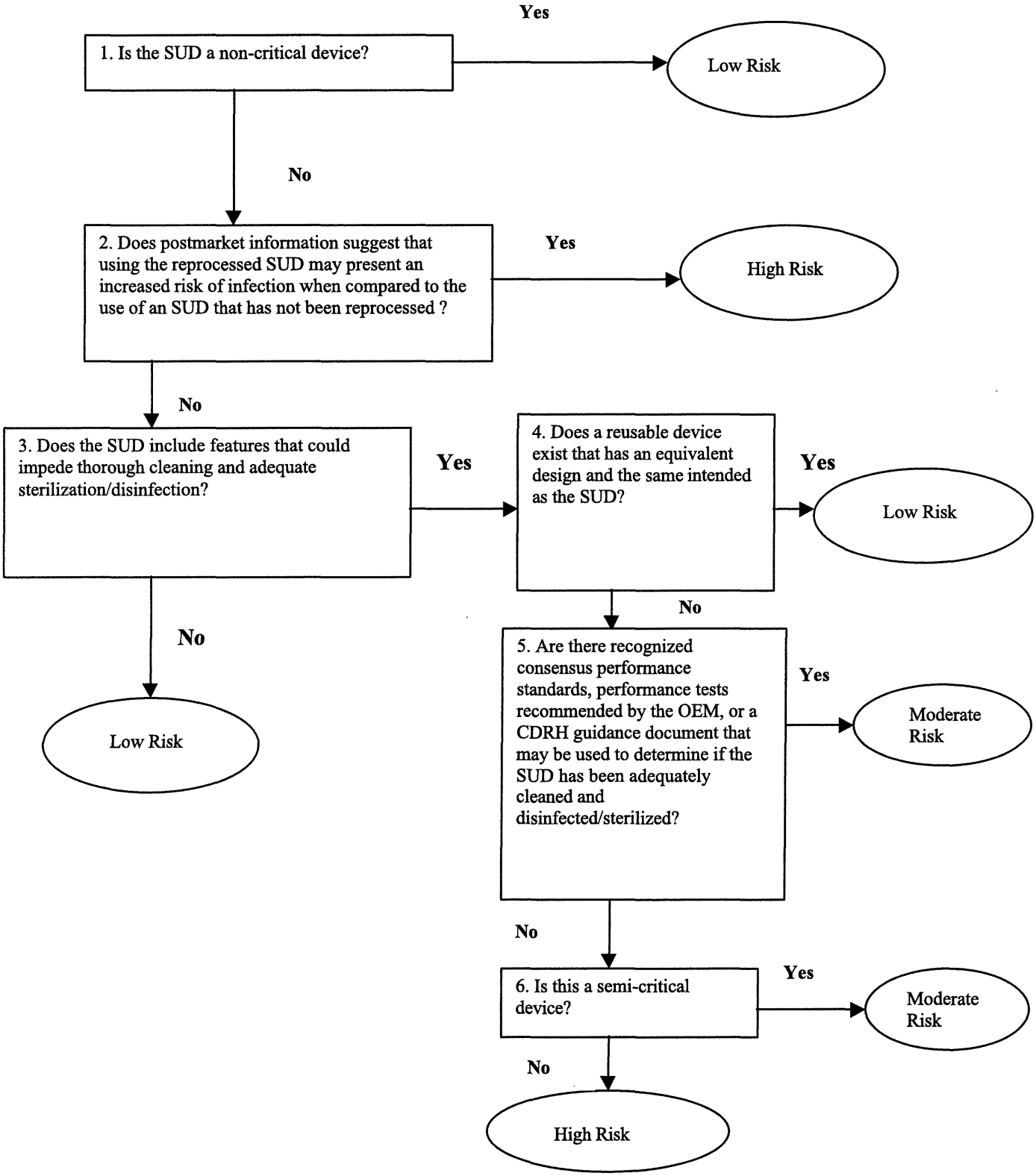
List of Frequently Reprocessed SUDs

Appendix 2 is a list of frequently reprocessed devices identified by FDA and categorized by risk. The list includes:

- the general medical specialty area,
- the generic name of the device,
- the classification regulation related to the generic type of device (see 21 Code of Federal Regulations),
- whether the generic type of device is exempt from premarket notification by regulation,
- the type of premarket submission that may be required for the device,
- the regulatory class of the device,
- the internal FDA procodes for the device, and
- the risk category under the RPS.

Appendix 1

Flowchart 1 – Infection Risk



Flowchart 2 – Inadequate Performance Risk