**Reprocessing, Sterility, and Shelf-Life**

**1 Reprocessing**

*【Reprocessing is defined as validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactive microorganisms by disinfection or sterilization. If the device(s) requires reprocessing, please consult the Reprocessing Guidance. Reprocessing documentation can be attached at the end of the “Reprocessing, Sterility, and Shelf-Life” section.*

*Resources:
Guidance:“Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”】*

1.1 Are cleaning or disinfection or sterilization instructions included in the labeling?

1.2 How many different sets of reprocessing instructions are included (maximum of 4):

*【If you have more than four sets of reprocessing instructions, provide information for four of the reprocessing instructions in this form. For the remaining reprocessing instructions, clearly identify the relevant information in the Reprocessing attachments.】*

1.3 Reprocessing Instructions 1

1.3.1 Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

1.3.2 Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.

*【Labeling should include instructions for a reprocessing method that reflects the physical design of the device, its intended use, and the soiling and contamination to which the device will be subject during clinical use. Appropriate reprocessing instructions depend on a variety of factors such as the type of patient contact, home vs healthcare facility use, contamination from hands, accidental events, etc. (Criterion 1 of FDA’s Reprocessing Guidance)】*

1.3.3 Cleaning Instructions

1.3.3.1 Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?

*【A device which has been opened in the sterile field, even if “not used” may have been handled with soiled golves, or subject to aerosolized contaminants, and would be considered contaminated. Therefore, if you recommend reprocessing “open-but-unused” devices, there should be cleaning instructions.】*

1.3.3.2 Is a Point-of-Use care instruction included (e.g., to prevent drying)?

*【Point-of-use care instructions should recommend prompt, initial cleaning steps and/or measures to prevent the drying of soil on the device surface prior to cleaning.(See Criterion 5.B. of FDA’s Reprocessing Guidance)】*

1.3.3.3 Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable.

(Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)

*【Some devices (e.g., cystoscopes and laparoscopes) have multiple components (e.g., camera, sheath, eyepiece) that must be dissembled and/or reassembled per the manufacturer’s reprocessing procedure. (See Criterion 5.C of FDA’s Reprocessing Guidance)】*

1.3.3.4 Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.

*【In the absence of a specific recommendation to “thoroughly clean” the device, inclusion of thorough and comprehensive cleaning instructions should satisfy this recommendation. (See Criterion 2 of FDA’s Reprocessing Guidance)】*

1.3.3.5 If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.

*【For more information regarding special accessories, see Criterion 5.A. of FDA’s Reprocessing Guidance.】*

1.3.3.6 Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.

*【Some reusable medical devices may be cleaned in a medical washer. For those devices, the reprocessing instructions should either include parameters for each step of the cleaning cycle (e.g., time, temperature, and specified detergent) or should refer to the labeling for the medical washer. (See Criterion 5.O. of FDA’s Reprocessing Guidance)】*

1.3.3.7 Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.

*【For more information about the specifications for cleaning, see Criterion 5.D. of FDA’s Reprocessing Guidance.】*

1.3.3.8 Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., “no visual contamination”), and 3) steps the user should repeat if the endpoint is not met.

*【For more information regarding visual inspection, see Criterion 5.H. of FDA’s Reprocessing Guidance.】*

1.3.3.9 Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.

*【Prior to terminal sterilization processes such as ethylene oxide or hydrogen peroxide, reusable medical devices are typically thoroughly dried. For steam sterilization, high-level disinfection, and liquid chemical sterilization, excess fluid is removed. (See Criterion 5.K. of FDA’s Reprocessing Guidance)】*

1.3.3.10 If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.

*【Caution should be exercised when using oil-based and silicone-based lubricants, as they may coat and protect surface microorganisms and reduce the effectiveness of certain sterilization methods, including steam and EO. They may even provide nutrients for microbial growth. (See Criterion 5.G. of FDA’s Reprocessing Guidance)】*

1.3.3.11 Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.

*【For more information regarding reuse life limits, see Criterion 5.L. of FDA’s Reprocessing Guidance.】*

1.3.3.2 Microbicidal Process

1.3.3.2.1 Sterilization

13.3.2.1.1 Please specifically cite the attachment(s) and page number(s) where the

instructions recommend the use of an FDA-cleared or legally marketed wrap,

pouch, or other method of maintaining sterility?

*【For more information about maintaining sterility, see Criterion 4 of FDA’s Reprocessing Guidance】*

13.3.2.1.2 For steam sterilization: Please specifically cite the attachment(s) and page number(s) where the instructions describe the general method (e.g., gravity or pre-vacuum) and all critical sterilization cycle specifications (time, temperature, and dry time). Type "N/A" if not applicable. View help text for more information.

*【See Criterion 5.I. of FDA’s Reprocessing Guidance.*

*The sterilization cycle should be consistent with the parameters listed in Appendix C of the Reprocessing Guidance document (i.e., is not an “extended” sterilization cycle and does not include ranges or “minimal values” for time or temperature).*

*For the majority of reusable medical devices, at least one of the following cycles should be included in steam sterilization instructions:*

*Gravity:*

*30 minutes at 121℃, OR*

*15 minutes at 132℃, OR*

*10 minutes at 135℃*

*Pre-vacuum:*

*4 minutes at 132℃, OR*

*3 minutes at 135℃.*

*(See Criterion 4 of FDA’s Reprocessing Guidance)*

*】*

13.3.2.1.3 For ethylene oxide: Please specifically cite the attachment(s) and page number(s) where the instructions describe the sterilization cycle parameters. Type "N/A" if not applicable. View help text for more information.

*【The sterilization cycle parameters should be within the specifications listed in Appendix C of the Reprocessing Guidance document.*

*The most common parameters are EO concentrations from 450 to 1200 milligrams per liter (mg/L), temperatures from 37℃ to 63℃ (99℉ to 145℉), exposure times from 60 to 360 minutes, and chamber humidity from 40% to 80%. (See Criteria 5.I. and Appendix C of FDA’s Reprocessing Guidance)】*

13.3.2.1.4 Other sterilization methods: Please specifically cite the attachment(s) and page

number(s) where the instructions describe the sterilization methods to enable the user to implement the cycle (e.g., sterilizer make, model, and cycle name for hydrogen peroxide cycles). Type "N/A" if not applicable.

*【For more information about implementing the sterilization cycle, see Criterion 5.I. of FDA’s Reprocessing Guidance】*

13.3.2.1.5 Post-process handling: Please specifically cite the attachment(s) and page number(s) where the instructions include the aeration time for removal of residual sterilants. Type "N/A" if not applicable.

*【See Criterion 5.I. of FDA’s Reprocessing Guidance. Some sterilization methods (e.g., EO) should include aeration times.】*

1.3.3.2.2 High-Level Disinfection/Liquid Chemical Sterilization

1.3.3.2.2.1 Please specifically cite the attachment(s) and page number(s) where the instructions recommend use of an FDA-cleared high-level disinfectant (HLD) or liquid chemical sterilant (LCS).

*【See Criterion 4 of FDA’s Reprocessing Guidance, as well as FDA’s website for FDA-cleared HLD/LCS below.*

*Resources:*

*FDA’s website for FDA-cleared HLD/LCS*

*<https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and>*

*】*

1.3.3.2.2.2 Please specifically cite the attachment(s) and page number(s) where the instructions recommend following HLD/LCS manufacturer’s instructions.

*【If contact time and temperature specifications are included, confirm that those specifications are consistent with the HLD/LCS manufacturer. If rinsing specifications are included, confirm that those specifications are consistent with the minimum specified by the HLD/LCS manufacturer. (See Criterion 4 of FDA’s Reprocessing Guidance)】*

1.3.3.2.2.3 Please specifically cite the attachment(s) and page number(s) where the instructions recommend complete immersion in HLD/LCS solution, including contact with all lumens.

*【Instruction should include removal of bubbles on the surfaces and flushing lumens until there are no air bubbles coming from the lumen.】*

1.3.3.2.2.4 Please specifically cite the attachment(s) and page number(s) where the instructions include instructions for rinsing, drying, and storage.

*【If specific rinsing instructions are included, there should be specification for rinse volume or time, rinse water quality, and number of rinses (or flushes). Storage instructions should allow continued drying of the device (e.g., hanging vertically in a well-ventilated area). (See Criteria 5.F. and 5.K. of FDA’s Reprocessing Guidance)】*

1.3.3.2.3 Intermediate/Low-level disinfection

1.3.3.2.3.1 Please specifically cite the attachment(s) and page number(s) where the instructions recommend use of a commonly available disinfecting agent (e.g., alcohol, CaviWipes).

*【See Criteria 3.C. and 5.O. of FDA’s Reprocessing Guidance.】*

1.3.3.2.4 None (cleaning alone)

1.3.3.3 Technically Feasible, Understandable, and Comprehensive

*【See Criteria 4, 5.M, 5.N., and 6 of FDA’s Reprocessing Guidance.】*

**2 Sterility**

*【Please consult the Sterility Guidance for more information.*

*Resources:*

*Guidance:“Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile”】*

2.1 How many sterilization methods are there (maximum of 4)?

*【If you have more than four sterilization methods, provide information for four of the sterilization methods in this form. For the remaining sterilization methods, clearly identify the relevant information in Sterility attachments.】*

2.2 Sterilization Method 1

2.2.1 Identify the device(s) / accessory(ies) / component(s) that is sterilized.

2.2.2 What is the Sterilization Method?

*【Est A= Established A: These are methods that have a long history of safe and effective use as demonstrated through multiple sources of information such as ample literature, clearances of 510(k)s or approvals of premarket approval (PMA) applications, and satisfactory Quality System (QS) inspections.*

*Est B= Established B: These are methods for which there are no FDA-recognized dedicated consensus standards, but for which published information on development, validation, and routine control is available.】*

2.2.3 What standard(s) were used for validation?

*【Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135-1:2007 or ISO 11134 or ISO 11137)】*

2.2.4 What is the Sterility Assurance Level (SAL)?

2.2.5 If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?

*【Pyrogenicity testing is recommended for implants, devices that directly contact the cardiovascular system, Cerebral Spinal fluid (CSF), or lymphatic system. In addition, it is recommended that devices labeled Non-Pyrogenic be tested.*

*Limits are:*

*2.15 EU/device if CFS contact;*

*Less than or equal to 0.2 Endotoxin Units(EU)/ml for Intraocular Fluids;*

*Less than or equal to 0.2 EU/device for Anterior segment solid intraocular devices (Intraocular lenses, Capsular tension ring devices, Glaucoma devices, and Phacofragmentation systems); and*

*20 EU/device for all other devices.*

*LAL=Limulus Amebocyte Lysate test.*

*Resources*

*Guidance: “Pyrogen and Endotoxins Testing: Questions and Answers”】*

2.2.6 Please provide a description of the packaging, the materials used, and a description of the package test methods.

*【Examples of packaging for the different sterilization methods includes:*

* *EO: Tyvek/Mylar or Tyvek/PETG (breathable);*
* *Steam: Tyvek Film or paper/plastic (steam permeable);*
* *Radiation: foil. Mylar, film;*
* *H2O2: breathable, no cellulose (i.e., no paper)*

*Depending on the nature of your device and how it will be used, FDA may request accelerated aging protocols and results for the packaging. If applicable, you may provide documentation of this testing in the next screen.】*

2.3 Guidance and Special Controls Adherence

**3 Shelf-Life**

3.1 Does your device have a shelf-life?

*【For Accelerated Lifetime testing, we recommend consulting standard ASTM F 1980-07 as a guide for determining shelf-life】*

3.2 What is the proposed shelf-life?

3.3 Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

**4 Reprocessing, Sterility, and Shelf-Life Documents**

4.1 Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.

*【Each attachment should contain the following: a) A summary of the non-clinical evidence that falls within this category; b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were not performed); c) A discussion to support why the evidence presented is sufficient to support the application.*

*End-User Sterilization: Information and validation of end-user sterilization where it is necessary for the end-user to sterile the device. This could include a description of the sterilization process (method, parameters), sterility Assurance Level (SAL) and, if applicable, the rationale on the durability of the product against two or more sterilizations.*

*Manufacturer Sterilization: Information and validation of manufacturer sterilization where the device is provided sterile.*

*Residual Toxicity: Contains information on the testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues.*

*Cleaning and Disinfection Validation: Contains information on the validation of cleaning and disinfection instructions for reusable devices.*

*Reprocessing of Single Use Devices, Validation Data: The required validation data including cleaning and sterilization data, and functional performance data demonstrating that each single use device (SUD) will continue to meet specifications after the maximum number of times the device is reprocessed as intended by the person submitting the premarket submission.*

*Product Stability: This should contain details relating to product stability under specified storage conditions and in final packaging or simulated conditions. Also include:*

* *The shelf-life (for each component if there are differences between components) and the proposed storage condition for the device*
* *A summary of the non-clinical evidence, covering shelf-life period when stored at the proposed storage condition*
* *Evidence to support stability of the medicinal substance contained in the device at the proposed storage condition (FDA Note: Medicinal Substances refers to drugs and biologics)*
* *Evidence of in-use stability supporting actual routine use (real or simulated)*

*Package Validation: Contains details relating to packaging integrity over the claimed shelf-life and in the packaging and distribution environment (transport and packaging validation) and when applicable, following exposure to the sterilization process. Non-clinical evidence covering shelf-life period should be included.*

*Resources*

*Guidance:“Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”*

*Guidance:“Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile”*

*Guidance:“Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed SingleUse Medical Devices” 】*