Classification of Absorbable Synthetic Wound Dressings
FDA Questions

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

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1. FDA has identified the following risks to health for absorbable synthetic wound dressings:

Identified Risk	**Description/Examples**
Toxicity	This can result from device materials or degradants of the absorbable materials, which can be toxic.
Adverse tissue reaction	This can result from the use of device materials, including any associated impurities, residues and degradants, which are not biocompatible.
Infection	This can result from inadequate device sterilization or inadequate packaging integrity.
Delays in wound healing	This can result from device materials or degradants of the absorbable materials, which may interfere with the wound healing process. This can also result from incomplete bio-resorption of the dressing into the wound.
Failure of device integration	This occurs when the dressing, which is intended to provide a temporary scaffold for cellular infiltration, does not effectively degrade in the wound, and thus resulting in dressing retention in the wound and interference with the wound healing process.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of absorbable synthetic wound dressings. In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these absorbable synthetic wound dressings.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:

    - insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, AND

    - if the device is purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing

impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if:

- general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND

- there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
    - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
    - establish special controls to provide such assurance, BUT
        I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
        II. does not present a potential unreasonable risk of illness or injury.

FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for absorbable synthetic wound dressings. Following is a risk/mitigation table which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks.

Risk/mitigation recommendations for absorbable synthetic wound dressings

Identified Risk	**Recommended Mitigation Measure**
Toxicity	Biocompatibility evaluation Performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Performance testing and descriptive information Pyrogenicity testing Labeling
Infection	Sterilization testing/validation information Shelf-life validation Labeling
Delays in wound healing	Biocompatibility evaluation

Identified Risk	Recommended Mitigation Measure
	Animal performance testing Performance testing and descriptive information Labeling
Failure of device integration	Animal performance testing Performance testing Labeling

Please discuss whether the identified special controls for absorbable synthetic wound dressings appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. Performance testing and descriptive information must demonstrate the functionality of the device to achieve the specified use, including establishing the physical and chemical characteristics of the device. The following must be provided:
   i) Identity, quantification, and purpose of each component in the finished product;
   ii) Specification and characterization of each component in the finished product; and
   iii) Final release specifications for the finished product.

2. Performance data must demonstrate the sterility of the device.

3. The device, including any degradants, must be demonstrated to be biocompatible, non-pyrogenic and contain endotoxin level within acceptable limits.

4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

5. Animal performance testing must demonstrate that the device materials and degradants do not delay the wound healing process and can be appropriately integrated into the surrounding tissues.

6. Performance data must demonstrate that the device performs as intended under anticipated conditions of use, including complete degradation of any absorbable material(s) in the wound and evaluation of expected worst-case conditions.

7. The labeling must include:
   i) A description of the intended user population.
   ii) Specific instructions regarding the proper placement, sizing, duration of use, frequency of dressing change, maximum use life per application of

the dressing, maximum total use life of the dressing, and removal of the dressing, if applicable.

iii) A list of each ingredient or component within the finished device, including the functional role of that ingredient or component within the device.

iv) If the device has non-resorbable components, a warning statement for the potential retention of those components in the wound or the surrounding area.

v) A contraindication for any known sensitivity to components within the device.

vi) A contraindication if there are incompatibilities with other therapies.

vii) A shelf life.

viii) A statement regarding when to discontinue use of the device after multiple reapplications based on biocompatibility and performance testing, if applicable.

ix) Any statements in the labeling must be clear such that they may be understood by the end user, supported by appropriate evidence, and consistent with the intended use of covering a wound, absorbing exudate, and maintaining appropriate moisture balance within the wound.

x) Disposal instructions.

3. **Please discuss whether you agree with FDA's proposed classification of Class II with special controls for absorbable synthetic wound dressings. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**