Hernia Mesh – Package Labeling Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact OHT4: Office of Surgical and Infection Control Devices/DHT4B: Division of Infection Control and Plastic Surgery Devices at 301-796-6970.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

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Table of Contents

I. Introduction 4
II. Background 4
III. Scope 5
IV. Labeling Recommendations 6
A. Product Package Labeling 6
Appendix A. Example Package Labeling 8

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) is issuing this guidance to provide labeling recommendations for hernia mesh devices. These labeling recommendations are being issued because suboptimal device selection associated with these devices has resulted in serious adverse events, including deaths.[1] The package labeling recommendations in this guidance, including the example in Appendix A below, are intended to help promote the safe and effective use of hernia mesh. When finalized, this guidance is intended to supplement the labeling recommendations in section XI of "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," for hernia mesh devices.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Hernia meshes represent a diverse group of medical devices featuring a wide variety of compositions, form factors, shapes, sizes, materials, and mechanical properties. They can be used in many different anatomic regions for different types of hernia repair. These factors can make it

[1] See e.g., FDA Manufacturer and User Facility Device Experience (MAUDE) Database, search of the product codes FTL and FTM from January 1, 2019 to November 21, 2024.

challenging, even for experienced healthcare providers, to choose the most appropriate mesh based on patient-specific considerations and surgical approach. Since January 1, 2019, FDA has received over 86,000 adverse event reports related to hernia mesh, of which the most common reported adverse events include adhesions, recurrence, pain, and infection. Based on FDA's review of these adverse event reports as well as the published literature, FDA believes that concise, consistent, and easily understandable package labeling of hernia meshes that contains certain clinically relevant information may facilitate the safe and effective use of these devices.[2] While the labeling of many hernia meshes currently on the market provides information on the composition, physical properties, mechanical properties, and intended uses, it can be difficult for healthcare providers to find the desired information quickly and easily. For example, some of the information may be provided in the more detailed labeling that is included inside the hernia mesh package (such as the package insert) rather than the package labeling. Standardized informative package labeling for hernia meshes may provide a more consistent format for disseminating certain clinically relevant information, making it easier for healthcare providers to find certain information needed to use the device safely and for the purposes for which it is intended.

III. Scope

The scope of this guidance is limited to certain surgical mesh devices under 21 CFR 878.3300 with the product codes listed in the table below and that are intended for use in hernia repair:

Product Code	Regulation Number	Name
EZX	878.3300	Mesh, Surgical, Metal
FTL	878.3300	Mesh, Surgical, Polymeric
FTM	878.3300	Mesh, Surgical
OWT	878.3300	Mesh, Surgical, Absorbable, Abdominal Hernia
OWU	878.3300	Mesh, Surgical, Non-Absorbable, Diaphragmatic Hernia
OWV	878.3300	Mesh, Surgical, Collagen, Diaphragmatic Hernia
OXF	878.3300	Mesh, Surgical, Absorbable, Plastic and Reconstructive Surgery
OXG	878.3300	Mesh, Surgical, Non-absorbable, Plastic and Reconstructive Surgery
OXH	878.3300	Mesh, Surgical, Collagen, Plastic and Reconstructive Surgery
OXI	878.3300	Mesh, Surgical, Absorbable, Large Abdominal Wall Defects
OXJ	878.3300	Mesh, Surgical, Non-absorbable, Large Abdominal

[2] See, e.g., Kahan, L. & Blatnik, J. *Critical Under-Reporting of Hernia Mesh Properties and Development of a Novel Package Label*, Journal of the American College of Surgeons, 226(2):p 117-125, February 2018, available at https://journals.lww.com/journalacs/fulltext/2018/02000/critical_under_reporting_of_hernia_mesh_properties.1.aspx.

Product Code	Regulation Number	Name
		Wall Defects
OXK	878.3300	Mesh, Surgical, Collagen, Large Abdominal Wall Defects
PIJ	878.3300	Collagen Surgical Mesh Containing Drugs

The following product codes under 21 CFR 878.3300 are outside of the scope for this guidance as they are not intended for use in hernia repair and are used for other intended uses such as orthopedics, gynecology, aesthetic use, and urology: JDJ, JDK, LZN, MCA, OLC, OOD, OQL, ORQ, OTM, OTN, OTO, OWR, OWS, OWW, OWX, OWY, OWZ, OXA, OXB, OXC, OXD, OXE, OXL, OXM, OXN, PAG, PAH, PAJ, QUW, QWJ.

IV. Labeling Recommendations

Hernia meshes are prescription devices and are exempt from having adequate directions for use[3] required under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(f)(1)) as long as the conditions in 21 CFR 801.109 are met.[4] Specifically, manufacturers of prescription medical devices, such as hernia meshes, are required as per 21 CFR 801.109 to provide labeling that "bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which [healthcare providers] can use the device safely and for the purpose for which it is intended . . . ." To help manufacturers develop informative package labeling consistent with the requirement of 21 CFR 801.109 to provide labeling that bears "information for use . . . under which [healthcare providers] can use the device safely and for the purpose for which it is intended," and to mitigate the safety issues for hernia meshes, FDA is providing the following recommendations. We intend for the package labeling recommendations below to supplement and enhance the information that is often already included in labeling for these device types. The Agency will continue to monitor hernia mesh adverse event reporting and update the labeling recommendations as warranted.

A. Product Package Labeling

FDA recommends that hernia mesh package labeling include the following information that we believe may facilitate the safe and effective use of the device:

- Mesh Components:

[3] "Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended." 21 CFR 801.5.

[4] This guidance is not intended to include a complete listing of all labeling requirements under the FD&C Act and FDA regulations that are applicable to hernia mesh. Also, this guidance should be used as a complement to other relevant FDA guidance documents containing additional labeling recommendations.

- Mesh composition (including the specific materials used, and whether those materials are absorbable synthetic, nonabsorbable synthetic, or biologic)
  - Identification of the source of any biologic/animal-derived materials
- Identification of barrier material, if present
- Identification and description of any added ingredients, such as antimicrobials

- Mesh Physical Properties:
  - Mesh size (i.e., dimensions)
  - Mesh pore size
  - Mesh thickness
  - Mesh density (i.e., weight)
  - Fiber (e.g., monofilament, braided filament)

- Mesh Mechanical Properties:
  - Mesh tensile strength
  - Mesh burst strength
  - Time to complete absorption, if absorbable

- Specific instructions regarding the proper application of the device for hernia repair including:
  - Intended anatomic location of placement of the product
  - Ideal method of fixation
  - Other information such as instructions regarding the removal of the product residuals prior to reapplication, if applicable

Please see Appendix A for an example of the hernia mesh package labeling containing the above recommended information. FDA recommends that the package labeling be presented in the form and manner as shown in the Appendix A example for ease of comprehension.

FDA believes that the device description and instruction information identified above will help mitigate the safety issues associated with hernia meshes and help manufacturers develop informative package labeling consistent with the labeling requirements under 21 CFR 801.109. Since these recommendations are based on known safety issues, FDA recommends that this information be considered for inclusion as current product labeling is updated, and that labeling included as part of future premarket submissions for hernia meshes incorporate the recommendations. For currently marketed hernia meshes, manufacturers should evaluate their labeling changes as recommended in FDA's guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device."

Appendix A. Example Package Labeling

The following is an example package labeling for a hernia mesh containing the recommended device description and instruction information as described in Section IV.A.

As stated in Section IV.A., FDA recommends that the package labeling be presented as shown in the following example for ease of comprehension.[5]

Device Facts	***Rx Only***
Mesh Components Base Material: Polypropylene (synthetic, non-absorbable) Barrier Material: Expanded Polytetrafluoroethylene Additional Materials: Polytetrafluoroethylene	
Mesh Physical Properties Mesh Size: 20cm x 30cm Mesh Pore Size: 0.100mm^2 Mesh Thickness: 1.1-1.2mm Mesh Density: 90grams/m^2 Fiber: Monofilament	
Mesh Mechanical Properties Tear Strength: 55.0 lbf Ball Burst Strength: 90.0 lbf	
Anatomic Site of Application for Hernia Repair: Intraperitoneal Onlay Mesh (IPOM)	
Method of Fixation: Tacks (permanent or absorbable) with or without Transfixing sutures	
Other Information:	
Questions or Comments? Please call 1-800-CAL-L2US	

[5] The example package labeling in Appendix A only focuses on certain device description and instruction information for hernia mesh devices and is not comprehensive of all device labeling elements as required under 21 CFR 801.109 or other provisions in FDA regulations and the FD&C Act.

Guidance History	Date	Description
Level 1 Draft Guidance	06/2025	See Notice of Availability for more information.*

*The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.

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