Designation: F2943 – 14

Standard Guide for Presentation of End User Labeling Information for Musculoskeletal Implants[1]

This standard is issued under the fixed designation F2943; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 The goal of this guide is to recommend a universal label format (across manufacturers and various implants) of content and relative location of information necessary for final implant selection within an implant's overall package labeling.

1.2 This guide recommends package labeling for musculoskeletal based implants individually processed and packaged with the intent of being opened at the point of use, typically in the operating room.

1.3 This guide identifies the necessary, "high priority" label content and recommendations for the layout and location of information for accurate implant identification by the end users in the operating room environment.

1.4 This goal is achieved by creating a partitioned, secondary area of an implant's package label or a separate label to present this information uniformly.

1.5 The authors of this guide identified the competing needs of regulatory requirements, manufacturing/distribution, and implant identification. It is recognized through our task group's efforts that, if a manufacturer elects to implement these recommendations, balancing these competing needs may necessitate changing a manufacturer's internal processes, relabeling their entire inventory (either at a single point in time or over a defined time period), or accepting duplicate information on an implant's package label. No additional compromises that would allow the primary goal of uniform implant label design across manufacturers were identified.

1.6 It is not the intent of this guide to limit or dictate overall package labeling content.

1.7 It is not the intent of this guide to supplant existing regulatory requirements (only to augment or complement existing regulatory label requirements).

1.8 The use or application of multiple languages is not prevented by this guide; however, use of more than one language is discouraged on the implant selection sublabel (ISSL) defined in this guide. The language of choice is left to the manufacturer and should be dictated by the end user and regulatory requirements in the jurisdictions where the device is marketed. International symbols should also be considered to avoid the need for multiple ISSLs where possible.

1.9 Use and implementation of this guide is optional and at the sole discretion of the implant's manufacturer. It shall be implemented with the following considerations:

1.9.1 The content and layout of any orthopedic implant label should be influenced by risk management activities and all label formats should be validated.

1.9.2 If internal risk management activities recommend deviation from this guide, the manufacturer is discouraged from implementing a hybrid label that partially applies the principles and recommendations in this guide.

1.10 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.11 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ISO Standards:*[2]

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

ISO 15223–1 Medical Devices—Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied—Part 1: General Requirements

3. Terminology

3.1 *Definitions:*

3.1.1 *body side, adj*—implants that are right/left specific and for which side of the body they are intended.

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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[2] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.1.1 *Discussion*—This may also include identifiers for medial/lateral or anterior/posterior.

3.1.2 *company, n*—the business that is primarily responsible for providing the product to the end user.

3.1.2.1 *Discussion*—It is preferred that this is reflective of the company designation that will be commonly used by the end user to identify the implant.

3.1.3 *end of the box (EOB), n*—the surface of an implant's packaging that is most commonly visible when the product is placed in inventory/storage (see Fig. 1).

3.1.3.1 *Discussion*—In the event a pouch is used instead of a box, this would be the most often visualized surface of the package. It is often the same surface used for identification and selection of the implant by the end users and attempts to balance the competing needs of regulation, manufacturing, distribution, and implant selection.

3.1.4 *end users, n*—individuals who participate in the act of selecting the requested implant from inventory for final implantation in a patient; these include, but are not limited to, the treating surgeon, operating room nurse, and operating room technician.

3.1.5 *fold, n*—bend in the packaging that forms a divide between two surfaces of the packaging.

3.1.6 *graphic, n*—generic schematic of the implant.

3.1.6.1 *Discussion*—With the schematic, a basic representation of an implant's features is provided and it may be used to assist in implant selection by allowing the end user to differentiate it from other systems.

3.1.7 *high-priority information, n*—subset of information required on the product labeling that is necessary for accurate identification of the implant for use in the operating room environment.

3.1.8 *implant, n*—implantable medical device intended to be totally or partially introduced into the human body or a natural orifice, or to replace an epithelial surface or the surface of the eye, by surgical intervention, which is intended to remain in place for at least 30 days after the procedure, and which can only be removed by medical or surgical intervention.

3.1.8.1 *Discussion*—This definition applies to implantable medical devices other than active implantable medical devices ("implantable medical device" definition from ISO 13485, Subclause 3.5).

3.1.9 *implant description, n*—brief, generic description using terminology comprehensible by all end users regardless of her/his technical knowledge of the implant.

3.1.10 *implant selection sublabel (ISSL), n*—subset of the primary label that is intended to augment/supplement the primary label (see examples in Fig. 2, Fig. 3, and Fig. 4).

3.1.10.1 *Discussion*—This area of the label shall include the necessary information for final implant selection presented in clear, uncluttered manner and is the only focus of this guide.

3.1.11 *package labeling, n*—written, printed, or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

3.1.11.1 *Discussion*—Some regional and national regulations refer to "labeling" as "information supplied by the manufacturer" (ISO 13485, Subclause 3.6 and ISO 15223–1, Subclause 3.4).

3.1.12 *primary label, n*—"main" package label of an implant, which includes all labeling needs such as regulatory requirements, an individual manufacturer's needs, and information for implant selection.

3.1.12.1 *Discussion*—Information may be included on any or all surfaces of an implant's packaging. Formatting and information location of this label is at the discretion of the manufacturer based on regulatory requirements.

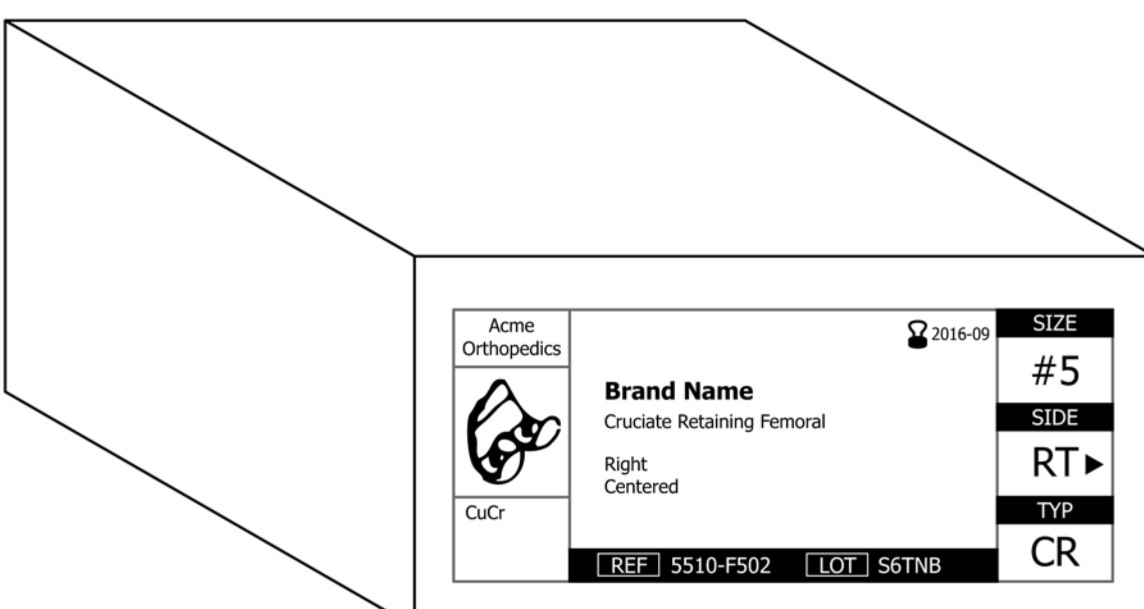

FIG. 1 End of Box

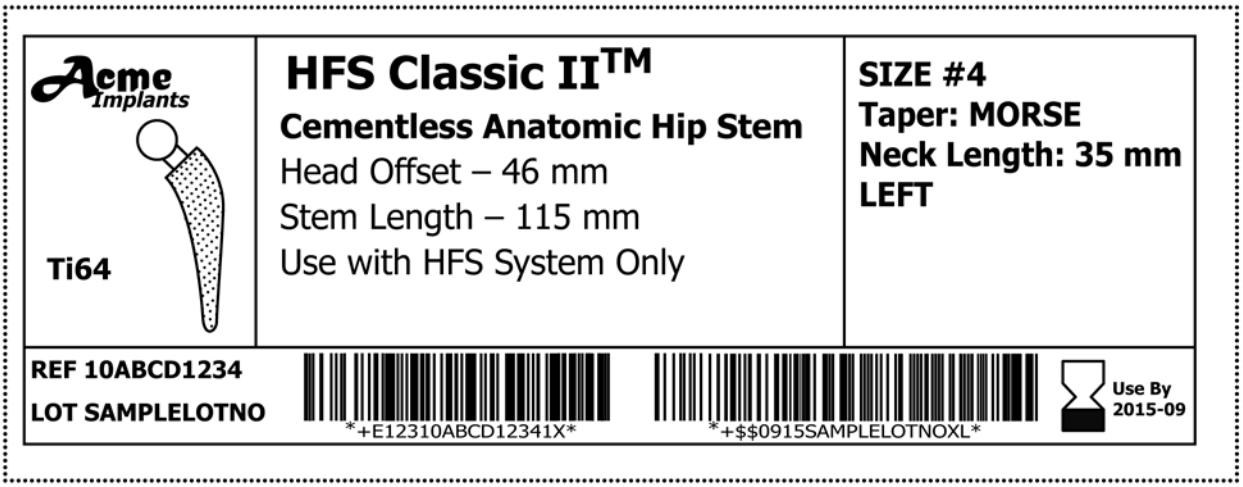

FIG. 2 Visual Representation of Guide Using ISSL as Primary Identifier on the End of the Box

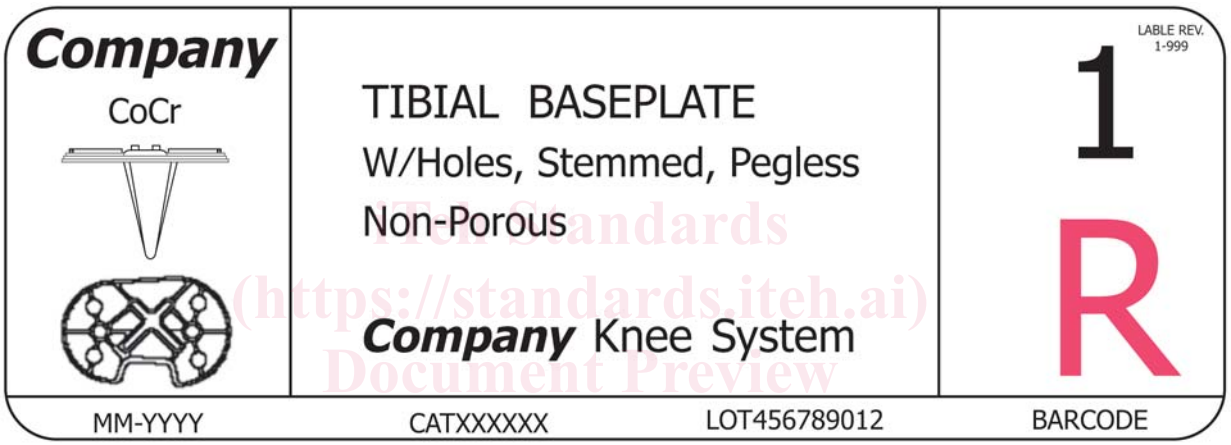

FIG. 3 Another Visual Representation of Guide Using ISSL as Primary Identifier on the End of the Box

3.1.13 *primary size, n*—main size designator when selecting the implant.

3.1.14 *secondary features, n*—additional sizes or characteristics (such as coatings, porous surfaces, groups, offsets, component capability, and so forth) that aid in appropriate selection of the selected implant.

3.1.15 *system, n*—brand name or "family" to which the implant belongs.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *musculoskeletal implant, n*—for this guide, this terminology shall include all implant types utilized for the care of musculoskeletal-based conditions, including arthroplasty, spine, fracture care, and tissue-engineered products.

4. Significance and Use

4.1 Implantable medical device labeling often results in a variety of label formats and information prioritization. This variability can be seen not only across different manufacturers but also across different implant types.[3] At present label design and layout is developed by a given manufacturer and represents balancing internal needs (such as manufacturing, distribution, and marketing), regulatory requirements within various markets, and end user needs (as identified by individual manufacturers performing "voice of the consumer" feedback on their label designs).

4.2 At no fault to any given manufacturer, this process, along with the manner in which label information competes for available "real estate" on a package, often leads to variable prioritization of label information and highly variable label designs. The impact of this variability on patient care is not well documented within the published literature. An article from *AAOS Now* in 2009 described potential issues around label variability and gave anecdotal evidence of its impact.[3]

4.3 No published literature demonstrating a clear and conclusive impact on patient safety resulting from implant label variability was identified. Despite this lack of evidence, anecdotal observations and input from various involved individuals

[3] Lowry, K. J., McGrath, M. S., Mihalko, W. M., "The Impact of Standardized Implant Labels," *AAOS Now*, March 2009, (http://www.aaos.org/news/aaosnow/mar09/clinical12.asp).

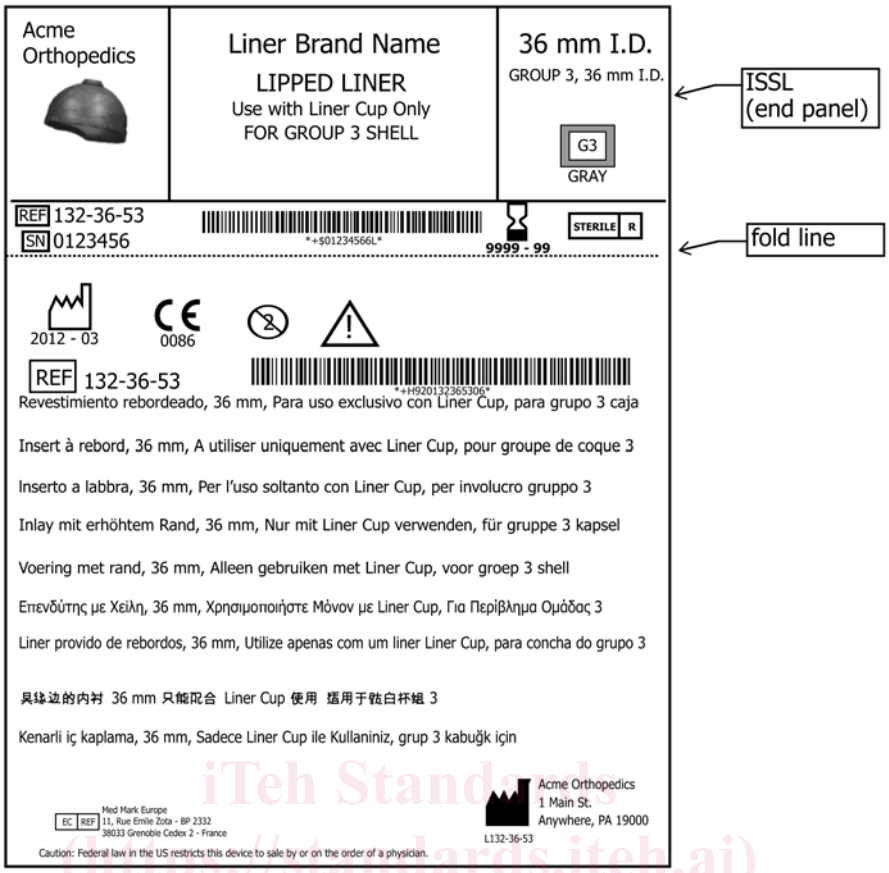

FIG. 4 Additional Example of Guide Using ISSL as Primary Identifier on the End of the Box

and organizations (surgeons, operating room nurses, hospital administrators, product representatives, and manufacturers) suggests a potential, although unproven, benefit for an increased standardization of implant labeling.

4.4 The authors of this guide believe it is important to highlight that no universally accepted method for validation of a label's effectiveness exists. Current validation methods consist of varying methods of customer feedback on an existing label design using formal customer questionnaires, informal customer feedback through individual polling, and internal manufacturer-driven studies. The label recommendations presented within this guide have not been validated as more or less effective than other existing implant labels currently in use.

4.5 These recommendations have been developed through the collaboration of an ASTM-sponsored task group with representation from large and small orthopedic implant manufacturers, orthopedic surgeons (specifically the Biomedical Engineering Committee from the American Academy of Orthopedic Surgeons), healthcare facility administrators, operating room nurses, the U.S. Food and Drug Administration (FDA), and the Canadian Healthcare System. The task group utilized "voice of consumer" feedback from previous manufacturer label initiatives combined with input from various end users on the task group. This process did not identify any given implant label format as being more or less effective but only attempts to prioritize information and recommend a universal format for this information. A manufacturer may determine that an alternative format may be more effective for its internal processes and elect not to follow these recommendations.

5. General Considerations

5.1 Labeling needs are often driven by competing regulatory requirements, manufacturing/distribution needs, and final implant selection needs.

5.2 The goal of this guide is achieved by creating an ISSL area of an implant's primary label which uniformly (across differing implants and manufacturers) presents information in a consistently organized format, in an easy-to-view and uncluttered manner (see examples in Figs. 2-4).

TABLE 1 Suggested Color Contrasts

Text	Background
Black	White
White	Blue
Blue	White
White	Black

5.3 The ISSL was developed to satisfy the needs of implant selection as well as a manufacturer's distribution and packaging needs.