Designation: F2943 – 13

StandardGuide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty[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 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.

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

1.4 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.

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

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

1.7 The use or application of multiple languages is not prevented by this guide; however, 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 ISSL where possible.

1.8 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:

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

1.8.2 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.

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

1.10 *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 Lables, 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.

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

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

[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.

Current edition approved April 1, 2013. Published May 2013. DOI: 10.1520/F2943-13.

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

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 striven to be 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, Clause 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 and 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, Clause 3.6 and ISO 15223–1, Clause 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 implants packaging. Formatting and information location of this label is at the discretion of the manufacturer based on regulatory requirements.

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,

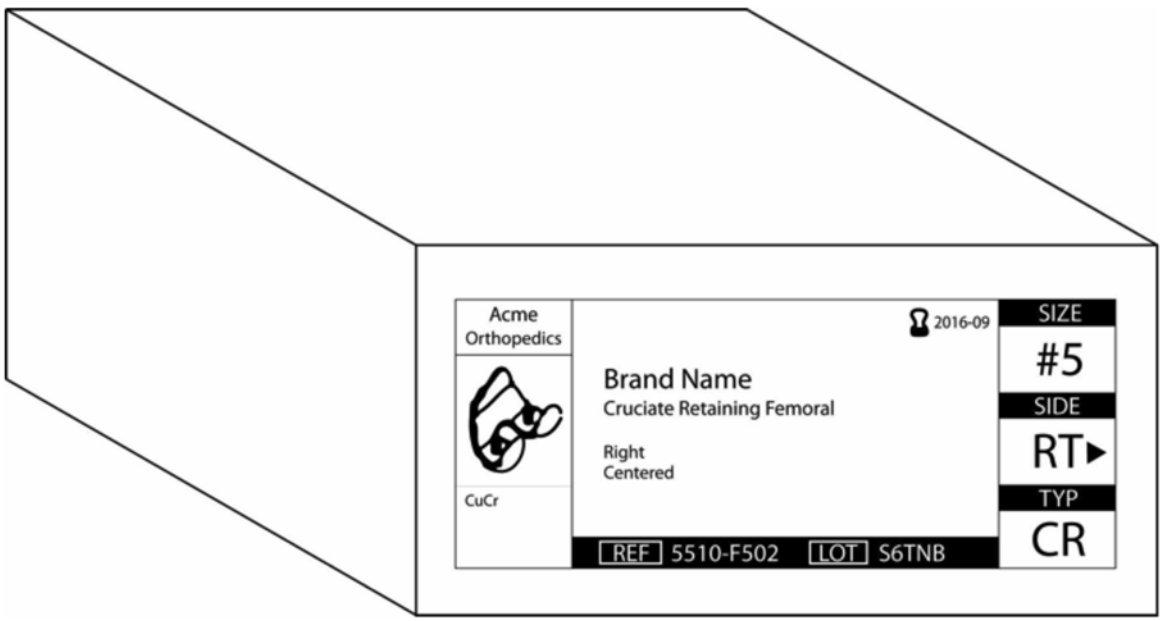

FIG. 1 End of Box

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

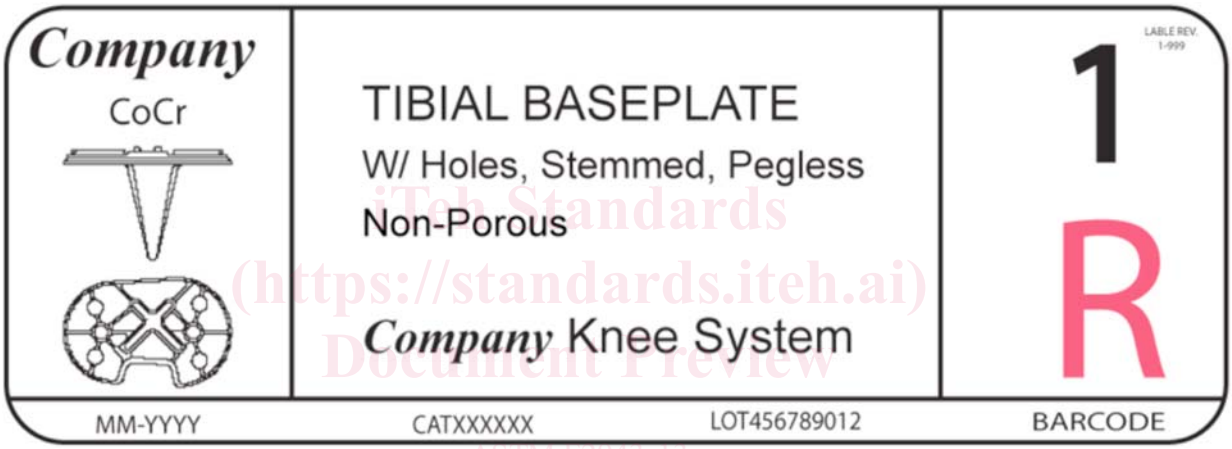

FIG. 3 Another Visual Representation of Guide Using ISSL as Primary Identifier on End of Box

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 *joint arthroplasty, n*—for this guide, this terminology shall to include all implant types that are intended to replace the function of an existing joint, including total joint arthroplasty, hemiarthroplasty, or unicompartmental arthroplasty.

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

[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).