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.

Current edition approved April 1, 2014. Published June 2014. Originally approved in 2013. Last previous edition approved in 2013 as F2943–13. DOI: 10.1520/F2943-14.

[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.

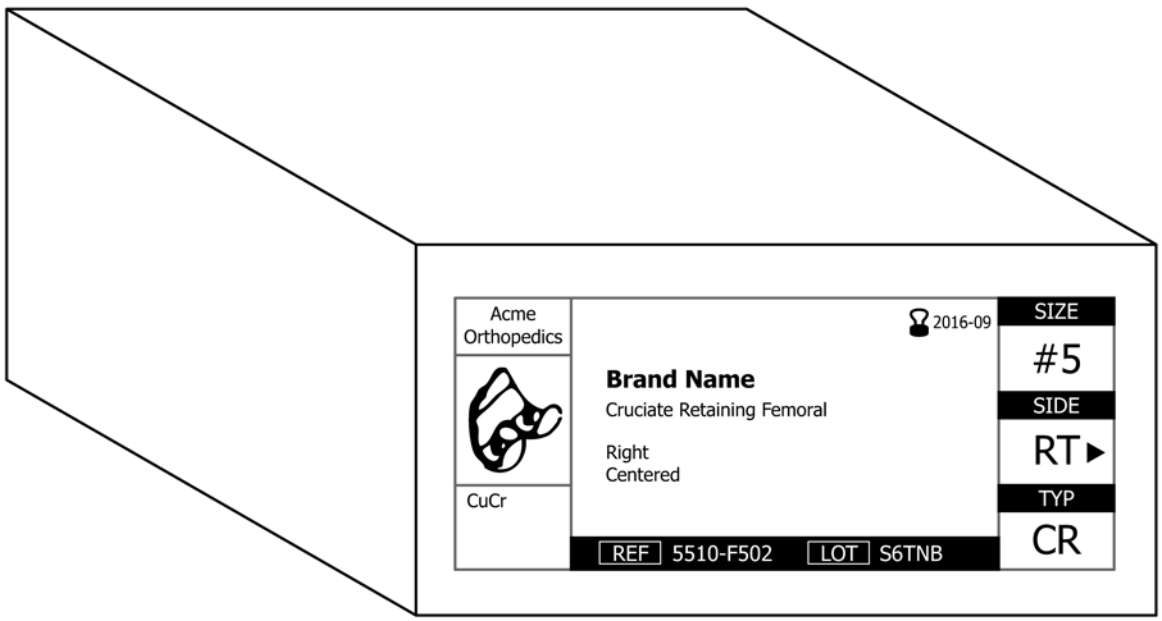

FIG. 1 End of Box

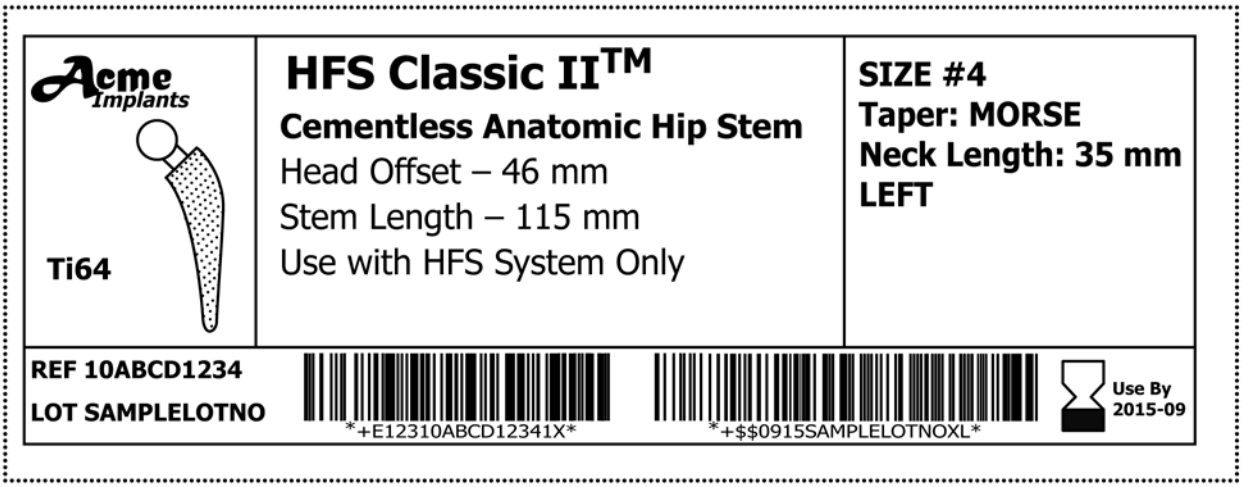

FIG. 2 Visual Representation of Guide Using ISSL as Primary Identifier on the End of the Box

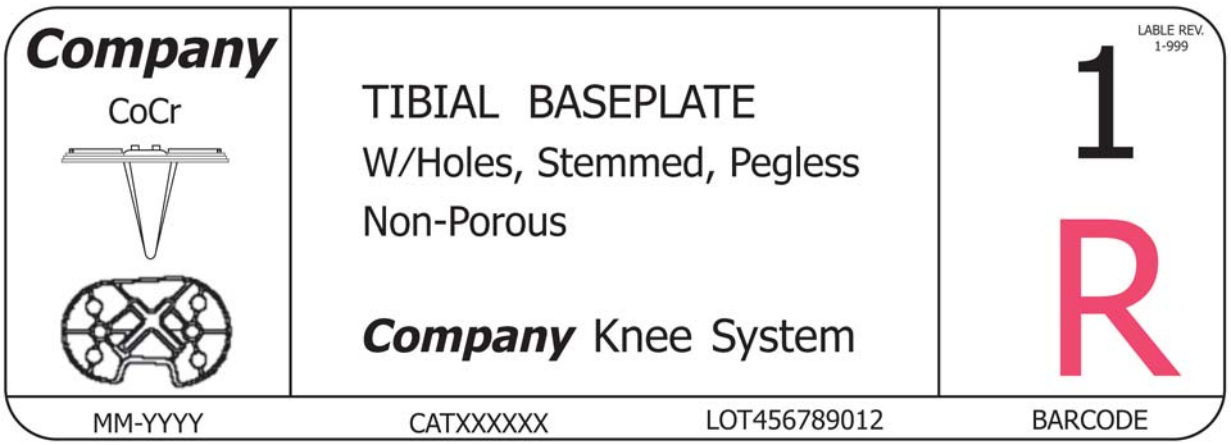

FIG. 3 Another Visual Representation of Guide Using ISSL as Primary Identifier on the End of the Box

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).

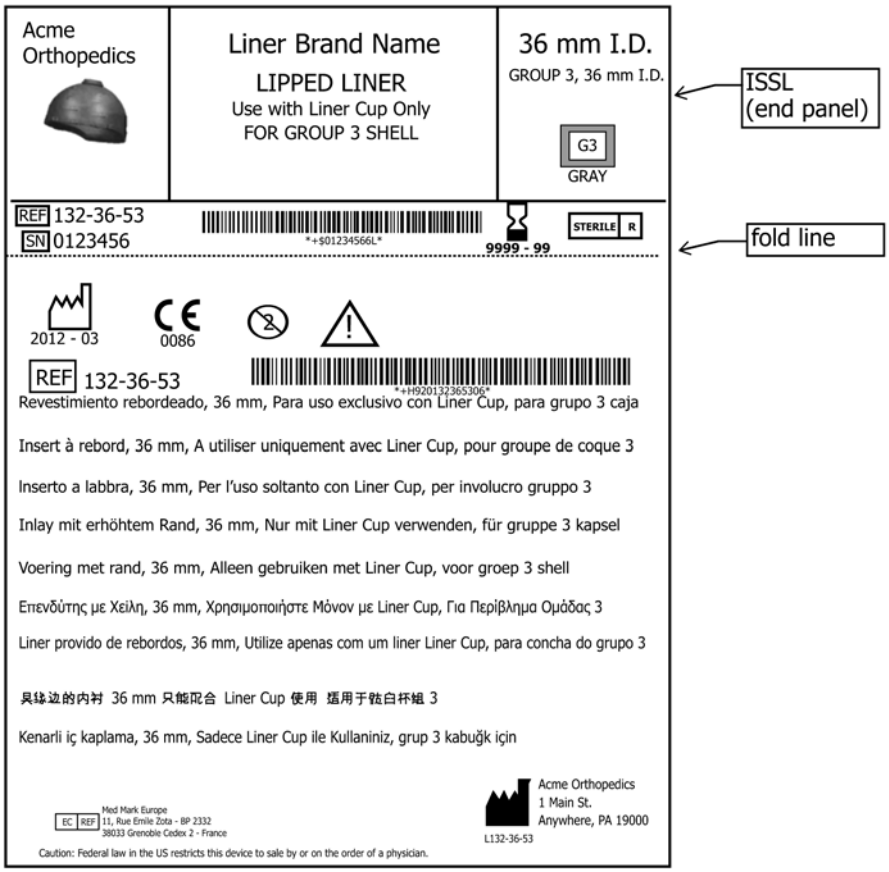

FIG. 4 Additional Example of Guide Using ISSL as Primary Identifier on the End of the Box

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.

5.3.1 The following general considerations are to be applied to the ISSL and a manufacturer is encouraged to consider them when developing additional areas of an implant's label. Additional information and recommendations may be found in the article by Haene.[4]

5.3.2 Universally accepted and published validation methods of package labeling for orthopedic implants do not currently exist. Therefore, manufacturers are encouraged to validate this guide's recommendations, or any alternative format, against a stated user's needs for a particular label. It is recommended that validation of a user's needs include the impact of other formatted labels in an operating room environment, which is out of the individual manufacturer's control.

5.3.3 Use of symbology should comply with existing standards (such as ISO 15223–1).

5.4 All information shall be presented with good visual contrast and with adequate space between information to prevent clutter. Suggested color contrasts are as in Table 1 (with black and white being preferred).

5.5 Additional regulatory needs or requirements, such as company address and so forth, shall be placed outside of the ISSL.

5.6 Package seams should not obstruct information within the ISSL.

5.7 Use of multiple languages within the ISSL is discouraged. If multiple languages are necessary, a separate, additional ISSL label located on a different surface from the primary ISSL is recommended. The primary language 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.

6. ISSL Location

6.1 The preferred or primary location of the ISSL is the end of the box for a given implant.

6.2 The alternate or secondary location of the ISSL is below the fold of the end of the box, on the adjacent surface.

6.3 Selection between the preferred or alternate location of the ISSL is at the discretion of the manufacturer based on package size restrictions or a manufacturer's internal needs.

6.3.1 It is recognized that placement of the ISSL below the fold of the end of the box may necessitate duplication of information on the implant's packaging.

7. ISSL Content Requirements

7.1 Information placed within the ISSL shall be prioritized and grouped into zones as demonstrated in Table 2. High priority information items are marked with an asterisk and shall be included on the ISSL for proper implant selection by an end user.

7.2 Required end user information (items with an asterisk) is deemed necessary information for implant selection by an end user and shall be included within the ISSL. Additional information listed in Table 2 may be included at the manufacturer's discretion.

7.3 Font sizing, spacing, use of coloring, and general formatting of information within a given zone of the ISSL is at the discretion of the manufacturer.

7.4 The manufacturer is encouraged to prioritize easy visibility/readability of required information for final implant selection by the end user.

7.5 The unique device identifier (UDI) should be included in Zone D and follow appropriate recommendations as set forth by the FDA.

8. ISSL Layout Guidelines

8.1 The area set aside by the ISSL shall be outlined and defined by a bold border in either black or a color as part of a color-coding scheme to help identify compatible implants.

8.2 The final size of the ISSL will be dictated by the amount of necessary information included (for example, larger labels will allow additional information) and space available for the ISSL.

8.3 The final size of the ISSL should be driven by the space necessary for visual presentation of included information and the available space on the package for the label.

8.4 The ISSL space shall be divided into four general zones (see Fig. 5). The final size of each zone is flexible and may be adjusted by the manufacturer's discretion. However, the relative location of each zone must be maintained and clear visual demarcations between each zone shall be maintained. Where it is not possible to maintain adequate spacing between zones, each zone shall be maintained by a fine line (as demonstrated in Fig. 5).

8.5 Information within Zones A, B, and C shall be presented in a consistent, top-to-bottom fashion as listed in Table 2.

8.6 Organization and inclusion or exclusion of information within Zone D is at the discretion of the manufacturer.

9. ISSL Zone Requirements

9.1 *Zone A:*

9.1.1 Zone A includes the leftmost portion of the label.

9.1.2 Company name or branding shall be placed at the top of this zone. The company's font, color, and type style may be preserved, based on the company's branding strategy.

9.1.3 Implant material, including coatings, shall be placed below the company name/branding.

9.1.4 A basic implant schematic shall be included in the lower portion of this zone.

9.2 *Zone B*—Zone B includes the central portion of the label and contains the brand name of the implant, the generic description of the implant, and any implant selection considerations.

9.3 *Zone C:*

[4] Haene, R. A., Sandhu, R. S., Baxandall, R., "Reading the small print—labeling recommendations for orthopaedic implants," *Ann R Coll Surg Engl*, Vol 91, No. 8, Nov 2009, pp. 653–657.

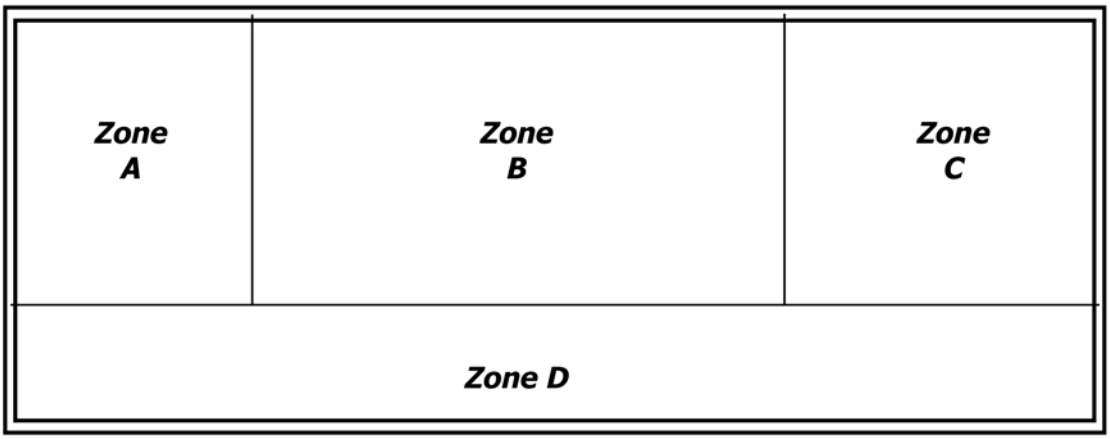

FIG. 5 Relative Zone Layout for the Implant Selection Secondary Label

TABLE 2 ISSL Information, Order of Prioritization, and Corresponding "Zone" Identification

NOTE 1—Where an astrisk "*" appears in the table, it indicates "high priority" information items which must be included on the ISSL.

Zone A	Zone B	Zone C	Zone D
1) Company name/logo* 2) Material, including coatings* 3) Implant schematic	1) Brand name 2) Implant description* 3) Implant selection considerations	1) Primary size* 2) Secondary size/features 3) Body side*	1) Expiration date 2) Part/reference number 3) Lot/batch code 4) UDI/Bar code 5) Quantity 6) Sterilization method

9.3.1 Zone C includes the rightmost portion of the label and contains critical size/side/feature information for proper implant identification.

9.3.2 The font of the primary size descriptor shall have good visual contrast and shall ensure readability "from a distance" as necessary for identification within an operating room environment. An associated size descriptor is optional.

9.3.3 Secondary size descriptors (if applicable) shall be located underneath the primary size descriptor, with adequate space separating the two identifiers.

9.3.4 The body side identifier (if applicable) shall be located underneath the secondary size descriptors. This will consist of one of the following two descriptors: "Right," or "Left," or "R" or "L" if appropriate. The font used for this identifier shall be prominent by using bold, reversed out, or color text properties, allowing the body side identifier to stand out from the other size descriptors.

9.3.5 Additional body side identifiers (such as anterior, posterior, medial, lateral, and so forth) may be placed in this area. However, their use and any abbreviations shall be done in a manner so as not to be confused with the descriptors listed in 9.3.4.

9.4 *Zone D:*

9.4.1 Zone D includes all areas of the ISSL underneath Zones A, B, and C (on the bottom portion of the label), and contains the part/reference number, batch/lot number, expiration date, sterilization method, bar code, and quantity.

9.4.2 Information allocated to Zone D (as defined in Table 2) may be moved to the bottom of Zone A, B, or C, if space allows and easy readability of required end user information (as identified within Zones A, B, or C) is maintained.

10. Keywords

10.1 end of the box; end user; implants; labels; size

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Examples of uniform labeling standards exist within ASTM International and are listed in the Bibliography for further review. Other industries have embraced the benefits of uniform labeling and these examples are provided for additional consideration. These include labels for food nutrition, standard international logistics shipping, and fertilizer. These examples can be found in the web-based bibliography.

X1.2 Issues around label variability are discussed within the literature. A report from Germany by Fakler et al identified 47 patients who had implants intended to be used in a cemented fashion used in an uncemented knee replacement surgery. This error was attributed to erroneous interpretation of English label packaging.[5] Haene et al from Britain also highlight potential issues and the impact of implant labeling designs and argue for "positive pressure…from the orthopaedic community in order to bring about a change so that all implant labels are of a high standard."[5]

X1.3 Additional standards that may have importance to labeling are listed with the bibliography and are provided for additional review.

[5] Fakler, J. K., Robinson, Y., Heyde, C. E., John, T., "Errors in handling and manufacturing of orthopedic implants: the tip of the iceberg of an unrecognized system problem?," *Patient Safety in Surgery*, Vol 1, No. 5, 2007.

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Web-based Documentation:

(1) Recommendations for Food Nutrition Labeling, developed by the Food and Drug Administration, http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/UCM265446.pdf, October 2009.

(2) Recommendations for the GS1 Logistics Label, developed by the Logistics Label Group, http://www.gs1.org/docs/transportlogistics/GS1_STILL.pdf, 2008.

(3) Recommendations for Fertilizer Labeling, developed by the Association of American Plant Food Control Officials, http://www.aapfco.org/pdf/label_brochure.pdf.

ASTM Standards:

(4) Practice D6398 to Enhance Identification of Drug Names on Labels

(5) Specification D4774 for User Applied Drug Labels in Anesthesiology

(6) Specification D4775/D4775M for Identification and Configuration of Prefilled Syringes and Delivery Systems for Drugs (Excluding Pharmacy Bulk Packages)

(7) D5022 Standard Specification for Identification of Vials and Ampoules Containing Concentrated Solutions of Drugs to be Diluted Before Use

(8) Test Method D7298 for Measurement of Comparative Legibility by Means of Polarizing Filter Instrumentation

ISO/Other Standards:

(9) ANSI/AAMI HE75:2009 Human factors engineering—Design of Medical Devices, Clauses 10, 11 & 12

(10) ANSI/AAMI/IEC 62366:2007 Medical Devices—Application of usability engineering to medical devices

(11) ANSI/AAMI/ISO TIR11139:2006 Sterilization of healthcare products—Vocabulary

(12) EN/ANSI/AAMI/ISO11607-1:2006 Packaging for terminally sterilized medical devices, Part 1: Requirements for materials, sterile barrier systems and packaging systems

(13) EN/ANSI/AAMI/ISO11607-2:2006 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes

(14) ISO 14630: Non-active surgical implants—General Requirements

(15) ISO 21534: Non-active surgical implants—Joint replacement implants—Particular requirements