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# AATB/ICCBBA Interim Guidance Document

## For use of ISBT 128 by North American Tissue Banks

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*This guidance document is a project of the North American Tissue Technical Advisory Group (NATTAG) and co-authored by members of AATB and ICCBBA.*

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# 1 Introduction

## 1.1 Purpose

ISBT 128 implementation is currently being undertaken by a number of North American tissue banks. The purpose of this document is to provide guidance on the implementation of the ISBT 128 Standard for tissues to those banks that are moving forward with the introduction of ISBT 128. Specifically it provides guidance on:

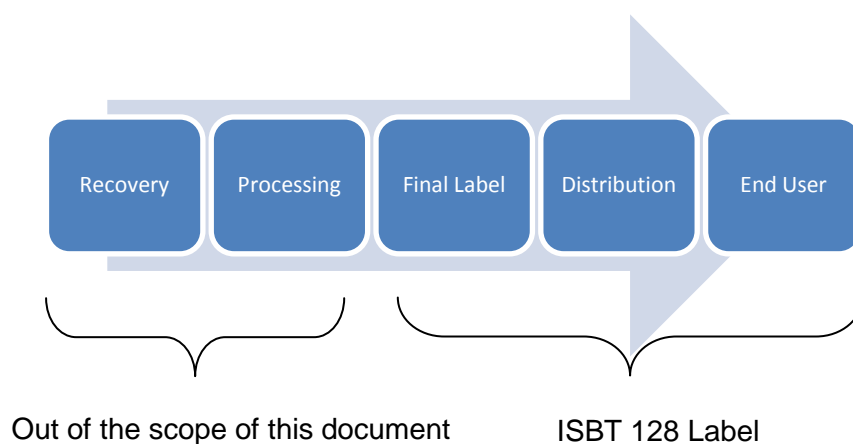
- Donation identification numbering
- Phased implementation of product coding
- Expiration date
- Label design
- Software design

## 1.2 Scope

This document has been recommended by the NATTAG and AATB's Standards Committee and approved by the Board of Governors of AATB, and acts as a supplement to the *ISBT 128 Standard Technical Specification*. It provides a means of final labeling of human tissue products in a manner that is compliant with the ISBT 128 Standard.

This interim guidance recommendation is limited to final product labeling as shown in Figure 1. Tissue banks and recovery organizations may continue to use their existing identification systems prior to final labeling or they may opt to introduce ISBT 128 identification from the point of recovery. Tissue processors will have the responsibility of ensuring traceability from the ISBT 128 final product identification back to other identifiers used earlier in the donation pathway.

**Figure 1 Scope of Document**



This document does not address the unique requirements of labeling of reproductive medicine products. Labeling of these products will be addressed in a future version of this document.

### 1.3 Intended Audience

The intended audience of this document is:

- staff (management, information technology, regulatory, technical, medical director, quality, and validation) of tissue banks in North America;
- staff (management, information technology, regulatory, technical, medical director, quality, and validation) of hospitals receiving tissue from these tissue banks; and
- vendors of software, equipment, labels, and supplies used by these tissue banks and hospitals.

### 1.4 Normative Reference

*ISBT 128 Standard Technical Specification*

(<http://iccbba.org/docs/tech-library/technical/technicalspecification.pdf>)

*ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product*

*Descriptions* (<http://iccbba.org/docs/tech-library/technical/standardterminology.pdf>)

### 1.5 Background

There is growing recognition at both the global level and within North America that there is a need to move towards standardization of the coding and labeling used on tissue products in order to improve traceability and enhance patient safety. Existing requirements ensure the use of distinct or unique identification numbers by a tissue processor, but do not require this uniqueness to extend outside the tissue bank. As a result a receiving hospital may receive identically numbered tissue products from two different tissue processors. With the widespread distribution of tissue products at both a national and international level there is increased risk of loss of traceability due to duplication of identifiers.

In May 2010 the World Health Assembly approved resolution WHA63.22 which urges member states to “encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation.”

ISBT 128 is a well-established international standard for coding and labeling of blood, cells, and tissues. It is used extensively for the coding and labeling of blood donations, and in 2008 the AABB made the use of ISBT 128 an accreditation requirement for their accredited blood banks and hospital transfusion services. Many hospitals in North America are already equipped to handle ISBT 128 blood and cellular therapy products through their transfusion laboratories and software could be updated to accept ISBT 128 tissue products. Some major software and labeling suppliers are already developing tissue banking modules for tissue bank and hospital use.

Cell therapy organizations have agreed to international standardization of coding and labeling for cellular therapy products using ISBT 128, and both FACT/JACIE and AABB are moving towards making this an accreditation requirement for these human derived products.

In tissue banking ISBT 128 is the only international standard currently available and is already in use in parts of Europe. AATB in cooperation with ICCBBA established a task group to investigate the use of ISBT 128 for tissues in North America. The North American Tissue Technical Advisory Group (NATTAG) has concluded that implementation of the ISBT 128 standard for human tissue products could facilitate important safety and traceability initiatives on a global level.

While AATB has yet to decide whether to require the use of ISBT 128 within its *Standards for Tissue Banking*, it is clear that a number of tissue banks are moving forward with implementation. It is important that any such early implementers adopt a consistent approach that will be compatible with any future standards requirements.

To that end, the NATTAG has prepared this interim guidance document in order to support single or multi-phase implementation approaches. It is recommended that tissue banks implementing ISBT 128 identification ensure that their systems are compliant with the operational and design guidance provided here.

## 2 Implementation Guidance

Implementation guidance is provided in the following sections. This guidance should be read in conjunction with the *ISBT 128 Standard Technical Specification* and the *ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*.

As can be seen from this guidance, ISBT 128 is a flexible standard and can accommodate different approaches to implementation. This document outlines several areas of flexibility:

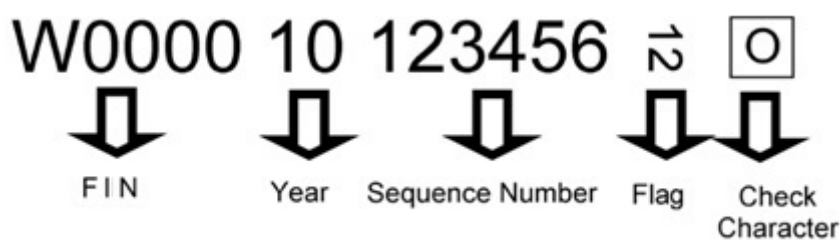
- Determination of the stage at which a Donation Identification Number is assigned
- Use of the year code within the Donation Identification Number
- Selection of a single or multi-phase implementation in regard to product description code selection
- Inclusion of an expiration date as part of the standardized ISBT 128 portion of the label (the electronically-readable symbol and the eye-readable text)
- Determination of the size and placement of the standardized ISBT 128 portion of the label
- Selection of linear versus two-dimensional symbols

While facilities may select from among these and other options, certain aspects of an ISBT 128 label must be standardized to ensure compatibility with others using ISBT 128 for coding and labeling. This document also describes these requirements.

### 3 Donation Identification Numbers

The ISBT 128 globally unique Donation Identification Number (DIN) [encoded within Data Structure 001] comprises three elements. The first element, the facility identification number (FIN), is assigned to a facility by ICCBBA. The second and third elements consist of a two-digit year number and a sequence number and these are assigned by the processing facility. Flag characters, used for process control, are also a part this data structure. A manual check character is added to the end of the number to verify correct keyboard entry.

**Figure 2 Globally Unique Donation Identification Number**



In order to obtain a FIN tissue banks will need to register with ICCBBA. Tissue banks may opt to have a single FIN and manage the sequence number allocation across all of their facilities centrally, or they may request multiple FINs with each facility controlling its own sequence number allocation.

ISBT 128 Donation Identification Numbers support the use of “flag characters” which can be used to facilitate automated process control. These flag characters are optional and, if not required, the flag value of “00” should be used. Systems receiving ISBT 128 labeled tissue should accept any valid final product flag characters (see Section 8).

Whenever ISBT 128 Donation Identification Numbers are printed in eye-readable format the manual entry check character should appear to the right of the Donation Identification Number, enclosed in a box. Note that the check character may be any one of the thirty seven characters in the set (0-9, A-Z, asterisk). Care should therefore be taken to use a font which clearly distinguishes between similar characters (0 and O, I and 1 etc.).

Where computer systems accept manual entry of a Donation Identification Number, the check character should always be a required part of the entry and software should verify the character is correct.

#### 3.1 When to Assign DIN

As this interim guidance is focused on the use of ISBT 128 on final product, it does not directly address the point at which the ISBT 128 donation numbering is introduced. Two possible situations are identified for informational purposes, but no recommendation is made as the most suitable option will vary according to the needs of the tissue bank.

### **3.1.1 Assignment at Time of Processing**

If existing numbering systems are used for the earlier part of the donation pathway, then the tissue processor will assign the ISBT 128 DIN some time during processing before final labeling of the product. The tissue processor is responsible for ensuring traceability between the ISBT 128 DIN and other identifiers

### **3.1.2 Assignment at Time of Recovery**

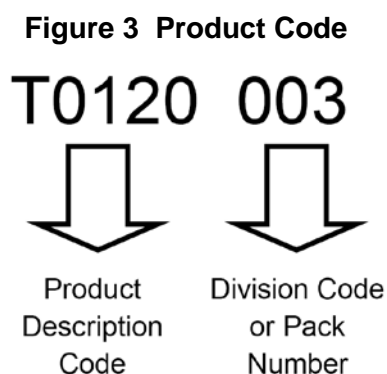
Some tissue banks may wish to assign the ISBT 128 DIN at the point of donation and this could be done either by the processor allocating a Donation Identification Number from their own range to the recovery organization, or by the recovery organization having its own FIN and managing identifiers themselves. In all cases the assigned DIN should remain with the tissue donation and appear on all final labeled products from that donation.

## **3.2 Year Code**

The assigning facility has the responsibility for ensuring the uniqueness of donation identifiers that they issue across a 100 year period. To help them to achieve this, the DIN structure includes a two-digit year code. This is a nominal year identifier and should not be used as an alternative to other date structures (such as collection date, expiration date, etc.). Its purpose is solely to support the requirement for 100 year uniqueness. Individual banks can determine how they wish to use the year identifier based on the point at which the DIN is assigned. Thus for a bank choosing to assign an ISBT 128 DIN at the time of donation, the year code could be aligned with the donation date. Alternatively, for a processor assigning the DIN, it may be more appropriate to align the year code with the date processing begins. In all cases it is essential to ensure that the policy is applied consistently within the facility and that secure algorithms prevent the duplication of an identifier.

## 4 Product Code

The ISBT 128 Product Code [Data Structure 003] comprises two elements. The first is a five-character product description code and the second is a three-digit division/pack number.



Full implementation of the ISBT 128 Standard includes the use of standardized product description codes. Work on developing the generic terminology required to support standard product coding is on-going; however this has proven to be complex due to the array of technologies employed and issues related to patents and branding. At the current time agreement has not been reached on a standardized product description coding database for use in North America, although product description codes requested by other countries or by individual tissue banks are encoded within ISBT 128 and can be utilized. For this reason, there are two options for the full implementation of ISBT 128.

### 4.1 Phased Implementation Approach

This approach is for those tissue banks that wish to proceed with the introduction of the globally unique ISBT 128 Donation Identification Number, but do not wish to use ISBT 128 product description codes prior to the development of a North American consensus on terminology and coding. In the first phase a globally unique Donation Identification Number, a pack number to uniquely identify each tissue graft prepared from the donation, and optionally an expiration date (all in ISBT 128 format) are introduced on all final labeled products. This information may be carried in addition to a processor's current label information.

To ensure a smooth transition to full implementation of ISBT 128 once the terminology has been finalized, a generic product description code (T0000) should be used on all phase 1 labels. This will simply identify the product as donated human tissue, but will act as a place marker which can be replaced by the specific tissue code a tissue bank assigns to it in the future. The generic product description code, T0000, should be used with the eye-readable text of "Donated Human Tissue".

The pack number is required to allow individual grafts to be identified. Each graft should be assigned a number from the range 001 to 999. By combining the Donation Identification Number, product description code and pack number, each individual product/graft is uniquely identified.

## 4.2 Single Phase Implementation Approach

Alternatively, tissue banks may wish to implement ISBT 128 fully in a single step by using the existing product description codes available in the ISBT 128 tissue database or by requesting new codes. Tissue Banks taking this approach need to recognize that once agreement on terminology has been reached, some existing codes may be retired and there will be a need to change the product description codes they assign to their final product to comply with the standard terminology. Existing stock would not need to be re-labeled as retired codes will be retained in the reference database for backward compatibility.

# 5 Expiration Date

The expiration date of the product is an optional element of the standardized ISBT 128 label at this stage, but if included it should be presented using the ISBT 128 Expiration Date and Time [Data Structure 005].

## Date and Time Text

When the date and time is encoded into an ISBT 128 data structure the text may be presented in one of two ways.

- If the text is included within the standardized area of the label, it should appear as described in the *ISBT 128 Standard Technical Specification* (e.g. 17 MAR 2010) or in compliance with ISO 8601-2004 extended format (2010-03-17).
- If the text is elsewhere on the label, it may be presented in any appropriate format.

## 6 Label Design

In order to provide a common presentation of key traceability information it is recommended that a portion of the label be standardized across all tissue processors. The location and size/orientation of this standard portion can be adjusted to suit tissue bank requirements (see examples in Figure 7 and Figure 8).

The following description applies to this ISBT 128 specific label area. It does not include all of the regulatory requirements for labeling. It is the responsibility of the tissue processor to ensure regulatory and standards requirements are met elsewhere on the label, and to ensure the consistency of information across the entire label. Where the generic code is chosen, suitable text describing the product should appear elsewhere on the product label.

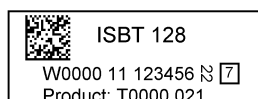
### 6.1 ISBT 128 Label Requirements

The ISBT 128 label area must have a white background.

The minimum information content is:

- The text “ISBT 128”;
- Bar coded Donation Identification Number (DIN), product description code and division code/pack number;
- The eye readable Donation Identification Number, flag characters (rotated 90° clockwise) and the boxed manual check character.
- The text “Product:” and the eye-readable product code (product description code and division code/pack number)

**Figure 4 Minimum Label Requirement**



In addition, the following information must appear on the label, and may or may not be in the ISBT 128 specific portion of the label:

- The text description of the product giving the product name and the division code/pack number;
- The eye readable expiration date.

The expiration date may be included in the bar code even if the text appears elsewhere on the label.

The tissue processor may opt to use either linear (Code 128) bar codes or a two-dimensional (Data Matrix) symbols.

See section 6.3 for examples of label designs that meet these criteria.

## 6.2 Electronically Readable Symbols

Linear bar codes are well established and in widespread use, and the underlying symbology, Code 128, can be read by all types of bar code scanners currently available. However, the number of bar codes required, and limitations on the minimum size of each bar code, means that they take up a significant proportion of the available label space leaving little room for human readable text. As each code has to be scanned individually, the time to read each label is longer than for the corresponding two-dimensional label.

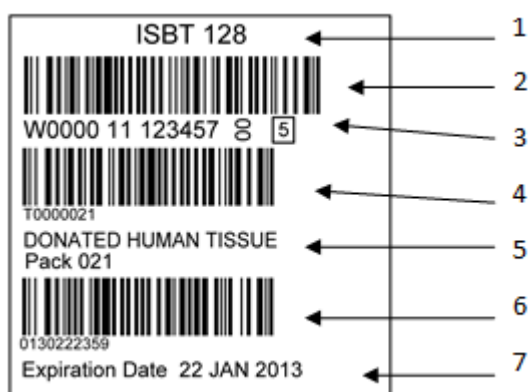
Two-dimensional (2-D) symbols are a newer technology and require an image scanner which is a more modern type of code reader. Image scanners can read both 2-D and linear bar codes, however these are less likely to already be in place in receiving hospitals. The information held in multiple linear bar codes can be encoded within a single 2-D bar code. The 2-D bar code takes up much less room than the corresponding linear codes leaving much more space for human readable text, and it is scanned in a single read thus reducing read times.

The choice of bar code type will depend on local circumstances. 2-D codes are likely to become more commonly used in hospital environments.

### 6.2.1 Linear Bar Code Option

This label design is based on a 50 mm x 50 mm template and can be placed at any position on the packaging. This label size is recommended but for special requirements, such as needing to accommodate dual language labeling or adapting the label to very small containers, the label size can be adjusted.

**Figure 5 Linear Bar Code Label Design**



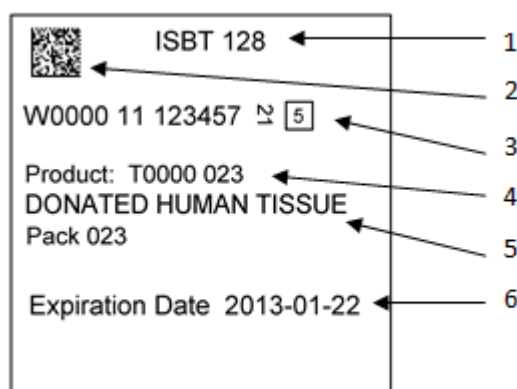
Reading from the top of the label, the content is as follows:

- 1) The text "ISBT 128" required to indicate that this is the ISBT 128 compliant section of the label
- 2) The bar coded Donation Identification Number [Data Structure 001]
- 3) The eye-readable Donation Identification Number, flag characters (rotated 90° clockwise), and the boxed manual check character
- 4) The bar coded Product Code [Data Structure 003] with the associated eye-readable text printed immediately underneath. (The text "Product:" is not required when this information appears immediately beneath the linear bar code.)
- 5) Optional – The text description of the product giving the product name and the division code/pack number.
- 6) Optional – The expiration date and time bar code [Data Structure 005], with associated eye-readable text printed immediately underneath.
- 7) Optional – The expiration date text using DD MMM YYYY format. (While required on the label, this text is optional in the ISBT 128 area.)

## 6.2.2 Two Dimensional Symbol Option

This label design is similar to that shown in section 6.2.1 but uses a single 2-D bar code to carry all of the information held in the three linear codes of the previous example.

**Figure 6 Two-Dimensional Symbol Label Design**



Reading from the top of the label, the content is as follows:

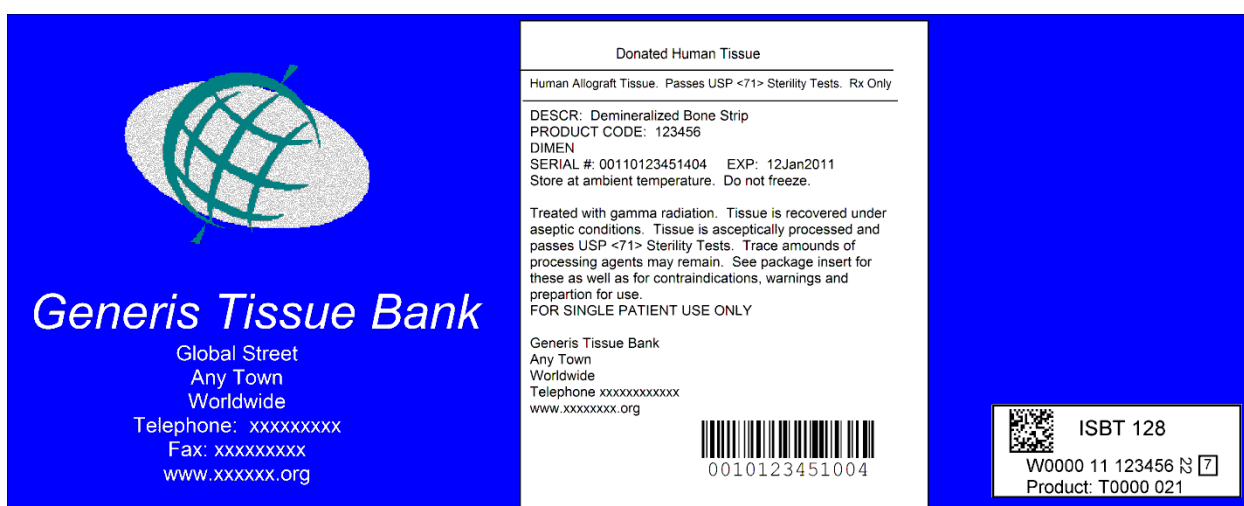
- 1) The text “ISBT 128” required to indicate that this is the ISBT 128 compliant section of the label
- 2) The two dimensional symbol containing a compound message carrying the data structures for Donation Identification Number and flag characters [Data Structure 001], Product Code [Data Structure 003], and optionally the expiration date and time [Data Structure 005]. See Structured Compound Messages 001 and 004 in the *ISBT 128 Standard Technical Specification* Reference Table RT017.
- 3) The eye readable Donation Identification Number, flag characters (rotated 90° clockwise), and the boxed manual check character.
- 4) The text “Product:” and the Product Code eye-readable text.
- 5) Optional – The text description of the product giving the product name and the division/pack number.
- 8) Optional – The expiration date text using DD MMM YYYY format. (While required on the label, this text is optional in the ISBT 128 area.)

### 6.3 Label Size and Placement

The size and placement of the standard portion of the label may vary within the constraints outlined in the ISBT 128 Label Requirements section.

For some containers physical dimensions limit the available label space and the previously described designs may be too large. In such cases the amount of eye-readable information may need to be reduced to the minimum. Figure 7 shows how this can be accommodated on a tissue product carton.



**Figure 7 Product Carton Label Example**



ISBT 128 Area of Label

In Figure 8 the ISBT 128 label portion of the label is in a strip on the left hand side. The Donation Identification Number, product description code, and division code/pack number appear in eye-readable characters. In this example the tissue processors internal identifiers are also present on other areas of the label.

**Figure 8 Vial Label Example**

ISBT 128  Product: W0000 11 123456 23 T0000 005	<b>Generis Tissue Bank</b> Donated Human Tissue. Passes USP <71> Sterility Tests. Rx Only  DESCR: <b>Half Tibial Cortical Strut (1 ea)</b> PRODUCT CODE: 550530 DIMEN: L:20.0cm T:9mm W:10mm  SERIAL #: 12345678912345    EXP: 23Jan2012 <b>FROZEN: Store at -40 C to -90 C</b>  Tissue is recovered under aseptic conditions. Tissue is aseptically processed and passes USP<71>Sterility Tests. Trace amounts of processing agents may remain. See package insert for these, as well as for contraindications, warnings and preparation for use. FOR SINGLE PATIENT USE ONLY.  123 ANY STREET ANYTOWN, CA 92000    (800) 123-4567	12345678912345 
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ISBT 128  
Area of  
Label

## 7 Label Locations

The ISBT 128 label should be available at the time of transplantation so that information can be directly scanned into patient records. This is essential to eliminate the risk of manual transcription errors at this critical point of information transfer. However, for tracking purposes the label will need to be scanned at various other points in the production and supply chain. To ensure this visibility of the label throughout the pathway from product release to transplantation, it may be necessary to have multiple copies of the label on different levels of packaging, or to make use of transparent outer packaging through which the underlying label can be scanned.

## 8 Guidance for Software Developers

Software written to print and read these labels should be compliant with the requirements of the *ISBT 128 Standard Technical Specification*. Additional information is available from ISBT 128 Implementation Guides.

When assigning and reading ISBT 128 identification, it should be understood that the DIN provides uniqueness of the donation (i.e., all tissue products identified with this DIN were derived from the same donation). Uniqueness of the individual tissue product is provided by a combination of the DIN, product description code, and division code/pack number. While the generic product description code is in use it may appear that uniqueness is provided by a combination of DIN and division number, but this is not the case once specific product description codes are introduced, and the product description code should always be regarded as part of the unique item identifier.

Where the ISBT 128 identification is being assigned to final product, systems must ensure that there is mapping between the assigned ISBT 128 number and other identifiers used earlier in the donation pathway.

When printing ISBT 128 labels the requirements of the *ISBT 128 Standard Technical Specification* must be applied. In particular, bar code size and density requirements and the need for sufficient quiet space around code symbols must be observed.

When writing software to read ISBT 128 labels it should be recognized that tissue product can be received from multiple sources and each source may use different options available within the ISBT 128 Standard. Software should therefore accommodate all valid scenarios. As an example, one tissue bank may opt not to use the flag characters in the Donation Identification Number data structure, and thus always provide donations with flag characters of "00". Another bank may choose to use the process control flags and thus have other values in the flag characters. Both options are valid, and so any valid flag character value should be accepted by the reading software. For similar reasons, software should be able to support the use of both multiple linear bar codes each containing a single ISBT 128 data structure and 2-D bar codes carrying multiple ISBT 128 data structures in a compound message.

Software design should take into account the two-phase approach to product coding and be able to receive tissue labeled either with the generic "donated human tissue" code, or with a valid product description code taken from the ICCBBA Product Description Code Database. Similarly, software should support electronic input of expiration date bar code if present, or manual entry if not available.

The following sample labels are provided to assist in software design and testing.

# Examples

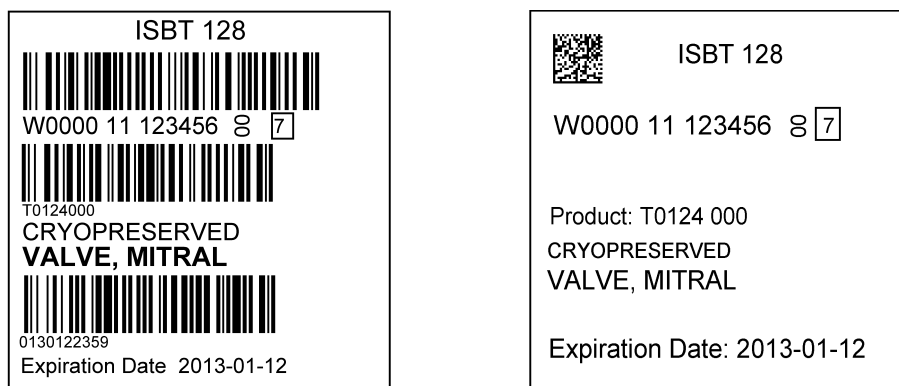
**Figure 9 Default Flag Characters, Generic Product Code**



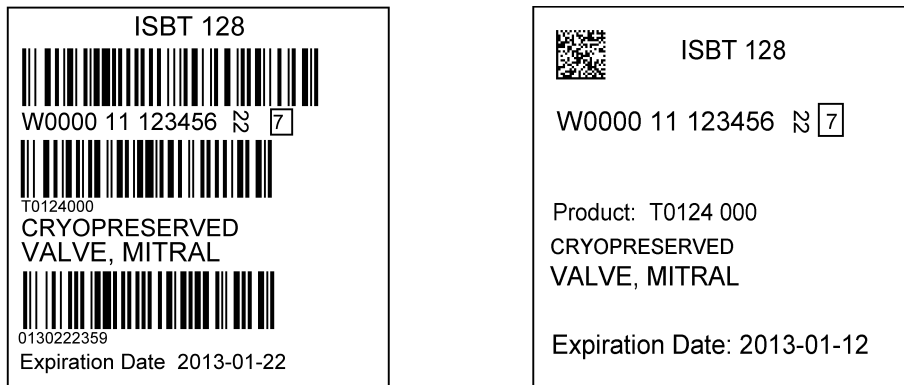
**Figure 10 Flag Characters Used, Generic Product Code**



**Figure 11 Default Flag Characters, Specific Product Code**



**Figure 12 Flag Characters, Specific Product Code**



**Figure 13 No Expiration Date**

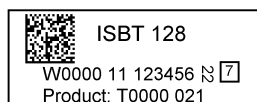


**Figure 14 Expiration Date Included**



### Figure 15 Small Vial Label

Expiration date is encoded into the 2D symbol and must appear in text elsewhere in the labelling.



## Glossary

General Terminology Used in ISBT 128 Coding	
Data Structure	Defined format for information transfer within ISBT 128. The data structure defines the data identifiers, the data content, and the means to encode specific information within the data content. It specifies the context and structure and provides the links to the appropriate reference tables for conversion of codes to meaningful information.
Data Content	The characters in a data structure that encode the desired message (a Product Code, for example)
Terminology Used in Donation Coding	
Donation Event	Recovery of donated tissues from a donor during a single recovery process.
Donation Identification Number (DIN)	A thirteen-character code that identifies tissues from a single donation event. This identifier allows each donation event to be uniquely identified globally for a period of 100 years. The DIN comprises three elements: the Facility Identification Number (FIN), DIN year code, and DIN sequence number.
Facility Identification Number (FIN)	A five-character alphanumeric code assigned to facilities licensed to use ISBT 128 by ICCBBA. The code provides a globally unique identifier that is an essential element of a Donation Identification Number.
DIN Year Code	A two-character numeric code assigned by the facility that is used to ensure uniqueness of a Donation Identification Number for a period of 100 years.
DIN Sequence Number	A six-character numeric code assigned by a tissue facility as part of the Donation Identification Number to ensure unique identification of each donation event.
Flag Character	A two-character numeric code that is an element of the Donation Identification Number Data Structure. Flag characters can be used to identify the specific instance of a DIN label (e.g. distinguish between the DIN label read from a sample tube and the DIN label read from the product packaging) and may be used to facilitate process control.
Check Character	A character used to ensure the accuracy of the data in a data structure when such data is entered manually via a keyboard. The value is calculated by applying an algorithm to the appropriate data (see <i>ISBT 128 Standard Technical Specification</i> for details). The check character is most often used in association with the Donation Identification Number Data Structure but may be used with some other ISBT 128 data structures.

	<p>Example of Donation Numbering:</p> <p style="text-align: center;">Donation Identification Number + Flag Characters + Check Character</p> <div style="text-align: center;"> <p style="font-size: 1.2em; font-weight: bold;">W0000 10 123456 N O</p> <p style="font-size: 0.8em;">             ↓            ↓            ↓            ↓            ↓              FIN            Year            Sequence Number            Flag            Check Character         </p> </div> <p style="text-align: center;">Donation Identification Number</p>
<p>Terminology Used in Product Coding</p>	
<p>Product Code</p>	<p>An eight-character ISBT 128 code that comprises the product description code and a division code/pack number. This code makes each product from a collection unique. This is the Data Content for the Product Code Data Structure.</p>
<p>Product Description Code</p>	<p>A five-character ISBT 128 alphanumeric code assigned to each unique product type listed in the ISBT 128 database.</p>
<p>Division Code</p>	<p>A three-digit number that uniquely identifies multiple products with the same product description code and Donation Identification Number. This code is generally sequentially assigned to products from the same donation event. May also be referred to as pack number.</p>
<p>Pack Number</p>	<p>See Division Code</p>
	<p>Example of Product Coding:</p> <div style="text-align: center;"> <p style="margin-bottom: 10px;">Product Code</p> <p style="font-size: 1.5em; font-weight: bold;">T0212012</p> <p style="font-size: 0.8em;">             Product Description Code            Division Code or Pack Number         </p> </div>