



ISBT 128 For Tissues

An Introduction

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1 Preface

A great deal of important information is presented on the label of a tissue product. The information varies from country to country according to licensing regulations, language differences, and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and that critical items such as the identification number, product description, and expiration date are clearly understood by medical personnel transplanting the graft. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

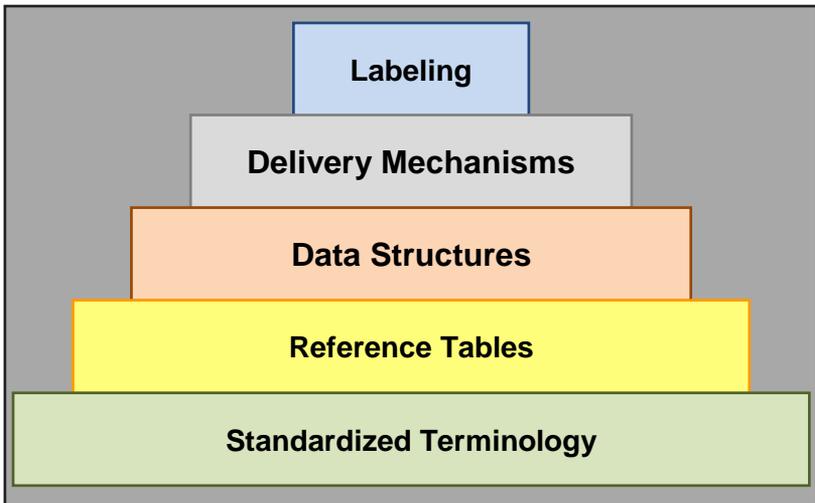
Tissue banking is very much a global endeavor and tissue products are regularly transferred across national boundaries. There is a clearly identified need for ensuring the unique identification of the donation throughout the world and for international agreement on product descriptions. These fundamental requirements are essential for effective traceability on a global scale. An editorial in the Bulletin of the World Health Organization (WHO) (<http://www.who.int/bulletin/volumes/91/5/12-116988/en/>) recognized the need for effective traceability of all medical products of human origin (MPHO), including blood, organs, bone marrow, cord blood, corneas, tissues, reproductive cells, and human milk, to ensure recipient safety and called for the global adoption of ISBT 128 as the coding system for all MPHO. WHO and ICCBBA have a joint work program to take forward this initiative, and ICCBBA has been recognized as a not-for-profit nongovernmental organization in official relations with WHO.

Increasingly, tissue establishments operate sophisticated computer systems to enhance safety and efficiency. Transfer of information between such facilities by electronic means ensures accuracy, but can only be effectively achieved in a global context by use of internationally agreed standards to define the information environment.

2 What is the Information Environment?

The information environment comprises a number of layers (Figure 1) each of which needs to be in place to ensure that standardization can be achieved.

Figure 1



Standardized Terminology

At the base lies the standardized terminology (ST-002 [ISBT 128 Standard Terminology for Medical Products of Human Origin](#)). Without clarity at this level any further attempt at standardization is lost. However, obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus. Terminology must be defined to ensure terms have the same meaning to all. For example, both high and low concentrations of glycerol are used in tissue banking and therefore the term “glycerol” has to be defined in terms of its concentration. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology needs to be accessible to all users of the standard.

Reference Tables

Once the standardized terminology is in place, these can be combined to give the required items of information. Reference tables are built to map each item to a suitable code. Such tables can be large and complex and it is essential that they are managed to ensure that they can be modified to meet the changing needs of clinical practice in a manner that maintains their integrity and avoids ambiguity or redundancy.

Product reference tables in particular need to combine a tightly defined structure with the flexibility to accommodate expansion and change in ways that cannot be anticipated.

Successful management of standardized terminology and reference tables requires input from clinical and scientific experts in the field and from information specialists. The tables themselves need to be published in a manner that allows all users of the standard to access the most up-to-date versions in a timely manner.

Data Structures

Having built reference tables which convert the clearly defined information into codes suitable for electronic transmission, it is necessary to define data structures in which to embed the data. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference tables for conversion of codes to meaningful information.

Data structures need to be clear and unambiguous and must take into account any constraints imposed by the anticipated delivery mechanisms. For example, data structures that will be used in linear bar codes are limited in the number of characters they can contain.

Delivery Mechanisms

The delivery mechanism is the means of delivering the electronic information. Probably the most well-known delivery mechanism is the linear bar code that has been used for many years.

Higher capacity delivery systems are available using 2-dimensional or reduced space symbology bar codes. These codes can carry much more information in each symbol. More recently the use of radio frequency identification (RFID) chips that can carry encoded information is being developed for medical products of human origin.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The standardized terminology, reference tables, and data structures of the information standard can be delivered as easily in a linear bar code as they can in an RFID tag. The standards themselves need to be adaptable in order to make best use of new delivery mechanisms as they are developed.

Labeling

The final element in the coding system is the associated labeling. Although there will be other labeling requirements that fall outside the coding system, an effective coding system needs to consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, there needs to be a mechanism that will ensure correct physical assignment of information to the product, and confidence in the association between electronically stored information and eye-readable printed information. This latter requirement must not be overlooked in the enthusiasm to embrace remotely re-writable tags.

The Information Environment

Together these elements form the Information Environment. For such a system to be, and to remain effective, it must be carefully designed and managed. There must be an ongoing dialogue between clinical users, scientists, information specialists, and equipment and software vendors to ensure that the standard continues to support rapidly developing clinical practice.

3 The ISBT 128 Standard

The ISBT 128 Standard provides the specification for many of the elements of the information environment required in transfusion and transplantation. It defines the lower three levels of the model; the standardized terminology, reference tables, and data structures. Minimum requirements are also defined for delivery mechanisms and labeling. By complying with ISBT 128, recovery and processing facilities can provide electronically readable information that can be read by any other compliant system.

ISBT 128 specifies:

- a donation numbering system that ensures globally unique identification;
- the information to be transferred, using internationally agreed reference tables;
- an international product reference database;
- the data structures in which this information is placed;
- a bar coding system for transfer of the information on the product label;
- a standard layout for the “Four Quadrant” format product label;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance. It has been extended beyond blood transfusion to include cellular therapy, tissues, organ, and banked human milk products. There are over 5,000 facilities in 87 countries registered to use ISBT 128, and this number continues to grow. More than 40 million blood, cell, and tissue products are labeled with ISBT 128 each year.

The most current version of the standard terminology is maintained on the ICCBBA website at www.iccbba.org.

4 Unique Donation Identification

ISBT 128 provides for unique identification of any donation worldwide. It does this by using a 13-character identifier built from three elements: the first identifying the recovery or processing facility that assigns the Donation Identification Number (DIN), the second is the year, and the third is a sequence number for the donation. For example:

G1700 17 600001                          

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product codes. The foundation of this system is a standard terminology which is constructed by international consensus to ensure global consistency in use and understanding. The standard terminology is maintained on the ICCBBA website and is publically available. Tissue terminology is currently managed through Tissue Technical Advisory Groups (see section 9).

New products are defined by combining pieces of information from the standardized terminology in a way that unambiguously describes the product. This process is made easier by the use of the concepts of component class and attributes.

This unique product description is assigned a product description code number that becomes incorporated into the ISBT 128 Product Description Database table, ensuring that the product will be accurately identified in any country in the world that is using ISBT 128.

New entries into the Product Description Code Database can be readily accommodated allowing the system to expand to meet a growing range of products without losing the overall structure of the coding system.

The following example is taken from the database table:

Component Class:	SKIN, FULL WITH HYPODERMIS
Attribute:	Frozen
Attribute:	Cell reduction process:Yes
Attribute:	Radiation sterilization

has a Product Description Code of T0326.

While the description of a product in the Product Description Codes Database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

6 Delivery Mechanisms

The delivery mechanism is the means by which the information is represented in a machine readable manner. The most common such mechanism is the linear bar code. ISBT 128 has traditionally been based on the linear bar code using Code 128 symbology. However, for tissue products a two dimensional Data Matrix symbol may be more of a suitable alternative.

A single Data Matrix symbol can carry the same information as encoded in multiple linear codes. This allows much more rapid scanning of tissues at the point of processing, issue, and receipt into the hospital inventory. In the tissue banking and cellular therapy fields the need to use very small containers means that label size is severely restricted and in these situations the use of a Data Matrix symbol may replace linear codes.

Figure 2 Comparative Size of Code 128 bar codes and a Data Matrix Symbol



The Data Matrix symbol on the left contains all of the information held in the three Code 128 bar codes on the right.

There is much interest in the use of RFID tags. This technology is still developing, but may provide benefits in some situations. ISBT 128 Compound Messages are compatible with RFID.

7 Product Labeling

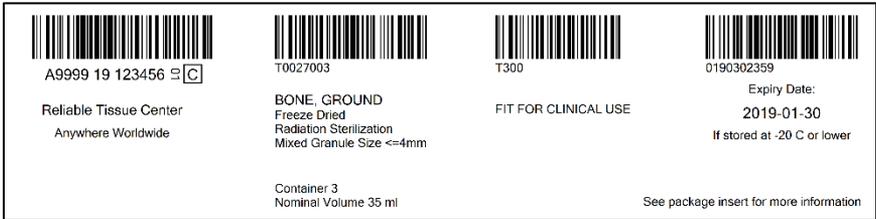
In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides a standard labeling format that ensures a consistent layout of the bar codes on “Four Quadrant” product labels. Critical eye readable information such as the Donation Identification Number, Product Code Description, and expiration date also appear in fixed positions on the label. This reduces the risk of confusion when products from multiple sources are being used.

When space is not an issue, two “Four Quadrant” label formats (see Figures 3 and 4) have been defined for tissues to ensure a consistent layout while retaining the flexibility to cater to a wide variety of container dimensions.

Figure 3 100 mm by 100 mm Label



Figure 4 200 mm by 50 mm Label



When space is an issue, ISBT 128 information may be contained in a smaller area and two-dimensional symbols may be used in place of linear bar codes. These small labels may be used when the container is too small for a "Four Quadrant" label.

Figure 5 65 mm by 34 mm Label with 2D Symbol

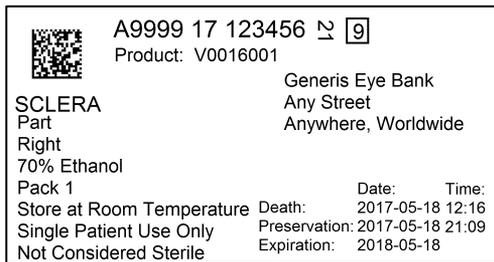
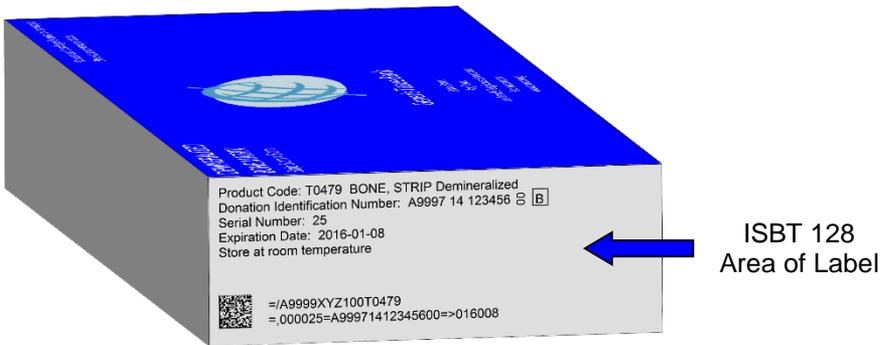


Figure 6 50 mm by 60 mm Label with Linear Bar Codes



Another situation in which a small label may be used is when the design of the label precludes devoting much space to the ISBT 128 information (e.g., when package label graphics and facility-determined text must be retained). In this case, a small ISBT 128 label can be placed anywhere on the package (front, back, side, end) where it will fit.

Figure 7 Use of Small Label on 360 mm by 100 mm Container



8 ISBT 128 and the Single European Code (SEC)

The SEC is a single European coding system that provides information on the main characteristics and properties of tissues and cells that fall under Directive 2004/23/EC of the European Parliament and of the Council. This directive applies to tissue and cell products released for circulation in the European Union unless specifically excluded in the regulation. It does not apply to products regulated under advanced therapy medicinal product regulations.

The implementing directive for the SEC is Commission Directive (EU) 2015/565. This directive further defines what elements comprise the SEC. Legislation requiring Tissue Establishments to apply the SEC take effect from 29 April 2017.

ISBT 128 is a voluntary standard in most countries, although it is mandated in some EU Member States. To comply with the SEC Directive, facilities that are currently using ISBT 128 can utilize data that is already bar coded to derive much of the required content.

To help in creating the SEC for products labeled with ISBT 128, ICCBBA has developed a tool that is now available on the ICCBBA website. The easy to use interface asks users to input specific product and Tissue Establishment information and will generate the eye-readable SEC, as well as the required barcode content.

For organizations responsible for clinical application, ICCBBA has created a data structure that will allow the encoded SEC to be automatically captured.

For facilities not yet using ISBT 128, implementation of both SEC and ISBT 128 simultaneously would save both time and effort. Many changes required for the SEC will involve similar process steps to the implementation of ISBT 128.

Figure 8 Example Label that includes SEC Information

	Z5499 17 123457  N
SCLERA	Product: V0007001
Part Sclera	Generis Eye Bank
Right	Any Street
Pack 1	Anywhere, Worldwide
Store at 2 to 8 C	Date: Time:
Single Patient Use	Death: 2017-05-04 12:16
Not Sterile	Preservation 2017-05-04 21:09
	Expiration: 2017-05-18
	SEC: PL001499Z549917123457
	A00V000700120170518

9 The Role of Technical Advisory Groups

ICCBBA involves international experts in blood, cellular therapy, tissue, and milk banking in the development and maintenance of the ISBT 128 standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly (both face-to-face and through conference calls) to further develop and expand the standard ensuring it continues to meet the needs of its users. The vital role of these groups cannot be overemphasized. It is only through the involvement of such expert panels that ICCBBA can be assured it has the knowledge base to anticipate the needs of its users in fields where change is constant. More than 300 experts participate in the ICCBBA TAGs.

Advisory groups for tissues are listed below:

- (International) Assisted Reproductive Technology Technical Advisory Group (ARTTAG)
- European Tissue Technical Advisory Group (ETTAG)
- (International) Eye Bank Technical Advisory Group (EBTAG)
- International Tissue Technical Advisory Group (ITTAG)
- North American Tissue Technical Advisory Group (NATTAG)

The groups comprise experts in recovery and processing of tissues (including ocular tissues), surgeons (transplant, corneal tissue, and retinal), regulators, professional society representatives, and vendors.

10 The Role of ICCBBA

ICCBBA is the not-for-profit standards body responsible for the management, development, and distribution of the ISBT 128 Standard and is a nongovernmental organization in official relations with the World Health Organization. It maintains a permanent office to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports technical advisory groups that include experts from both the transfusion/transplantation community and relevant manufacturers. Fees collected by ICCBBA from registered facilities are used to support these functions.

Through its activities ICCBBA provides the management support essential to sustain standard coding in the complex and rapidly changing tissue banking environment. In particular it delivers:

- 1) stability – users can be confident in the stability of the standard to satisfy the long time periods over which information has to be retained;
- 2) user focus – the user community are the experts in their field and ICCBBA, through its Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs;
- 3) flexibility – as clinical and scientific knowledge grows there is rapid development with changing information needs. ICCBBA ensures that the standard is flexible enough to accommodate these needs;
- 4) responsiveness – in these rapidly developing medical fields ICCBBA ensures that the standard is able to respond to user needs in a timely manner;
- 5) globalization – ISBT 128 is a truly international standard with endorsement worldwide;
- 6) compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility.

Blood, cellular therapy, tissue, organ, banked human milk collection facilities, and manufacturers of equipment or software that uses ISBT

128, are required to register with ICCBBA and pay a registration and an annual license fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA website at www.iccbba.org.