



ISBT 128 For Tissues

An Introduction

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Table of Contents

1	Preface	5
2	What is the Information Environment?	6
3	The ISBT 128 Standard	12
4	Unique Donation Identification	13
5	Product Descriptions	14
6	Delivery Mechanisms	15
7	Product Labeling	16
8	ISBT 128 and the Single European Code (SEC)	19
9	The Role of Technical Advisory Groups	21
10	The Role of ICCBBA	22

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.

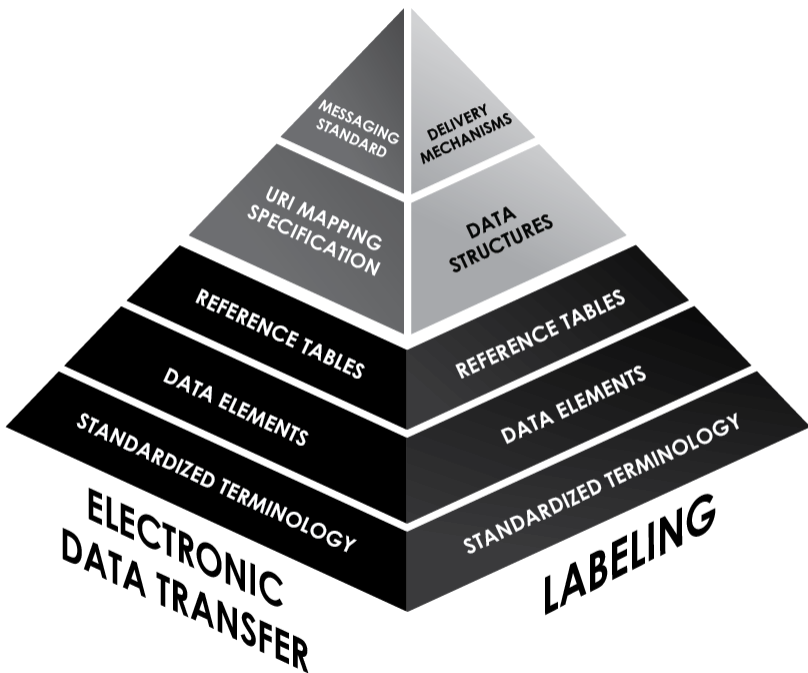
Tissue banking is very much a global endeavor and tissue products are regularly transferred across national boundaries. There is a clearly identified need for ensuring the unique identification of the donation throughout the world and for international agreement on product descriptions. These fundamental requirements are essential for effective traceability on a global scale.

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 model describes how ISBT 128 organizes information to achieve standardization for both labeling and electronic messaging for medical products of human origin.

The foundation of the information environment contains standardized terminology, data elements, and reference tables. These layers support the structures, mechanisms, specifications, and standards necessary to print labels and create electronic messages. These layers are illustrated and described below.



Standardized Terminology

At the base lies the standardized terminology ([ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin](#)) that will ensure a common understanding of terms. ISBT 128 Standard Terminology is the foundation used for both labeling and electronic messaging. Without clarity at this level any further attempt at standardization is lost. Obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus.

ICCBBA ensures that an internationally agreed upon standardized terminology is defined at the required level of granularity. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology is accessible to all users of the standard and ISBT 128 stakeholders.

There are terms regularly used in certain categories of MPHO that require an appropriate level of granularity to clearly convey the characteristics of the product. For tissues, glycerol may be used at different concentrations for different processing steps.

Data Elements

Product information and characteristics such as the Donation Identification Number, product divisions, and Product Description Code constitute a data element. Data elements can be encoded within data structures suitable for use in bar codes applied to product labels, and they can also be identified by a unique resource identifier (URI) in the form of a uniform resource locator (URL) for use in electronic messaging. Data elements provide a mechanism to unambiguously define pieces of information. The data elements are used to build data structures, and in some instances, more than one data element is needed to encode a data structure.

Example:

The product code data structure contains up to 3 data elements: the Product Description Code, the Collection Type, and the Divisions code.

Reference Tables

Reference tables are built to code/decode a single or multiple data elements to provide data compression for use in a data structure. Such tables can be large and complex, and it is essential that they are managed to ensure that they can be modified to meet changes within clinical practices in a manner that maintains their integrity and avoids ambiguity or redundancy.

Reference tables combine a tightly defined structure while allowing the flexibility to accommodate expansion and change in ways that cannot be anticipated.

Successful management of standardized terminology, data elements, and reference tables requires input from both clinical experts in the field and information specialists. The tables are published in a manner that allows all users of the Standard to access the most up-to-date versions in a timely manner.

Together, the standardized terminology, data elements, and reference tables provide the basis for accurately relaying information about medical products of human origin, whether on the label or via electronic data transfer.

Electronic Data Transfer

URI Mapping Specification for use in Electronic Messaging

To support the transmission of ISBT 128 information via electronic messaging, ICCBBA has developed a dictionary of data elements ([ST027 ISBT 128 Dictionary of Standard Data Elements](#)). The information carried in these elements maps to the same information carried in data structures to ensure that information from either source is consistent. Each data element is identified by a unique resource identifier (URI) in the form of a uniform resource locator (URL).

To view an example of a Product Description Code, please go to <https://www.isbt128.org/uri/ProductDescriptionCode>.

Messaging Standard for use in Electronic Messaging

ISBT 128 provides specifications ([ST-020 ISBT 128 Standard for XML](#)) for use in electronic messages to convey information regarding MPHO in a consistent and standardized format.

The MPHO Unique Identifier is a single unique instance identifier developed to provide the basic elements of traceability. The MPHO Unique Identifier was developed to store traceability information on any MPHO and provides a single identifier for use in electronic messaging and electronic health records and should be used as the identifier element for the HL7 FHIR BiologicallyDerivedProduct resource.

This identifier can be created from a standard ISBT 128 label and clearly identifies the specific product being referenced in an electronic message. Specifications for the MPHO Unique Identifier are detailed in [ST-026 ISBT 128 Standard for the Medical Products of Human Origin \(MPHO\) Unique Identifier](#).

Electronic Messages

The development of a standardized approach to incorporate ISBT 128 data elements into electronic messages is an important step in improving the communication between healthcare organizations involved in the production and clinical application of MPHO. By adopting this Standard, organizations will be able to benefit from the MPHO-specific standardized terminology and standard reference tables of ISBT 128 in a wide range of contexts and securely transfer more information about MPHO products with far greater flexibility.

Labeling

Data Structures for use in Labeling

Having built reference tables which convert the clearly defined information into codes suitable for use in bar codes applied to product labels, 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 must be clear and unambiguous and consider 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.

Data identifiers indicate the type of information being conveyed within data structures. It is imperative that the appropriate data identifiers are used for each data structure to ensure the correct interpretation of the encoded information.

Delivery Mechanisms for use in Labeling

The delivery mechanism is the means of delivering the electronic information encoded within data structures. The most well-known delivery mechanism is the linear bar code that has been used in blood transfusion practice 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 must be adaptable to make the best use of new delivery mechanisms, such as Bluetooth Low Energy tags, as they are developed.

Information Environment Summary

Every ISBT 128-labeled product carries a standardized label where product information is encoded in bar codes or electronic tags. Although there will be other labeling requirements that fall outside the coding system, an effective coding system should 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 the 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 rewritable tags.

While highly effective and secure, labeling does have some limitations. In particular, the amount of information that can be encoded on the label depends on the amount of label space available to accommodate bar codes. Thus, as noted in previous sections, ISBT 128 has evolved to allow ISBT 128 information to be transmitted in electronic messages used in healthcare applications in a manner that is compatible with its existing labeling standards, giving the Standard the ability to overcome the limitations of bar codes.

The information environment works together to ensure that accurate ISBT 128 information is encoded within an electronic message or label to accurately identify MPHO products. 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, information specialists, and equipment and software vendors to ensure that the Standard continues to support rapidly developing clinical practices, ensures traceability, improves biovigilance efforts, and increases patient safety.

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.isbt128.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   U

where:

G1700 identifies the recovery or processing facility (in this case NHS Blood & Transplant, Tissue Services, Colindale, United Kingdom);

17 identifies that the DIN was assigned in 2017;

600001 is the sequence number of the donation assigned by the recovery or processing facility.

The two digits printed vertically are flag characters that allow individual bar codes in a number set to be discretely identified providing an option to add process control.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is manually entered into a computer system through the keyboard to verify the accuracy of the keyboard entry.

Facility codes are assigned by ICCBBA who maintain a database of all registered facilities on their website (www.isbt128.org). A lookup program allows lookup of individual facility codes. ICCBBA licensed facilities and vendors are able to download a full listing of all registered facilities.

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.

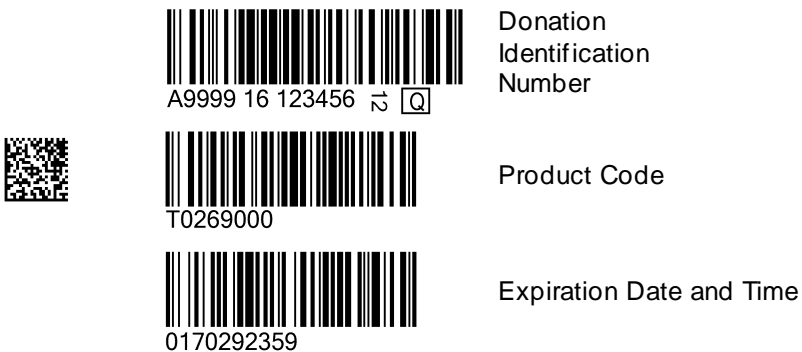
While the description of a product in the Product Description Codes Database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

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

	
A9999 19 123456 Ⓢ C	T300
Reliable Tissue Center Anywhere Worldwide	FIT FOR CLINICAL USE
	
T0027003	0210302359
BONE, GROUND Freeze Dried Radiation Sterilization Mixed Granule Size <=4mm	Expiry Date: 30 JAN 2021 If stored at -20 C or lower
Container 3 Nominal Volume 35 ml	See package insert for more information

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

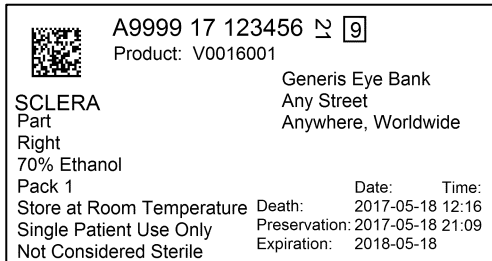
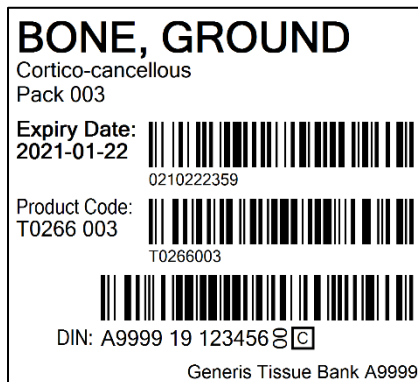
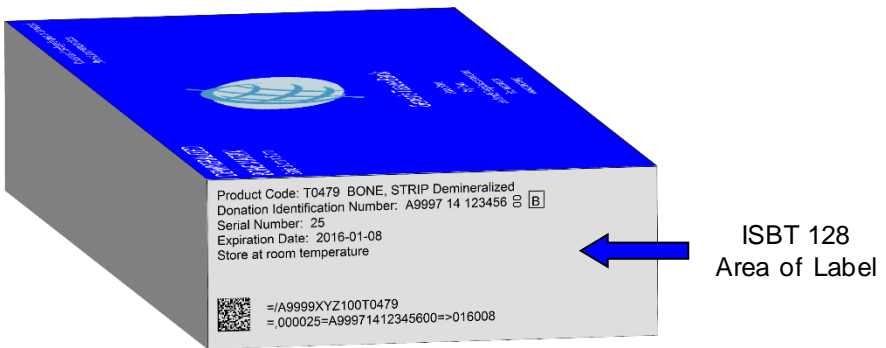


Figure 6 50 mm by 60 mm Label with Linear Bar Codes



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 \approx 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. 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.isbt128.org.