

# ***ISBT 128*** ***For Tissues***



## ***An Introduction***



***ISBT 128***

***More than Identification***





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# Table of Contents

1	Preface.....	5
2	What is the Information Environment? .....	6
3	The <i>ISBT 128</i> Standard .....	9
4	Unique Donation Identification.....	10
5	Product Descriptions .....	11
6	Delivery Mechanisms .....	12
7	Product Labeling.....	13
8	The Role of Technical Advisory Groups.....	16
9	The Role of ICCBBA.....	17

# 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.

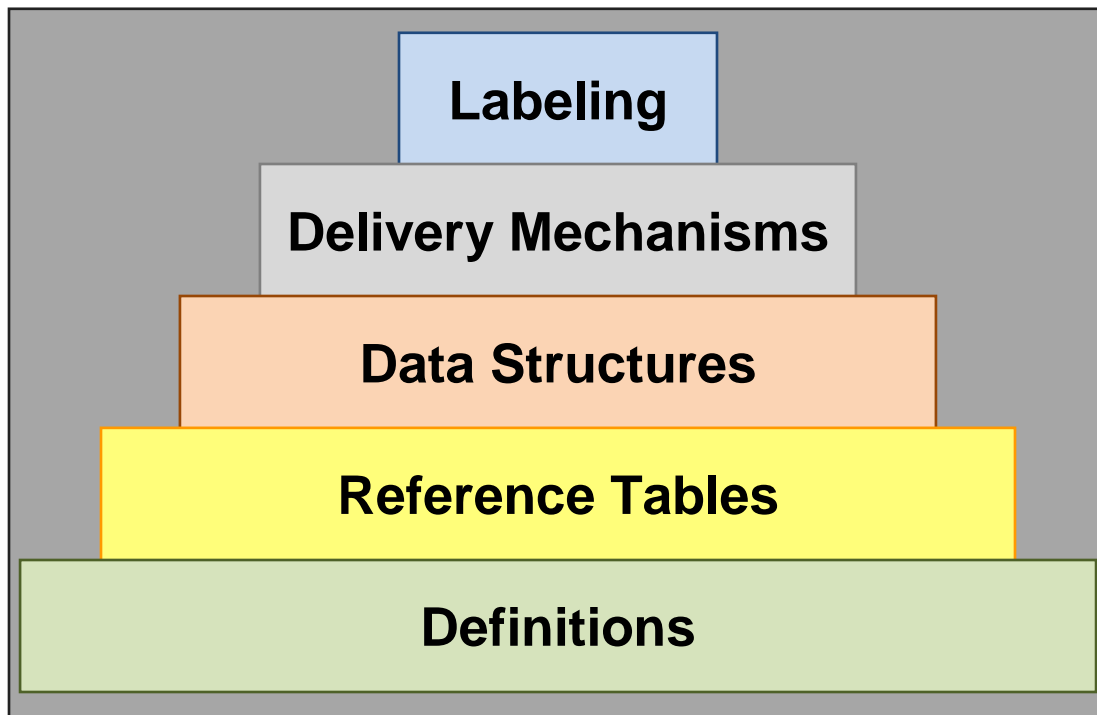
Tissue banking is very much a global endeavor and tissue products are regularly transferred across national boundaries. There is a clearly identified need for ensuring the unique identification of the donation throughout the world and for international agreement on product descriptions. These fundamental requirements are essential for effective traceability on a global scale, and this has been recognized in World Health Assembly Resolution WHA 63.22.

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



### Definitions

At the base lies the dictionary of definitions that will ensure common understanding of terms. Without clarity at this level any further attempt at standardization is lost. However, obtaining agreement on definitions at the necessary level of detail involves careful analysis and robust consensus. Terminology must be defined to ensure the term 'glycerolized' has the same meaning to all. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The dictionary of definitions needs to be accessible to all users of the standard.

## Reference Tables

Once the definitions are in place, these can be combined to give the required items of information. Reference tables are built to map each item to a suitable coding. 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 which 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 which cannot be anticipated.

Successful management of definitions 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 Mechanism

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 in blood transfusion practice for many years. There are in fact several types of linear bar codes including the old fashioned Codabar system that was only capable of encoding numeric information, and Code 128, a bar code standard widely used in coding standards such as GS1 and *ISBT 128*.

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 we are seeing the development of radio frequency ID chips which can carry encoded information.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The definitions, 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 Information Environment hierarchy 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 definitions, reference tables, and data structures. Minimum requirements are also defined for delivery mechanisms and labeling. By complying with *ISBT 128*, collection 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 (linear or 2-dimensional) for transfer of the information on the product label;
- a standard layout for the product label;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance and is now widely endorsed by professional associations in transplantation and transfusion. It is used for the coding and labeling of blood, cellular therapy and tissue products. By the end of 2009, more than 3,500 facilities in 67 countries across six continents were 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.

## 4 Unique Donation Identification

ISBT 128 provides for unique identification of any donation worldwide. It does this by using a 13 character identifier built up from three elements, the first identifying the collection or processing facility, the second the year, and the third a sequence number for the donation. For example:

**G1700 10 600001** 

1
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where:

**G1700** identifies the collection or processing facility (in this case National Health Service Blood and Transplant, England, United Kingdom);

**10** identifies the collection year as 2010;

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

The two digits printed vertically allow individual bar codes in a number set to be discreetly identified hence 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 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.iccbba.org](http://www.iccbba.org)). A lookup program allows lookup of individual facility codes. ICCBBA licensed facilities and vendors are able to download a full listing of all licensed 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 the European and North American Tissue Technical Advisory Groups of ICCBBA.

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

This unique product description is assigned a product 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 dictionary 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.

An example taken from the database tables is:

Component Class:	Achilles Tendon
Modifier:	Freeze Dried
Attribute:	Irradiated
Attribute:	Single

has the product code T0087.

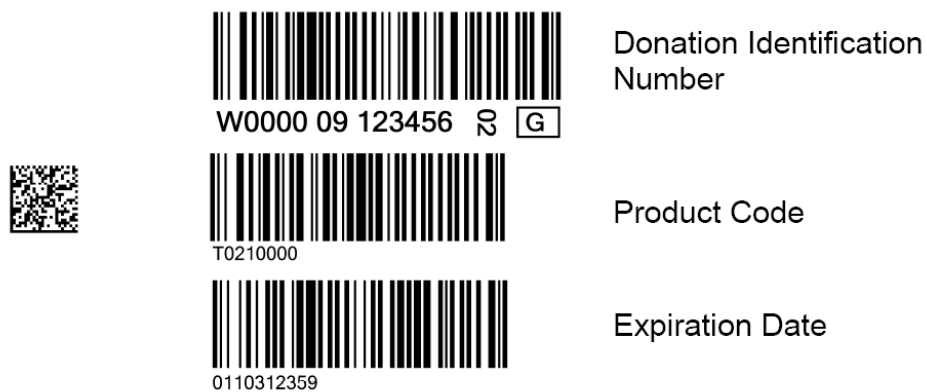
While the description of a product in the product code database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

## 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 the Code 128 symbology and this is still required on blood donations. However, for tissue products a two dimensional Data Matrix code may be a more suitable alternative.

A single Data Matrix code can carry the same information as encoded in multiple linear codes. This allows much more rapid scanning of units at the point of Tissue Processing Establishment issue and receipt into the hospital inventory. In the Cellular Therapy and Tissue Banking fields the need to use very small containers means that label size is severely restricted and in these situations a use of Data Matrix code may replace linear codes.

**Figure 2 Comparative size of Code 128 and Data Matrix Codes**



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






There is much interest in the use of radio-frequency identification (RFID) tags. This technology is still developing, but may provide significant 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 number of standard labeling formats that ensure a consistent layout of product labels with the bar codes, and critical eye readable information (such as donation identification number, product description and expiration date) appearing 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 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**

	
W0000 10 123456 	T300
Accurate Tissue Provider Anywhere, Worldwide	FIT FOR CLINICAL USE
	
T0027003	0120222359 Expiry Date
FREEZE DRIED GROUND BONE IRRADIATED MIXED GRANULE SIZE <4 mm	22 JAN 2012 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. This small label may be used when the container is too small for a 100 mm by 100 mm label.

**Figure 5 50 mm by 50 mm Label with 2D Symbol**

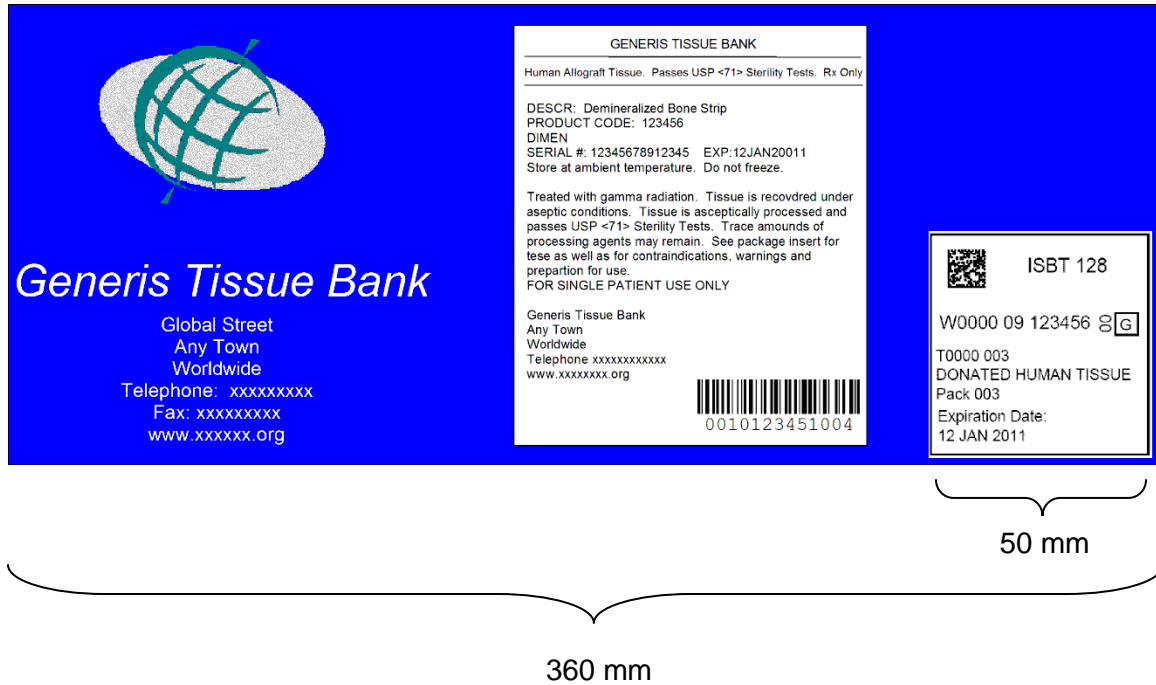


**Figure 6 50 mm by 50 mm Label with Linear Bar Codes**



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, the small ISBT 128 label can be placed anywhere on the package (front, back, side, end) where the 50 mm square label will fit.

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



## 8 The Role of Technical Advisory Groups

ICCBBA involves international experts in blood, cellular therapy, and tissue banking in the development and maintenance of the 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 150 experts participate in the ICCBBA TAGs.

For tissues, there are three advisory groups: the North American Tissue Technical Advisory Group (NATTAG), the European Tissue Technical Advisory Group (ETTAG) and the international Eye Bank Technical Advisory Group (EBTAG). The groups comprise experts in recovery and processing of tissues (including ocular tissues), surgeons (transplant, corneal tissue, and retinal), regulators, representatives from standard-setting organizations and vendors.

## 9 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 made up of 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 (e.g. EC requirements for data to be stored and traceable for 30 years);
- 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 and Tissue 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](http://www.iccbba.org).