



# ***ISBT 128***

## ***For Tissues***

### ***An Introduction***





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# 1 Copyright

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## 2 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 unique identification number, expiration date, and product description are clearly understood by medical personnel transplanting the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

In today's world of international databases of patients and donors, multinational disaster relief programs, and military operations, tissue collected in one country may be used in another. In such situations the criteria identified above still have to be met.

Increasingly, facilities dealing with the collection and transplantation of tissue operate sophisticated computer systems to enhance safety and efficiency. The use of bar coding for donations and samples is an effective means of both speeding up the information transfer process and eliminating the risk of transcription errors. Combined with the use of on-line test equipment it can ensure the secure labeling and release of product hence enhancing patient safety.

Transfer of information by electronic means ensures accuracy, but can only be effectively achieved in a global context by use of internationally agreed standards for both the information and its delivery mechanism.

*ISBT 128* provides such an international standard. It 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 the electronic transfer of the information from the product label to a computer system without the risk of transcription errors;
- a standard layout for the product label;
- a standard reference for use in electronic messaging.

## **3 Background to *ISBT128***

*ISBT128* was originally developed as a replacement for the ABC Codabar system of labeling blood and blood components. The standard, originally accepted by the International Society of Blood Transfusion (ISBT) Council in 1994, gained widespread acceptance and is now endorsed by the AABB, European Plasma Fractionators Association, and European Blood Alliance. By the end of 2006, facilities in 50 countries across six continents were registered to use *ISBT128* and this number continues to grow.

In 2000, the Tissue Banking Service within England's National Blood Service was looking for a standardized and secure way to identify tissue products. They recognized the potential for using *ISBT128* and set up a project to evaluate the suitability of this standard for tissue labeling. The outcome of this evaluation was positive, and a co-operative effort between UK Tissue Banks and ICCBBA Inc. led to the development of a tissue product database and a tissue labeling standard, both now available from ICCBBA Inc.

*ISBT128* offers a reliable and secure system for the identification of tissue products and satisfies the most stringent regulatory requirements for traceability.

Tissue identification using *ISBT128* is now in use in England and Denmark and other nations are actively looking to introduce the system.

## 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 facility, the second the year, and the third a sequence number for the donation. For example:

G151707600001  

where:

G1517 identifies the collection facility (in this case Welsh Blood Service, Wales, United Kingdom);

07 identifies the collection year as 2007;

600001 is the sequence number of the donation assigned by the collection 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 into the collection process.

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.

Collection facility codes, also known as Facility Identification Numbers (FINs) are assigned by ICCBBA, Inc, who maintains a database of all registered facilities on their Website. The collection center associated with a given FIN can be identified using a look-up program (Figure 1) on the ICCBBA, Inc website. Currently this look-up program may be found at [http://www.iccbba.org/reg\\_facilitylookup.cgi](http://www.iccbba.org/reg_facilitylookup.cgi).

**Figure 1 Registered Facility Look-up Program**

*Registered Facility Information*

Search Results:

<b>Facility ID:</b>	G1517
<b>Firm Name:</b>	Welsh Blood Service
<b>City:</b>	Pontydlun
<b>State/Province:</b>	Wales
<b>Country:</b>	United Kingdom
<b>Postal Code:</b>	CF72 9WB

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Search again:

Facility Number:

A single donation number is assigned to cover a donation event - all components collected during that event carry the same number and are distinguished from each other by the product code.

Together the donation number and product code can uniquely identify the specific tissue product from a particular donor, and even distinguish individual packages of the same product.

## **5 Data Structures for Critical Information**

In addition to the donation identifier, many other pieces of important information need to be provided with a tissue donation. *ISBT128* provides data structures for the following:

ABO and Rh(D) Blood Groups;

Product Description (see next section);

Type of Donation (Volunteer, Directed, Autologous, etc);

Expiration Date (and Time);

Red Cell Phenotyping Information;

HLA Typing Information;

Donor Identification Number;

as well as a number of other data structures covering such areas as patient identification number, patient date of birth and staff member identification.

## 6 Product Description Databases

*ISBT 128* provides a comprehensive and highly flexible system for assigning product description codes. New codes are built by specifying a combination of a component class, a modifier (if needed), and a range of possible attributes. A unique combination of these values 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*.

Coding begins with selection and definition of terms by the international user community. These terms are divided into groups called

- Classes (a general description of the product),
- Modifiers (further defining the product) and
- Attributes (providing detailed information about the product).

The terms and definitions are found in a document called *ISBT 128 Product Coding: Bounded Lists and Definitions* that may be found on the ICCBBA, Inc Website. An example from this document is:

Cancellous Bone Peg (a class) is defined as:

CANCELLOUS BONE PEG	Cancellous bone, cut as a single piece of nominally 15 x 15 x 30mm.
------------------------	---

Freeze dried (a Modifier) is defined as:

Freeze Dried	Processed to remove extraneous tissue and, in the case of bone, to deplete trabecular bone marrow. Freeze-dried to less than 5% residual moisture.
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Single and Irradiated (both Attributes) are defined as:

Single	issued as a single item
--------	-------------------------

and

Irradiated	exposed to gamma irradiation at a target absorbed dose of not less than 15kGy in the final container
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The terms may be combined for a complete description of a product:

Component Class: Cancellous Bone Peg  
 Modifier: Freeze Dried  
 Attributes: Single  
 Irradiated

The product, once described, is given a product description code. For example, the product description code for this product is T0055.

Other examples include:

Component Class: Skin, Small  
Modifier: Glycerolized  
Attributes: Irradiated

has product description code T0104.

Component Class: Valve, Aortic  
Modifier: Cryopreserved  
Attributes: None

has product description code T0122.

The product description code is combined with a container number to produce the product code. The system allows up to 999 container numbers associated with a single product description. In this way each individual pack of a product such as ground bone can be identified and tracked.

Component classes, modifiers, and attributes, together with the database of assigned codes, are maintained by ICCBBA Inc.

Where description codes are required for products not yet defined, a simple request process is available and these can be added to the database within a matter of a few weeks.

# 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 product labels with the bar codes, and critical eye readable information (such as 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.

Two label formats (see Figures 2 and 3) have been defined for tissues to ensure a consistent layout while retaining the flexibility to cater to a wide variety of container dimensions. Example labels are illustrated below.

**Figure 2 100 mm by 100 mm Label**



**Figure 3 200 mm by 50 mm Label**



## 8 ISBT 128 Data Structures

The data structures specified in *ISBT 128* are simply the formal definitions of how information is to be identified and electronically presented. These definitions allow software developers to provide the interfaces necessary to output and input messages containing *ISBT 128* data structures. When used in bar coding, each data structure commences with specified data identifier characters. These ensure that there can be no ambiguity arising from a user scanning the wrong bar code on a label.

The data structures also provide a standard reference that allows transfusion and transplantation information to be encoded within electronic messages such as HL7.

## 9 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 and this is still used where space permits. With very small containers, label size is severely restricted. In these situations a more efficient two-dimensional Data Matrix code can be used. By using the *ISBT 128* Compound Message, many pieces of information can be combined into a single code that occupies a very small area.

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.

## 10 The Role of ICCBBA, Inc.

ICCBBA, Inc is a non-profit organization that has the responsibility for the management, development, and distribution of the *ISBT 128* specification and databases. It maintains a permanent office to manage the registration of facilities, updating of reference tables and databases, and development of additional functionality. It supports technical advisory groups made up of experts from both the transfusion/transplantation community and relevant manufacturers.

Blood, Cellular Therapy, and Tissue collection facilities, and manufacturers of equipment or software that uses *ISBT 128*, are required to register with ICCBBA, Inc and pay a registration and an annual license fee. Registered organizations obtain access to all ICCBBA, Inc documents and databases.

For further information on *ISBT 128* visit the ICCBBA, Inc Website at [www.iccbba.org](http://www.iccbba.org).