

10 Myths about ISBT 128

We will have to share proprietary information about our products to get ISBT 128 Product Codes

You do not have to share any proprietary information with ICCBBA. ICCBBA product codes are based on generic descriptions of products and do not go down to the level of individual proprietary processes. You would select the ISBT 128 product code that best describes your product at the generic level to form the ISBT 128 element of your product code.

Our product codes will be identical to our competitors

In developing ISBT 128 for tissues, ICCBBA has introduced a processor specific element into the product coding system. The product code in ISBT 128 now comprises a standardized ISBT 128 product description code that describes the product at the generic level, and a facility product code that is assigned by the tissue processor to identify their specific products.

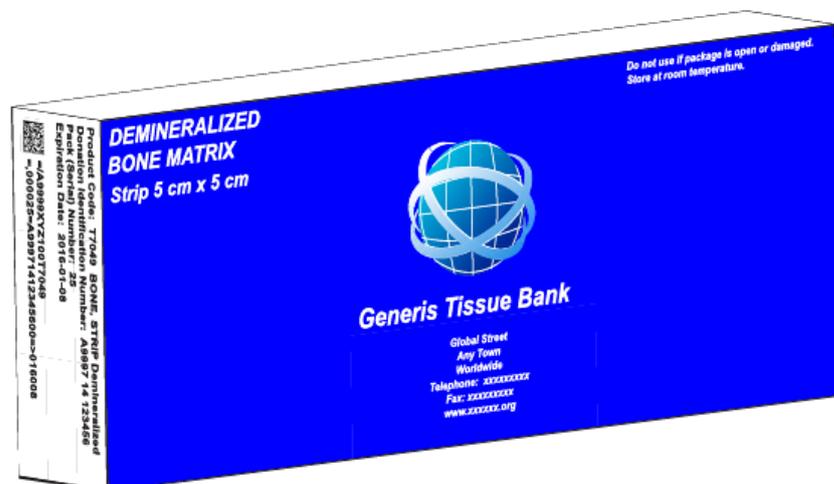
We will have to re-engineer our entire information management process to use ISBT 128

ISBT 128 only requires standardized coding on final product. Tissue banks can continue to use existing systems for information management within the tissue bank. The ISBT 128 information can be generated at final labelling as long as the donation identification number is the same for all tissue processed from one donor, and the tissue bank retains the information links to ensure it can track back from the ISBT 128 information to its internal records. Having said this, many user facilities have discovered that rolling out ISBT 128 through their entire processing operation has helped to improve efficiency and accuracy.

We will be forced to use a standard label design and lose our proprietary image

Traditional ISBT 128 labeling used in blood transfusion and cellular therapy involves a high degree of standardization of the label design. In developing a solution for tissue ICCBBA have recognized the importance of proprietary packaging design and have therefore minimized the amount of standardized information required. ISBT 128 now only requires a portion of the package label to be standardized, carrying the ISBT 128 bar code and essential eye-readable information. Tissue processors have flexibility over where this standard information is positioned. Proprietary naming and descriptions are not affected. See example below where the ISBT 128 information has been placed on the end flap of the package.

ISBT 128
Information



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Once we start using ISBT 128, ICCBBA may significantly increase its fees

ICCBBA has been providing the ISBT 128 Standard for 20 years and has developed a reputation for responsible financial management and use of resources. Annual license fees are determined by the ICCBBA Board of Directors who are volunteer experts, many working for organizations licensed with ICCBBA. Board Members receive no remuneration, and have no long term association with ICCBBA (max 7 years) thus they can maintain the necessary balance and independence to ensure stakeholders receive good value for money.

ISBT 128 is no better than other standards approved for UDI

ISBT 128 has been specifically designed to meet the special traceability needs of medical products of human origin. In particular it incorporates the identification of the donor within the standard to ensure this identification is globally unique and is presented in a standard format. The donation identification number and standard generic product code, together with the growing international consensus supporting ISBT 128, are the unique features which make ISBT 128 the clearly recognized solution for labelling all tissue products. As stated by the World Health Organization: "ISBT 128, managed by ICCBBA, is the sole global standard for the identification and coding of medical products of human origin."

Hospitals will not be able to read ISBT 128 codes

ISBT 128 has been in use in the US for many years. The entire US blood supply uses ISBT 128 so any hospital that provides transfusion support will be familiar with ISBT 128. Cellular therapy and eye banking professionals in the US are committed to implementation of ISBT 128. The great majority of hospitals will have computer systems capable of reading ISBT 128 codes for blood transfusion. A number of software vendors have developed, or are developing, systems capable of managing tissue labelled using ISBT 128.

Traceability will be the same regardless of the coding system used

Traceability in tissue banks is already effective and rapid, and the adoption of any of the approved coding systems is unlikely to impact upon this. However traceability through distributors and hospitals to final use is of variable quality and in some cases tracking can take a long time. Use of ISBT 128 will provide a standard coding platform which software systems can utilize to provide rapid tracking throughout the entire supply chain. The standard presentation of the donation identification number is crucial to effective tracking and recall and is unique to ISBT 128.

The choice of coding system will not impact our exports

There is a growing consensus at the international level on the need for global standards in tissue and cell terminology and coding. This is clearly stated in World Health Assembly Resolution 63.22 (2010). ISBT 128 is recognized as the sole global standard suitable for this role, and implementation is moving forward in a number of countries. Facilities in 22 countries are now using or implementing the standard for tissues and there is little doubt that the global convergence towards ISBT 128 will continue. ISBT 128 the only coding system approved for use in the UDI by FDA that is also approved for use in the Single European Code (SEC) which will be required to appear on all tissues distributed in the EU. Other coding systems may be used on exports to the EU but the allocation of a SEC by the importing tissue establishment will be considerably more complex.

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We will have to provide sensitive commercial information to ICCBBA

ICCBBA is a standards organization and provides the ISBT 128 Standard and its associated reference tables and databases. In order to support globally unique identification of medical products of human origin ICCBBA manages the register of facility identifiers, and for this purpose retains basic information on licensed facilities (including name, address, country, contact details) some of which appears in the public register available to licensed facilities (see example of public information below).

FIN	Firm Name	City	State/Prov	Country	ZIP	Web Site	Alt Name	Country code	Type of Facility
G1016	Scottish National Blood Transfusion Service-Tissues	Edinburgh	Scotland	United Kingdom	EH17 7QT	www.scotblood.co.uk		GB	BCF;

In addition, ICCBBA holds activity information (for tissue banks, total number of grafts distributed). This is used for license billing purposes only and remains confidential. ICCBBA holds no information on the products prepared by tissue banks or the processes used to prepare them.