

**Title:** ISBT 128 and Traceability from Point of Origin to Point of Use

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### Abstract

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**Background:** A key aspect of biovigilance—essential to safeguarding communities—is traceability. Standardization supports traceability in the manufacturing and distribution of medical products of human origin (MPHO). However, identification of gifted human tissue materials from the point of origin is critical for lookback in the event of an adverse event, such as disease transmission. ISBT 128 supports biovigilance efforts as an international standard for the transfer of information associated with MPHO, specifically through globally unique identification starting from the point of donation.

**Hypothesis:** ISBT 128 standards for identification of MPHO can facilitate retrieval of data related to the point of origin for human tissues.

**Methods:** *ISBT 128 Standard Technical Specification (ST-001)* was developed collaboratively with a broad range of stakeholders in various MPHO branches and supports the international traceability of human tissue materials from the point of origin to the point of use via a globally unique identifier that can link donor and patient records without compromising anonymity. Within the ISBT 128 standard, the globally unique donation identification number (DIN) can be combined with other ISBT 128 key elements of traceability, as follows:

1. A product description code (PDC), assigned at the point of collection or production.
2. A division identifier (DIV), assigned at production, if applicable.
3. A processing facility identification number [FIN(P)], assigned by the facility assigning the product code, if different from the facility that assigned the DIN.

Figure 1 shows an ISBT 128 label with these elements, collectively known as the MPHO Unique Identifier. Following GTPs, facilities record these data elements manually or

(ideally) enter them electronically in collection and production tracking and tracing software to be easily retrieved.

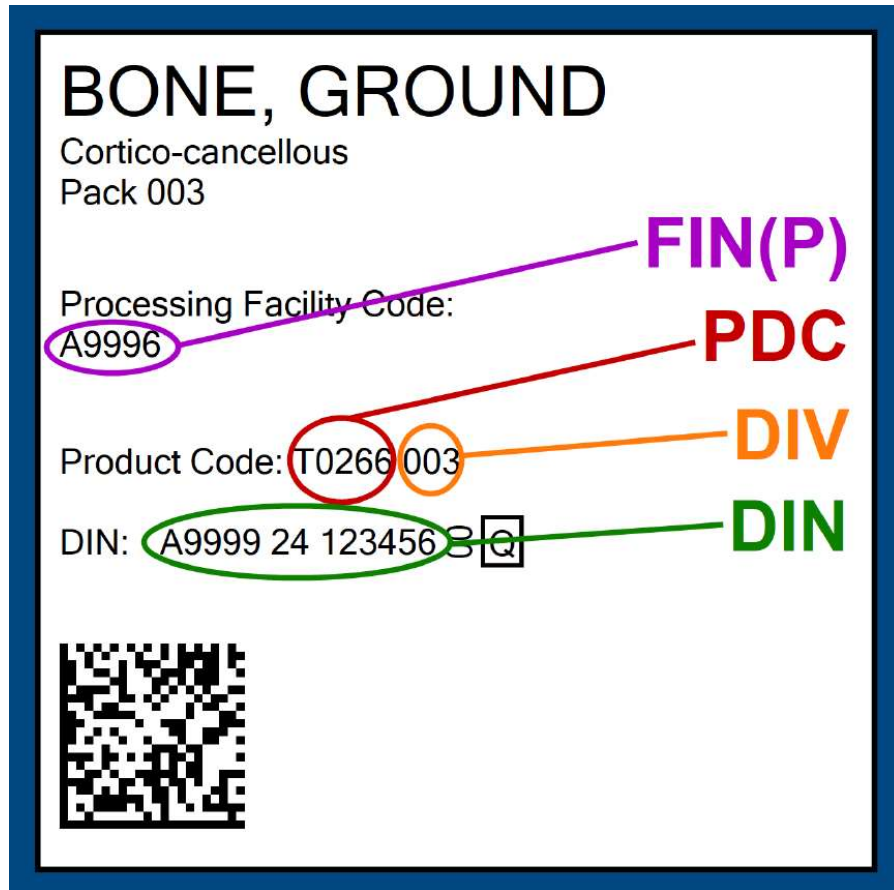


Figure 1

**Results:** ISBT 128 globally unique identification can effectively support the international traceability of MPHO. It can be integrated into existing local and national track and trace systems, throughout all stages of human tissue products, from the original gift to processing, handling, distribution, and use.

This internationally recognized identification system can facilitate the seamless exchange of human tissue material between different healthcare facilities and enhance operational efficiency. Furthermore, it can help strengthen biovigilance and reduce the time interval between detecting a safety or quality risk in human tissue products and their effective recall worldwide.

**Conclusion:** Through ISBT 128 standards for identification of gifted tissue materials of human origin, data related to the point-of-origin can be readily retrieved, supporting the rapid responses to adverse events critical to biovigilance efforts.

# ISBT 128 and Traceability from Point of Origin to Point of Use

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## Background

A key aspect of biovigilance—essential to safeguarding communities—is traceability. Standardization supports traceability in the manufacturing and distribution of medical products of human origin (MPHO). However, identification of gifted human tissue materials from the point of origin is critical for lookback in the event of an adverse event, such as disease transmission. ISBT 128 supports biovigilance efforts as an international standard for the transfer of information associated with MPHO, specifically through globally unique identification starting from the point of donation.

## Hypothesis

ISBT 128 standards for identification of MPHO can facilitate retrieval of data related to the point of origin for human tissues.

## Methods

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## Results

ISBT 128 globally unique identification can effectively support the international traceability of MPHO. It can be integrated into existing local and national track and trace systems, throughout all stages of human tissue products, from the original gift to processing, handling, distribution, and use (see figure 2).

This internationally recognized identification system can facilitate the seamless exchange of human tissue material between different healthcare facilities and enhance operational efficiency. Furthermore, it can help strengthen biovigilance and reduce the time interval between detecting a safety or quality risk in human tissue products and their effective recall worldwide.

## Conclusion

Through ISBT 128 standards for identification of gifted tissue materials of human origin, data related to the point of origin can be readily retrieved, supporting the rapid responses to adverse events critical to biovigilance efforts.

Figure 1

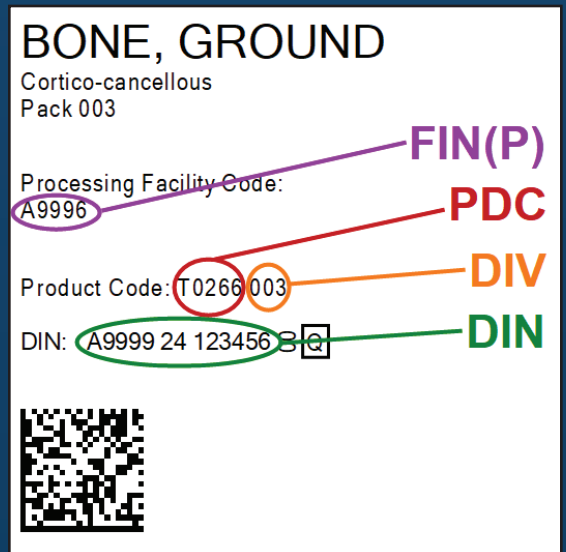


Figure 2

