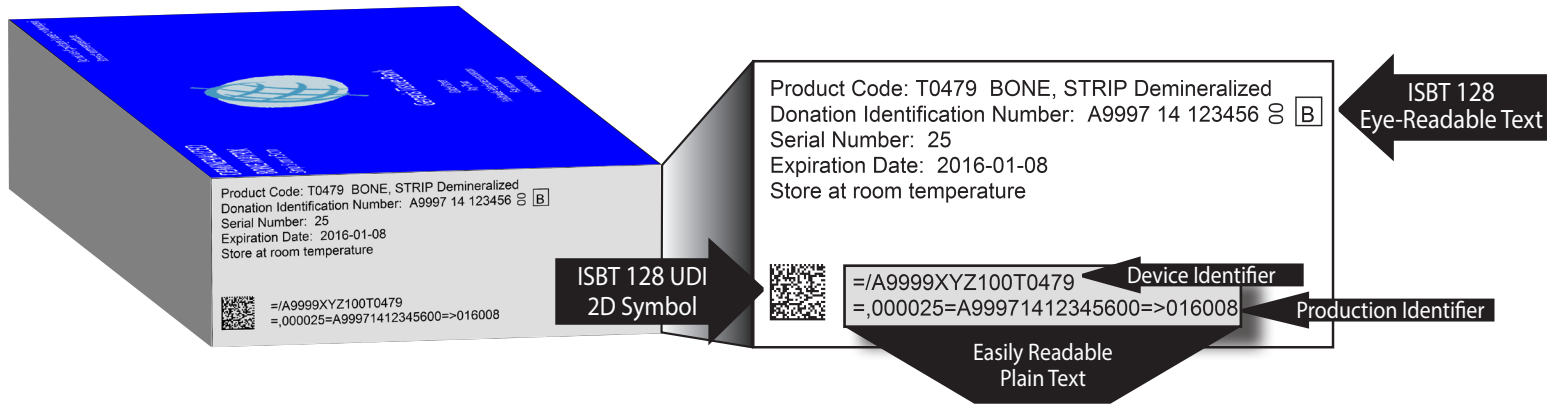


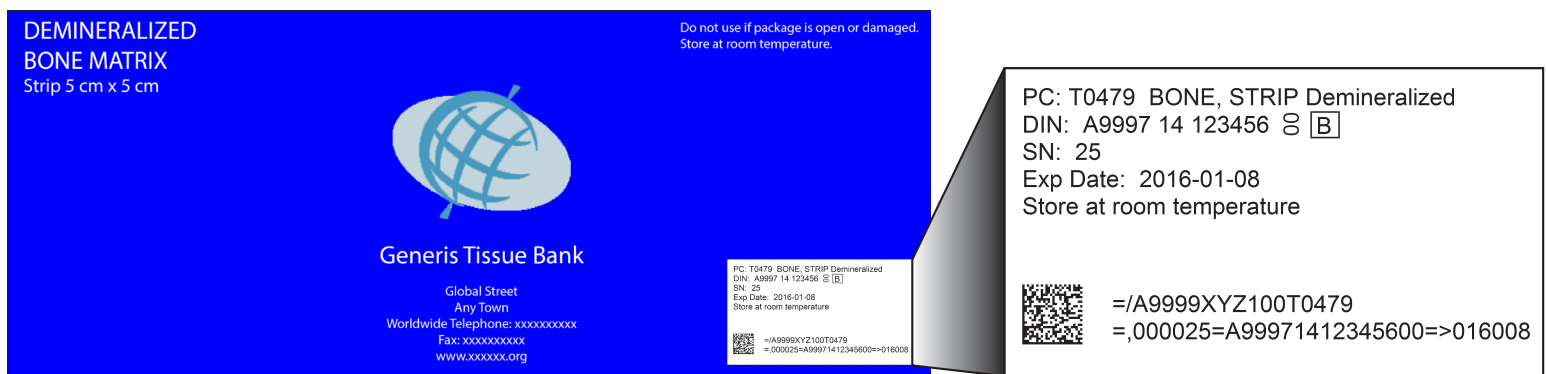
USING ISBT 128 UNIQUE DEVICE IDENTIFIER ON MEDICAL DEVICES THAT CONTAIN HUMAN TISSUE



Medical devices containing Human Cells, Tissues, or Cellular and Tissue-Based Products (HCT/P) labeled using ISBT 128 will provide UDI information, including the Donation Identification Number, in a standardized electronically-readable format and in eye-readable text. These illustrations show examples of how the information may be presented. The two-dimensional symbol contains the critical tracking information. Receiving systems should be programmed to scan and interpret this symbol to provide optimal efficiency and accuracy.



| Item | Recommended Abbreviation(s) | What it Identifies |
|----------------------------------|-----------------------------|--|
| Donation Identification Number | DIN | This identifier links the product to its donor (the Distinct Identification Code as required by 21 CFR 1271.290(c)). |
| Product Code | Prod Code or PC | This code identifies the type of product (e.g., bone powder or a pre-sutured tendon). |
| Pack Number or Serial Number | Pack or SN | This code uniquely identifies a specific product for a given DIN and Product Code. |
| Expiration Date | Exp or Exp Date | The date on which the product should no longer be used. |
| Manufacturing or Production Date | Mnf Date or Prod Date | The date on which the product was made. |
| Lot Number | Lot No. or LN | This identifier links to a production record of the process or the tissue. |
| Device Identifier | DI | The FDA UDI Device Identifier (identifies the specific version or model of a device and the labeler of the device). |
| Production Identifier | PI | The FDA UDI Production Identifier (information that more precisely identifies the device). |



GS1 and ICCBBA Joint Guidance recommends use of ISBT 128 on medical devices containing HCT/P.