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# TISSUE ALLOGRAFT CODING AND TRACEABILITY IN UNIVERSITI SAINS MALAYSIA TISSUE BANK

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### **SUMMARY**

Tissue banking in Malaysia was pioneered by the Universiti Sains Malaysia (USM) Tissue Bank in the early 1990s. Since then, allografts from the bank have been distributed to surgeons from private and government institutions around the country. The wide distribution of the graft to surgeons requires the bank to properly document the data and information regarding the respective graft for traceability purpose. The need of graft identification and traceability is further emphasized by the current standards ISO 9001 and ISO 13485. Hence, USM Tissue bank has adopted a coding system in order to comply with established standards and the need to provide graft with proper quality assurance. Coding of type of graft and any materials used in the graft processing starting from donor donation until distribution were created to ensure the identification and traceability based on coding system are traceable. Each tissue donated to the bank is assigned to unique coding after fulfilling certain mandatory criteria. The unique coding assigned to the graft enable the differentiation of type of tissue donated, the undergoing process and later the graft produced. The coding system is applied to cover the whole duration of the graft in the bank. The designed coding systems permit the tissue being traced between the donors to end user back and vice versa. In term of traceability, each graft are accompanied with records and forms designated to represent the undergoing status of the graft. These forms and records are later compiled and maintained in the bank for reference purposes. The coding system used by USM Tissue Bank has been effective for identification and traceability of tissue graft back and forth with proper documentation and record.