creos™ allograft

Processing summary

The creos allografts portfolio offers you a wide range of particulate grafts and a 100% demineralized bone matrix (dbm) putty (creos allo.gain) as well as a pericardium barrier membrane (creos allo.protect). The allograft tissue bank follows strict processing procedures in order to ensure safe tissue grafts of the highest quality for transplantation.

At a glance

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Donor selection process & recovery

Every donor is thoroughly evaluated using medical and social history assessment, medical records, blood tests, culture results, physical examinations and autopsy reports (when performed). In-house medical doctors review all donor information, and, if found acceptable, the tissue is released for processing. Donors are recovered by recovery organizations throughout the United States and are registered with the FDA as an HCT/P establishment pursuant to 21 CFR part 1271. Each donor can be tracked from recovery to distribution to the end-user.

Testing

All donors are tested and found negative (acceptable) for anti-HIV 1/2, HBsAg, anti-HBc, anti-HCV, HIV NAT, HBV NAT, HCV NAT, and syphilis. Communicable disease testing is performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493.

Processing, bioburden reduction & sterilization

Prior to processing, each individual recovered tissue undergoes microbiological cultures to ensure pathogenic organisms are not introduced to the processing environment. *All allograft processing is performed in cleanrooms that are classified as ISO Class 5 (Class 100), cycling HEPA filtered air approximately 535 times per hour. Furthermore, the processing facility is constructed to ensure a unidirectional laminar airflow from the HEPA filters installed in the ceiling to returns installed on the lower wall.*

A patented bioburden reduction process, in combination with terminal irradiation, provides a Sterility Assurance Level (SAL) of 10-6 in their final packaging following ISO 11137 Method 2B. A 10-6 SAL means the probability of a graft being non-sterile is 1 in 1,000,000. Tissues are sterilized using gamma irradiation.

Tissue bank facility located in Kettering, OH

Storage & distribution

A centralized tissue management system is used to track each tissue graft from recovery to final distribution using a unique identification number that includes the six-digit donor number and the sequential graft number. Lyophilized grafts can have up to a 5-year expiration date and putty grafts can have up to a 2-year expiration date from the date of packaging.

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