Each lot of Demineralized Bone Matrix (DBM) incorporated into ALLOMATRIX® C, ALLOMATRIX® Custom, ALLOMATRIX® DR, and ALLOMATRIX® RCS Putties is evaluated in vitro using a surrogate cell-based assay. The bioassay measures the proliferation of Saos human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductivity index). Results from this bioassay were correlated to the athymic rat model and to clinical results of assayed DBM alone.

Or

Each lot of DBM incorporated into ALLOMATRIX® C, ALLOMATRIX® Custom, ALLOMATRIX® DR, and ALLOMATRIX® RCS Putties is assayed in vitro for a native protein (BMP-2) as a surrogate test marker for osteoinductive potential. Results from this immunoassay were correlated to the athymic rat model for the DBM alone and the ALLOMATRIX® Putty. Although only one native protein is used as the test marker, it is the combination of various proteins that is responsible for its osteoinductive potential.

Testing each lot of DBM with this cell-based bioassay or immunoassay assures that only DBM with osteoinductive potential is used in the ALLOMATRIX® C, ALLOMATRIX® Custom, ALLOMATRIX® DR, and ALLOMATRIX® RCS Putties. The combination of DBM, Cancellous Bone Matrix (CBM), and binding medium has not been evaluated for osteoinductivity; therefore, it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the in vitro bioassay or immunoassay, will correlate with human clinical performance of ALLOMATRIX® C, ALLOMATRIX® Custom, ALLOMATRIX® DR and ALLOMATRIX® RCS Putties.

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Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

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   This study correlated the results from the in vitro bioassay to results in the athymic rat model and clinical results of the DBM.


3. Data on file at Wright Medical Technology, Inc.