

DBM Osteoinductivity Potential Certificate (150827-0)

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 assay¹. The bioassay measures the proliferation of Saos human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductivity index)¹. Results from this bioassay were correlated to the athymic rat model² and to clinical results of assayed DBM alone¹.

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 potential³. Results from this immunoassay were correlated to the athymic rat model for the DBM alone and the ALLOMATRIX® Putty³. 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 bioassay¹ or immunoassay³ 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* bioassay¹ or immunoassay³, will correlate with human clinical performance of ALLOMATRIX® C, ALLOMATRIX® Custom, ALLOMATRIX® DR and ALLOMATRIX® RCS Putties.

ALLOMATRIX® is a registered trademark of Wright Medical Technology, Inc.

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1. Wilkins, R.M. (1999) Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture *Advances in Tissue Banking*. 3:113-124. This study correlated the results from the *in vitro* bioassay to results in the athymic rat model and clinical results of the DBM.
2. Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in composite grafts of bone marrow and bone matrix, *Clin Orthop* 1980 Jul-Aug;(150):288-300.
3. Data on file at Wright Medical Technology, Inc.