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LONDON, UK (GlobalData), 27 August 2014 - While three-dimensional (3D) printing has been lauded as a game-changing development in the medical devices industry, the technology is battling to convince surgeons that it is a financially viable treatment for craniomaxillofacial (CMF) reconstruction, says an analyst with research and consulting firm GlobalData.

Linda Tian, GlobalData's Analyst covering Medical Devices, says that the lack of insurance coverage for patient-specific implants and insufficient reimbursement for complex trauma cases are deterring many CMF surgeons from participating in medical training for using pre-surgical planning and 3D-printed implants.

These concerns follow the recent US Food and Drug Administration (FDA) approval of OsteoFab Patient-Specific Facial Device (OPSFD), manufactured by Oxford Performance Materials and now the only FDA-cleared, 3D-printed polymeric implant for both cranial and facial indications.

Tian states: "The processing chain, from data acquisition to 3D printing of CMF patient-specific implants, has proven to be practical and uncomplicated.

"However, 3D printing might continue to be plagued by a major weakness in terms of its future growth within the orthopedic industry, namely the need for hospital administrators to cut costs associated with high-volume surgeries, such as trauma."

The analyst notes that while 3D-printed implants may theoretically reduce the overall cost of facial implant ownership by reducing the operating time, hospital stay duration, and chance of procedure complications, there is a lack of clinical evidence suggesting the actual cost-effectiveness of 3D-printed implants in CMF surgeries.

Despite this, GlobalData expects that OPSFD's approval will lead to a further rise in the utilization rate of custom-made devices for mid-face reconstruction, mandible reconstruction, orthognathic surgeries, and possibly expanded indications.

Tian continues: “Over the next five years, the medical devices sector will see more partnerships between small contract 3D-printing service firms and large orthopedic companies seeking to explore opportunities in this revolutionary technology.

“This will occur as the clinical community increasingly acknowledges the efficiencies of a serviced-based approach to personalized surgery that combines expertise in medical imaging, surgical simulation and 3D printing.”