

## Business market access limitations of 3D implants

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### Abstract :

The introduction of three-dimensional (3D) printing for orthopaedic implant manufacturing between 2007 and 2009 marked a significant technological advancement, particularly in optimising the bone–implant interface. This additive manufacturing technique enables the production of highly porous trabecular structures that enhance primary mechanical stability and promote osseointegration. Since its inception, 3D printing has matured considerably within orthopaedics, with applications expanding from patient-specific custom implants (such as revision acetabular cups) to mass-produced standard implants (such as the Delta-TT Cup from Enovis and the Trident II from Stryker).

Two principal additive manufacturing technologies are currently employed in orthopaedic implant production: EBM (Electron Beam Melting) and SLM (Selective Laser Melting). Each process presents distinct advantages and limitations. EBM offers a higher deposition volume of approximately 80 cm<sup>3</sup> per hour and generates lower residual stresses in the finished component. Conversely, SLM achieves a superior surface finish with lower roughness values ( $R_a$ : 10–20  $\mu\text{m}$ ) and greater structural precision, making it particularly suited for fine-detail geometries.

Registering standard 3D-printed implants in Europe requires compliance with specific requirements under the Medical Device Regulation (MDR 2017/745). Unlike conventionally machined devices, additively manufactured implants must meet their own technical specifications, adding complexity to an already rigorous approval process. A key challenge is validating the manufacturing process itself, which includes equipment qualification (installation, operational, and performance), control of critical process parameters, and powder management protocols. The finished product must also undergo extensive quality controls, including mechanical testing, anisotropy evaluation, heat treatment verification, porous surface characterisation, structural integrity assessment, and residual porosity analysis.

These additional regulatory requirements, which are specific to implants manufactured using 3D printing, are hindering the access of these promising devices to the market. Therefore, it is essential to simplify these procedures while ensuring patient safety, as both surgeons and patients would benefit from the superior biological fixation and customisation offered by this technology.