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Additive Manufacturing and Medical Devices: Case studies, Technical Concerns and Research

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The past decade has seen a steady increase in the marketing of medical devices produced via additive manufacturing (AM). This presentation discusses the technical concerns surrounding AM in the context of medical devices. While unprecedented complexity is possible, maintaining safety and effectiveness requires a more nuanced understanding of the interdependent chemical, physical, software and process traits of creating an AM medical device. This presentation will feature historical perspective, cite specific technical concerns and describe a few medical device case studies. Additionally, it will highlight FDA research and an upcoming FDA guidance document, both of which aim to identify and help address these technical concerns.