ADDITIVE MANUFACTURING E DISPOSITIVI MEDICI
CARATTERIZZAZIONE DI MATERIALI PER LA STAMPA 3D

# Ricerca sui materiali per la stampa additiva dei DM: caratteristiche di sicurezza e proprietà funzionali dei materiali

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# CARATTERIZZAZIONE DI MATERIALI PER LA STAMPA 3D

Negli ultimi anni il rapporto tra sanità e industria è divenuto sempre più stretto, accrescendo la frequenza delle connessioni con ***material scientist/fablab/technology provider*** per le forniture di materiali e tecnologie rispondenti a specifici requisiti prestazionali.
Nel corso del progetto, è stata sviluppata una **ricerca documentale** - con focus particolare sullo stato dell'arte italiano ed europeo - sul tema della caratterizzazione dei materiali per la stampa 3D, con un'indagine delle conoscenze attuali e delle tecniche e processi correlati, attraverso l'analisi di banche dati disponibili e consultabili da aziende e professionisti.
L'indagine ha preso in esame, inoltre, materiali e tecnologie in fase di studio, risultati attesi e gli sviluppi futuri.

Nel rapporto tra sanità e industria sempre più stretto, si evidenza la necessità che materiali e tecnologie rispondano a specifici requisiti prestazionali. Diventa importante l'accesso alle conoscenze attuali e alle tecniche e processi correlati, attraverso l'analisi di banche dati disponibili e consultabili.

# Analisi di banche dati disponibili e consultabili da aziende e professionisti: upgrade a livello europeo (ed extraeuropeo)

R&Dmatech dispone di una rete di partner a livello italiano, europeo ed extraeuropeo, la cui collaborazione è consolidata nel corso di collaborazioni pluriennali.

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In particolare per il progetto «ADDITIVE MANUFACTURING E DISPOSITIVI MEDICI» ci si è avvalsi della documentazione fornita da IDTechEx.

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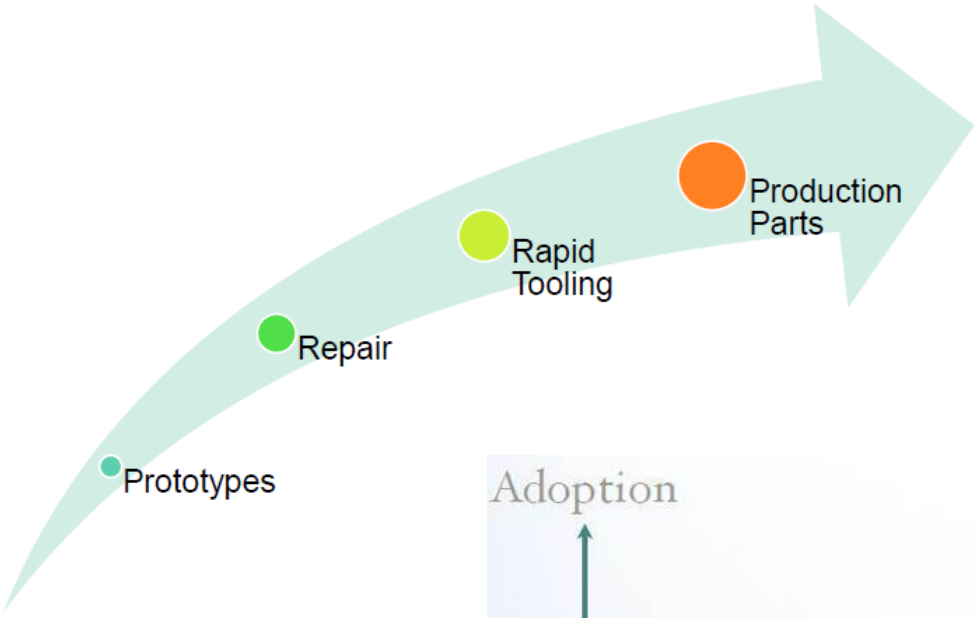
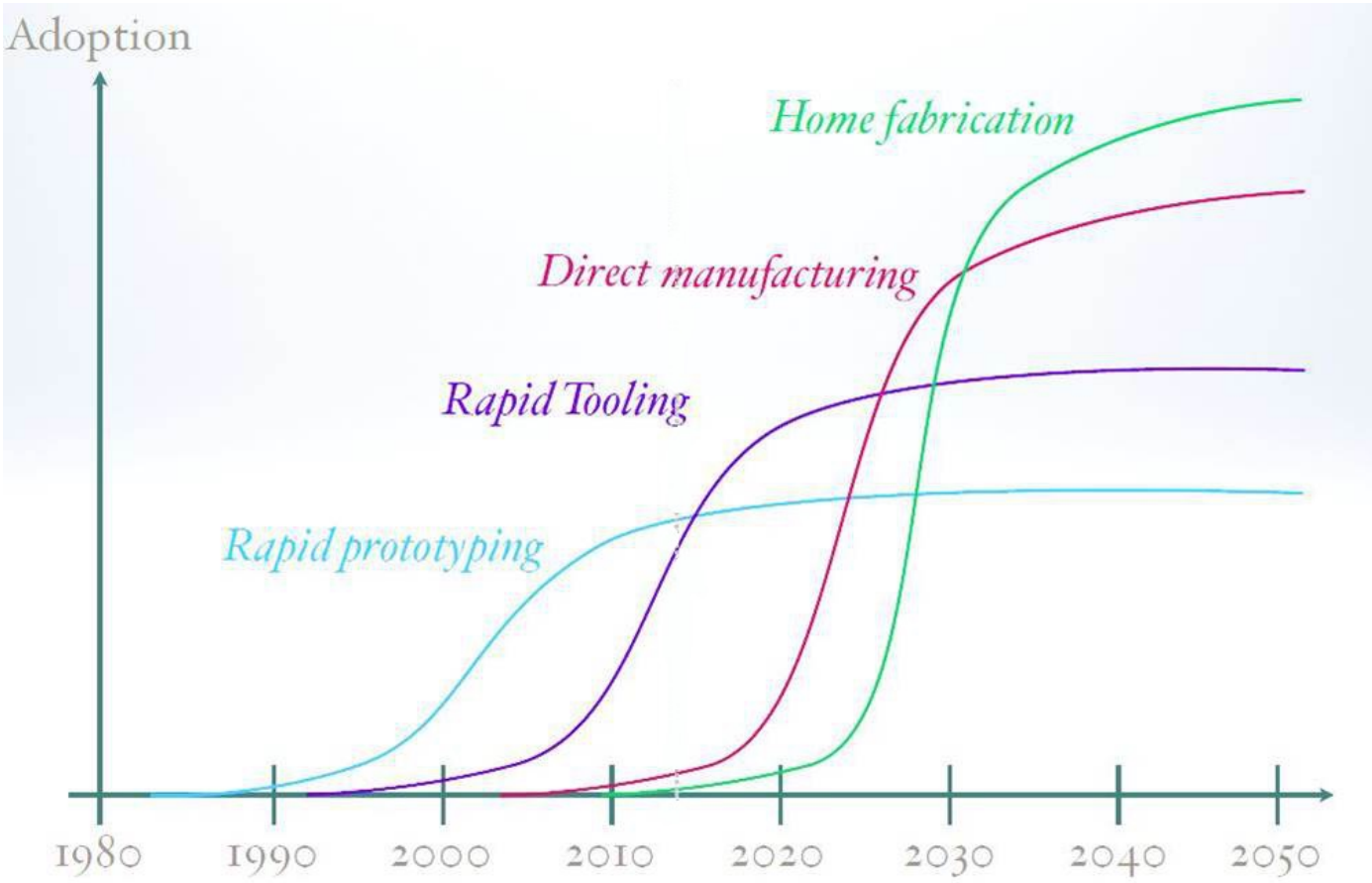
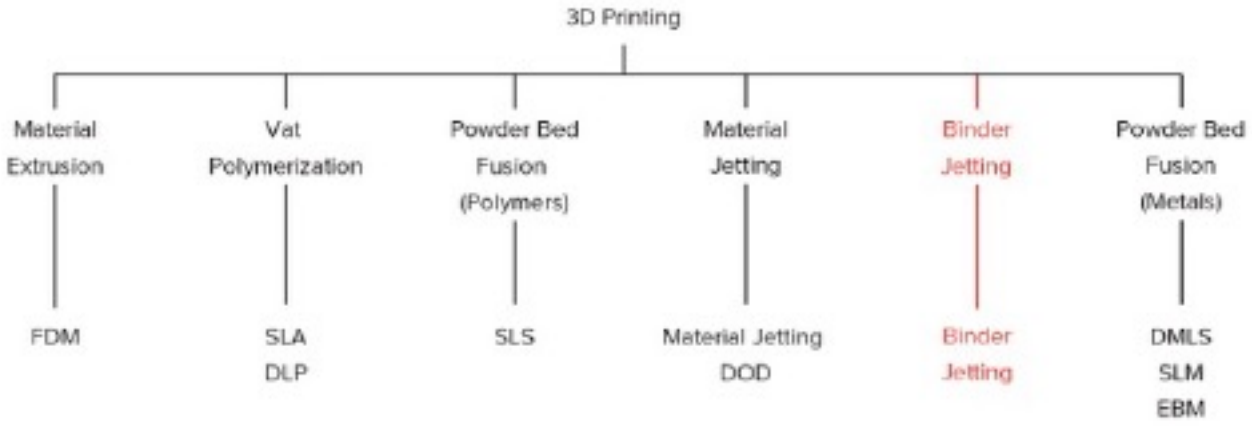
# Il presente e il futuro della stampa 3D



## Tecnologie:

Stereolithography
Polyjet
Fused Deposition Modelling
Selective Laser Sintering
Selective Laser Melting
Direct Metal Laser Sintering
Electron Beam Melting
Inkjet printing
Laser Engineered Net Shaping
3D Screen Printing
Film Transfer Imaging
Aerosol Jet




## Tipologie di industrie:

Aerospaziale
Settore automobilistico
Prodotti di consumo
Architettura
Medico/odontoiatrico
Gioielleria
Arti del design
Di fonderia
Servizi di prototipazione

# I sette diversi tipi di processi di stampa 3D

La stampa 3D è definita come una forma di controllo numerico computerizzato (CNC) in cui un prodotto viene fabbricato in modo additivo attraverso l'interazione di software con hardware fisico come scanner, stampante e materiali.

| Tipo di processo | Acronimo | |
|---|---|---|
| Vat Photopolymerisation | SLA, DLP, CLP, CLIP |  |
| Material Extrusion | FDM, FFF, TPE, ADAM |  |
| Material Jetting | Polyjet, MJP |  |
| Powder Bed Fusion | SLS, SLM, DMLS, EBM |  |
| Directed Energy Deposition | DED, RPD, EBAM |  |
| Binder Jetting | MJF, SPJ |  |
| Sheet Lamination | LOM, UAM, CBAM |  |

# Perché adottare la stampa 3D ?

Consente  alla produzione di diventare di più lean:

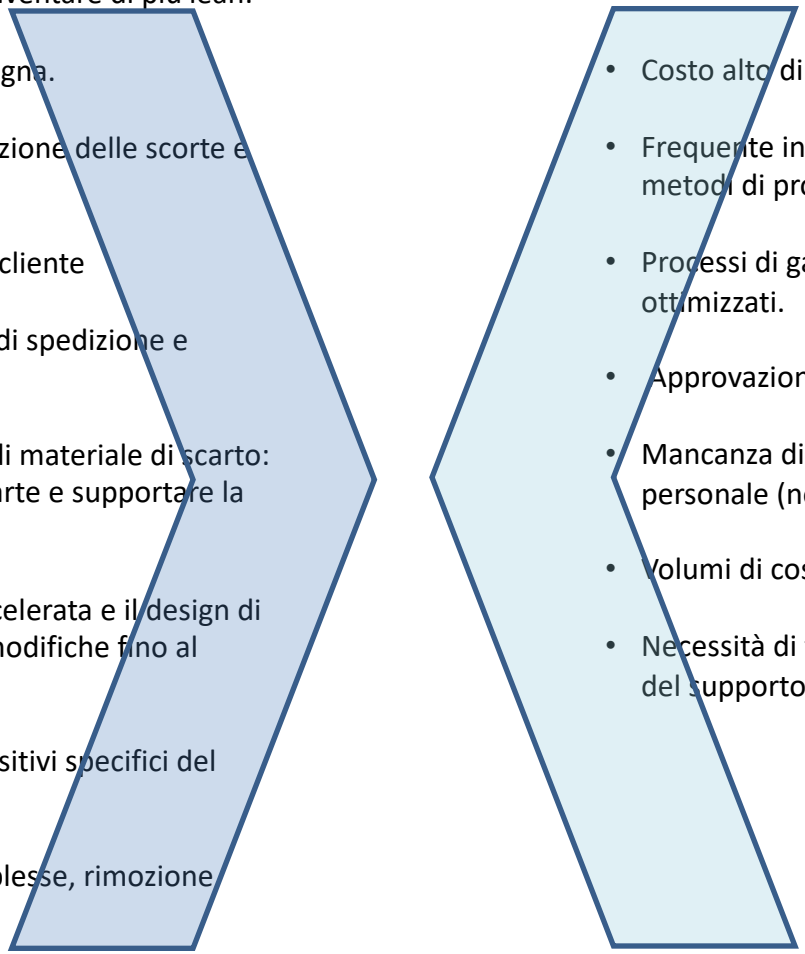
• Riduzione dei tempi di consegna.

• Produzione su richiesta (riduzione delle scorte e spese generali associate).

• Produzione prodotto presso cliente interno/esterno
posizione per ridurre le spese di spedizione e logistica.

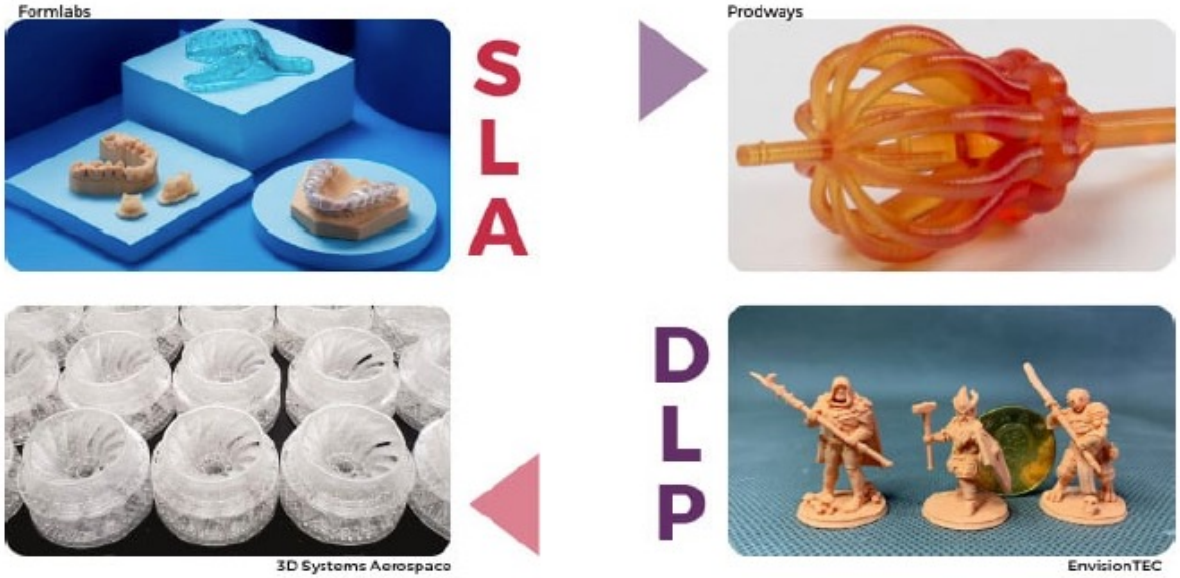
• Riduzione della produzione di materiale di scarto: utilizzare solo materiale per parte e supportare la costruzione.

- L'iterazione del design è accelerata e il design di prodotto può includere le modifiche fino al punto di produzione.
- Personalizzazione per dispositivi specifici del paziente.
- Nel caso di geometrie complesse, rimozione imiti dovuti ad utensili



- Costo alto di macchine e materie prime.
- Frequente incoerenza ed errori costruttivi rispetto a metodi di produzione tradizionali.
- Processi di garanzia della qualità non ancora ottimizzati.
- Approvazione e regolamentazione.
- Mancanza di conoscenze tecniche e/o operative con personale (non ancora aggiornato).
- Volumi di costruzione limitati
- Necessità di finiture successive, come la generazione del supporto o pressatura isostatica a caldo (HIP).

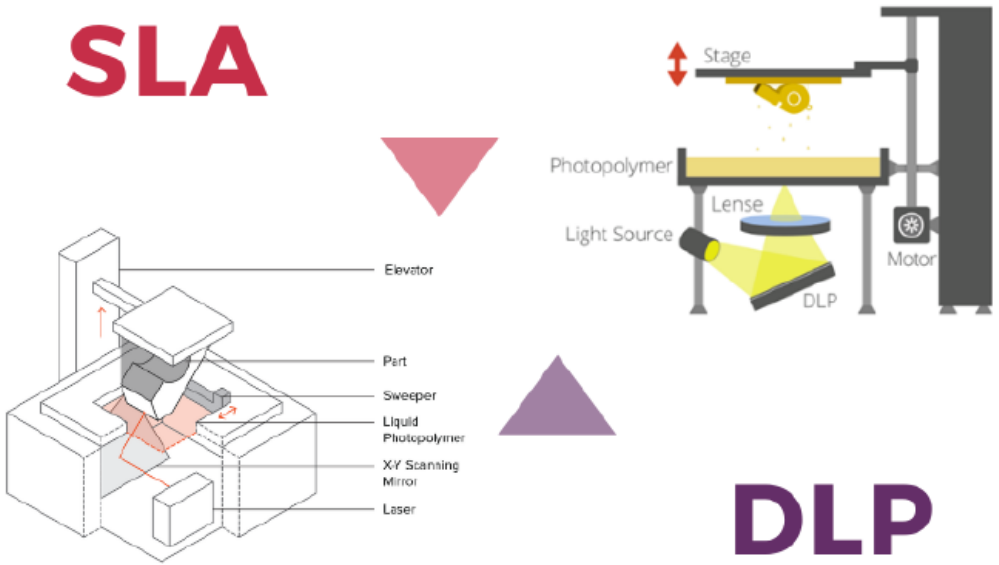
La crescita del mercato nella stampa 3D sta attualmente affrontando barriere in aree di costo, capacità tecnica e istruzione.




*SLA e DLP: la precisione è notevole in entrambe le tecnologie*

| SLA | DLP |
|---|---|
| **Caratteristiche**<br>• Processo di stampa: il laser polimerizza la resina punto per punto (permette una maggiore precisione)<br>• Spessore strato*: 25-200 microns<br>• Volume max di stampa*: 300 x 335 x 200 mm<br>• Resine*: clear, castable, dental, flexible, tough | **Caratteristiche**<br>• Processo di stampa: il proiettore polimerizza tutto lo strato di resina in una volta sola (permette una maggiore velocità di stampa)<br>• Spessore strato*: 5-150 microns<br>• Volume max di stampa*: 450 x 371 x 399 mm<br>• Resine*: trasparente, modellabile, dentale |
| **Prezzo**<br>Da 1.700 € a 420.500 € | **Prezzo**<br>Da 120 € a 71.500 € |
| **Produttori**<br>• 3D Systems<br>• Formlabs<br>• DWS | **Produttori**<br>• EnvisionTEC<br>• Prodways<br>• Asiga |

*SLA e DLP a confronto. Le specifiche si riferiscono a una stampante 3D desktop.*




*Diagrammi relativi ai processi di stampa SLA e DLP (crediti foto: 3D Hubs / bitfab)*

# Principali fornitori di stampanti 3D

# The future of 3D printing in medicine and dentistry

2019/2029

Dr Bryony Core and Dr Nadia Tsao

Uno dei settori chiave che ha sfruttato con successo i vantaggi della stampa 3D è il settore medico e dentistico.

La stampa 3D consente la produzione di una vasta gamma di dispositivi che va da apparecchi acustici ad allineatori Invisalign® o agli arti protesici che sono adattati per soddisfare il esigenze specifiche del paziente pur aderendo a un quadro normativo ristretto. La gamma di applicazioni non si limitano ai dispositivi medici o alle protesi: lo sviluppo dei tessuti nell'ingegneria continua ad evolversi, c'è spazio per l'impianto di tessuti viventi come parte di medicina rigenerativa.

# Odontoiatria

i flussi di lavoro stanno diventando sempre più digitalizzati, dalle impronte ottiche dirette prese con scanner intraorali dai dentisti alla progettazione assistita da computer e a produzione di restauri e altri apparecchi nei laboratori odontotecnici.

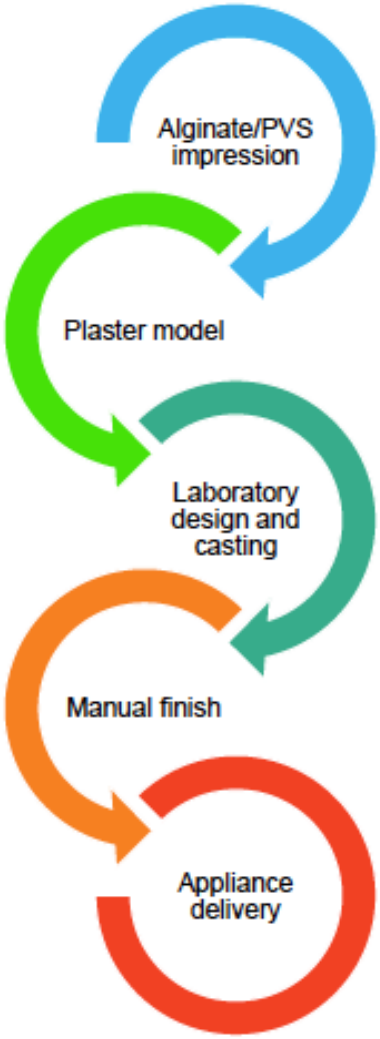
- Diagnosi e pianificazione del trattamento
- Protesi e odontoiatria restaurativa
- Ortodonzia
- Implantologia
- Chirurgia orale

# Il flusso di lavoro dell'odontoiatria digitale

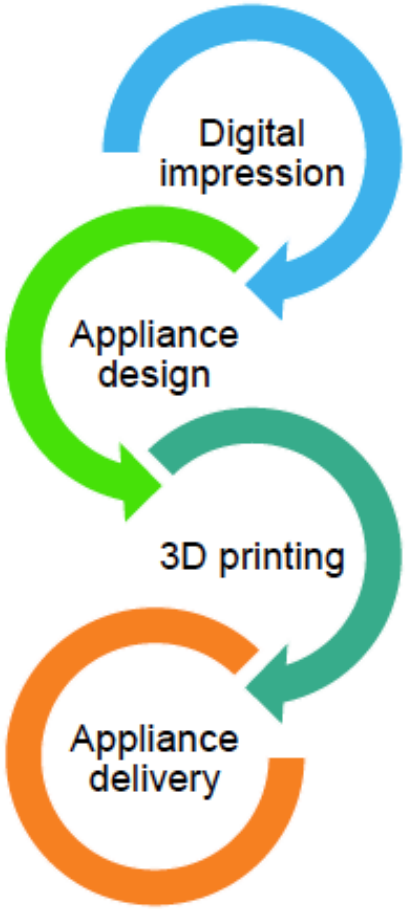
Rispetto ai tradizionali flussi di lavoro di produzione, lo sviluppo di apparecchi con la stampa 3D ne conferisce diversi potenziali vantaggi.

Molte  persone avranno familiarità con lo spiacevole processo di avere un'impronta in alginato o PVS : questo disagio è uno dei motivi per cui i dentisti sempre più stanno adottando scanner intraorali digitali. Con il processo di produzione digitale questa scansione può essere utilizzata direttamente nella progettazione dell'apparecchio e il dispositivo può essere prodotto rapidamente con una stampante 3D.

Un altro vantaggio è che la stampante 3D può quindi essere immediatamente utilizzata per fabbricare un apparecchio con una flessibilità che è difficile trovare altrove.
IL dispositivo viene quindi consegnato al paziente.  Infatti, via via che il software diventa più familiare e intuitivo, gli stessi dentisti possono scegliere di adottare la tecnologia essi stessi  riducendo ulteriormente i tempi di consegna.
Tuttavia, i tempi di consegna possono ancora essere ridotti se la produzione è esternalizzata a un laboratorio odontotecnico




Flusso di lavoro di casting tradizionale

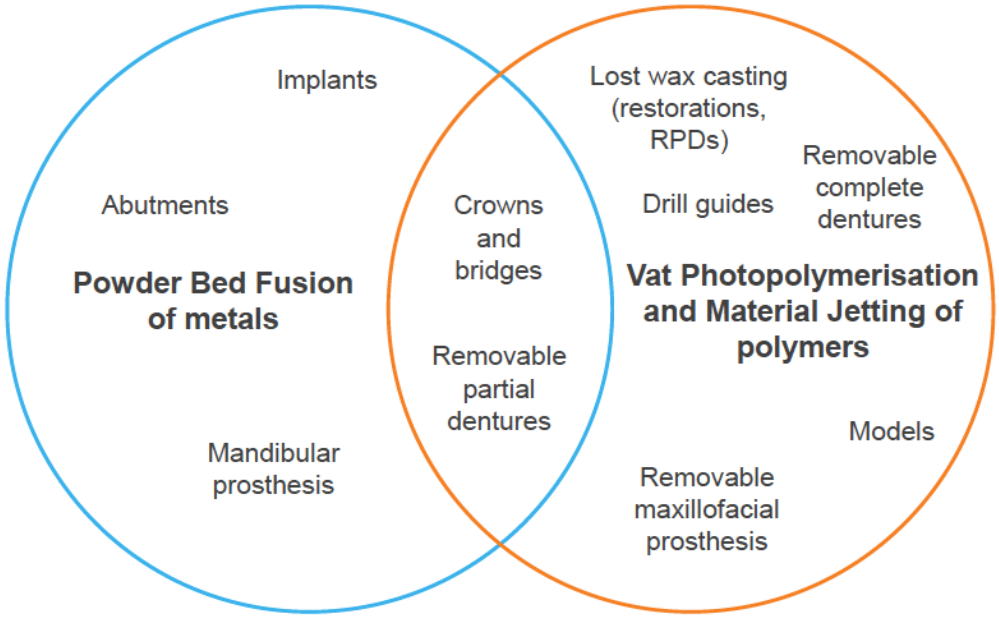



Flusso di lavoro stampa 3D

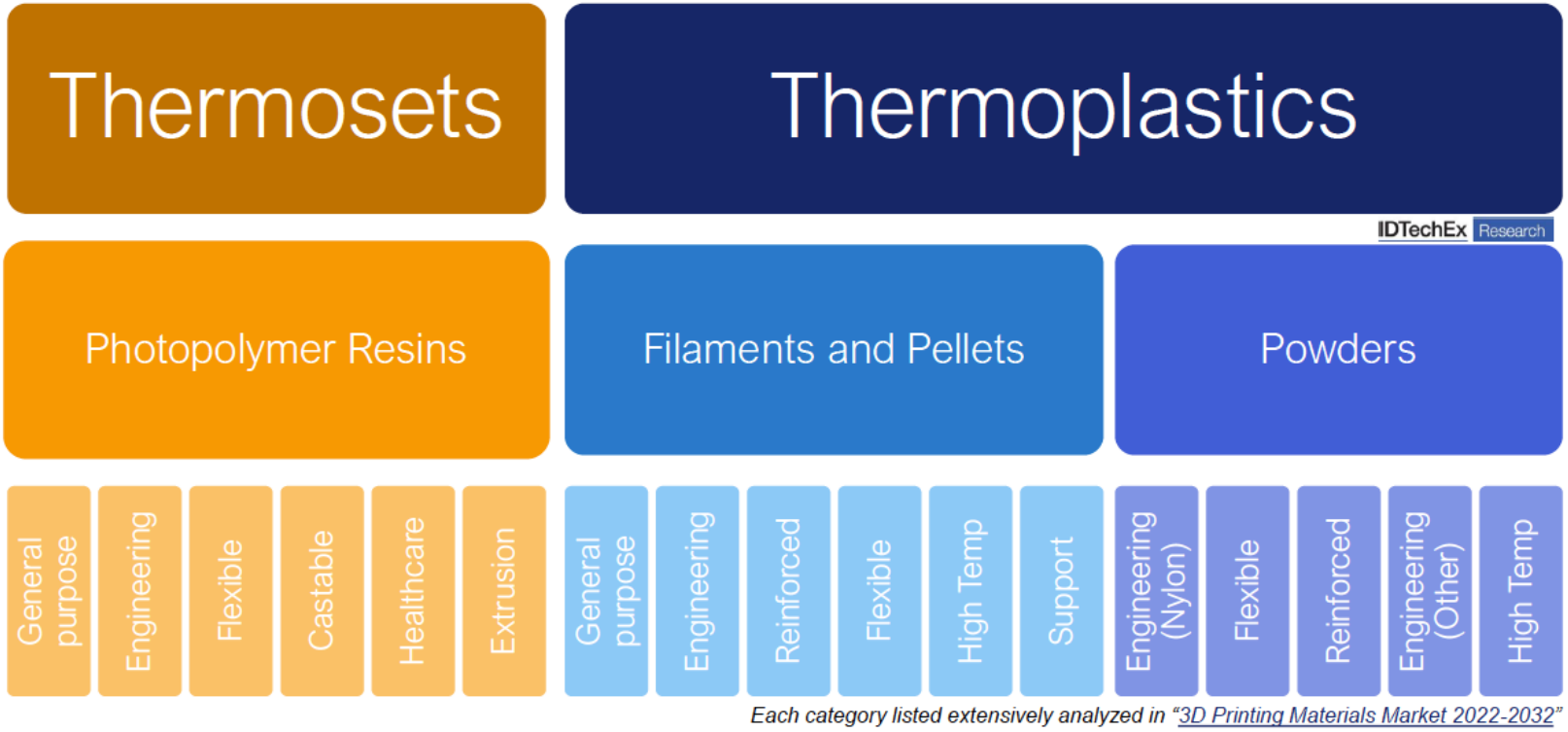
# Processi e materiali di stampa 3D per applicazioni dentali

Per applicazioni dentali, ci sono
tre processi principali impiegati:
la fotopolimerizzazione o
getto di materiale fotosensibile per generare componenti in materiale polmerico, o il letto di polvere
fusione di polveri metalliche (power bed)

Le polveri metalliche sono tipicamente utilizzate per creare protesi  a lungo termine o permanenti, mentre, a causa della loro
proprietà, le resine fotosensibili
vengono utilizzati per creare restauri o modelli temporanei.



**Materiali polimerici per la stampa 3D**




Con l'aumentare del portafoglio di materiali polimerici, le applicazioni per i polimeri si espandono in più aree  oltre la prototipazione

# Photosensitive resins – Resine fotosensibili

Le resine fotosensibili sono ideali per produrre parti molto lisce con un'elevata precisione dimensionale.

## Descrizione del materiale

- Resina di metacrilato liquido sensibile ai raggi UV polimerizza per solidificare all'esposizione ai raggi UV (da 385 a 405 nm)
- Una vasta gamma di colori e trasparenze sono disponibili per consentire l'applicazione da modelli a restauri provvisori.

## Processi di stampa compatibili

- Fotopolimerizzazione in vasca
- SLA/DLP/CLP (sistemi 3D e molti altri)
- Getto di materiale
- Polyjet (Stratasys)
- Multijet (Sistemi 3D)

l colore e la risoluzione delle resine fotosensibili hanno una vasta gamma di applicazioni, ma sono limitati a causa del loro aspetto e della loro resistenza.

## Vantaggi

Precisione: risoluzione fino a submicron. Gli acrilati sono biocompatibili e alcuni materiali sono approvati dalla FDA come dispositivi medici di Classe IIa.

La gamma di colori incontra una varietà di applicazioni da modelli, vassoi, guide per strumenti, splint e restauri.
E' possibile incorporare altri materiali nella resina, ad esempio per dare proprietà microbiche.


Ibrido microriempito

Bilancia perfettamente opacità e traslucenza
NextDent C&B Micro Filled Hybrid è un materiale biocompatibile di Classe IIa sviluppato per corone e ponti. L'equilibrio tra riempitivi inorganici e resina conferisce al materiale la sua forza.

Il materiale è facile da rifinire e lucidare e può essere colorato con tutti i tipi di kit di colorazione per compositi. Grazie al perfetto equilibrio tra opacità e traslucenza, la corona stampata si fonde perfettamente tra i denti esistenti. Disponibile nei colori BL, N1, N1.5, N2, N2.5 e N3.

Materiale NextDent Crowns e
Bridges Micro Filled Hybrid (MFH).

E' infuso con cariche inorganiche per maggiore resistenza all'usura.
Può essere macchiato con kit per la colorazione dei compositi.


## Specifications

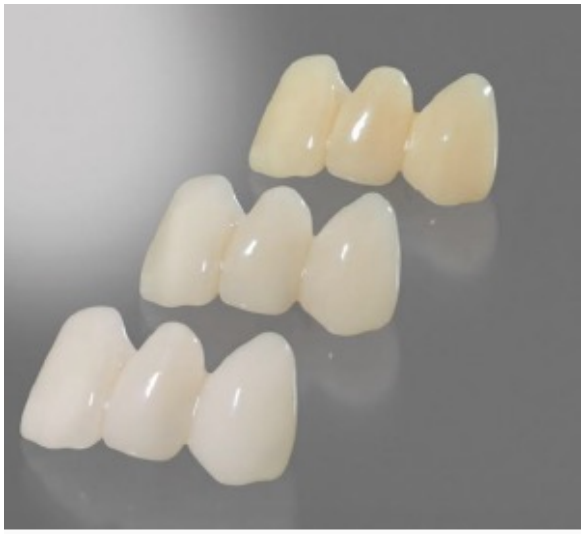
| Property | Requirement | Result | ISO standard |
|---|---|---|---|
| Flexural strength | ≥ 50 MPa | 107 | ISO 10477 |
| Sorption | ≤ 70 µg/mm3 | 54 | ISO 10477 |
| Solubility | ≤ 15,5 µg/mm3 | 5,9 | ISO 10477 |
| Biocompatibility | Non-cytotoxic | Comply | ISO 10993-1 |
| Biocompatibility | Non-mutagenic | Comply | ISO 10993-1 |
| Biocompatibility | Not induce any erythema or edema reactions | Comply | ISO 10993-1 |
| Biocompatibility | Not a sensitizer | Comply | ISO 10993-1 |
| Biocompatibility | Not cause systemic toxicity | Comply | ISO 10993-1 |

The material is available in 1 Kg containers.

https://nextdent.com/products/cb-mfh-micro-filled-hybrid/

## Svantaggi

Non adatto per la realizzazione di restauri permanenti a causa della scarsa resistenza alla trazione rispetto ai restauri CEREC fresati.
Conoscenza attuale limitata del comportamento materiale per una esposizione a lungo termine alla saliva.
I materiali plastici sono meno attraenti della ceramica e quindi possono rimanere limitati ad applicazioni esteticamente non impegnative.
Spazio bianco per materiale adatto alla stampa diretta di allineatori.



DETAX's Freeprint temp UV A1, A2 and A3 per corone provvisorie e ponti.


Materiale della corona permanente

CROWNTEC è una resina composita di alta qualità che può essere utilizzata per produrre in modo additivo restauri permanenti biocompatibili tra cui corone, inlay, onlay, faccette e denti artificiali per protesi. Questo materiale di Classe IIa approvato dalla FDA (autorizzazione 510(k)) e con marchio CE offre le migliori proprietà della categoria.

Nell'ambito della soluzione di odontoiatria digitale NextDent, i laboratori e le cliniche odontoiatriche sono in grado di produrre questi dispositivi dentali che sono il 30% più resistenti rispetto a quelli prodotti con metodi convenzionali, riducendo allo stesso tempo lo spreco di materiale.

CROWNTEC è disponibile in cinque tonalità di denti per adattarsi ai denti del paziente per un'estetica dall'aspetto naturale, inclusi SW (colore sbiancante), B1, A1, A2 e A3, secondo lo standard VITA®.

## Specifications

| Property | Result |
|---|---|
| Consistency | Middle viscous, homogeneous |
| Color | According to VITA® standard |
| Depth of cure (DIN EN ISO 4049) | ≥ 1,5 mm |
| Flexural strength (DIN EN ISO 4049) | > 150 MPa (Mean) |
| E-Modulus (DIN EN ISO 4049) | > 4000 MPa |
| Barcol hardness | > 40 |
| Shelf life | 4 years |
| Medical device | Class IIa |

The material is available in 0.5 Kg containers.

**TERA HARZ TC-80 DP**

## Il primo materiale al mondo per la stampa 3D di C&B e sottostrutture a lungo termine.

**Alcune sue caratteristiche fisiche e tecniche, come durezza e modulo elastico, molto simili alla zirconia, permettono di ottenere manufatti altamente performanti attraverso un metodo di produzione che elimina gli sprechi e di massima efficienza.**

**TC-80DP è biocompatibile, conforme e certificato ai sensi degli standard CE FDA**

**Dispositivo Medico classe IIA.**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### PROPRIETÀ DEL MANUFATTO STAMPATO

**Colore**
A1, A2, A3

**Durezza Shore**
≥ 90 Mpa (ISO 6872)

**Resistenza alla flessione bi-assiale**
≥ 350 Mpa (ISO 10477)

**Resistenza alla flessione**
≥ 220 Mpa (ISO 10477)

**Modulo elastico**
≥ 4500 Mpa (ISO 10477)

### COMPATIBILITÀ

Tera Harz TC-80 DP è compatibile con tutte le stampanti 3D a 405 nm.

### FORMATO

1 kg

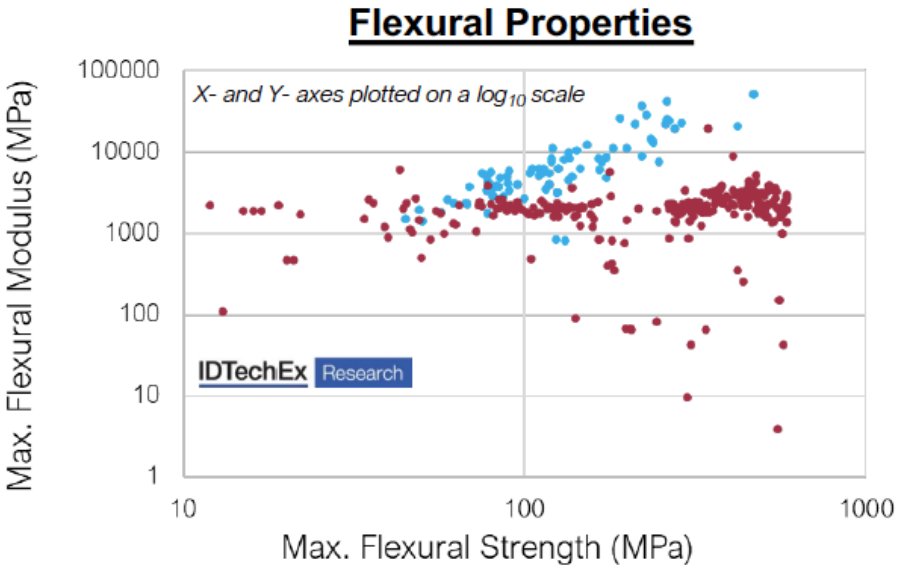
## Principali sviluppatori di resine fotosensibili dentali

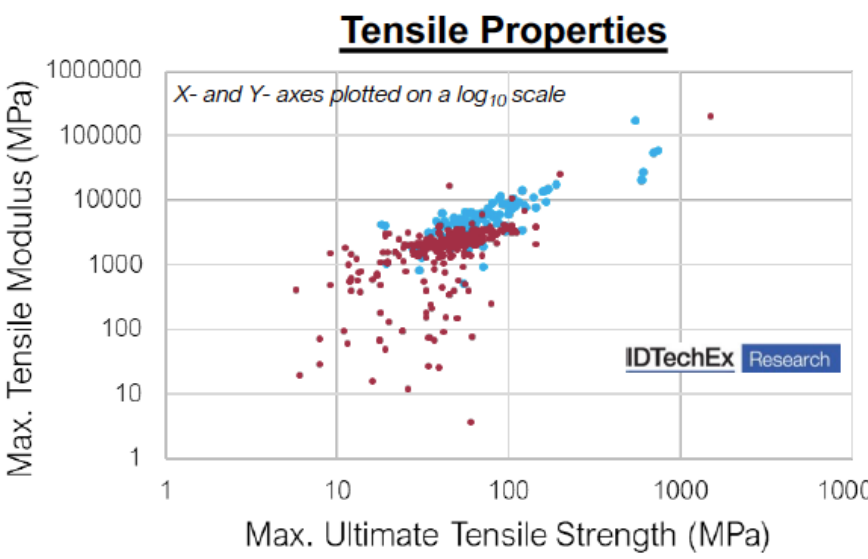

Diversi produttori di stampanti 3D hanno una linea di resine, ma queste tendono ad essere più limitate rispetto agli sviluppatori di tecnologia dentale.

Esempio di partnership per lo sviluppo dei materiali costituite nel 2021/inizio 2022


Le collaborazioni stanno cambiando il modo in cui i materiali di stampa 3D polimerici arrivano sul mercato

# Filamenti: confronto composito vs polimero




Questi grafici (tracciati su scala logaritmica) confrontano le proprietà di flessione e trazione tra filamenti termoplastici in composito (o rinforzato) filamenti termoplastici senza rinforzi.

# Caso di studio

Panoramica del caso

La stampa 3D ha democratizzato il processo di produzione, consentendo agli utenti domestici di creare prodotti che normalmente vengono creati da professionisti nel bene e nel male. Questo caso di studio viene fornito come monito.

Lo studente universitario Amos Dudley ha preso in mano l'ortodonzia quando ha deciso di riallineare i suoi sovraffollati incisivi centrali e laterali in alto a destra. Piuttosto che cercare l'aiuto di un ortodontista qualificato, ha intrapreso diversi passaggi per generare uno stampo, scansionare il modello (in alto a destra), animare il riallineamento degli incisivi nel tempo e generare un file STL per ogni fase del riallineamento.

Ogni allineatore vacuform buck è stato stampato sulla Stratasys Dimension 1200 es del suo dipartimento (e un allineatore trasparente prodotto (in basso a destra).

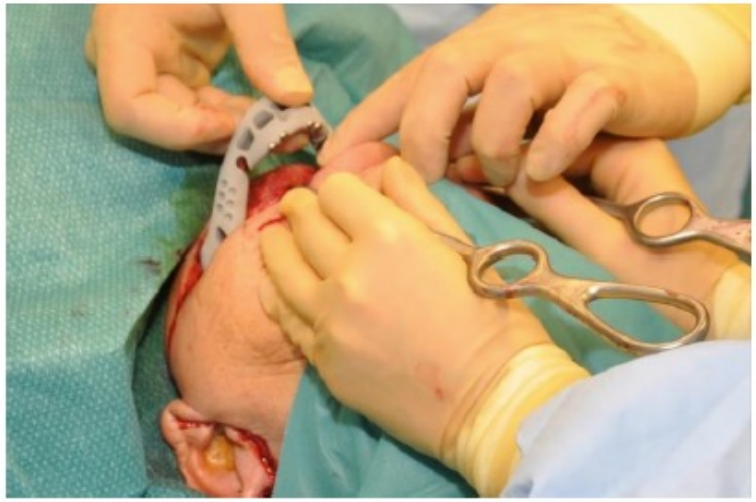
Mentre Amos Dudley potrebbe aver replicato il processo senza causare lesioni a se stesso, l'ortodontista praticante Brent Larson, professore associato di ortodonzia presso la School of Dentistry dell'Università del Minnesota, ha avvertito che "le soluzioni fai-da-te sono sempre allettanti a causa della possibilità di risparmiare denaro, ma questo non è come il rimodellamento domestico in cui se ti trovi nei guai puoi sempre chiamare un professionista in seguito .....[ il danno potrebbe comportare la perdita della radice del dente di supporto, la recessione gengivale o, nel peggiore dei casi, la perdita di denti.

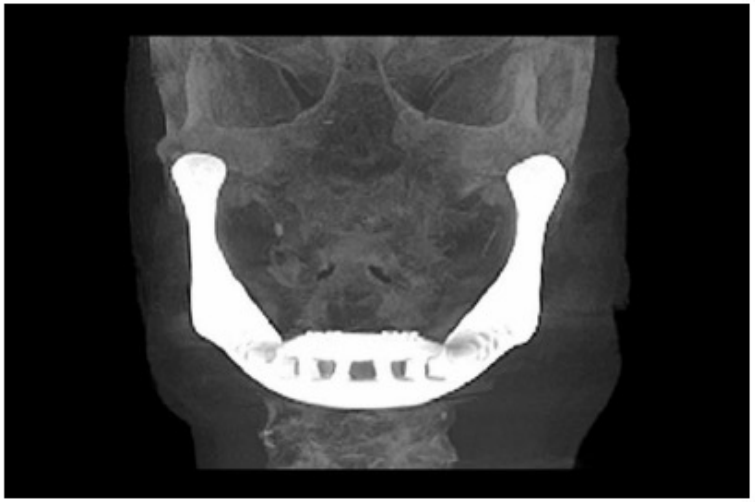
Image source: amosdudley.com/weblog/Ortho (accessed 28 August 2018).

La stampa 3D può potenzialmente aumentare la prevalenza dell'odontoiatria fai-da-te, ma rimane un'impresa pericolosa.

# Caso di studio

chirurgia ricostruttiva mandibolare: la fusione del letto di polvere metallica può creare protesi permanenti in poche ore.





Nel 2012 l'Università di Hasselt, in Belgio, ha creato la prima mascella stampata 3D in titanio personalizzata al mondo. L'intervento di impianto è stato effettuato su un paziente di 83 anni affetto da osteomielite cronica con lo scopo di ripristinare la funzione respiratoria, masticatoria e vocale oltre a mantenere l'aspetto estetico, diversamente sarebbero andati perduti se l'osso danneggiato fosse stato rimosso e non sostituito con una protesi.

La protesi mascellare è stata progettata per incorporare caratteristiche anatomiche, utilizzando le stampanti per sinterizzazione laser di polveri metalliche LayerWise: è stata fusa la polvere di lega di titanio per creare la protesi in poche ore, rispetto a diversi giorni con altre lavorazioni tradizionali. L'intero componente è stato rivestito con un composto sostitutivo osseo di idrossiapatite.

La mascella del paziente è stata ricostruita in un intervento durato quattro ore, un quinto del tempo necessario per quello tradizionale chirurgia ricostruttiva. Poco dopo il risveglio, il paziente è stato in grado di verbalizzare poche parole e dopo un giorno era in grado di deglutire.

Punti di forza: la stampa 3D ha consentito l'incorporazione di caratteristiche anatomiche come teste condilari e canale mandibolare

Punti di debolezza: la protesi in metalli è tre volte più pesante dell'originale mandibola

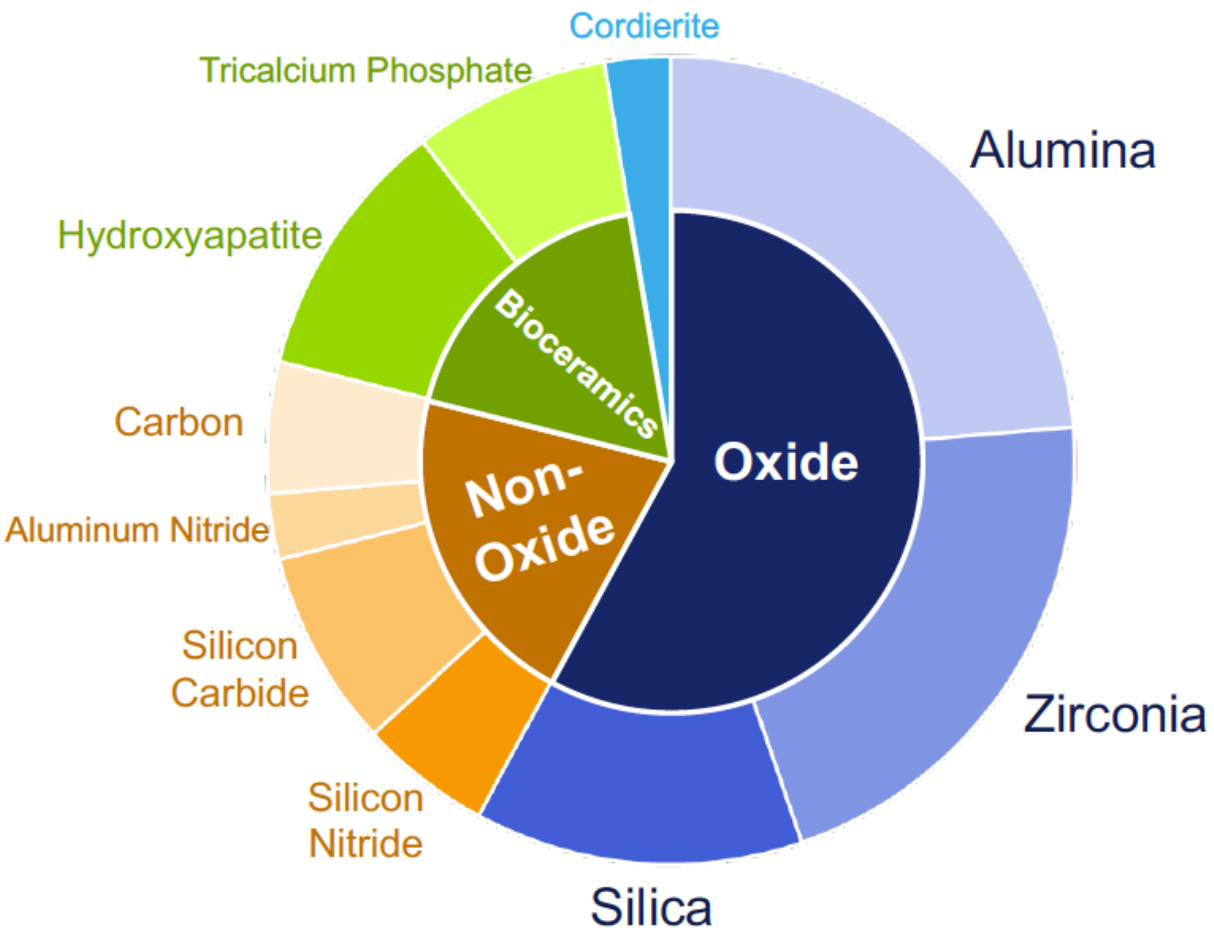
Opportunità: utilizzo di un materiale ceramico leggero che si avvicina di più nella densità specifica dell'osso migliorerebbe risultati per le protesi a lungo termine

## Mercato dei materiali per la stampa 3D 2022-2032


La catena del valore della stampa 3D rappresenta un'enorme opportunità di crescita potenziale nel prossimo decennio: si prevede che il mercato globale dei materiali di stampa 3D varrà 29,5 miliardi di dollari nel 2032.


La segmentazione di IDTechex del variegato mercato dei materiali per la produzione additiva

# Materiali ceramici per la stampa 3D sul mercato




Questo grafico conta le diverse ceramiche materiali disponibili per la stampa 3D industriale e rappresenta la loro quota di mercato per numero di prodotti disponibili. Questo include i materiali venduti dai produttori di stampanti 3D e materiali realizzati da aziende chimiche per la produzione di stampa.

Questo grafico esclude i materiali ceramici "qualificati dal cliente». Questi sono materiali che i clienti della stampante 3D hanno utilizzato con successo, tuttavia non sono ufficialmente venduti dai produttori di stampanti 3D come materiali ceramici 3D.

38 diversi materiali ceramici per uso industriale per la stampa 3D sono disponibile in commercio ( a giugno 2021).

Partnership annunciate nel 2022 che coinvolgono materiali per AM




Metalli

Polimeri

Ceramiche e Biomateriali

**Esempio di nuovi materiali sviluppati per l'AM**

https://www.z3dlab.com/products

# Creating Innovations That Make a Difference
# EOS 3D Printing for Medical Technology

Additive manufacturing offers the medical industry great freedom of design, adaptability and functional integration. For the manufacturers of dentures, medical and orthopedic technology products, orthoses and prostheses, this creates many far-reaching opportunities. There is complete control over the shapes, materials and specific designs based on patient-specific data which makes it possible to offer more individual treatments, simplifies biomechanical reconstruction and enables innovative therapy methods to be implemented quickly.

> *With more than 30 years of experience in manufacturing all kinds of machines and solutions for additive manufacturing, we have accompanied and supported our customers across a diverse range of exciting and innovative medical projects. In doing so, we have learned to understand the specific requirements of this market.*

We design our production technology to reflect our knowledge of the challenges associated with certifications and material-specific requirements. For better patient care.

**Organizzazione internazionale per la standardizzazione (ISO)**

L'Organizzazione internazionale per la standardizzazione (ISO) ha sviluppato la norma **ISO 10993** cercando di standardizzare i test di biocompatibilità.
ISO 10993 è uno standard in 20 parti che valuta gli effetti dei materiali dei dispositivi medici sul corpo. Utilizza matrici per suddividere i dispositivi medici in tre categorie: superficie, comunicazione esterna e impianto. Questi sono ulteriormente suddivisi in sottocategorie in base al tempo di esposizione (limitato, prolungato e permanente), come mostrato nella Tabella. La norma ISO 10993 non è una lista di controllo, ma più una guida utilizzata per fornire le informazioni per indirizzarti nella giusta direzione e progettare un programma di test. Fortunatamente per noi, la maggior parte dei produttori di materiali o delle aziende di stampa hanno eseguito una discreta quantità di questi test.

I materiali che detengono questa certificazione possono essere sterilizzati tramite metodi standard del settore che consentono loro di essere a diretto contatto con il paziente, in una camera bianca e con impianti o protesi personalizzati. Questa certificazione aiuta a gestire il rischio biologico e garantisce che la risposta dell'ospite non sia negativa o dannosa.

## Table 1: ISO 10993-1 Biocompatibility Testing Selection Criteria

| Medical device categorization by | | | Biological Effect * | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Nature of body contact | | Contact duration | | | | | | | | |
| Category | Contact | A - limited (≤ 24 h) B - prolonged (> 24 h to 30 d) | ytotoxicity | ensitization | ritation or caneous reactivity | temic toxicity (acute) | hronic toxicity acute toxicity) | enotoxicity | nplantation | iocompatibility |
| Surface device | Skin | A | X | X | X | | | | | |
| | | B | X | X | X | | | | | |
| | | C | X | X | X | | | | | |
| | Mucosal membrane | A | X | X | X | | | | | |
| | | B | X | X | X | | | | | |
| | | C | X | X | X | | X | X | | |
| | Breached or compromised surface | A | X | X | X | | | | | |
| | | B | X | X | X | | | | | |
| | | C | X | X | X | | X | X | | |
| External communicating device | Blood path, indirect | A | X | X | X | X | | | | X |
| | | B | X | X | X | X | | | | X |
| | | C | X | X | | X | X | X | | X |
| | Tissue/bone/ dentin | A | X | X | X | | | | | |
| | | B | X | X | X | X | X | X | X | |
| | | C | X | X | X | X | X | X | X | |
| | Circulating blood | A | X | X | X | X | | | | X |
| | | B | X | X | X | X | X | X | X | |
| | | C | X | X | X | X | X | X | X | |
| Implant device | Tissue/bone | A | X | X | X | | | | | |
| | | B | X | X | X | X | X | X | X | |
| | | C | X | X | X | X | X | X | X | |
| | Blood | A | X | X | X | X | X | | X | X |
| | | B | X | X | X | X | X | X | X | X |
| | | C | X | X | X | X | X | X | X | X |

Note:
a The "X" indicates data endpoint that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

**Stampa 3D biocompatibile**

Ora che abbiamo esaminato ciò che vogliamo in definitiva, possiamo considerare l'approccio migliore per arrivarci. A seconda delle esigenze e dell'applicazione biocompatibile, esistono diverse tecnologie di produzione additiva che si adattano meglio di altre. È per questo motivo che Stratasys offre diversi materiali biocompatibili su tre diverse piattaforme di stampa 3D. Di seguito è riportata un'analisi delle diverse tecnologie e delle relative applicazioni suggerite, sebbene non siano limitate a queste.

**Tecnologia FDM: per parti più grandi e robuste**

Ultem 1010
ABS-M30i
ISO PC

**Tecnologia PolyJet: per modelli più piccoli e iperrealistici**

VeroContactClear
MED610
MED625
Biocompatible Digital ABS

**Tecnologia P3: per la qualità dello stampaggio a iniezione in resine ad alte prestazioni**

MED 412
MED 413
Loctite 3843
BASF UltraCur3d ST45

Ognuna di queste piattaforme tecnologiche offre diverse opzioni di materiali e la possibilità di creare prototipi, maschere e dispositivi biocompatibili, protesi e altro ancora

# FDM Materiali bicompatibili

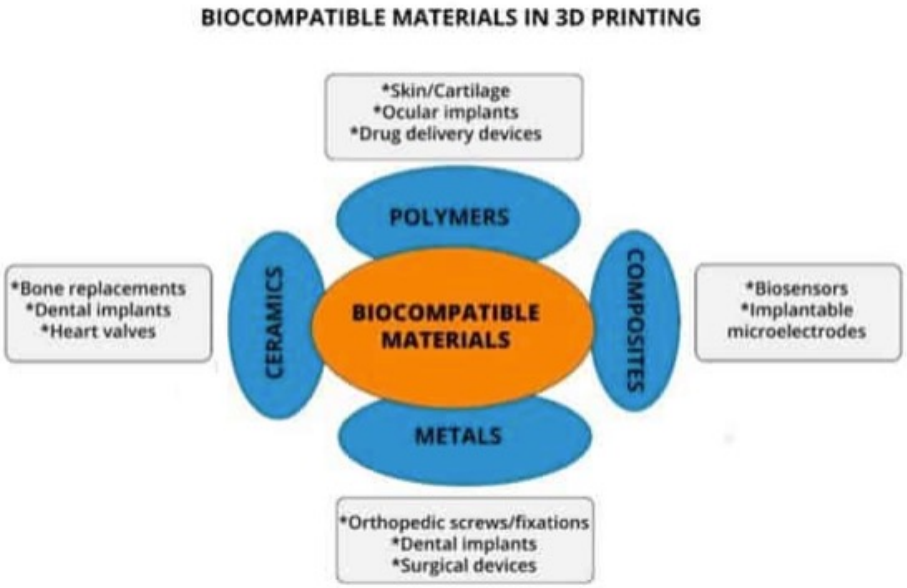
**ULTEM1010**

È un materiale termoplastico FDM ad alte prestazioni e presenta la più alta resistenza alla trazione, agli agenti chimici e al calore rispetto a qualsiasi materiale termoplastico FDM disponibile fino ad oggi sulla piattaforma. Ha la certificazione per il contatto alimentare NSF 51 ed è biocompatibile secondo la certificazione ISO 10993 e USP Classe VI. Può essere sterilizzato utilizzando l'autoclave e altri metodi, rendendolo adatto per strumenti medici come guide chirurgiche o anche come dispositivi di supporto per la sterilizzazione. Ha il coefficiente di espansione termica di qualsiasi materiale FDM e un HDT di oltre 420 gradi Fahrenheit, che lo rendono adatto a molte applicazioni di utensili industriali e altre parti che richiedono una combinazione unica di resistenza e stabilità termica.

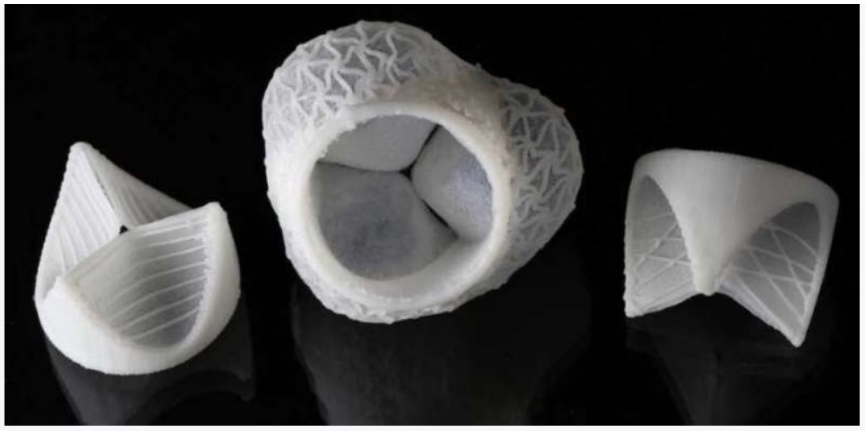
**MED625**

Per macchine PolyJet: un materiale trasparente flessibile che vanta anche le certificazioni ISO 10993. MED625 presenta un allungamento a rottura di circa il 50% e ha una durezza Shore di 75 A, che lo rende ideale per applicazioni come vassoi per bonding indiretto ortodontico e maschere gengivali per impianti. Sebbene queste due applicazioni orali abbiano senso grazie agli standard di biocompatibilità degli impianti orali a breve termine, potrebbero essere applicate a un'ampia gamma di applicazioni che richiedono flessibilità e biocompatibilità.

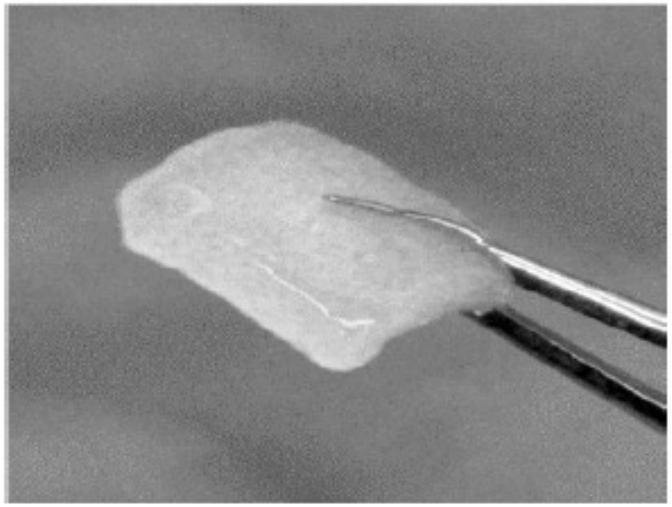

*Application of biocompatible materials*




https://xometry.eu/en/biocompatible-3d-printing-overview/



# Quali opportunità con l'ingegneria tissutale e la biostampa 3D?



Tessuto, pelle ingegnerizzata (in senso orario dall'alto), epitelio corneale e cartilaginea per applicazioni nella medicina rigenerativa

Fonte
Organogenesi, J TEC, Istogenica

# 3D bioprinting process

## Preparation

- 3D imaging
- Construct design
- Preparation of cell culture
- Preparation of bioink for structural support

## Printing

- Import model into bioprinter
- Layer-by-layer deposition of cell suspension with or without bioink
- Crosslinking of support material

## Maturation

- Cell adhesion to scaffold
- Self-assembly of cells
- Cell differentiation
- Maturation in bioreactor

## Application

- Testing
- Implantation

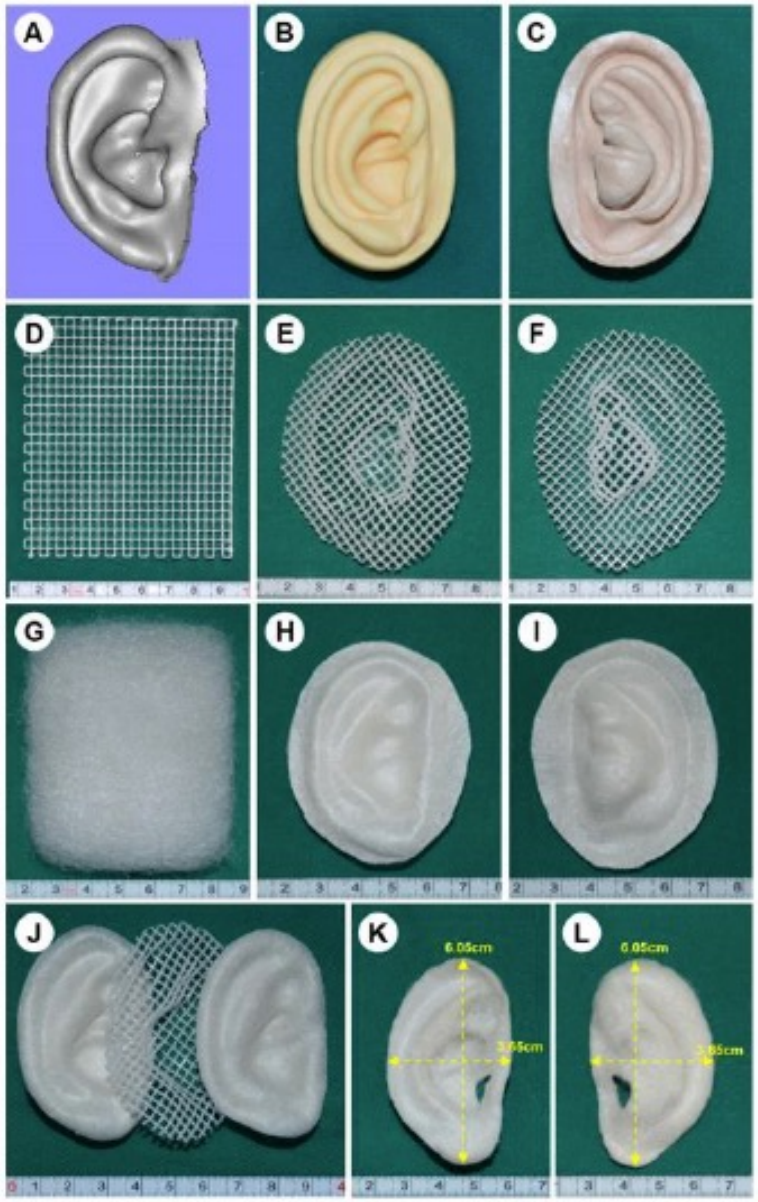
**Impalcature stampate 3D**

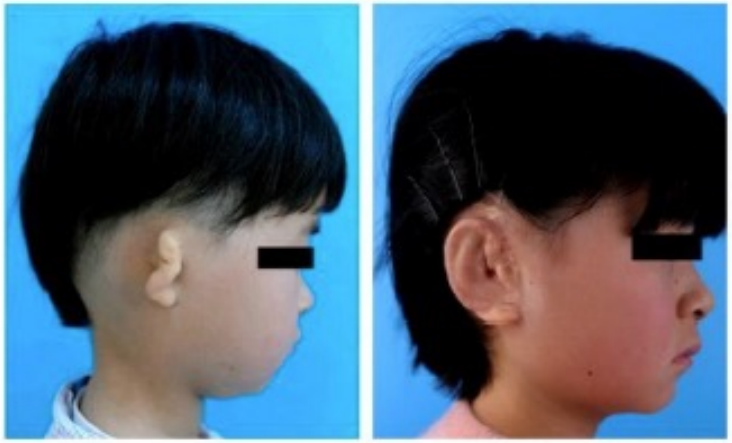
sono strutture artificiali utilizzate per supportare la formazione di tessuti 3 D. Può proteggere e localizzare le cellule e mantenere l'integrità della struttura 3 D desiderata. Dovrebbe avere pori grandi e interconnessi, dimensioni dei pori (solitamente intorno a 250 300 µm, ma può avere un diametro fino a 500 µm) consente la facile diffusione di molecole, aita anche la migrazione di gas nella struttura e aiuta anche la diffusione e proliferazione delle cellule. Un'impalcatura meccanicamente stabile è
cruciale per mantenere la struttura 3D.

L'impalcatura stessa può essere modificata con molecole solubili come antibiotici, agenti chemioterapici o fattori di crescita per un effetto aggiuntivo.

Altri potenziali trattamenti includono l'esposizione al plasma e l'introduzione di gruppi funzionali peptidici per migliorare l'attaccamento cellulare, la migrazione e proliferazione.

*3D printed ear scaffold.*



Pre-OP Post-OP 30m

*Right: To create the scaffold, a 3D digital image (A) was first 3D printed to create a negative mold (B, C). A 3D printed PCL mesh scaffold (D) was molded into shape (E, F), and further covered on both sides (J) by a PGA sponge which was also molded into shape (H, I). Above: Before and after images of one of the patients.*

*Source:* Zhou et al. In vitro regeneration of patient-specific ear-shaped cartilage and its first clinical application for auricular reconstruction. EBioMedicine. 28:287-302.

# Material overview – polymer scaffold

### Material description

- Biocompatible, biodegradable, and bioresorbable materials.
  - Common: PLA, PCL, PLGA, hydroxyapatite, PEEK


### Compatible printing processes

- Thermoplastic extrusion
- Material jetting
- Stereolithography
- Selective laser sintering


# Material overview – hydrogel

### Material description

- Hydrogel mimics the natural extracellular matrix and supports cells during the printing and maturation process.
  - Animal-based: collagen, gelatin, Matrigel, fibrin, chitosan
  - Plant-based: alginate, agarose


### Compatible printing processes

- 3D bioprinting
- Thermoplastic extrusion
- Vat photopolymerization

**Hydrogels are an essential support material in the fabrication of living tissue from individual cells.**

## TESTING

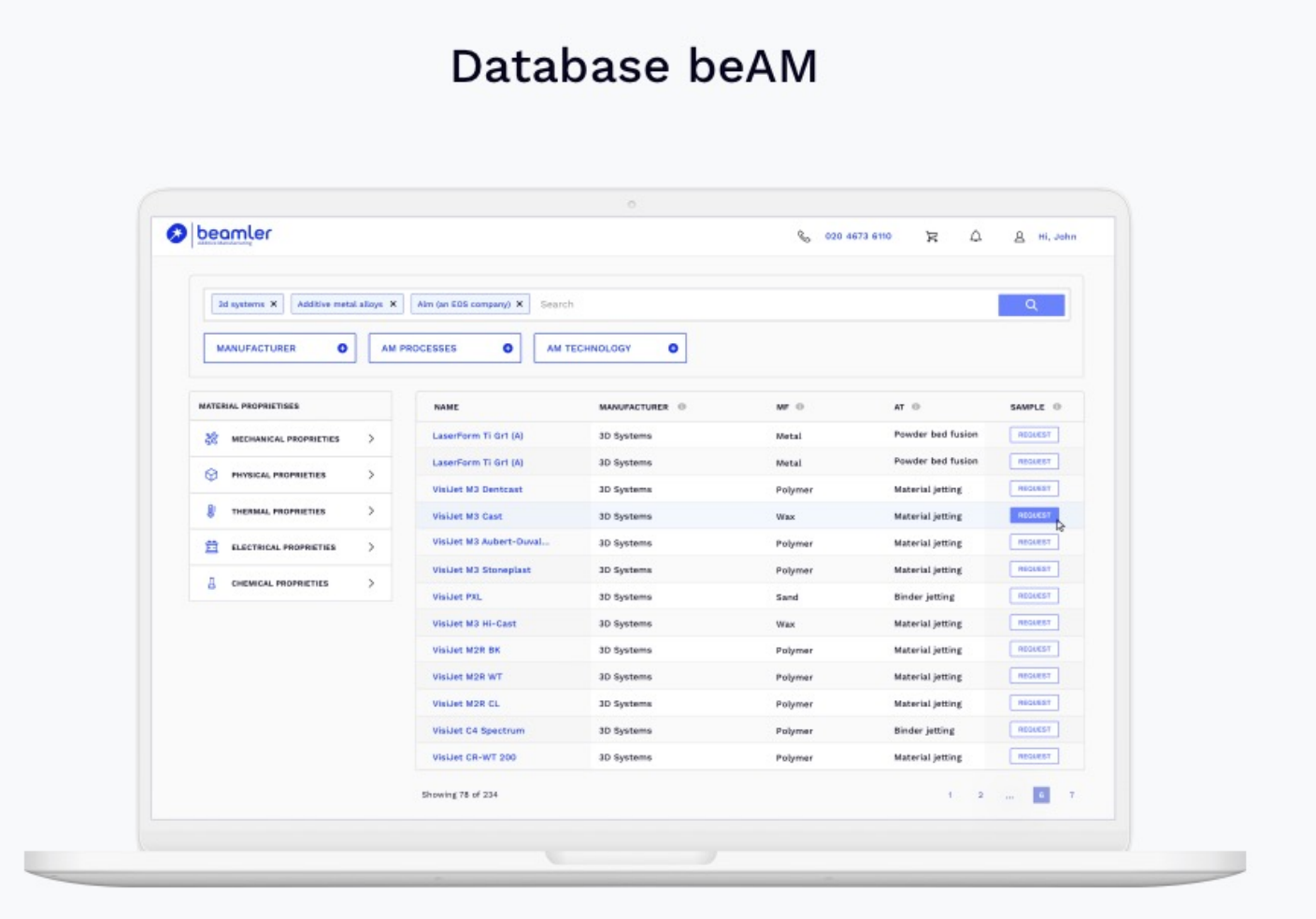
SUPPORTO ALLE AZIENDE DEL SETTORE BIOMEDICALE NELLO STUDIO DELLE PERFORMANCE, NELLA VALIDAZIONE DI NUOVI DISPOSITIVI E NELL'UTILIZZO DI NUOVI MATERIALI IN CONFORMITÀ AI PRINCIPALI REGOLAMENTI EUROPEI E NORMATIVE VIGENTI.
Il settore biomedicale si contraddistingue per estrema innovazione e forte regolamentazione, per questo è necessario garantire alti standard di qualità. Oltre alla richiesta di analisi sulla conformità e sicurezza dei materiali polimerici o metallici che compongono i dispositivi medici già in commercio, è nata l'esigenza sia di valutare le performance funzionali dei dispositivi in fase di sviluppo sia di completare la stesura del fascicolo tecnico necessario per il processo di marcatura CE.


https://www.tec-eurolab.com/biomedicale/

Tutti i materiali di stampa 3D in un unico database
Trova il materiale migliore per il tuo progetto di stampa 3D con il database beAM

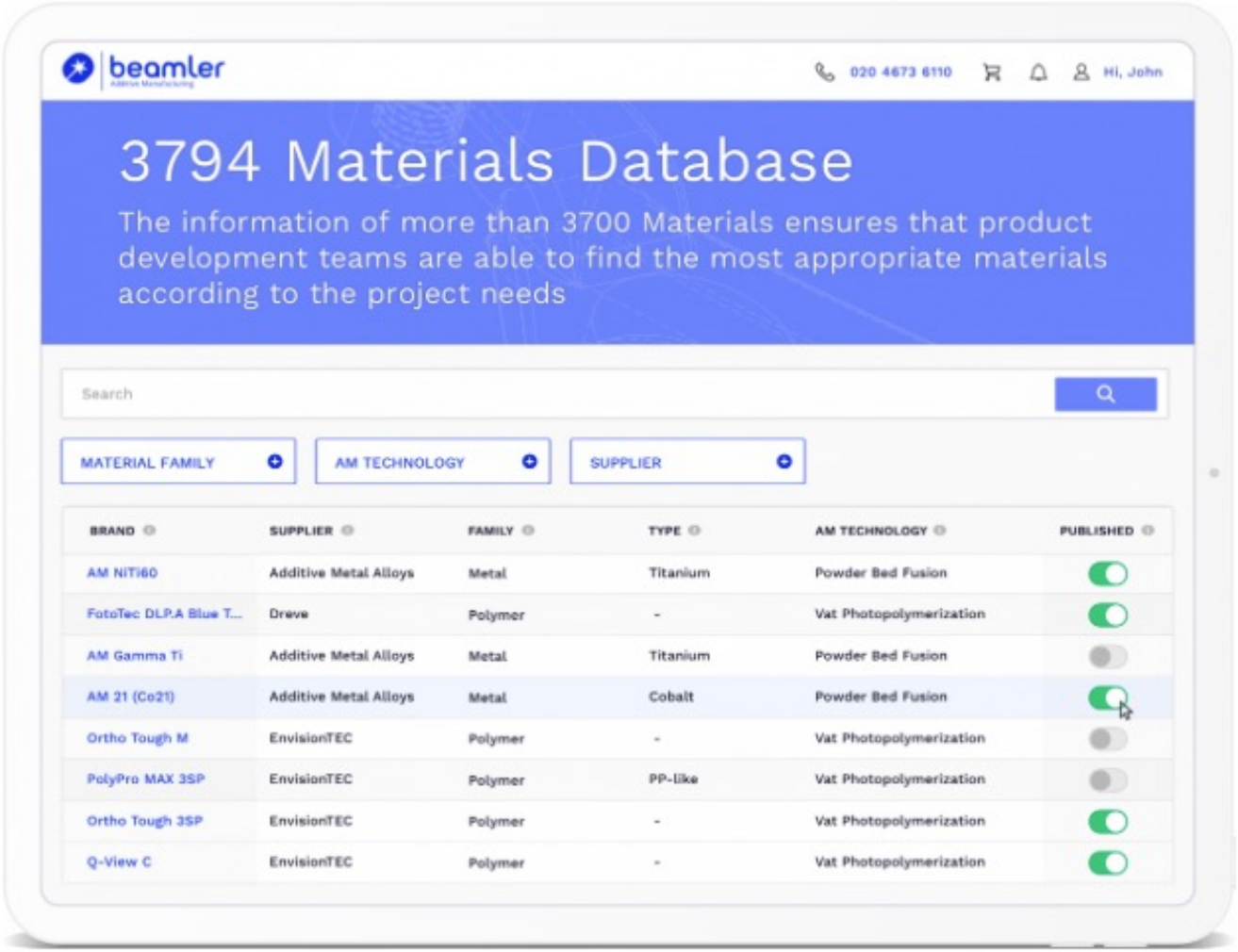
https://www.beamler.com/it/materiali-di-stampa-3d-database/

beamler
Additive Manufacturing



## Cerca e filtra le proprietà del materiale

I dati beAM possono essere organizzati e filtrati da numerosi parametri che facilitano il confronto di più proprietà tecniche. Ciò consente agli ingegneri di effettuare analisi significative e di migliorare la collaborazione e il trasferimento delle conoscenze all'interno del proprio team.



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# Intro - What is Digital Dentistry?

**So what exactly is Digital Dentistry?**

This growing segment of the dental industry includes a broad range of digital or computer-based devices and technologies.

This includes intraoral scanners, digital imaging, CAD/CAM, CNC milling machines, various design software and now 3D printing!

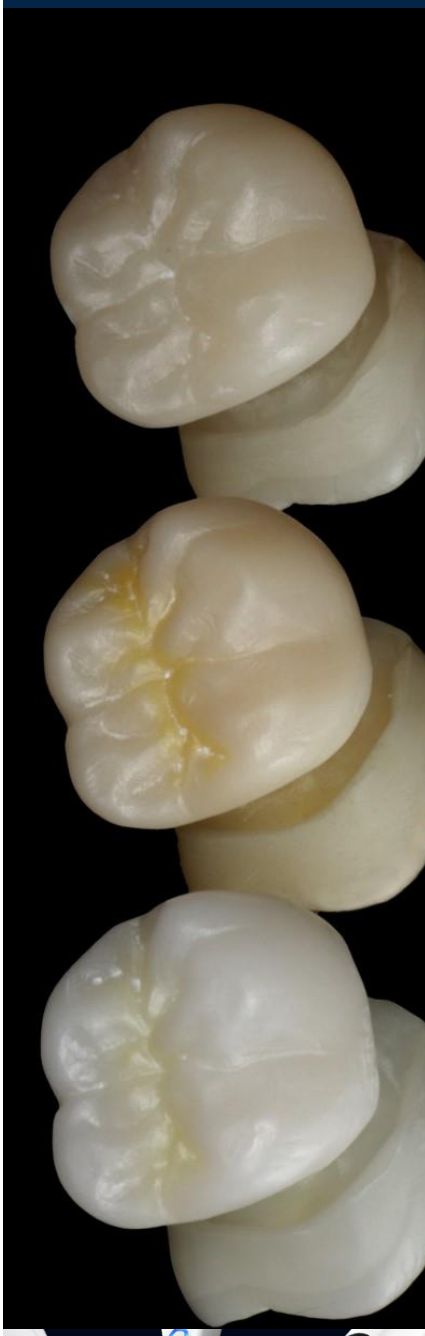
In other words, ***digital dentistry is a complete workflow that leverages multiple tools and systems to create 3D models of a patient's dental anatomy.***

It also produces accurate dental restorations such as dentures, crowns, dental implants, bridges, etc. using CNC milling equipment or a 3D printer.

And once these models are created, they can be used repeatedly to produce the same type of restorations without having to repeat the process of capturing dental anatomy in a traditional impression.

This not only saves you a ton of time and resources, but over time, you'll inevitably increase revenue, customer satisfaction, AND profit to your practice.

And with more revenue, you can expand your practice to new heights.



02

# Benefits & Opportunity of Digital Dentistry.

**The opportunities that come with Digital Dentistry are virtually endless.**

But you don't have to make the change from manual or analogue to digital methods overnight.

The transition can actually be done gradually.

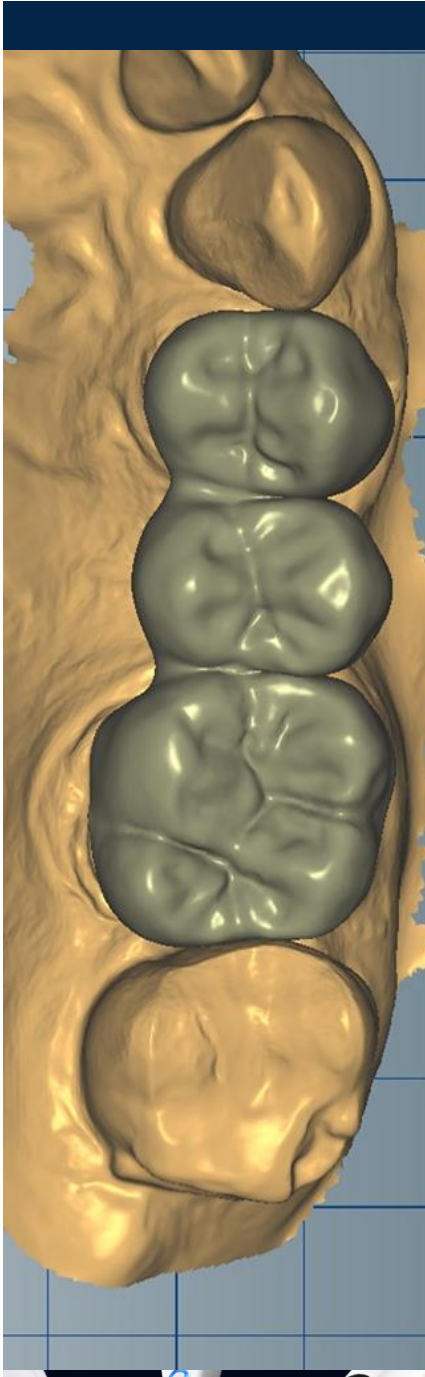
But before we get too far ahead, let's talk about some of the benefits (and opportunities) of using digital tools in your practice.

Many of the steps you'd normally take to produce molds, crowns, restorations, etc. can be performed faster, and much more efficiently through digital technologies. In fact, the "old school" methods could be made obsolete in the near future as more dentists upgrade the technology in their practice.

The risks for errors are considerably reduced as well. For example, data captured digitally remains permanently available, making it easy to reproduce dental work if something went wrong.

What's more, digitized processes provide more accurate data and better possibilities for visualizing treatment options and can therefore enhance the communication between the dentist and technician, as well as the dentist and patient.

In other words, most procedures can be standardized, and the quality of the processed materials enhanced. Another benefit is that dentists can choose between manufacturing certain restorations in the office and outsource others to a dental lab.



02

This means dental technicians can spend more time on designing restorations instead of focusing on lengthy preparatory work.

And in some cases, there may be no need to do any preparatory work at all.

Even more, there are now additional technologies, from electronic health records to face scans, that help dental professionals right from the beginning with diagnostics, treatment planning, and restoration design.

***All this information interconnects, making it much easier to include all dental specialties, and even artificial intelligence tools in the treatment planning process.***

Should you choose to go fully digital, possibly the greatest benefit to your practice would be the added convenience of all systems being able to “talk” to each other without any limitations.

Laboratory owners and dentists should *at the very least* consider including digital technologies and CAD/CAM in their procedures.

These technologies are starting to become more commonplace in everyday dentistry.

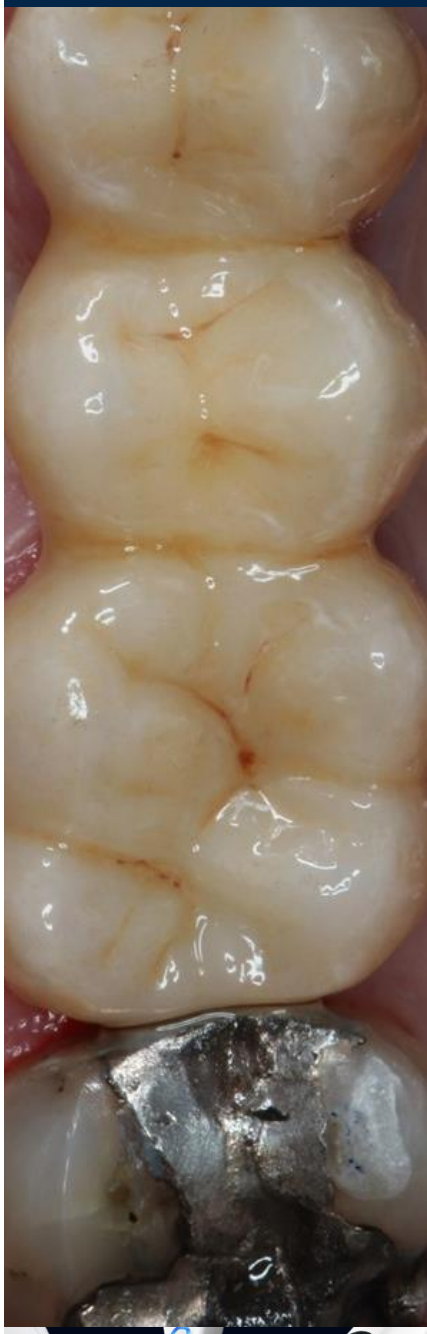
But by no means do you have to make an all-or-nothing decision to upgrade your practice.

Take your time...

For newcomers, the best approach is to adopt a “middle of the road'' strategy, meaning certain steps are digitized while other processes remain more traditional.

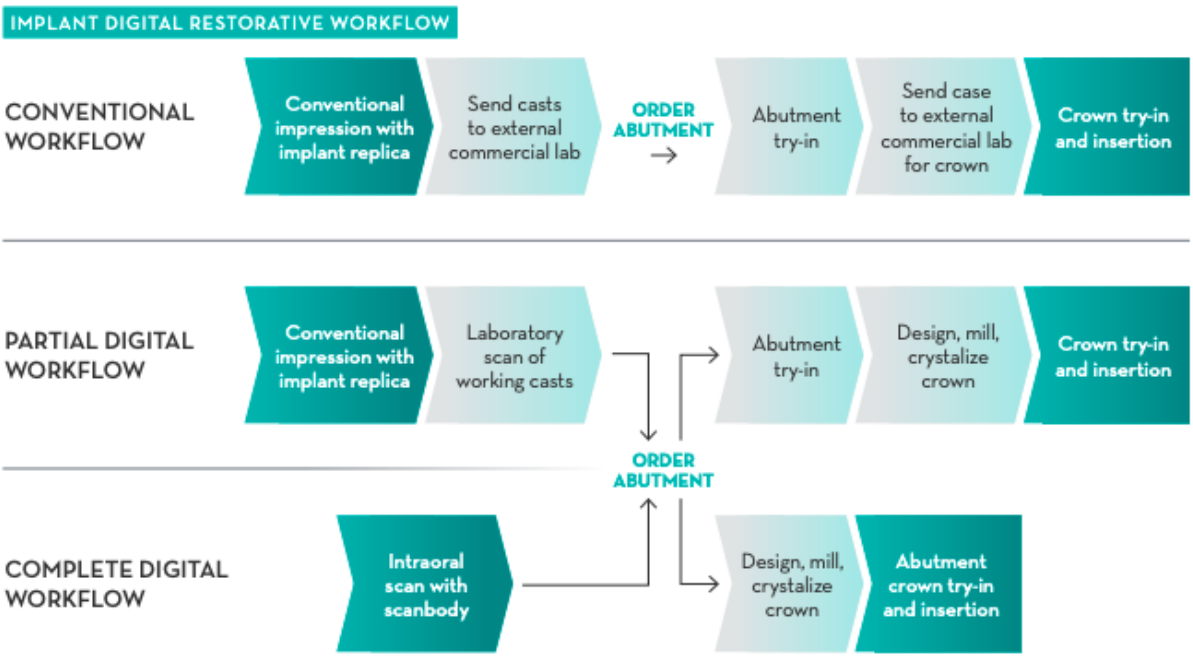
*The good news is, “old school” and digital methods can be easily combined until you’re ready to upgrade completely.*

For example, you may choose to invest in a intraoral scanner initially and then move to in-house milling later on.



02

So if your're more comfortable with a more slower approach, then by all means, do what works best for you!




Using new technology with your existing workflow can also allow for a positive return on your investment before purchasing any other digital tools.

This new tech could also add protection when it comes to the LEGAL side of dentistry.

If your medical-legal advisors instruct you to keep all plaster models for a certain number of years, just have one of your team-members “scan” the models for archiving, then dispose of the physical versions to free up storage space.

These are just a few of the benefits and opportunities of moving your practice towards the future of the dental industry.

Next, will talk about how going digital can have an impact on your practice’s revenue.

03

# Impact on Revenue.

**These days, Dentists and Dental technicians are under enormous pressure.**

With so many practices competing on price, and increasingly high expectations from patients to produce high-quality crowns, fillings, smile designs, etc., finding a balance between customer satisfaction and revenue has become quite challenging.

The good news is, Digital Dentistry can raise profits by reducing the time, materials, and space necessary to complete procedures.

It also enhances the experience for your customers because there will be no need for messy, uncomfortable impressions or molds.

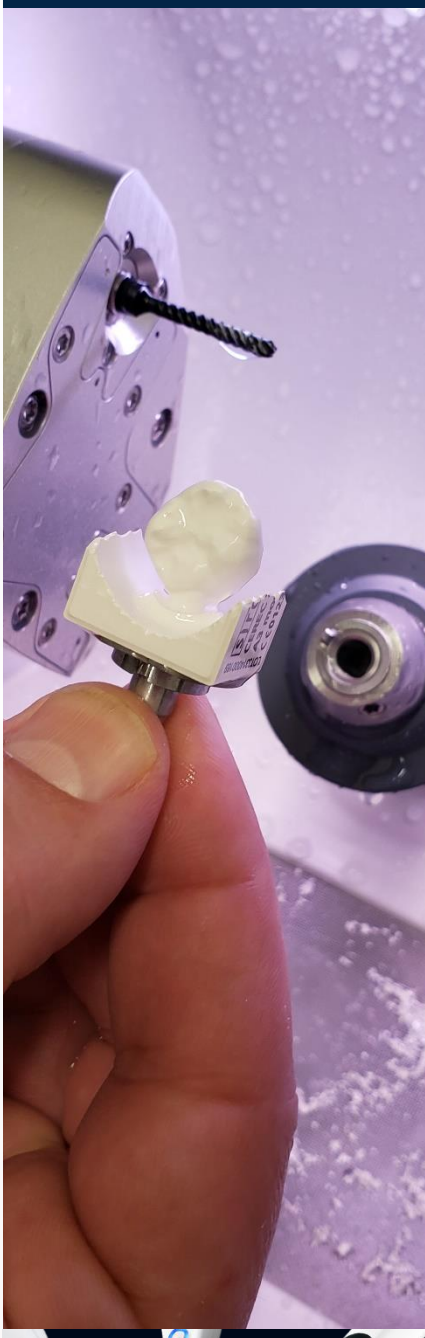
And since the procedures will be done using digital tools, fewer appointments are needed because of increased precision.

Perhaps the best aspect of this is the fact that it can be done while sticking to the same pricing strategy you're already used to.

As a matter of fact, a study conducted at two separate universities found that digital single-unit crown fabrication for tooth-supported restorations resulted in a **cost reduction** of **25 - 40%** when compared to traditional techniques!

***But here's where things REALLY get interesting...***

Those same studies revealed that digital single-unit crown fabrication through the complete digital workflow for implant-supported restorations resulted in a **cost reduction** of **52 - 60%!**



03

But that's just the beginning.

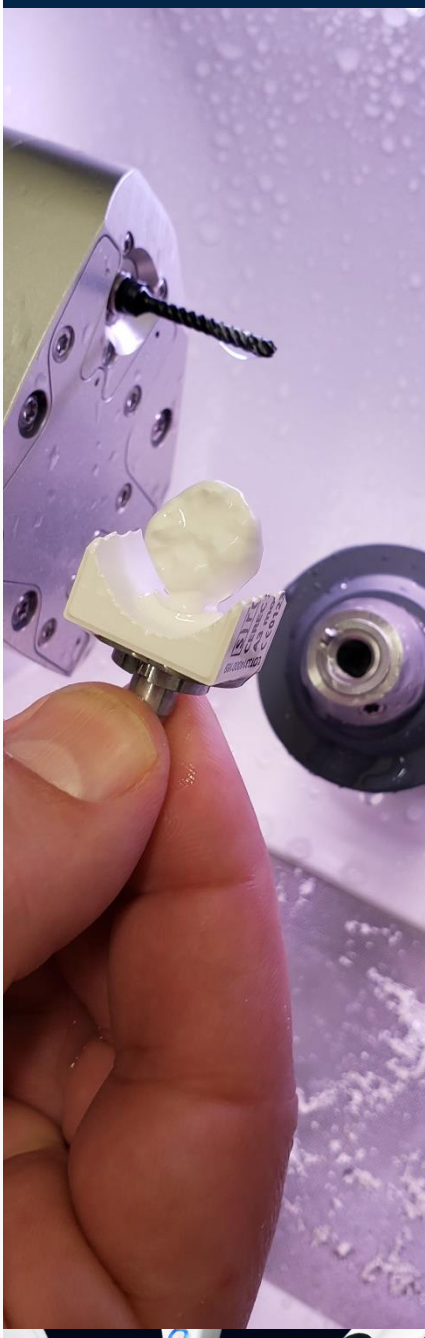
*The University of Illinois found profit margins for single-unit, tooth-supported restorations via conventional and digital workflows to be 9% and 45%, respectively.*

*And last but not least, The Medical University of South Carolina found profit margins for single-unit, tooth-supported restorations via conventional, digital impression, and digital-single visit workflow are 10%, 33%, and 40%, respectively.*

In conclusion, when compared to the traditional approach, Digital Dentistry is hands-down the best way to save money, increase revenue, and grow your practice.

Without needing to go back to college, or having to work harder to make things happen.

Now that we've covered potential ROI, let's take a look at customer experience and retention!



04

# Improved Customer Experience and Retention.

**Digital scanning and digital workflow can bring a whole new level of profit AND efficiency to your practice.**

But to get the most out of this transition, it's extremely important to put the patient at the center of your new digital process.

No matter what, patients should have the best experience possible when visiting your office.

When you make them the "center of the universe," patients will not only appreciate all the improvements that come with upgrading your tools (more efficient processes, increased speed, improved service), but they'll also make sure everyone else knows how great you and your staff-members are as well!

So if you haven't realised it yet, word of mouth marketing is the most valuable piece of credibility your practice can gain - and it's free!

But "better processes, increased speed, and improved service..." is really broad and ambiguous.

Let's get more specific, shall we?

First, digital impressions are far more comfortable for patients.

*The scanning process is fast, and files are produced that can be easily shared with other specialists or a dental lab.*

Compared to using old school methods, if a portion of a traditional impression comes out faulty, the entire process has to be repeated until it's done right.

04

However, with digital tools, a specific part of the mouth can be quickly reimaged if needed.

Going digital can also strengthen your prepping skills, as taking a scan of your prep will let you quickly see where your crown margins are, and identify any errors that need to be corrected.

CAD/CAM also supports dental techs with implementing more complex workflows, and delivers a level of precision that can easily be reproduced.

***Simply put, dentists can concentrate on perfecting aesthetics and function, instead of fumbling around with cumbersome, old-world dental tools.***

Speaking of aesthetics…

Many people think that with CAD/CAM technologies, everyone is getting the same smile.

No two people on Earth are exactly alike, which means that everyone's facial features and bone structures are different as well.

Which also means that regardless of a Dentist using a CAD/CAM file to give patients a new smile, they'll still be the same unique individual they were before coming to you for help.

By using scan files of natural dentition to design and restore teeth and smiles, the end-result looks and functions like the patient was born with the smile that you created.

In other words, patient care can be individualized like never before.

Being able to boost someone's confidence, and make them feel good about themselves by giving them a new smile using a CAD/CAM file that's been customized to fit that specific person is totally worth it.

04

But being a Dentist, Orthodontist, or other dental related specialist is about much more than selling the “perfect” smile.

Our job as doctors is also about the long-term monitoring of our patients and their various conditions. Luckily, Digital Dentistry can help by providing patients with better, and more accurate dental care than what was possible in the past.

Modern Digital methods also allow for more subtle and precise processing methods.

This makes it easier to perform even more MINIMALLY invasive procedures, and to preserve as much of the natural tooth structure as possible.

Operators can also choose to work with a broader spectrum of materials as well.

Additional materials, such as zirconia, e.max and hybrid ceramics are also suitable for CAD/CAM procedures.

Now that we’ve covered customer experience and how to keep them happy, let’s find out how much it’s going to cost you to get started in this growing industry.

05

# Getting Started.

**Investing in state-of-the-art equipment in any industry is admittedly expensive.**

The good news is, costs are coming down across the board as technology becomes more accessible.
But regardless of the costs, an experienced & forward-thinking business owner will always keep an eye on the trends of his / her industry.

As mentioned earlier, the Doctors who'll become most successful in the NEW ERA of Dentistry will look to make timely investments that:

***1.Improve performance.***

***2.Reduce costs.***

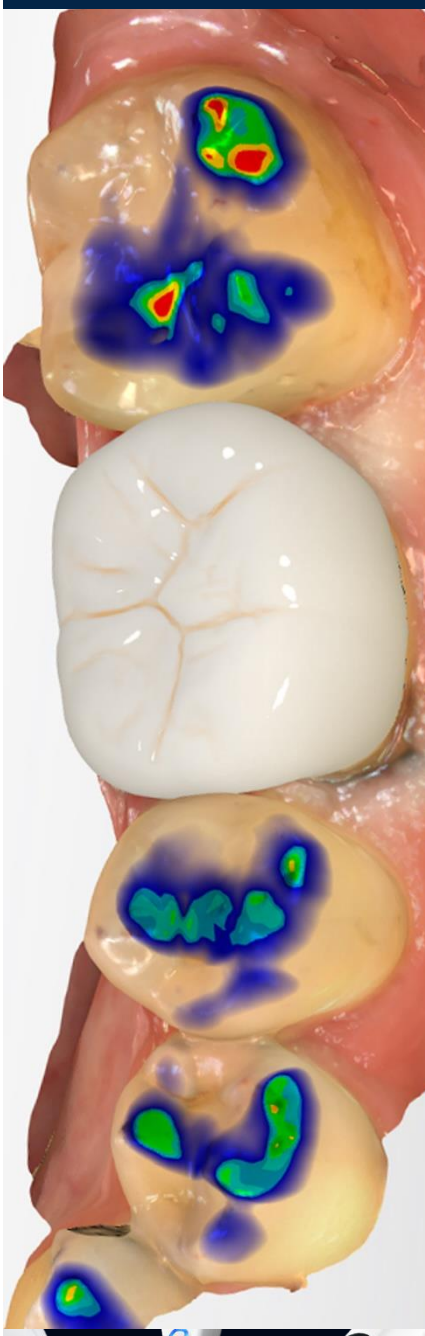
***3.Deliver a return on investment.***

*And ultimately...*

***4."Future-proof" the business.***

Across the globe, patients' access to high-quality oral healthcare has greatly improved.

Scanning teeth with optical scanners and fabricating dental restorations with digital technologies has become very common, and customized dental restorations that look nice, are well-fitted, and use quality materials means GREATER COMPETITION across the board.



05

And with patients gaining access to the internet in more places, connecting directly with the Dentist of their choice is now easier than ever.

So if you're still on the fence about moving away from traditional, analogue dental tools, at least consider incorporating some aspect of CAD/CAM into your practice.

But this doesn't have to be some huge leap of faith.

***Digital equipment can be adopted in stages over a manageable period of time, allowing you to fully recoup from one investment before making the next.***

This also ensures that you don't exceed your budget all at once.

For instance, an intraoral scanner is a good place to start as it can easily integrate with an otherwise analogue workflow.

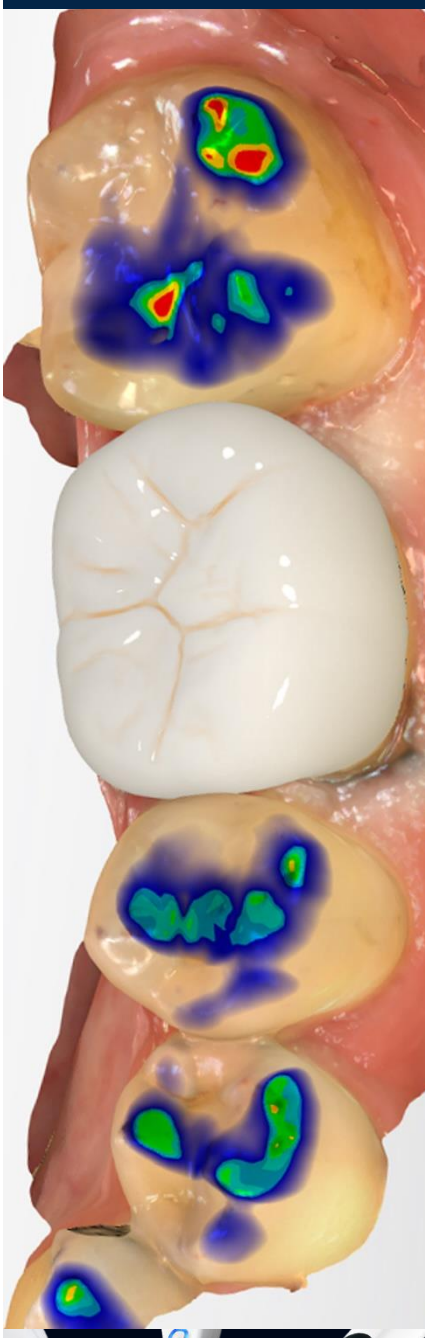
Once the scan is complete, the restoration will need to be designed.

At this point, if you and your team are not used to designing crowns, inlays, or other restorations, you'll need to get the necessary training from your machine's dealer or view our courses at iDD.

Next, you'll need to decide if you are more of an "architect", or an "engineer."

Over the years, I've found that most dentists like to be "architects," as they enjoy the creative process, and prefer to delegate the technical design to an experienced technician, then email the scan to get the final design.

But if you're an "engineer," you'll want to personally scan, design, and process the digital print/mill from scan, all the way through to the finished product.



05

This means taking complete control of the outcome, and thinking the procedure through from start to finish.

After that, you'll need to determine your digital workflow needs based on how often you expect to use the scanner.

Once you figure that out, it's time to determine what skills will be needed to integrate digital workflow into your practice, and who will provide technical support.

*The 10,000 hour rule states that it usually takes around 10,000 hours to MASTER a new skill.*

*But with the right training, strategic practice, and strong support network, you and key members of your staff can become proficient with your new tool in a fraction of the time it would take to learn on your own.*

Then, once everything is implemented, digital, in-housed milled ceramic restorations can be completed within one appointment instead of two or three via the conventional way.

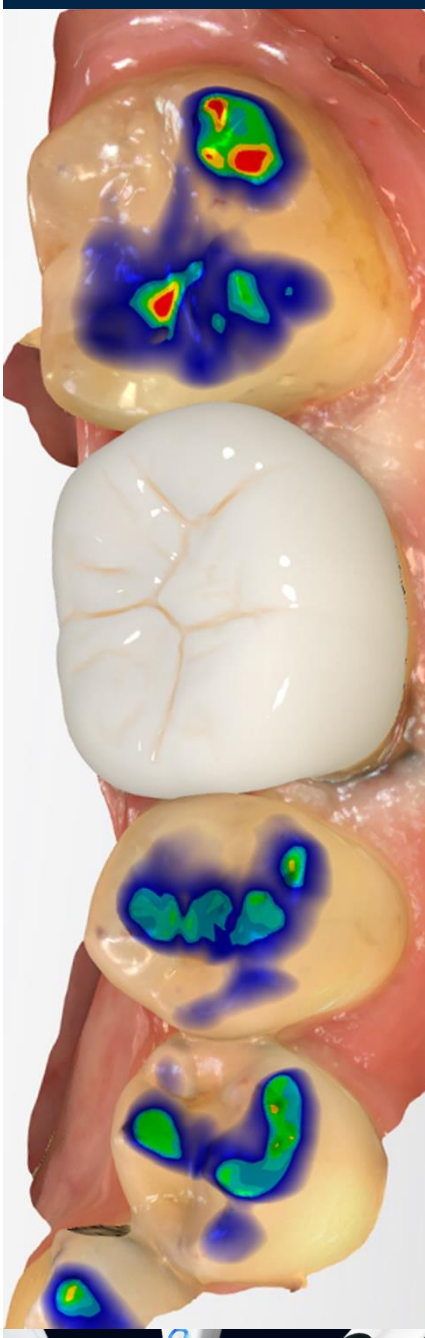
This ultimately means less time in the chair for certain patients, and more availability for new clients.

With a more efficient workflow, the time saved from pouring and mounting analogue casts, your practice should see more revenue in the long run.

For instance, with a chairside milling unit, a simple calculation of the number of restorations milled in-house per month, multiplied by the fee charged per restoration, will reveal how long it will take to repay the cost of the equipment.

Are you starting to see the possibilities that come with Digital Dentistry?

Next, will talk about what to do next, and how to transition from beginner to advanced in the shortest amount of time possible.



06

# Next Steps...

**Taking the time to read this ebook is a step in the right direction.**

I hope I've cleared up any confusion you may have had about Digital Dentistry, and inspired you to transition your practice from analog, towards using digital, CAD/CAM tools on a daily basis.

Many patients will be excited to learn that their new smile will be scanned, saved, and restoration designed before their eyes, and that your ability to fabricate restorations in-house while they wait eliminates the need for a second visit.

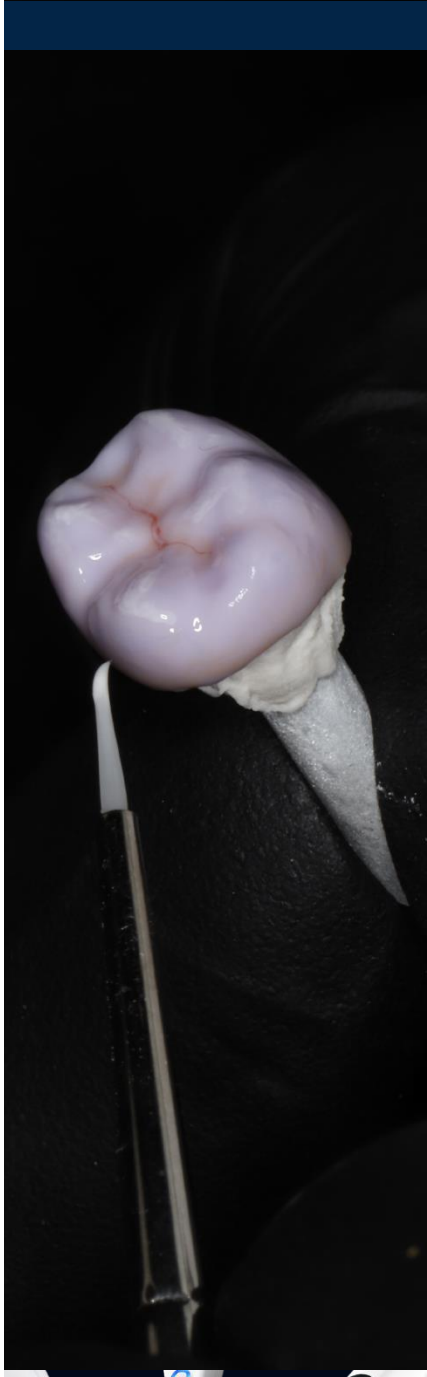
Still haven't decided to use digital technology yet?
I understand that there's no "one-size-fits-all" answer to these questions.

But rather than trying to figure things out on your own, it's best to have both a mentor, and a private network of new & experienced Digital Dentists who've been down the same path as you.

And since my ultimate goal is to provide that, AND help as many innovative & forward-thinking Dentists as possible build thriving practices.

I'm officially inviting you to become a member of iDD Online!
***With our training, you can get started in this growing industry with COMPLETE CONFIDENCE.***

We'll help you determine which which intraoral scanner, milling macine and printer make the most sense for you based on your needs - such as taking digital scans for aligner treatment, making retainers for orthodontic retention, or making implant stents to integrate with your CT scans and software.
We'll also get you and your staff trained on how to use every single tool you integrate into your practice.
But that's just the beginning...



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Once you become a member of iDD Online, you'll also get exclusive access to our private Facebook group, where you can rub elbows with other successful dentists who've enhanced their customer experience, increased revenue, and revolutionized their practice with Digital Dentistry.

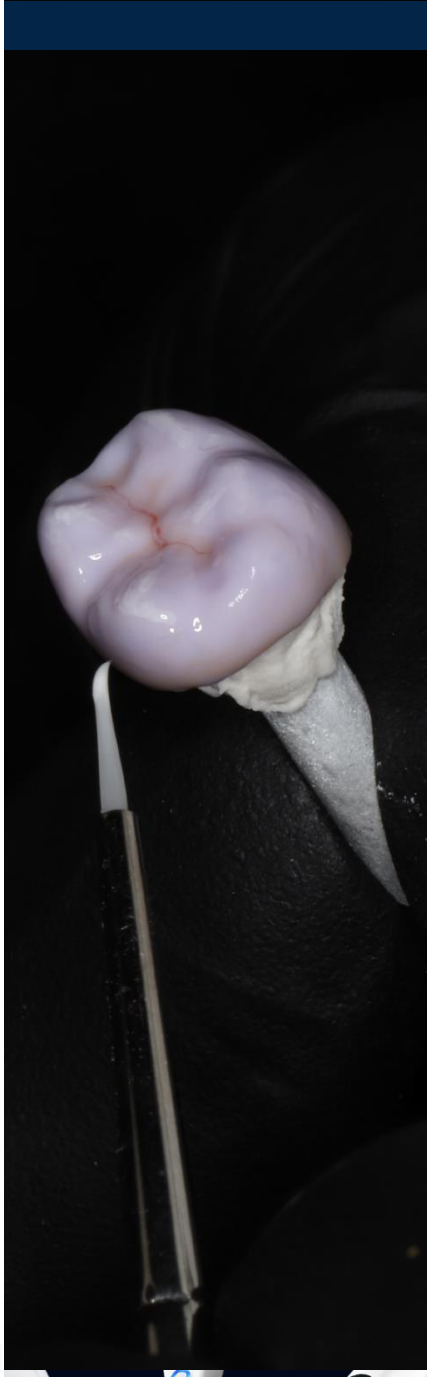
But iDD is much more than classes on how to run a more profitable business.

It's about becoming as efficient, helpful, and forward-thinking as possible.

Because when you focus on those three things, massive success is just a "scan" away.

So if you're ready to modernize your practice, and give more patients POSITIVE, and long-lasting results that they desire:

**Click Here to join The Institute of Digital Dentistry Now!**



# Source


https://dmg-connect.com/articles/embarking-on-a-digital-journey/

https://penntoday.upenn.edu/news/embracing-digital-dentistry

https://content.ivoclarvivadent.com/en/digital-dentistry-and-dental-technology-the-dental-world-in-transition

https://dmg-connect.com/articles/3-reasons-you-should-opt-for-digital-dentistry/

https://www.prosthodontics.org/assets/1/7/ACP_Digital_Dentistry_Curriculum.pdf


# Material Data Sheet

## General:

It is known that the addition of Zirconium and Niobium to Titanium alloys provides an excellent combination of corrosion resistance and biocompatibility. ZTM14N powder belongs to the ZTi-Med® family and it is a ternary titanium alloy specifically made for additive manufacturing. ZTM14N powder offers a very good strength-ductility ratio, low density, high biocompatibility which means no Aluminum and Vanadium are found in contrast to Ti64 alloy. The mechanical properties of ZTM14N are very close to those of the human bone and its Young modulus is very close to the bone's when compared to Titanium. This adapted mechanical properties reduces drastically the friction between the bone and the medical implant, removing therefore the "stress shielding effect" which causes the loosing of implants. Because of its unique properties, ZTM14N offers a large range of applications such as medical and luxury.

## Materials structure:

ZTM14N processing parameters were first developed on a powder bed fusion machine (PBF). Bulk parts were firstly made and later counterparts with different complex geometries were produced. The microstructure of the as- built state of ZTM14N parts under electron microscopy mainly shows fine β grains depending on chemical composition and post heat treatment. ZTM14N alloy was also processed through post heat treatments such as hot isostatic pressure (HIP) to obtain a full density and high fatigue resistance.

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Phone : +33 1 75 38 98 92 | E-mail : ahattal@z3dlab.com

# ZTM14N [1]

| Physical and Chemical Properties | | | |
|---|---|---|---|
| Mass density [2] | ~ 5.56 g/cm³ | | |
| Component density [3] | > 99.9 % | | |
| Melting point | ~1614 °C | | |
| Particle size [4] | | 25 – 45 – 63 – 100 µm | |
| Particle shape | | Spherical | |
| Max. Chemical composition [Mass fraction in %] [5] | | Element | |
| | | Ti | Bal |
| | | Zr | 21.46 |
| | | Nb | 27.12 |
| | | C | 0.039 |
| | | H | 0.0008 |
| | | N | 0.018 |
| | | O | 0.15 |

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# Material Data Sheet

## ZTM14N [1]

| Mechanical Data at 25°C<br>**Layer thickness 30 µm**<br>M: Mean<br>SD: Standard deviation | | | As-built | | Forged [7] | Ti64 [8] |
|---|---|---|---|---|---|---|
| | | | M | SD | | |
| **Tensile test [6]** | | | | | | |
| Tensile strength | $R_m$ [MPa] | | 752 | 6 | 753 | 860 |
| Offset yield strength | $R_{p0.2}$ [MPa] | | 710 | 4 | 729 | 795 |
| Elongation at break | A [%] | | 15 | 1.5 | 14.5 | 10 |
| Young's modulus | E [GPa] | | 42* | 1 | - | 113 |
| **Hardness test [9]** | | | | | | |
| Vickers micro-hardness | $HV_{0.2}$ | | 320 | 5 | 170 | 340 |
| **Roughness measurements** | | | | | | |
| Roughness average | $R_a$ [µm] | | 6 | 2 | - | - |

ZTi-Med® meting parameters are developed and enhanced at Z3DLAB facility. The physical and mechanical properties of ZTi-Med® made via additive manufacturing in addition to its powder were analyzed and tested according to ASTM and ISO standards by The French National Centre for Scientific Research (CNRS). More details about measurements procedures used by Z3DLAB are available upon request. We inform our clients that they are responsible for the qualified verification

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[1] Property and ownership of Z3DLAB. Further details are provided upon request.

[2] Subject to minor change within the range of possible chemical composition.
Measurements according to ASTM-B962 and ASTM B923.

[3] Rough value, subject to minor change within the range of possible heat treatments.
Theoretical density measurements via XRD.
Density measurements via Helium Pycnometry.
99.999% density obtained after HIP post-treatment.

[4] With respect to powder material.

[5] Chemical composition numbers are average values; each element was measured according to ASTM E2371-13, GB/T-4698. 14-2011, GB/T-4698.15-2011, GB/T4-698.7-2011, GB/T -4701.1-2009.

[6] Tensile tests were performed according to ASTM E8; testing machine Zwick 10KN; testing speed 0.001 s-1 at room temperature. The numbers are average values and are determined from samples with horizontal and vertical orientation

[7] Tensile tests were performed according to ASTM E8; testing speed 0.001 $s^{-1}$ at room temperature. The numbers are average values.

[8] Minimum values according to ASTM F3001-14: Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion.

[9] Micro-hardness testing according to ASTM E384.

* Heat treated state

# Dental Materials

**Advanced materials for superior digital dentistry and orthodontics.**

The Stratasys Dental Series 3D printers use the superior accuracy, high precision and dimensional stability of PolyJet materials to create a range of dental appliances, restorations and models with consistency and exactness.

**Clear Biocompatible (MED610™)**

Transparent, bio-compatible material that is medically approved for temporary in-mouth placement.

Ideal for: Orthodontic appliances, delivery and positioning trays and surgical guides

**Flexible Biocompatible (MED625FLX™)**

Flexible, biocompatible material that is certified for temporary in-mouth placement.

Ideal for: Orthodontic indirect bonding trays and implant gingival masks

**Biocompatible VeroGlaze™ (MED620™)**

Opaque white material with A2 shading designed to provide the best color match in the industry. VeroGlaze is medically approved for temporary in-mouth placement up to 24 hours.

Ideal for: Veneer try-ins and diagnostic wax-ups

**VeroDent™ (MED670™)**

Natural peach-tone material with high-quality detail, strength and durability.

Ideal for: Dental and orthodontic models including clear aligner arches

**VeroDentPlus™ (MED690™)**

Dark beige material that creates amazingly fine features and finish. VeroDentPlus also offers excellent strength and durability, and delivers a higher level of opacity than VeroDent.

Ideal for: Dental and orthodontic models including clear aligner arches

**Triple-Jetting technology**

In addition, standard 3D printing materials provide composites with these advanced features: Gum-like textures, range of colors to represent natural tooth and gum shades, ability to render anatomy such as nerve canal, jaw and teeth in contrasting materials, all in one print

| Property | Standard/ Procedure | Clear Biocompatible MED610 | Biocompatible VeroGlaze MED620 |
|---|---|---|---|
| Tensile Strength (MPa) | D-638-03 | 50 – 65 | 55 – 65 |
| Elongation at break (%) | D-638-05 | 10 – 25 | 15 – 25 |
| Modulus of elasticity (MPa) | D-638-04 | 2,000 – 3,000 | 2,300 – 3,300 |
| Flexural Strength (MPa) | D-790-03 | 75 – 110 | 80 – 100 |
| Flexural Modulus (MPa) | D-790-04 | 2,200 – 3,200 | 2,300 – 3,200 |
| HDT 0.45 MPa (ºC) | D-648-06 | 45 – 50 | 45 – 50 |
| HDT 1.82 MPa (ºC) | D-648-07 | 45 – 50 | 45 – 50 |
| Izod Notched Impact (J/M) | D-256-06 | 20 – 30 | 20 – 30 |
| Water Absorption (%) | D-570-98 24HR | 1.1 – 1.5 | .1 – 1.5 |
| Tg (ºC) | DMA E | 52 – 54 | 52 – 54 |
| Shore Hardness (D) | Scale D | 83 – 86 | 83 – 86 |
| Rockwell Hardness (scale M) | Scale M | 73 – 76 | 73 – 76 |
| Polymerized density (gr/cm$^3$) | ASTM D792 | 1.17 – 1.18 | 1.17 – 1.18 |
| Bio-compatibility | DIN EN ISO 10993-1:2009 | Approved | Approved |
| Support Removal Type | – | WaterJet | WaterJet or soluble* |

# Dental Materials

| Property | Standard/ Procedure | VeroDent MED670 | VeroDentPlus MED690 |
|---|---|---|---|
| Tensile Strength (MPa) | D-638-03 | 50 – 60 | 54 – 65 |
| Elongation at break (%) | D-638-05 | 10 – 25 | 15 – 25 |
| Modulus of elasticity (MPa) | D-638-04 | 2,000 – 3,000 | 2,200 – 3,200 |
| Flexural Strength (MPa) | D-790-03 | 75 – 110 | 80 – 110 |
| Flexural Modulus (MPa) | D-790-04 | 2,200 – 3,200 | 2,400 – 3,300 |
| HDT 0.45 MPa (ºC) | D-648-06 | 45 – 50 | 45 – 50 |
| HDT 1.82 MPa (ºC) | D-648-07 | 45 – 50 | 45 – 50 |
| Izod Notched Impact (J/M) | D-256-06 | 20 – 30 | 20 – 30 |
| Water Absorption (%) | D-570-98 24HR | 1.1 – 1.5 | 1.2 – 1.5 |
| Tg (ºC) | DMA E | 52 – 54 | 52 – 54 |
| Shore Hardness (D) | Scale D | 83 – 86 | 83 – 86 |
| Rockwell Hardness (scale M) | Scale M | 73 – 76 | 73 – 76 |
| Polymerized density (gr/cm$^3$) | ASTM D792 | 1.17 – 1.18 | 1.17 – 1.18 |
| Bio-compatibility | DIN EN ISO 10993-1:2009 | – | – |
| Support Removal Type | – | WaterJet or soluble* | WaterJet or soluble*t |

| Property | Standard/ Procedure | MED625FLX |
|---|---|---|
| Tensile Strength (MPa) | D-412 | 3 – 5 |
| Elongation at break (%) | D-412 | 45 – 55% |
| Compressive Set (%) | D-395 | 0.5 – 1.5% |
| Shore Hardness (Scale A) | D-2240 | 73 – 77 |
| Tensile Tear Resistance (kg/cm) | D-624 | 8 – 12 |
| Polymerized density (gr/cm$^3$) | D-792 | 1.16 – 1.17 g/cm$^3$ |
| Bio-compatibility | EN ISO 10993-1 | Approved |
| Support Removal Type | – | WaterJet |

For detailed material specifications of non-dental materials, please see the PolyJet Materials Data Sheet. All data provided herein, which is related to consumables, was collected from specific specimens and test conditions and is provided for information only. Characteristics may vary if different specimens and test conditions are applied. Unless expressly provided in writing, no warranties are made and warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

*Soluble support is available on the Eden260VS Dental Advantage™, Objet260 Dental™ and Objet260/500 Dental Selection™. No full bio-compatibility on soluble support.

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# Introduction to 3D Bioprinting

## With Dr Nadia Tsao, Technology Analyst

After over 15 years of research and development in academia and industry, several main applications of 3D bioprinting technology are ready to be realised. This webinar will provide a concise introduction to 3D bioprinting, including details of the technologies, applications, and market forecasts covered in the IDTechEx report 3D Bioprinting 2017 – 2027: Technologies, Markets, Forecasts.

This webinar will include:

- Background and history of 3D bioprinting
- Introduction and discussion of major printhead
- Status of 3D bioprinting in 2017, including key trends and applications
- Market outlook 2017 – 2027

*www.idtechex.com/3Dbio*

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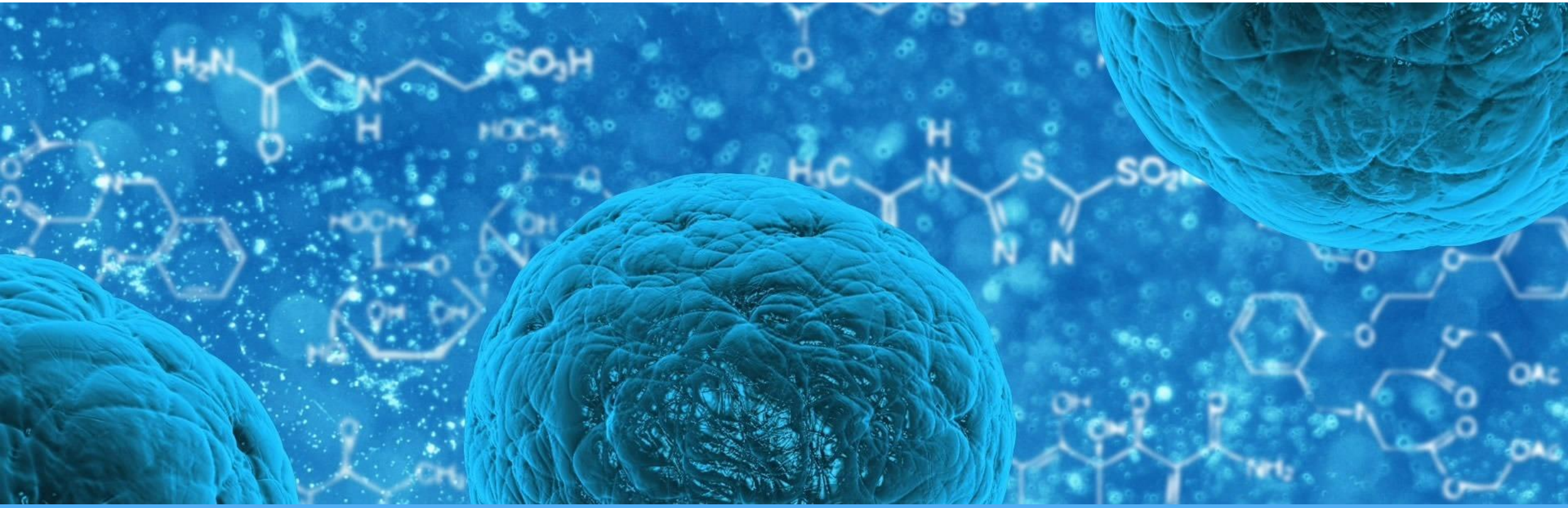
IDTechEx Research

# Introduction to 3D Bioprinting

## With Dr Nadia Tsao, Technology Analyst



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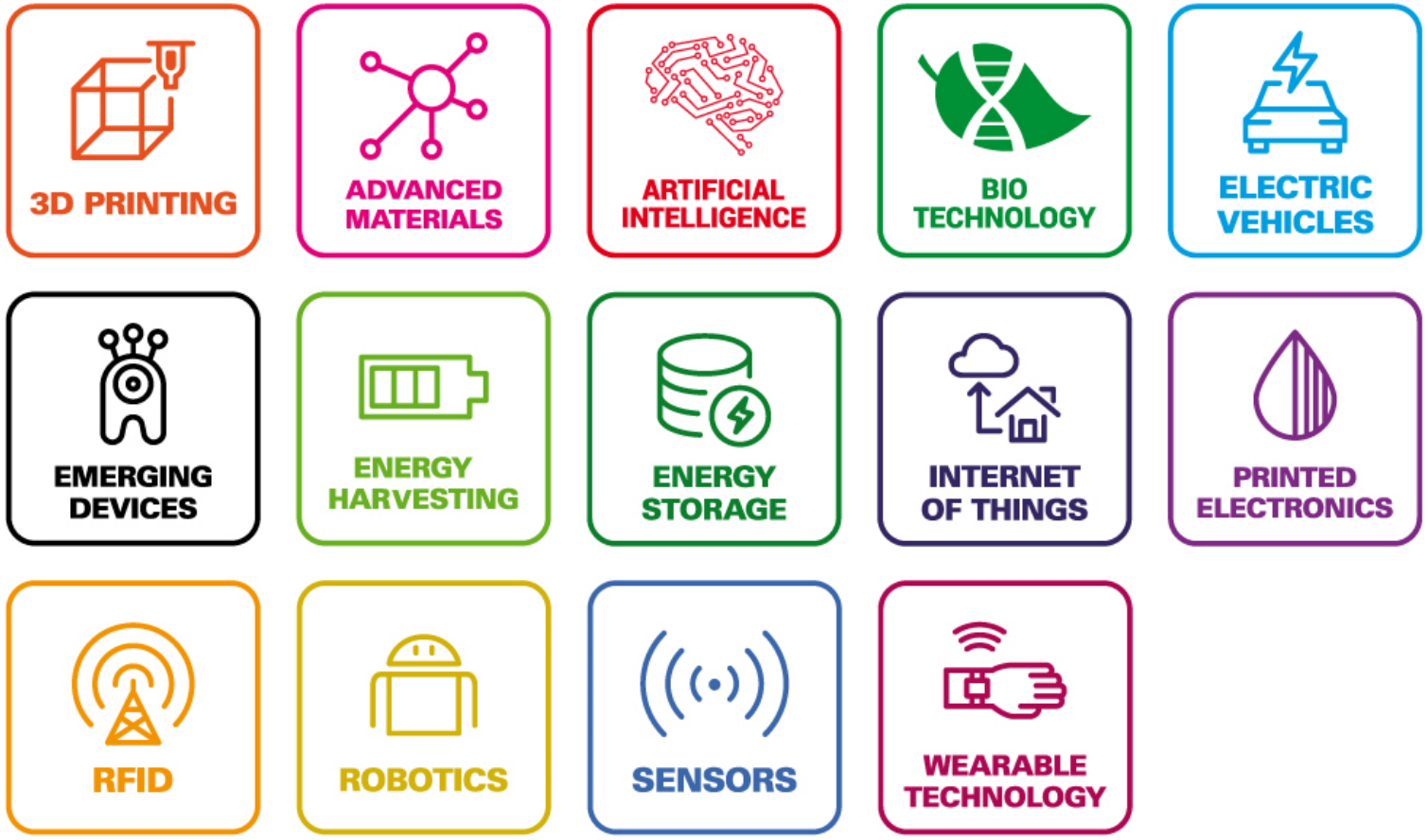


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# What is 3D Bioprinting?

> “3D bioprinting is the deposition of living cells of any type in a spatially controlled manner in the absence of any pre-existing scaffold and in more than a single (2D) layer such that the cells largely survive the printing process”

- This definition was introduced to limit the scope of research to a cohesive collection of technologies that are used to fabricate 3D tissues, and thus the following “bioprinting” technologies are not considered:
  - Printing of proteins such as enzymes and antibodies
  - 2D printing of cells such as for high throughput testing
  - 3D printing for biological/medical purposes such as the creation of patient-specific bone replacements

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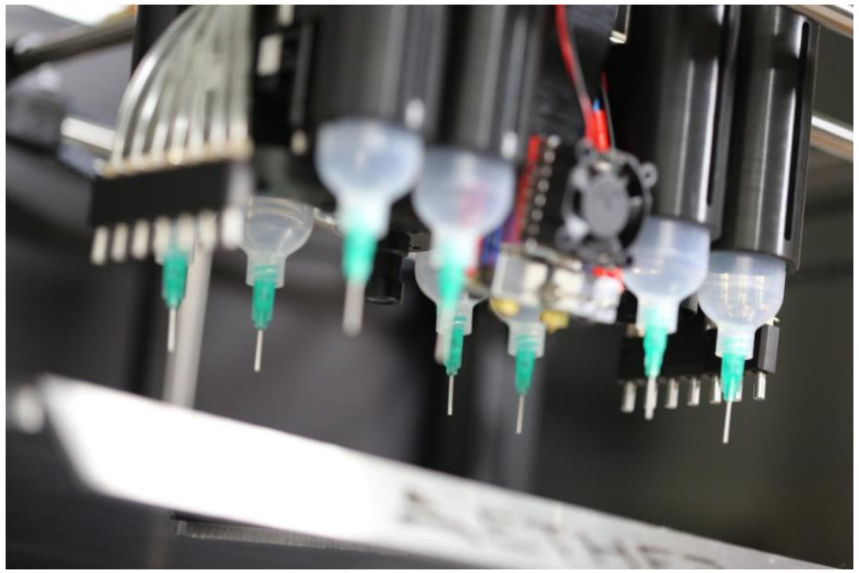
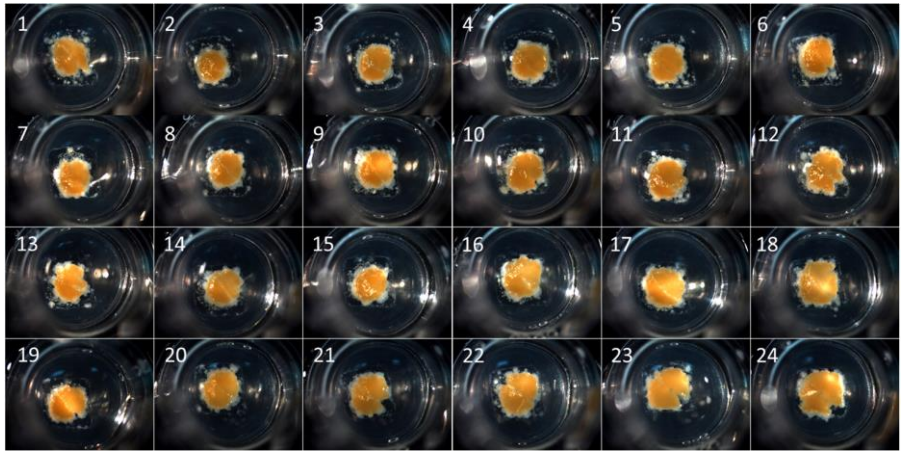
# In a nutshell…






*Source:* Aether, Organovo

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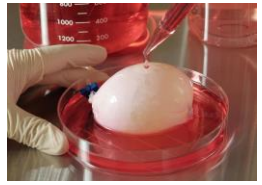
# Major 3D Bioprinting Firsts



1987
Biological material printed – Klebe

1999
Transplant of manually seeded 3D printed scaffold – Atala

2002
Extrusion printing of cells – Muelhaupt

2004
Laser-based printing of cells in 3D – Chrisey

2010
*In situ* bioprinting of skin onto injured mice – Atala

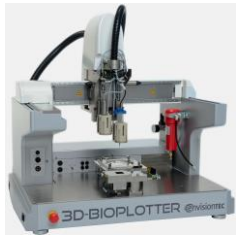

2015
Bioink company founded – Cellink

*Past*

*Present*

Laser-based printing of cells in 2D – Odde and Renn
1999

Commercial bioprinter – EnvisionTEC
2000

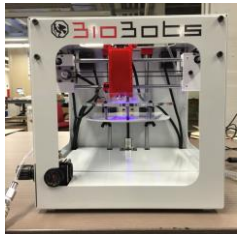



Inkjet printing of cells – Boland
2003

3D bioprinting company founded – Organovo
2007

organovo™

Microvalve printing of cells – Shu
2013




Low-cost bioprinters emerge – Biobots
2014

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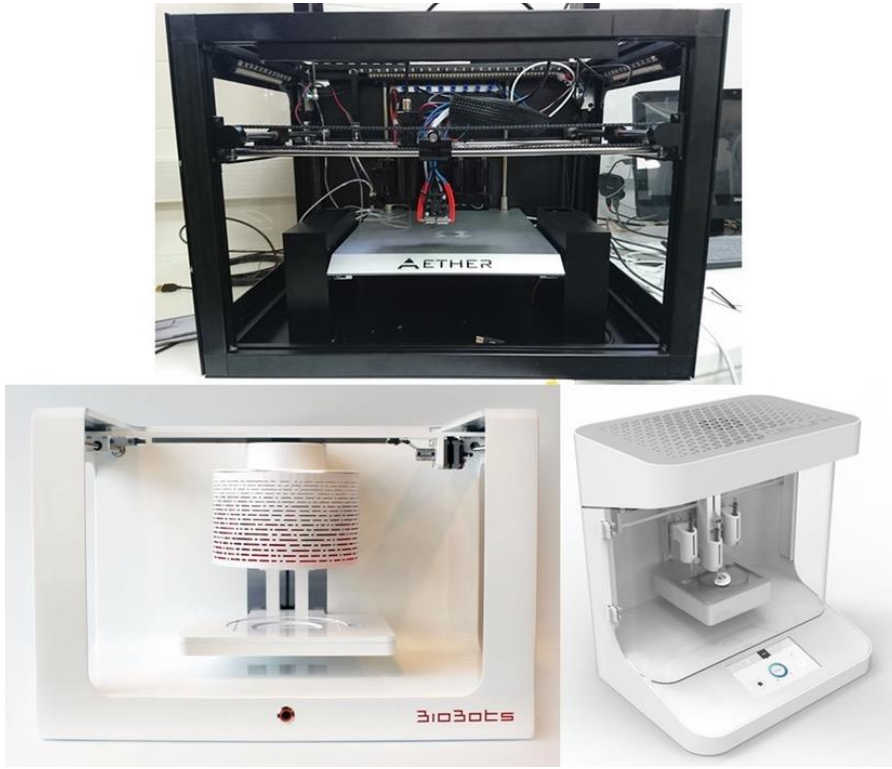
# Advantages of 3D Bioprinting

Using 3D bioprinting techniques to create 3D tissue constructs offers additional advantages over other 3D cell culturing methods.

- Ability to maintain accurate and precise control over cell placement
- Ability to replicate native form and function
- Ability to shorten tissue engineering timescales
- Ability to up-scale




*3D bioprinters released in 2017.*

*Source: IDTechEx, BioBots, Cellink*

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# 3D Bioprinting Process

## Preparation

- *3D imaging*
- *Construct design*
- *Cell culture*
- *Preparation of bioink*

## Printing

- *Import into bioprinter*
- *Layer-by-layer deposition*
- *Crosslinking*

## Maturation

- *Cell adhesion to scaffold*
- *Cell differentiation*
- *Maturation in bioreactor*
- *Self-assembly*

## Application

- *Testing*
- *Implantation*

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# 3D Bioprinting Process







**Preparation**

- *3D imaging*
- *Construct design*
- *Cell culture*
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**Printing**

- *Import into bioprinter*
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- *Crosslinking*

**Maturation**

- *Cell adhesion to scaffold*
- *Cell differentiation*
- *Maturation in bioreactor*
- *Self-assembly*

**Application**

- *Testing*
- *Implantation*

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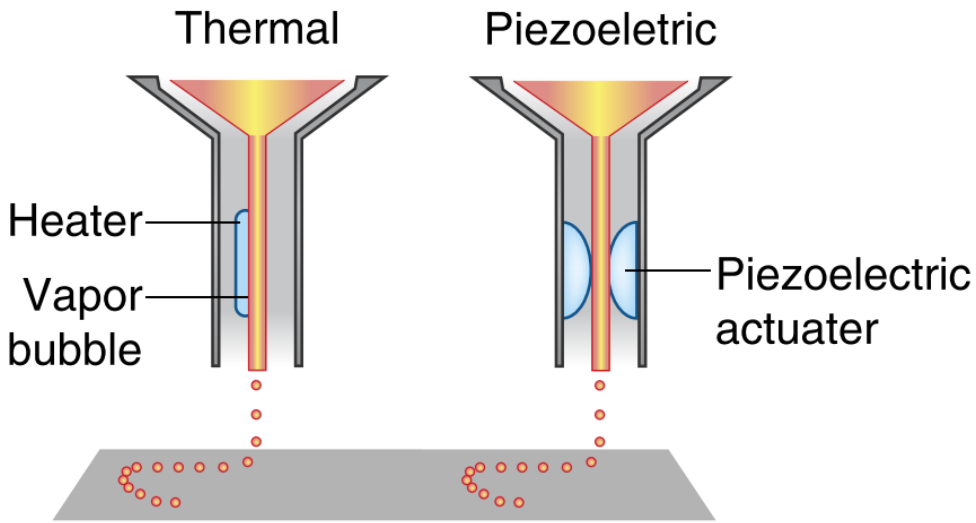
# Inkjet

- Droplet on demand
- Bioink ejection by thermal or piezoelectric actuator
- Strengths
  - Accessible
  - Non-contact
  - High resolution
  - High dispensing
- Weaknesses
  - Limited printable viscosities
  - Nozzle clogging
  - Long build time




*Schematic of thermal and piezoelectric inkjet printheads.*

*Source:* Murphy SV, Atala A. 3D bioprinting of tissues and organs. Nature Biotechnol. 2014, 32, 773 – 85.

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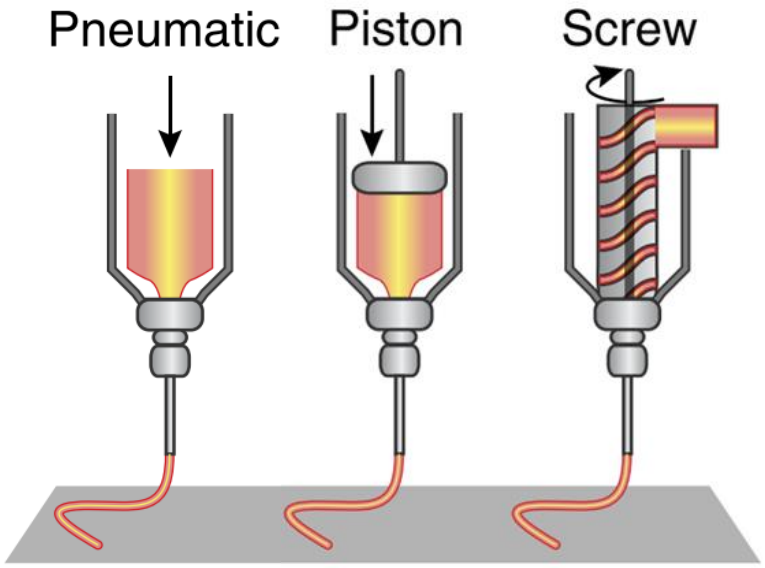
# Extrusion

- Continuous printing process (tubular trace)
- Bioink extrusion by compressed gas, piston-driven (motor or compressed gas), and screw
- Strengths
  - Quick build time
  - Compatible with high viscosity materials
  - Easy set up and use
  - Low cost
- Weaknesses
  - Lower printing resolution
  - Nozzle clogging




*Schematic of pneumatic, piston- and screw- driven extrusion printheads.*

*Source:* Murphy SV, Atala A. 3D bioprinting of tissues and organs. Nature Biotechnol. 2014, 32, 773 – 85.

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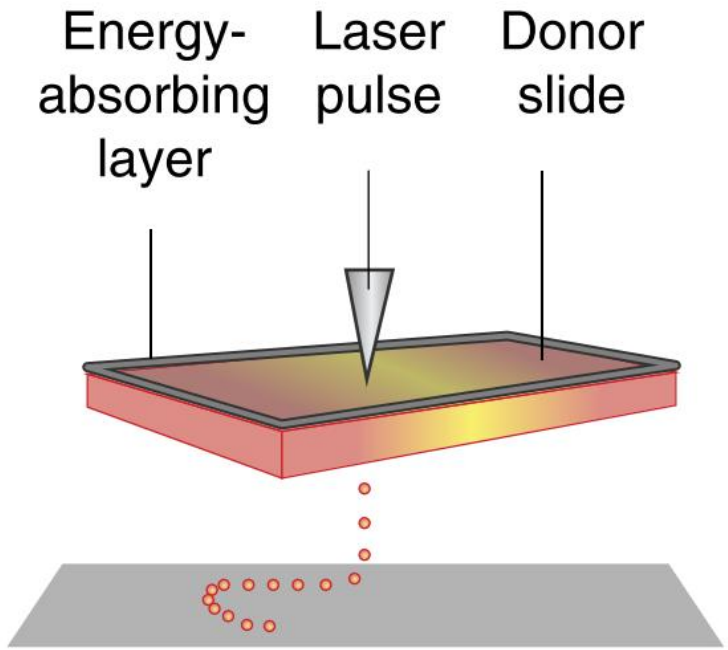
# Laser-Induced Forward Transfer

- Droplet on demand (from bioink ribbon)
- Bioink ejection by pulsed laser beam
- Strengths
  - High dispensing speed
  - High printing resolution
  - Non-contact
  - No clogging
- Weaknesses
  - Difficult set up
  - Expensive
  - Long build time
  - Contamination by toxic residues




*Schematic of a laser-induced forward transfer printhead.*

*Source:* Murphy SV, Atala A. 3D bioprinting of tissues and organs. Nature Biotechnol. 2014, 32, 773 – 85.

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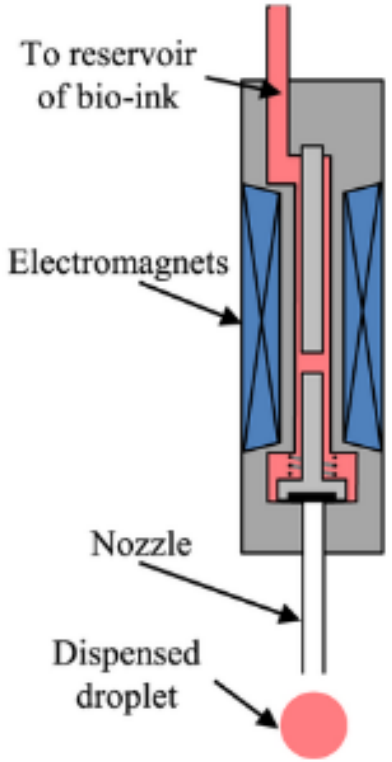
# Microvalve

- Droplet on demand
- Bioink ejection by compressed gas when valve open
- Strengths
  - Non-contact
  - Low cost
- Weaknesses
  - Long build time
  - Nozzle clogging




*Schematic of a solenoid-based microvalve printhead.*

*Source:* Faulkner-Jones A et al. Bioprinting of human pluripotent stem cells and their directed differentiation into hepatocyte-like cells for the generation of mini-livers in 3D. Biofabrication. 2015, 7.

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# 3D Bioprinting Players

## 3D Bioprinter Manufacturers

3Dbots
CELLINK
Anyprint
DIGILAB
MicroFab TECHNOLOGIES • INC.
symme3D
GESIM
Eurobotics
microdrop TECHNOLOGIES
REGEMAT 3D
regenHU BIOSYSTEM ARCHITECTS
Bio3D technologies
envisionTEC
CELLBRICKS
Advanced SOLUTIONS LIFE SCIENCES
nScrypt
3DISON
IZUMI INTERNATIONAL
SeeD
AETHER

## Tissue Service Bureaus

Regenovo
BioDan Group
SKIN CREATIONS LAB
3dbio
Aspect biosystems
TeVido BioDevices
organovo™
poietis make tissues real
3DS 3DYNAMIC SYSTEMS
EPIBONE grow your own bone
OxSyBio
CYFUSE
cellenion ENHANCING LIFE

# 3D Bioprinting in 2017

- Large and growing academic community

- Rapid expansion of players in 3D bioprinting in the last 2 years
  - Established companies launched new modules for existing equipment
  - Affordable 3D bioprinters launched 2016 – 2017 from companies founded in 2014 – 2015
  - New tissue types being provided

- Tissue service bureaus experiencing strong sales growth
  - Revenues have doubled for several companies
  - New research collaborations with key players in pharmaceutical and consumer goods industries

- Technology ready for several applications, strong headway made in others

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# Product Testing in Consumer Products


*Images such as the above are used to demonstrate the cruelty that animals are subjected to during safety testing of consumer products. Here, rabbits were immobilised for eye irritancy tests.*

- Since March 2013, the European Commission has imposed an absolute ban on animal testing of:
  - Any cosmetics and personal care products, or
  - Any ingredients therein
  - Products and ingredients imported from outside the EU
- This ban is the culmination of efforts to reduce animal testing since 2004
- Companies in this sector are turning to 3D bioprinting as an alternative testing methodology which can satisfy their regulatory obligations to ensure that new products are safe to use.

*Source: Brian Gunn/IAAPEA*

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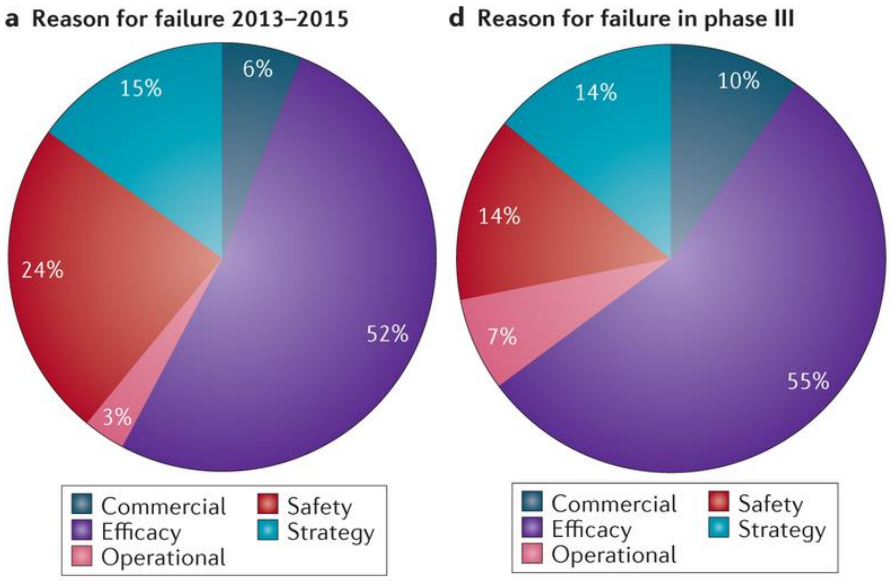
# Product Testing in Pharma and Biotech




*The early determination of safety issues for drug development is currently the most viable product value proposition of the 3D bioprinting industry. Late-stage failures are especially costly for the company – ideally, safety issues should have been identified in earlier phases of development.*

*Source:* Harrison RK. Phase II and phase III failures: 2013 – 2015. Nat Rev Drug Discov. 2016, 15, 817-8.

- Urgent need for human disease modelling platforms to complement existing studies
- 3D bioprinted tissue has the potential to be more relevant than the current gold standard for preclinical testing and development
  - 2D cell culture
  - Animal models
- Product development through 3D bioprinted tissues could offer several advantages
  - Avoidance of costly late-stage failures
  - Streamline drug discovery
  - Rapidly repurpose or retest existing candidates

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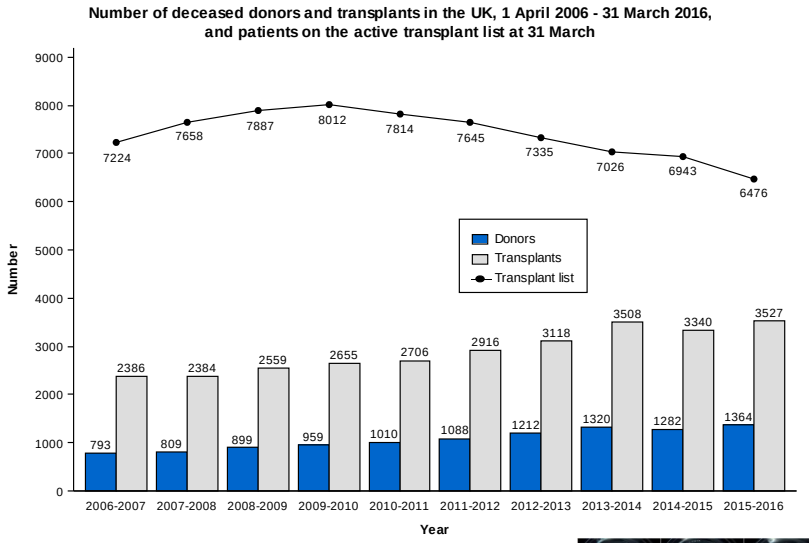
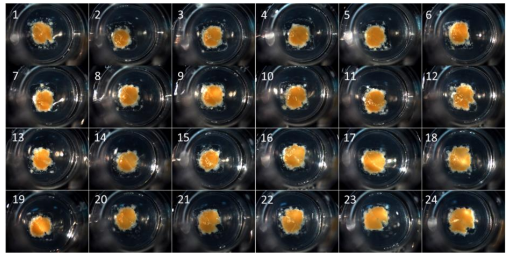
# Regenerative Medicine



*There is a high unmet need for organs, of which liver and kidney are the most crucial. Organovo has begun work to bring a 3D bioprinted liver patch to market (3D bioprinted liver model tissue shown).*

- Currently, organs are harvested from recently decreased donors, or tissue banks storing cadaveric tissues
- High unmet need for organs for transplant
  - Kidney
  - Liver
- Despite improvements in number of donors, unlikely to meet growing demand
- Potential benefits are ready availability (allogeneic) or personalised tissues with reduced risk of transplant rejection (autologous)

*Source:* NHS Blood and Transplant, Organovo.

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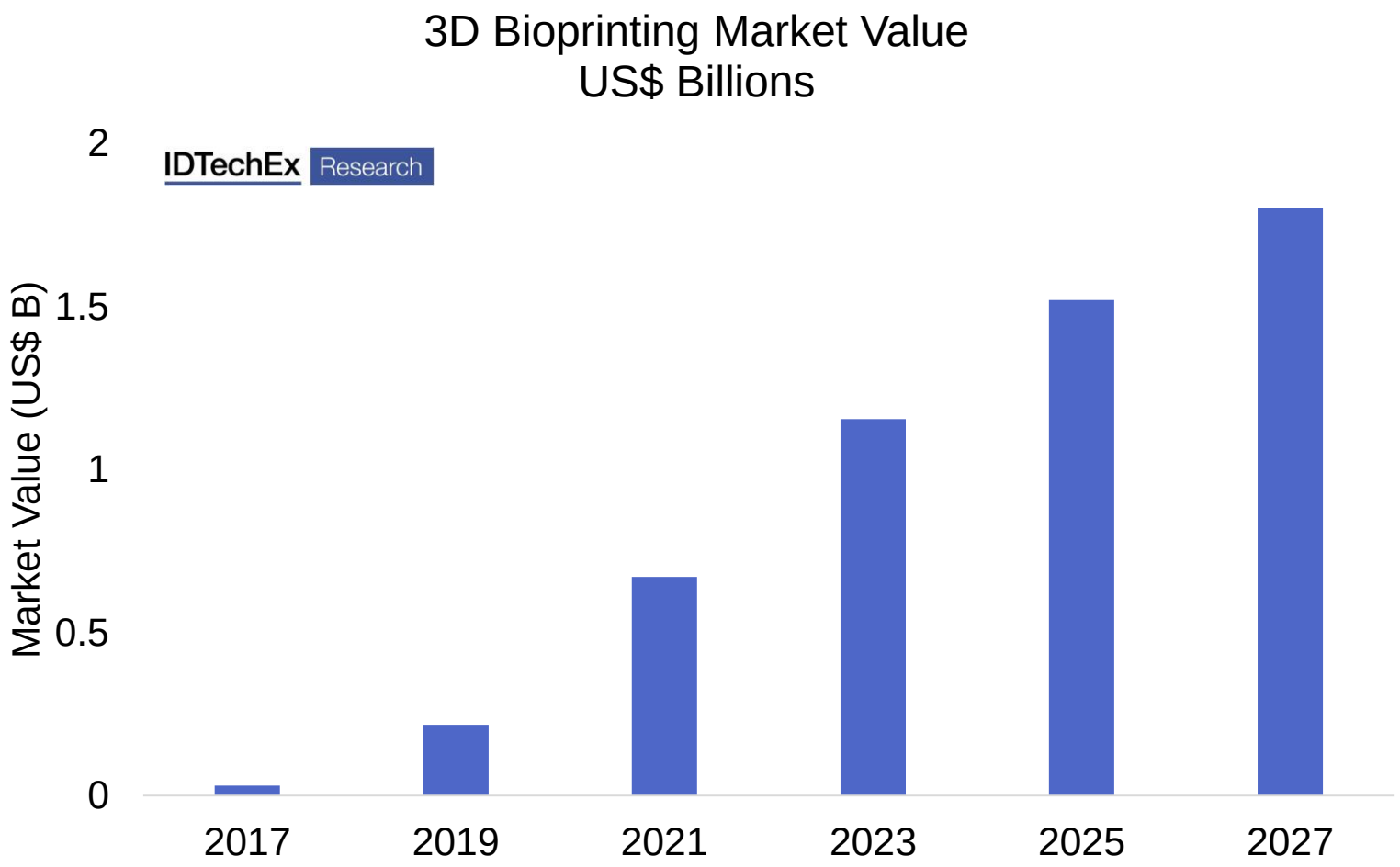
# Overall 3D Bioprinting Market Forecast 2017 – 2027




- The overall market for 3D bioprinting, including both 3D bioprinted tissue and 3D bioprinters is expected to grow to an estimated total value of $1.8 billion USD by 2027.
- Please refer to the report 3D Bioprinting 2017-2027: Technologies, Markets, Forecasts for the full 10-year market forecast segmented by markets for 3D bioprinters and 3D bioprinted tissues.

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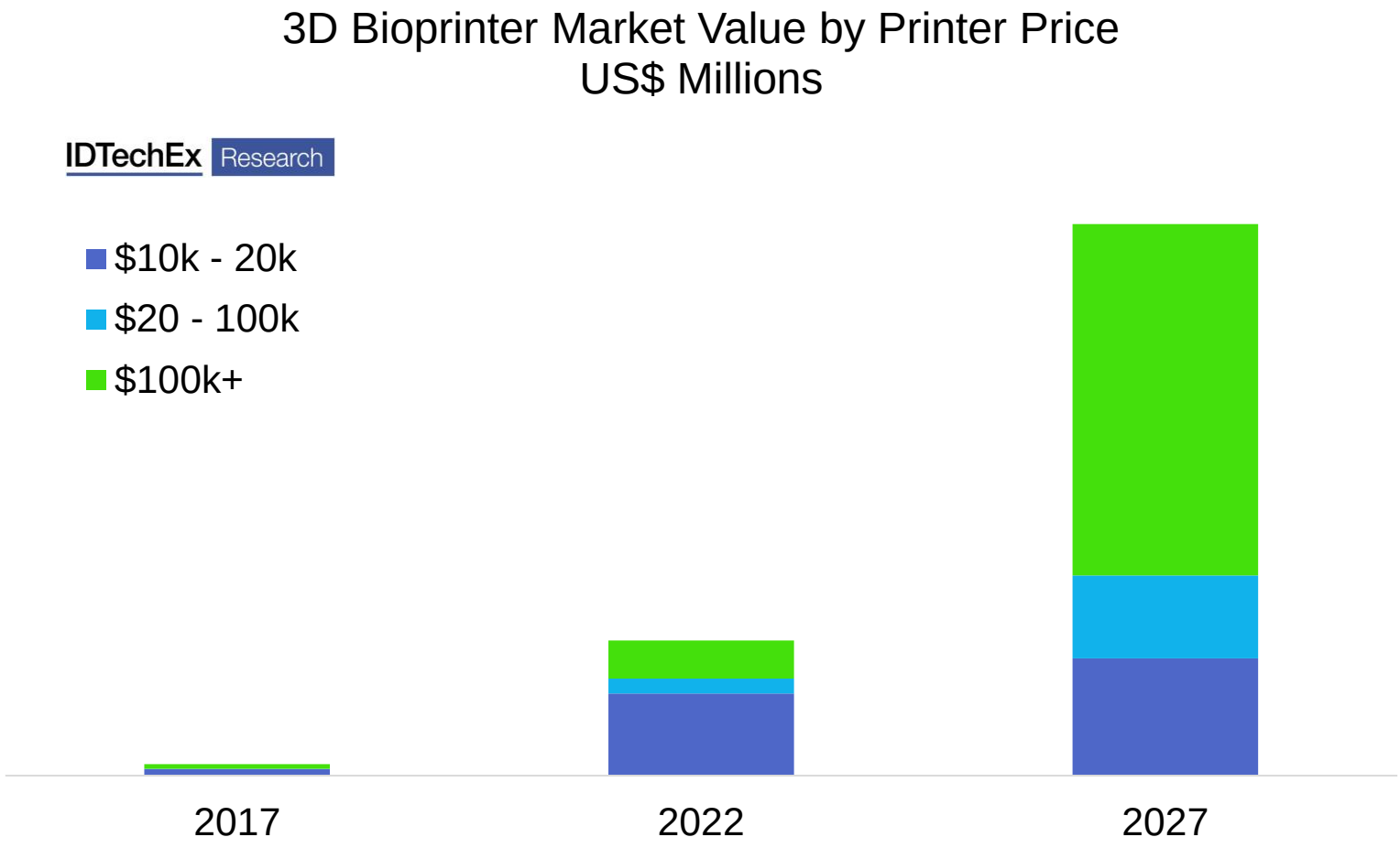
# 3D Bioprinter Market Forecast 2017 – 2027




- Each segment of the 3D bioprinter market is expected to grow within the next 10 years
- Market growth is lead by the printers in the $10k – $20k in the first few years
- The growth in market value will then be driven by the > $100k systems as requirements for automation increase
- 3D bioprinters priced $20k – $100k will experience moderate growth throughout

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# 3D Bioprinting 2017 – 2027: Technologies, Markets, Forecasts

*Opportunities in cosmetics and consumer product testing, drug development and regenerative medicine*

This report provides a comprehensive view of the 3D bioprinting market, giving detailed analysis on the four main technologies and several key applications. The report forecasts the overall 3D bioprinting market, which is also segmented by application of 3D bioprinted tissues, and by 3D bioprinter price point.

For more details, please visit www.idtechex.com/3Dbio

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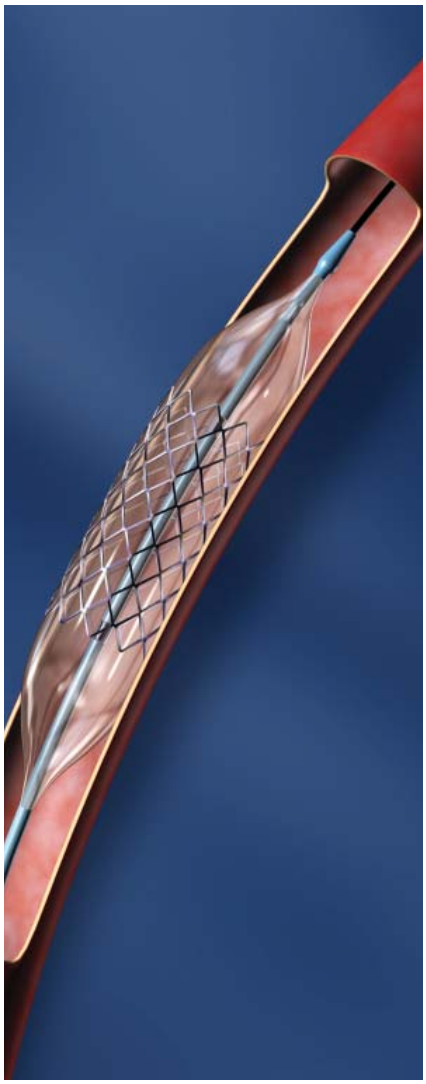
# GUIDELINES FOR COMPLIANCE: MEDICAL EQUIPMENT MADE BY 3D PRINTING AND ADDITIVE MANUFACTURING

# GUIDELINES FOR COMPLIANCE: MEDICAL EQUIPMENT MADE BY 3D PRINTING AND ADDITIVE MANUFACTURING TECHNIQUES

Additive manufacturing, also known as 3D printing, is a rapidly growing manufacturing process using specialized equipment to build a physical object from a three-dimensional digital model. This process typically places many thin layers of material, such as polymers, one above the last in succession as instructed by the digital design to create an object. This manufacturing method lends itself extremely well to applications in the medical devices industry.



The additive manufacturing designer can use virtually any 3D based modeling technique (CTscans, MRI scans or a combination of imaging modalities) to create a digital design which can then be produced using a variety of additive manufacturing techniques. This application of scanning and digital manufacturing can use a patient's own anatomy to create a truly personalized medical device or surgical guide for a particular procedure.

Additive manufacturing use in medicine presents a number of technical considerations that must be addressed to ensure patient safety -- the material selection, the additive manufacturing process, the design software associated with the modeling, and the cleaning and sterilization of the finished product.

This document contains guidelines for selecting the appropriate safety standards and routes to conformity for your device produced with 3D printing and additive manufacturing techniques.

The driver for this guide is to associate 3D printing and additive manufacturing techniques with the relevant existing safety standards for the various routes to conformity of medical equipment.

There are several standards publications, from the IEC, US, ISO and others, that adequately cover safety aspects of 3D printing and additive manufacturing equipment. The intent of this guide is not to introduce new requirements, but to explain appropriate existing standards with supplemental considerations to address the best route to conformity for medical devices and their chosen markets.

# ROUTES TO CONFORMITY FOR DEVICES PRODUCED USING 3D PRINTING AND ADDITIVE MANUFACTURING

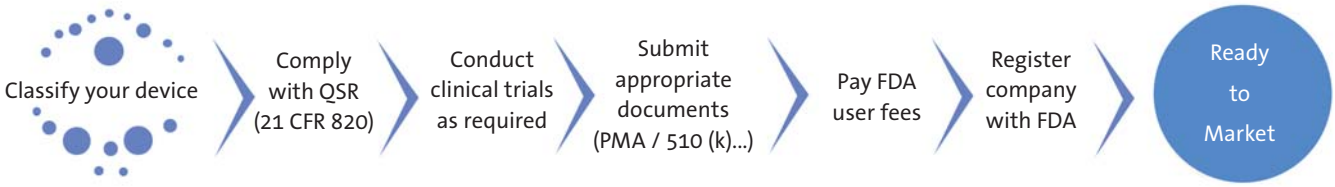



Figure 1: Route to Conformity for the US market


Figure 2: Route to Conformity for the Canadian market

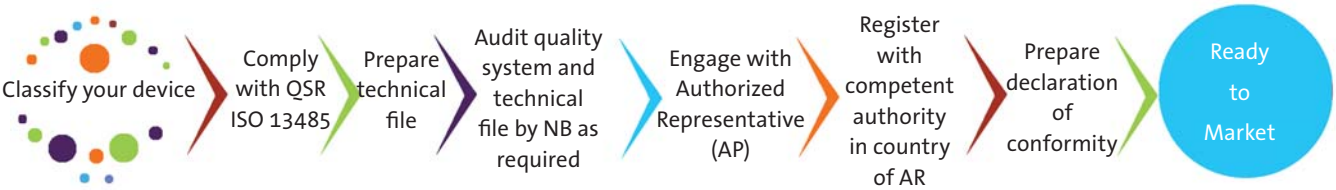



Figure 3: Route to Conformity for the EU market

Note: The above graphical representations are the critical high-level steps of very complex processes needed to bring a device to market. All submissions and registrations should be reviewed and approved by a company's regulatory department.

# TESTING ASSURANCE

The ability to use 3D printing and additive manufacturing processes to specifically match a device to patients and their needs is impressive. Whether it is specifically matched for patients or mass-produced, it is incumbent on a manufacturer to address many safety and efficacy questions of its finished products. As an example, regulators do not "approve" materials for use in specific medical applications or devices. When tests are conducted in accordance with the consensus standards such as ISO 10993, the material can be recognized as biocompatible.

For the final product, it is a manufacturer's responsibility to assure the biocompatibility and general compliance with stated requirements of the finished product, for the intended use of the device. In addition, the manufacturer must assure that the device is compliant with the relevant General, Collateral and Particular standards applicable to the product. Some of these non-clinical test standards and their description are outlined briefly below.

### Physico-Chemical Analyses

To demonstrate the suitability of a medical device having direct or indirect patient contact, a material characterization pursuant to ISO 10993-18 needs to be performed as a requirement in ISO 10993-1. Materials can be characterized using chemical, physical, morphological and mechanical test methods. Also, all leachable and extractable chemical substances should be identified and have their toxicity evaluated. Such kind of investigations should be performed before starting with biological testing.

### Biocompatibility

For medical devices, the biocompatibility of a product has to be evaluated pursuant to the harmonized standard ISO 10993 series "Biological evaluation of medical devices." ISO 10993-1 classifies medical devices regarding the nature of their body contact, their contact duration, and by the names of the respective biological test methods and applicable standards.

### Microbiological Basic Tests for Process Supervision

Medical devices contaminated with pathogens may be a source of infection for humans. According to regulators, devices must be designed and manufactured in such a way as to eliminate or reduce the risk of infection to the patient, user or third parties as much as possible. The microbiological basic tests inform the manufacturer about the microbiological status of their products at the end of the production process, support the evaluation of applicable sterilization efforts and disinfection properties and help to control the manufacturing processes.

### Cleaning, Reprocessing, Sterilization

Typically, medical devices are subjected to a first-time cleaning process at the end of the manufacturing process. This cleaning process within the scope of the manufacturing process should be validated in order to consistently produce clean and biocompatible products. Reusable devices are subjected to a defined cleaning and disinfection process and are typically sterilized afterwards. Such processes need to be validated before including them in the Instructions For Use (IFU).

### Shelf Life of Devices & Packages

According to ISO 11607-1, the specific properties of medical devices and their packaging systems must remain stable during their shelf life. Consequently, medical device manufacturers should perform appropriate validation studies in order to justify shelf life and transport stability of their devices. This includes the validation of the packaging processes, like forming and sealing process of sterile barrier systems, pursuant to ISO 11607-2. In the course of a combined stability and packaging validation study, packed (sterile) devices are subjected to a thermal accelerated and regular real-time aging and to a transport simulation (pursuant ISTA or ASTM standards).

### Product Testing

For various medical devices, specific product standards exist. Such standards should be used in order to evaluate the performance and safety of the final product.

# BIOLOGICAL CLASSIFICATION AND ASSOCIATED BIOLOGICAL EFFECTS

| Medical device categorization by | | | Biological effect* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Nature of body contact | | Contact duration A - limited (≤24h) B - Prolonged (>24h - 30d) C- permanent (>30d) | Cytotoxicity | Sensitization | Irritation or intracutaneous reactivity | Systemictoxiity (acute) | Subchronic toxicity (subacute toxicity) | Genotoxicity | Implantation | Haemocopatibility |
| Category | Contact | | | | | | | | | |
| Surface device | Skin | A | X | X | X | | | | | |
| | | B | X | X | X | | | | | |
| | | C | X | X | X | | | | | |
| | Mucosal membrane | A | X | X | X | | | | | |
| | | B | X | X | X | | | | | |
| | | C | X | X | X | | X | X | | |
| | Breached or compromised surface | A | X | X | X | | | | | |
| | | B | X | X | X | | | | | |
| | | C | X | X | X | | X | X | | |
| External communicating device | Blood path, indirect | A | X | X | X | X | | | | X |
| | | B | X | X | X | X | | | | X |
| | | C | X | X | | X | X | X | | X |
| | Tissue, bone, dentin | A | X | X | X | | | | | |
| | | B | X | X | X | X | X | X | X | |
| | | C | X | X | X | X | X | X | X | |
| | Circulating blood | A | X | X | X | X | | | | X |
| | | B | X | X | X | X | X | X | X | X |
| | | C | X | X | X | X | X | X | X | X |
| Inplant device | Tissue, bone | A | X | X | X | | | | | |
| | | B | X | X | X | X | X | X | X | |
| | | C | X | X | X | X | X | X | X | |
| | Blood | A | X | X | X | X | X | | X | X |
| | | B | X | X | X | X | X | X | X | X |
| | | C | X | X | X | X | X | X | X | X |

Table 1: Biological Classification and Associated Bilogical Effects

*Note: The "X" indicates data endpoint can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

# FDA DRAFT GUIDANCE DOCUMENT - INITIAL AND SUPPLEMENTARY TEST FOR CONSIDERATION

| Medical device categorization by | | | Biological effect[a] | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nature of body contact | | Contact duration A - limited (≤24h) B - Prolonged (>24h - 30d) C- permanent (>30d) | Cytotoxicity | Sensitization | Irritation or intracutaneous reactivity | Systemic toxiity (acute) | Subchronic toxicity (subacute toxicity) | Genotoxicity | Implantation | Haemocopatibility | Chronic toxicity | Carciogenicity | Reproductive / Developmental | Biodegradation |
| Category | Contact | | | | | | | | | | | | | |
| Surface device | Skin | A | X | X | X | | | | | | | | | |
| | | B | X | X | X | | | | | | | | | |
| | | C | X | X | X | | | | | | | | | |
| | Mucosal membrane | A | X | X | X | | | | | | | | | |
| | | B | X | X | X | O | O | | O | | | | | |
| | | C | X | X | X | O | X | X | O | | O | | | |
| | Breached or compromised surface | A | X | X | X | O | | | | | | | | |
| | | B | X | X | X | O | O | | O | | | | | |
| | | C | X | X | X | O | X | X | O | | O | | | |
| External communicating device | Blood path, indirect | A | X | X | X | X | | | | X | | | | |
| | | B | X | X | X | X | O | | | X | | | | |
| | | C | X | X | O | X | X | X | O | X | O | O | | |
| | Tissue, bone, dentin + | A | X | X | X | O | | | | | | | | |
| | | B | X | X | X | X | X | X | X | | | | | |
| | | C | X | X | X | X | X | X | X | | O | O | | |
| | Circulating blood | A | X | X | X | X | | O^ | | X | | | | |
| | | B | X | X | X | X | X | X | X | X | | | | |
| | | C | X | X | X | X | X | X | X | X | O | O | | |
| Inplant device | Tissue, bone | A | X | X | X | O | | | | | | | | |
| | | B | X | X | X | X | X | X | X | | | | | |
| | | C | X | X | X | X | X | X | X | | O | O | | |
| | Blood | A | X | X | X | X | X | | X | X | | | | |
| | | B | X | X | X | X | X | X | X | X | | | | |
| | | C | X | X | X | X | X | X | X | X | O | O | | |

Table 2: FDA Draft Guidance Document - Initial and Supplementary Test for Consideration

Notes: X ISO Evaluation tests for condsideration

\+ Tissue includes tissue fluids and subcutaneous spaces

^ For all devices used in extracorporeal circuits

O Additional categories which should be addressed in FDA submissions, either by inclusion of the testing or a rationale for its omission

a The "X" indicates data endpoint that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adquate, additional testing is not required.

# APPLICABLE STANDARDS FOR MEDICAL DEVICES

| | | United States | Canada | European Union |
|---|---|---|---|---|
| **General Standards** | **IEC 60601-1: 3rd Edition** | | X | |
| | **EN 60601-1: 3rd Edition** | | | X |
| | **ANSI60601-1: 2005** | X | | |
| **Collateral Standards** | **IEC 60601-1-2** | X | X | X |
| | **IEC 60601-1-6** | X | X | X |
| | **IEC 60601-1-8** | X | X | X |
| | **IEC 60601-1-11** | X | X | X |
| **Particular Standards*** | **IEC 60601-2-xx** | X | X | X |
| | **IEC 80601-2-xx** | X | X | X |
| **Biocompatibility Standards** | **ISO 10993** | X | X | X |

Table 3: Applicable Standards for Medical Devices

*Note: There are national and international standards in force not referenced in this table that should also be used as applicable to your medical device.

Many medical device manufacturers are challenged during the development process to choose the right standards to evaluate their product/system design. It is incumbent on the device manufacturer to develop a comprehensive test plan for compliance to all the applicable testing and market entry requirements. This typically is accomplished by working with regulatory, design, manufacturing, clinical and consulting partners to develop the comprehensive testing plan. The testing should address the clinical, environmental, use and distribution hazards associated with the device and its use during the products end use life.

Resources:

IEC http://members.iecee.org/iecee/ieceemembers.nsf/IECEEScopeInStandard

ISO http://www.iso.org/iso/home.html

FDA http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/results.cfm

Health Canadahttp://hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst-eng.php

Europe
http://ec.europa.eu/growth/single-market/european-standards/index_en.htm

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# ABS-M30i

ABS-M30i is a high strength material well suited for the medical, pharmaceutical and food packaging industries. Parts manufactured with ABS-M30i material are biocompatible (ISO 10993 USP Class VI)* and can be gamma or EtO sterilized. When combined with Fortus® 3D Printers, ABS-M30i gives you biocompatible parts with excellent mechanical properties that are well suited for conceptual modeling, functional prototyping, manufacturing tools and production parts.

ABS-M30i is a high strength material well suited for the medical, pharmaceutical and food packaging industries. Parts manufactured with ABS-M30i material are biocompatible (ISO 10993)* and can be gamma or EtO sterilized. In addition, ABS M30i has passed ISO 18562 testing for gas and airway parts for use in respiratory and ventilation medical devices. When combined with Fortus® 3D Printers, ABS-M30i gives you biocompatible parts with excellent mechanical properties that are well suited for conceptual modeling, functional prototyping, manufacturing tools and production parts.

| Mechanical Properties[1] | Test Method | Value |
|---|---|---|
| Tensile Strength (Type 1, 0.125”, 0.2”/min) | ASTM D638 | 36 MPa<br>(4,650 psi) |
| Tensile Modulus (Type 1, 0.125”, 0.2”/min) | ASTM D638 | 2,400 MPa<br>(350,000 psi) |
| Tensile Elongation (Type 1, 0.125”, 0.2”/min) | ASTM D638 | 4% (4%) |
| Flexural Strength (Method 1, 0.05”/min) | ASTM D790 | 61 MPa<br>(8,800 psi) |
| Flexural Modulus (Method 1, 0.05”/min) | ASTM D790 | 2,300 MPa<br>(336,000 psi) |
| IZOD Impact, notched (Method A, 23 °C) | ASTM D256 | 139 J/m<br>(2.6 ft-lb/in) |
| IZOD Impact, un-notched (Method A, 23 °C) | ASTM D256 | 283 J/m<br>(5.3 ft-lb/in) |

| Thermal Properties[2] | Test Method | Value |
|---|---|---|
| Heat Deflection (HDT) @ 66 psi, 0.125” unannealed | ASTM D648 | 96 °C (204 °F) |
| Heat Deflection (HDT) @ 264 psi, 0.125” unannealed | ASTM D648 | 82 °C (180 °F) |
| Vicat Softening Temp. (Rate B/50) | ASTM D1525 | 99 °C (210 °F) |
| Coefficient of Thermal Expansion (flow) | ASTM E831 | 8.82x10-05 mm/mm/°C<br>(4.9x10-05 in/in/°F) |
| Coefficient of Thermal Expansion (flow) | ASTM E831 | 8.46x10-05 mm/mm/°C<br>(4.7x10-05 in/in/°F) |
| Glass Transition (Tg) | DSC (SSYS) | 108 °C (226 °F) |
| Melting Point | --------- | Not Applicable[3]<br>(Not Applicable[3]) |

| Electrical Properties[4] | Test Method | Value Range |
|---|---|---|
| Volume Resistivity | ASTM D257 | 1.5x1014 - 6.0x1013 ohm-cm |
| Dielectric Constant | ASTM D150-98 | 2.9 - 2.7 |
| Dissipation Factor | ASTM D150-98 | .0053 - .0051 |
| Dielectric Strength | ASTM D149-09, Method A | 370 - 80 V/mil |

# ABS-M30i

| Other[2] | Test Method | Value |
|---|---|---|
| Specific Gravity | ASTM D792 | 1.04 |
| Specific Gravity | ASTM D785 | 109.5 |
| Food Safety Certification | NSF 51 | Certified |

| System Availability | Layer Thickness Capability | Support Structure | Available Colors |
|---|---|---|---|
| Fortus 450mc™<br>Fortus 900mc™ | 0.013 inch (0.330 mm)<br>0.010 inch (0.254 mm)<br>0.007 inch (0.178 mm)<br>0.005 inch (0.127 mm)[5] | Soluble Supports | Ivory |

The information presented are typical values intended for reference and comparison purposes only. They should not be used for design specifications or quality control purposes. End-use material performance can be impacted (+/-) by, but not limited to, part design, end-use conditions, test conditions, etc. Actual values will vary with build conditions. Tested parts were built on Fortus 400mc™ @ 0.010" (0.254 mm) slice. Product specifications are subject to change without notice.

The performance characteristics of these materials may vary according to application, operating conditions, or end use. Each user is responsible for determining that the Stratasys material is safe, lawful, and technically suitable for the intended application, as well as for identifying the proper disposal (or recycling) method consistent with applicable environmental laws and regulations. Stratasys makes no warranties of any kind, express or implied, including, but not limited to, the warranties of merchantability, fitness for a particular use, or warranty against patent infringement.

*It is the responsibility of the finished device manufacturer to determine the suitability of all the component parts and materials used in their finished products.

[1]Build orientation is on side long edge.

[2]Literature value unless otherwise noted.

[3]Due to amorphous nature, material does not display a melting point.

[4]All Electrical Property values were generated from the average of test plaques built with default part density (solid). Test plaques were 4.0 x 4.0 x 0.1 inches (102 x 102 x 2.5 mm) and were built both in the flat and vertical orientation. The range of values is mostly the result of the difference in properties of test plaques built in the flat vs. vertical orientation.

[5] 0.005 inch (0.127 mm) layer thickness not available for Fortus 900mc

**For more information regarding biocompatibility of our FDM materials please visit this page: Biocompatibility of our FDM materials**

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