formlabs.com/medical

Formlabs is an industry-leading provider of 3D printers and materials that are used by healthcare providers to support the practice of medicine. Please consider local regulations, material data sheets, patient information, and institutional requirements before 3D printing or using anatomical models. For more information, visit our regulatory information page:
***https://formlabs.com/industries/medical/regulatory-information/**.*

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The Power of 3D-Printed Medical Devices:

Proven Regulatory Strategies & Quality Recommendations for Additive Manufacturing

October 2021

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

114k
look to us for the latest in quality

FEATURED IN

THE WALL STREET JOURNAL.
THE VERGE
TechCrunch
Forbes
QUALITYDIGEST
MDDI
Inc.
MedTech Intelligence
MED DEVICE ONLINE
MedicalDesign & OUTSOURCING
TNW THE NEXT WEB
Entrepreneur
MPO

"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

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Introduction and Technology Overview

Formlabs uniquely combines accuracy, power, and affordability.

low cost & unreliable

Industrial quality on the desktop

30+ compatible materials

Plug & Print

Free software + ***QA/RA support***

Affordable price point ***($3,499+)***

high performance & detail
Often $100K-$500K

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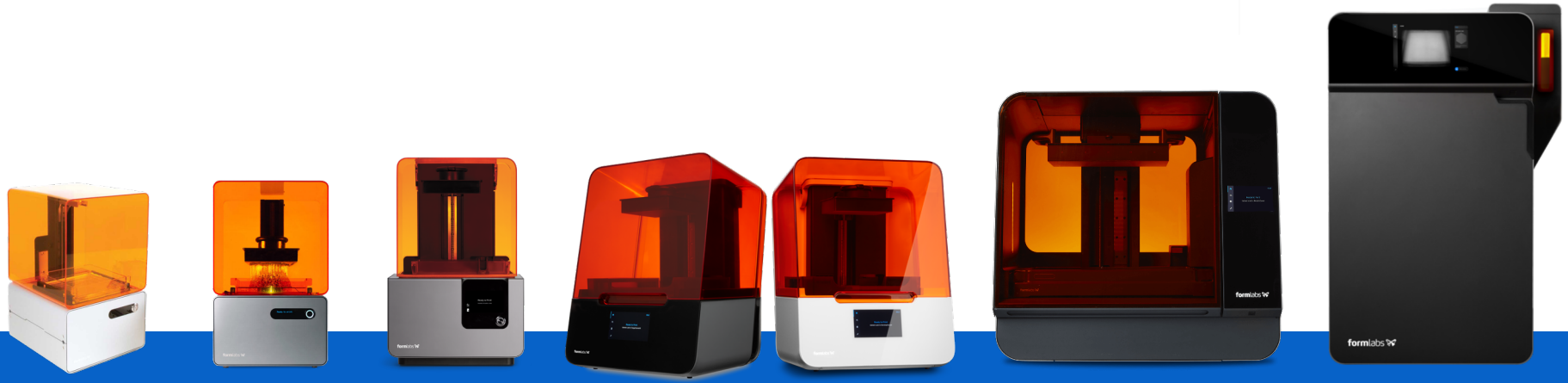
Timeline: SLA and SLS Print Engines



FORM 1	FORM 1+	FORM 2	FORM 3 + 3B	FORM 3L + 3BL	Fuse 1
2012	2014	2015	2019	2020	2021

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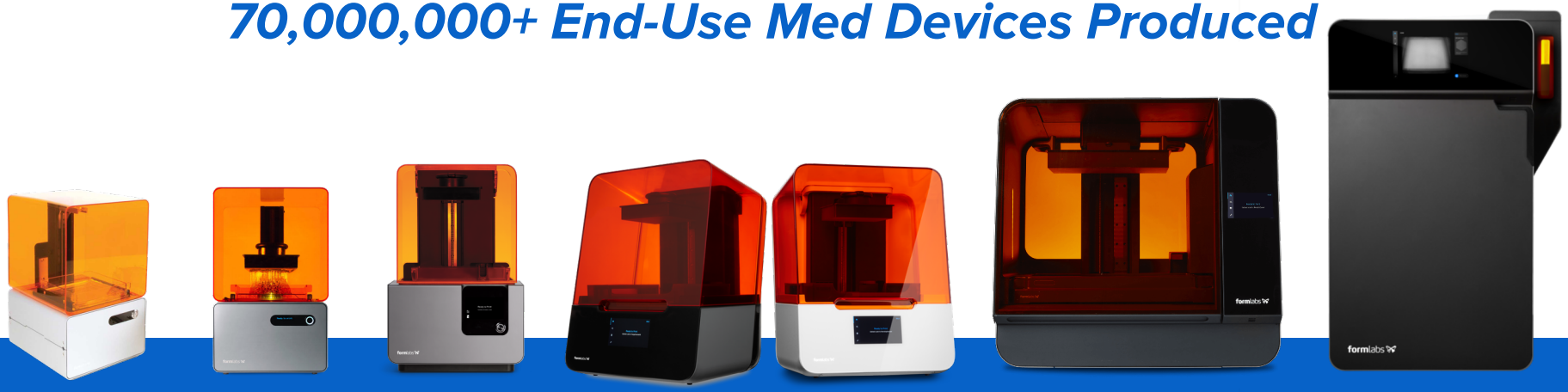
Timeline

75,000+ Printers Sold
300,000+ Surgeries Supported
70,000,000+ End-Use Med Devices Produced



FORM 1	FORM 1+	FORM 2	FORM 3 + 3B	FORM 3L + 3BL	Fuse 1
2012	2014	2015	2019	2020	2021

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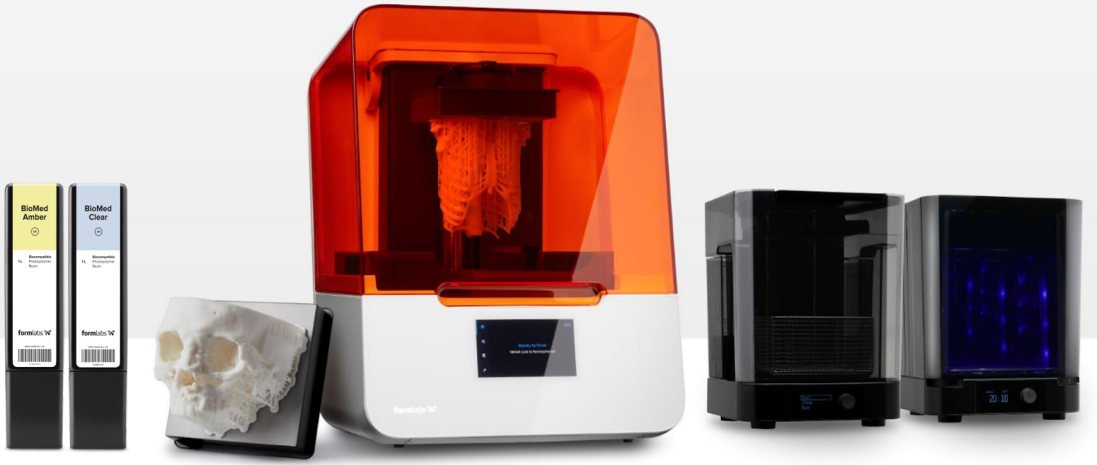


*Cartridge System with **30+** Easily-Swapped Materials*

*Biocompatible, sterilizable resins made in **ISO 13485** facility*

Summary of Quality + Regulatory Foundations

1 Pre-COVID

- ***ISO 10993** testing on several resins*
- ***ISO 13485** certified, FDA-registered facility*
- ***Sterilization reports:***
  10 materials x 4 modalities
- *ISO Certified Class 8 Clean Room*

2 Since COVID

- ***FDA EUA** (industry first)*
- ***ISO 18562** testing: gas pathway uses*
- *Clinical trial + quality systems support*
- *BioMed Resin w/ **USP Class VI** + **FDA MAF***

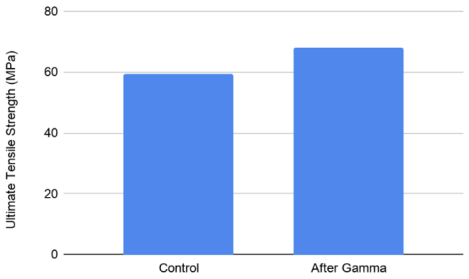
Range of opportunities with biocompatible materials

	Contact Type	Skin	Mucosal Membrane	Mucosal Membrane	Breathing Gas Pathways	Pharmaceutical Containers, Drug Delivery, and Medical Device Components
	Duration of Contact	**> 30 days**	**<24 hr**	**>30 days**	**> 30 days**	**> 30 days**
	ISO Standard	**EN ISO 10993-1 EN ISO 10993-3 EN ISO 10993-5**	**EN ISO 10993-1 EN ISO 10993-3 EN ISO 10993-5**	**EN ISO 10993-1 EN ISO 10993-3 EN ISO 10993-5 EN ISO 10993-10 EN ISO 10993-11**	**EN ISO 18562-1 EN ISO 18562-2 EN ISO 18562-3 EN ISO 18562-4**	**USP <88> Class VI**
Medical (SLA) *[Footnote 1]*	BioMed Clear Resin	✓	✓	✓	✓	✓
	BioMed Amber Resin	✓	✓			
Dental (SLA) *[Footnote 1]*	Dental LT Clear V2 Resin	✓	✓	✓		
	Surgical Guide Resin	✓	✓			
	Custom Tray Resin	✓	✓			
	IBT Resin Resin	✓	✓			
	Temporary CB Resin	✓	✓	✓		
	Permanent Crown Resin	✓	✓	✓		
	Denture Base Resin	✓	✓	✓		
	Denture Teeth Resin	✓	✓	✓		
	Dental LT Clear V1 Resin	✓	✓	✓		
Engineering (SLA)	Tough 1500 Resin	✓				
Fuse (SLS)	PA 12 Powder	✓	✓			
	PA 11 Powder	✓				

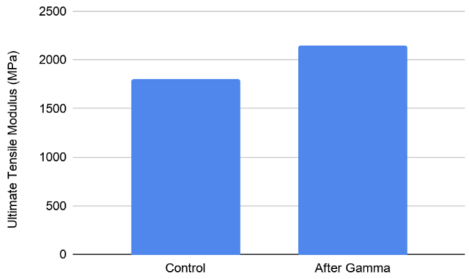
[Footnote 1] - *All Medical and Dental Resins listed above are ISO 13485 and ISO 14971 compliant*

Sterilization Reports for 10 Materials Now Available: Dimensional Integrity, Mechanical Properties, Cytotoxicity, and Color measured Before and After Autoclave (5x), E-Beam, Gamma, and EtO

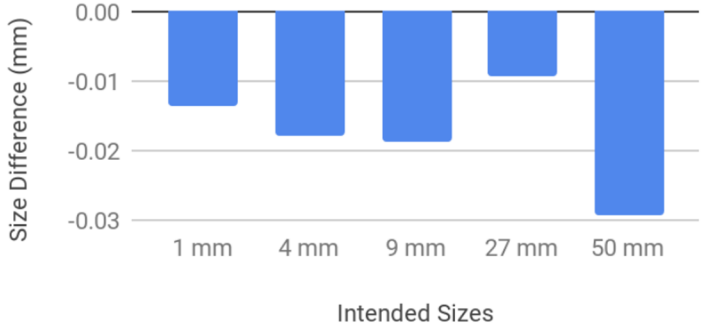
Change in Ultimate Tensile Strength (MPa)



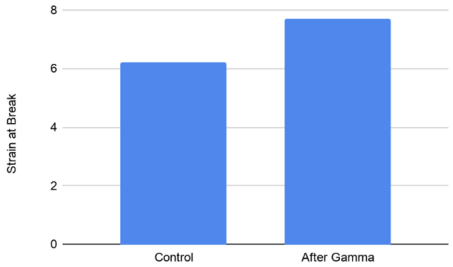
Change in Ultimate Tensile Modulus (MPa)



Changes in Dimensional Features of BMC after Gamma Sterilization



Change in Strain at Break



TDS Details

Samples printed with BioMed Clear Resin has been evaluated in accordance with ISO 10993-1:2018, ISO 7405:2018, ISO 18562-1:2017 and has passed the requirements associated with the following biocompatibility endpoints:

ISO Standard	Test Description[3]
EN ISO 10993-5:2009	Not cytotoxic
ISO 10993-10:2010/(R)2014	Not an irritant
ISO 10993-10:2010/(R)2014	Not a sensitizer
ISO 10993-3:2014	Not mutagenic

ISO Standard	Test Description[3]
ISO 10993-17:2002 ISO 10993-18:2005	Not toxic (subacute/subchronic)
ISO 18562-2:2017	Does not emit particulates
ISO 18562-3:2017	Does not emit VOCs
ISO 18562-4:2017	Does not emit hazardous water-soluble substances

Range of Med Device Use Cases

Patient-specific to mass produced

- *Prototypes: R&D and Pre-IM Tooling*
- *Manufacturing Aids*
  - *Jigs, Fixtures, Molds*
- *Limited run tooling*
- *Final-Use Devices + Surgical Tools*

*Trusted by **thousands of medical device firms and hundreds of hospitals worldwide.***
Referenced in over 1,800 clinical publications.

Commercial Medical Devices: Case Studies

In-House Prototyping: increase speed, cut time & costs

djosurgical™

> *Before DJO Surgical brought the Form 2 onboard, we relied almost exclusively on outside vendors for prototypes. Turnaround time was typically quick, but the cost was prohibitive. Today, we are running six Formlabs machines, and the impact has been profound.* **Our rate of prototyping has doubled, cost has been reduced 60%**, *and the level of print detail allows for* **clear communication of designs with orthopaedic surgeons**. *No other print technology we evaluated combined reliability, cost effectiveness and quality in the same way.* **Formlabs has changed how we work.**

Alex Drew
Sr. Mechanical Project Engineer, Advanced Technologies

djo surgical®

60%

Reduction in R&D Prototyping Expense

- Prior to Formlabs implementation all rapid prototyping was performed offsite
- Burdensome procurement procedures
- High cost per part

4x

Increase in Concept Iteration

- High part cost increased hesitancy for engineers to elevate designs to physical prototypes
- Resulting in increased time to deliver initial concept to design surgeon panels

80%

Reduction in Some Production Fixture Applications

- Consumable fixtures for abrasive finishing were a good fit for additive production
- High complexity
- Multi-material
- Low volume

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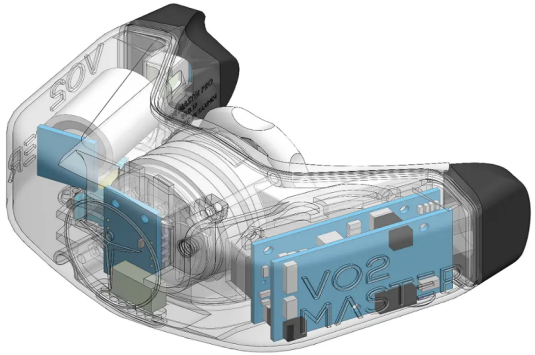
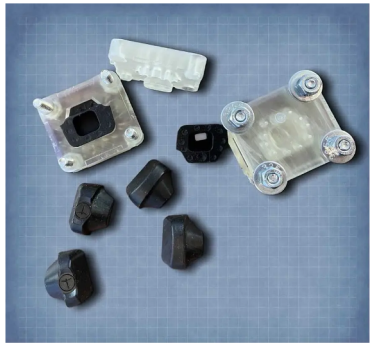
INTERVIEW

3D Printing The Next Generation Of Metabolic Analyzers



“We can test multiple different tolerances per day, and print around 27 variants in a week on a single Form 3. You could never do that before the advent of high-quality in-house 3D printing. Injection molding is just too expensive. Without Formlabs printers, we would not be able to build this device.” - Pete O’Brien, VO2 Master

- *Final Housing*
- *Molds*
- *Prototypes*




200
Herald DCA
(albuterol sulfate)
Inhalation Aerosol
100 mcg per actuation
120
Herald DCNA
(beclomethasone dipropionate)
Nasal Aerosol
100 mcg per spray
120
Herald BAI
(beclomethasone dipropionate)
Inhalation Aerosol
80 mcg per actuation
Brahms DPI
(flubicasone furoate/ vilanterol)
92/22 mcg
Inhalation Powder
30 doses
30

INTERVIEW

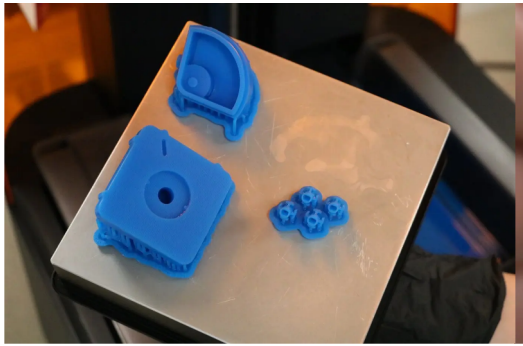
Innovative, Low-Cost Inhalers Enable Access for Millions: 3D Printing Powers Lean R&D for Medical Devices

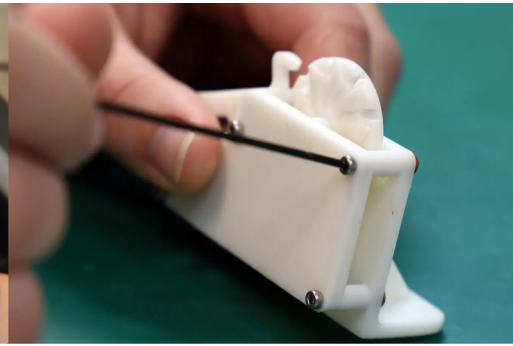
INHALER CASEWORK	IN-HOUSE 3D PRINTING	OUTSOURCED 3D PRINTING
Cost	£11	£250
Lead Time	1-2 Days	1-2 Weeks

“The Form 3 has allowed us to print fine features and delicate meshes, and to optimise the device during the design phase. We have the ability to model a part, change it on the fly, and have the physical part in a few hours. We can cut out the third-party supplier, and we get the parts more quickly. The Form 3s are absolutely essential to us.”

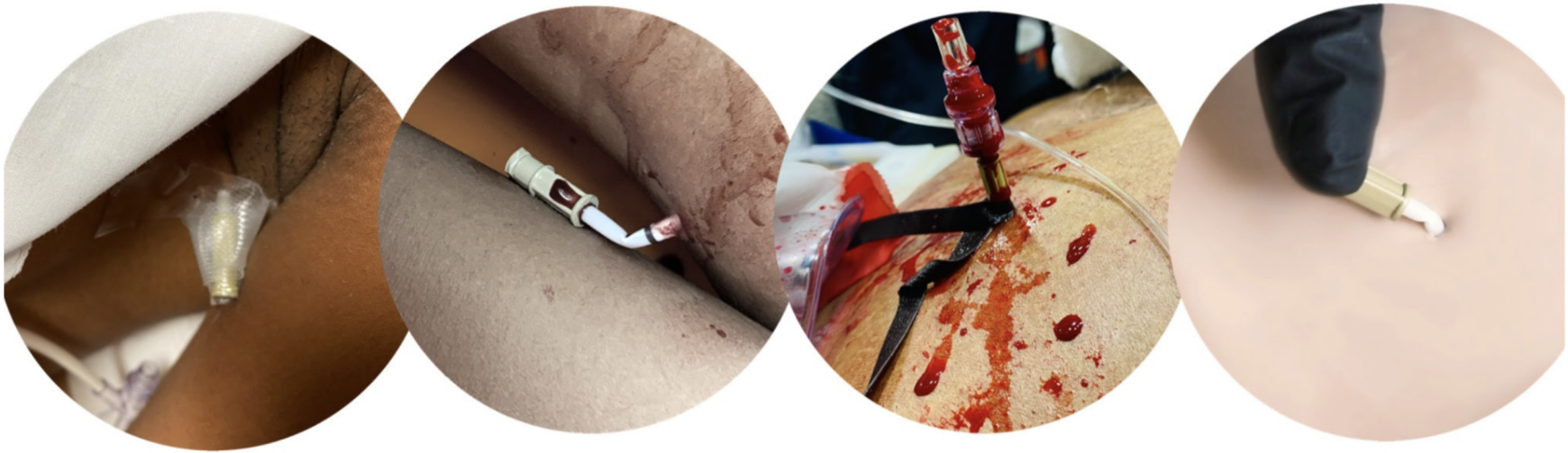
Uses with eight materials

- *Final mouthpieces for patient trials*
- *Tooling w/ small, intricate features*
- *Fixtures and functional gears*
- *Flexible, silicone-like seals*
- *Prototypes (looks and feels like)*





In the combat setting, tension pneumothorax is the second leading cause of death, and often it is preventable



Bending, kinking, and dislodgement of ND catheters directly contribute to patient mortality

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INTERVIEW

Veteran and Paramedic Develops 3D Printed Device that Prevents Collapsed Lung Complications

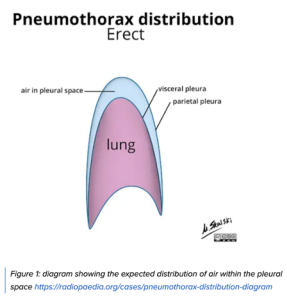
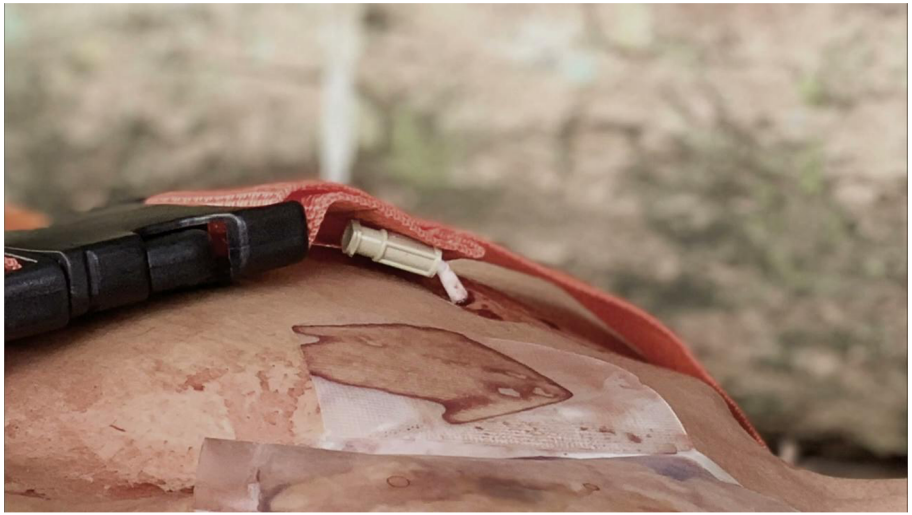
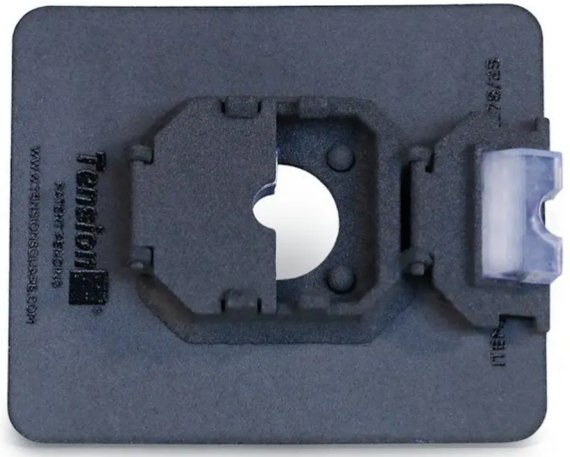
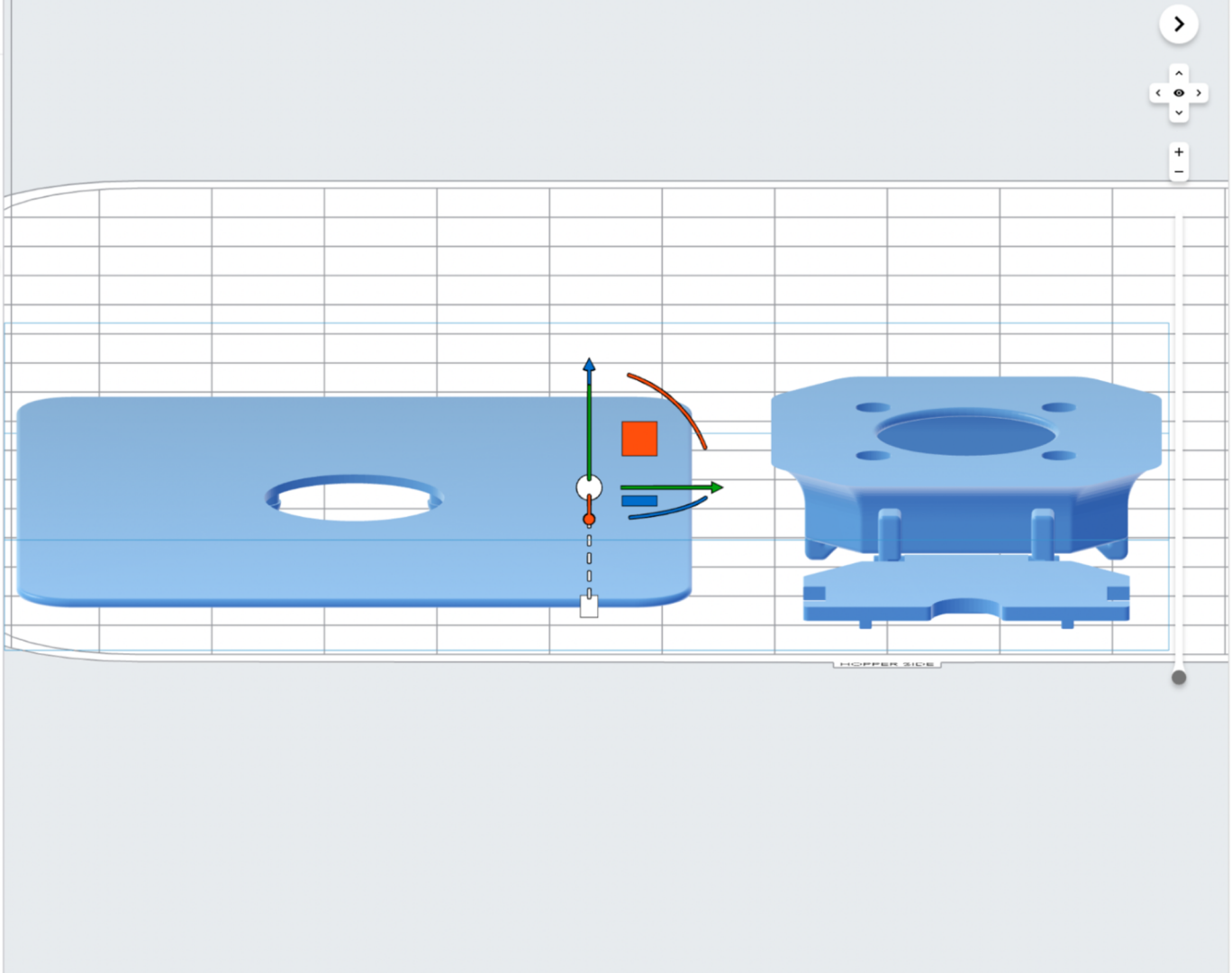


Figure 1: diagram showing the expected distribution of air within the pleural space https://radiopaedia.org/cases/pneumothorax-distribution-diagram







JOB INFO

PRINTER

DISCONNECTED

DapperQuoll

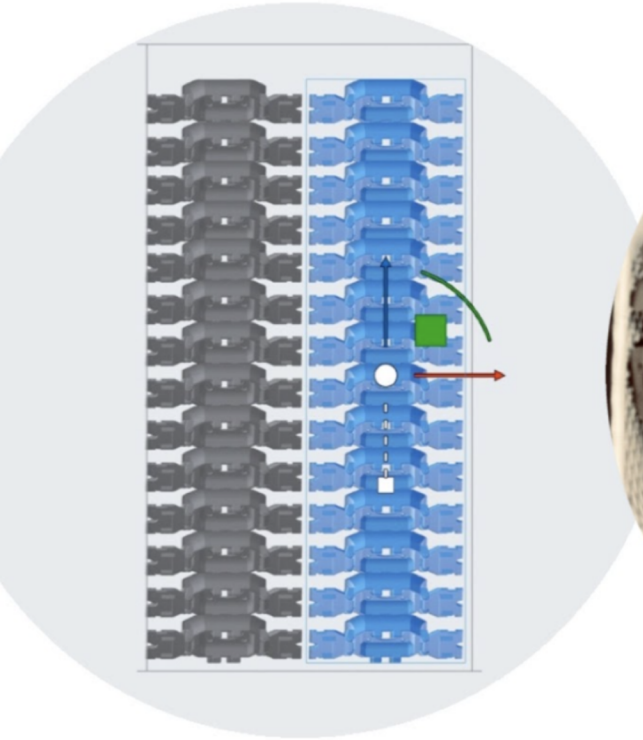
Powder	Nylon 12 V1
Layer Thickness	0.110 mm

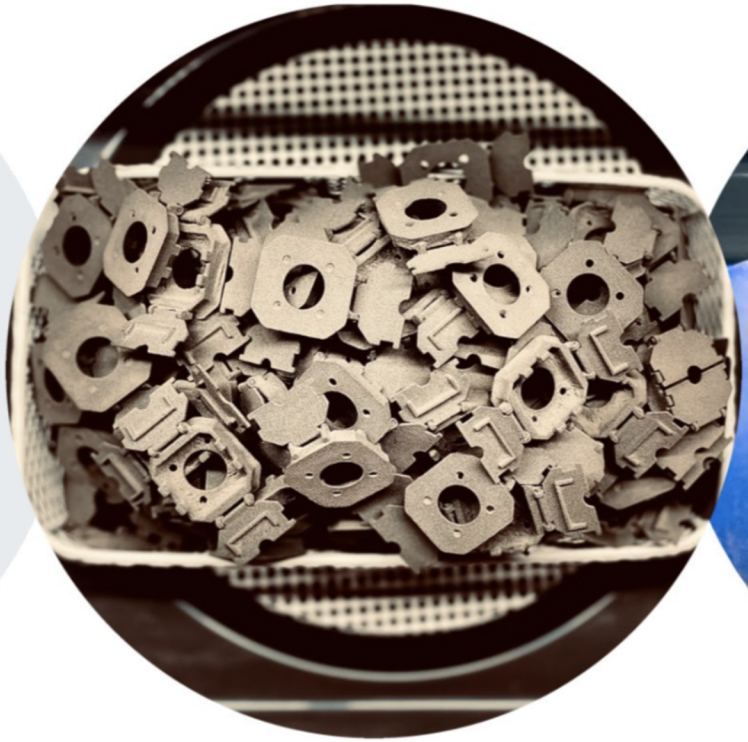
DETAILS

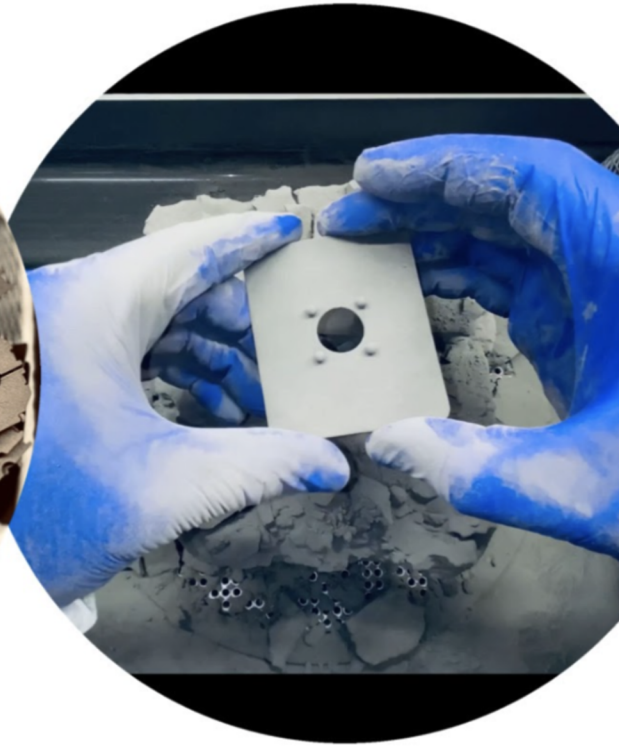
Print Time	--
Fused Powder: < 0.01 kg Unfused Powder: 0.16 kg	--
Total Powder	0.17 kg
Packing Density	5%
Layers	92

MODEL LIST (2)

- base_rev_w...24_21_80mm
- housing_rev_w_1_24_21

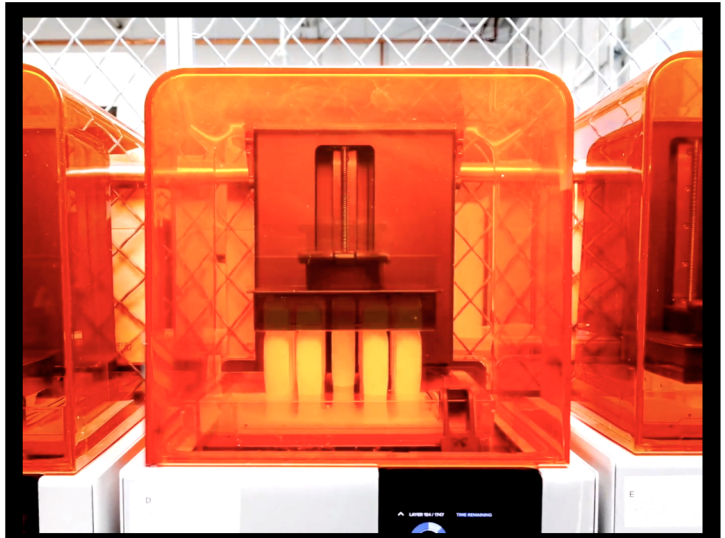




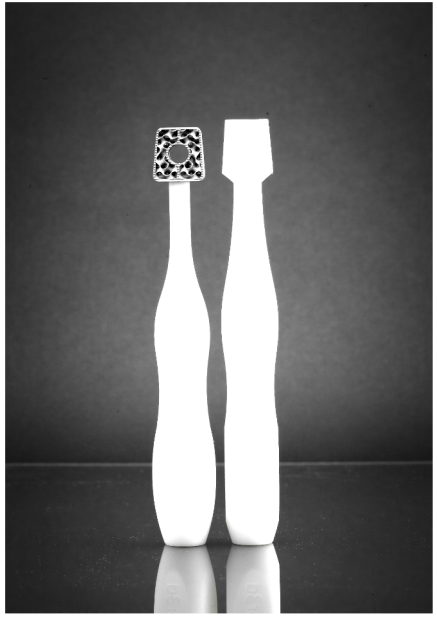


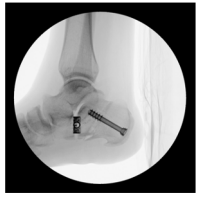
Combination Handle/Inserter for Osteotomy Wedges

Individually sterilized and packaged as alternative to large, expensive kitted trays



Strong, single-use instrumentation fabricated using Stereolithography 3D printing technology





Restor3D NOVO™ Technology

https://www.restor3d.com/technology

“

“the two reasons we have stuck with Formlabs are production flexibility and the ability to incrementally scale. The investment into one of your printers is significantly less than investing half a million dollars to buy one metal printer. So over time we can continue to tack on to our Formlabs fleet as we need to scale incrementally, and do so in a sustainable way that doesn't require a huge capital investment upfront.”

Cambre Kelly, VP of Research and Technology

Why did Restor3D invest in Formlabs?

- *Titanium implant can be **threaded** onto polymer "inserter"*
- *Parts are **biocompatible** + can be **sterilized** (gamma and steam)*
- *Parts **withstand impact** when malleted + show up under intraoperative **fluoroscopy** (x-ray)*
- *One platform from **prototyping to production** + can add throughput as demand increases*

Commercially Available Sleep Apnea Device

Emergency Medical Supply Production

Health Canada approved.
EtO sterilization validation.
4M swabs printed.
https://canswab.healthcare/

ISO 13485:2016 | FDA ESTABLISHMENT REGISTERED | AS9100D | CONTROLLED GOODS PROGRAM | ISO 9001:2015

Point-of-Care Manufacturing of Medical Devices

Crisis

3D Printed NP Swabs

- *Teams from USF Health, Northwell Health, and Formlabs worked together to design, test, and clinically validate swabs to address the shortage from traditional manufacturers*
- *The NP swabs cleared all testing, and the 3D printed versions have performed as well as or better than traditional swabs[1]*
- *Design optimized for efficacy, safety, and comfort*
- *Partnered with hospitals and government entities for distribution*

Key Metrics

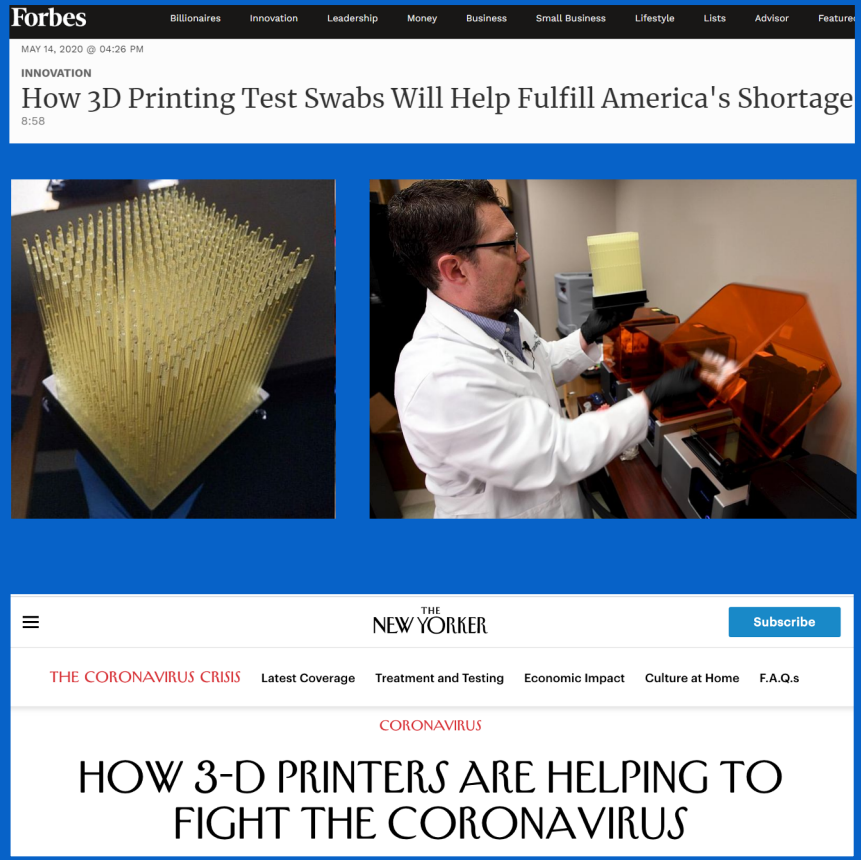
*Concept, clinical trial, and clinical use in **3 weeks***	*Cost per part with 3D printing: **$0.23***
*Capacity: **300-500** swabs/printer/day*	*Decentralized printing of **70M+ NP** swabs worldwide*

USF HEALTH

Northwell Health

1 https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1366/5903830

1. Cost calculated as 300mL of resin/324parts at $249/L of resin



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Crisis

BiPAP to Ventilator Convertors

With the number ventilation machines in limited supply, hospitals struggled to meet patient needs at the onset of the pandemic.

Northwell Health ***served 450+ patients with 3D printed adapters*** *that converted readily available, underutilized bi-level positive airway pressure (BiPAP) machines, typically used for patients suffering from sleep apnea, into* ***functional invasive mechanical ventilators.***

The FDA granted Formlabs and Northwell an Emergency Use Authorization (EUA) to mass produce these adapters.

Cost and ROI

- *Cost per part with 3D printing:* ***$4.04***[1]
- *Print Capacity: 190+ per day*
- *Cost for Additional Ventilator, if available: $25K +*
- ***<4 converted BiPAPs*** *for ROI*[2]

Source: https://www.formlabs.com/news/northwell-3d-printed-respirator-ventilators

1 Cost calculated as 389.52mL of resin/24 parts at $249/L of resin

2 Assuming 10-printer lab and cost avoidance of additional ventilators purchased at $25,000

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"The BiPAP conversion tool helps with the unpredictable nature of a surge at a specific hospital. The great unknown is, how many ventilators do you really need if there is a surge? This helps alleviate the concern."

Dr. Hugh Cassiere, *Medical Director for Respirator Services, North Shore University Hospital*

Northwell Health operates 23 hospitals in the New York City area and is the largest health system in New York State

Northwell Health

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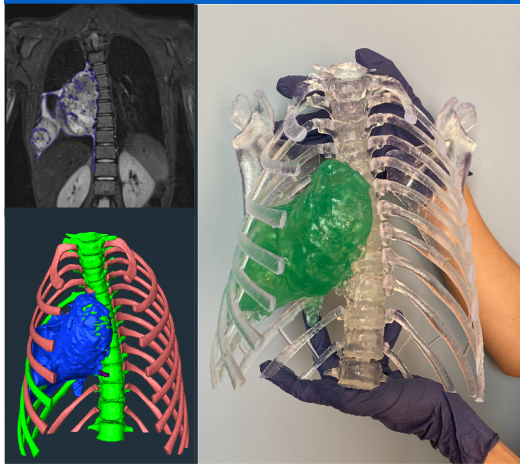
Custom Devices Printed at the Point-of-Care

Under the practice of medicine

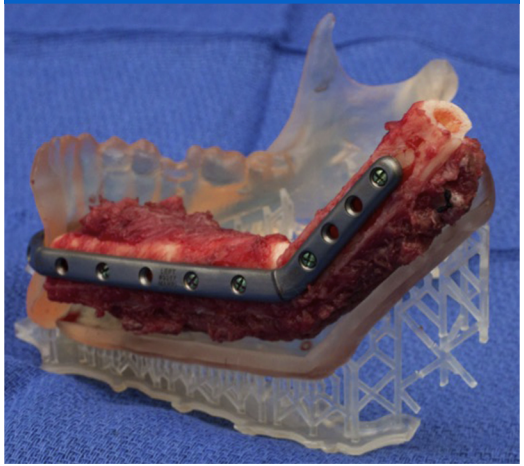
"The patient was out of the OR and in recovery at 2pm. This is normally a day-long procedure."

Ear, Nose, and Throat Surgeon, ***Mayo Clinic***

Preoperative Planning Models



Intraoperative Implant Sizing Tools



Intraoperative Cut + Drill Guides and Resection Jigs

Patient-specific tools start with CT/MR imaging

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Compassionate Use Authorization

→ *Restored Hearing*

FDA grants VA first ever compassionate use for 3D-printed hearing device

WASHINGTON — The Department of Veterans Affairs (VA) received compassionate use approval from the Food and Drug Administration (FDA) in February for a groundbreaking in-house developed medical device to help improve the quality of life of a Veteran with a rare hearing condition.

FDA's compassionate use authorization allows patients access to prototype medications, biologics and medical devices for medical treatment outside of clinical trials when no comparable or satisfactory alternative therapy options exists.

"VA was granted the ability to prescribe an experimental 3D printed audiological device specifically designed for a single patient," said VA Director of 3D Printing Network Beth Ripley, M.D., PhD. "The 76-year-old Veteran patient has a rare medical condition that causes the ear canal to collapse and muffle sound."

The 3D printed stent is inserted in the external ear canal to keep it from collapsing and allow sound to pass through. The device is not surgically implanted and can be easily removed by the patient. This unique hearing aid was designed and created by the integrated 3D printing network team at the Ralph H. Johnson VA Medical Center in Charleston, South Carolina.

In 2017, VA started integrating and developing its 3D Printing Network. Since then, the network has expanded to more than 60 VA medical centers exploring possible uses of the technology in clinical settings.

Learn more about more about VA's 3D Printing Network VA's 3D Printing Network.

FDA Approves VA-Made 3D-Printed Hearing Device for South Carolina Veteran

Patient Michael Nicoletti holds up the stent he helped co-design with Veterans Affairs officials. MICHAEL ROMEO III/RALPH H. JOHNSON VA MEDICAL CENTER

VA | U.S. Department of Veterans Affairs

Quality Recommendations

Point of Care (health institution) vs manufacturer

Requirements and Considerations	***Point of Care Manufacturer (hospital)***	***Medical Device Manufacturer***
Established Quality System	***US:*** *Not Required (but some elements are recommended)*	*Required*
	EU: *Required*	*Required*
Regulatory Premarket submission	*Not Required**	*Required*
Regulatory Postmarket submissions	*May be Required*	*Required*

Design Control

- *Mechanical Properties Required*
  - *Predicate standards/specifications*
- *Biocompatibility*
  - *Type and duration of contact*
  - *MDR Art 10.4.1*
- *Geometry*
  - *Accuracy*
  - *Sterilization modalites*

1. *ISO 13485:2016 - Clause 7.2.2/7.3*
2. *21 CFR 820.30*
3. *MDR Art 5(f)*

DEVICE CATEGORIES			BIOLOGICAL EFFECTS							
Device Type	Body Contact	Contact Duration **Limited** ≤ 24 Hr **Prolonged** 24 Hr–30 Days **Permanent** ≥ 30 Days	Cytotoxicity	Sensitization	Irriation or Intractuaneous	Reactivity System (Acute) Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatability
SURFACE DEVICES	Skin	Limited	X	X	X	-	-	-	-	-
		Prolonged	X	X	X	-	-	-	-	-
		Permanent	X	X	X	-	-	-	-	-
	Mucosal Membrane	Limited	X	X	X	-	-	-	-	-
		Prolonged	X	X	X	0	0	-	0	-
		Permanent	X	X	X	0	X	X	0	-
	Breached or Compromised Surfaces	Limited	X	X	X	0	-	-	-	-
		Prolonged	X	X	X	0	0	-	0	-
		Permanent	X	X	X	0	X	X	0	-
EXTERNAL COMMUNICATING DEVICES	Blood Path, Indirect	Limited	X	X	X	X	-	-	-	X
		Prolonged	X	X	X	X	0	-	-	X
		Permanent	X	X	0	X	X	X	0	X
	Tissue/Bone/Dentin Communicating†	Limited	X	X	X	0	-	-	-	-
		Prolonged	X	X	0	0	0	X	X	-
		Permanent	X	X	0	0	0	X	X	-
	Circulating Blood	Limited	X	X	X	X	-	0‡	-	X
		Prolonged	X	X	X	X	0	X	0	X
		Permanent	X	X	X	X	X	X	0	X
IMPLANT DEVICES	Tissue/Bone	Limited	X	X	X	0	-	-	-	-
		Prolonged	X	X	0	0	0	X	X	-
		Permanent	X	X	0	0	0	X	X	-
	Blood	Limited	X	X	X	X	-	-	X	X
		Prolonged	X	X	X	X	0	X	X	X
		Permanent	X	X	X	X	X	X	X	X

X = ISO 10993-1 tests 0 = Additional tests that may be applicable † = Tissue includes tissue fluids and subcutanous specs ‡ = For all devices used in extracorporial circuits

Supplier Controls

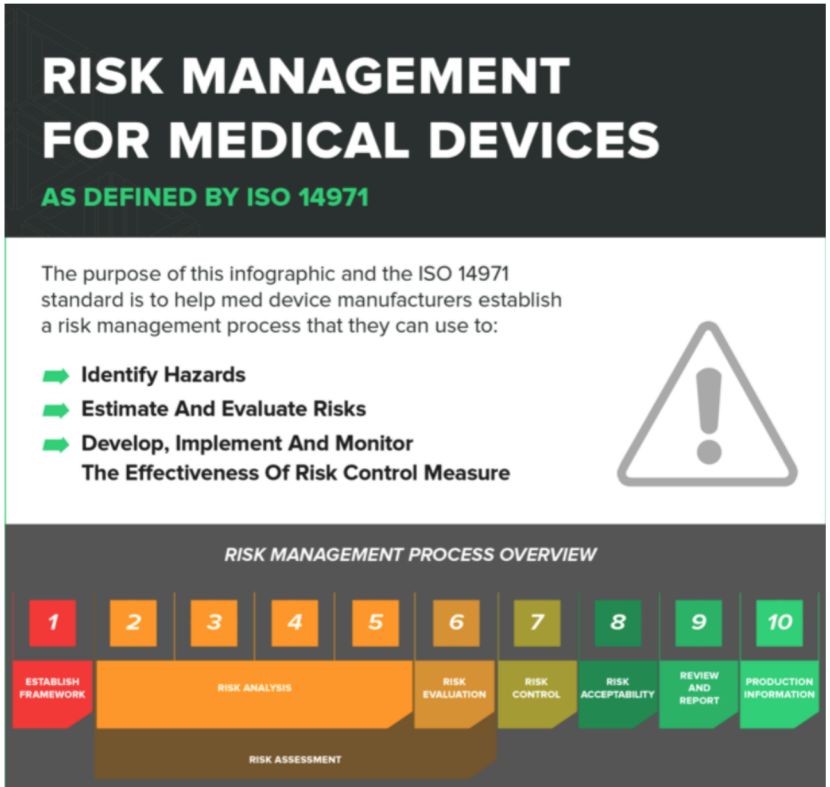
Applicable to device manufacturers

Source	Requirement	Formlabs Resources	Status
21 CFR 820.50(b) ISO 13485, Clause 7.4.2	An agreement for changes	Quality Agreement templates	✓
21 CFR 820.80(b) ISO 13485, Clause 7.4.3	Verification of Product Specifications	Certificate of Compliance Certificate of Analysis	✓
21 CFR 820.50(a)(1) ISO 13485, Clause 7.4.2(d)	Supplier's quality requirements	ISO 13485:2016 certified	✓

Risk Management

Applicable to device manufacturers and EU PoC manufacturers

- *Follow ISO 14971*
  - *Common hazards*
    - *Biocompatibility*
      - *Trusted materials/validated printers/post-processing*
    - *Sterilization*
      - *Worst case scenario testing*



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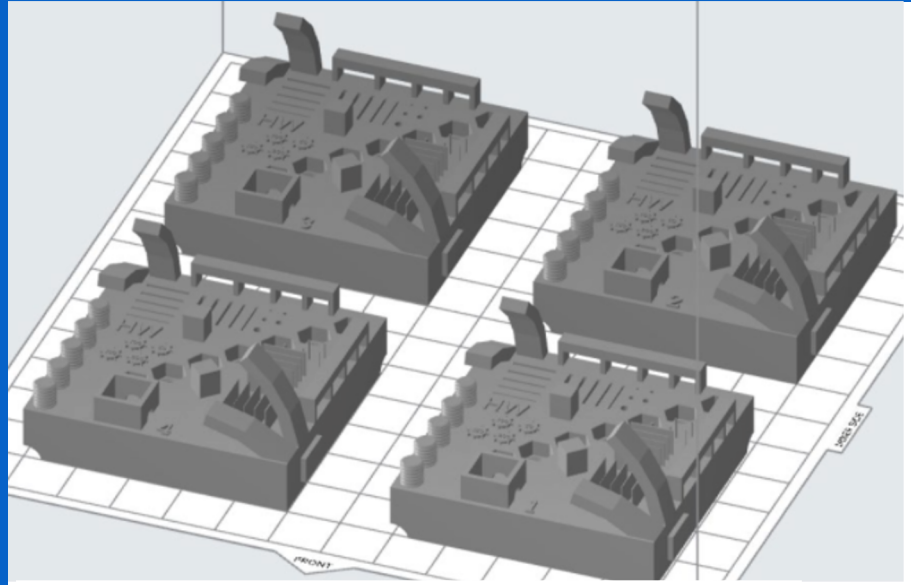
Process Validation

Applicable to device manufacturers, recommended for all

IQ	OQ	PQ
Ensure equipment is qualified and installed correctly ● *Work space* ● *Voltage* ● *Consumables* *Applicable to:* ● *Printer* ● *Wash* ● *Post Cure*	*Demonstrate process/equipment can run at specified challenge/control limits* ● *Printer* ○ *Build volume* ○ *Build platform placement* ○ *Orientation* *Use coupons* ● *Wash* ○ *IPA saturation* ○ *Time* ● *Post Cure* ○ *Time/Temperature* ○ *UV intensity*	*Confirm process can produce a consistent result* ● *Performed under production conditions* ○ *Parts per build platform* ● *Real patient scans* ○ *Representative of design criteria requirements*

Process Validation Resources

- *Templates*
- *.stl coupons*
- *Software release notes for changes*
- *Changes in material notifications*



Form 3B

The following were recommended updates for Form 3B printers:

VERSION	DATE	DOWNLOAD	WHAT'S NEW
1.14.7	August 16, 2021		• **Compatible with PreForm 3.18.0 and later** • Added mixer recalibration wizard • Improved tank detection • Improved cartridge detection • Improved tank lifetime display • Improved print reliability • Various bug fixes

Regulatory Strategies

US Device Risk Classification

Applicable to device manufacturers

CLASS	RISK	EXAMPLES	SAFETY/EFFECTIVENESS CONTROLS	REGULATORY PATHWAYS
I	Low	Tongue depressor, hospital beds	**General Controls** • With Exemption • Without Exemption	**Self registration** or **510(k)**
II	Medium	Absorbable suture, blood pressure cuffs	**General Controls** • With Exemption • Without Exemption **Special Controls** • With Exemption • Without Exemption	Most class II devices are cleared under a **510(k)** pre-market notification submission Few devices of class II are approve under **PMA** 10-15% devices require **clinical trial**
III	Highest	Implantable pacemaker, coronary stent	**General Controls** **Special Controls** **Pre-market authorization**	**Pre-market approval (PMA)** Almost all require clinical Data

Custom Devices (US)

Applicable to device manufacturers

	Patient Matched Device	Custom Device
FDA Submission (if applicable based on product)	*Yes*	*No*
Limited on number sold	*No*	*5 per year for each indication*
Can be used if there is a market alternative	*Yes*	*No*
Can market freely	*Yes*	*No*
Exempt from general controls	*No*	*No*
Requires yearly production reporting to FDA	*No*	*Yes*

Class II Product Codes

Applicable to device manufacturers

Regulation	Product Code	Description	Discussion
21 CFR 892.2050	*LLZ*	*Picture archiving and communications system*	*3D printed anatomical models function like a digital equivalent for diagnostic purpose*
21 CFR 872.4120	*DZJ*	*Bone cutting instrument and accessories*	*Instrument (or accessory) used to cut into the jaw*
21 CFR 888.3030	*PBF*	*Single/multiple component metallic bone fixation appliances and accessories*	*Patient specific templates based on pre-operative plan and to fit a specific patient. Guides used to assist a surgeon in guiding the marking of bone and/or guiding surgical instruments*

Guidance Document Best Practices

Technical Considerations for Additive Manufactured Devices

- *All of Section V must addressed in Device Description (Section 10)*
  - *RTA: It is recommended that each sub-section of Section V of the Guidance be described/addressed in the revised Device Description, as applicable.*
    And
    Please carefully examine section V.A-G
- *Section C-Software Workflow*
  - *(2) Digital Device design to Physical Device should consider detailing "build preparation software"*
    - *Build Volume, Supports, slicing, build paths*
- *Section D-Material Controls*
  - *Identity of material and its testing/test methods (consider device master files)*
    - *RTA: You have provided a MSDS, dimensions, and manufacturer information. Please also include a description of its material composition and available colorants/pigments.*
- *Section E-Post-Processing*
  - *Describe "detrimental effects of post-processing"*
    - *AI: coupons may be used for material property assessments if the coupon undergoes identical processing (including post-printing processes, cleaning, etc.) to that of the final finished device.*

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Guidance Document Best Practices (cont)

Technical Considerations for Additive Manufactured Devices

- *Section F-Process Validation and Acceptance Activities*
  - *Use coupons, document: process monitoring and when revalidation is required*

- *Section VI Device Testing Considerations*
  - *Not all need to be addressed, but if other methods are chosen, document why*
    - *RTA: you have not addressed Section VI. Device Testing Considerations per the aforementioned FDA Guidance Document. Please address all relevant items per FDA Guidance*
- *D. Material Characterization*
  - *"Chemical component should be provided. If material chemistry information in a device master file (MAF) will be referenced, you should include a right to reference letter from the MAF holder"*

EU MDR Risk Classes

Risk Class

Rule	Class	Description	Exceptions
1	*I*	*All non-invasive devices unless one of the rules set out hereinafter applies*	*Unless another rule set applies*
7	*IIa*	*All surgically invasive devices intended for short-term use*	● *Heart* ● *Central circulatory system* ● *Central nervous system*

*"**accessory** for a medical device": an article which, not being itself a medical device, is intended to be used together with a particular medical device(s) to enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);*

Custom Devices (EU)

Applicable to device manufacturers

	Patient Matched Device	Custom Device
Specifically made in accordance with a written prescription	*No*	*Yes*
Prescription gives specific design characteristics	*No*	*Yes**
Device can be mass produced	*Yes*	*No*
Produced in a batches	*Yes*	*No*

Dimensions and/or geometric parameters (such as DICOM files from scans) are NOT considered **specific design characteristics on their own. Additional measured data or information (such as the thickness and the number, type, and positions of fixation screws, choice of material, shall also be provided for in the prescription*

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MDR Article 5 vs custom vs PMD

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Requirement	Health Institution	Custom Device	Patient Matched Device
QMS	Yes	Yes	Yes
Annex I GSPR	Yes	Yes	Yes
DoC/CE Mark	No[1]	No[2]	Yes
Annex II Documentation	No[3]	No[4]	Yes
Annex III Documentation	No	No[5]	Yes
Clinical Evaluation	No	No	Yes

1. *"Declaration" with three specific items (manufacturer/address, etc.) and justification no market alternative*
2. *CMD's need a "statement" with eight specific items (manufacturer/address, patient , etc.)*
3. *Document manufacturing facility and process, the design and performance data, the intended purpose*
4. *Documents design, manufacture and performance of the device, including the expected performance*
5. *PMCF is required if applicable*

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Conclusions

US

- *Determine if practice of medicine exemptions apply (21 CFR 807.65)*
  - *Apply appropriate QMS provisions*
- *Determine device risk classification*
- *Implement compliant QMS*
- *Select appropriate premarket pathway*
- *Follow the guidance document (Technical Considerations for Additive Manufactured Medical Devices)*

EU

- *Determine if Article 5 exemptions apply*
- *Determine if device is “Custom Made”*
- *Determine device risk class*
  - *Class IIa devices will require a conformity assessment with a Notified Body*

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Questions

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