PARAGON
Rapid Technologies

Revolutionising medical device development

with Digital Light Synthesis™ technology

PARAGON-RT

What’s inside?

- A brief introduction to Paragon and Digital Light Synthesis™ technology (DLS™ technology)
- Where does DLS™ technology fit in the medical devices manufacturing marketplace?
- Why it is different from other 3D printing and rapid prototyping technologies
- How can DLS™ technology help your medical device development business?

About us

When it comes to saving or enhancing lives, continuous breakthrough innovation is paramount. The faster you can get your device to clinical trials, or your model into the surgery, the better the outcome for all.

We have been helping the medical industry to develop innovative devices since 2003. Our broad spectrum of services and technologies support a wide range of materials specifically designed for medical sector.

We've helped our medical innovation customers to innovate, develop, test, improve and produce high quality parts. We've supported them through concept visualization and design iterations. We've given them the tools needed for quick decision-making. We've helped them shorten product development cycles. We've helped them to find production solutions. We've been flexible and kept costs down. And we've made sure they're happy. Time and again.

AM for Medical Device Manufacture

Additive manufacturing (3D printing) applications in the medical innovation field now go way beyond validation prototyping. The advancement of technologies and materials has enabled the development of patient-specific models and devices and volume manufacture of single use items with cost and time efficiencies previously unimagined.

Designers have been leveraging advantages in both new printing software and new resins which has led to a reduction in the number of processing steps and subsequently costs of manufacturing. There is a host of technology for additive manufacturing available to the sector.

Recognising that our clients are on an eternal mission to create products that push boundaries in terms of innovation and performance, in 2018 we invested in 3 Carbon digital manufacturing printers.

Digital Light Synthesis™ technology

Technically a 3D printing process, Carbon Digital Light Synthesis™ technology (DLS™ technology) uses digital light projection, oxygen permeable optics, and programmable liquid resins to produce parts with excellent mechanical properties, resolution, and surface finish. The process creates parts up to 100 times faster than more traditional 3D printing methods. With a wide array of resins specifically designed for end-use, parts printed with Digital Light Synthesis technology are much more like injection-moulded parts.

DLS™ technology is for volume production rather than prototyping. With the medical device market being driven by digital manufacturing, DLS comes into its own for medical devices comprising parts made up of unmouldable, complex geometries; or when a percentage of component parts are modified to enable that device to perform different or multiple functions.

DLS™ technology provides device designers with the freedom to produce multiple variations of such components without incurring significant tooling costs each time an adjustment is made. It provides device designers with an opportunity to produce 1000s of precise copies of each of their final parts with 'at scale' pricing. And, with an array of mechanical properties and material choices available, medical device designers and manufacturers can be secure in the knowledge that the parts printed with DLS™ technology are biocompatible (some are sterilisable); and can be adjoined to injection-moulded parts without the worry of mechanical failure.

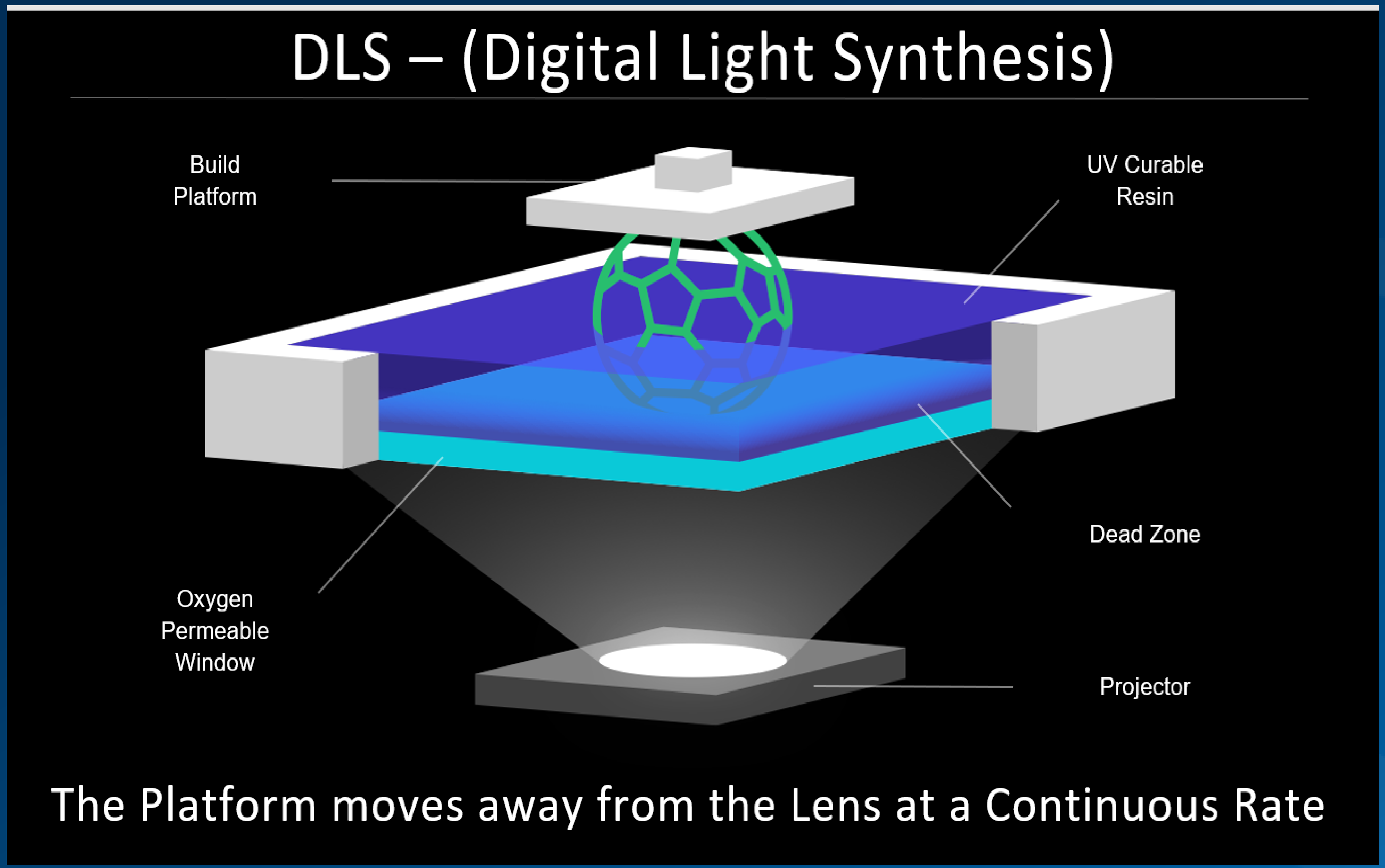
The Digital Light Synthesis™ technology advantage

Digital Light Synthesis™ technology uses a High Intensity Light shone through an Oxygen Permeable Lens to Cure the resin above.

The subsequent parts with any support structure are attached to the platform

The clever element, and the differential between DLS™ and more traditional 3D printing methods, is that the platform moves away from the lens at a constant speed. This makes parts much stronger - there are no weaknesses between layers; the density of the material is much greater; and the resultant parts' properties are comparable with injection moulding.

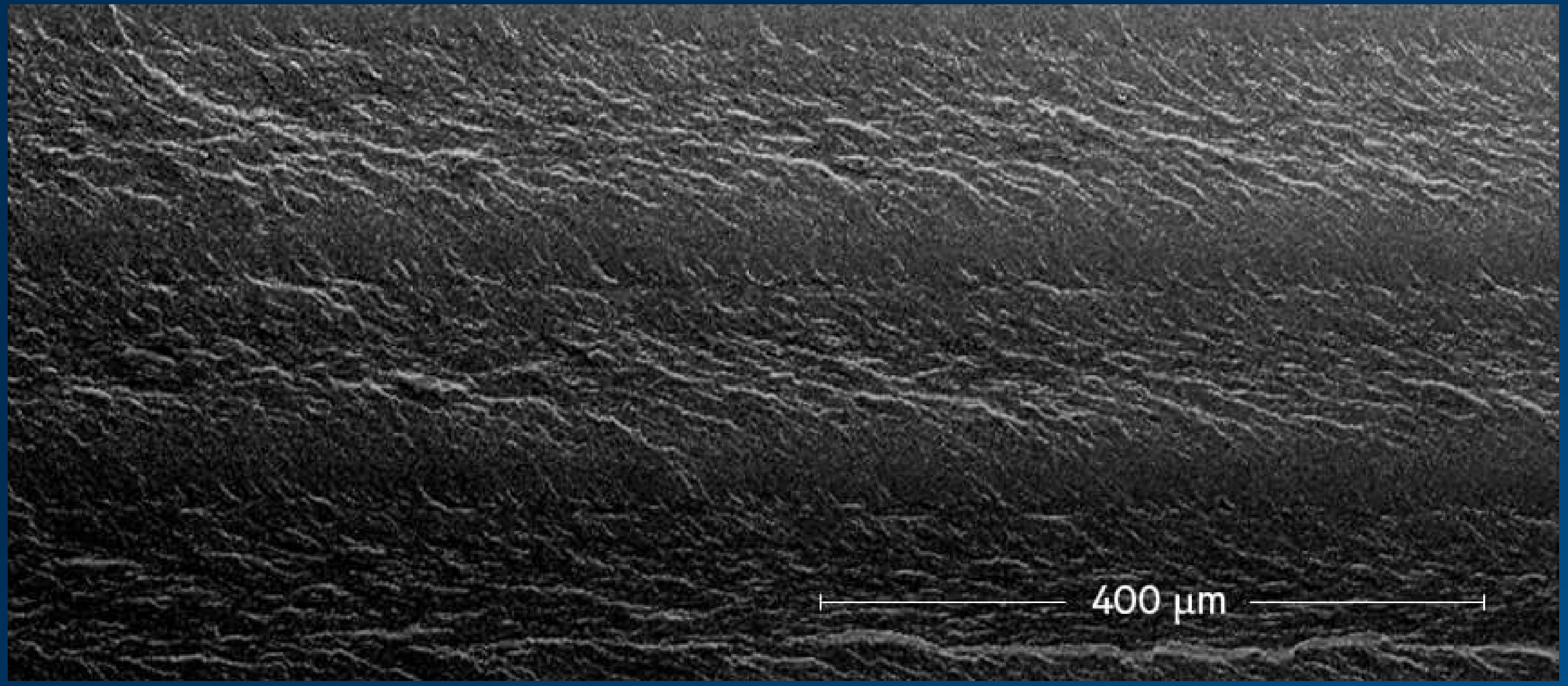
This enables us to print parts which are production intent, from resins which have been produced to withstand a very wide range of conditions.



The Digital Light Synthesis™ technology difference

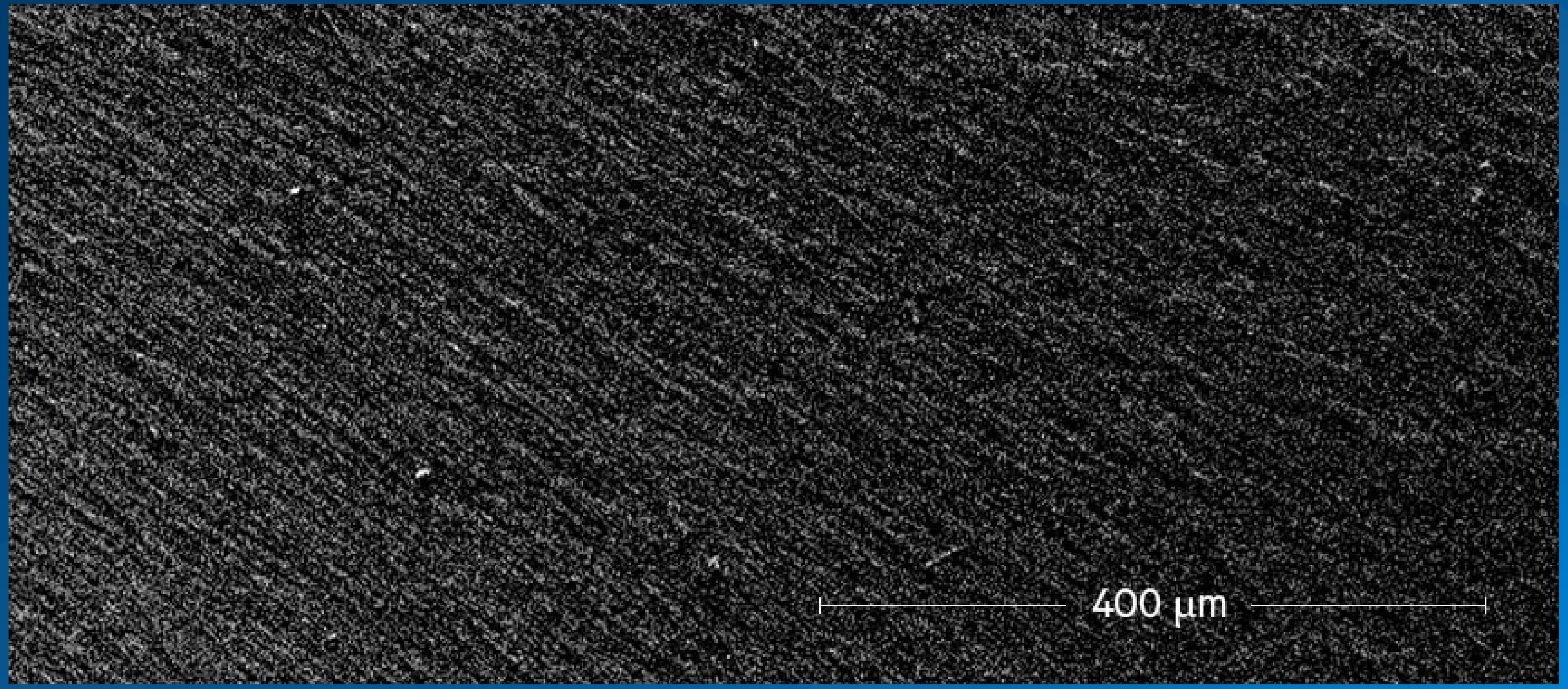
Traditional 3D printing methods

3D printed parts are notoriously inconsistent. Their mechanical properties vary depending on the direction the parts were printed due to the layer-by-layer approach.



Digital Light Synthesis™ technology

Parts printed with Digital Light Synthesis™ are much more like injection-moulded parts. Digital Light Synthesis™ produces consistent and predictable mechanical properties, creating parts that are solid on the inside.



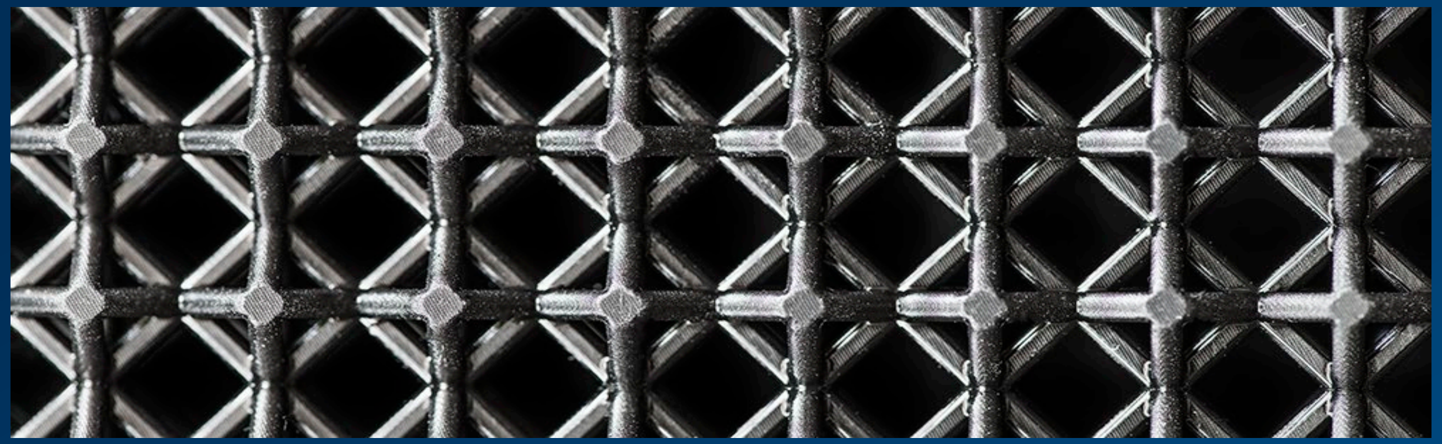
Digital Light Synthesis™ technology applications in the medical sector

PARAGON-RT

Materials overview

MPU Medical Polyurethane

Biocompatible, sterilisable,



EPU Elastomeric Polyurethane

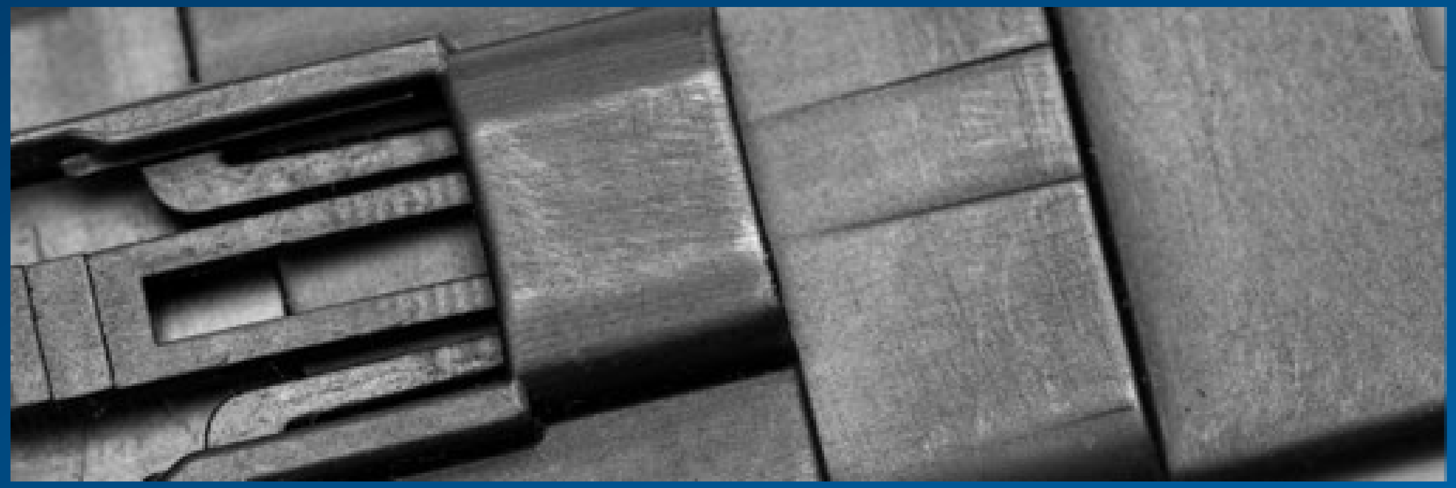
Highly elastic, resilient

RPU Rigid Polyurethane

Tough and abrasion resistant, stiff

UMA Prototyping Resin

General purpose



EPX Epoxy

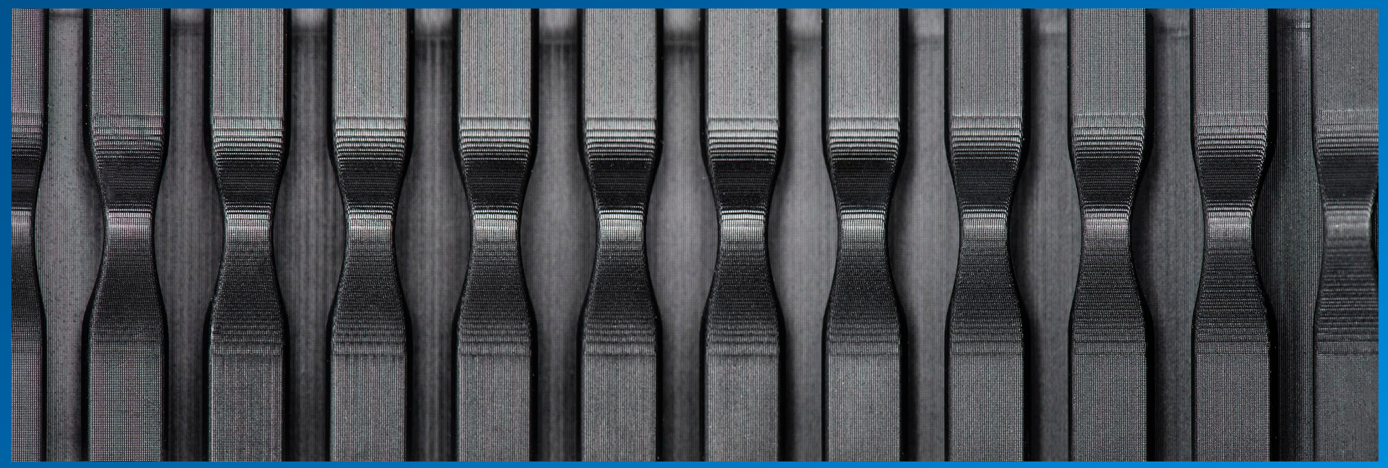
Temperature resistant, strong and accurate

CE Cyanate Ester

High temperature resistance, strength, and stiffness

SIL Silicone-urethane

Soft, biocompatible and tear resistant



FPU Flexible Polyurethane

Tough, impact, abrasion resistant with moderate stiffness

Carbon® Materials Biocompatibility Overview

	UMA 90	RPU 70	RPU 130	EPU 40	SIL 30	EPX 82	CE 220	MPU 100
Cytotoxicity[1]	✓	✓	✓	✓	✓	✓	✓	✓
Irritation[2]	✓	✓	✓	✓	✓	✓	✓	✓
Sensitisation[2]	✓	✓	✓	✓*	✓	✓	✓	✓
Acute Systemic Toxicity	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested	✓
Implantation	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested	Not tested	✓

1. ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
2. ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation (GPMT)

* Sensitisation for EPU 40 specifically used the Closed Patch Sensitisation Study rather than the GPMT

PARAGON-RT

MPU 100 – Carbon's first medical-grade resin

All DLS™ technology resins are biocompatible.

Product Name: Medical Polyurethane 100

Target Applications: Medical Capital Equipment and Single use medical devices

Key Features:

- Production-ready medical-grade polymer
- Engineering grade mechanical properties with abrasion and chemical resistance
- Tested to USP V1 and ISO 10993-5 and 10-biocompatibility
- Sterilisable with ethylene oxide, e-beam and gamma
- Maintains its biocompatibility post-sterilization
- Certificate of Analysis available
- Master file available with FDA

MPU 100 – Carbon’s first medical-grade resin

All DLS™ technology resins are biocompatible.

MPU 100 passes the following:

- ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for Irritation and skin sensitivity (GPMT)
- USP VI - includes irritation, acute systemic toxicity and implantation

DLS™ technology applications in medical device manufacture

Medical Equipment System Components

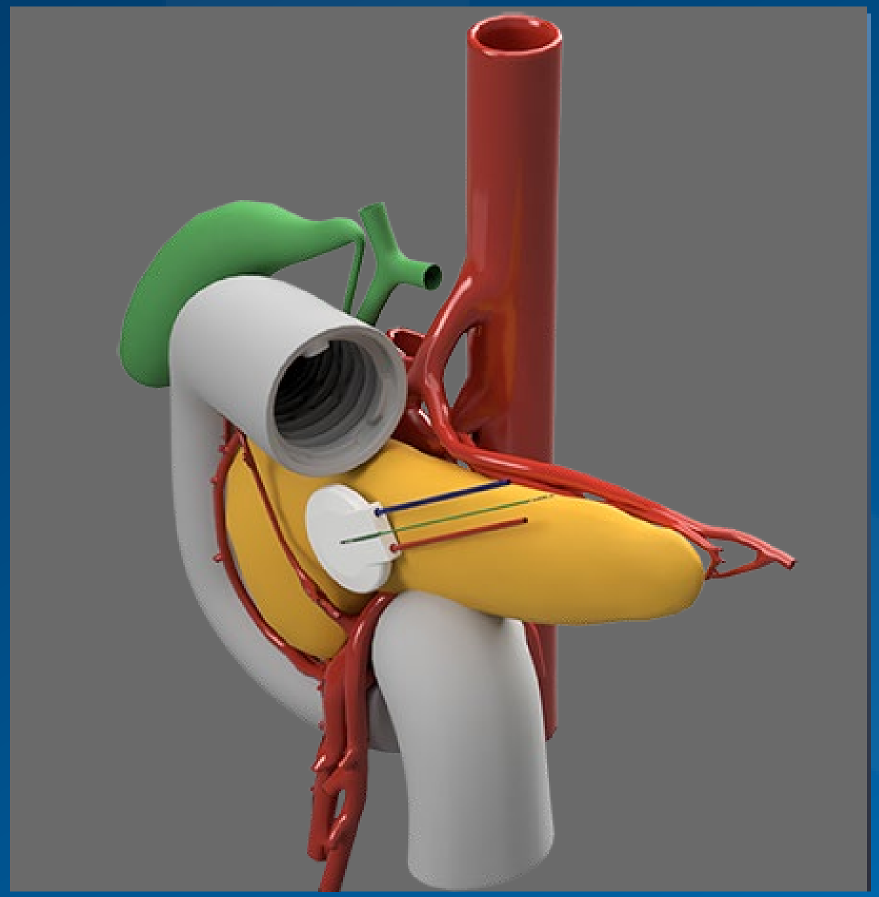
Examples: Cable guides, covers, etc. for imaging systems, robotics systems, diagnostic / analytical equipment, etc.

Single use surgical instruments

Examples: handles, trials, guides, etc.

Non-surgical devices

Examples: Plagiocephaly helmets, orthotics, hearing aids, etc.



Drug delivery

Examples: Iontophoretic devices, micro-needles, drug absorbers.

PARAGON-RT

How can DLS help the medical innovations industry?

- No need for any tooling. This leads to shorter lead times and hugely reduced up-front investment costs.
- Save on engineering changes, which can sometimes be as costly as the tooling itself. Quite simply, if you change your CAD, printing can start again immediately
- Faster to market – straight into production means economies of scale.

PARAGON-RT

Faster to market

Depending on Size and Complexity

4 Weeks | 8 Weeks

Injection Mould Lead Time – to 1st Off

2 to 3 Working Days

DLS

Typical Injection Mould times are 4 to 6 weeks. This can be longer depending upon the size and complexity of parts. Reducing times usually comes at cost.

First offs created with DLS™ technology typically take 2 to 3 days to produce and send to the customer.

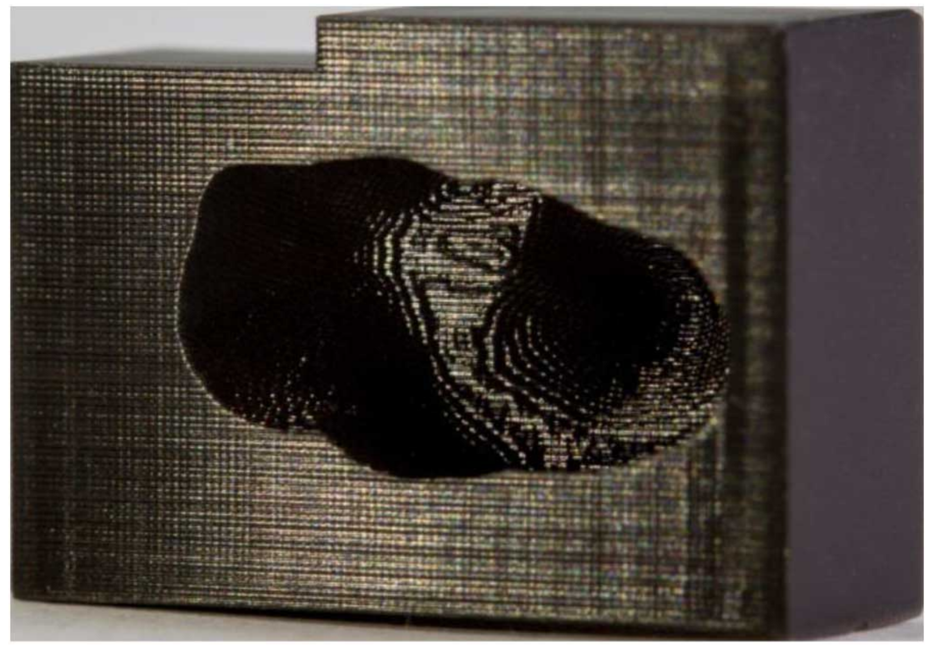
Like Injection Moulding, designs can be tweaked at this stage. It's also an opportunity to optimise build performance through re-orientation on the platforms.

The key difference is that this usually only takes another 2 to 3 days, thus reducing lead times by weeks or months.

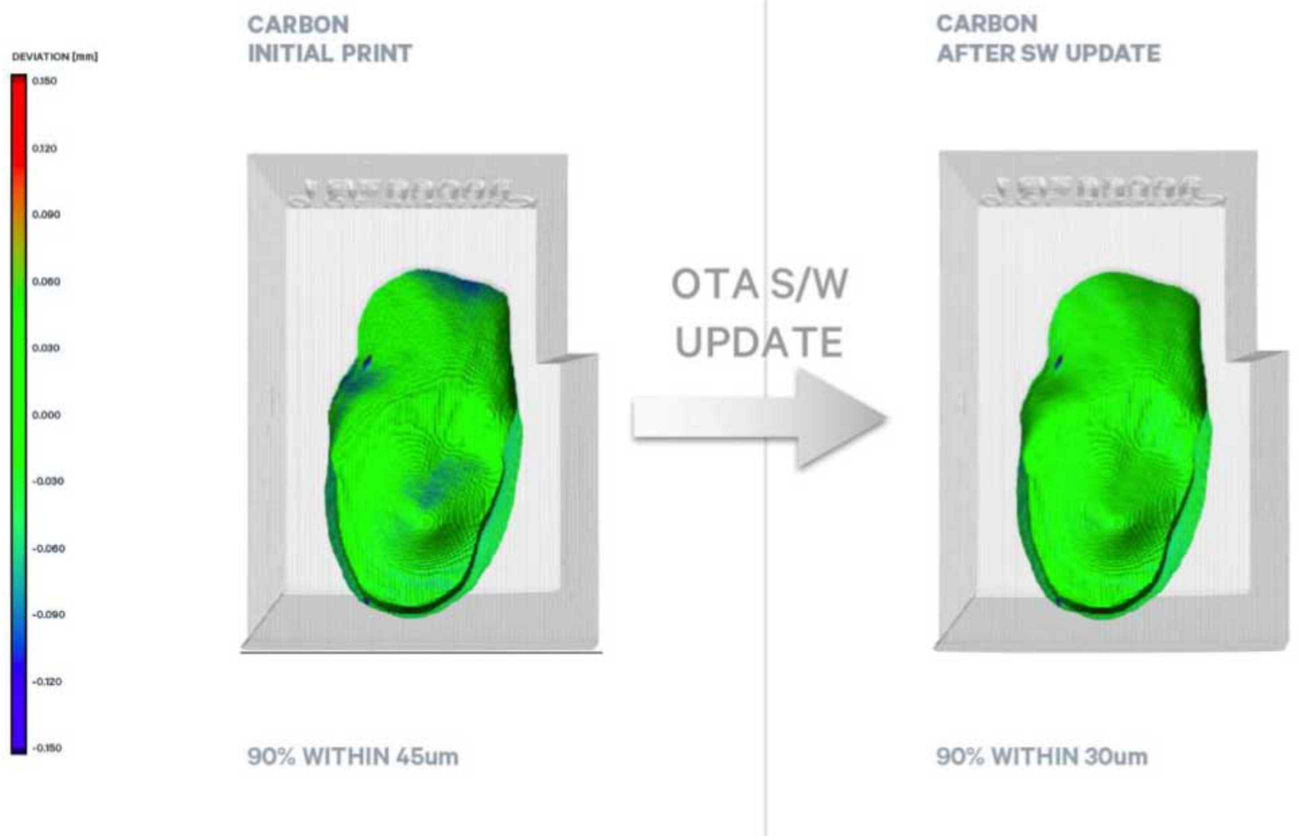
DLS™ technology in action – courtesy of Carbon®

earlens

EARLENS HEARING-AID MOLDS



MOLD PRODUCED USING CARBON



Description:

- Earlens was looking to improve the speed while maintaining accuracy of production molds used for making custom hearing aids.

The challenge:

- Conventional SLA mold production process was slow, taking 3-6 hours
- Meeting the mold's anatomical accuracy specification required physical optimization and fine-tuning of the SLA printer hardware, a tedious and and non-scalable process

The solution:

- 4x to 8x faster: Print times of only ~45 mins with Carbon's M Series printers + PR 25 black material
- Adaptive manufacturing: OTA software update on Carbon printers to rapidly optimize the printing process to meet accuracy specification, no physical hardware optimization required
- Accurate: 90% of points within +/- 30 microns

DLS™ technology in action – courtesy of Carbon®

MANUAL INTRAOSSEOUS INFUSION MEDICAL DEVICE

LUNAR

Description:

- LUNAR design wanted to design a low -cost manual intraosseous infusion device for the Indian market within four months

The challenge:

- Conventional manufacturing methods require expensive tooling costs and long development cycles
- Simple product design needed with excellent device grip
- Strong material mechanical properties, biocompatibility, and compatibility with multiple sterilization methods required

The solution:

- Carbon's 3D manufactured device met cost and time to market goals
- Simplified product design: part consolidation + digital texturing for better grip and product performance
- Carbon's RPU 70 material met all material requirements

PARAGON-RT

Why Digital Light Synthesis™?

In conclusion

- Medical innovations customers can enjoy previously unachievable performance thanks to the quality and design freedom of Digital Light Synthesis™ technology.
- With the material properties and production scale that DLS™ provides, medical device parts become lighter by replacing functional metal components with performance plastics, or replacing complex assemblies with a single printed part.
- Digital manufacturing also streamlines the supply chain, where parts can be printed on-demand from the cloud, not stocked for years in a costly climate-controlled environment.

Eat. Sleep. Make. Repeat.

Contact Us

Paragon Rapid Technologies
T: 01325 333 141
E: info@paragon-rt.com