

Collaboration for Mass Production of Certified 3D-Printed Nasal Swabs

Source: Aenium Engineering



3D-printed nasal swabs with
porous-specific activated
surface on the head plus
highly flexible stick

Challenge

The disruption of the global supply chain coupled with the sudden surge in demand for COVID-19 test kits led to the need to locally develop and manufacture cost-effective and reliable nasal swabs for the PCR test kits.

Solution

High-volume manufacturing with EOS PA2200 material and EOS polymer additive manufacturing (AM) systems to fulfill the requirements of class IIa medical devices. AM & medical knowledge to accelerate design development and manufacturing of such components.

Results

Nasal swabs certified by the Spanish Health Authority

Up to 40000 swabs printed per day

Decentralized on-demand production in Europe and North America

Production of Medical Devices with Industrial 3D Printing in Europe and North America

The COVID-19 pandemic tested global health care capabilities. Supply chains were disrupted, requiring local agile solutions for certified medical devices. Many companies are collaborating with their local governments to provide critical medical devices such as ventilator components, ICU critical parts, face shields, face mask filters, etc., to fight the shortages.

In this context, a collaborative R&D consortium was created in March 2020 to develop certified medical devices and ramp up mass production in North America and Europe. This consortium included Aenium Engineering and Burloak Technologies, who worked closely with EOS' Additive Minds applied engineering team, the Canadian and Spanish health authorities and hospitals, as well as a Spanish genomic laboratory (ITALCyL).

Challenge

The demand for COVID-19 test kits combined with the empty inventory of conventionally manufactured nasal swabs made it clear that additive manufacturing would be the ideal technology for bridging this gap. However, there were challenges that needed to be overcome. The first challenge was the sampling itself. It is essential for the test swab to preserve the virus's integrity to allow RNA detection by means of

reverse transcriptase real-time PCR. A solution is needed with a porous-specific activated surface on the head plus a highly flexible stick which cannot be manufactured conventionally. The second challenge was the high demand for a cost-effective solution. Aenium and Burloak developed a model for producing up to 40,000 swabs per day on multiple EOS AM systems.

Short Profile

Aenium Engineering is a Spanish company that employs EOS polymer systems, materials, laboratories and engineering optimization as well as qualification capabilities. They provide high-value responsible solutions with innovative qualified new materials in metals and plastics.

Further information
www.aenium.es

Canadian-based Burloak Technologies is equipped with the latest additive manufacturing capabilities and a wide industrial portfolio. They develop highly responsible certified components and R&D solutions, thought innovative materials, senior engineering and industrial expertise.

Further information
www.burloaktech.com

And the third challenge: Nasal swabs are a class IIa medical device, requiring a specific certification for testing and qualification to fulfill medical standards. Therefore, a typically long certification procedure with the public administration and laboratories to approve the intended use was required.

Solution

Aenium started clinical trials with the Spanish authorities on April 25, 2020, and performed hundreds of clinical comparisons with commercial nasal swabs. In the clinical trials, RNA was processed by one-step RNA real-time PCR using two kits RT-PCR (BGI) and ref. RR064A (Takara) to detect SARS-CoV-2. Both nasal swabs included an endogenous control, obtaining positive results compared with the same clinical trials over other certified conventionally manufactured commercial swabs. Aenium and Burloak developed a RNA-free nasal swab with specific laboratory-tested parameters. The nasal swabs were manufactured on EOSINT P 385, EOS P 396 and EOSINT P 760 systems using EOS PA2200 material. A full procedure for ensuring the performance, including clinical performance, technical properties and medical device requirements was achieved for Europe and North America. Rapid Manufacturing Systems (www.rmsiberia.com) contributed to the mass production vision

"This is the first 3D-printed nasal swab certified by a government agency and was made possible by collaboration between Aenium, Burloak, Additive Minds and many others. It demonstrated the great opportunity for empowering private-public consortia in the fight against global challenges using industrial 3D printing – an inspiration for others worldwide."

*Jose Miguel Ampudia,
 Chief Technical Officer and R&D Manager at Aenium Engineering*

of offering market value for the nasal swabs industrialization. Based on this success, more products are in the pipeline (e.g. pediatric nasal swabs).

Results

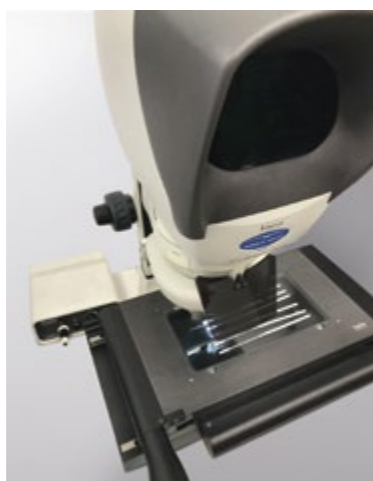
Aenium is working with the Spanish government and hospitals to produce hundreds of thousands of medical nasal swabs for use in COVID-19 test kits. ITALCyL, a public laboratory, and other Spanish laboratories have tested the performance and done the clinical validation to successfully achieve AEMPS (Spanish Agency of Medicines and Medical Products) certification for the mass production of this IIa class medical device. Burloak is helping North American hospitals and public health systems to increase production capabilities

and fight against stockouts of this critical medical device.

- Clinical tests have demonstrated the performance of the 3D-printed nasal swab, a class IIa medical device, as an effective option compared to the commercial nasal swabs.
- Nasal swabs can be produced anywhere in the world according to a decentralized model thanks to additive manufacturing.
- EOS industrial 3D printing polymer solutions enabled agile production for a fast response due to supply chain gaps with a highly accepted material in the medical sector.
- On-demand manufacturing: No expensive tooling needed, just start the systems and qualify the process.



Optic microscopy and surface activated structures analysis
 Source: Aenium Engineering



3D-printed and packaged nasal swabs ready for use in COVID-19 test kits.
 Source: Aenium Engineering

Clinical Trials

Patient N°	Conventionally Manufactured Nasal Swabs				Aenium 3D-Printed 7875 Nasal Swabs			
	Red	Green	Green	Green	Green	Green	Green	Green
	Method 1	Method 2	Method 3	Method 4	Method 1	Method 2	Method 3	Method 4
1	39.06	40.00	23.59	28.48	40.00	40.00	22.57	27.43
2	38.65	40.00	22.60	27.92	35.75	40.00	22.77	27.79
3	18.92	23.91	23.37	29.12	18.67	22.94	22.65	28.92
4	40.00	40.00	23.07	29.07	40.00	40.00	20.93	26.04
5	40.00	40.00	20.08	24.75	38.80	40.00	24.27	31.25
6	36.72	38.95	24.85	30.83	37.92	37.21	24.29	29.62
7	35.11	35.57	24.33	30.21	31.79	34.10	22.97	28.43

Excerpt from the clinical trial results (n=60) comparing conventionally and additively manufactured nasal swabs

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