Case Study: Kallisio

Medical device startup turns to Ricoh's 3D printing, manufacturing and distribution services to deliver a patient-customized solution for better cancer care

About our customer

Radiation plays a crucial role in cancer treatment, but it can also pose challenges when it comes to providing precision therapy and protecting surrounding healthy tissue. Kallisio, a medical device company focused on developing innovative solutions to improve cancer care, set out to advance head and neck cancer (HNC) radiation treatment by using 3D printing to rapidly and cost-effectively turn around patient-specific oral immobilization devices.

> "Ricoh's extensive 3D facilities and delivery expertise have strengthened our vision of closing a huge clinical gap in head and neck cancer care through 3D medical printing, manufacturing and distribution. We're now able to provide customized immobilization oral devices that have been shown to reduce toxicity and unnecessary complications for patients. With Ricoh as our partner, we focus on what's most important to us — developing innovative patient-centric solutions."
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> — Rajan Patel, CEO of Kallisio

Challenge

- Build a superior, patient-customized oral immobilization device to improve HNC care
- Collaborate with a partner offering advanced 3D medical printing, manufacturing & distribution services
- Deliver a solution that is cost-effective with rapid turn-around

In one study, researchers found that 80% of HNC patients develop radiation-induced complications, such as severe oral mucositis, in the first 3-4 weeks of treatment. However, intraoral stents have been found to reduce severe oral mucositis by 77.6%, which demonstrates the immense need. There were already devices in the market that tried to address these issues, but they proved to be ill-fitting, ineffective, complicated and cumbersome to use.

Kallisio found a better way to deliver improved patient care by developing Stentra™, an immobilization oral stent exclusively licensed from The University of Texas MD Anderson Cancer Center. However, they needed a partner with expertise in 3D printing, manufacturing and distribution to bring their device to market. At a radiation oncology conference, Kallisio met Ricoh.

Solutions

- 100% case-customized Stentra oral immobilization device for better patient care
- Ability to be manufactured on-site at the Point-of-Care
- Rapid, scalable production using Ricoh's compact 3D printing studio; advanced post-processing innovations

Cancer care is unfortunately widespread, with head and neck cancer therapy estimated at $5.46 billion, and $1.58 billion of incremental cost to treat side effects such as radiation-induced oral mucositis.

The American Cancer Society's most recent estimates for new oral cavity and oropharyngeal cancer cases in the United States alone reach 58,000, demonstrating a massive potential to improve therapy for hundreds of thousands of patients.

"The partnership between Kallisio and Ricoh has been pivotal in commercializing Stentra, allowing us to bring this innovative, patient-specific solution to a broader audience. By working together, we are not only improving treatment but also democratizing access to advanced care for more head and neck cancer patients," Gary Turner, Sr. Director, Additive Manufacturing at Ricoh.

Together, Ricoh and Kallisio are exploring the potential for Point-of-Care studios at select customer sites with radiation oncology programs. Point-of-Care studios are specialized setups within healthcare facilities that can enable onsite production of the oral stent. This localized manufacturing reduces lead times, allows rapid additional customization for specific patient needs, creates job opportunities within the hospital's community, and enables the hospital to act as a device production hub for other hospitals in the region. The studios integrate seamlessly with hospital workflows, supported by Ricoh's Clinical Applications Specialists and on-site Clinical Engineers. Additionally, Stentra can be manufactured in Ricoh's growing presence of Point-of-Care medical 3D printing facilities across the country.

Results

- Highly customized, patient-specific oral stents with tongue deviation designed for optimal fit; improved care
- Streamlined workflow, enabling delivery from scan to stent in as little as 3 days, requiring just one patient visit
- Eligible for reimbursement under existing CPT codes

The partnership with Ricoh helped expedite the final stages of design, production scaling, and market readiness, which took about six months. Today, radiation oncologists can order Stentra through RICOH 3D for Healthcare's Clinical Applications team, paving the way for medical professionals to use cutting-edge tools, improving care for head and neck cancer patients undergoing radiation treatment. Kallisio anticipates rapid growth and is well-positioned to scale production through its partnership with Ricoh, making Stentra readily available to radiation oncology teams across the United States.

Learn more about how Ricoh's 3D for Healthcare services can help streamline processes and develop innovative solutions to complex challenges.

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