Klarity® Prints™

POWERED BY 3D SYSTEMS

Technology Guide

Personalize radiotherapy with VSP® Bolus

3D SYSTEMS®

Additive Manufacturing Solutions
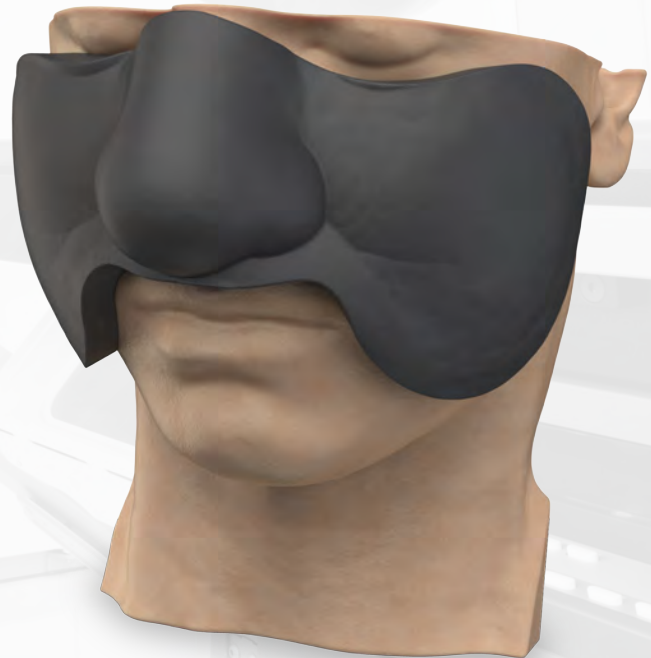
VSP® Bolus is an FDA cleared patient-specific solution to help optimize radiotherapy targeting. With a complete workflow from design to delivery, Klarity Prints™ Bolus makes personalization easy. How do we do it? This technology guide goes behind the scenes to explore the material, software, 3D printer and process used to design and deliver a bolus that conforms to each patient and to the contours of broad range of anatomies.

Background

Radiotherapy is a treatment modality used in approximately half of all cancer cases to target and kill cancerous cells.[1,2] Many treatment options require the use of a bolus which attenuates the radiation beam to alter the dose at desired tissue depths.

A common clinical solution is a slab bolus, which is placed on the patient's targeted treatment anatomy to act as an extra layer of tissue. However, patient-specific boluses have shown in improvement in patient conformality and have demonstrated improved radiotherapy plan dose conformity.[3] To that end, 3D Systems developed Klarity Prints™ Bolus to offer an FDA-cleared, elastomeric, 3D-printed and patient-specific solution for radiation oncology.

The Klarity Prints™ Bolus solution is based on the digital workflow used in our industry-leading VSP(R) surgical planning solutions to personalize devices for orthopedic and orthognathic surgeons. We partner with device manufacturers, hospitals and clinical teams to innovate custom solutions, and over the past two decades, 3D Systems has delivered devices for over 150,000 patient-specific cases.

3D printing technologies

The Klarity Prints™ Bolus workflow begins with the submission of patient CT data through a physician-facing portal. Using D2P® (DICOM-to-print) software, the patient's skin tissue is segmented into a 3D model. Biomedical engineers use information from the radiotherapy treatment plan and the patient 3D model to create a uniform thickness bolus using Geomagic® Freeform®, a volumetric modeling software tool specializing in non-parametric patient contours. The patient-specific bolus is optimized for 3D printing in 3D Sprint®, 3D Systems' build preparation software.

Ordering and project progression tracking is managed via our Klarity Prints™ Bolus planning portal. This secure, cloud-based application provides visibility into our design, production and delivery workflow, and by integrating the software above, it streamlines and expedites the development process.
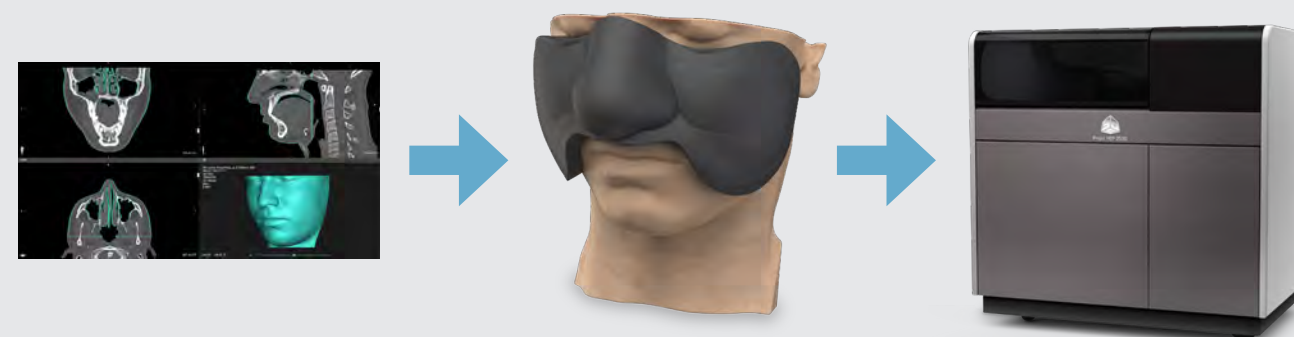
Klarity Prints™ Bolus is printed on the ProJet® MJP 2500 Plus, a multi-jet printer with a large build platform to accommodate a broad range of anatomical features. This printer delivers high accuracy and repeatability and quick turnaround. The MJP platforms that print Klarity Prints™ Bolus are operated within 3D Systems' ISO 13485 certified and FDA registered manufacturing facilities.

About Klarity

Klarity is at the forefront of radiotherapy technology and innovation. Klarity's superior products and personalized service have established the company as a worldwide leader, providing clinics with improved solutions for patient positioning, treatment planning, brachytherapy, and custom devices.

Klarity is proud to partner with 3D Systems to provide printed biocompatible bolus products to advance personalized care and improve the patient experience.

About 3D Systems

When it comes to personalizing patient outcomes, you can count on our 3D printing technologies and industry-leading expertise. Over the past 30 years, 3D Systems has manufactured over 2 million medical devices, delivered more than 150,000 patient-matched cases, and supported the clearance of 100+ FDA and CE-marked devices.

Complete design to delivery workflow

3D Systems leveraged expertise in patient-specific device manufacturing workflows, materials, 3D printing processes and medical regulatory requirements to develop a physician-centric service.

The Klarity Prints™ Bolus service model enables clinicians to use an FDA-cleared patient-specific bolus for their oncology cases with limited device design burden. There is no need to purchase printer platforms or software to order and use personalized bolus.
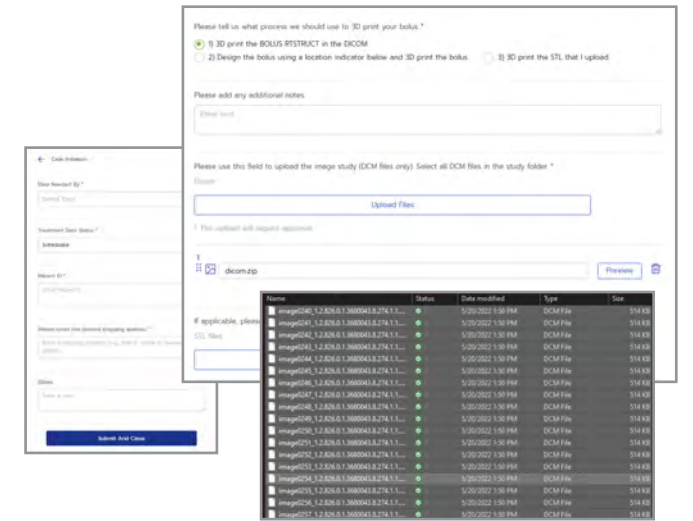
How much time does the process take?

Once you submit an order for Klarity Prints™ Bolus, designing and printing each patient-specific bolus is quick. Choose from two options:

Physical characteristics of the 3D printed material

The VisiJet® M2E-BK70 was selected for Klarity Prints™ Bolus for its elastomeric and biocompatible properties, which include:

Density: VisiJet M2E-BK70 has a physical density that is close to water at 1.15 g/cm³

Durometer: The material has a Shore A hardness of 70. It is pliable enough to flex around complex tissues, but durable to maintain fit on the patient.

Biocompatibility: The biocompatibility evaluation for the Klarity Prints™ Bolus was conducted in accordance with International ISO Standard 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Simulated use testing: A clinically relevant validation study was performed, where Klarity Prints™ Bolus was shown to conform to the patient anatomy and deliver the intended superficial dose.

OPTION 1: Standard Manufacturing					
DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5

Submit on Day 0 ———————————————————— Bolus is shipped on Day 5

OPTION 2: Expedited Manufacturing					
DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5

Submit on Day 0 ———————————— Bolus is shipped on Day 3

Process for ordering and clinical use

There are just two simple steps for ordering and using Klarity Prints™ Bolus. You can use our intuitive portal to order and track delivery.
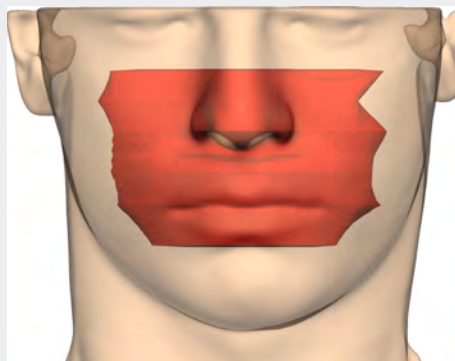
STEP 1: Submission

If you need 3D Systems to design and 3D print your patient-specific bolus…

Submit patient CT images with an indication of the treatment site, desired bolus thickness and any margin or wrap notes. Please use one of the following treatment identifiers for reference:
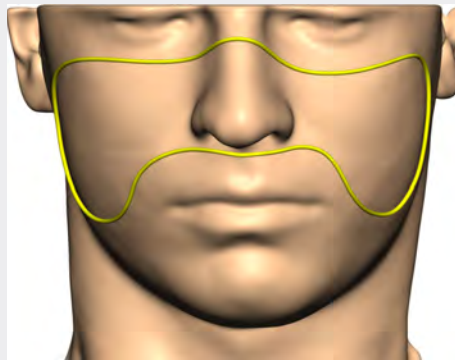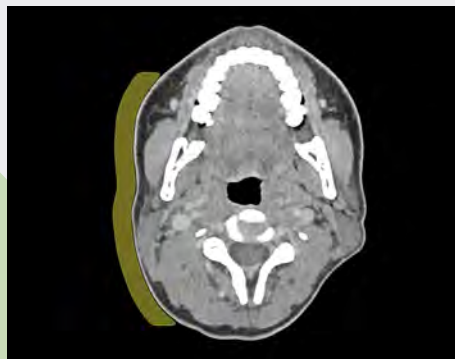

CT SPOT® with physical indicators used during the patient scan

PTV or treatment volume(s) to design the bolus over

If you already designed a patient-specific bolus and need 3D Systems to 3D print it…

Submit a RTSTRUCT or an STL file of the bolus you designed indicating the following:

The reference location in the bolus you designed using your treatment planning system.

STEP 2: Clinical approval and simulation

The device is designed for single-patient use as each bolus is patient-specific. Verify that the bolus conforms to patient and verify the treatment plan prior to the first dose with a CT of CBCT scan.

Using Klarity Prints™ Bolus

- Place on the patient for each treatment fraction
- Use to overcome the skin-sparing effect and target the appropriate tissue

Achieve personalization without the hassle

- Improve patient comfort, fit and pliability with our biocompatible elastomeric material
- Reduce potential air gaps for improved treatment
- Eliminate the need for barriers; the material can be applied directly to the skin
- Reuse the device throughout the course of treatment
- Wrap the bolus 360 degrees around the patient anatomy, if needed, enabled by the elastomeric properties of the material

Head and neck, uniform thickness, patient-specific bolus

Large limb, uniform thickness, patient-specific bolus

Start the Conversation.

Reach out to us via casecoordination@3dsystems.com or (720) 643-1001, if you want to:

- Request material samples
- Consult with a 3D Systems expert
- See if this product is available at your institution
- Create an account in our secure upload portal
- Get pricing information

1. Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment: estimating optimal utilization from a review of evidence-based clinical guidelines. Cancer. 2005;104:1129-1137.

2. Begg AC, Stewart FA, Vens C. Strategies to improve radiotherapy with targeted drugs. Nat Rev Cancer. 2011;11:239–253.

3. Dyer BA, Campos DD, Hernandez DD, Wright CL, Perks JR, Lucero SA, Bewley AF, Yamamoto T, Zhu X, Rao SS. Characterization and clinical validation of patient-specific three-dimensional printed tissue-equivalent bolus for radiotherapy of head and neck malignancies involving skin. Phys Med. 2020 Sep;77:138-145. doi: 10.1016/j.ejmp.2020.08.010. Epub 2020 Aug 20. PMID: 32829102.

Get started

Visit 3Dsystems/radiotherapy and schedule a consultation via our contact form.

Indications for Use: The 3D Systems Klarity Prints™ Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. Klarity Prints™ Bolus is generated using input from radiation therapy professionals and medical imaging data to produce a bolus that is specific to the patient being treated. The Klarity Prints™ Bolus product is verified and approved by the radiation therapy professional prior to use on the patient and is intended for patients of all ages receiving radiotherapy treatment. Klarity Prints™ Bolus was evaluated using 6 MV photons but has not been assessed for use with protons, electrons, or at orthovoltage X-rays.

Klarity

600 Industrial Parkway

Heath, OH 43056

Phone 740 788 8107

Fax   740 788 8109

info@klaritymedical.com

www.klaritymedical.com

MM-1269 Rev B

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