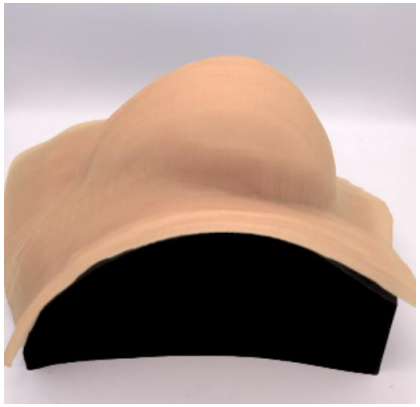
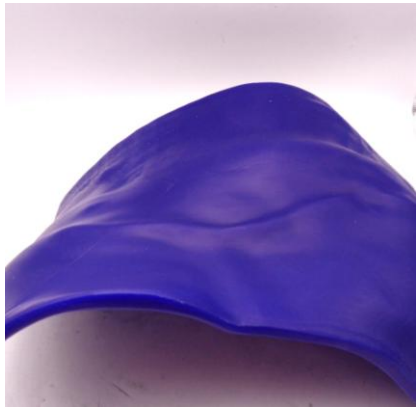






FlexiBol®

STARTER GUIDE


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INTRODUCTION

HISTORY

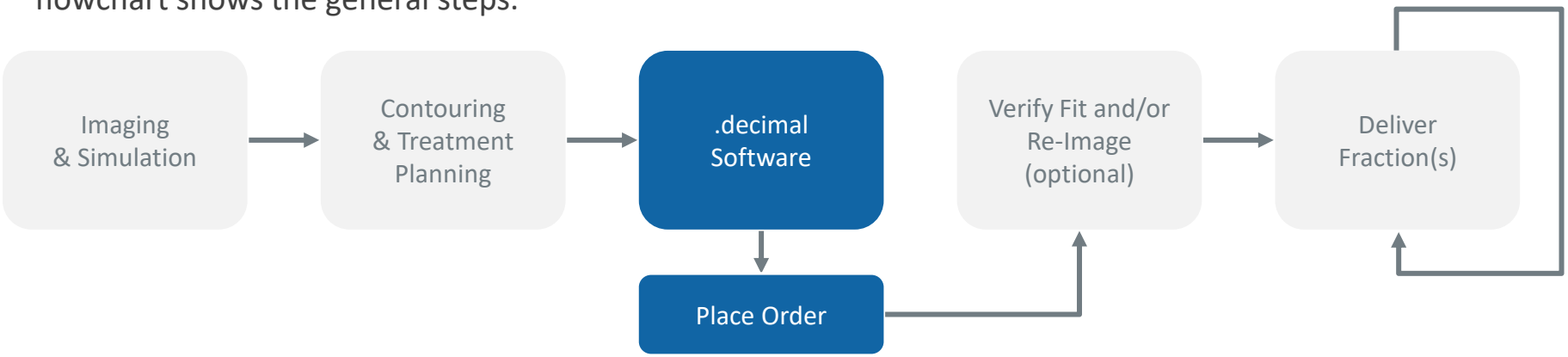
.decimal received FDA clearance for FlexiBol™ in July 2021. We started shipping them for clinical use the same month.

PURPOSE OF THIS DOCUMENT

The purpose of this document is to share some of the valuable insights we have learned, after working with customers across the country and having manufactured and shipped to them many hundreds of FlexiBol devices.

WORKFLOW

Designing and ordering FlexiBol devices fits seamlessly into your workflow. The following high-level flowchart shows the general steps.



IMAGING AND CT SIMULATION

PATIENT POSITION AT INITIAL SIMULATION

As required for modern treatment planning and delivery regardless of bolus, take care to image and simulate the patient in the intended treatment position.

FlexiBol silicone boluses are comfortable and flexible, so it is recommended to try to avoid planning for bolus that will be underneath heavy body parts (e.g., patient's head) as this may cause the bolus to be compressed or bunched under the weight of the patient.

Try adjusting the patient position, if possible, to avoid or at least limit this scenario.

RE-IMAGING AND/OR FIRST FRACTION

After you receive your FlexiBol, you are ready to fit it on the patient.

You can verify the fit during your next meeting with the patient and/or during a second simulation prior to treatment. Alternatively, and after some experience, you may verify the fit at the time of the first fraction. 3D imaging or on-board image guidance (e.g., cone-beam CT) can help verify the fit between the bolus and the patient surface.

COMPRESSION CAPS, SLEEVES AND SOCKS

In many cases, you will find that the use of compression devices helps in holding the bolus in place while maintaining comfort. Please refer to the later section in this document.

Materials and Density

FlexiBol boluses are made of silicone. The physical density is estimated to be 1.03 g/cm^3.

Further experimentation and measurements have independently calculated a relative electron density of approximately 1.025 g/cm^3.*

You should expect CT numbers in the imaged FlexiBol volumes to be higher than expected for this density if using a simple CT-to-electron density curve. The reasons for this are as follows:

- The relationship between electron density and CT numbers is not one-to-one† in that inorganic materials (e.g., high-Z elements) will undergo photoelectric interactions when irradiated with diagnostic x-ray energies, resulting in higher attenuation than materials undergoing just Compton scattering.
- Some inorganic materials are found in the silicone we use for the FlexiBol.
- Also, the anti-fungal additive in the FlexiBol silicone contains trace amounts of high-density metallic ions.

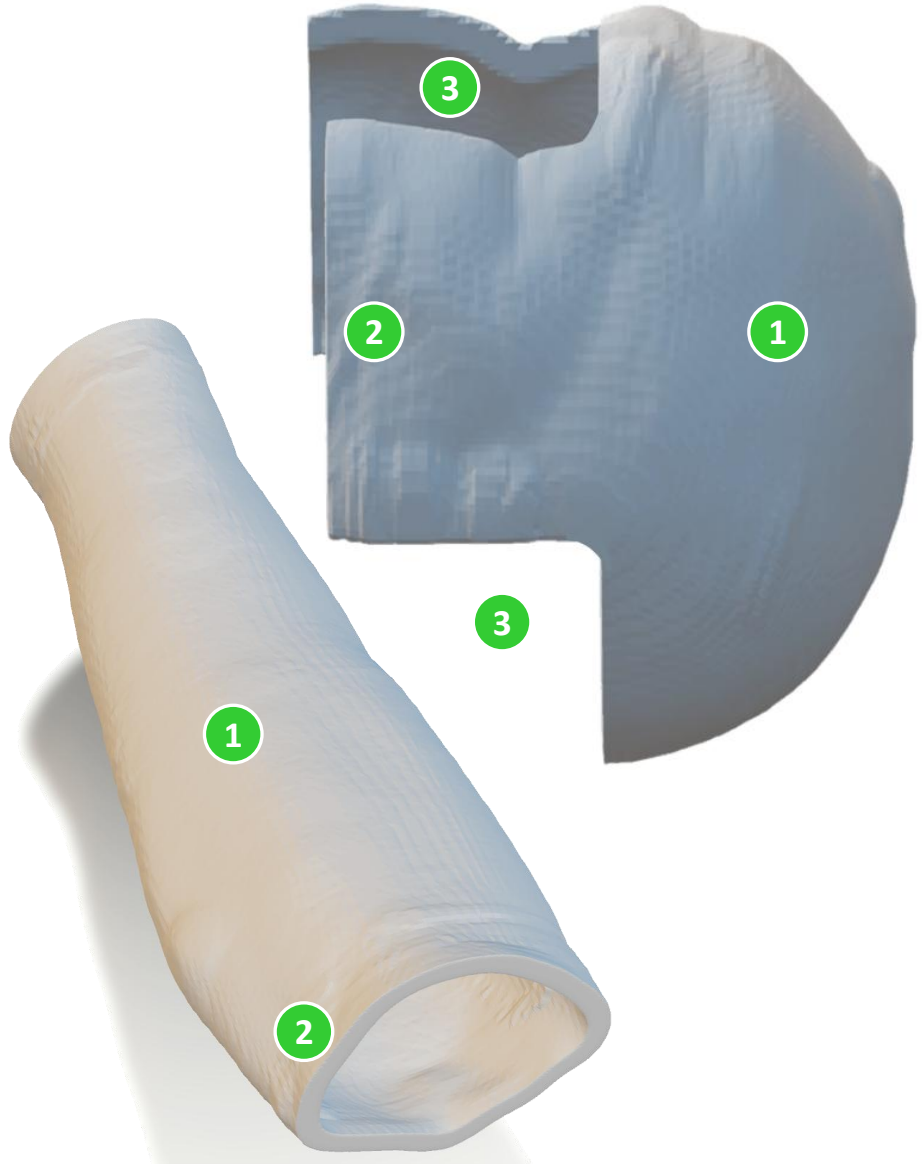
***** More information regarding these tests can be found in our White Paper: FlexiBol Electron Density

† For more information about the lack of direct correlation in CT-density conversions, here is one helpful reference: https://pubmed.ncbi.nlm.nih.gov/33382794/

Bolus Design & TPS Best Practices

GOOD PRACTICES IN YOUR TPS

DO	**1. Create a smooth bolus structure.** Use the planning system's 3D views to confirm smoothness.
DO	**2. Trim the bolus to the treatment area leaving adequate clinical margins.** We recommend a 1-2 cm margin. An excessively large bolus may impact the price and turnaround time.
DO	**3. Avoid complex surfaces (e.g., ears, eyes, and nose) when not in treatment field.** Use generous clearance around the ears especially.
DO	**4. Always review the bolus in 3D view** Viewing the final 3D bolus shape greatly enhances the visibility of many common defects, such as small holes and disjointed pieces.



Bolus Design & TPS Best Practices

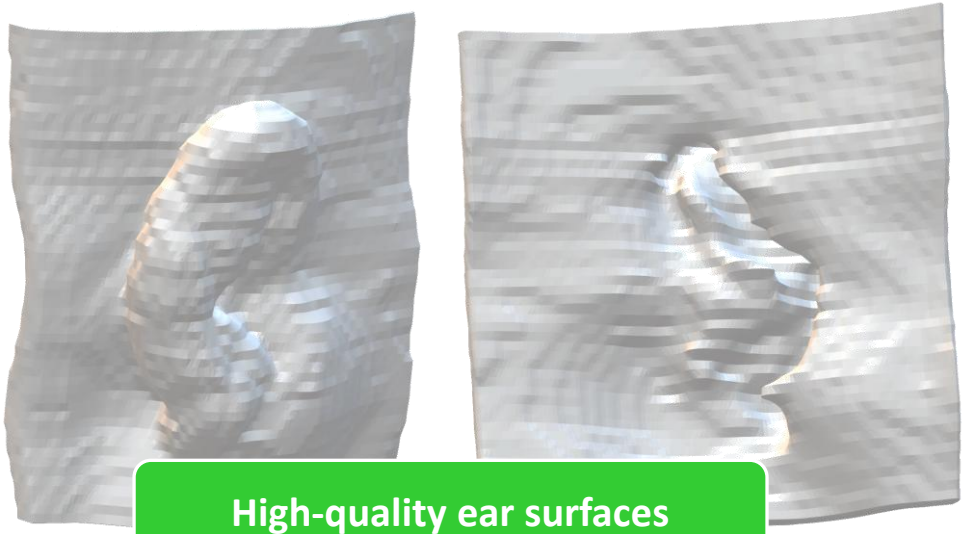
SPECIAL CONSIDERATIONS FOR EARS

FlexiBol is soft and pliable enough to fully encase ears. However, the fit of the bolus is highly dependent on the quality of the contoured structures that contain or abut an ear (e.g., patient external structure and bolus structure).

Since ear shapes can change rapidly in the axial direction, 2D contours may look reasonable on axial CT slices but have holes or non-uniform areas when viewed in 3D.

We highly recommend performing a careful review using the 3D view feature of your TPS ***before*** placing your order for a bolus covering an ear.

Also, be sure the ear is in the treatment position during the initial CT sim, including placement of any plugs or other immobilization items that will be present during treatment.



High-quality ear surfaces



Problematic ear surface

Accessories: Caps, Sleeves, and Socks

IMMOBILIZING THE FLEXIBOL ON THE PATIENT SURFACE

FlexiBols are made from flexible silicone material, and in some shapes and orientations on the patient, gravity can cause the bolus to “sag” or hang away from the skin.

Due to its soft, stretchy nature of our FlexiBol material, silicone-based tape is the ideal adhesive for securing these boluses.

Velcro straps, Coban wraps, and other materials that can cling to themselves can also work well to position the FlexiBol.

For boluses used on the head, elastic wig caps are included in your shipment are essential positioning aids. They are designed to be stretched over the bolus to secure it in place, prevent gravity-induced sagging, and reduce material bunching underneath immobilization devices (e.g. masks). We recommend keeping the wig cap with the bolus to ensure it does not get lost.

For other treatment sites, pantyhose, and arm sleeves are other alternatives that can be used for positioning the FlexiBol, as they provide uniform pressure over the entire bolus, thereby minimizing “bunching” and sagging.

Recommended Step-by-Step Setup Protocol

1. Position the bolus while the patient is sitting upright
2. Apply the positioning aid over the bolus
3. Confirm fit and transition the patient to the treatment position
4. Secure any immobilization devices, taking care to ensure the bolus remains in close contact with the skin at all times





Verify compatibility for radiotherapy applications before purchase

Bolus Positioning Tips

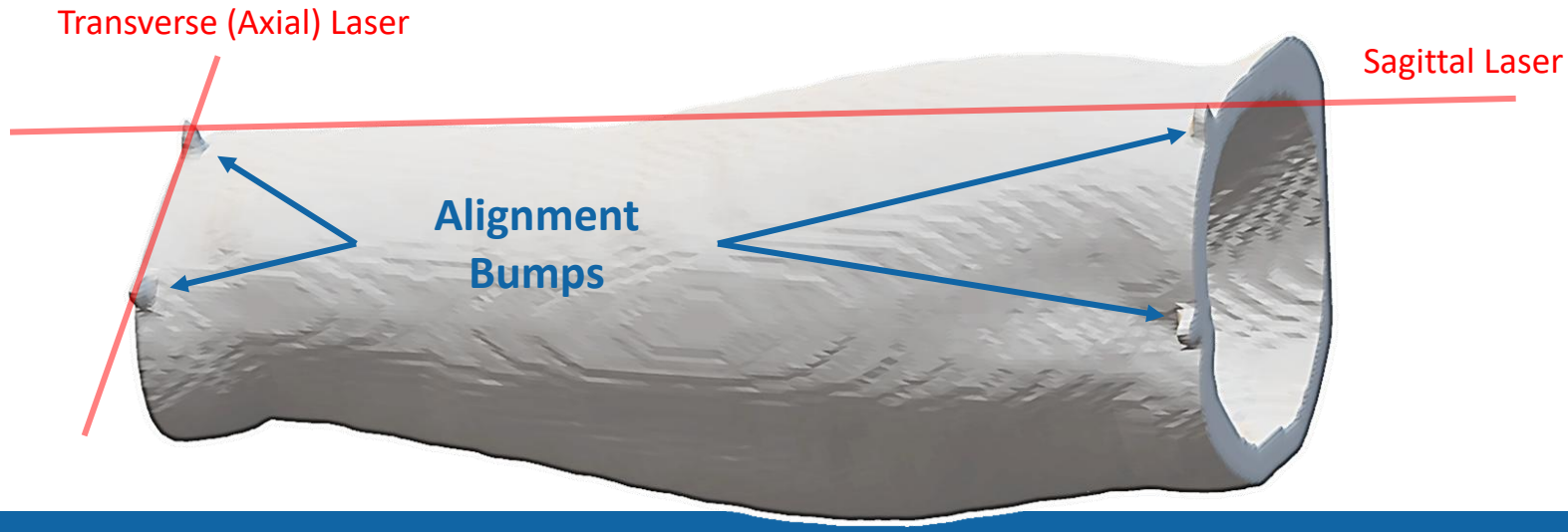
CONVENTIONAL EXTERNAL MARKING IS NOT IDEAL

FlexiBol devices are made from a water resistant, non-porous material, and therefore marking the bolus exterior using ink, stickers, or other methods may not be permanent.

DESIGNING FIDUCIALS INTO THE FLEXIBOL

Some users have reported great success in improving day-to-day bolus alignment by including small “bumps” at the edges of the bolus, which can be aligned using the lasers in the treatment room.

Note that we recommend bumps as opposed to notches, because bumps are more easily modeled in the mold fabrication process.



Turnaround Times

EXPECTED TURNAROUND & DELIVERY

Most FlexiBols will ship FedEx Overnight on *Day 3** after the order is received. Therefore, your FlexiBol should arrive to your clinic on the fourth day after the order is placed.

3:00 PM EST is the cut off to determine the date of receipt of your order.

- For orders received before the cutoff time, *Day 1* is the day the order is received.
- For orders received after the cutoff time, *Day 1* is the following business day.

To illustrate by example,

- An order placed on Monday before 3:00 PM EST will ship Wednesday for a Thursday delivery
- An order placed on Monday after 3:00 PM EST will ship Thursday for a Friday delivery.

*Rush processing is available for an additional fee

PROCESSING OF COMPLEX DESIGNS

Depending on the size and/or complexity of your bolus design, we may need more time to fulfill your FlexiBol order.

Delivery time (and cost) for each special case of a complex FlexiBol cannot be determined until the order has been received and our engineering department has a chance to review the bolus design.

Once the engineering team has reviewed the design, you will receive a call from .decimal Customer Service to communicate an estimated delivery date and cost, both of which will depend on the size and complexity of the structure.

This call from Customer Service should come within half a business day after receipt of the order for the complex device.

TRACK YOUR ORDER

You can check your order status at https://direct.dotdecimal.com using your authorized user account.

Custom Holders and Phantoms

CUSTOM HOLDER

We do offer 3D printed holders in the shape of the patient's anatomy for an additional fee.

These holders are made to model the inside surface of each custom FlexiBol.

These holders have dual use as a QA phantom if you want to image (e.g., with cone-beam CT) to verify the custom bolus shape without the patient present.



