

Listing of patient-matched 3D-printed radiotherapy bolus on the Australian Register of Therapeutic Goods

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Introduction

3D-printed radiotherapy bolus meets the Australian Therapeutic Goods Administration (TGA) definition of a patient-matched medical device and is therefore subject to regulatory provisions. Specifically, a manufacturer must have the device listed on the Australian Register of Therapeutic Goods (ARTG) as a class I non-measuring, non-sterile device before it can be supplied (i.e. used clinically). This requires a statement or demonstration of compliance with Essential Principles, which define the requirements for safety and performance, the satisfaction of which is summarised for bolus devices.

Hazard and risk assessment

A risk assessment was performed by a medical physicist, and peer reviewed by an engineer, radiation therapist and physics director. Potential hazard categories were taken from the essential principles checklist, and where potential failure modes existed, controls to minimise risk were conceived and implemented (e.g. quality control tests, instructions for use, technical file documentation).

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Potential Hazard (Source of Harm) Design (Intention - Design)	Potential Failure Mode (Potential Hazard)	Potential Effect of Failure (Impact of Hazard)										
Inadequacy of performance characteristics for the intended use	Yes	Modelling or manufacturing process parameters	Poor conformity to patient topography or incorrect radiological attenuation, resulting in underdosing or overdosing dose delivery	3	3	Perform QC: medical professional review (TR), visual and manual inspection (TI), dimensional checks (TS), density checks (TR), ongoing verification (TS)	3	1	3	Design Summary, PFI	Acceptable	
Inadequacy design parameter: Diffuse	Yes	Insufficient material used for device thickness	Material not used in accordance with procedure, resulting in underdosing or overdosing dose delivery	3	1	Material not used in accordance with procedure, acceptable, appropriate address: Perform QC: visual and manual inspection (TI), dimensional checks (TS), density checks (TR)	3	1	3	Design Summary	Acceptable	
Inadequacy design parameter: Weight	No	Design parameter does not apply to large heavy devices			0				0			Acceptable
Inadequacy design parameter: Surface roughness	Yes	Inadequate post-processing of printed device (e.g. removal of support)	Patient discomfort, poor conformity to patient topography, resulting in underdosing or overdosing dose delivery	1	1	Support structures are removed during post-processing: Perform QC: visual and manual inspection (TI)	1	1	1	Design Summary	Acceptable	
Inadequacy design parameter: Porosity	Yes	Device printing error resulting in underdosing or overdosing dose delivery	Incorrect radiological attenuation, resulting in underdosing or overdosing dose delivery	3	3	Perform QC: visual inspection and manual (TI), density checks (TR)	3	1	3	Design Summary	Acceptable	

Design and manufacturing plan

The technical file for the type of device included a design and a manufacturing plan, informed by ISO 13485. These:

- described the device and how it differed from other solutions (e.g. sheet bolus, wax);
- identified the stakeholders in design and production;
- listed the design and manufacturing requirements (e.g. radiological, geometric, material properties);
- described the design and manufacturing processes (e.g. segmentation, printing, post-processing);
- established the responsibilities of staff members;
- described how the design or manufactured device was verified or validated as meeting the requirements (e.g. quality control tests);
- summarised the instructions for use (e.g. assessment of fit, handling, cleaning, disposal of device).

Conclusion

The supply of in-house manufactured radiotherapy bolus was facilitated with the ARTG listing. The document templates and processes developed for bolus (and other Herston Biofabrication Institute devices) have subsequently been used for the ARTG listing of radiotherapy immobilisation and positioning devices manufactured and supplied at point-of-care.

Case specific documentation

For each patient case, the documentation requirements were specified in the technical file for the type of device. The request, design approval (within contour system), fabrication and quality control was captured within our oncology information system, MOSAIQ. This approach allowed responsibilities to be assigned to specific staff or staff groups, and allowed the planning therapist ultimately responsible for the device to monitor progress.

Task
3D Device Structure Approved
3D STL Exported for Production
3D Print Preparation
3D Print and Post Processing Complete
3D Device Wax/Pb Production
3D Device Visual and Manual Inspection
3D Device Physics QA
3D Device labelled and Packaged
3D Device Delivered
3D Pre-Treatment Fitting Required
3D Device Code Capture

3D Device QA
Physics results record
Bolus / Moulds
Version 1.1, May 2021

Patient ID
Plan name / ID
Device STL file
Device QA date
Physicists

Overall agreement
 Satisfactory
Overall device output is in accordance with the required PDI within 1% of the target value.

Overall agreement
 Satisfactory
Overall device output is in accordance with the required PDI within 0.2% of the target value.

Comments: Some geometric difference on edges, but otherwise very good agreement throughout. 3D printing RT notified of decreased RED.

Physics QA status: Pass Fail

Results attached in MOSAIQ

Patient specific quality assurance require the acquisition of a CT image of the device, which was used for an assessment of relative electron density (by Hounsfield Unit conversion) and geometric agreement with approved model (by Hausdorff distance calculation). This process was automated through in-house developed software. Ongoing maintenance and quality control testing of the printer was implemented within the departmental QATrack+ system database. A consumable inventory system was implemented within our mould room.