

Silicone Bolus

Instructions for Use

Version 1

Important information is enclosed. Do not discard

©2023 Antidote Biomedical Version 1 February 2023

All rights reserved.

All trademarks and registered trademarks are the property of their respective owners.

Contents of package protected by one or more of PCT/AU patents pending and corresponding patents in other jurisdictions. Purchase of this package does not act to grant a use license under these patents in any jurisdiction outside of Australia.

Manufactured by:

Antidote Biomedical 10/1 Bell Street Preston , VIC , 3072 Australia



Website: <u>https://www.antidote.com.au/</u> Customer care: <u>https://www.antidote.com.au/contact/</u>

SILICONE BOLUS

Table of Contents	
1. SYMBOLS AND DEFINITIONS	4
2. SILICONE BOLUS GENERAL DESCRIPTION	5
2.1 Included with Purchase:	6
2.2 Intended Use & Indications	6
2.3 Contraindications	6
2.4 Intended User(s)	7
3. MAINTENANCE, CLEANING, STORAGE AND HANDLING	8
3.1 Maintenance and Cleaning	8
3.2 Disposal, Storage and Handling	
4. TECHNICAL INFORMATION AND SPECIFICATIONS	9
4.1 Biocompatibility	9
4.2 User Environment	9
4.3 Technical Specifications	9
CONTACTING CUSTOMER CARE	10

1. SYMBOLS AND DEFINITIONS

	Caution
SN	Serial Number
LOT	Lot Number
~~	Date of Manufacture
	Manufactured By
Ĵ	Keep Dry
	Consult Instructions for Use
	Temperature Limit
	Storage Humidity Limitation
	Single patient multiple use



2. SILICONE BOLUS GENERAL DESCRIPTION

When it comes to improving the accuracy of radiation therapy, a custom silicone bolus is an obvious choice for clinicians and radiation therapy business managers. Firstly, its similarity in density to human tissue makes it ideal for providing a homogeneous and uniform dose distribution to the tumour. Further, given the bolus maintains its customised shape while having considerable flexibility, it can be reproducibly positioned with minimal air gaps ensuring that the planned dose distributed is consistently delivered.

Moreover, the ease of use of silicone bolus has further benefits to the patient and treating department. It is easy to mould and conform to the tumour's shape, making it a versatile and user-friendly option for radiation therapists while improving patient comfort compared to traditional bolus. Additionally, it significantly reduces set-up time due to its soft, pliable nature, making it an all-around very cost-effective option.

Silicone bolus has a similar density to human tissue, specifically 1.09 ± 0.01 , while the customised shape results in minimal bolus to skin air gaps. This is why a more uniform dose distribution is delivered to the tumour at each treatment fraction.

Being highly flexible, silicone bolus are easy to apply and readily conform to the changing contours of the patient throughout their treatment. Given these points they are a versatile and user-friendly option for radiation therapists and patients alike.

Bolus is used in radiation therapy where a patient requires full prescription dose on the skin surface. The bolus acts as a tissue equivalent material, placed on the patient skin to account for the build-up region of the treatment beam.

2.1 Included with Purchase:

- Patient custom-made silicon bolus
- Instructions for Use Manual

2.2 Intended Use & Indications

Silicone bolus has a similar density to human tissue, specifically 1.09 ± 0.01 , while the customized shape results in minimal bolus to skin air gaps.

Bolus is used in radiation therapy where a patient requires full prescription dose on the skin surface. The bolus acts as a tissue equivalent material, placed on the patient skin to account for the build-up region of the treatment beam.



Radiation Therapists are responsible for following the IFU and appropriate Radiation Therapy Workflows. Suppose a staff member identifies an error in a procedure. In that case, they are responsible for communicating the error to their appropriate QA Manager and, or Treatment Leader and addressing any potential impact that it may have before proceeding.

2.3 Contraindications

There are no known contraindications for the Silicon Bolus.

2.4 Intended User(s)

All intended users will have read the Instruction for Use Manual to gain competent knowledge of the device, its intended use, and settings.

Silicone Bolus is only used by suitably qualified professional users such as Radiation Oncologists, Medical Physicists, and Radiation Therapists (Pre-treatment & Treatment). Silicone bolus is only intended to be utilised in radiation therapy, where a patient requires a total prescription dose on or near the skin surface. The silicone bolus acts as a tissue-equivalent material placed on the patient skin to account for the build-up region of the treatment beam.

Patients

- 3D bolus is suitable for all indications where skin surface (e.g., skin target volumes) requires the total prescription dose.
- Each Silicone Bolus is patient-specific and identified with a unique identification which is required to be checked before use

Practitioners

- Certified medical practitioners (Radiation Therapists)
- Radiation Oncologists
- Medical Physicists

3. MAINTENANCE, CLEANING, STORAGE AND HANDLING

3.1 Maintenance and Cleaning

Store in cool, dry, place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Clean using soap and water daily or as needed.

Approved disinfectant chemicals/ingredients include:

- o Iso Propyl Alcohol
- o Sodium diamphoacetate and coco phosphatidyl PG-dimonium chloride are primary surfactants used in baby wipes. These chemicals don't strip the skin of natural oils and also decrease skin irritation potential.

3.2 Disposal, Storage and Handling



There are no user-repairable components in the Silicon Bolus. Please dispose of the device properly under all local and national regulations. The device shall be disposed of as biological. Include bagging for disposal.



Keep dry.



DO NOT cut, trim or alter the Silicone Bolus. If you feel modifications are needed, please contact your healthcare provider.



Keep at room temperature 18°C-25°C.



Keep dry and store indoors from extreme humidity

3.3 Re-use

Store in cool, dry, place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Clean using soap and water daily or as needed.



Single patient multiple use



Keep at room temperature 18°C-25°C.



Keep dry and store indoors from extreme humidity

4. TECHNICAL INFORMATION AND SPECIFICATIONS

4.1 Biocompatibility

Silicone Bolus is biocompatible with human tissue.

4.2 User Environment

Store in cool, dry, place away from heat, direct sunlight, strong oxidizers and any incompatibles. Store in approved containers and protect against physical damage. Clean using soap and water as needed.

TECHNICAL SPECIFICATIONS FOR SILICONE BOLUS		
Model	Silicone Bolus 2.0	
Storage Conditions	18°C-25°C 30%-60%RH	
Operational Conditions	18°C-25°C 30%-60%RH	
Minimum Expected Service Life	12 Months	
Skin Reactivity	Non-Irritant as per the requirements of OECD TG 439, in	
	accordance with the EU classification R38 and GHS category 2	
	requirements: Tests for irritation and skin sensitization.	

4.3 Technical Specifications

CONTACTING CUSTOMER CARE

If you have any additional questions, concerns, require assistance setting up and maintaining your device or have encountered an unexpected operation or event, please contact Antidote Biomedical at:

Antidote Biomedical 10/1 Bell Street Preston , VIC , 3072 Australia

Website: <u>https://www.antidote.com.au/</u> Customer care: <u>https://www.antidote.com.au/contact/</u>