GrayDuck Stents[™] and GrayDuck Dart[™] Oral Positioning Devices



TECHNICAL DATA SHEET

PRODUCT NAMES	GrayDuck Stent and GrayDuck Dart
PRODUCT NUMBERS	GDS001 GrayDuck Stent, medium size GDS002 GrayDuck Stent, small size GDS003 GrayDuck Dart
GENERAL DESCRIPTION	GrayDuck Stent and GrayDuck Dart are currently the only custom-fitted bite block systems that can position the tongue in one of several positions; laterally (left or right), depressing (downward) or a combination thereof.
INDICATIONS FOR USE	The GrayDuck Stent and GrayDuck Dart are intended to be used by or under the direction of a licensed physician for repeat positioning and immobilization of a patient's tongue and jaw while undergoing or receiving a course of external beam radiation therapy for treatment of cancer and other diseases.
MR SAFE	Yes
INTEGRATION	The products may be used with many types of thermoplastic masks.
FDA CLEARANCE	Yes
CE MARKED (EU DOC)	Yes
OTHER COUNTRY REGISTRATIONS	Available upon request.
COUNTRY OF MANUFACTURE	USA

PACKAGING

UNIT PACK	Each	
UNITS / BOX	Four	
SHELF LIFE	n/a	
WARRANTY	See website for Product Warranty Statement	
STERILIZATION	Not sterile	

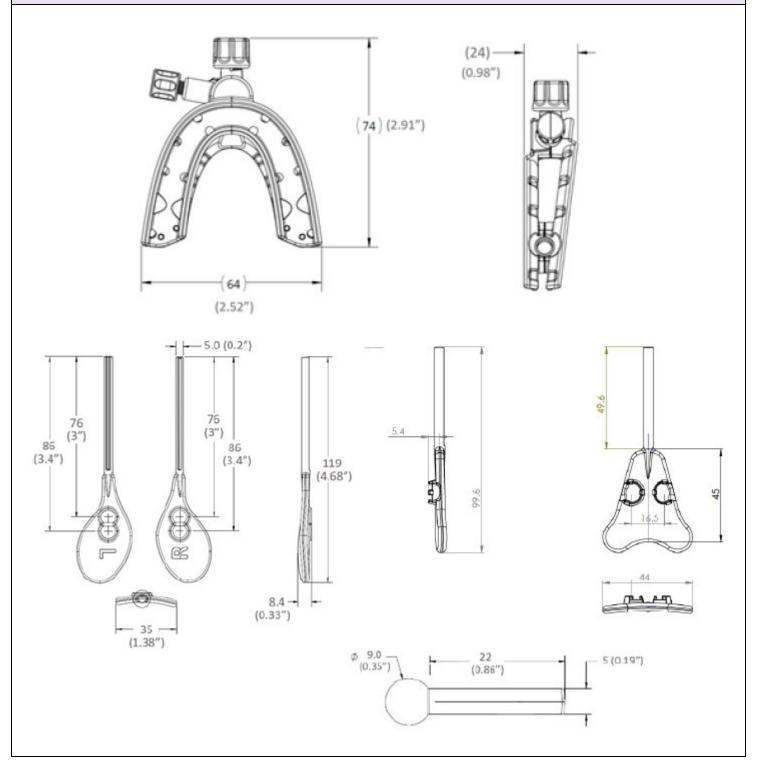
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COMPONENT	GDS003 GrayDuck Dart				
PRIMARY MATERIALS	Polycarbonate. Ethylene Vinyl Acetate				
WEIGHT (APPROX)	1.4 oz (40 g)				
DIMENSIONS (MM)	2.06" x 1.87" x 1.87" (5.2 cm x 4.7 cm x 4.7 cm)				
	LOCATION		PROTON WATER EQUIVALENCY R80		
DOSIMETRIC PROPERTIES	Middle of the tongue depressor		0.44 cm		
	Performance Specifications are for reference only, values may vary based on setup and equipment.				
TECHNICAL DRAWING	G - GDS003				
Spacer				All units in inches	
Stent insert (bite ma	terial)	4.155		.119	
		4.243		1.319	



COMPONENT	GDS001 GrayDuck Stent, medium size			
PRIMARY MATERIALS	Polycarbonate. Ethylene Vinyl Acetate			
WEIGHT (APPROX)	2 oz (56 g)			
DIMENSIONS (MM)	2.91" x 2.52" x 0.98" (7.3 cm x 6.5 cm x 2.5 cm)			
DOSIMETRIC PROPERTIES	LOCATION	PROTON WATER EQUIVALENCY R80		
	Middle of the tongue depressor	0.44 cm		
	Performance Specifications are for reference only, values may vary based on setup and equipment.			



TECHNICAL DRAWING - GDS001

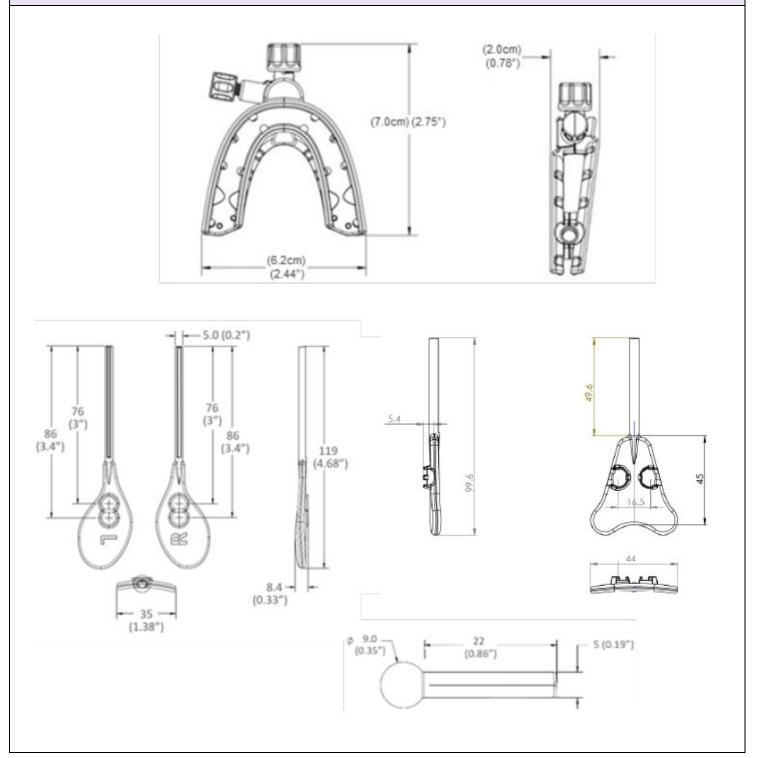


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COMPONENT	GDS002 GrayDuck Stent, small size			
PRIMARY MATERIALS	Polycarbonate. Ethylene Vinyl Acetate			
WEIGHT (APPROX)	1.8 oz (52 g)			
DIMENSIONS (MM)	2.75" x 2.4" x 0.78" (7.0 cm x 6.2 cm x 2.0 cm)			
DOSIMETRIC PROPERTIES	LOCATION	PROTON WATER EQUIVALENCY R80		
	Middle of the tongue depressor	0.44 cm		
	Performance Specifications are for reference only, values may vary based on setup and equipment.			



TECHNICAL DRAWING - GDS002



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COMPONENT	GDS003 GrayDuck Dart				
PRIMARY MATERIALS	Polycarbonate. Ethylene Vinyl Acetate				
WEIGHT (APPROX)	1.4 oz (40 g)				
DIMENSIONS (MM)	2.06" x 1.87" x 1.87" (5.2 cm x 4.7 cm x 4.7 cm)				
	LOCATION		PROTON WATER EQUIVALENCY R80		
DOSIMETRIC PROPERTIES	Middle of the tongue depressor		0.44 cm		
	Performance Specifications are for reference only, values may vary based on setup and equipment.				
TECHNICAL DRAWING	G - GDS003				
Spacer				All units in inches	
Stent insert (bite ma	terial)	4.155		.119	
		4.243		1.319	

