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

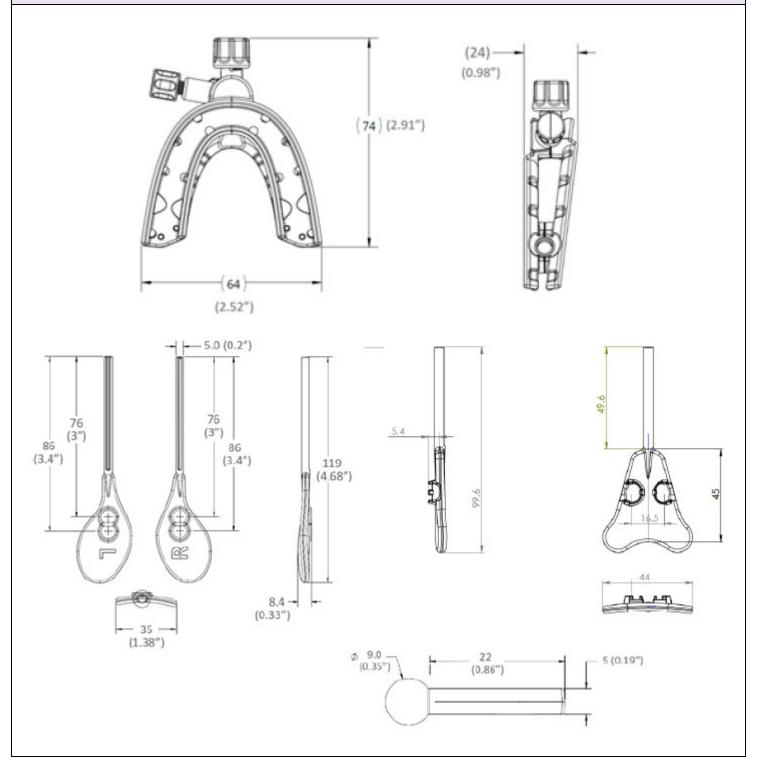
| UNIT PACK | Each | |
|---------------|--|--|
| UNITS / BOX | Four | |
| SHELF LIFE | n/a | |
| WARRANTY | See website for Product Warranty Statement | |
| STERILIZATION | Not sterile | |

TECHNICAL DETAILS

| 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) | | | |
| | 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 - GDS001



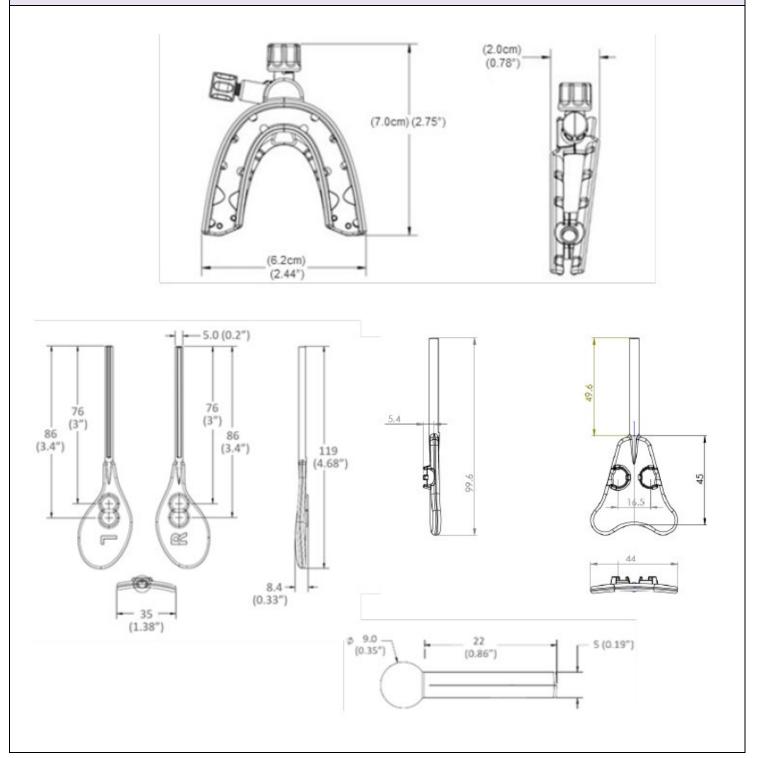
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TECHNICAL DETAILS

| 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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TECHNICAL DETAILS

| | 1 | | | 1 | | |
|--------------------------|--|-------|------------------------------|---------------------|--|--|
| 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 | | |

