

GrayDuck Stents™

CIVCO Technical Data Sheet



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|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Product Name | GrayDuck Stents | |
| Product Number | GDS001, medium size | GDS002, small size |
| General Description | GrayDuck Stents, for oral positioning and immobilization of the tongue, are currently the only custom-fitted bite block system that can position the tongue in one of several positions. | |
| Indications for use | The GrayDuck Stent is 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. | |
| MRI Compatible | Pending | |
| Integration | Compatible with all CIVCO thermoplastic types | |
| FDA Clearance | Yes | |
| CE Marked (EU DOC) | Yes | |
| Other Country Registrations | Available upon request | |
| Intellectual Property (IP) | US Patent # 9,504,537 and other patents pending | |
| Country of Manufacture | USA | |

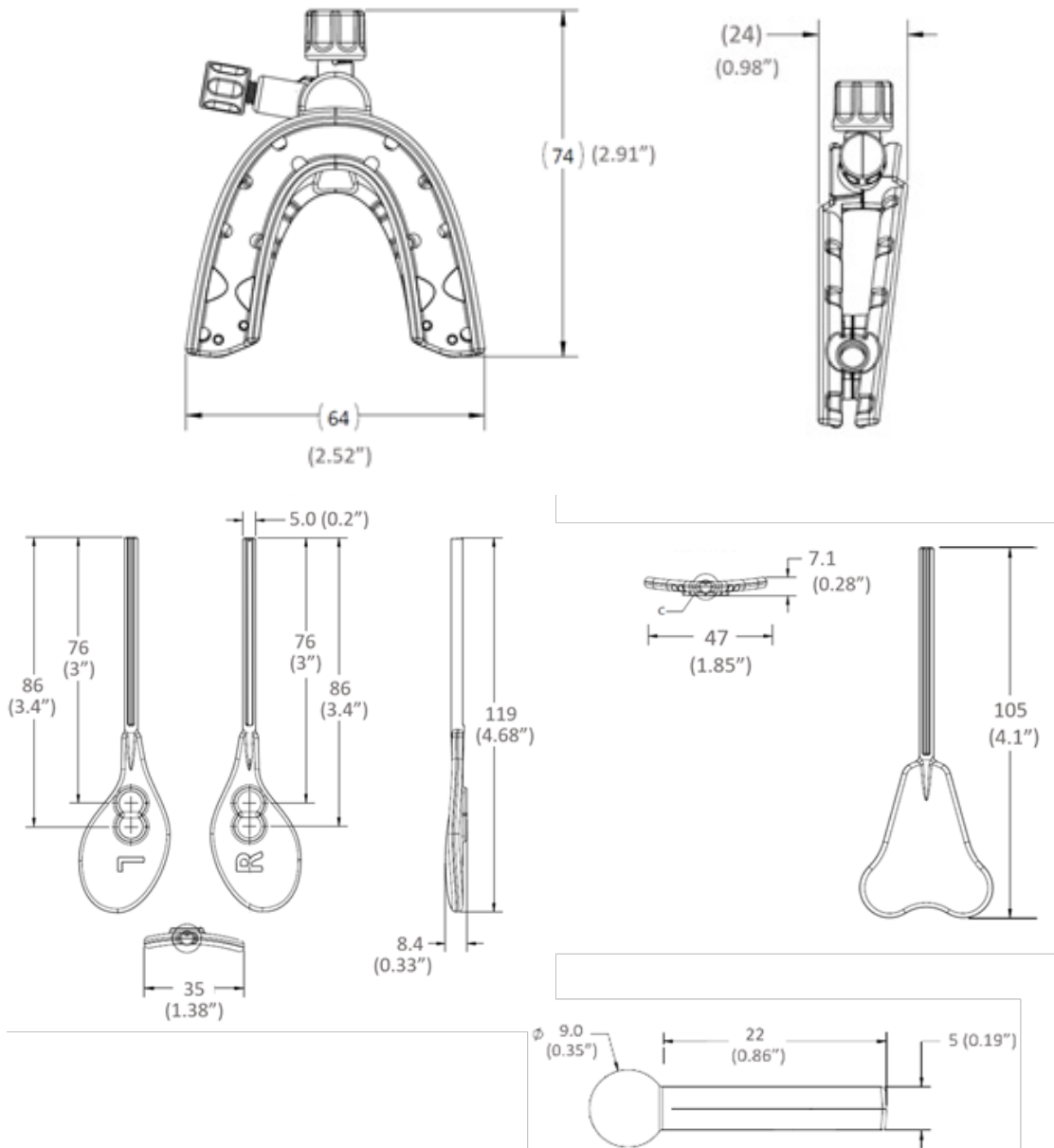
Technical Details

Primary Materials Polycarbonate. Ethylene Vinyl Acetate

Weight (approx) 2 oz (56 g)

Dimensions 2.91" x 2.52" x 0.98" (7.3 cm x 6.5 cm x 2.5 cm)

Technical Drawing (GDS001)



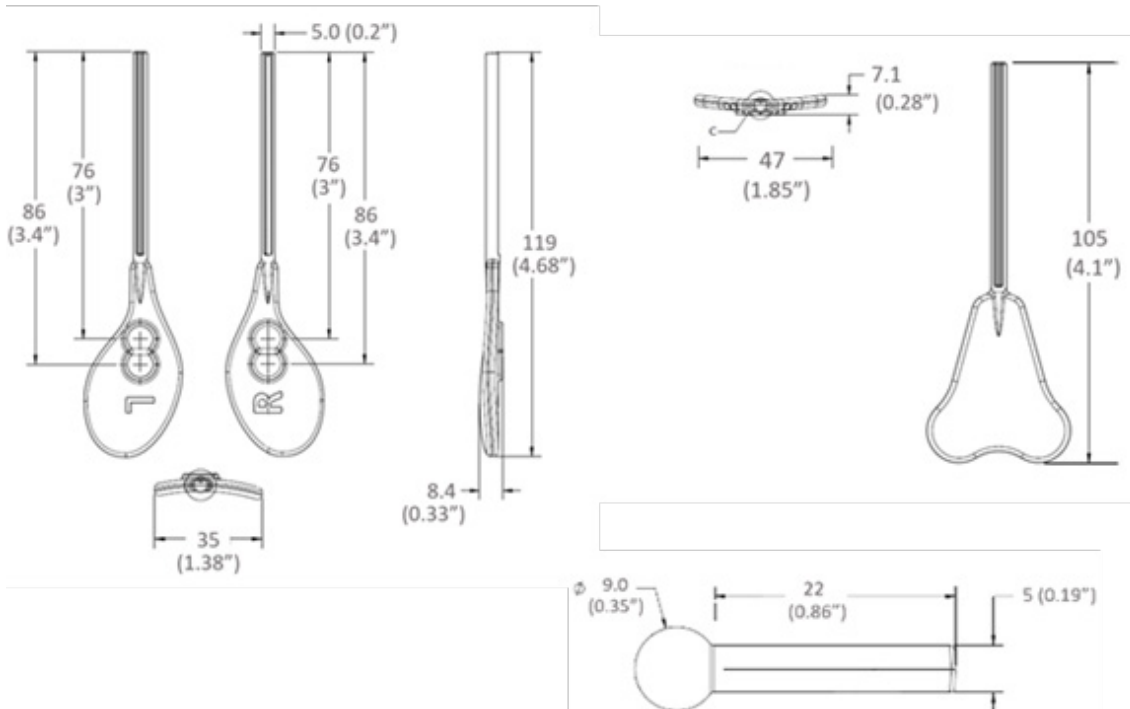
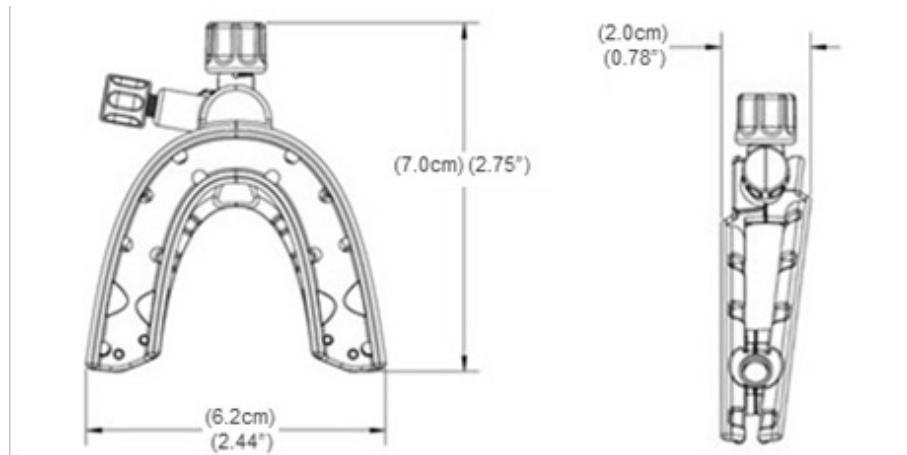
Technical Details

Primary Materials Polycarbonate. Ethylene Vinyl Acetate

Weight (approx) 1.8 oz (52 g)

Dimensions 2.75" x 2.4" x 0.78" (7.0 cm x 6.2 cm x 2.0 cm)

Technical Drawing (GDS002)



Packaging

| | |
|----------------------|------------------------------------------------------------------|
| Unit Pack | Each |
| Units / Box | Four |
| Shelf Life | n/a |
| Warranty | See CIVCO website for Product Warranty Statement |
| Sterilization | Not sterile |

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