

Solstice™ MR SRS Immobilization System

TECH DATA SHEET

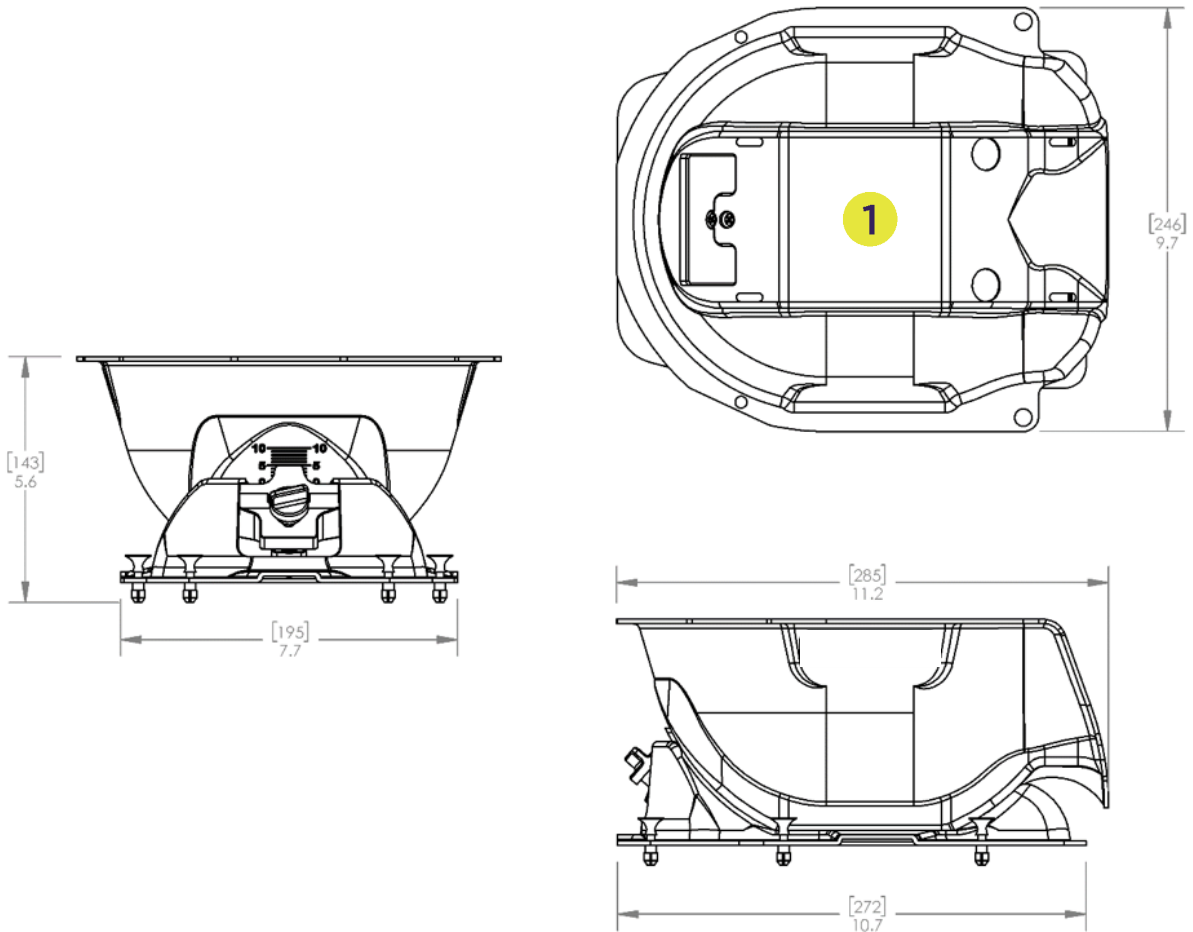


PRODUCT NAME	Solstice MR SRS Immobilization System
PRODUCT NUMBER	CHS03MR Solstice, Glass Fiber MR, Posifix® CHS04MR Solstice, Glass Fiber MR, Type-S™
KITS THAT INCLUDE THIS PRODUCT	CHS03MRSGK, CHS04MRSGK, CHS03MRK, CHS04MRK
GENERAL DESCRIPTION	The Solstice MR system is comprised of a glass fiber head support, customizable cushion and dedicated thermoplastic that create a highly customizable and comfortable head and neck immobilization system. Variable pitch capability provides increased setup options during MR imaging.
INDICATIONS FOR USE	<p>SOLSTICE MR SRS WITH ACCUFORM™</p> <p>The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the head, brain, and neck, including Stereotactic Radiosurgery (SRS), Stereotactic Radiotherapy (SRT), Surface Guided Radiation Therapy (SGRT) and electron, photon, and proton treatments. The device is also used during image acquisition, including Computed Tomography (CT) Magnetic Resonance (MR) Imaging, to support treatment planning.</p> <p>SOLSTICE MR WITH HEADREST</p> <p>The device is indicated to position and/or immobilize adult and pediatric patients undergoing radiation therapy of the head, brain, and neck, including Surface Guided Radiation Therapy (SGRT) and electron, photon, and proton treatments. The device is also used during image acquisition, including Computed Tomography (CT) Magnetic Resonance (MR) Imaging, to support treatment planning.</p>
MR SAFE	Yes
INTEGRATION	For use with Posifix or Type-S acrylic baseplates and/or MR overlays
FDA CLEARANCE	Yes
CE MARKED (EU DOC)	Yes
OTHER COUNTRY REGISTRATIONS	Available upon request
COUNTRY OF MANUFACTURE	USA

TECHNICAL DETAILS

PRODUCT NAME	Solstice, Glass Fiber MR, Posifix			
PRODUCT NUMBER	CHS03MR			
PRIMARY MATERIALS	Bowl: Glass Fiber Base: Kydex-T			
WEIGHT (APPROX)	1.5 lbs (0.68 kg)			
DIMENSIONS (MM)	285 L x 246 W x 131 H (max)			
DOSIMETRIC PROPERTIES	LOCATION	FIELD SIZE	ATTENUATION 6 MV	ATTENUATION 18 MV
	1-Bottom of bowl base	8 cm x 8 cm	1.8%	1.25%
	Performance Specifications are for reference only, values may vary based on setup and equipment.			

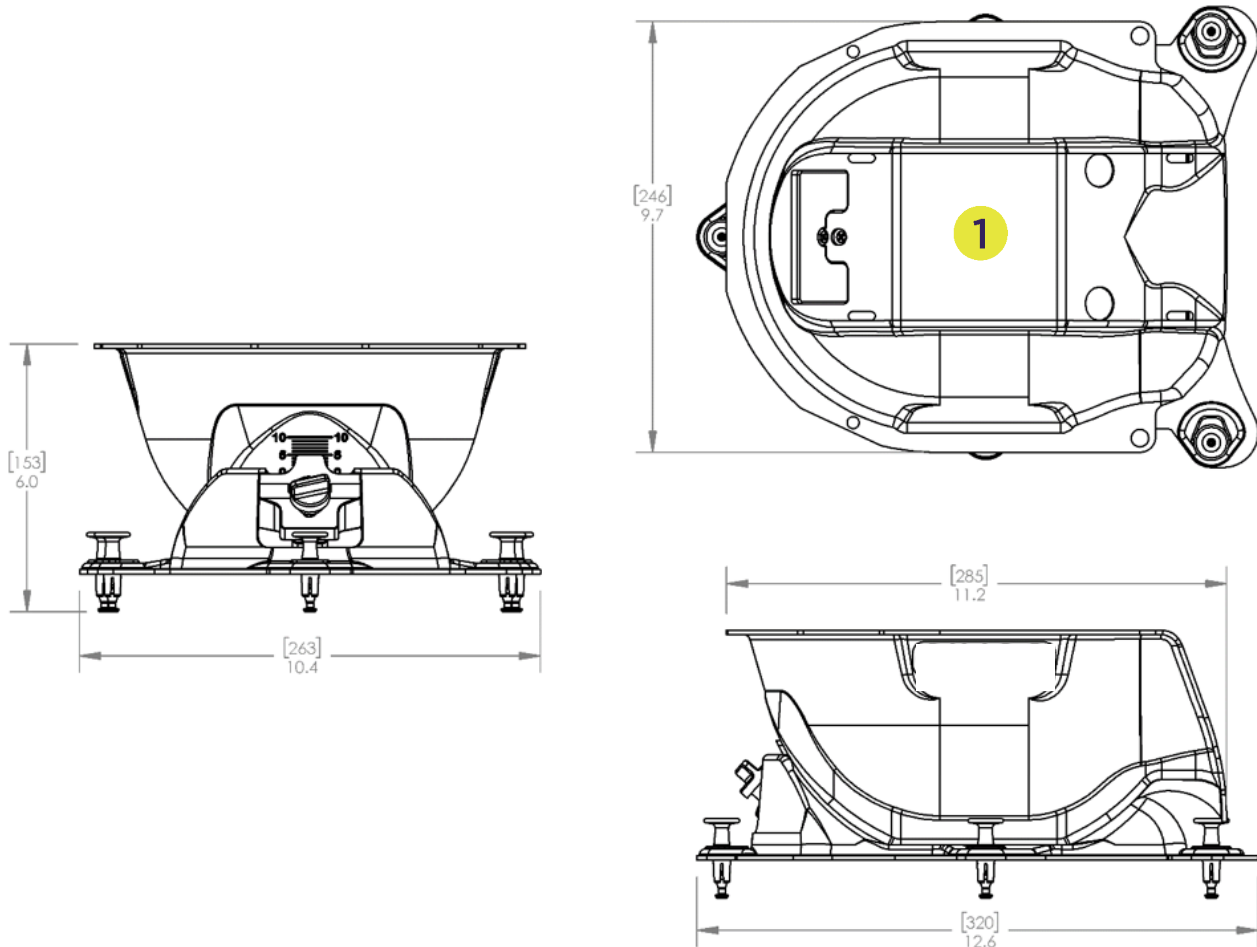
TECHNICAL DRAWING



TECHNICAL DETAILS

PRODUCT NAME	Solstice, Glass Fiber MR, Type-S			
PRODUCT NUMBER	CHS04MR			
PRIMARY MATERIALS	Bowl: Glass Fiber Base: Kydex-T			
WEIGHT (APPROX)	1.5 lbs (0.68 kg)			
DIMENSIONS (MM)	320 L x 263 W x 131 H (max)			
DOSIMETRIC PROPERTIES	LOCATION	FIELD SIZE	ATTENUATION 6 MV	ATTENUATION 18 MV
	1-Bottom of bowl base	8 cm x 8 cm	1.8%	1.25%
	Performance Specifications are for reference only, values may vary based on setup and equipment.			

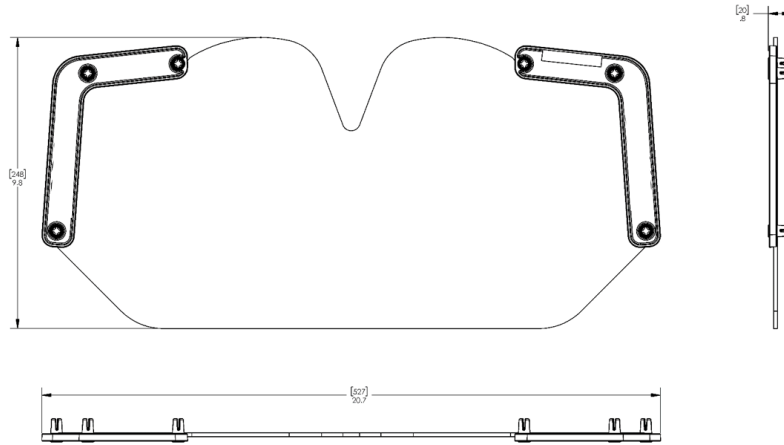
TECHNICAL DRAWING



TECHNICAL DETAILS

PRODUCT NAME	Shoulder Thermoplastic, Aquaplast RT® Solid, Type-S
PRODUCT NUMBER	MTAPSSTS
PRIMARY MATERIALS	Polycaprolactone, Polycarbonate, Delrin
WEIGHT (APPROX)	0.46 kg/ 1.02 lbs
DIMENSIONS (MM)	248 L x 527 W x 20 H

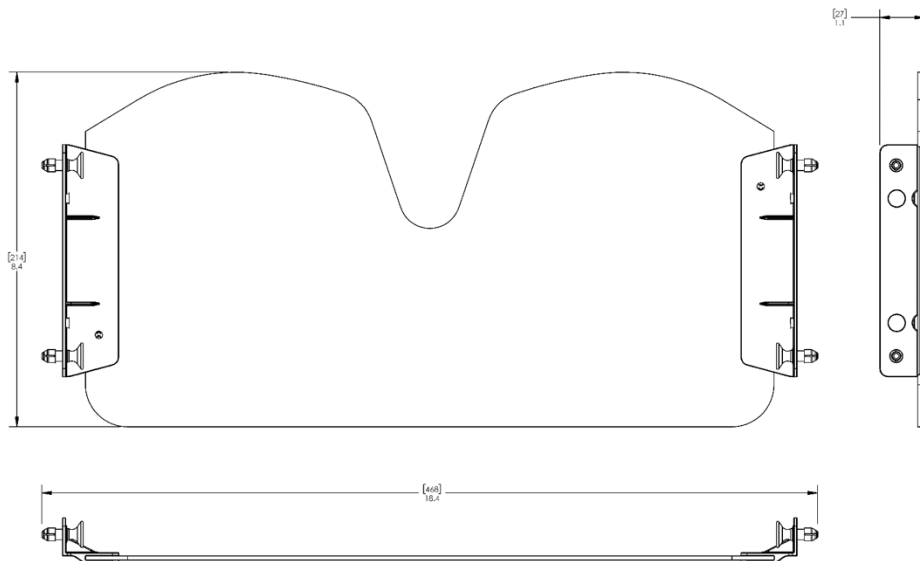
TECHNICAL DRAWING



TECHNICAL DETAILS

PRODUCT NAME	Shoulder Thermoplastic, Aquaplast RT Solid, Posifix
PRODUCT NUMBER	MTAPSSPF
PRIMARY MATERIALS	ABS - Black, Polycaprolactone, Polycarbonate, Nylon
WEIGHT (APPROX)	0.29 kg/ 0.65 lbs
DIMENSIONS (MM)	214 L x 468 W x 27 H

TECHNICAL DRAWING



AQUAPLAST RT IMRT REINFORCED™ STYLE 18

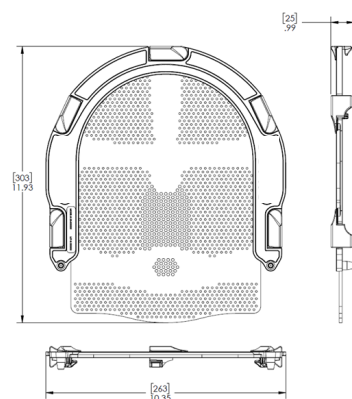
Standard Frame

Head Only, 303 L x 263 W x 25 H (mm)

MTAPCID1832

3.2 mm thickness

0.5 lbs (0.23 kg)



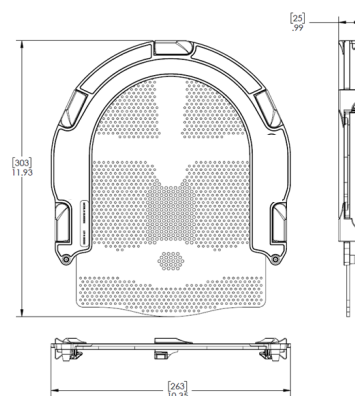
Narrow

Head Only, 303 L x 263 W x 25 H (mm)

MTAPCIN1832

3.2 mm thickness

0.5 lbs (0.23 kg)



AQUAPLAST RT CLEARVISION™

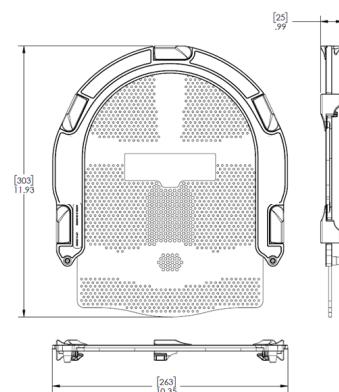
Standard Frame

Head Only, 303 L x 263 W x 25 H (mm)

MTAPCID1832SG

3.2 mm thickness

0.5 lbs (0.23 kg)



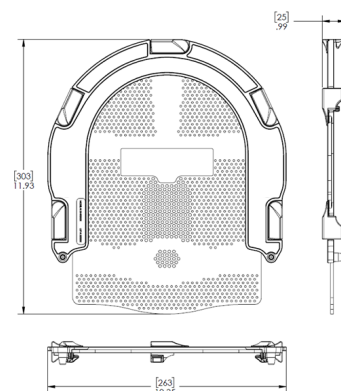
Narrow

Head Only, 303 L x 263 W x 25 H (mm)

MTAPCIN1832SG

3.2 mm thickness

0.5 lbs (0.23 kg)



TECHNICAL DETAILS

3.2 IMRT REINFORCED, CLEARVISION		
PRIMARY MATERIALS	Polycaprolactone, Polycarbonate	
ATTENUATION (UNSTRETCHED MASK)**	SOLID REGIONS: 6MV: 1.03% 18MV: 0.21%	
THICKNESS	3.2 mm (.125)	
PERFORATION (SURFACE)	Varies (IMRT Pattern)	
DENSITY	1.145 g/cm ³	
SURFACE FEELING	Smooth	
COLOR	White	
ODOR	None	
BIOCOMPATIBLE	Yes	
TRANSPARENT WHEN ACTIVATED	Yes	
	WATERBATH	DRY HEAT OVEN*
ACTIVATION TEMPERATURE	75° C / 165° F	75° C / 165° F
ACTIVATION TIME, HEAD-ONLY	5 min	8-11 min
ACTIVATION TIME, SHOULDER	7-9 min	8-11 min
MOLDING TIME (MAXIMUM)* ^A	1 min 30 sec	N/A
HARDENING TIME* ^B	8 min 30 sec	N/A
TIME TO COMPLETION (MINIMUM)* ^C	10 min	N/A

*NOTE: Temperatures and times for dry heat oven may vary depending on model

TEST PROCEDURES USED TO ACQUIRE DATA

Definitions*

- A Molding Time= the time frame available from when the mask is removed from the waterbath to the time that the mask can no longer be molded or formed.
- B Hardening Time= the time between the molding and completion time where the mask should be cooling and hardening on its own without being manipulated or molded.
- C Time to Completion= the total time from when the mask is taken out of the waterbath or dry heat oven to when the mask can be removed from the patient.

Attenuation Test Conditions**

- A 100 cm SAD
- B 10 x 10 cm Field Size
- C 6 MV Dmax = 1.5 cm
18 MV Dmax = 3.0 cm

PACKAGING

UNIT PACK	Each
UNITS / BOX	One
SHELF LIFE	n/a
WARRANTY	See CQ Medical website for Product Warranty Statement
STERILIZATION	Non-Sterile
LAUNCH DATE	May 2020

ACCESSORIES

SYSTEM CUSTOMIZATION	<p>Thermoplastic MTAPCID1832 Solstice Thermoplastic, IMRT Reinforced Style 18 MTAPCIN1832 Solstice Thermoplastic, IMRT Reinforced Style 18, Narrow MTAPCID1832SG Solstice Thermoplastic, ClearVision MTAPCIN1832SG Solstice Thermoplastic, ClearVision, Narrow MTAPSSTS Shoulder Thermoplastic, Standard White Solid, Type-S MTAPSSPF Shoulder Thermoplastic, Standard White Solid, Posifix</p> <p>AccuForm Cushions MTACL2035 20 x 35 cm Chamfered MTACL2035HF 20 x 35 cm Chamfered Half Fill</p> <p>Headrests CHS40K Headrest Kit (includes B,C & F), Qty 3 CHS40 Headrest B, Qty 1 CHS41 Headrest C, Qty 1 CHS42 Headrest F, Qty 1</p> <p>Precise Bite™ MTCBPBITE Standard, Qty 5 MTCBPBITES Small, Qty 5 MTCBPBITETD Standard with Tongue Depressor, Qty 5 MTCBPBITETDS Small with Tonue Depressor, Qty 5</p>
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