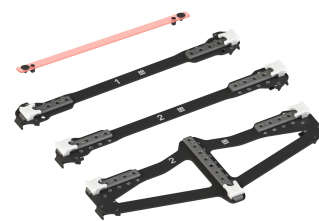


ThermFix™ Immobilization System

TECHNICAL DATA SHEET

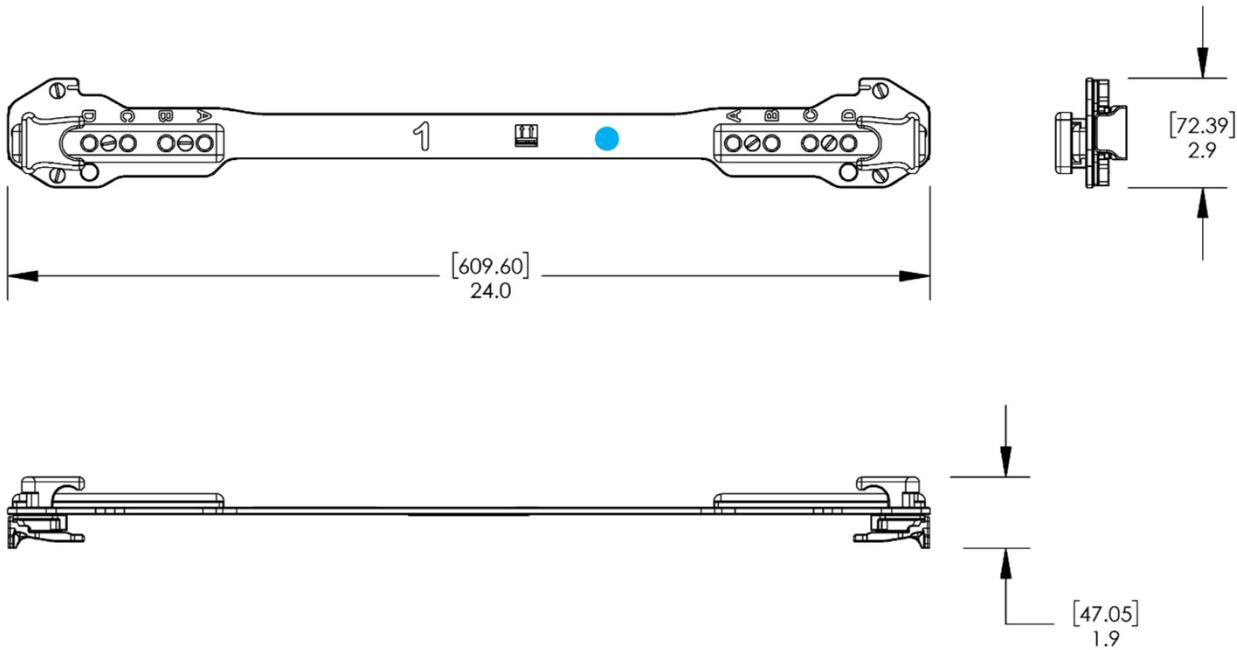


PRODUCT NAME	ThermFix Immobilization System
PRODUCT NUMBER	THRMFX100 Base Package: Includes Superior Bar, Inferior Bar, Spacing Tool THRMFX101 Pelvic Package: Includes Superior Bar, Hip & Pelvic Bar, Spacing Tool THRMFX102 Complete Package: Includes Superior Bar, Inferior Bar, Hip & Pelvic Bar, & Spacing Tool
GENERAL DESCRIPTION	The ThermFix Immobilization System uses a single sheet of thermoplastic that can be formed over the patient's breast, thorax, abdomen, hip, or pelvis to aid in reproducibility and positioning. The ThermFix Bars easily attach and index to the TotalRT™ All in One Platform or Universal Couchtop™ and provide 1 cm indexing.
INDICATIONS FOR USE	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.
COMPATIBLE THERMOPLASTICS	MTHFX1822S, MTHFX1822S.4S, MTPLHA0201, MTHFX1822, MTHFX18222.4, MTPLHA0202, MTFHI1822, MTFHI18222.4, MTPLHAI0203, MTPLHA01, MTPLVCSUB8. See page 6
MR SAFE	THRMFX100, THRMFX101, THRMFX102 and compatible thermoplastics
INTEGRATION	Bars attach to Prodigy™ 2 indexing on TotalRT™ Platform and Universal Couchtop™
FDA CLEARANCE	Yes
CE MARKED (EU DOC)	Yes
OTHER COUNTRY REGISTRATIONS	Available Upon Request
COUNTRY OF MANUFACTURE	USA

TECHNICAL DETAILS

COMPONENT	MTWBL002 ThermFix Superior Bar			
PRIMARY MATERIALS	Garolite G10, PVC, Nylon			
WEIGHT (APPROX)	0.23 kg / 0.5 lbs			
DIMENSIONS (MM)	72 L x 610 W x 47 H (min.)			
DOSIMETRIC PROPERTIES	LOCATION	THICKNESS	FIELD SIZE (CM²)	ATTENUATION 6 MV PHOTONS
	● See blue dot below	0.47 cm	5 x 5	2.49%

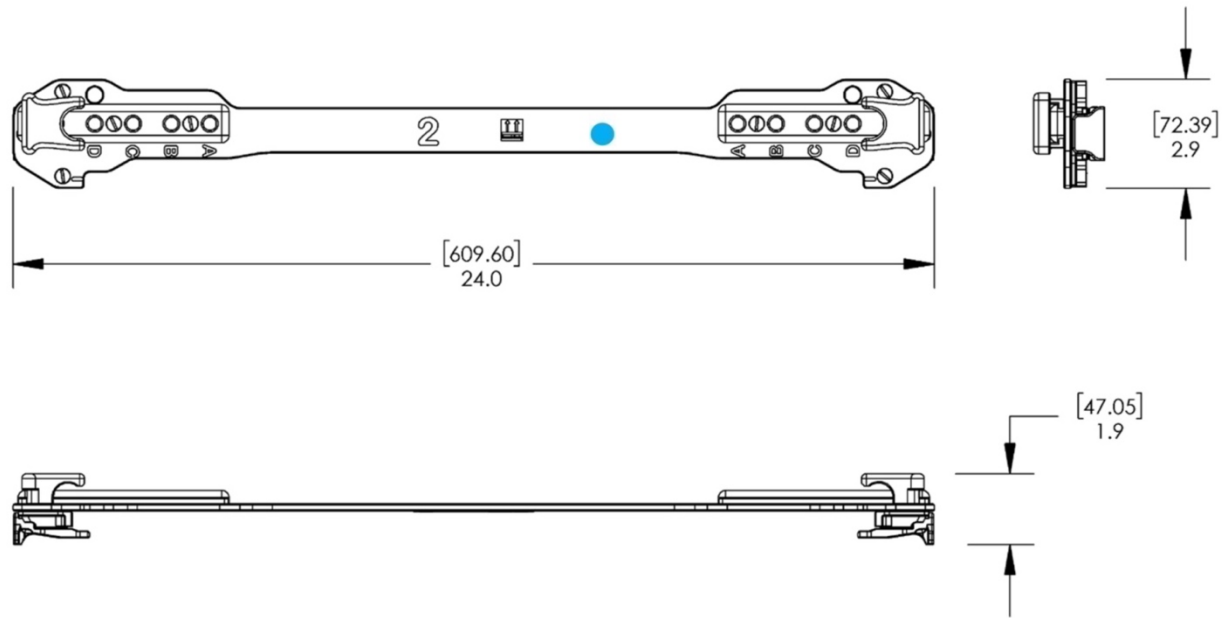
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	MTWBL003 ThermFix Inferior Bar
PRIMARY MATERIALS	Garolite G10, PVC, Nylon
WEIGHT (APPROX)	0.23 kg / 0.5 lbs
DIMENSIONS (MM)	72 L x 610 W x 47 H (min)
DOSIMETRIC PROPERTIES	See page 2

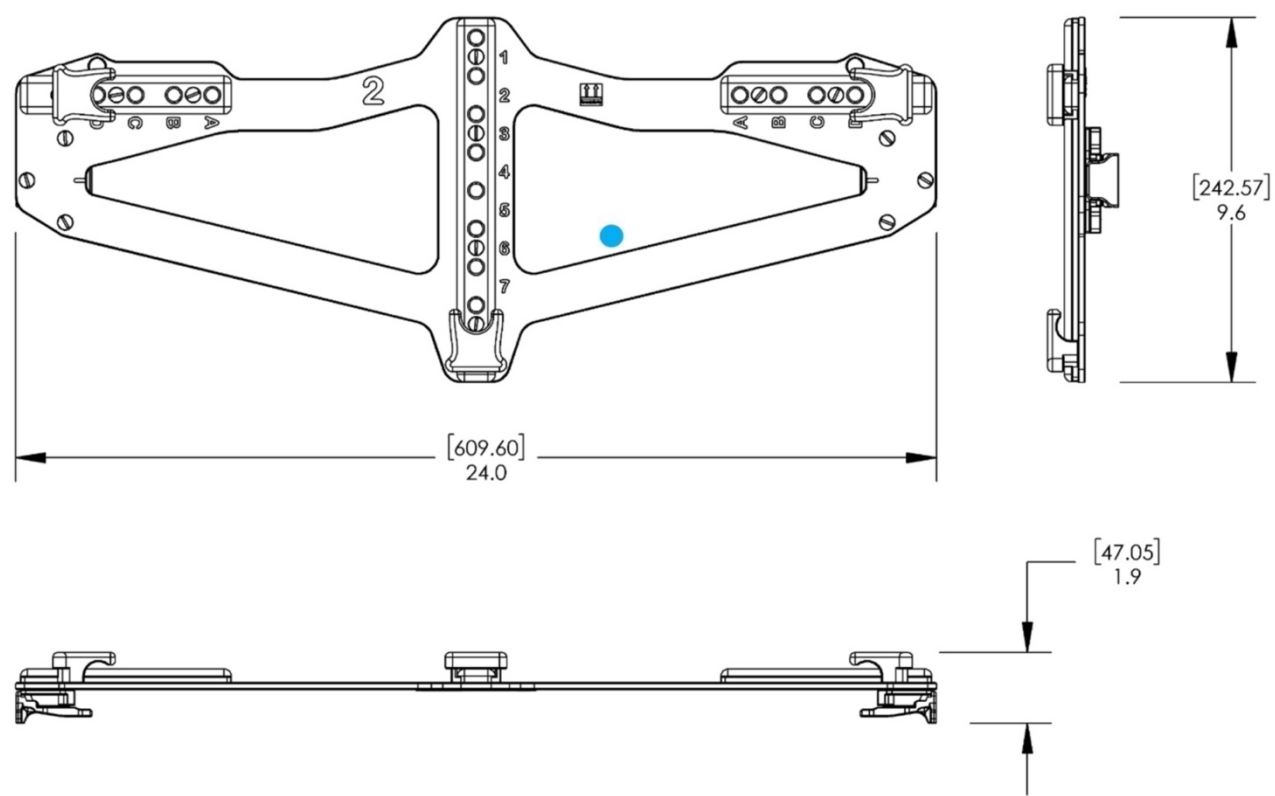
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	MTWBL004 ThermFix Hip & Pelvic Inferior Bar
PRIMARY MATERIALS	Garolite G10, PVC, Nylon
WEIGHT (APPROX)	0.5 kg / 1.2 lbs
DIMENSIONS (MM)	243 L x 610 W x 47 H (min)
DOSIMETRIC PROPERTIES	See page 2

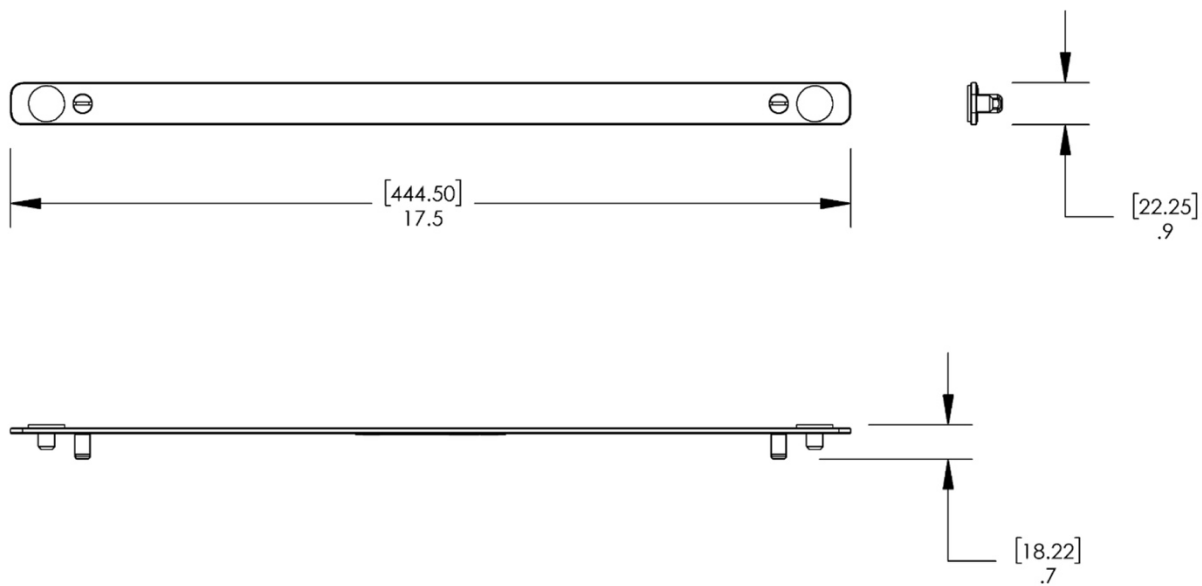
TECHNICAL DRAWING



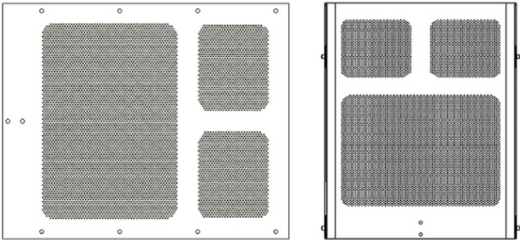
TECHNICAL DETAILS

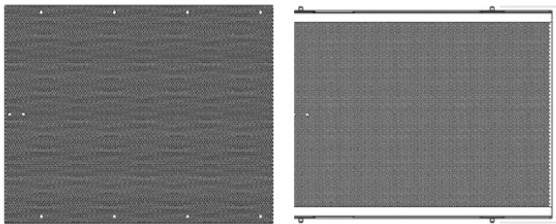
COMPONENT	MTWBL005 ThermFix Spacing Tool
PRIMARY MATERIALS	Acrylic
WEIGHT (APPROX)	0.1 kg / 0.2 lbs
DIMENSIONS (MM)	22 L x 445 W x 18 H (min)

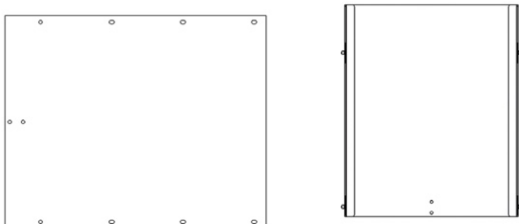
TECHNICAL DRAWING



THERMOPLASTIC TECHNICAL DETAILS

IMRT REINFORCED™				
	Thickness	Weight	Dimensions	
MTHFI1822 (reloadable)	3.2 mm	1 lb (0.45 kg)	559 L x 457 W	
MTHFI18222.4 (reloadable)	2.4 mm	1 lb (0.45 kg)	559 L x 457 W	
MTPLHAI0203 (no groin piece, disposable)	3.2 mm	1.2 lb (0.54 kg)	559 L x 445 W	

Perforated				
	Thickness	Weight	Dimensions	
MTHFX1822 (reloadable)	3.2 mm	1 lb (0.45 kg)	559 L x 457 W	
MTHFX18222.4 (reloadable)	2.4 mm	1 lb (0.45 kg)	559 L x 457 W	
MTPLHA0202 (no groin piece, disposable)	3.2 mm	1.76 lb (0.80 kg)	559 L x 461 W	

Solid				
	Thickness	Weight	Dimensions	
MTHFX1822S (reloadable)	3.2 mm	1 lb (0.45 kg)	559 L x 457 W	
MTHFX18222.4S (reloadable)	2.4 mm	1 lb (0.45 kg)	559 L x 457 W	
MTPLHA0201 (no groin piece, disposable)	3.2 mm	1.2 lb (0.54 kg)	559 L x 445 W	

THERMOPLASTIC TECHNICAL DETAILS

2.4 Standard Perforation

3.2 Standard Perforation

2.4 IMRT Reinforced

3.2 IMRT Reinforced

Primary Materials	Polycaprolactone, White ABS							
Attenuation (Unstretched Mask)**	6MV: 0.53% 18MV:0.03%		6MV: 0.72% 18MV: 0.12%		6MV: 0.81% (solid region) 18MV: 0.21% (solid region)		6MV: 0.81% (solid region) 18MV: 0.21% (solid region)	
Thickness	2.4 mm (.094")		3.2 mm (.125")		2.4 mm (.094")		3.2 mm (.125")	
Perforation (Surface)	38% (Standard)		38% (Standard)		Varies (IMRT Pattern)		Varies (IMRT Pattern)	
Density	1.145 g/cm3							
Surface Feeling	Smooth							
Color	White							
Odor	None							
Biocompatible	Yes							
Transparent when Activated	Yes							
	Waterbath	Dry Heat Oven	Waterbath	Dry Heat Oven	Waterbath	Dry Heat Oven	Waterbath	Dry Heat Oven
Activation Temperature	75° C / 165° F							
Activation time	6 min	4-8 min	6 min	4-8 min	7-9 min	8-11 min	7-9 min	8-11 min
Molding Time (maximum)* ^a	1 min 15 sec	N/A	1 min 30 sec	N/A	1 min 30 sec	N/A	1 min 30 sec	N/A
Hardening Time* ^b	8 min 45 sec	N/A	8 min 30 sec	N/A	8 min 30 sec	N/A	8 min 30 sec	N/A
Time to Completion (minimum)* ^c	10 min	10 min	10 min	10 min	10 min	10 min	10 min	10 min

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.

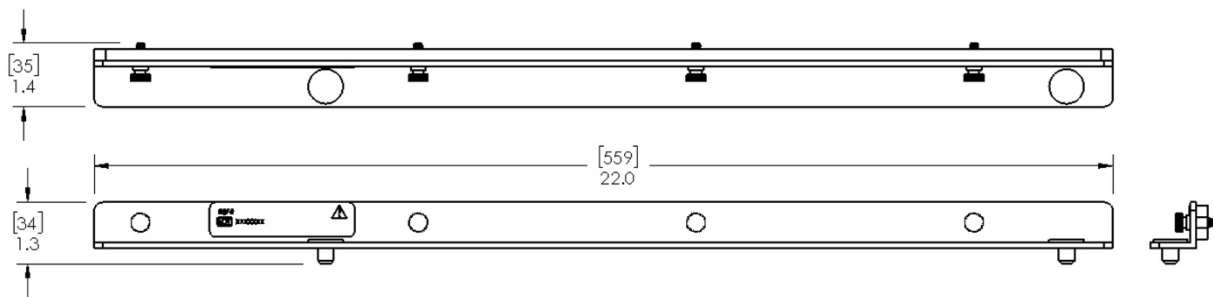
Attenuation Test Conditions**

- a) 100 cm SAD
- b) 10 x 10 cm Field Size
- c) 6 MV Dmax = 1.5 cm
- d) 18 MV Dmax = 3.0 cm

TECHNICAL DETAILS

COMPONENT	MTPLHA01 Reloadable Handles (x2) (groin piece included)
PRIMARY MATERIALS	Clear Polycarbonate, Thermoset Polyester, White Nylon
WEIGHT (APPROX)	0.54 kg / 1.2 lbs
DIMENSIONS (MM)	559 L x 35 W x 34 H (max)

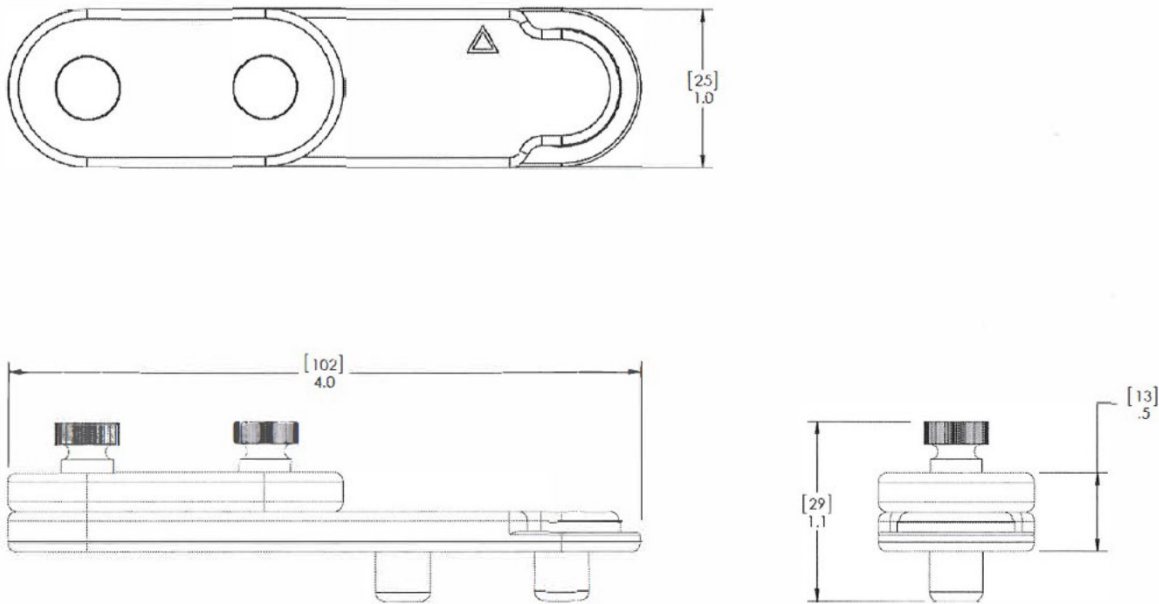
TECHNICAL DRAWING



TECHNICAL DETAILS

COMPONENT	MTPLVCSUB8 Thermoplastic Groin Piece, Reusable
PRIMARY MATERIALS	Clear Polycarbonate, White Nylon
WEIGHT (APPROX)	0.03 kg / 0.056 lbs
DIMENSIONS (MM)	25 L x 102 W x 13 H (max)

TECHNICAL DRAWING



PACKAGING

UNIT PACK	Each
UNITS / BOX	One device – may have several component parts in box Thermoplastic: Qty 5
SHELF LIFE	Not Applicable
WARRANTY	See CQ Medical Website for Product Warranty Statement
STERILIZATION	Non-Sterile
LAUNCH DATE	February 2023

ACCESSORIES

SYSTEM CUSTOMIZATION	ThermFix Bars are compatible with Thermoplastic (see page 6)
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