

Body Pro-Lok ONE™

Respiratory Belt

TECHNICAL DATA SHEET

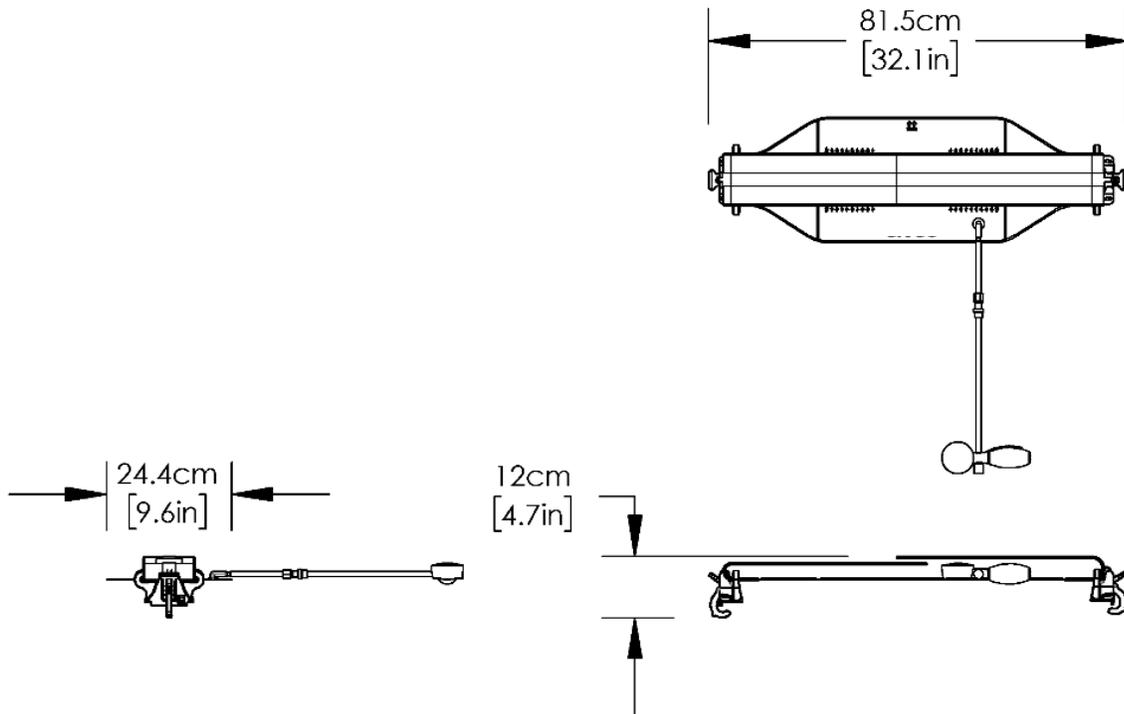


PRODUCT NAME	ONE Respiratory Belt
PRODUCT NUMBER	BPL026
GENERAL DESCRIPTION	The respiratory belt provides pneumatic compression and immobilization to the abdominal region.
INDICATIONS FOR USE	The device is indicated to assist in the proper positioning of patients for radiation therapy including electron, photon and proton treatments, and simulation including CT and MR image acquisition.
INTENDED USE	The device is part of a system intended to immobilize, position and reposition patients undergoing stereotactic radiation therapy including SBRT. The device is intended to apply abdominal compression for managing movement and tumor motion during respiration while maintaining maximum comfort to the patient.
MR CONDITIONAL	<p>Respiratory Belt: Non- clinical testing has demonstrated the Respiratory Belt is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:</p> <ul style="list-style-type: none">• Static magnetic field of 1.5 T and 3.0 T• Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)• Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than 0.5°C after 15 minutes of continuous scanning.• In non- clinical testing, the image artifact caused by the device extends up to 114mm from the gauge of the Respiratory Belt when imaged with a gradient echo pulse sequence and a 3.0 T MRI System. Image artifact was also observed up to 9mm from the belt clamp (BPL026 and BPL006 only).• Accessory Hand Pump with Pressure Gauge is MR Conditional. Refer to manufacturer’s instructions for conditions of safe use.
INTEGRATION	Connects directly to couchtop or platform.
FDA CLEARANCE	Yes
CE MARKED (EU DOC)	Yes
OTHER COUNTRY REGISTRATIONS	Available upon request
COUNTRY OF MANUFACTURE	USA

TECHNICAL DETAILS

COMPONENT	BPL026 ONE Respiratory Belt		
PRIMARY MATERIALS	Polyurethane Coated Nylon, White, Black and Cream Acetal		
WEIGHT (APPROX)	0.86 kg (1.90 lbs)		
DIMENSIONS (CM)	81.5 L x 24.4 W x 12 H		
DOSIMETRIC PROPERTIES	LOCATION	ATTENUATION 6 MV PHOTONS 10 X 10 FIELD SIZE (CM²)	ATTENUATION 18 MV PHOTONS 10 X 10 FIELD SIZE (CM²)
	Velcro	2.4%	1.83%
	Strap Nylon	1.14%	1.15%
	Belt Nylon	.79%	.87%
	Performance Specifications are for reference only, values may vary based on setup and equipment.		

TECHNICAL DRAWING



PACKAGING

UNIT PACK	Each
UNITS / BOX	One device-may have several component parts in box
SHELF LIFE	Not Applicable
WARRANTY	See website for Product Warranty Statement
STERILIZATION	Non-Sterile
RELEASE DATE	January 2021