kVue[™] Encompass[™] SRS Insert

TECHNICAL DATA SHEET



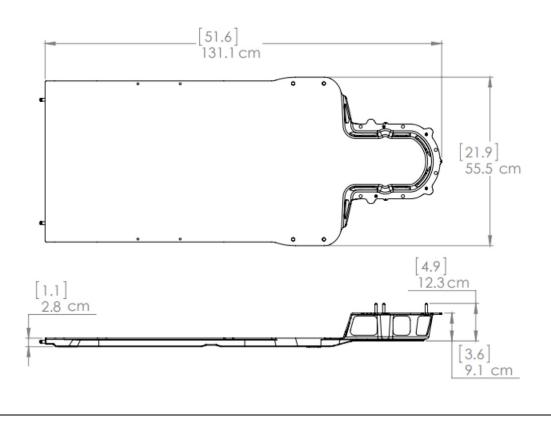
PRODUCT NAME	kVue Encompass SRS Insert
PRODUCT NUMBER	RT-4600KV-01
GENERAL DESCRIPTION	A highly specialized, non-invasive immobilization solution for stereotactic radiosurgery. Encompass is validated for use with Varian HyperArc.
INDICATIONS FOR USE	The Encompass SRS Immobilization System provides noninvasive stereotactic head and neck immobilization by using a patient specific thermoplastic mask that conforms to the patient's features to provide accurate, reproducible positioning, repositioning and immobilization. The Encompass SRS Immobilization System allows patient to undergo diagnostic imaging in the same position as that of treatment, enabling radiation therapy.
MR STATUS	Not intended for use in an MR environment.
INTEGRATION	Insert mounts directly to the kVue couchtop through the OneTouch Latch.
FDA CLEARANCE	Yes
CE MARKED (EU DOC)	Yes
OTHER COUNTRY REGISTRATIONS	Available upon request
COUNTRY OF MANUFACTURE	USA



TECHNICAL DETAILS

COMPONENT	RT-4600KV-01 kVue Encompass SRS Insert		
PRIMARY MATERIALS	Foam Cored Composite		
WEIGHT (APPROX)	4.5 kg / 10 lbs		
MAX PATIENT WEIGHT	249 kg / 550 lbs		
DIMENSIONS (CM)	131.1 L x 55.5 W x 2.8 H (Head Portion: 9.1 H with Pins 12.3 H)		
DOSIMETRIC PROPERTIES	6 X FFF BEAM	10 X FFF BEAM	6 X BEAM
	3.4% - 3.8%	2.9% - 3.4%	3.3% - 3.6%
	Karen Chin Snyder, Ilma Xhaferllari, Yimei Huang, M. Salim Siddiqui, Indrin J. Chetty, Ning Wen; Evaluation and verification of the Encompass™ couch insert for intracranial stereotactic radiosurgery, Journal of Applied Clinical Medical Physics, 19:4:222–229 (2018)		

TECHNICAL DRAWING





PACKAGING

UNIT PACK	Each
UNITS / BOX	(1) Encompass Device, (1) E0 SRS Headrest, Handgrip Array (pair)
SHELF LIFE	Not Applicable
WARRANTY	See CQ Medical Website for Product Warranty Statement
STERILIZATION	Non-Sterile
LAUNCH DATE	2015

ACCESSORIES

SYSTEM CUSTOMIZATION	COMPATIBLE WITH: Encompass SRS Fibreplast System with Optional IntegraBite (RT-B889KYCF2) E0 SRS Headrest (RT-4600-10) E2 SRS Headrest (RT-4600-12) E4 SRS Headrest (RT-4600-14) Hand Grip Array (RT-4525HGA) Encompass SRS Anterior Only Fibreplast Mask (RT-B889KYCF2A) SRS Cushion Support (RT-4600-20)
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