Solstice™ Immobilization System

INSTRUCTIONS FOR USE (IFU)



INDICATIONS FOR USE / INTENDED USE

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), to support treatment planning.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

⚠ WARNING

- Verify all angles of treatment, attenuation characteristics and WET values prior to treating patients.

 Product shape may have slight variations; the same device must be used for a patient throughout setup and treatment cycles.

 Do not use if device appears damaged.

 Ensure accessory device is properly located.

 Device is for use with CQ Medical specified accessories only.

- Ensure device is secure prior to use.

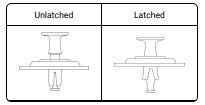
 Verification image should be taken to confirm patient position prior to treatment.

 Do not use excessive force on device. Injury or device damage may occur.

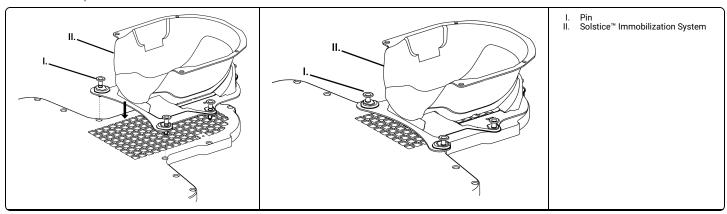
 Ensure device/patient does not move for duration of set-up and treatment.

USING SOLSTICE™ IMMOBILIZATION SYSTEM

NOTE: Ensure pins are unlatched.

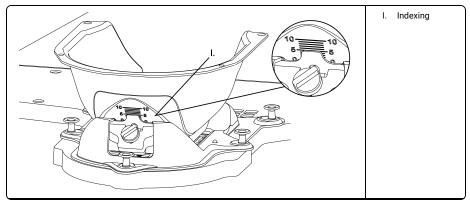


- Attach head fixation to extension. Use all available pins to secure head fixation to extension.



↑ WARNING

- Bowl indexing does not relate to patient isocenter.
- For initial setup, position indexing location at 5.



NOTE: If using AccuForm™ cushion, proceed to steps 4-10. If using headrest, refer to manual provided with headrest.

- Prepare AccuForm™ cushion press spray bottle nozzle slightly into cushion and squeeze a shot of water into cushion at one inch intervals across surface to ensure even dampening. Dab cushion with dry towel to remove excess water. Flatten AccuForm™ cushion to a uniform thickness.
- Hold cushion over device opening. Align superior edge of cushion with superior edge of bowl. Lower patient's head into head support.

⚠ WARNING

- · Position cushion below thermoplastic attachment edge of bowl, ensuring inferior edge of cushion at neck area does not limit pitch functionality.
- 8. Allow cushion to set (harden) approximately 20 minutes.

NOTE: Instruct patient not to move while cushion is setting.

- Remove patient from cushion without putting pressure on cushion to avoid deforming cushion. Allow cushion to air dry completely (approximately 24 hours).

⚠ WARNING

- Do not use heat to dry cushion.

REPROCESSING

⚠ WARNING

- Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- 1. Clean surface of device by removing visual contaminants with common germicidal or antiseptic wipe, such as quaternary ammonium or isopropyl alcohol wipes. If visual contamination cannot be removed, repeat cleaning steps and if necessary, discontinue use.

MAINTENANCE

Inspect for damage such as cracks, breakage, or warpage. User should not service device. If service is needed, contact CQ Medical.

STORAGE

⚠ WARNING

Store device on a flat surface. Do not stack.

Solstice™止动系统 简体中文

使用说明 / 用途

本设备用于对这样的成人和儿童患者进行定位和/或固定:这些患者正在进行头部、大脑和颈部的放射治疗,包括:表面引导放射治疗 (SGRT),以及电子、光子和质子治疗。本 设备还可在图像采集过程中使用,包括计算机断层扫描(CT),以便为治疗计划提供支持。

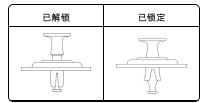
联邦(美国)法律限制本器械只能由医生销售或订购。

- 在治疗患者之前,请验证所有的治疗角度、衰减特性和WET值。 产品外形可能略有差异;在整个设定与治疗疗程中,应使用同一设备服务患者。 如果设备有损坏迹象,请勿使用。 确保附件设备已正确入位。 设备只能与CQ Medical 指定的附件一起使用。

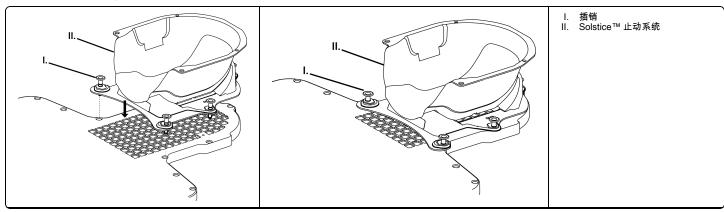
- 设备才能与 CQ Medical 有足的附件一起使用。 使用前确保器械紧固。 治疗前应拍片确认患者的位置。 切勿对设备用力过度。否则可能会导致人身伤害或设备损坏。 确保设备/患者在设置和治疗过程中保持不动。

使用 SOLSTICE™ 止动系统

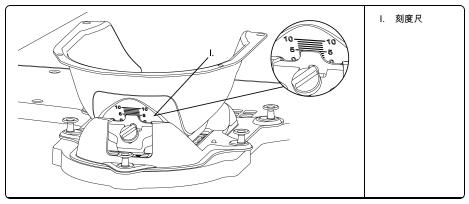
注意: 确保插销已打开。



- 将头部固定装置连接至延展板。
- 请使用所有可用的插销,将头部固定装置固定至延展板上。



- 碗刻度不涉及患者等中心点。
- 在进行初始设置时,将刻度位置固定在 5 处。



注意: 如果使用 AccuForm™ 垫子,请继续执行步骤 4-10。如果使用 头枕,请参阅随 头枕提供的手册。

- 4. 准备 AccuForm™ 垫子 轻轻将喷水瓶的喷嘴压入垫子,在表面以一英寸的间隔将一股水挤入垫子,以确保湿润均匀。 使用干毛巾轻拍垫子以去除多余水分。
- 将 AccuForm™ 垫子弄平,确保厚度一致。 在设备开口的上方,固定住垫子。将垫子的上边缘同碗部的上边缘对齐。 降低患者的头部,进入头部支承之中。

简体中文

- 放置垫子,让其低于碗部热塑性材料的连接边缘,确保颈部区域的垫子下边缘不会限制倾斜功能。
- 8. 允许垫子凝固 (硬化)大约20分钟。

注意: 指示患者在垫子凝固期间不要移动。

- 9. 将患者从垫子移开,同时不要对垫子施加压力,以避免垫子变形。 10. 使垫子完全风干*(大约24小时*)。

<u></u> 警告

- 切勿将垫子加热进行干燥。
- 11. 连接热塑性材料(*请参阅热塑性材料手册*)。 12. 根据需要,调整碗刻度的位置。

注意: 顺时针旋转螺钉至更小螺距。 逆时针旋转螺钉加大螺距。

再处理

<u></u> 警告

- 此产品的用户有义务和责任为患者、同事及其自身提供最高级别的感染控制。为了避免交叉感染,请遵守您所在单位制定的感染控制政策。
- 1. 使用普通杀菌剂或消毒搌布(如:季胺盐或异丙醇搌布),移除所看见的污染物,清洁器械的表面。所看见的污染物如果无法移除,请反复执行清洗步骤,并在必要时停止

维护

注意: • 检查是否存在损坏,例如裂纹、破裂或变形。 • 用户不应对设备进行维修。如果需要维修,请联系 CQ Medical。

贮存

• 在平面上储存设备。不要堆叠。



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