

# KCI THERAPEUTIC Support Systems

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## PRONE THERAPY & KCI ROTOPRONE™ THERAPY GUIDELINES





## Important Information for Users:

Please consult treating physician and product instructions for use prior to patient placement. The *RotoProne™ Therapy System Operations Manual* can be located under the foot end of the patient surface. Indications, contraindications, risks and precautions and safety tips exist for the KCI Prone Therapy products and must be consulted prior to use. Individual patient conditions may vary. This is not intended as a comprehensive guideline or protocol, or as a guarantee or warranty of product performance or clinical outcomes. These guidelines are to assist the treating physician in establishing treatment protocols for product and therapy application. Information is subject to change without notice.

## Notice to Users:

Federal law restricts this device to sale or rental by or on the order of a physician.





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# Introduction

The following clinical guidelines for prone positioning are based on clinical studies, evidence based research and best practices in ICUs with extensive experience in prone positioning critically ill patients.

## About Acute Respiratory Distress Syndrome (ARDS):

ARDS is a devastating inflammatory disease of the lung characterized by the sudden onset of pulmonary edema and respiratory failure, usually in the setting of other acute medical conditions resulting from direct or indirect injury.<sup>1</sup> Patient mortality associated with ARDS is estimated between 32% and 45%.<sup>2</sup> Clinical conditions sometimes associated with the development of ARDS include:

### Direct lung injury<sup>3</sup>

- Pneumonia
- Aspiration of gastric contents
- Inhalation injury
- Near drowning
- Pulmonary contusion
- Fat embolism

### Indirect lung injury<sup>3</sup>

- Sepsis
- Severe trauma
- Acute pancreatitis
- Cardiopulmonary bypass
- Massive transfusions
- Drug overdose

As its name implies, ARDS is a syndrome, or a condition defined by a group of signs and symptoms. In 1994, the American European Consensus Conference on ARDS established the following universal definitions intended for clinical and investigational application:

## Acute Respiratory Distress Syndrome<sup>4</sup>

- Acute onset
- Oxygenation: A partial pressure of arterial oxygen to fractional inspired oxygen concentration ratio  $\leq 200\text{mmHg}$  (regardless of PEEP)
- Bilateral pulmonary infiltrates on chest radiograph
- Pulmonary artery wedge pressure  $\leq 18\text{mmHg}$  or no clinical evidence of left atrial hypertension



## About Prone Therapy:

Clinical research has shown the effectiveness of prone therapy in improving oxygenation<sup>2</sup> in ARDS patients. Two more recent studies, one utilizing the RotoProne™ Therapy System, have demonstrated that prone therapy may reduce mortality in ARDS patients when implemented early and applied for longer periods of time.<sup>5,6</sup> Although outcomes will vary and there can be no assurance for a specific patient, proning in general has been shown to:

- Enhance the mobilization of pulmonary secretions, thus optimizing the effectiveness of physiotherapy techniques<sup>7</sup>
- Reduce the risk of iatrogenic lung injury resulting from mechanical ventilation<sup>8</sup>
- Reduce the risk of ventilator-acquired pneumonia<sup>9</sup>

# Recommended Patient Selection Criteria

KCI offers two therapy systems that accommodate prone therapy. The TriaDyne™ Proning Accessory Kit\* can be used on both the TriaDyne™ II and the TriaDyne Proventa™ to facilitate manual prone positioning. The RotoProne™ Therapy System can automate the proning process and provide the added benefit of Kinetic Therapy™.

## Indications for Prone Therapy:

- Treatment and prevention of severe pulmonary complications such as ARDS<sup>4</sup>
- Patients requiring postural drainage of pulmonary secretions<sup>7</sup>
- Patients who are expected to require prolonged periods of mechanical ventilation<sup>8,9</sup>

*\*See Appendix for TriaDyne™ II and TriaDyne Proventa™ Proning Accessory Kit.*

## Indications for RotoProne™ Therapy:

Patient conditions for which the applications of Prone Therapy along with Kinetic Therapy™ are indicated include:

- Treatment and prevention of pulmonary complications associated with immobility

## Contraindications for RotoProne™ Therapy:

- Unstable cervical, thoracic, lumbar, pelvic, skull\*\* or facial\*\* fractures
- Cervical and/or skeletal traction
- Uncontrolled Intracranial Pressure (ICP)
- Patient weight below 88 pounds/40 kilograms
- Patient weight above 350 pounds/159 kilograms
- Patient height less than 4 feet, 6 inches/137 centimeters
- Patient height in excess of 6 feet, 6 inches/198 centimeters

*\*\*Only contraindicated for Prone Therapies.*



## Risks and Precautions for RotoProne™ Therapy:

Use of the RotoProne™ Therapy System is typically prescribed for patients at high risk of mortality. Although use of the RotoProne™ Therapy System is thought to help caregivers address potentially life-threatening conditions, proning itself may present inherent risks of serious injury. For instance, some studies and caregiver experience have suggested or reported risk of the following in relation to proning in general:

- Skin breakdown and/or pressure necrosis
- Wound dehiscence
- Cardiac arrest
- Loss of invasive lines or tubes or extubation (endotracheal and oral)
- Edema and/or swelling
- Splenic rupture
- Blindness and other consequences of damage to the ocular nerve
- Corneal abrasion
- Myositis ossification
- Venous air embolism
- Increased intraorbital pressure
- Central retinal artery occlusion
- Pain and discomfort
- Difficulty performing CPR

Precautions may also need to be taken when using this product with certain patient conditions, including but not limited to:

- Hemodynamic instability
- Severe agitation
- Uncontrollable claustrophobia or fear of confinement
- Uncontrollable diarrhea
- Intolerance to face down position
- Wounds at risk of dehiscence while in the prone position
- Patient in the prone position with open sternal wound or thoracic post-surgical incision
- Patient in the prone position with open abdomen
- Any implant that potentially increases the risk of skin breakdown including but not limited to breast implants or penile prosthesis
- Pregnancy
- Extensive facial trauma
- Any other unstable fracture not listed as a contraindication
- ICP monitoring or intracranial drainage devices



## Therapy Recommended Guidelines

### Patient Response to Prone Therapy:

Approximately 75% of ARDS/ALI patients may respond with improved oxygenation.<sup>3</sup> However, the length of prone time required for patient response may vary.

**Patients are categorized as responders based on the following criteria:**<sup>7,10</sup>

- Increase in PaO<sub>2</sub> of more than 10mmHg after 30 minutes of prone positioning
- Increase in PaO<sub>2</sub>/FiO<sub>2</sub> ratio of more than 20 or 20% within two hours of patient being turned from supine to prone

**Patients are categorized as non-responders based on the following criteria:**<sup>7,10</sup>

- PaO<sub>2</sub> was unchanged after prone positioning

*Note: If the initial attempt at prone positioning does not elicit a positive response with regards to oxygenation, this does not preclude additional attempts with prone positioning to improve oxygenation. There have been reports of patients who did not respond on the initial attempt that did respond at subsequent attempts of prone positioning showing an improvement in PaO<sub>2</sub>.<sup>11</sup>*

### Frequency and Duration of Prone Therapy:

There are no standard guidelines to delineate optimal duration or frequency of prone positioning. Although there is increased risk of serious skin breakdown and other serious complications with prolonged proning, patients can remain in the prone position for as long as they tolerate the position, up to 20 hours daily.<sup>10,12</sup> Length of prone time and frequency of prone/supine episodes may vary from patient to patient. Consult with the treating physician to obtain orders on frequency and duration of prone positioning and follow any facility-established protocols.

### Frequency and Duration of RotoProne™ Therapy:

- With the use of the RotoProne™ Therapy System, the maximum recommended prone time interval is three hours and 15 minutes. The patient should be brought back to supine for approximately 45 minutes for general patient care and to help minimize facial edema and then returned back to the prone position.
- While in the prone position, it is recommended that patients be continuously rotated to at least 40 degrees for a minimum of 18 hours per day for maximum benefit.

- Assess patient skin condition at frequent intervals depending on patient condition. This assessment is recommended at least every four hours.
- See specific pressure points for skin care under RotoProne™ Therapy System Safety Tips for further information.

*Note: When considering use of prone positioning and RotoProne™ Therapy, the healthcare team must also weigh other physiologic factors when a patient remains in a stationary position for an extended period of time. The potential for skin injury and edema formation can be minimized by following established turning protocols. The longer time spent in a single position requires that the support surface provide greater pressure reduction or relief than a standard hospital mattress.<sup>13</sup>*

### **Early Intervention Factors:**

Initiating therapy early (within 24 hours) in the course of ARDS may help to improve patient outcomes.<sup>14,15</sup> There is evidence to support proning the patient as soon as the patient meets the criteria for ARDS.<sup>14</sup> It is important to train and educate the ICU staff on the early recognition of signs and symptoms of pulmonary complications, the practical application of prone positioning and the use of a specific therapy system. For the RotoProne™ Therapy System, it is recommended to place the patient within 24 hours of the P/F ratio trending below 200.

### **Prior to Initiation of Prone Therapy:**

- The clinician should collaborate with a multidisciplinary committee and physician to determine the need for Prone Therapy.
- The clinician should inform the patient and the patient's family about the therapy and rationale for prone positioning. (See the *Patient and Family Information About the RotoProne™ Therapy System*, Lit # 2-A-163.)
- A physician's order is required to initiate prone positioning as an intervention.



# Recommended Prone Therapy and RotoProne™ Therapy Placement Procedures

Always follow particular instructions of the proning device being used. See the *RotoProne™ Operations Manual* for step-by-step patient placement, instructions, cautions, warnings and safety tips located underneath the foot end of the patient surface.

## Patient Preparation:<sup>16,17</sup>

- Prior to proning, perform any nursing interventions that require access to the anterior body surface (such as wound dressings or emptying of ileostomy/colostomy bags, etc.) to minimize the need to return the patient to a supine position prematurely.
- Verify the position and security of the ET tube and/or tracheostomy tube. Double tape the ET tube for added security, assess the security of ties on the tracheostomy tube. Assess the patient for suctioning and mouth care needs. Perform interventions per facility protocols if necessary. Readdress and secure all lines. Evaluate all lines for sufficient slack to complete the turn.
- Move the cardiac leads (ECG) to the patient's back to minimize the risk of skin breakdown while in the prone position. Evaluate the waveform quality and any arrhythmias.
- Lubricate and cover eyes per facility protocol to minimize the risk of corneal abrasions. Position the head so that there is no direct pressure placed on the eye or the orbit to minimize the risk of injury from prolonged and/or increased pressure to the eye, retina or optic nerve.

## Placing the Patient in the Prone Position:

Both manual and automated techniques can be used to place a patient in prone position.

### Manual Prone Positioning:

- May require up to six people, depending upon the size and complexity of the patient.<sup>18</sup>



- Observe the patient through two full rotation cycles and check the following:
  - Adjust slack in lines as necessary.
  - Observe the patient for movement or shift within the side support packs and re-tighten or adjust as necessary.
  - Ensure there are no potential obstructions in path of unit rotation.

*Caution: Obstructions such as tables or equipment may impede the unit's rotation cycle causing sudden movements of the patient support frame, which may result in patient or caregiver injury. Assure all obstructions are removed from the patient support frame's rotation cycle area.*

## Ongoing Patient Assessment<sup>16,17,19</sup>

- Assess the patient frequently while in the prone position.
- There is an increased risk of serious skin breakdown and other serious complications with prolonged proning such as pressure ulcers and facial edema.
- Assess the patient's response to therapy. Most patients may "respond" with a significant improvement in oxygenation. However, if the patient experiences a significant drop in SpO<sub>2</sub> and does not improve after several minutes of increased FiO<sub>2</sub>, the patient should be returned to the supine position.
- Assess the security of the ET tube and/or tracheostomy tube. Ensure that all lines and tubes are secure and connected.
- Assess the patient for proper body and extremity alignment. To prevent neuropathy, avoid overextension or compression of any joints. If manually proning, provide passive range of motion per physician to minimize the risk of joint or nerve injury due to prolonged immobility.
- Manual prone positioning requires frequent position changes to minimize the risk of skin breakdown. Assess the patient's skin for skin breakdown at regular intervals, regardless of the proning method.
- Assess for facial edema. Most Prone Therapy patients experience some degree of dependent edema. While in the prone position, many patients will develop a significant amount of facial edema. Rotating the patient back to the supine position will assist in minimizing and/or resolving significant facial edema due to prone positioning. In addition, maintaining the bed in a Reverse Trendelenburg will also minimize facial edema.
  - When using RotoProne™ Therapy, the face pack foams will need to be replaced at least every 72 hours or sooner if they become saturated. The face pack foam should be checked daily for saturation.

- Assess and zero any transducers prior to recording hemodynamic measurements. Blood pressure and pulmonary artery pressure readings will fluctuate with the rotation of the patient.

## **Consult with the physician regarding the appropriateness of the following interventions:**

### **Sedation:**

Assess the patient's level of consciousness and comfort level by using a sedation and pain scale per hospital protocol. Many patients may already be receiving sedation and/or paralytic agents prior to the use of prone positioning due to ventilator management. Some patients may require additional sedation while in the prone position. Consult with the treating physician for guidance and orders regarding sedation use.

### **Nutrition:**

Nutrition is critical to the recovery from ARDS. Pulmonary aspiration is one of the most serious complications of enteral feeding. Consider the use of transpyloric feedings. Delivery of nutrients directly into the small intestine minimizes the risk of pulmonary aspiration.

The risk for aspiration is highest while turning the patient from supine to prone. It is recommended to turn off any feeding tube at least 45-60 minutes prior to positioning the patient to prone. Once the patient is in the prone position, resume feeding. It may be helpful to position the bed in a Reverse Trendelenburg position to help minimize the risk for aspiration. Consult with the treating physician for guidance and orders regarding tube feeding and bed positioning.

### **Discontinuance Criteria:**

Improvement in oxygenation as defined by the physician and/or multidisciplinary committee on prone positioning.

For further information regarding KCI's Prone Therapy products and recommended guidelines for use, please contact your local KCI representative or call 1-800-275-4524.



## RotoProne™ Therapy System Safety Tips

**Skin Care** - Fitting the Head Support, Face Pack, Lower Leg Proning Packs or other packs too tightly may increase pressure points, possibly leading to skin breakdown. Assess skin at frequent intervals depending on patient condition (at least once every four hours). Give extra attention to skin at pressure points and locations where moisture or incontinence may occur or collect. Common pressure points include, but are not limited to, the face, ears, axilla, shoulders, sides and upper and lower extremities. Early intervention may be essential to preventing serious skin breakdown. Do not leave patient in a stationary position for more than two hours. Consider the use of topical skin lubricants or barriers to minimize risk of skin breakdown.

**Face Pack** - Position Face Pack to ensure visibility of the eyes and to avoid pressure on or around the patient's eyes and ears. Ensure appropriate forehead foam has been selected and inserted into forehead pack. Remove Face Pack at regular intervals to assess the eyes, ears and facial skin. Prolonged, increased intraocular pressure may cause eye injury, including blindness. Ensure all Face Pack buckles are secure before proning patient.

**Side Support Packs** - Maintain a one-inch clearance (approximately two fingers) between the end of the Side Support Pack and the patient's axilla. Never place the Side Support Pack snugly against patient's axilla. Undue pressure on axillary blood vessels and nerve injury may result.

**Therapy System Height** - The unit should always be in the lowest practical position when the patient is unattended. Make sure area under and around unit frame is clear of objects, persons and parts of body before adjusting height.

**Lock Pin** - The Lock Pin should be fully engaged in the zero degree supine position when rotation is stopped. Make sure area under and around unit frame is clear of objects, persons and parts of body before pulling the Lock Pin to allow rotation.

**Tube and Line Management** - Prior to activating rotation, assess the security of all invasive lines and tubes to accommodate a full 360 degrees of rotation and minimize the risk of binding, disconnecting or dislodging. Tubes and lines should always have slack for rotation and patient movement. Tubes and lines must always be routed through head end of unit and secured within the Tube Management

System or the circular opening at the foot end of the unit, just beneath the Main Display Panel. Do not hang or tie any equipment or lines on sides of patient support frame.

- Route ventilator tubes and other upper body lines to head end of unit through open Top Frame Hoop.
- Secure lines and tubing in Tube Management System at head of unit.

**Ventilator Management** - Always rotate the patient surface from the supine position toward the ventilator, to reduce risk of extubation.

**Hatches** - Always make sure hatches are closed and locked in position prior to rotating patient surface. Use caution when opening and closing hatches. Keep extremities, hair, clothing or other objects clear of hatch openings to avoid injury or damage. Unlatched hatches and Hatch Center Bar may pose risk of injury or damage if allowed to drop freely.

**Moving Parts** - Keep all equipment, tubes and lines, loose clothing, hair and parts of the body away from moving parts and pinch points.

**Fluids** - Avoid spilling fluids on unit controls. If spills do occur, unplug unit. Clean fluid from unit, wearing rubber gloves to avoid any possibility of shock. Fluids remaining on controls can cause corrosion, which may cause components to fail or to operate erratically, possibly producing hazards for patient and caregiver.

**Patient Restraints** - Whether and how to use restraints is a decision that should be based on each patient's individual needs and should be made by the patient and the patient's family, physician and caregivers, in keeping with facility protocols. Monitor restrained patients frequently. Do not tie restraints on sides of patient support frame.

**CPR** - Caregivers and other hospital personnel are required to become familiar with the CPR function and the emergency release procedures for automatically or manually rotating the patient surface to a supine position, as well as the other procedures required to access the patient in case of an emergency.



**Avoid Fire Hazards** - To minimize the risk of fire, connect the unit's power cord directly into a wall-mounted outlet. Do not use extension cords or multiple outlet strips. Review and follow FDA's Safety Tips for Preventing Hospital Bed Fires (dated December 18, 2003) and other information referenced at <http://www.kci1.com/products/FDASafetyAlert>.

**Power Cord** - Ensure power cord is kept free from all pinch points and moving parts and is not trapped under casters. Improper handling of the power cord can cause damage to the cord, which may produce risk of fire or electric shock.

**Brakes** - Caster brakes should always be locked once the unit is in position.

**Transport** - Always use two people when transporting unit.

**Scale Readings** - Scales/patient weights are for reference only. Scale readings should not be relied upon for medication dosage. All equipment on the unit is included in weight displayed.

**General Protocols** - Follow all applicable safety rules and institution protocols concerning patient and caregiver safety.

# Ordering Information

## **KCI Contact Information:**

If you have any questions, or for additional information, please contact your local KCI representative or contact KCI directly at 1-800-275-4524. Visit our website at [www.kci1.com](http://www.kci1.com).



## Appendix

### Indications for Prone Therapy utilizing the TriaDyne™ II and TriaDyne Proventa™ Proning Accessory Kit:

- Treatment and prevention of pulmonary complications associated with immobility

### Contraindications for Prone Therapy utilizing the TriaDyne™ II and TriaDyne Proventa™ Proning Accessory Kit:

- Unstable cervical, thoracic, lumbar, pelvic, skull or facial fractures
- Cervical and/or skeletal traction
- Uncontrolled Intracranial Pressure (ICP)
- Patient weight above 300 pounds

### Risks and Precautions for Prone Therapy utilizing the TriaDyne™ II and TriaDyne Proventa™ Proning Accessory Kit:

Consult with a physician regarding the risks versus potential benefits when considering the use of prone position in the following patient conditions:

- Skin breakdown and/or pressure necrosis
- Wound dehiscence
- Cardiac arrest
- Loss of invasive lines or tubes or extubation (endotracheal and oral)
- Edema and/or swelling
- Splenic rupture
- Blindness and other consequences of damage to the ocular nerve
- Corneal abrasion
- Myositis ossification
- Venous air embolism
- Increased intraorbital pressure
- Central retinal artery occlusion
- Pain and discomfort
- Difficulty performing CPR

Precautions may also need to be taken when using this product with certain patient conditions, including but not limited to:

- Hemodynamic instability
- Severe agitation
- Uncontrollable claustrophobia or fear of confinement
- Uncontrollable diarrhea
- Intolerance to face down position
- Wounds at risk of dehiscence while in the prone position
- Patient in the prone position with open sternal wound or thoracic post-surgical incision
- Patient in the prone position with open abdomen
- Any implant that potentially increases the risk of skin breakdown including but not limited to breast implants or penile prosthesis
- Pregnancy (second/third trimester)
- Extensive facial trauma
- Any other unstable fracture not listed as a contraindication
- ICP monitoring or intracranial drainage devices



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