



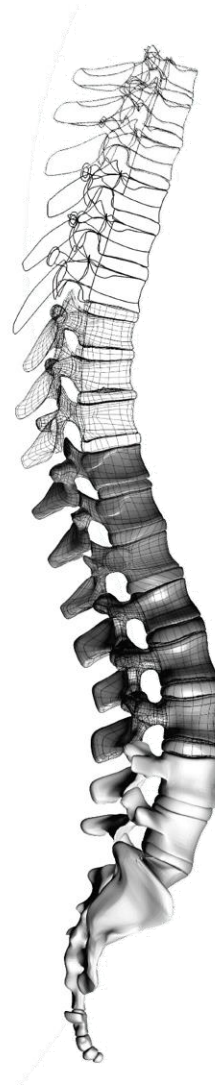
# SPINOLOGICS

*Leading the development of improved spinal care™*

CERVISION™

Indications For Use (IFU)

2018-03-07



CONCEPT

DESIGN

PRACTICE

## SPINOLOGICS

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## INTRODUCTION

The **CERVISION** system is the first and only positioning system to couple the movement of the patients shoulders and arms. This advantageously provides the unique ability to safely and comfortably position a patient's upper limbs as desired. The **CERVISION** system is fully adjustable to all patients and installs easily on all operating tables. The **CERVISION** system works with anterior or posterior positioning and will always provide consistent and accurate x-rays of the cervical spine, precluding the need for delays and repeat x-rays.

Optimize and simplify your cervical spine surgery with the **CERVISION**

Indication for use: The CERVISION is designed to provide caudal retraction of the shoulders and to support and locate patient arms during spinal and neck procedures.

# CERVISION

*Optimize and simplify your cervical spine surgery*

## Cervision™

Product number: ULP-400K

**Indication for use:** The CERVISION is designed to provide caudal retraction of the shoulders and to support and locate patient arms during spinal procedures.

**General:** The CERVISION™ is a simple and effective apparatus to comfortably position a patient's shoulders and arms.

**Storage:** Store at room temperature.

**Contraindications:** None known.

**CAUTIONS:** The CERVISION™ is a disposable single use device. Do not reuse as performance is not guaranteed and contaminations may occur. As with all OR positioning devices, care must be taken when using this product and adequate monitoring of patient is required in order to prevent injury resulting from improper use. Do not use with shoulder girdle injuries. It is advised to use neuromonitoring to avoid brachial plexus injury. If an audible crackling sound of the Velcro® is heard when pulling (6), the Velcro® upper holding limit of the Velcro® has been reached, reduce tension by adjusting tension locks, Intermittent release of tension is recommended for prolonged surgeries. As always, surgeon is to determine if patient is stable enough to use this traction device.

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# CERVISION

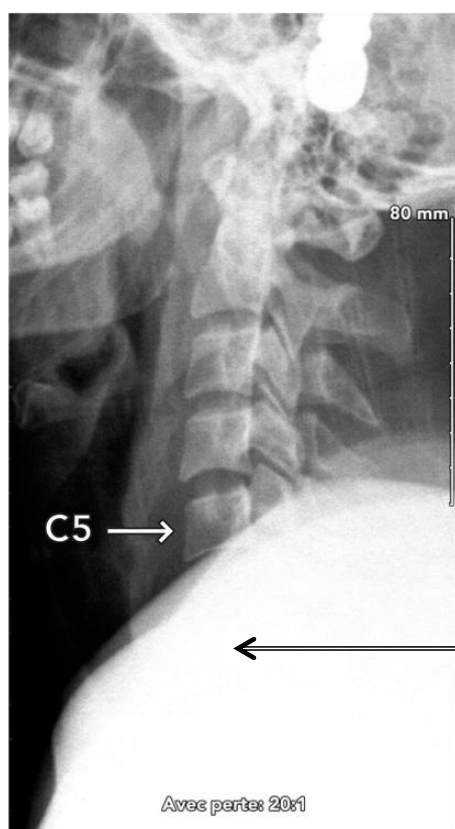
*Optimize and simplify your cervical spine surgery*

## CLINICAL NEED

Current methods of positioning patients' arms during cervical procedures are crude, time consuming, insufficient, and consequently costly to the establishment.

Arms must be drawn caudally and supported adjacent to patient to effectively expose the cervical spine

## Intraoperative radiographs



Gardner-Wells tongs  
30 lbs traction

Provides consistent  
and accurate x-rays  
of cervical spine -  
precludes need for  
repeat x-rays and  
positioning delays

← Area of interest



Gardner-Wells tongs  
30 lbs traction  
+  
**CERVISION™**

# CERVISION

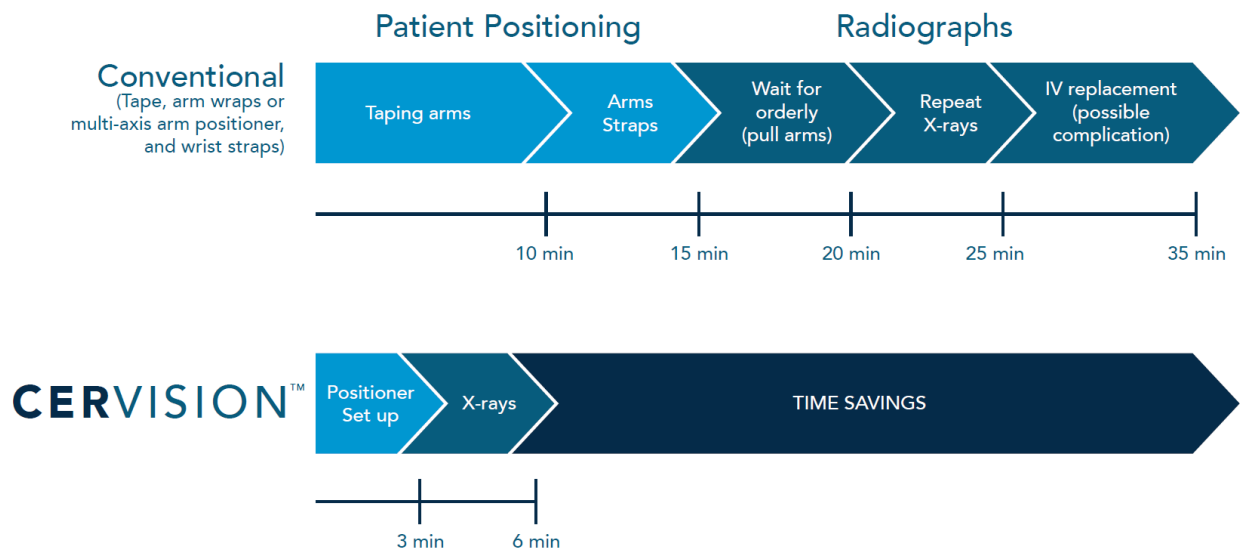
*Optimize and simplify your cervical spine surgery*



Prone position



Supine position



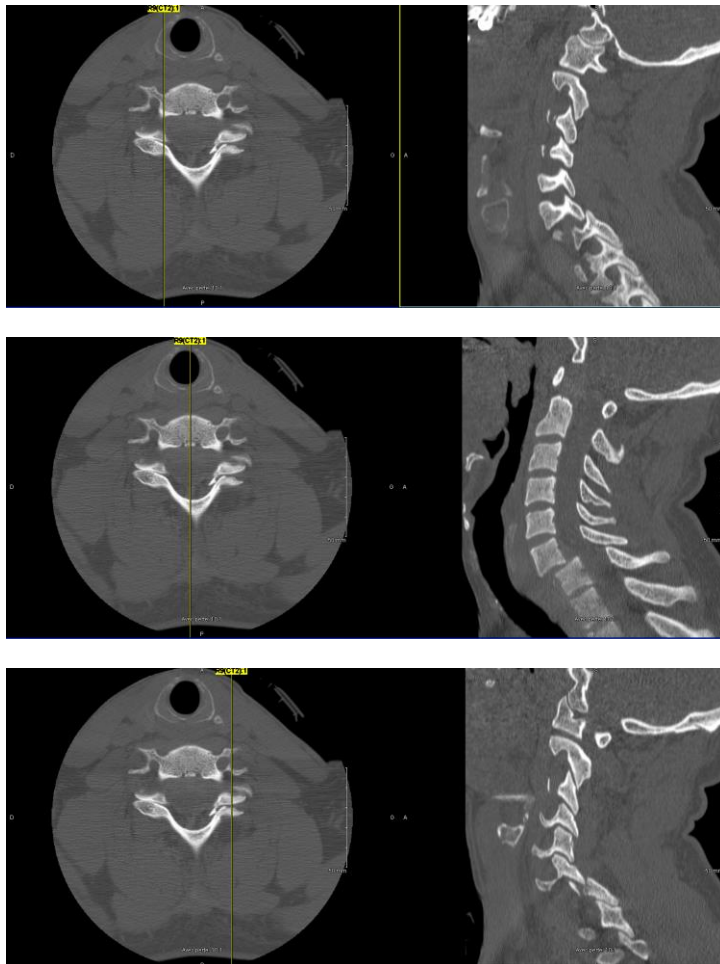
# CERVISION

*Optimize and simplify your cervical spine surgery*

## Case example

- 30 years old male
- Motor vehicle accident
- C6-C7 fracture-dislocation
- Complete C6 tetraplegia

### Preoperative CT scan



### Preoperative MRI





### STEP 1: Immobilize the head and place chin strap



The installation guidelines are the same whether the patient is prone or supine.

### STEP 2: Attach buckle to base of operating table



May be attached anywhere level with or below patient's shoulders (as made possible by the buckle)



### STEP 3: Place arm cover under arm



Respect table and arm direction as indicated inside.

For the PRONE POSITION: Thumbs down 👎

For the SUPINE POSITION: Thumbs up 👍

### STEP 4: Fold arrow 1



Respect table and arm direction as indicated inside

### STEP 5: Enclosing the arm



Secure arms while allowing IVs sufficient room

### STEP 6: Enclosing the shoulder



Firmly press all Velcro connections (note that neck strap to be placed under the patient may be already positioned beneath patient as observed here)

### STEP 7: Repeat for 2<sup>nd</sup> arm

PRONE POSITION



SUPINE POSITION



### STEP 8 and 9: Place front and back neck straps

PRONE POSITION



SUPINE POSITION



Front and back neck straps serve to stop the shoulder straps from moving laterally.  
Position and adjust accordingly to tighten the shoulder straps medially.

\*Note: some prefer to position the back neck strap before installing the second cover and then secure it prior to enveloping the arm. Alternatively, the arm covers and the back neck strap may be positioned prior to placing the patient on the table.





### STEP 10: Place arm strap maintaining the iliac crest exposed

PRONE POSITION



SUPINE POSITION



\*Note: Arm strap serves to maintain the position of the arms (stops lateral movement)

### STEP 11: Anterior and posterior positions— leave straps accessible for adjustment during surgery



To increase tension, pull straps



To reduce tension lift tensioner



Arterial lines are easily accessible, protected, and remain uncompromised during positioning.

\*Note: Scissors can be use to create openings in the arm sleeve if needed.

Method	Conventional (Tape, arm wraps or multi-axis arm positioner, and wrist straps)	CERVISION
Set up	10 minutes	<b>3 minutes</b>
Adjustment for x-ray	3-5 minutes (must wait for orderly)	<b>none</b>
Problems and complications	Tape burn, tape tear or non-adherence	-
	Insufficiently draws shoulders caudally	
	Limited access to arm after final positioning	
	Occluded IVs or arterial lines	
	Exposes orderly to radiation	
	Jeopardizes sterile environment	
	Inconsistent control of traction (repeat x-rays required)	
	Need for arm board or support (cumbersome for surgeons and C-arm)	
<b>Total Cost/case</b>	<b>\$535-915</b>	-
Material Cost	\$15	-
OR Cost ( \$40-60/minute)	\$520-900	-

## Results of clinical testing

The **CERVISION™** is a simple and effective apparatus to comfortably position and maintain a patient's shoulders and arms.

1. Reduces surgery time
2. Works with anterior or posterior positioning
3. Provides consistent and accurate x-rays of the cervical spine
4. Precludes need for repeat x-rays
5. Improves working proximity to patient
6. Installs safely and easily on all hospital beds
7. Conforms seamlessly to surgical environment (IVs, EKG leads, and reveals iliac crest for possible autograph)
8. Intraoperative adjustability
9. Improves patient comfort
10. Disposable



For more information and to place an order please contact Spinologics Inc.

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