SPINOLOGICS

Leading the development of improved spinal care™

CERVISION™

Indications For Use (IFU)

2017-08-17

CONCEPT

DESIGN

PRACTICE

SPINOLOGICS

www.Spinologics.com
Boul. Crémazie Est, Suite #630
Montréal, QC, H2M 2V1
Canada
T +1.888.988.2747
F +1.888.988.2747

DESIGN TEAM AND FOUNDERS

Hubert Labelle, M.D.

Full Professor, Department of Surgery, Faculty of Medicine, University of Montreal
Orthopedic surgeon, CHU Sainte-Justine University Hospital.

Stefan Parent, M.D., Ph.D.

Associate Professor, Department of Surgery, Faculty of Medicine, University of Montreal
Orthopedic surgeon, CHU Sainte-Justine University Hospital
Orthopedic surgeon, Hopital du Sacre-Coeur de Montreal

Jean-Marc Mac-Thiong, M.D., Ph.D.

Assistant Professor, Department of Surgery, Faculty of Medicine, University of Montreal
Orthopedic surgeon, Hopital du Sacre-Coeur de Montreal
Orthopedic surgeon, CHU Sainte-Justine University Hospital

Mark Driscoll, P.Eng., Ph.D.

Active member, Order of Engineers of Quebec
Active member, Intellectual Property Institute of Canada

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.

Spinologics Inc.
545 boul. Crémazie Office #630, Montreal, QC, Canada, H2M 2V1
www.spinologics.com, info@spinologics.com, 1-888-988-2747

CERVISION

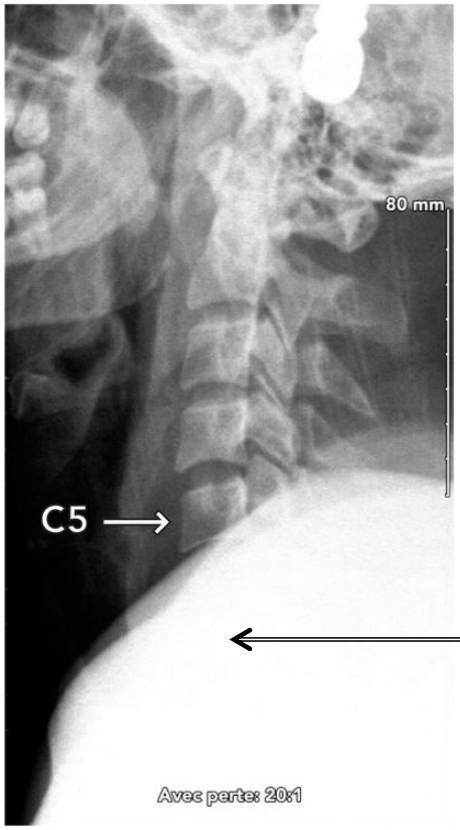
Optimize and simplify your cervical spine surgery

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

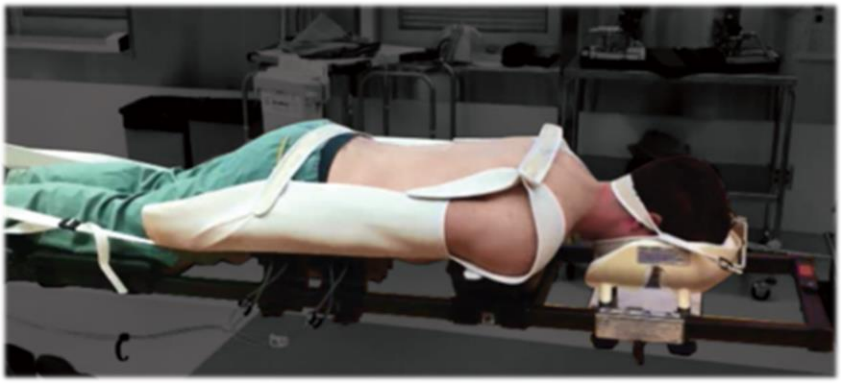
Provides consistent and accurate x-rays of cervical spine - precludes need for repeat x-rays and positioning delays

Area of interest

Gardner-Wells tongs
30 lbs traction
+
CERVISION™

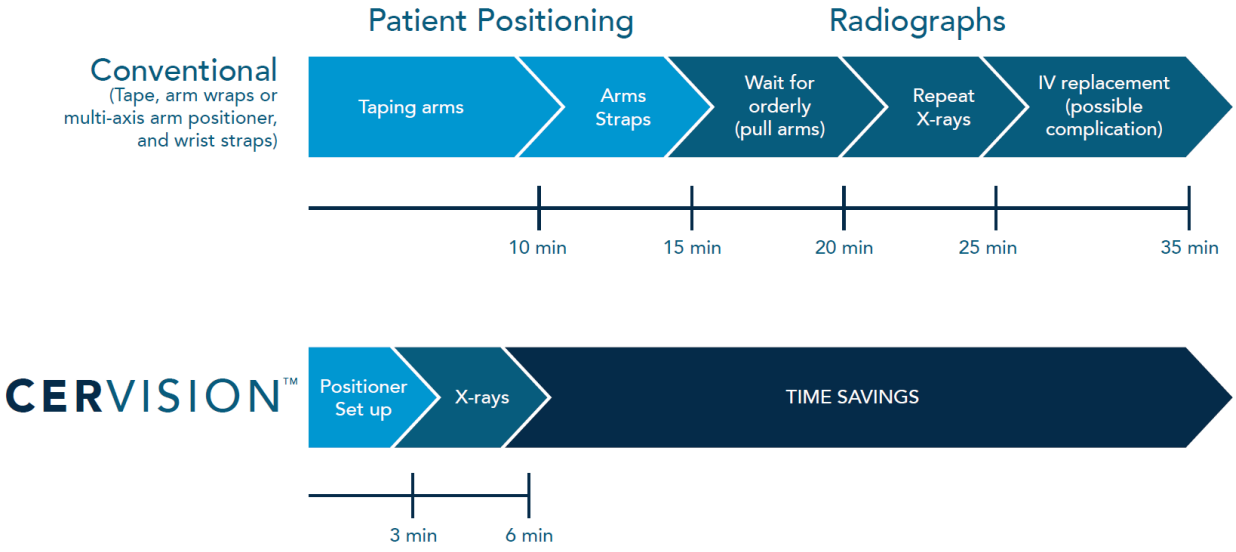
CERVISION

Optimize and simplify your cervical spine surgery



Prone position

Supine position



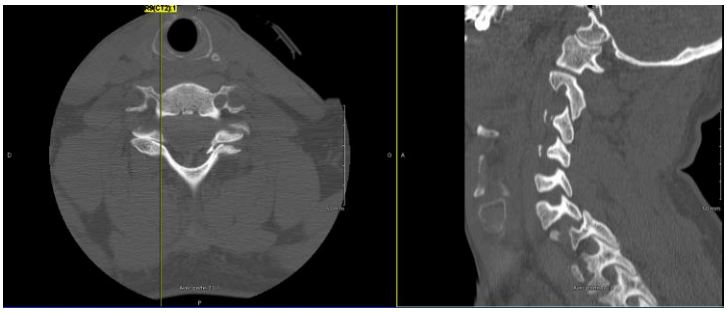
CERVISION

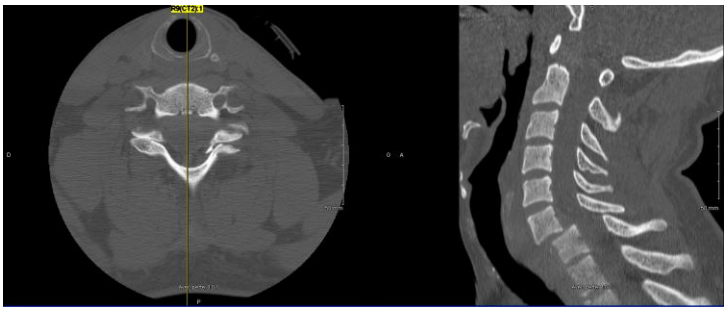
Optimize and simplify your cervical spine surgery

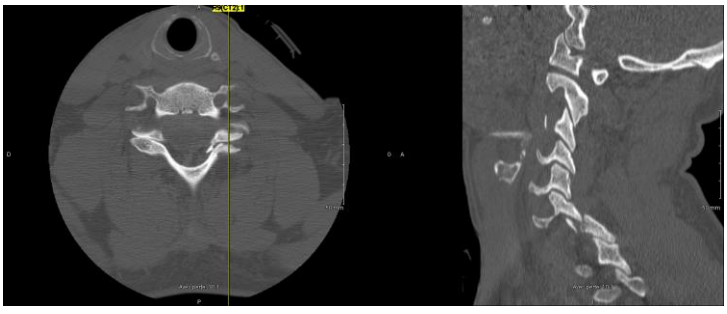
Case example

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

Preoperative CT scan







Preoperative MRI

STEP 1: 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 2: Place arm cover under arm

Respect table and arm direction as indicated inside

STEP 3: Fold arrow 1

Respect table and arm direction as indicated inside

STEP 4: Enclosing the arm


Secure arms while allowing IVs sufficient room

STEP 5: 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 6: Repeat for 2nd arm


STEP 7 and 8: Place front and back neck straps

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

*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 9: Place arm strap maintaining the iliac crest exposed

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

STEP 10 (optional): Place chin strap

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

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.

Method	Conventional (Tape, arm wraps or multi-axis arm positioner, and wrist straps)	CERVISION
Set up	10 minutes	**3 minutes**
Adjustment for x-ray	3-5 minutes (must wait for orderly)	**none**
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)	
Total Cost/case	**$535-915**	-
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 maintains 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.

1-888-988-2747
info@spinologics.com

SPINOLOGICS
545 boul. Crémazie
Office #630, Montreal
QC, Canada
H2M 2V1
1-888-988-2747
www.spinologics.com
info@spinologics.com