



Exersides Refrains System





Multiple levels of Refrains, restraint, resistance exercise & freedom safely match patients' everchanging condition to comply with CMS mandate of 'Least Restraint Necessary'!



Unlike Wrist Restraints

No Head-to-Hand for self-extubation; Loosens with edema

Unlike Mitts

Easy access to and visualization of Hand. No squeezing mitts together to self-extubate

PADIS GUIDELINES

Devlin JW, Skrobik Y, Gélinas C. et al. Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU. Crit Care Med. 2018 Sep;46(9)

RECOMMENDATIONS: ... studies...paradoxically report higher rates of the events that their use is intended to prevent. These events include more unplanned extubations and frequent reintubations; greater unintentional device removal; longer ICU LOS; increased agitation; higher benzodiazepine, opioid, and antipsychotic medication use; and increased risk for delirium or disorientation.

Patients' perceptions...provoke strong emotional responses that persist after the ICU stay. Given the prevalence, unintended consequences, and patients' perceptions of physical restraint use, critical care providers should closely weigh the risks...before initiating or maintaining physical restraint use. Although certain countries report a "restraint-free" ICU environment, it may be possible that their use of bedside sitters and/or pharmacologic restraints is increased.

ACCM Clinical Practice Guidelines

Maccioli, GA, Dorman, T, Brown BR. Clinical practice guidelines for the maintenance of patient physical safety in the intensive care unit: use of restraining therapies--American College of Critical Care Medicine Task Force 2001-2002. Crit Care Med. 2003 Nov;31(11):2665-76.

RECOMMENDATION: The choice of restraining therapy should be the least invasive option capable of optimizing patient safety, comfort, and dignity.

Refraint™ & Guidelines

Exersides™ allows compliance with PADIS Guidelines & ACCM recommendations. With Exersides, you can easily minimize patient restraint and sedation AT ALL TIMES to ensure patient and staff safety.

In The News

WSJ: How to Minimize Permanent Mental Trauma from an ICU Stay	Mar 2, 2018
PBS News Hour: Why a stay in the ICU can leave patients worse off	Jun 16, 2017
NY Times: Nightmares After the I.C.U.	July 22, 2013

Pilot Study Results

Rutland Regional Medical Center, Vermont

April 2017

Results:

Less sedation, more mobility, more interaction, better SAS scores

Questionnaires:

Patients, Family and Staff reported better satisfaction with Exersides™ than traditional restraints

Patients using the *Exersides™* restraint alternative required less sedation, had better agitation scores, and spent more time moving and interacting than patients using wrist restraints.

n=10	Pre-study propofol (mcg/kg/hr)	During study propofol (mcg/kg/hr)	SAS *	Time spent moving (hrs)	Time spent interacting (min)
Traditional wrist restraints	26±18.2	20±11.7	3.2±0.4	0±0	2.2±4.4
<i>Exersides™</i> Refraint© System	28±8.4	11.2±10.0	4±0.7	2.6±1.6	66±73.8

*Sedation-Agitation Scale; 1=comatose, 4=calm and cooperative, 7=dangerously agitated

Clinical Trial

University of Vermont Medical Center 2018

Pilot Safety And Feasibility Study Of A Novel Restraint Device In Critically Ill Patients With Acute Respiratory Failure.

Benjamin H. Lin, Biren B. Kamdar, Marie T. Pavini et al. 2019

Subjects: Adult intubated ICU patients

Results:

Safe No tube/line removal; no device removal

Well-accepted by patients, family and staff

Feasible to measure Phase II outcomes

	Day 1 (n = 7)		Day 2 (n = 4)	
	Exersides™	Traditional Restraint	Exersides™	Traditional Restraint
Time in restraint (mean hours ± SD)	4.0±0.6	2.1±1.9	1.8±2.1	3.8±1.2
Wrist activity level, median (IQR) ^a	59 (16-177)	92 (24-213)	92 (28-213)	77 (22-206)
RASS sedation score (mean ± SD) ^b	-1.5±1.8	-0.5±1.8	-0.6±1.5	-1.7±1.2
CAM-ICU delirium (n) ^c	1	1	1	1
Satisfaction with Exersides™ (mean ± SD) ^d	3.3±0.7		3.8±0.4	

^a Represented as median (IQR) number of non-zero movements per 30-second epoch, as measured using bilateral wrist actigraphy. Left and right wrist data combined.

^b Richmond Agitation-Sedation Scale (RASS)

^c Confusion-Assessment Method (CAM-ICU)

^d Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) device subscale, higher score is better with a range from 1 (not satisfied at all) to 5 (very satisfied)

RESEARCH

Delirium and Restraints

Precipitating Factors for Delirium in Hospitalized Elderly Persons Predictive Model and Interrelationship With Baseline Vulnerability Inouye SK, Charpentier PA, *JAMA*. 1996;275(11):852-857

- ❖ **RESULTS:** ...independent precipitating factors for delirium... : use of physical restraints (adjusted relative risk [RR], 4.4; 95% confidence interval [CI], 2.5 to 7.9)

Predictors of Physical Restraint Use

Luk E, Sneyers B, Rose L. Predictors of physical restraint use in Canadian intensive care units. *Crit Care*. 2014;18(2).

- ❖ **RESULTS:** Restrained and never-restrained patients had similar baseline characteristics... however, restrained patients were agitated and over-sedated...more...

Early Mobilization and Restraints

Koo KK, Choong K, Cook DJ, et al. Early mobilization of critically ill adults: a survey of knowledge, perceptions and practices of Canadian physicians and physiotherapists. *CMAJ Open*. 2016 Aug 18;4(3).

	All clinicians (n=311)	Physicians (n=194)	Physiotherapists (n=117)
Patient barrier			
Physical restraints	64 (20.6%)	50 (25.8%)	14 (12.0%)
Excessive sedation	187 (60.1%)	112 (57.7%)	75 (64.1%)

Costa DK, White MR, Ginier E. Identifying barriers to delivering the ABCDE bundle to minimize adverse outcomes for mechanically ventilated patients: A systematic review. *Chest*. 2017 Aug;152(2).

- ❖ **RESULTS:** Perceived patient barriers to early mobilization in the intensive care unit: Patient and staff safety concerns

RESEARCH

Mehta S, Cook D, Devlin JW, et al for the SLEAP Investigators and the Canadian Critical Care Trials Group. Incidence, risk factors and outcomes of delirium in mechanically ventilated adults. Crit Care Med. 2015 Mar;43(3):557-66.

- ❖ **RESULTS:** Restrained patients had: Lower APACHE II mean scores; More delirium; More device removal; More reintubation; All statistically significant

PICS and Post-Traumatic Stress

Rotondi, A J. Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. Crit Care Med. 2002 Apr;30(4):746-52.

- ❖ **RESULTS:** 44.8% remembered being restrained; 86% of those were moderately to severely bothered by it.

Hatchett C, Langley G, Schmollgruber S. Psychological sequelae following ICU admission at a level 1 academic South African hospital. South Afr J Crit Care. 2010 Nov;26(2).

- ❖ **RESULTS:** An unexpected finding of this study was that patients who had memory of physical restraints in the ICU were six times more likely to develop symptoms of PTS than those with no memory of physical restraints.

Bassi E, Ceresola M. Use of physical restraints in adult ICU patients to prevent patient-initiated device removal: a systematic review. Università di Bologna Facoltà di Medicina e Chirurgia Master in Evidence Based Practice e Metodologia della Ricerca Clinico Assistenziale. Relazione di fine Master di Bologna. 2011 Oct.

- ❖ **RESULTS:** One third or more of the self-extubation events occurred despite use of wrist restraints leaving the effectiveness of physical restraints an unresolved issue... as it can heighten agitation and may have devastating physical and psychological effects on the patients.

Sedation and Physical Restraints

Mehta S, Burry L, Cook D, et al. Daily Sedation Interruption in Mechanically Ventilated Critically Ill Patients Cared for With a Sedation Protocol: A Randomized Controlled Trial. JAMA. 2012;308(19):1985–1992.

- ❖ **RESULTS:** Daily sedation interruption is associated with more restraint use (OR 1.84, 95% CI 1.27, 2.67)

COSTS

Delirium: \$4B-\$16B/year in US

Pressure Injury: \$17.5k/ulcer

Pulmonary infectious complications: \$17k/incident

Sedation costs: \$50/day/intubated patient

Encephalopathy: \$11k/incident

Unplanned extubations: \$35k each

Sitter Costs: \$160/shift

Readmission: \$11.2k/readmission

Tracheostomy hospital costs: \$10k-150k

PICS readmission costs: \$26k/5yrs/patient

Ventilator Days: \$1.5k/day

ICU Days: \$4k/day if intubated

Hospital Days: \$1.5k-2k/day

Strategy to assess cost savings: Track above complications.

COSTS

RN/LNA cost to use assuming 5 days in restraints:

Wrist Restraints: 1 minute to don pair/30 secs to doff; 2 minutes qshift to remove to check wrist IVs, a-lines and to deal with edema/skin integrity issues = 31.5 minutes

Mitt Restraints: 1 minute to don pair/30 secs to doff; 2 minutes qshift to check back of hand IV, FSG, p.ox, hand edema, skin integrity, circulation, 1 minute to replace (if untied) when patient self-removes restraint or ETT/feeding tube= 36.5 minutes

Sleeve restraints: 1 minute to don pair/30 secs to doff; 1 min q hour to remove pair to check skin, IVs, clean arm and use BP cuff; 1 min to replace when patient self-removes = 126.5 minutes

Exersides™: 1 minute each to don each/ 30 secs to doff pair; no time to check IVs, a-lines, p.ox, FSG, circulation, skin integrity, edema, or to reposition patient = 2.5 minutes

RN training

This should not require extra staff since we will train super-users. Training can be done remotely and can be scheduled to maintain appropriate patient care staffing ratios.

Product change-over costs:

You will likely maintain some of your current restraints. Therefore there should be no product change-over costs.

Payor mix:

Your payor mix for restraints will depend on whether you list Exersides™ as a line item or as part of the room charge, in which case it is the payor mix for your entire hospital.

Effort toward recognition for Magnet Status financial benefits:

Major bonus! We can provide references and trial results for your documentation and pitch.

Exersides Price:

Exersides can be purchased as re-usable or single-patient use. Contact us for a specific Price List. Ongoing education and support is FREE with a contract.

Exersides™ is a tremendous cost savings over traditional restraints given the billions of hospital dollars spent on pressure injury, sedation and immobility complications, readmission etc.

FAQ

Is Exersides disposable or reusable?

Exersides™ comes in a single-use form and a re-usable form with disposable soft kits. They can be cleaned quickly and easily with traditional ICU cleaning wipes and sprays or in a sterilizer.

How do you store Exersides?

The reusable portion of Exersides™ can be cleaned and stored with other hospital supplies. If needed for the same patient, they can be easily cleaned with your traditional ICU cleaning wipes and sprays. Disposable Soft Kits can be reapplied to the cleaned frame.

What about documentation?

We provide language that supports your decision to define the Exersides Refrains as a non-restraint when not attaching the restraint strap. Attaching the optional restraint bed strap is considered restraint and requires the same documentation as for traditional restraints.

Can Exersides™ affect our MIPS score? Or my Press-Ganey score?

Yes. In our Pilot Study, questionnaires revealed a greater satisfaction by patients and family (as well as staff). These *satisfaction* scores will boost reimbursement. Another point to consider is the anticipated reduction in the *complications* of sedation and prolonged length of stay when calculating those reimbursement allowances.

Can Exersides™ go in an MRI?

Yes.

Is Exersides™ latex-free?

Yes.

When do I use Exersides™?

Exersides™ can be used with intubated as well as delirious or dementia patients.

FAQ

Is Exersides™ for both arms?

Yes. This is best for mobility and safety.

Why is Exersides™ bigger?

Sometimes bigger makes your job easier. Keep in mind, overhead lifts and stand assist devices replaced gait belts!

How do you use Exersides™?

1. Minimize Sedation
2. Minimize Restraint: No Bed Strap > Exercise Strap > Rigid Strap
3. Repeat

Can Exersides™ be removed emergently?

Exersides™ removes in a few seconds although it does not need to be removed for CPR.

How do you put it on a patient?

1. Place hand in Wrist Strap and buckle. Snap hand shield in place.
2. Adjust Arm Rod Length using latch lock.
3. Adjust and buckle Shoulder Strap.

Who can I contact with questions?

Email us at hello@exersides.com or call us at (802) 821-1002.

Refraint™





A ‘No-Tie Zone’

Exersides™ is based on the concept of “Refraint™,” which refers to the least restraint necessary including a ‘no-tie’ configuration.

While it may seem counter-intuitive, agitated patients may actually do better with less restraint. In many cases, their agitation stems from the sensation of being restrained. Once the restraints are reduced or removed, agitation can actually be reduced, leading to a **calmer** patient.

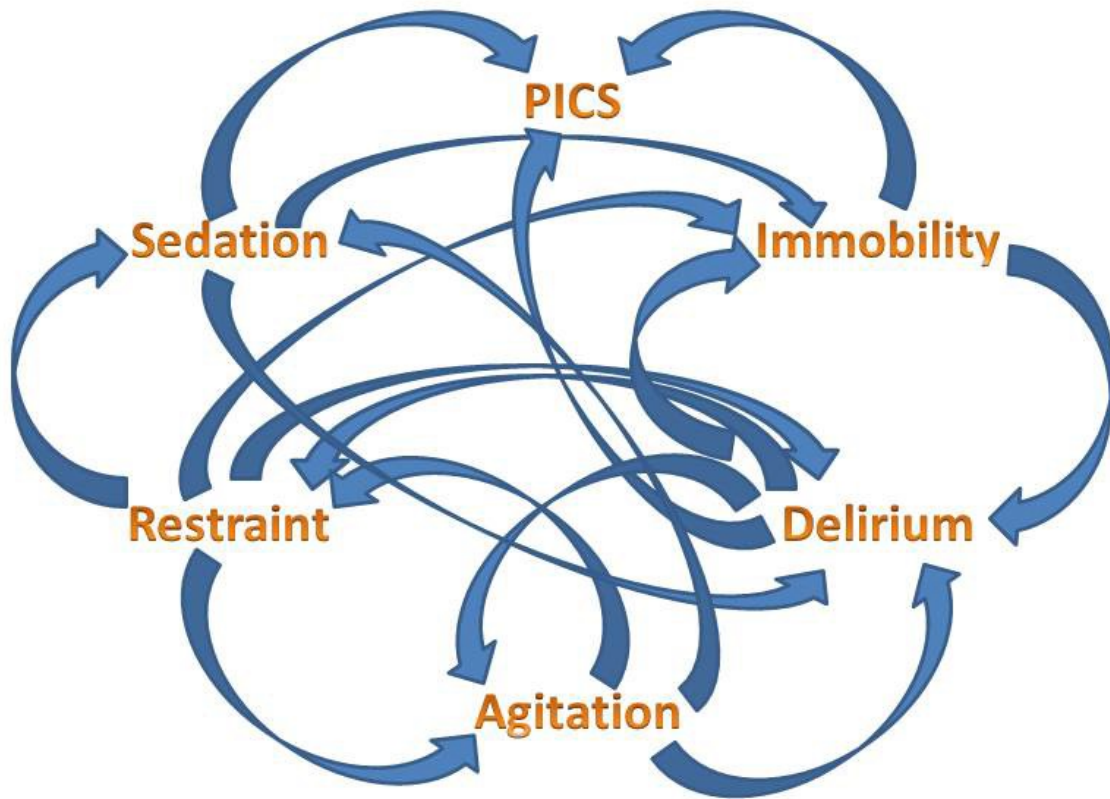
Of course patients and staff must be **safe**. That’s what’s great about Exersides™. With the exercise strap or no strap, safety is designed into the Refraint™.

The concept of Refraint™ is supported by several initiatives designed to improve critical care, including:

-  *ERAS: Enhanced Recovery after Surgery*
-  *ICU Rehab*
-  *ABCDEF Bundle for ICU*
-  *PICS Initiatives*

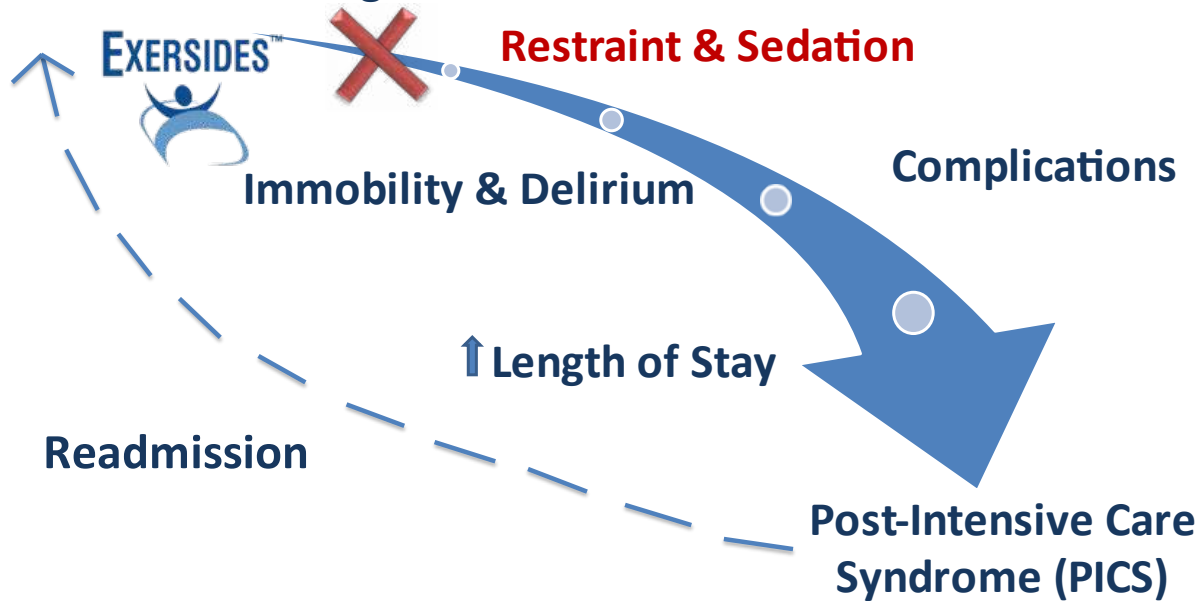
What’s so bad about traditional restraints?

Traditional restraints can create a downward spiral leading to delirium, ICU-acquired weakness and culminating in Post-ICU Syndrome. The SPIDAR Web below illustrates that Sedation, PICS, Immobility, Delirium, Agitation and Restraints are all intertwined like a web, each one connected with another by published data.



SPIDAR web[©]

Confusion & Picking at IVs



Refrain™ & Sedation Minimization

How do I minimize sedation AND restraint?

First minimize sedation (chemical restraint) to a comfortable level for the patient that allows the most interaction or non-agitated movement. Then, select a level of restraint, or Refrain™, to match the patient's predictability for safe arm movement. Repeat this process until both sedation and restraint are completely minimized and the patient can safely move.

Do I need extra sedation for Exersides™?

Definitely not. The purpose of Exersides™ is to promote non-agitated movement. You may find that if a patient is allowed to move, they may be less agitated and therefore require less sedation. Try it!

Do I need a sitter for Exersides™ if the patient is not sedated?

No. As long as the nurse chooses an appropriate Exersides™ configuration based on the predictability of the patient, safe arm mobility is possible.

We don't use restraint – only versed, morphine and fentanyl.

Newsflash: Those are sedating and considered chemical restraint. That said, patients may need some amount of sedation to have non-agitated predictable safe arm movement. Challenge yourself and see how low you can go.

Do I need to stop all sedatives to use Exersides™?

No. Some patients do not require any sedation ever and some do. If patients are allowed to move, they may require less. Always minimize.

What happens if the patient becomes agitated and moves too much?

Agitated movement is not good. It is better to find the least amount of sedation required by the patient than to select the next more restrictive level of Exersides™. Minimize sedation first, then minimize restraint.

Refraint™ & Early Mobilization

How early is ‘Early’?

Some hospitals wait 2 days before mobilizing patients! Exersides™ allows mobilization the MOMENT the patient is able.

How often should I mobilize my patient?

Many patients only receive physical/occupational therapy sessions for 1/2 hour per day! Exersides™ allows movement 24 hours per day at the patient’s own pace.

Who is needed to mobilize a patient?

Most hospitals require a Physical Therapist, Occupational Therapist, Respiratory Therapist, and a Nurse or LNA to mobilize patients. Exersides™ allows patients to move themselves and perform their own Active Range of Motion!

Is Early In-Bed Mobilization safe?

Certainly, but nursing judgement is required to assess a patient’s readiness for safe movement. Fortunately, there are several levels of mobility to choose from and you will find one that is right for you and your patient.

Can Family be involved?

Most definitely! We believe it is healthy for family members to be involved in the healing process of their loved one. You may want to provide a general guideline for family to make the most of this precious asset.

The Exersides Refraint System™ principles are supported by Surgeons, Intensivists, Psychiatrists and Therapists. SCCM & CMS Guidelines recommend what only Exersides™ offers.

EXERSIDESTM



not restraint...
RefrainTM