

Instructions For Use

Indications for Use

Patients assessed to be at risk of entanglement in vital interventions such as vascular access lines or breathing equipment.

Caution

Federal law restricts this device to sale by or on the order of a Licensed Practitioner.

Manufacturer

Healthy Design Ltd. Co. 13 Willow St Rutland, VT 05701

Phone: (802) 821-1002



Contraindications and Precautions

Contraindications: DO NOT USE if prone, upper limb injury, or if an IV or wound site could be compromised by the device.

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

Warnings & Precautions:

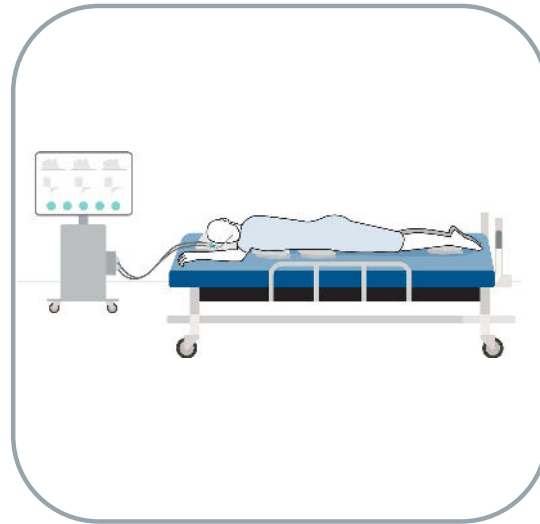
- Assure device has restraint level commensurate with ability for harm.
- Patient struggling in device may cause skin damage.
- Keep lines and tubes from tangling in device.
- Keep equipment out of reach.
- Attach bed and endotracheal tube alarms to monitor patient.
- Do not stand within arms' length of the device if wearer is flailing.
- Device contains hard surface which can cause injury or damage. Assure patient comfort and protection.
- Clean with your institution-recommended EPA-registered cleaners specific for patient infection profile.
- Use Universal Precaution.
- Assure that device is securely assembled prior to usage.
- Dispose of soiled soft goods using Universal Precautions according to your institution's recommendations.
- Restricting movement may cause emotional or physical injury. Consult a Licensed Independent Practitioner.
- Do not apply if patient arm is compressed at device Arm Tube e.g., obesity, deformity.

Storage Requirements: Do not store in direct sunlight. Store in temperatures between 12-24°C / 55-75°F. Hand Shields store flat. Maintain integrity of packaging. Do not remove labels.

DO NOT apply Exersides[®] Refraint[®] if patient



is aggressive
or combative



is prone



has fracture

Before applying Exersides[®] Refraint[®]



cover at-risk skin



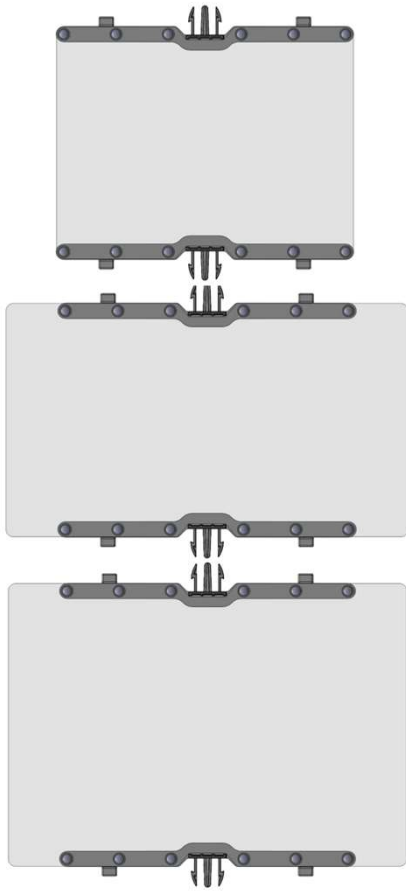
move equipment
out of reach



secure bed and
endotracheal tube alarms

Inspect device for damaged or missing parts.

Application



Choose Hand Shield

Regular: Standard size

Long: Longer hands

Tall: A-line protection
and dressings



Buckle Exercise and Restraint Bed Straps to bed frame.

KEEP IN MIND:

The Bed Straps must not be connected to a moving part such as a bed rail.

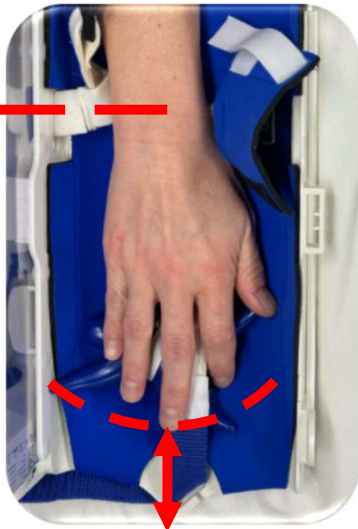


Place pillow under patient elbow.

KEEP IN MIND:

If the pillow is not in place, the Wrist Strap may pull on the wrist.

Place patient hand onto Hand Rest to secure wrist.



Align wrist with lateral slot.
Middle finger tip at least
1.5" from frame edge.



Buckle at back of hand.
Pad should be under Buckle.



Close pad
around buckle.

Application



Place nearby vascular lines and cords in Wrist IV Holder.

Assure lines are secure and not compressed.

Application



TheraPete™ slides along Wrist Strap by reversing Therapete tab and can be attached/detached. Place TheraPete™ in patient palm.

A remote, phone or nurse call button may also be placed in patient palm. 10



Assure strap wraps around smallest portion of wrist. Strap through loop towards thumb.

Slide 11

ECO

Remove slide? L/R tags

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Remove slack from Wrist Strap



pull strap



wrap around and stick



close tabs to secure

Assure no tension at wrist.

Application



With patient's arm temporarily straight, open arm tube latch to extend tube and angle shoulder plate flat to Deltoid. Close latch. Note markings on arm tube for sizing.

KEEP IN MIND:

Final arm tube length should allow slight elbow bend while no tension at Wrist Strap.

Place IVs and cords in Latch Pad IV Holder.

Application



Click Hand Shield prongs into Frame holster.

Assure hand cannot reach outside Hand Shield. If so, use Long Hand Shield.

KEEP IN MIND:

Nurse call/ TV remote/ cell phone may be placed inside Hand Shield.

Application

Wrap Axillary Strap under Axilla and upward to close in place.

Attach firmly.

Assure the Axillary Strap is loose enough to slide hand between strap and Axilla but no looser.



1



2



3

Secure Axillary Strap



Insert upper tab into
Shoulder Plate loop.



Join Axillary
Strap tabs



Secure lines in
IV holder.

Axillary Strap may appear loose near Shoulder Plate but may not at Axilla.

ABC Check

A

AXILLA

Assure Axillary Strap is not too tight.

Your fingers can slide between strap & Axilla.

Check lines through Axillary Strap holder.

B

BEND

Readjust as needed to assure some elbow bend.

Note size number on Arm Tube.

Check lines through Latch Pad holder.

C

CIRCULATION

Assure adequate circulation to hand.

There should be no tension at the wrist from strap.

Check lines through Wrist Strap holder.

OPTIONAL: Choose Exercise or Restraint Strap



For resistance exercise, use white strap. Insert strap upward through Frame side loop.



Secure hook & loop together firmly.



To convert into a restraint, use blue strap.

KEEP IN MIND: Exercise Bed Strap may be considered a restraint, if used as a means of reducing mobility rather than for resistance exercise.



Unclip Hand Shield prongs to open.

Lift Hand Shield for patient care.

Application



Hand Shield can remain open by clipping prongs into outer holster.

Application



LuciLoop

Apply to verticalized or seated patients to relieve any tension at the wrist.

1. Position blue neck pad at back of neck.
2. Insert closed tabs through Shoulder Plate loops.
3. Attach open black tabs onto strap to size.

Removal Process



Remove IVs from all IV holders.



Open shield and unbuckle Wrist Strap.



Detach Axillary Strap.

Removal Checks



Free IVs and cords at

- wrist
- elbow
- shoulder



Take care not
to entangle Ivs.



Unclip bed straps.

Turning Patients



Loosen or remove bed straps from bed frame prior to turning patient.

Keep bed straps connected to the Refraint[®] to maintain control of extremities if needed.

Lower the upper bed rail on the side that patient is turning towards.

Do NOT roll patient onto the Refraint[®].





Temporarily position arm to the side with pillow support.

Turn patient toward this side.

KEEP IN MIND:

Place sheet or blanket barrier if catheters, tubes or drains are exposed.



Do not leave upper arm in excessive extension.

Do not stack Refraints[®] on top of each other.

Turning Checks

Adjust arm position for comfort, using pillows as needed.

Tighten or reattach bed straps as appropriate.

Raise siderails as needed per your organization's policies.

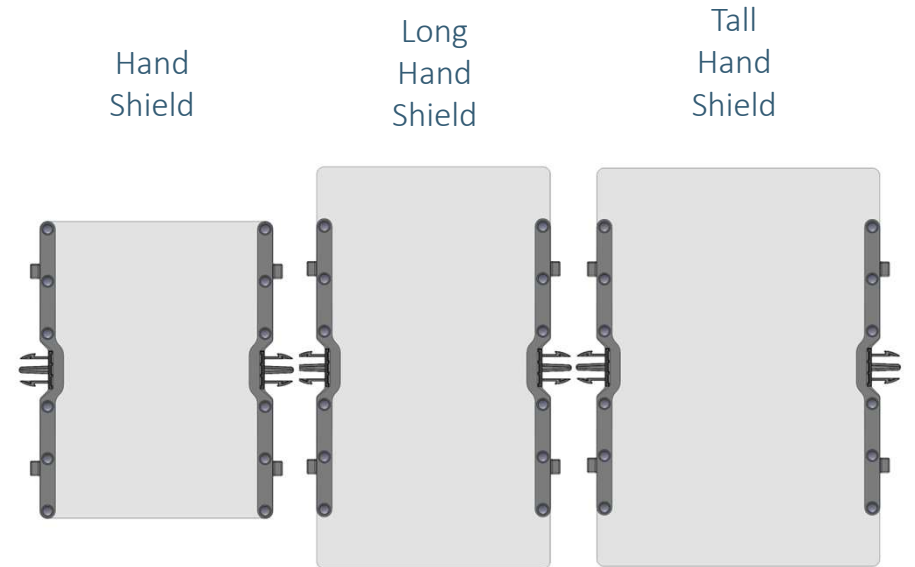
KEEP IN MIND:

Four siderails may be considered a restraint.

Assembly

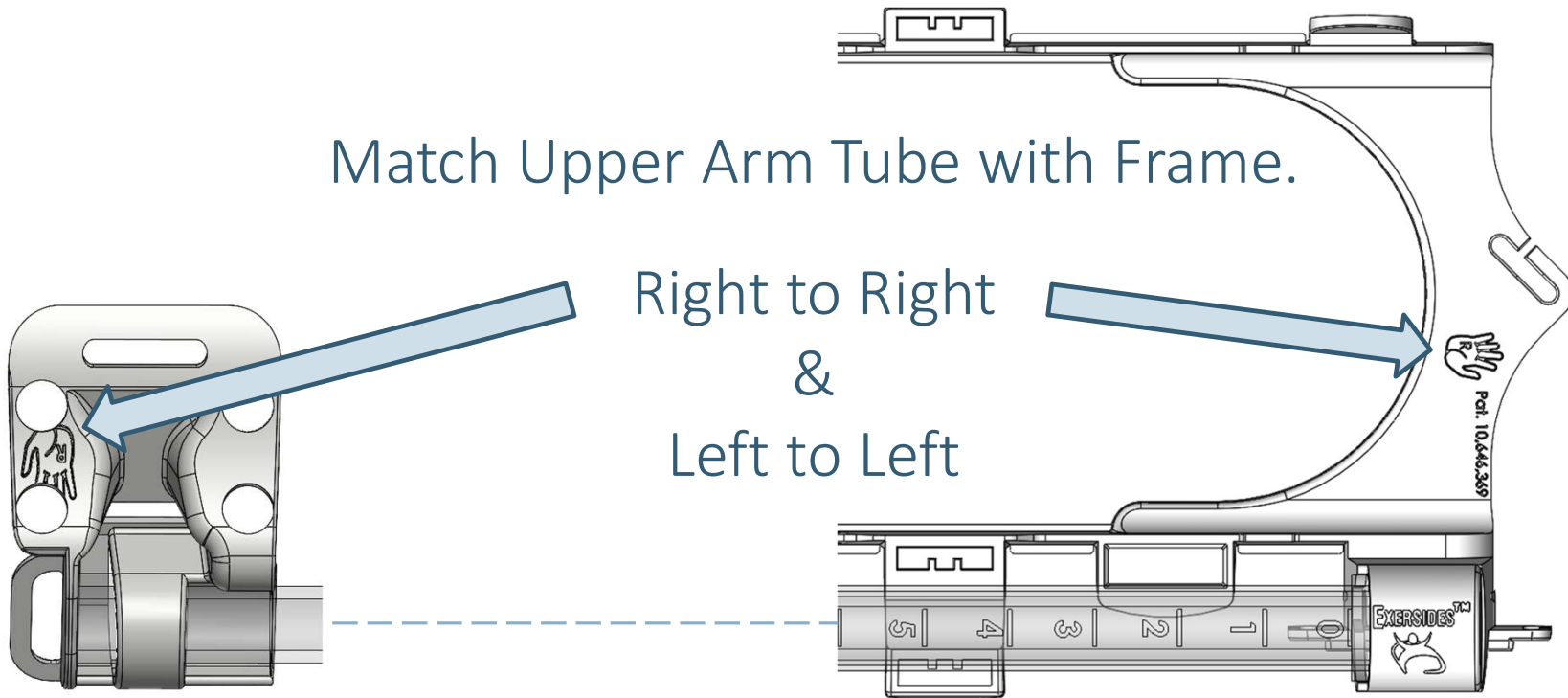


PARTS



Match Upper Arm Tube with Frame.

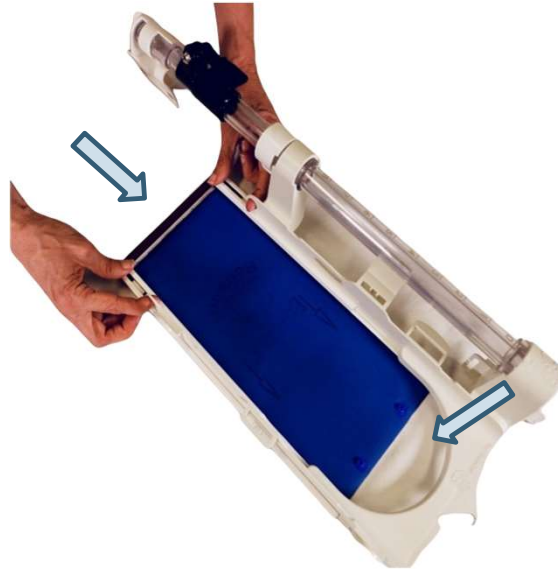
Right to Right
&
Left to Left



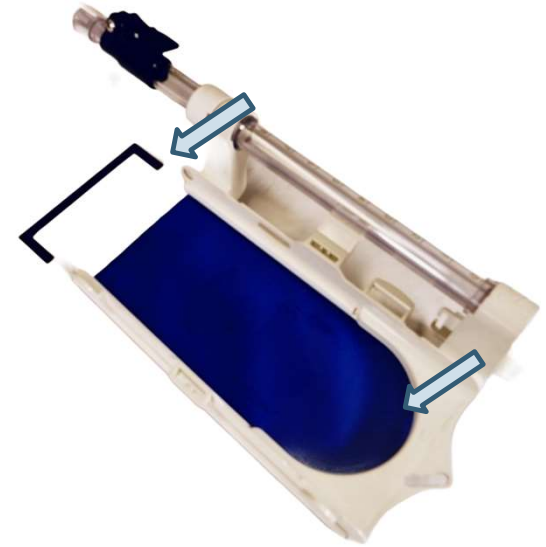
Assembly



Place Frame
into Fabric Base tracks.



Push to slide
Fabric Base fully onto Frame.



Discard guide once
Fabric Base is in place.

Slide Fabric Base tracks onto Frame.

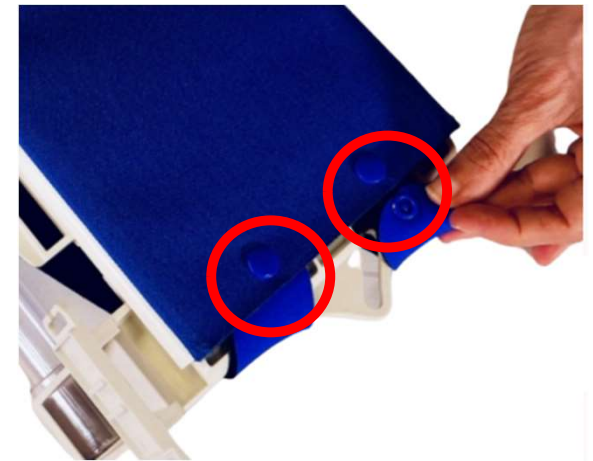
Attach Hand Rest Pad



Place Hand Rest Pad over Fabric Base.



Snap Hand Rest Pad through Frame snap holes.



Snap Hand Rest Pad onto Fabric Base.

Attach Wrist Strap



Insert clasp through side slot.



Slide adjuster onto inside side plate prongs.



Slide strap through front slot & side plate prongs.

KEEP IN MIND:

Left and right tags are included on wrist straps to match with left and right Frames.

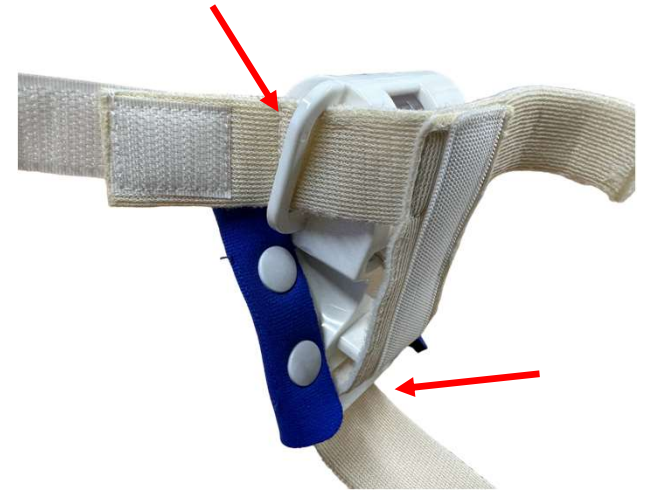
Secure Axillary Strap and Shoulder Pad



Snap Shoulder Pad onto Shoulder Plate.



Insert clasp through slot.



Insert Axillary Strap through slots. 33

Finished Device



Keep LuciLoop and Hand Shields with unit.
Optional: Attach Hand Shields into Frame holsters.

To clean Refraint[®] Frame, follow your institution's cleaning protocols for non-critical equipment.



Device must be completely dry before replacing soft materials.



Do not place device on heaters, radiators, or other hot surfaces to speed drying. Do not use hair dryer to speed drying.

Do not use abrasive cleaners.

KEEP IN MIND:

Device may be cleaned for SAME PATIENT ONLY.



Store in temperatures
between

12°C-24°C
55°F-75°F

Store Hand
Shields flat.

Slide 37

ECO

Is 75 degrees accurate?

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Materials

Adhesives

Caseway SC-325 Polycarbonate Cement,
LocTite 401 Instant Adhesive 135430,
Temporary Adhesive Fabric Glue Stick

Hard Non-Porous Parts

PC-PBT w/ 20% Glass Fiber, PC-ABS, ABS,
Polycarbonate, Nylon, PVC, Stainless Steel,
Acrylic

Soft Porous Parts

Latex-Free Elastic, Polyurethane Foam,
Polyester, Neoprene, Nylon Fibers,
Polypropylene, Satin, Grosgrain

Markings

Water or alcohol based Ink, Chalk, Label

