Kinn™ Automatic Volume Management System Instructions For Use

Product Overview

The Kinn Automatic Volume Management System is a socket volume management system that features automatic volume adjustment and vertical shock. The Kinn system is attached to the distal end of the socket with a lamination plate or 4-hole adapter. Kinn contains a shock absorber that reduces vertical forces and activates the volume management mechanism through compression of the system. The volume management system's manual and automatic tensioning allow for active and passive socket fit optimization. The maximum tension setting can be adjusted per patient preference.

Note: Kinn is not a suspension system; it is a volume management system. The prosthetist must choose the appropriate suspension system for the patient.

Detailed Product Description

Vessl's Kinn system enables patients to have a prosthetic socket that automatically adjusts to the limb, providing comfort with every step. Engineered to adapt seamlessly to natural fluctuations in limb volume, the Kinn system ensures a stable and consistent interface pressure throughout the day. By actively managing volume changes, it enhances fit, reduces discomfort, and provides a reliable, worry-free prosthetic experience. For the prosthetist, this reduces redundant follow-up appointments and sock ply management education meetings, and focus on making more prostheses for more patients.

This kit seamlessly integrates the cutting-edge Kinn mechanism with a paneled socket system, resulting in a volumetric, automatically adjusting prosthetic socket that dynamically accommodates limb volume fluctuations. This advanced mechanism is engineered to automatically manage changes in limb volume, ensuring a stable and consistent interface pressure on the limb, regardless of gradual volume variations throughout the day.

The Kinn system features a vertical shock absorber designed to efficiently dissipate impact with each step, significantly reducing strain and enhancing overall comfort. Utilizing the kinetic energy absorbed from walking, the Kinn system powers its automatic volume adjustment mechanism, ensuring a precise fit. Designed for both function and aesthetics, it seamlessly integrates with the distal end of a paneled socket, providing a sleek, low-profile solution. By eliminating the bulky protrusions typically associated with adjustable sockets, the Kinn system delivers a streamlined, natural look while optimizing comfort and performance.

Features

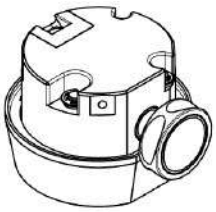
- **Volumetric Automatic Adjustment:** Automatically adjusts to accommodate limb volume fluctuations. Allows the patient to focus on life rather than adjusting their socket.
- **Consistent Interface Pressure:** The patient and prosthetist work together to set the ideal socket panel tension setting; from that point on, the Kinn system maintains stable pressure on the limb regardless of volume changes.
- **Vertical Shock Absorber:** With up to 6 mm of shock absorption, the Kinn system reduces the impact of ground reaction forces during initial heel contact. The reduced forces on the residual limb and joints provide more comfort throughout the day.
- **Kinetically Powered:** With each step, the shock absorber is compressed, and the kinetic energy drives the mechanical volume adjustment system.
- **Seamless Socket Integration:** The Kinn system attaches to the distal end of any socket. The low profile and anatomic shape enable the Kinn system's performance without bulky protrusions.

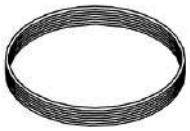
Benefits

- **Enhanced Patient Comfort:** Provides a stable, comfortable fit throughout the day.
- **Reliable Performance:** Ensures consistent support and pressure management.
- **User-Friendly for Patients and Prosthetists:** Offers a hassle-free experience with the option for manual adjustments as needed. The fabrication process fits into established workflows to ensure seamless integration for the prosthetist.
- **Improved Mobility:** Reduces strain and enhances overall comfort for daily activities.
- **Innovative Solution:** Addresses common challenges, setting new standards in prosthetic technology.

Kit Components

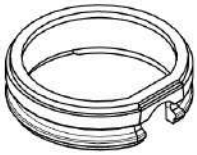

Lamination plate

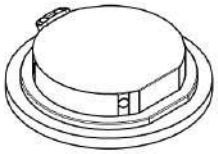

Main Kinn Assembly


Tube


Cable and cable threader tool


Indicator

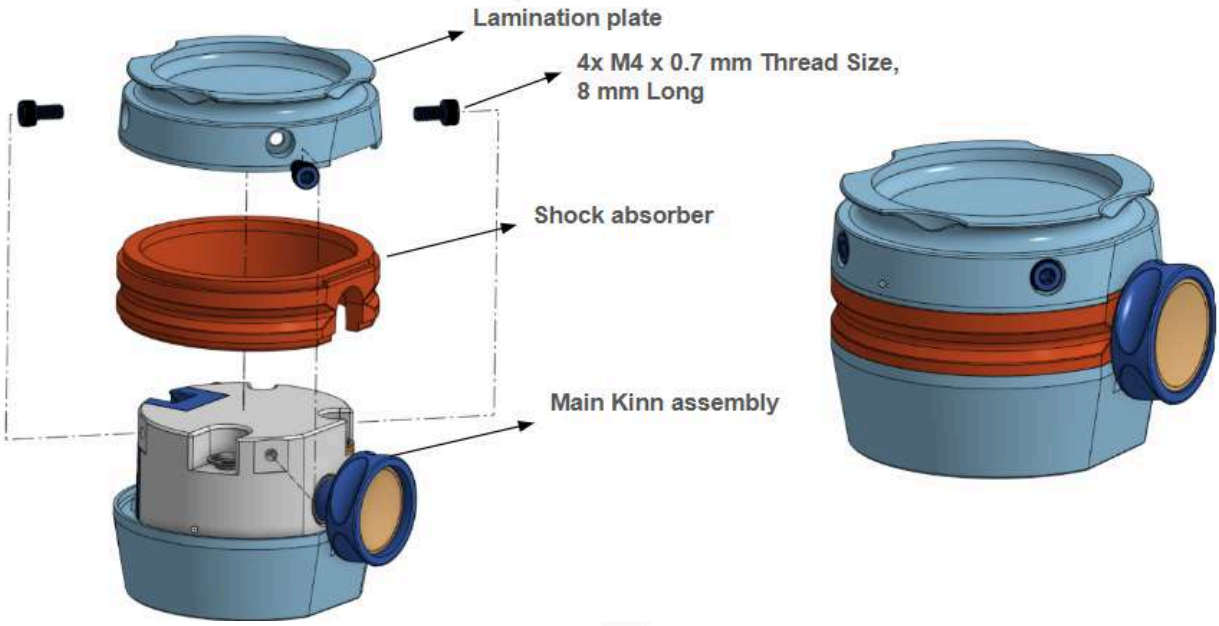

Shock absorber


Lamination dummy plug


4x M4 x 0.7 mm Thread Size, 8 mm Long


M4- Hex L-Key


M3- Hex L-Key



1. 1 x Lamination Dummy Plug
2. 1 x Main Kinn Assembly
3. 1 x Shock Absorber
4. 1 x Cable
5. 1 x Cable Tool

6. 1 x Lamination Plate OR 4-Hole Adapter
7. 1 x Tube with sheath
8. 4 x M4 Screws with Allen key
9. 1 x Tension Setting Indicator
10. 1 x M4 Hex- Allen Key
11. 1 x M3 Hex- Allen Key

Technical Specifications

Build Height	2.35” /59.5mm (Uncompressed)
Vertical Compression	Up to 6mm
Kinn Unit Weight	1lb / 0.450kg
Platform Diameter	66mm
Lamination Plate Diameter	72mm
Tube Length	1.5m (tube for single cable)
Tube Outer Diameter	4mm (tube for single cable)
Cable Weight Rating	900lb / 400kg
Cable Length and Type	1.5m of 1.4mm Dyneema cable
Patient Weight Limit	275lbs / 125kg
Shock Absorber, Soft Rating	100lbs to 200lbs
Shock Absorber, Medium Rating	200lbs to 265lbs
Shock Absorber, Firm Rating	265lbs to 275lbs
Recommended L-Codes	L-5783 (Addition to lower extremity, user adjustable, mechanical, residual limb volume management system), L-5988 (Addition to lower limb prosthesis, vertical shock reducing pylon feature)

Symbol Glossary

Icon	Information	Source
	Indicates the item is a medical device	ISO 15223-1:2021
	Indicates the medical device manufacturer Accompanied by Name of Manufacturer, Address, and Date of Manufacture	ISO 15223-1:2021
	Serial Number	ISO 15223-1:2021
	Catalogue number	ISO 15223-1:2021
	Do not use if the package is damaged and consult the *instructions for use*	ISO 15223-1:2021
	Fragile, handle with care	ISO 15223-1:2021
	Keep dry	ISO 15223-1:2021
	Indicates the temperature limits to which the *medical device* can be safely exposed	ISO 15223-1:2021

Icon	Information	Source
	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1:2021
	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021
	Unique device identifier	ISO 15223-1:2021
Rx Only	For prescription use only	FDA guidance: Use of Symbols in Labeling (DA-2013-N-0125)
REV	Revision of the product	None

Product Safe Use Guidelines

The Kinn system may only be used by certified prosthetists. The Kinn system is intended to be used in conjunction with custom-fabricated prosthetic sockets and traditional prosthetic componentry.

Failure to follow the Instructions for Use may cause product failure and void the warranty.

Warnings and Precautions:

- Do not overtighten the pre-set tension (for the prosthetist) nor the manual dial (for the patient) — excessive tension may cause discomfort or circulatory issues.
- Must be installed by a licensed professional.
- Inspect cable for fraying and wear patterns regularly (daily for the patient, at each follow-up visit for the prosthetist); replace every 6 months proactively.
- Avoid exposure to open flame or sharp edges.
- Please review the indications, contraindications, and FAQ sections of the manual before use. These instructions should be read prior to fitting and followed to ensure the proper integration of the Kinn system into the patient's prosthetic leg.
- The shock absorber's stiffness is based on weight. Please provide accurate patient information so that the appropriate product may be selected.
- When utilizing a pin lock suspension system with a Kinn socket, ensure the pin is fully engaged before the patient starts walking. If the patient experiences difficulty engaging or disengaging the lock, tell them to first press the Kinn release button to relax the socket panels, then try again.

Cable Maintenance

- Routinely check for wear or damage; look for broken fibers in the cable around areas of high wear.
- Replace the cable if a significant amount of fibers are broken, and proactively replace the cable every 6 months.
- Loss of suspension can occur if the cable fails.
- Keep cable away from open flame and sharp edges (and instruct patients to do the same).

Indications for use

- Transtibial or transfemoral amputees
- Unilateral or bilateral
- Patient weight under 275lbs / 125kg
- Patient experiences limb volume change
- Patient benefits from shock absorption

Contraindications

- Use of the posterior mount foot

Ordering Information

Reach out to support@vesslpro.com for all ordering information.

Fabrication, Assembly, and Operation

There are two means by which Kinn can be adjusted: manually by twisting the dial, and automatically through walking motion. The automatic adjustment relies on a preset tension. This next section explains how to adjust the system and the preset tension.

Manual Socket Panel Tension Adjustment

1. The manual dial of the Kinn system manually tightens the panel system with forward rotation. Warning: the manual tensioning dial can tighten the socket panels beyond the maximum tension setting for the automatic system.
2. The release button, when pushed, will disengage the Kinn system and release the tension in the cable, relaxing the socket panels.
3. The manual dial also acts as a visual indicator; it lets you know if the line is being reeled in or not. When the dial stops rotating, the pressure limit has been reached.

Note: The manual dial is intended for fine-tuning the fit upon donning or for temporary adjustments to sudden, significant volume changes. If the patient uses the manual dial frequently, this may indicate that the Automatic Tension Setting needs to be adjusted.

Automatic Socket Panel Tension Adjustment

1. The automatic socket tensioning system does not require any patient action other than ambulation.
2. Every step taken compresses the shock absorber, initiating panel compression, thereby tightening the system and socket panel fit until the maximum tension limit is met.
3. As the limb reduces in volume, the system automatically adjusts to maintain an ideal fit.
4. The release button will release the tension in the system, thereby relaxing the socket panels.

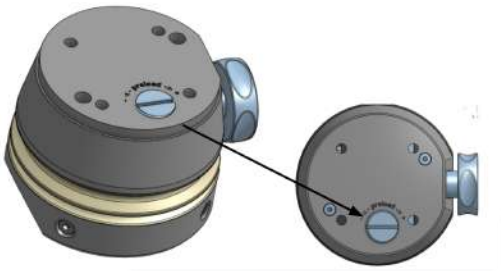
Customization

Shock Absorber

1. When ordering, select the correct shock absorber by using the patient weight and table in the Technical Specifications section above.
2. If the patient prefers a stiffer or more pliant shock absorber, a replacement shock absorber of a different durometer can be ordered and switched out in the clinic.

Tension Setting

The set screw on the distal face of the Kinn system sets the maximum tension of the socket panels. The setting is based on patient and prosthetist preference.



1. The max tension setting can be adjusted using the provided Tension Setting Indicator. Our customTension Setting Indicator will show you how tight you've set the tension in the cable, with lower values indicating a looser fit.

2. Attach the Tension Setting Indicator to the screwdriver. Use the indicator to note the initial depth, which serves as a reference. Subsequent adjustments to increase or decrease tension can then be made incrementally based on this starting point, as needed by the patient.

3. Thread the screw inward (clockwise) to increase the maximum tension limit.

4. Unthread the screw (counterclockwise) to decrease the maximum tension limit.
5. Have the patient don the prosthesis and manually tighten the socket panels by turning the manual dial until the socket is comfortable.
6. Have the patient walk on the prosthesis for 5-10 min and evaluate the socket fit. You can use a Sharpie to mark the manual dial and have the patient walk until the manual dial stops rotating.
7. If the socket is loose, tighten the screw ½ a turn and repeat steps 5 and 6.
8. If the socket is too tight, loosen the screw ½ turn and repeat steps 5 and 6.

Donning Socket - Patient Instruction

1. Before donning the socket, press the release button and loosen the panels on the socket to allow for easier donning.
2. Slide the limb into the socket and take appropriate steps to secure the suspension system used.
3. Turn the manual dial until the socket panels tighten to the desired level on the limb.
4. Stand and walk. Every step taken will automatically tighten the socket panels until the set tension level has been reached.

Doffing Socket - Patient Instruction

1. Sit down and unload weight from the prosthesis. The Kinn system will not release until it is unloaded.
2. Press the release button on the Kinn system.
3. The panel system should now be loose enough to comfortably doff the socket; additional cable can be pulled out to further loosen the system by pulling on the panels.
4. Remove the prosthesis.

Definitive Lamination

The kit comes with a lamination plate or a 4-hole adapter. When laminating the socket, ensure a space between the bottom of the pin lock and the top of the Kinn system is created to allow the pin to extend through the lock without hitting the top of the Kinn lamination plate or 4-hole adapter.

1. Flexible Inner Socket:
    a. Pull a flexible inner liner.
    b. Use the flexible material of choice with a final thickness of approximately 3-4mm.
2. First Lamination:
    a. Laminate a layer over the mold/flexible inner liner. Ensure the lamination has one braid to prevent the tube from being pulled through.
    b. Include lock-in lamination per the lock manufacturer's instructions.
    c. Prep the surface of the initial lamination by roughing/sanding and thoroughly cleaning with rubbing alcohol.

d. Ensure the pin release button and the Kinn dial are fabricated on the same side.

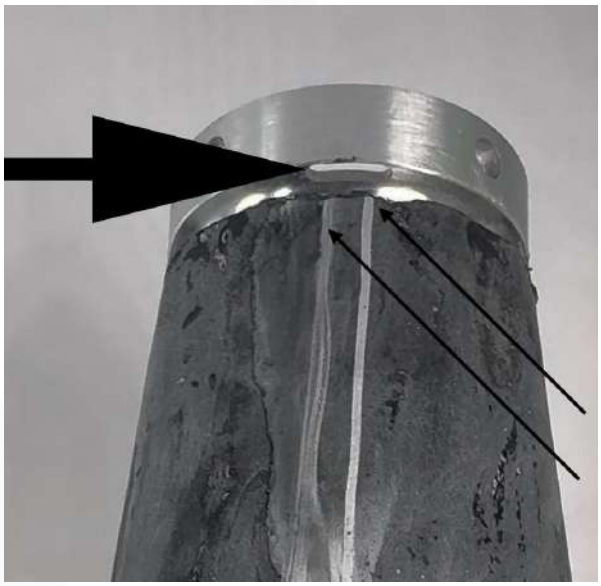
3. Transferring alignment:
    a. Attach the Kinn system to the lamination plate.
    b. Install the pyramid adapter onto the distal end of the Kinn system.
    c. Attach the Kinn system to the vertical alignment jig.

4. Lamination Plate attachment:
    a. The rotational direction of the lamination plate is critical. Ensure that the Cable Tubing Insertion Port is aligned with the planned tubing pathway (most common is lateral for a medial release button).
    b. Apply fast-curing adhesive to the proximal side of the lamination plate.
    c. Adhere the socket to the lamination plate with appropriate alignment. Ensure no sharp edges/surfaces.
    d. Add an expanding foam to give the prosthesis a better shape.
    e. If alignment was transferred, remove the Kinn system.

5. Panel and Tubing Layout:
   a. Draw the tubing pathway onto the socket and draw lines on the socket from the start point to the end point, horizontally crossing each panel twice. The image (Fig. 1) shows lines drawn on the carbon fiber lamination. Draw the tubing pathway from the start point to the end point, crossing each panel horizontally twice. Refer to Fig. 1 for the example of the carbon fiber lamination.

Fig. 1

   b. The tubing will begin and end at the Cable Tubing Insertion Port on the lamination plate on the lateral side of the socket. The orientation of the lamination plate is critical; the Cable Tubing Insertion Port should be on the lateral side so that the dial is located on the medial side. Bisect the posterior of the socket and draw a vertical line. At the distal end of the socket, mark the start and end points of the tubing on either side of the line with a ¼ inch space separation.



c. Fig. 2 is a posterior view of the socket (grey), tubing pathway (red), and panels (blue); Fig. 3 is an anterior view. The tubing will start at the Cable Tubing Insertion Port on the lateral side of the lateral side of the socket. Wind the tubing up and around each panel 0.5" from the bottom edge of the panel, keeping it parallel to the bottom of the panel. Curve around 0.5" from the last panel, keeping the curve radius no sharper than 15mm, and then follow the same path back to the Cable Tubing Insertion Port. The tubing should be evenly spaced on each panel, parallel on each panel, and 0.5" away from the top and bottom edges of each panel. The example above is a common 3-panel configuration (1 medial, 1 posterior, 1 lateral), but you can choose whichever panel configuration is best for your patient.

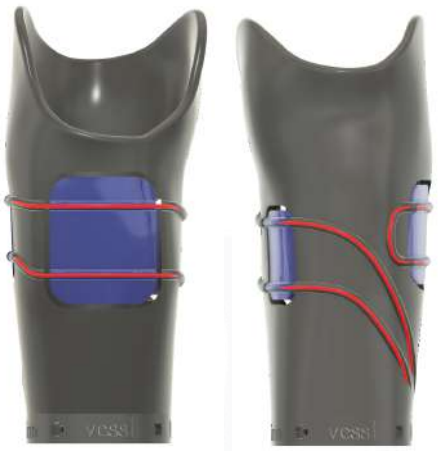
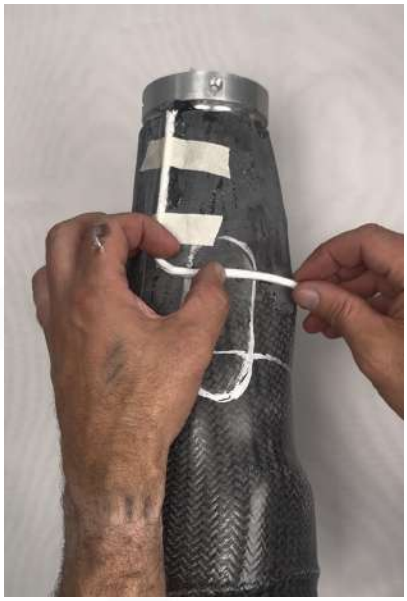


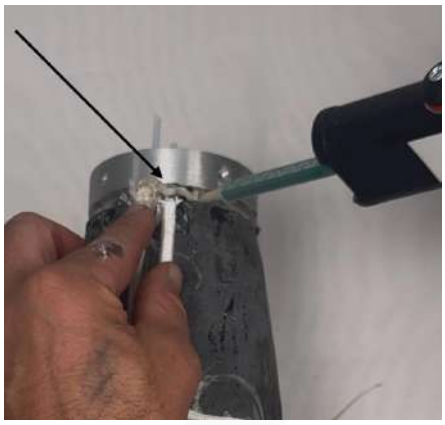
Fig. 2 Fig.3

6. Glue on Tubing:
    a. Ensure that the tubing has a nylon sleeve overtop.
    b. Take one end of the tubing and place it through the cable entry slot on the lamination plate. Leave 1" of length inside the lamination plate.
    c. Using a dot of glue every 2cm, adhere the tubing to the socket along the tubing pathway lines drawn. It is recommended to use super glue and an accelerator to speed up the process.



    d. Cut the tubing so that 0.5" can be placed through the Cable Tubing Insertion Port on the lamination plate.

e. Pack the ends of both tubes with clay in order to prevent resin from entering.



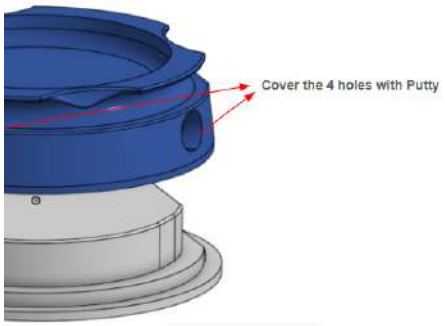
f. Using a fast-setting adhesive (Fabtec), seal the Cable Tubing Insertion Port.

7. Insert Lamination Dummy

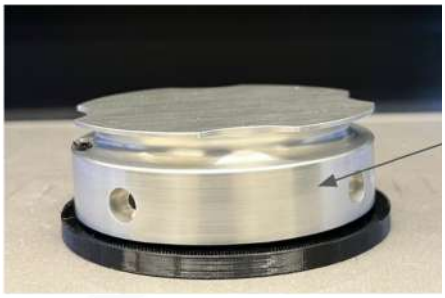
a. Apply a thin coat of petroleum jelly to the outside of the large lamination dummy.

b. Place the large lamination dummy into the distal surface of the lamination plate. Ensure that the terminal ends of the tubing are inserted into the dummy.

c. Fill the 4 screw holes with putty.



d. Apply stretch tape over the exposed distal surface.

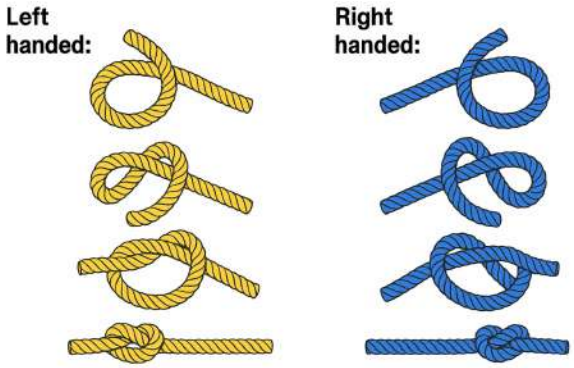


8. Second Lamination:
   a. Pull lamination materials over the socket, tying into the lamination plate groove and reflecting back over the socket.
   b. Pull PVA bag and laminate as usual.
   c. Laminate the socket using caution to not displace the tubing or Cable Tubing Insertion Port.
   d. Extra resin will be needed. Use caution to remove air bubbles around the tubing.
   e. Toward the end of lamination, tape can be applied over the lamination plate to squeeze out excess resin.

9. Cut panels:
    a. Remove the socket from the mold and remove the flexible inner socket.
    b. Remove the lamination dummy.
    c. Mark the locations of the panels.
    d. With caution, cut along the lines with a cast saw or Dremel for more precise cuts.
    e. Sand all edges till smooth.

10. Pad panels:
    a. Scuff the back side of each panel.
    b. Glue padding to the back of each panel piece.
    c. Pads should be made of a medium-density foam of ~5mm and should be convex with skived edges.

11. Cable panels:
    a. Clear out all tubing of clay and sanding debris. You can put some paper towels on the end of the cable tool and pull it through the tubing several times to clear it.
    b. Tie a single overhand knot into one end of the cable (see diagram).



    c. Using the cable tool, feed cable through the socket and panels, starting and ending at the Cable Tubing Insertion Port.
    d. Use caution to correctly orient each panel.

e. Leaving no more than 10cm (4”) of all excess cable length on each end, tie the two ends of the cable together to create a stopper knot. If tying one knot is too large on the spool, you can tie one knot at each end of the cable.

Kinn System Assembly

1. Attach cable to spool:
    a. Slide the shock absorber over the cable (see image on the right).
    b. Feed cable through the spool side of the main Kinn Assembly.
    c. Loosen the screw on the spool.
    d. Place the cable and knots under the spool screw and then tighten the spool screw. Ensure that the cable spool is wrapping around in the correct direction.
        - Left Leg: Attach the cable so it is positioned to the left of the spool.
        - Right Leg: Attach the cable so it is positioned to the right of the spool.

e. Twist the manual dial to pre-wrap 2 rotations of cable onto the spool.
f. Use the cutout at the top of the inner shell for fastening the spool screw.

2. Attach the Inner Shell Assembly to the socket.
    a. Ensure the shock absorber is aligned with the dial cutout. While holding the shock absorber and the outer shell, withdraw the inner shell to reveal the four female screw features located at the top region of the inner shell.
    b. Align the inner shell with the lamination plate and proceed to fasten the four M4x0.7 screws. (Tighten to a torque of 2.5 N·m).

Troubleshooting and Field Servicing

Replacing the shock absorber

1. Remove four screws from the collar.
2. While pressing the release button, pull down on Kinn.
3. Remove the line from the spool by unfastening the screw on the spool.
4. Slide off the shock absorber and replace it with a new one by sliding it in place.
5. Reattach the line to the spool.
6. Fit Kinn back into the collar and align the four screw holes.

7. Screw in four screws to secure Kinn in place.

Replacing the cable

1. Remove four screws from the collar.
2. While pressing the release button, pull down on Kinn.
3. Remove the cable from the spool and pull the cable out of the tubing.
4. Thread the new cable through the tubing and attach it to the spool.
5. Pre-thread some of the cable around the spool.
6. Fit Kinn back into the collar and align the four screw holes.
7. Screw in four screws to secure Kinn in place.

Fine-tuning panel compression

1. If the panels are not compressing the limb enough, try:
    a. Tightening the distal set screw,
    b. Adding padding to the panels to make them thicker, and/or
    c. Ensure there is no excessive line on the spool. If the spool is too full, it can prevent additional line from being reeled in. Spool capacity may be exceeded if more than 10cm (4") is used as described above.
2. If the panels are compressing the limb too much and the patient feels too much pressure, try loosening the distal set screw.
3. Ensure the panels are moving as the patient walks; use chalk or a Sharpie to mark the cable and check its position after the patient walks for a couple of minutes. If the line is not moving, detach Kinn and check that the line is not getting pinched within the Kinn assembly (for example, getting pinched on the spool or where the Kinn assembly connects to the lamination plate).

Using the manual dial

1. When the panels are completely relaxed (i.e., you have pressed the release button) and you twist the manual dial, it should be easy to twist.
2. If the patient has donned the socket and is trying to use the manual dial to tighten the panels against the limb, it is normal that the manual dial is difficult to turn. That is an intentional design feature to ensure the patient does not overtighten the system.

Aligning the Kinn assembly holes with the lamination plate holes

1. If the holes of the main Kinn assembly are sitting under the shock absorber, pull up on the manual dial to unseat the Kinn assembly from the shock absorber and align the Kinn assembly holes with the lamination plate holes.

Inserting tubing into the lamination dummy

1. If the full 0.5” of tubing does not seat fully into the lamination dummy, try trimming the tubing slightly shorter and securing the dummy firmly in place with tape and downward pressure.
2. Ensure the dummy remains stable and flush before proceeding to lamination.

Attaching the cable and spool screw

1. Fully remove the spool screw, then position the cable and knots in place.
2. Apply a small amount of Vaseline to the tip of the allen wrench to hold the screw steady during reinsertion.

Selecting a valve and suspension system

1. Vessl does not prescribe a specific valve type or locking mechanism, as these will vary based on patient needs and clinical preference.
2. If using a pin lock suspension system with the Kinn socket, ensure the pin is fully engaged before the patient begins walking.
3. If difficulty engaging or disengaging the pin lock is encountered, press the Kinn release button first to relax the socket panels and then retry.

4. For guidance on valve selection and compatible locking mechanisms, contact Vessl support at support@vesslpro.com or call 226-376-1525.

Manufacturer Contact Information

Reach out to support@vesslpro.com or call 226-376-1525. Vessl's address is 100 Collip Circle, London ON Canada, and you can find more information on our website at vesslpro.com.