

Clevisphere™ Joint Model 747

PRODUCT GUIDE

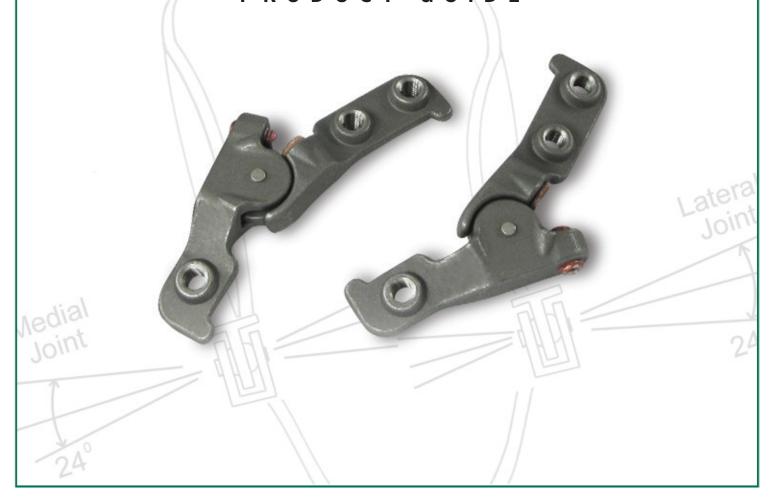




Table of Contents

l.	Indications for Use	3
II.	Fabrication Procedures	3
III.	Frequently Asked Questions	14
IV.	Additional Resources	16

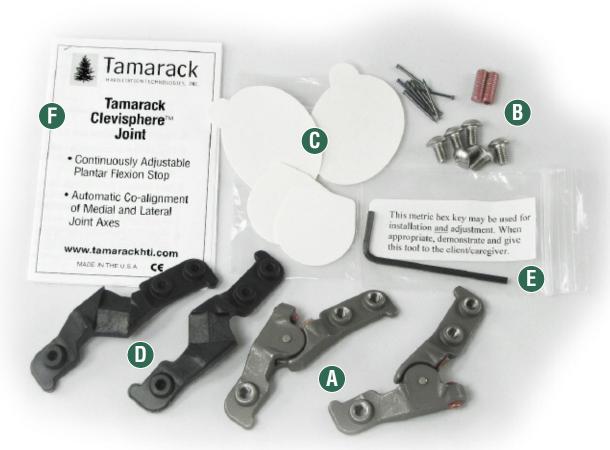


Fig. 1:

747 Package contents:

- A Clevisphere joints (Adjustable stop, stainless steel)
- B Fasteners (stainless steel screws)
- Cosmetic patches (ShearBan®)
- Molding dummies with nails
- E 2.5mm hex key
- Assembly/installation instructions



Tamarack Clevisphere Joints are made in the USA by Tamarack Habilitation Technologies, Inc. and are subjected to continual rigorous testing and inspections to assure the highest quality and performance.

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I. Indications for Use

Tamarack Clevisphere Joints are ideal for articulating ankle joints in lowerextremity orthoses when adjustable plantar flexion control is needed.

Tamarack Clevisphere Joint design features:

- The Orthotist can choose to use line-of-progression or anatomical joint alignment. No special attention or fixturing is necessary, since the joints automatically co-align to a single axis when installed in pairs.
- Tamarack Clevisphere Joints provide continuously variable plantar flexion stop adjustment. No additional plantar flexion control hardware is necessary, reducing bulk on the posterior aspect of the orthosis for a better fit into the shoe.
- Fabrication is very easy. Clevisphere joints can be used in thermo-formable and thermo-set materials.

II. Fabrication Procedures

Cavities that optimize the function of the Tamarack Clevisphere Joints should be generated using Tamarack Clevisphere molding dummies. The molding dummies (Fig. 2) are designed to form a tight cavity for good joint anchoring within the orthoses. Molding dummies lose their shape with repeated use. They should be discarded after one use.

The mold should be rectified as necessary to ensure orthopedic support and provide needed clearances. Either mechanical (line-of-progression) or anatomical joint alignment can be chosen for dummy placement. One of the advantages gained by using the Tamarack Clevisphere Joint is that these joints automatically co-align to a single joint axis. This expedites fabrication, allows for design variations (joint axis location), enhances durability, and delivers "no bind" free movement of the articulation.



Fig. 2
A pair of molding dummies is included with each package.



Fig.3

This photo shows the modified mold, stockinet, Tamarack Clevisphere molding dummies, nails, and putty.



Fig. 4, 5, 6 (below)

For an AFO with adjustable plantar flexion stop, the dummy ears must point anteriorly, and the end with the two bosses (for two mounting screws) should be proximal, as shown (Fig. 6).

PLEASE NOTE:

The two molding dummies are not identical (Fig. 5, 6).

Pull thin stockinet over the mold prior to attaching the molding dummies.

Align the molding dummies on the plaster model in accordance with where you wish the orthotic ankle axis to be located. Use the supplied nails or cement to fix the dummies to the model in the desired location. The dummies are not flexible. Any gaps must be filled with plaster, putty, or clay. Medial and lateral components will automatically align with each other. They will not bind unless misaligned by more than 12° relative to each other.

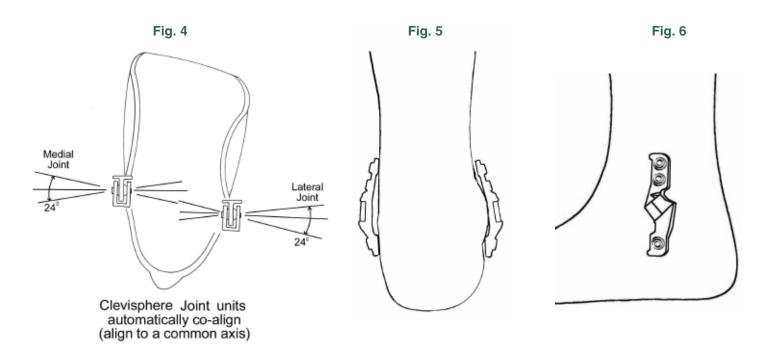




Fig. 7, 8 Molding dummies are positioned on the mold prior to applying putty.

Fig. 9, 10 Proper application of putty is shown at right.

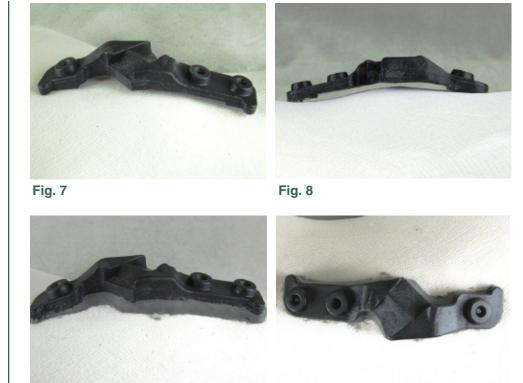


Fig. 9 Fig. 10

Fig. 11, 12 The application of putty is too heavy.

This creates a cavity that will not adequately anchor the joint.



Fig. 12

Fig. 13, 14 The application of putty is too light.

This creates a cavity that will make it difficult to remove the dummy and install the Clevisphere joint.

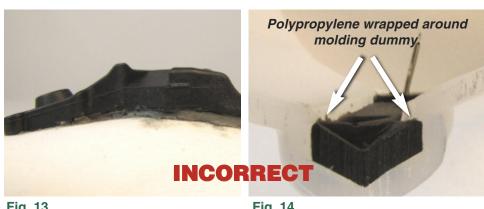


Fig. 13 Fig. 14



Fig. 15Typical vacuum forming process.

Fig. 16

Use a nail set or the head of a nail to form a divot at the screw centers. This will help the drill bit stay in place when the screw clearance holes are formed.

Fig. 17

Good vacuum forming result
(plastic is pulled tight around
the mold and the molding
dummy)

Vacuum form or laminate to form the orthosis shell. Tamarack recommends using .25" polypropylene. Other materials and methods such as carbon fiber layup may be suitable. We do not recommend using co-polymer or polyethylene.



Fig. 15



Fig. 16



Fig. 17



Allow cooling (thermosetting) to occur. Remove the AFO shell from the mold in one piece. An ideal, well-formed cavity is formed to securely anchor the Clevisphere Joint.



Fig. 19



Fig. 20

Fig. 18

Rough cut the AFO. Remove the waste from the mold. This will make it easier to access the AFO. Remove the AFO from the mold. Support the AFO to avoid breakage.



Pull the dummy out of the cavity by grabbing the protruding nail with pliers.

Otherwise cut through the dummy when you separate the foot section from the calf section. You can then pry the dummy out.



Fig. 21

Add trim lines, closely following the contour of the molding dummy.



Fig. 21



Fig. 22

Fig. 22

Separate the foot section from the calf section using a thin bladed saw, such as a fine-tooth coping saw. Be sure to cut within the trim lines.

Begin by bisecting the joint cavity. Turn the AFO over and cut through the second cavity as you did the first.



Fig. 23

Place the blade into the cuts on both sides and continue to cut to the posterior.

Keep cutting - the blade will continue to make one smooth line connecting the joint cavities.

Fig. 24

Remove the dummies, if necessary, and drill holes for attachment screws.

Use a 5.5mm or 7/32" drill bit.



Fig. 23



Fig. 24



Fig. 25, 26, 27

Good anchoring conditions.

There is enough material for proper joint support.

Be sure to not remove too much material.

Fig. 28

Poor cavity formation – This cavity
will not support or control
the Clevisphere joint and
is not recommended.

This was created by too much putty. Low vacuum or low thermo-formable material temperature may create a similar cavity.

Fig. 29
Poor anchoring conditions!

Too much material has been removed, reducing joint anchorage.

Remove excess material following trim lines. Leave adequate material around the Tamarack Clevisphere joint to ensure good anchorage.





Fig. 26



Fig. 25

Fig. 27



Fig. 28

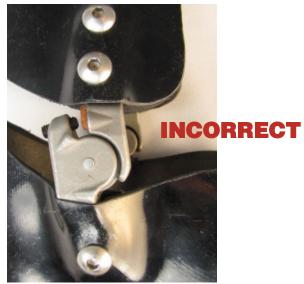


Fig. 29



Fig. 30

Use a de-burring tool to smooth the edges in the cavity area. Grinding the plastic removes too much plastic to optimally anchor the joint.



Fig. 30



Fig. 31

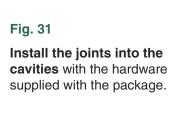




Fig. 32

Make sure that the screw does not protrude into the orthosis, but is at least half way through the Clevisphere.



Fig. 32



Fig. 33

This screw is protruding. It may cause skin damage. Use a shorter screw.



Fig. 34 Install cosmetic patches.

Cosmetic patches made with ShearBan® make excellent covers to keep the orthosis and joint area clean.



The adjustment screw comes with medium-strength thread-locker already applied. Adjustments will progressively loosen the thread-locker. Reapply thread-locker as necessary.

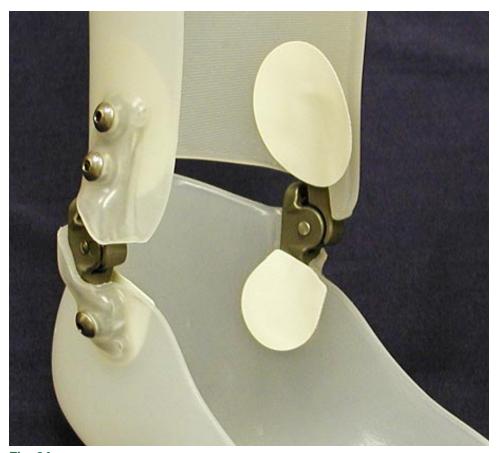


Fig. 34

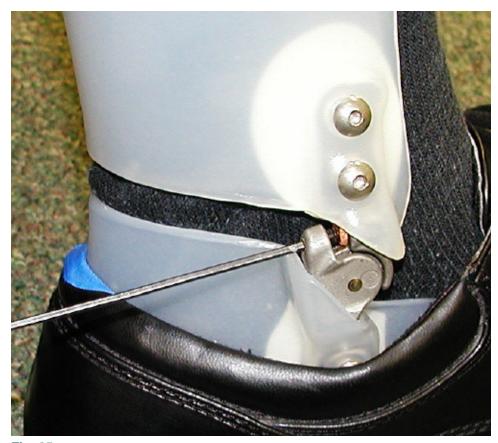


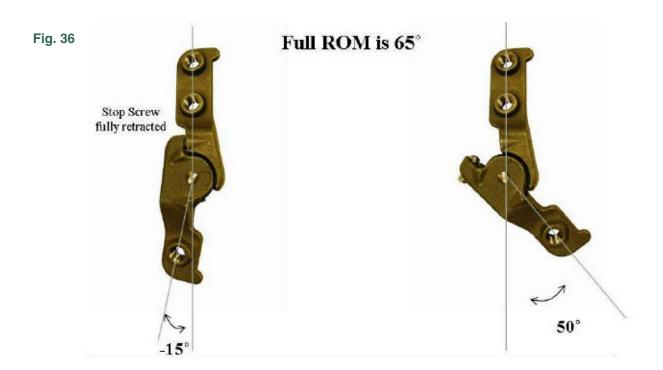
Fig. 35



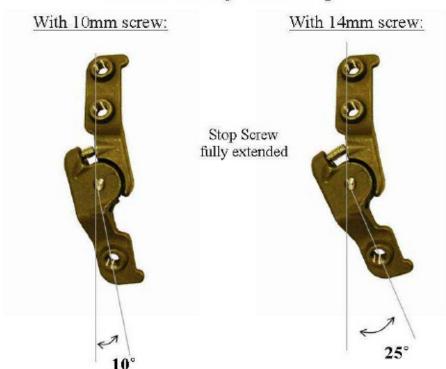
III. Frequently Asked Questions

Q: What is the full range of motion allowed by the Clevisphere Joint?

The Clevisphere joint has a total range of motion covering 65°, 15° plantar and 50° dorsi from the neutral position.



ROM with adjustable stop





Q: What L-codes should I use for billing?

L-code suggestions for providers in the USA can be found on our website, www.tamarackhti.com.

Q: Why should I use molding dummies?

It does not damage the Tamarack Clevisphere Joint to use it in the vacuum forming process. However, plastic forming (either vacuum forming or lamination) with the actual joint may reduce product performance. The use of molding dummies offers the following benefits:

- The molding dummy is shaped to allow the greatest Clevisphere Joint range of motion after installation by making a cavity which is neutral in both sagittal and transverse planes.
- If putty around the perimeter of the Clevisphere joint is not adequate, the Clevisphere joint may be very difficult to remove. It may be damaged in the process.
- The stand-off pads also ensure that the joint and its mounting hardware will be recessed for better skin clearance.

Q. Can I use Clevisphere Joints installed "backwards"?

Tamarack does not endorse the use of this joint as a variable dorsiflexion stop in an ambulatory orthosis. In almost all ambulation situations, stopping dorsiflexion subjects the joint and its anchorage to much higher moments than the joint was designed for. There are some pediatric as well as non-ambulatory variable dorsiflexion stop applications for which the Clevisphere Joint is useful. If you choose to use the Clevisphere joint in this manner, be sure to reinforce the area supporting the Clevisphere joint with additional polypropylene.

Q: How do I modify the AFO to make it wider in the ankle area (e.g., widen the area to relieve for malleolus contact or to make a growth adjustment)?

If the medial malleolus is contacting the medial aspect of the Tamarack Clevisphere Joint or other parts of the AFO shell, here is a simple solution to try before heating and bulging: place a medial wedge under the calcaneous (inside the AFO) – this will often relieve the medial malleolus. If this does not work, or you need to make the AFO shell wider for other reasons, try leaving the Tamarack Clevisphere Joints mounted in the AFO. Heat the surrounding area (except for directly on the cavity area) and push outwards as though it is a solid ankle AFO.

Q. How can I keep the adjustment set screws from migrating?

- 1. Apply a liquid thread-locker to the screw. Be sure to follow the manufacturer's instructions, assuring a good bond.
- Replace the M5x10 hex socket set screw with a long M5x14 hex socket set screw. Add a 5mm hex nut to the back of the set screw. Tighten the nut against the Clevisphere joint to lock the set screw in place.





IV. Additional Resources

Replacement and optional hardware for Tamarack[®] Clevisphere[™] Joints

- Attachment Screw: Stainless Steel, M5x8mm, Button Head, Hex Socket, Cap Screw
- · Adjustment Screw: Stainless Steel, M5x10mm, Hex Socket, Set Screw
- · Adjustment Screw, Long: Stainless Steel, M5x14mm, Hex Socket, Set Screw
- Cosmetic Patch, 12 per pack, Tamarack part number 749-747



• 2.5mm hex driver, Tamarack part number T-740-4LM



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