

TCC-EZ® – TOTAL CONTACT CAST SYSTEM

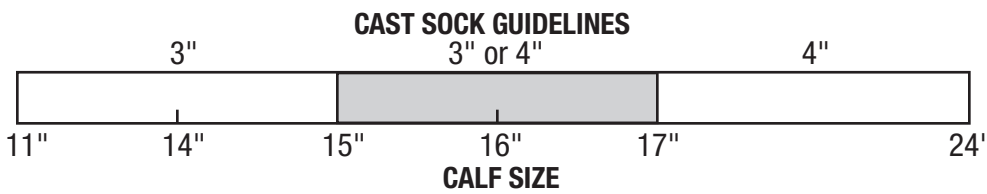
1. Product Description

The TCC-EZ Total Contact Cast System provides the healthcare provider with a primary dressing and the necessary components to apply a total contact cast. The TCC-EZ system includes instructional materials for application and removal.

System Contents- Available in sizes 3" and 4"

1 Primary Dressing	1 roll Paper Tape
1 Tan Stockinette	2 rolls Plastic Tape
1 Tibial Crest/ Malleolar/Foot Pad	1 sheet Physician Instructions/Cautions
1 White Protective Sleeve	1 sheet Patient Instructions with Removal Instructions
1 Cast Sock	1 Outer Boot

*2. USE THESE SIZE CHARTS TO DETERMINE PROPER SOCK AND BOOT FIT



TCC-EZ BOOT GUIDELINES

	REGULAR	LARGE	EXTRA LARGE
Men	6-10	10.5-13 wide	13.5-18 X-wide
Women	5-11.5	11.5+ wide	11.5+ X-wide

SHOE SIZE

Patients who wear wide shoes may need to be evaluated for a Large or Extra Large Boot regardless. Large and Extra Large boots also available as Charcot Boots for a rocker bottom deformity.

3. Indications/Intended Use

The TCC-EZ Total Contact Cast System is indicated for the treatment of:

- Non-infected neuropathic foot ulcers without involvement of deeper structures (tendon, joint capsule or exposed bone)
- Post-operative care (i.e.: Charcot reconstruction, delayed primary closures)
- Charcot Neuroarthropathy
- Pre-ulcerative conditions

The TCC-EZ is intended to be used in patients that are not infected and have adequate blood supply to the involved foot, in conjunction with standard wound care regimens.

4. Contraindications

The TCC-EZ is contraindicated for use in:

- Ulcers that have signs of clinical infection
- Neuropathic foot ulcers with involvement or exposure of deeper structures (tendon, joint capsule, or bone)
- Ulcers that are deeper than they are in width
- Patients with vascular status not adequate for healing
- Patients with allergies to cast components
- Patient's foot exceeds boot size
- Patient's calf exceeds size limit
- Foot deformity not accommodated by outer boot

5. Warnings

The TCC-EZ Total Contact Cast System should be recommended and supervised by a physician or licensed healthcare provider. If the vascular

status is not adequate for healing or the wound is infected or involves deeper structures (tendon, joint capsule, or exposed bone) do not apply the TCC-EZ. Infection must be ruled out before treating patients with the TCC-EZ. Inappropriate use of the total contact cast could result in serious injury to the patient and/or potential loss of limb. Improper removal of the total contact cast may also result in injury to the patient.

The TCC-EZ should be removed and the patient reassessed prior to reapplication in all of the following circumstances:

- If the cast is "loose" or "rubbing" or "pistoning"
- If the cast is causing pain
- If the patient develops fever, chills, nausea, or vomiting
- If the cast gets wet
- If the patient or healthcare provider has other cause for concern, such as claustrophobia

6. Cautions

Federal Law restricts sale of this device to or on the order of a physician or licensed practitioner.

- See reverse side instructions for appropriate application and removal of the TCC-EZ.
- Emergency Removal Instruction Card should be provided to the patient in the event that an unfamiliar healthcare provider must remove the TCC-EZ. If the cast is removed in a hospital or emergency room the cast removal technician must be informed that the cast is only padded along the tibial crest, over the dorsum of the foot, on the malleoli, and over the toes. These are the only safe places to cut with a saw to remove the cast.

7. Application and Removal Instructions

See reverse side.

8. Frequency of Cast Change

Frequency of cast changes will depend upon clinical assessment by the healthcare provider. Use of the TCC-EZ system will result in decreased edema in the leg and unwanted movement of the foot and leg within the cast. After initial application, the patient must be examined in 2 to 3 days for decreases in leg volume that could allow the leg to "piston" (slide). Pistoning requires immediate recasting. A TCC-EZ that consistently pistons requires weekly recasting. A TCC-EZ that does not piston must still be changed every week or at least every two weeks as the leg atrophies. Patients must be vigilant for changes described in the Patient Instructions sheet, which may require an immediate cast removal or change. The following are general guidelines for use.

Forefoot Ulcers

1. The first cast change will take place 2-3 days after the first cast is applied to prevent pistoning and maintain total contact as swelling in the leg decreases.
2. Subsequent cast changes should take place weekly thereafter unless otherwise indicated.
3. Patient should wear a cast for 1 to 2 additional weeks after ulcer has healed or until skin returns to full thickness to decrease chance of ulcer recurrence.

Midfoot/Rearfoot Ulcers

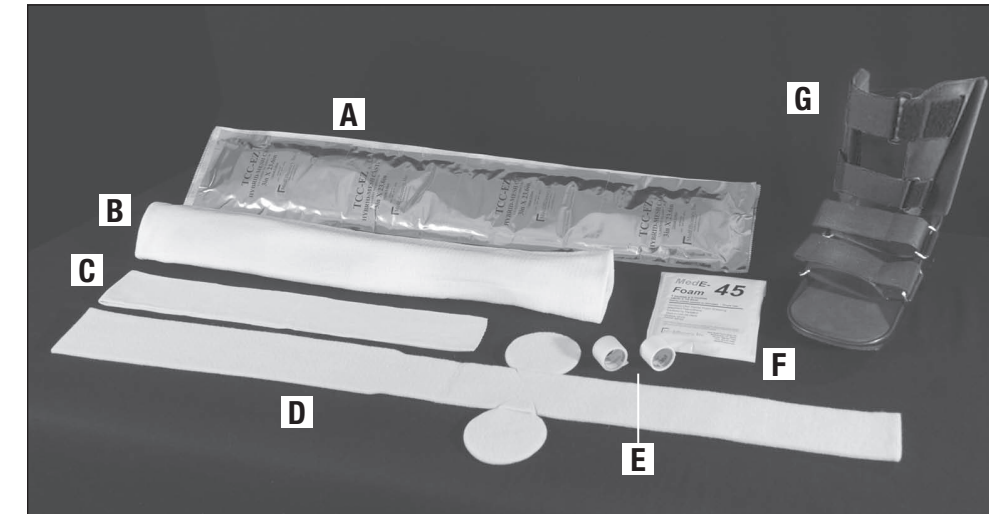
1. The first cast change will take place 2-3 days after the first cast is applied to prevent pistoning and maintain total contact as swelling in the leg decreases.
2. Subsequent cast changes may be as often as twice per week to accommodate the larger high-exudate ulcers.
3. Patient should wear a cast for 1 to 2 additional weeks after ulcer has healed or until skin returns to full thickness to decrease chance of ulcer recurrence.

Charcot Neuroarthropathy

1. The first cast change will take place 2-3 days after the first cast is applied to prevent pistoning and maintain total contact as swelling in the leg decreases.
2. Subsequent cast changes will take place weekly until edema has subsided.
3. Thereafter cast changes may be extended to two week intervals until coalescence is achieved.

TCC-EZ®

TOTAL CONTACT CAST SYSTEM



KEY

- A Cast Sock
- B White Protective Sleeve
- C Tan Stockinette
- D Tibial Crest/ Malleolar/Foot Pad
- E Paper/Plastic Tape
- F Primary Dressing
- G Outer Boot



* Photo of completed cast



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TCC-EZ® – APPLICATION INSTRUCTIONS

I. PATIENT PREPARATION

* NOTE: See Size Chart on back

- Apply foam dressing to ulcer area and secure with paper tape. If sterile dressing package appears compromised, **DO NOT USE.** (Fig. 1)
- Apply thin tan stockinette.
 - Pull stockinette over entire foot extending to knee, smoothing out any wrinkles. **Avoid disrupting the tape and dressing.**
 - Smoothly fold distal end over dorsum, leaving space between toes and stockinette and secure with plastic tape.
 - Cut excess stockinette. (Fig. 2)
- Apply protective felt padding.
 - Align circular flaps over malleoli with shorter/narrower portion towards knee. (Fig. 3)
 - Use plastic tape to secure circular pads to malleoli, then tape along tibia. **Do not tape around entire leg.**
 - Loosely wrap remaining protective felt padding to cover toes and plantar surface of foot. Leave a finger's width space beyond longest toe to ensure toes are not impinged. (Fig. 4)
 - Secure in place with plastic tape at dorsum of foot, under arch, and behind heel. Cut any excess padding to allow for approximately 1-3 inches of padding beyond heel. (Fig. 5)
 - Trim corners of heel for optimal cast contact. (Fig. 4)
- Open clear plastic bag containing protective white sleeve and remove from bag.
 - Starting with a 2 inch fold, roll sleeve into doughnut shape. (Fig. 6)
 - Place sleeve over toes and unroll sleeve extending toward knee leaving 2 inches of tan stockinette exposed.
 - Pull sleeve to cover toes leaving approximately 2-4 inches of excess beyond toes.
 - Ensure all existing protective layers are not being disrupted or binding toes. Loosely fold excess sleeve over dorsum of foot and secure with plastic tape.**
 - Cut excess sleeve. (Fig. 7)
 - Cut excess felt padding at knee even with the white protective sleeve and fold the tan stockinette over the white protective sleeve.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7

II. CASTING

❖ **Use 70°F – 75°F temperature tap water. Cooler water will negatively impact the activation process but may cause delamination from cast.**

- Just prior to casting, place patient in a prone position with leg flexed at knee. (Fig. 8)
- Apply cast sock.
 - Starting with a 2 inch fold, roll cast sock into a doughnut shape, leaving approximately 2-3 inches of unrolled sock. (Fig. 9)
 - To ensure thorough saturation, completely immerse rolled cast sock into water for 5 full seconds, counting slowly. Give two gentle squeezes under water.
 - Remove from water and squeeze gently and shake to remove excess water. Do not wring.
 - Use one gentle stretch and position sock so unrolled end extends beyond toes by approximately 2-3 inches. (Fig. 10)
 - Gently unroll sock towards knee. (Fig. 11)
 - Fold back excess cast sock to widest point of calf to shorten cast length. Fold the proximal edge of stockinette distally covering all loose edges.
 - Immediately** place patient's foot in a 90° neutral position. (Fig. 12)
 - If necessary, slide fingers between patient's dorsum of foot and sock to smooth out wrinkles in any layers.
 - Loosely fold excess sock over dorsum of foot. Smooth and contour fold at toes to attach to cast. Do not impinge toes (Fig. 13)
 - Use wet gloves to smooth and contour cast to leg, ankle area, arch and Achilles tendon. Ensure all layers are smooth and toes are not impinged. (Fig. 14)
- Continue to smooth cast and maintain foot in a neutral position with ankle as close to a 90° angle as possible for 2 to 3 minutes until cast is firm enough that patient cannot overcome cast. Then allow patient to sit for remainder of drying time.**
- Allow cast to dry 15 minutes until toe area of cast is cool and hardened. Some flex in the cast is normal and to be expected.



Fig. 8



Fig. 9

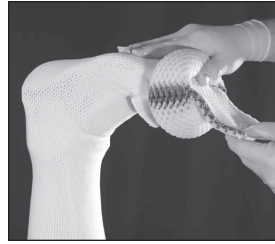


Fig. 10



Fig. 11



Fig. 12



Fig. 13



Fig. 14

- Apply outer boot. On patients where the foot is deformed or so large that it cannot fit within the upright struts of the boot, the device is contraindicated.
 - Place hardened cast between upright struts of walker boot.
 - Ensure struts align with (are parallel to) patient's tibia and fibula and place the heel at the rear of the boot. (Fig. 15)
 - Secure ankle strap, toe strap and then top straps to keep walker boot positioned properly relative to patient's leg during ambulation.
 - Adjust top straps so they are snug around the patient's leg. Instruct patient that these straps must be snug at all times.
- ALLOW THE PATIENT TO LIGHTLY WEIGHTBEAR. RESTRICT AMBULATION FOR 24 HOURS POST CAST APPLICATION. INSTRUCT PATIENT THAT OUTER BOOT MUST ALWAYS BE WORN FOR AMBULATION. AMBULATION WITHOUT BOOT WILL CAUSE INSTABILITY, DAMAGE CAST, AND DELAY PROGRESS. CHARCOT PATIENTS MUST WEAR OUTER BOOT AT ALL TIMES.**
- ❖ **Recommendation: Cover cast to protect the other foot and leg, especially while sleeping.**



Fig. 15



Fig. 16

III. REMOVAL OF CAST

❖ **IMPORTANT: DO NOT BIVALVE CAST TO REMOVE. ENSURE YOU ARE FAMILIAR WITH PROPER TECHNIQUE OF USING CAST SAW.**

- Remove outer boot.
- At top of cast, cut tan stockinette horizontally and pull protective felt padding towards knee.
- Use cast saw with hands always in contact with patient and saw.
 - Cut down anterior crest of tibia and across dorsum of foot. (Fig. 16)
 - Make second cut across toes.
 - Make optional cut across malleoli if necessary.
- Use bandage scissors to cut protective white sleeve from knee to toes. (Fig. 17)
- Pull protective felt padding away from tibia and dorsum of foot. (Fig. 18)
- Use bandage scissors to cut tan stockinette.
- Remove foot/leg by grasping cast edges, spreading, and pulling off like a boot. Take care due to sharp edges. Do not impinge on toes. (Fig. 19)
- Dispose of properly.



Fig. 17



Fig. 18



Fig. 19