

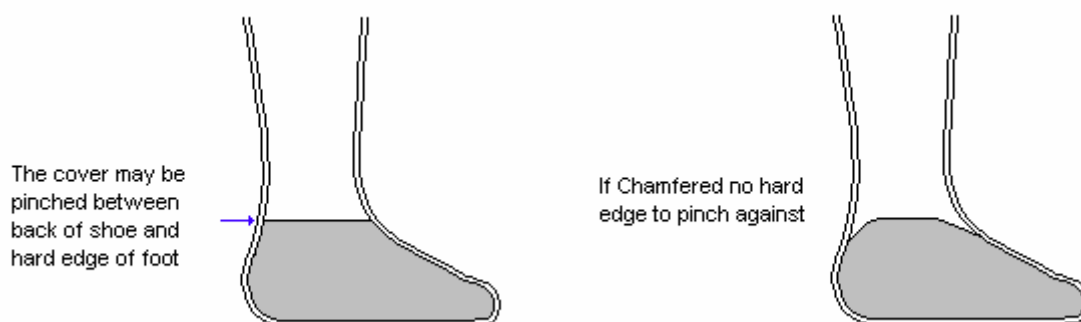
## TECHNICAL INFORMATION

### **Skinergy™ Silicone Leg Cosmeses**

#### **IMPORTANT NOTE! :**

**READ THE FOLLOWING INFORMATION TO FAMILIARISE YOURSELF WITH SKINERGY COVERS. USER INFORMATION IS ALSO PROVIDED, PLEASE GIVE THIS TO THE USER.**

**Skinergy** Covers provide a durable and realistic cosmetic finish for trans tibial prostheses. They are manufactured from a Silicone based polymer, **Tufsil 2**, using a seamless process. **Tufsil 2** is used for this application because it has excellent cleaning properties, is tear resistant and can be stretched in any direction by over 25% allowing it to conform accurately to the underlying structure. It is recommended that the cover is fitted over a firm inner cosmesis such as Plastazote™, alternatively it can be used to cover an exo-skeletal shell. It is not recommended that **Skinergy** Covers be fitted to soft foams. When this is necessary, compression of the foam should be avoided by carving the foam to provide a snug, but not tight fit. **Skinergy** Covers are usually retained by tension when stretched against the inner cosmesis. If this is not possible, the Silicone adhesive provided can be used to retain it. **It is important to graduate the transition between the Plastazote™ and the foot shell**, this is done by sanding the outer, upper, edge of the foot shell to form a generous 45° chamfer. The shin foam is profiled to match and the two components are bonded together using a contact adhesive once the prosthesis has been satisfactorily aligned. It is particularly important to form this transition over the Achilles tendon aspect of the foot.



**Skinergy** Covers have been designed to directly replace fabric covers without the need for changing the foot used, although it is sensible to check the foot with shoes that are likely to be worn. With some feet it may be necessary to grind cosmetic material from the tips of the toes and to increase space between the first and second toes, however, it is important to ensure that the keel is not affected during the grinding process. The covers are provided in a range to accommodate foot sizes 220mm to 300mm with a choice of two calf sizes, either large or small (see table overleaf)

**Skinergy** Covers are available in 12 **RSLSTEEPER** standard shades with custom nails and micro detail texturing. Swatches are available on request (Part no. E18733 for standard finish).

Whilst the unique properties of **Tufsil 2** resist tearing and puncturing, it is good practice to trim edges cleanly with a sharp scalpel blade rather than leave jagged edges with a knife or scissors. Because the material allows considerable stretch these covers will also accommodate devices that absorb torsion and allow ankle adjustment. They may be cleaned daily by simply using soap and water.

**Skinergy** Covers should not be considered to form part of the prosthesis suspension however, they may be used to smooth the transition between socket and skin. Sensible precautions should be taken to observe and prevent any adverse effects from constriction. Some individuals are sensitive to silicone based materials. Where an obvious skin reaction to silicone occurs, use of these covers is contra-indicated.

The cover is not designed to be waterproof, small holes will allow ingress of moisture which may cause damage to metallic components in the prosthesis structure. The user should be asked to guard against this and inspect the cover carefully for damage on a regular basis, particularly if they are using it in environments where exposure to moisture is likely to occur, for instance pool side, beach or snow based activities. It may be necessary to provide a spare cover. If the cover is used to enhance the appearance of a beach or shower prosthesis these constraints do not apply.

**IMPORTANT NOTE ! :** The sole of the cover will become slippery when wet. For poolside, shower or beach activities sandals, “flip flops” or other appropriate footwear should be worn.

**Donning Instructions:**

Remove the **Skinergy** cover from the packaging and lightly lubricate the outside of the cover with a water based lubrication jelly. Turn the cover inside out and roll it back on to the prosthesis ensuring any trapped air is expelled. Once the **Skinergy** cover is fully rolled on, clean it with a damp cloth to remove excess lubricant. The cover can then be trimmed, and secured as appropriate.

**Limb Maintenance:**

The re-alignment, maintenance or exchange of components is simple if the cover is held in place by tension. Simply roll it down to make these adjustments.

**Attachment to the Socket:**

If, instead of suspending the cover by tension it is necessary to secure it in place, an **improved** adhesive is now supplied in the box. It is also available separately, kitted with spare patches.

Roll down the cover, exposing about 2.5 cm (1”) of the socket and remove any foam in this area. Clean around the top of the socket and the matching area inside the cover to remove dust, oil, talc or any other substance that may prevent adhesion, using a solvent based residue free cleaner. Run a bead of adhesive around the brim and smear so that a thin film about 1.5 cm wide covers the socket surface up to the edge. Roll the cover over the socket edge and hold the cover in place. Heat the outer surface of the cover with a hot air gun for about 60-90 seconds taking care not to overheat or create hot spots. Hold the cover firmly against the prosthesis using an elasticated bandage. The adhesive will cure to about 90% strength in 20 minutes. Cut the surplus **Skinergy** away with a sharp blade or scissors.

This method works well for laminated sockets however the glue provided does not adhere to materials used for draped sockets, with these an interface is required. Sometimes it is also necessary use the following technique when the cover must be removed for adjustments.

Make a thin cotton / linen strip about 1.5cm wide and fix this to the proximal socket brim using a petroleum based contact adhesive. When the glue is fully dry, raise a napp on the cloth with coarse glass paper. Use the **Skinergy** adhesive and the technique described above to secure the cover to the fabric.

If it is likely that a more permanent bond is required Loctite™ 406 or 424 can be used, primer 770 improves adhesion. **Note: Follow the manufacturer’s instructions.** Removal without damage is not possible using this method.

**Reinforcement and Forming Access Holes (“Patching”):**

The patching technique can be used to form access holes, where access to foot bolts is necessary and where the cover may not simply be rolled down. Firstly, the area where the access hole is required should be cleaned with isopropyl alcohol. A leather patch or similar protective material should then cut to size, placed over the foot bolt hole and secured by using double sided tape, this will provide a backing to cut against to avoid damaging the sole of the foot. The cover should then be rolled on to the prosthesis. Using a 25mm punch (Part no. NCT9740), the access hole can then be cut and the protective patch removed through the hole.

**NOTE! :** When twisting the punch to cut the hole in the cover, ensure that the cut is made in one strike.

The **Skinergy** patch can then be glued in the same manner as explained in the “Attachment to the Socket” section. **Note:** 2 **Skinergy** patches are provided with each cover, however the **Skinergy** Patch Kit is also available (Part no. E22630 for Standard finish), which contains 5 patches and the required silicone adhesives. Alternatively **Skinergy** patches may be ordered separately in packs of 5 (Part No E22632 for Standard finish). The adhesives can also be used for silicone to silicone patching if required. When silicone surfaces are to be bonded, both surfaces must be cleaned with isopropyl alcohol before applying the adhesive. **Always follow manufacturers instructions when handling adhesive materials.**

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