

Skinergy™ Plus

Technical Information



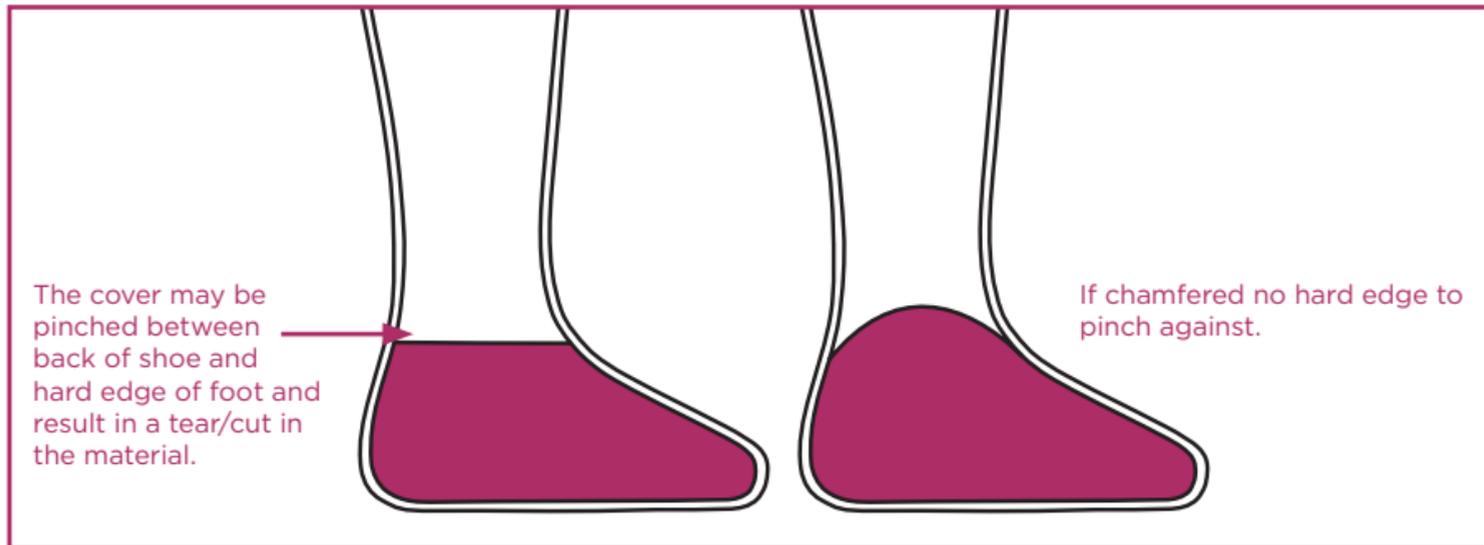
Skinergy™ Plus Leg covers provide a durable, realistic cosmetic finish for transtibial prostheses. The covers are manufactured using a seamless process from a silicone-based polymer, with excellent cleaning properties and tear resistance. The covers can be stretched in any direction by over 25% allowing it to conform accurately to the underlying structure and to accommodate devices that absorb torsion and allow ankle adjustment. Available in 19 TrueFinish™ skin shades featuring custom nails and micro detail texturing, they may be cleaned daily with soap and water.

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. They are designed to directly replace fabric covers without the need to change the foot although it may be necessary to grind cosmetic material from the tips of the toes and to increase space between the first and second toes. It is important that the keel is not affected during the grinding process.

We recommend fitting the cover over a firm inner cosmesis such as Plastazote™, alternatively, it can be used to cover an exoskeletal shell. It is not recommended to fit Skinergy™ Plus covers to soft foams, however, if necessary to do so compression of the foam should be avoided by carving the foam to provide a snug, but not tight fit.

Skinergy™ Plus covers can be retained by tension when stretched against the inner cosmesis. If this is not possible, the silicone adhesive supplied can be used to secure it.

It is important to graduate the transition between the Plastazote™ and the foot shell. Grind 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. It is particularly important to form this transition over the Achilles tendon aspect of the foot.



Donning instructions

Note: Provided the detailed fitting instructions, supplied in this document, are followed there are no specific qualifications required to fit this device.

1. Remove the Skinergy™ Plus cover from the packaging and lightly lubricate the outside of the cover with a water based lubrication jelly i.e. KY Gel.
2. Reverse the cover, so the lubricated outer surface is now inside.
3. Starting from the toes roll the cover onto the prosthesis. It is not necessary to heat the cover.
4. Check the foot cover is fitted properly, particularly around the heel and toes.
5. Once the Skinergy™ Plus cover is fully fitted, clean it with a damp cloth to remove excess lubricant.
6. 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 socket

An adhesive is supplied with each Skinergy™ Plus cover and is also available to order separately.

1. Roll down the cover, exposing about 4cm of the socket, lightly abrade the top of the socket and corresponding section of the cover fabric reinforcement with a medium abrasive paper.
2. Paint both roughened surfaces with a contact adhesive or run a bead of the supplied adhesive around the brim and smear to a thin film.
3. Roll the cover back up over the socket edge of the prosthesis and hold the cover in place.
4. Cut the surplus cover material away with a sharp blade. If using the supplied adhesive, wait 24 hours for the adhesive to fully cure before trimming the excess cover.

To watch the video demonstrating this technique, please visit www.youtube.com/steepergroupUK

If a more permanent bond is required, Loctite™ 406 or 424 can be used, primer 770 improves adhesion, however it should be noted that removal without damage is not possible using this method.

Note: Always follow manufacturer's instructions when handling adhesive materials and other chemicals. Wash hands thoroughly following use.

Reinforcement and forming access holes

The patching technique can be used to form access holes, where access to foot bolts is necessary. A colour swatch can be ordered to cover the hole.

1. A leather patch, or similar protective material, of the appropriate size, should be placed over the foot bolt hole and secured using double sided tape. This will provide a backing to cut against and avoid damaging the sole of the foot.
2. Roll the cover onto the prosthesis.
3. Using a 25mm punch the access hole can be cut and the protective patch removed through the hole. When twisting the punch to cut the hole in the cover, ensure that the cut is made in one strike.
4. Abrade both of the surfaces to be bonded together with fine sandpaper.
5. Apply contact adhesive around the edge of the swatch and the surface to which it will be bonded. Allow both surfaces to dry thoroughly.
6. Place the swatch over the hole in the cover and press to give a good contact around the hole.

Nail polish

Skinergy™ Plus will accept nail polish/varnish applied directly to the surface however the varnish may flake off due to the material being flexible. To improve adhesion, create an interface between the silicone and the varnish by taking a small piece of clean fine cotton or linen cloth and cutting “nail” shaped pieces from it. Smear the supplied adhesive onto the nail bed. Position these fabric nails onto the glue, pressing firmly to force the glue into the fibres. Cure for about 15 minutes or gently warm the surface with a hairdryer to speed the reaction, and then paint the surface with nail varnish. Usually, three coats will be required to provide a smooth surface. A new coat of varnish can be applied as necessary. Finally, wash the surface of the leg cover with soap and water.

The varnish can be removed with a regular acetone-based nail polish remover, but use caution as this may result in some cumulative damage to the leg cover. Do not immerse the leg cover in acetone.

Additional information

Skinergy™ Plus covers should not be considered to form part of the 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 contraindicated.

The cover is not designed to be waterproof, small holes will allow ingress of moisture that may cause damage to 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. 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 pool side, shower or beach activity, sandals or other appropriate footwear should be worn.

Warning: Do not expose Skinergy™ Plus to naked flame or excessive heat. Avoid prolonged exposure to direct sunlight.



Product ordering information

Part No Split Toe	Part No Close Toe	Foot Size (mm)	Ankle Circ.		Mid Calf Circ.		Top of Cover Circ.		Floor to -	
			Min	Max	Min	Max	Min	Max	Mid Calf	Cover Top
TLC22LS	TNS22LS	220 / 230	20	25	28	35	26	32.5	32	55
TLC22RS	TNS22RS	220 / 230	20	25	28	35	26	32.5	32	55
TLC22LL	TNS22LL	220 / 230	20	25	32	40	30	37.5	32	55
TLC22RL	TNS22RL	220 / 230	20	25	32	40	30	37.5	32	55
TLC24LS	TNS24LS	240 / 250	22	27.5	31	39	29	36	34.5	57
TLC24RS	TNS24RS	240 / 250	22	27.5	31	39	29	36	34.5	57
TLC24LL	TNS24LL	240 / 250	22	27.5	35	44	33	41	34.5	57
TLC24RL	TNS24RL	240 / 250	22	27.5	35	44	33	41	34.5	57
TLC26LS	TNS26LS	260 / 270	22	28	32	40	30	37.5	37	61
TLC26RS	TNS26RS	260 / 270	22	28	32	40	30	37.5	37	61
TLC26LL	TNS26LL	260 / 270	22	28	37	46	35	44	37	61
TLC26RL	TNS26RL	260 / 270	22	28	37	46	35	44	37	61
TLC28LS	TNS28LS	280 to 300	24	30	34	42.5	32	40	39.5	66
TLC28RS	TNS28RS	280 to 300	24	30	34	42.5	32	40	39.5	66
TLC28LL	TNS28LL	280 to 300	24	30	39	49	37	40	39.5	66
TLC28RL	TNS28RL	280 to 300	24	30	39	49	37	40	39.5	66

Note: All measurements in cm with the exception of foot size, in mm. See overleaf for advice on specifying the colour required.

To define the colour required, please refer to the colour swatch and add the descriptor to the order number. For instance, when E5 is required for part number TNS24LL, the order number will become TNS24LL/E5. This number orders a Skinergy™ Plus for a closed toe foot, size 240mm, left with a large calf, colour E5.

Colour Swatch - E24655

The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. Steeper, therefore, reserves the rights to introduce changes and withdraw products without notice.

Warranty

The supplied product comes with a 3-month warranty from the date of fitting. This covers manufacturing based defects that directly affect the performance characteristics of the cosmesis. This warranty does not cover 'normal use'. Care must be taken wearing the cosmesis without suitable footwear as this could lead to premature failure from sharp objects / materials. I.e. Sharp footwear straps across heel, gravel, stones etc.

In the event of quality issue/query, the supplied RSLIT372 Polymer production QC inspection card should be retained and this be provided in the event of product return. Failure to provide this information could delay processing the return and affect the warranty.

Important Information

- The Skinergy™ Plus Silicone Leg Cosmesis is a Class I Medical Device which meets the general safety and performance requirements in MDR 2017/745 Annex I
- If a serious incident occurs relating to the device, full details should be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- For safe disposal, please return your prosthesis to your prosthetic clinic.
- The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The Company therefore reserves the right to introduce changes and withdraw products without notice.



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RSLIT011 Issue 8
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