



Dream Skin Natural Definition

Product Manual

Fillauer®

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Intended Use/Purpose

DreamSkin Natural Definition is a Cosmetic cover for lower limb prosthetics. Using a dual layer PVC with added fibers and airbrush technique DreamSkin has a deeper definition and a more natural look. Available in a red and yellow scale with eight colors in each scale, DreamSkin is available in 16 colors covering most skin tones. DreamSkin Natural Definition is treated with a Micro Coated surface making it more durable and stain resistant compared to other skins.

DreamSkin is intended for single patient use only.

Performance Characteristics

- Good cosmetic definition for a natural look
- Durable with good tear resistance
- Low fabric friction
- Dirt and stain resistant
- Water resistant
- Meets ISO 22523
- Available in 16 different skin colors (use Natural Definition color guide)
- Dream Skin is delivered expanded for easy donning

Material

- PVC (free from all heavy metals and phthalates)
- MCV (free from all heavy metals and phthalates)

Natural Definition Guide

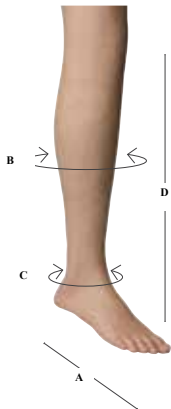
For your convenience we made the Natural Definition Guide to help determine which color to choose for your patient. The guide consists of two different scales, R and Y (Red and Yellow). Each has 8 different colors to choose from to cover most skin tones.



Product number 611200003

Size Chart

FOOT SIZE (A)	CALF SIZE MIN (B)	ANKLE SIZE MIN (C)	LENGTH (D)
21 - 22 cm	12.0 in. (305 mm)	7.5 in. (190 mm)	19.7 in. (500 mm)
23 - 24 cm	12.6 in. (320 mm)	7.9 in. (200 mm)	21.7 in. (550 mm)
25 - 26 cm	13.4 in. (340 mm)	8.2 in. (210 mm)	23.6 in. (600 mm)
27 - 28 cm	14.0 in. (355 mm)	8.5 in. (215 mm)	21.7 in. (550 mm)
29 - 30 cm	14.6 in. (370 mm)	8.7 in. (220 mm)	25.6 in. (650 mm)



Storage and Handling

Do not place this product in direct sunlight for longer periods of time. When not in use, store in a cool, clean, dry and dark area.

Warnings and Precautions



WARNING: Using acetone or similar chemical solvents will damage the cosmetic cover and will void the warranty.



WARNING: Do not use silicone spray when donning Dreamskin on the prosthesis.



WARNING: Do not expose the Dreamskin to color pigments when donning Dreamskin on the prosthesis.



WARNING: Be careful not to overheat the skin, max. 100° C. Overheating will damage the vinyl, deform underlying foam, and void the warranty.



NOTICE: Attachment and removal of this cosmetic cover must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be done by the clinician and not by the user.



NOTICE: Abnormal or improper environmental conditions will lead to malfunction and damage of the cosmetic cover and is not covered under the warranty of the device. This cosmetic cover must not be subjected to dust/debris, harsh chemicals, abrasives, vibration, activities which would damage the biological limb, or prolonged exposure to extreme temperatures (<-15C or >50C) (<5F or >122F).

Specifications and Preparations Before Use

Dream Skin Natural Definition is delivered expanded for easy donning. After the skin is in position you just simply apply heat to the material, max. 100° C. The skin will shrink to the underlying cosmesis.

Fitting Instructions

It is necessary to use a foam cover underneath the cosmetic skin. To make donning easier, all Dream Skins are expanded and has talcum on the inside.

- Be sure toes and heel are orientated correctly. Gather and pull Dream Skin Natural Definition over the foot. Avoid air pockets and wrinkles on the plantar surface.

- Skin should be stretched just enough to remove slack and wrinkles. With skin in correct position, pull over proximal edge. CAUTION: Overstretching will cause tension on the skin and a greater risk of splitting.

- Heat lightly to conform skin to contours and prevent wrinkles, CAUTION: Be careful not to overheat the skin. Overheating will damage the vinyl, deform underlying foam, and void the warranty.

- It is not necessary to glue skin in any area other than the proximal brim. Prepare skin to be glued by cutting away excess material. Cut line should be 5 cm above the proximal brim and should follow the curve. Sand the socket's surface with sandpaper until it is rough, then clean with alcohol before gluing.



- Apply adhesive on both surfaces to the top edge of the brim in small sections. Then press the surfaces together with the highest possible pressure or apply a thin line of super glue to the top edge of the brim in small sections (5 - 10 cm at a time).

- Fold skin over edge and apply pressure until dry. Alternate medial and lateral sides to avoid wrinkles. Allow glue to dry completely.

- Using a sharp scalpel, carefully trim unattached skin along the inside edge of the socket.

- If adjustments to the foot are necessary in the future, simply grind along the top of the socket and reflect the skin. The same Dream Skin may be reused following this method of fabrication.



NOTICE: Dream Skin Natural Definition is shipped with an expanded ankle section for easy donning. Once the prosthesis is on, you can reduce the ankle section for a custom fit with the use of light heat from a heat gun or by placing the prosthesis in the oven.



Combination of Devices

Dream Skin Natural Definition is compatible with most prosthetic feet. For best results, Fillauer recommends using a design with formed toes rather than a smooth shell.

When you combine DreamSkin Natural Definition with the Absolute Sleeve, you not only get excellent suspension of the prosthesis, but you also have a perfect solution for shower and bath!

Disposal/Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

If possible, recycle the Dreamskin as plastics.

User Information

The providing health care professional must review the following information directly with the user:

Attachment and removal of this cosmetic cover must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be done by the clinician and not by the user.

Care and Maintenance

Dreamskin features a unique microcoating, designed to resist staining with normal washing. Clean with soap and water or rubbing alcohol(70%).



WARNING: Do not use Acetone, MEK, or any other solvents. Solvents will damage the coating and void the warranty.



NOTICE: Although our unique micro-coating resists most forms of marks, it is not resistant to all staining agents. For best results, Dreamskin should be cleaned as soon as possible after marks are incurred to reduce the possibility of permanent staining. Marks left overnight may become permanent.



NOTICE: If the cosmetic cover has any holes or tears, contact your health care provider.

Frequently asked questions

The color difference between the foot and the socket shows through the skin.

This usually occurs when either the foot or the socket is a different color than the skin. This can be solved simply by applying one or two layers of stockinette under the skin.

Can I use any prosthetic foot with Dream Skin Natural Definition?

Dream Skin Natural Definition is compatible with most prosthetic feet. For best results, Fillauer recommends using a design with formed toes rather than a smooth shell.

Does Dream Skin Natural Definition come in a split toe version?

Yes, there is a split toe version of Dream Skin Natural Definition.

How do I choose the proper size?

Dream Skin Natural Definition comes available in left and right, in 5 sizes based on foot size. Each skin is designed to accommodate two sizes of feet (21–22 cm, 23–24 cm, 25–26 cm, 27–28 cm, and 29–30 cm). Please refer to the sizing guide.

Is the skin removable?

Yes, the skin can be removed if care is taken not to tear the material from the proximal brim. It is re-commended that a practitioner familiar with the product remove the skin.

Can I paint the toenails of my Dream Skin Natural Definition?

Yes, the toenails can be painted. However, not all nail polish will work. Please note that the use of acetone, MEK, or any other solvents will damage the coating and void the warranty. The ankle area of the Dream Skin Natural Definition is too large.

Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the Instructions for Use. The device must only be operated with tested modular components. The manufacturer is not liable for damage caused by component combinations that were not authorised by the manufacturer.

Warranty

This product has 6 month warranty against manufacturer defects.

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