User manual MySkin

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product nr:	445
date of manufacture:	

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1 Instructions for use

1. INSTRUCTIONS FOR USE

This document contains information for both professionals and prosthetic users.

This document provides instructions for fitting and using the Hy5 MySkin glove and should be read prior to use. It is recommended that the use of this manual is in conjunction with instructions from a clinician experienced in upper limb and myoelectrical prostheses. Follow the safety instructions to avoid damage to the product or possible injury.

MySkin is used to protect the Hy5 MyHand. The material of the glove is silicone combined with a strong inner mesh lining making the glove robust and durable.

The glove comes in several different skin colours, matte black and translucent. The matte black and translucent variants are without skin detailing. Talk to your local clinical expert to find the perfect colour for you.

1.1 INTENDED USE

MySkin is developed to be used on the Hy5 MyHand prosthesis. The MySkin glove is made for use in everyday activities.

AUTION! — If the glove is used for extreme activities, it can become damaged or rip.

Before use, check the glove for visible damage.

2. DONNING

- Roll the sleeve of the glove back on itself up to the level of the wrist area.
- 2. Under power, close the fingers of the hand to an approximately half-closed position.
- 3. Gradually pull the glove down over the hand. When the glove is approximately half-way mounted to the hand, align the fingers and thumb with the corresponding openings in the glove
- 4. Pull the glove over the remainder of the MyHand.
- 5. Inspect the glove ensuring that it is mounted all the way down onto the fingers, and that the finger tips are correctly in place
- After donning is complete, check that the MyHand functions as expected and that the fingers correctly form a pinch grip when closed.

3. PRODUCT LIFETIME

The product lifetime of MySkin diminishes or increases depending on the level of everyday use. The glove is subject to natural wear and tear depending on individual use. The glove should be replaced when rips or signs of wear start to appear. Please contact your local clinician when replacement is needed.

4. ENVIRONMENTAL CONDITIONS

Operating temperature when used over MyHand prosthesis: +5C to + 35C (+41F to 95F).

Storage and transport temperature: +5C to + 35C (+41F to 95F).

⚠ CAUTION!	 Keep the	glove	away from	open	flames
CAUTION:	and othe	r heat	sources.		

5. CLEANING

Only clean the glove according to the instructions in this manual. Clean the product often to avoid dirt or stains permanently contaminating the silicone material. To clean your MySkin, you only need water, hand soap and a dry cloth. Cleaning instructions as follows:

- 1. Make sure the glove does not have any tears or holes.
- 2. Rinse the glove with water.
- 3. If there are stains or dirt, massage the area with hand soap.
- 4. Dry the glove with a lint free cloth. Let it air dry fully.

6. DISPOSAL

When disposing of the MySkin glove, please follow the guidelines for disposal of waste plastics (silicone) in your country.

7. CE

The MySkin glove is classified as a class I device and meets the requirements of the European Directive 93/42/EEC for medical devices.

8. TECHNICAL DATA

Size	7 ¾
Colours	6 skin tones, matte black and translucent
Variants	Right / left

9. SAFETY/CAUTIONS

- Only use the glove after reading the instructions for use.
- The glove can be damaged if it comes in contact with a sharp object.
- Do not expose the glove to environmental conditions outside those specified.
- · Check the glove regularly for damage.
- If damaged, do not use the glove.
- Clean the glove immediately if dirty to prevent permanent damage.

10. INCIDENT REPORTING

Complaints or accidents involving Hy5 products should be reported via the 'contact' page on the Hy5 website www.hy5.no







FDA

FDA Registration Number: 3014936213



CE mark

Declaration of conformity according to the applicable European directives



Legal manufacturer

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