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For further information please visit
www.tipstim.com

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Therapy glove to be used in combination
with tipstim® pulse generator

INSTRUCTIONS FOR USE

For size & dexterity see information
on the label inside the glove





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IMPORTANT NOTE

PLEASE MAKE SURE TO READ ALL INFORMATION PROVIDED IN THESE INSTRUCTIONS FOR USE AND IN THE INSTRUCTIONS FOR USE OF TIPSTIM® PULSE GENERATOR. BEFORE USING TIPSTIM® GLOVE.

THESE INSTRUCTIONS FOR USE ARE AN INTEGRAL PART OF THE MEDICAL DEVICE. BE SURE TO ALWAYS KEEP THEM WITH THE MEDICAL DEVICE.

Do not use the **tipstim® glove** if you do not fully understand any aspect of operating the system. Please refer to a qualified supplier for assistance.

Intended use

tipstim® glove is a class I medical device. It is intended for sensitive electrical stimulation of the fingertips of the upper extremities. **tipstim® glove** is intended for the use in combination with **tipstim®** pulse generator only.



tipstim® glove is approved for single patient use only and must be replaced after 100 applications of 60 minutes each.




Medical application areas


tipstim® glove is used to treat patients with incomplete sensomotoric hemiparesis and monoparesis (paralysis) as a result of brain damage (caused by stroke) and CRPS type 1 (Complex Regional Pain Syndrome) and improves the sense of touch and mobility of the hand.




www.tipstim.com

EXPLANATION OF GRAPHIC SYMBOLS AND PRODUCT MARKING

 **DANGER** Indicates a direct hazard carrying a high risk of death or serious injury if not avoided.

 **WARNING** Indicates a medium risk which could result in death or serious injury if not avoided.

 **CAUTION** Indicates a possible danger that may result in minor or moderate injury if not avoided.



Consult instructions for use



Manufacturer (see label inside glove)



Item number **tipstim® glove**
(see label inside glove)

Version

Product version (see label inside glove)



LOT number (see label inside glove)



CE marking



Caution – follow the instructions



Protect medical device from moisture
(IP 00 acc. to DIN EN 60529)



Keep medical device away from
sunlight and from heat



Medical device not to be disposed of
with normal/household waste



Not suitable for pacemaker wearers



Prevention of danger/risk



Temperature



Humidity



Air pressure



Medical Device



Single patient – multiple use



Patient information website

SAFETY INSTRUCTIONS AND WARNINGS

 **DANGER**

Possible risk of interference with cardiac pacemakers

→ **tipstim® glove** should not be used by patients fitted with a pacemaker. **Exception:** explicit permission by a medical specialist.

Possible risk of danger to patients with cardiac damage

→ **tipstim® glove** should not be used by patients with cardiac damage. **Exception:** explicit permission by a medical specialist.

Danger to children and untrained users

→ Keep **tipstim® glove** away from children and untrained users.

Possible risk of damage to implanted medical products

→ **tipstim® glove** should not be used by patients with medical implants. **Exception:** explicit permission by a medical specialist.

Possibility of deviations in the output parameters by unauthorized attempts to repair or to clean

- Do not attempt to repair **tipstim® glove**. Do not wash, use bleach, iron, dry-clean or tumble-dry **tipstim® glove**. Do not turn **tipstim® glove** inside out.

Risk of Deviations in the output parameters or electric shock caused by liquid in the medical device

- Do not expose the product to high humidity. Do not clean **tipstim® glove** with water or other liquids. Not to be used outdoors.

Ignition of highly combustible substances

- Always keep the product away from highly combustible materials.

Possible risk to health by painful stimulation pulses

- **tipstim® glove** to be used for a maximum of 100 applications of 60 minutes each. After that, **tipstim® glove** must be replaced for safety reasons.

Possible risk to health (heart, head, genitalia, spinal cord, neck) by electrical stimulation

- Only use **tipstim® glove** as per the instructions for use at all times.

Incorrect use of tipstim® can lead to possible damage to health

- Only use **tipstim® glove** as per the instructions for use at all times and always keep these instructions for use with the product.



tipstim® glove is approved for single patient use only

- If serious incidents occur in connection with this medical device, you are obliged to report these incidents to the manufacturer of this medical device and to the competent authority in your country.

WARNING

Possible risk of danger by electric shock

→ Do not connect **tipstim® glove** or its components/accessories directly to mains power supply. Always remove any kind of hand or finger decoration (e.g. rings) before starting the therapy. Avoid strong hand and finger movements during the therapy as this might lead to contact interruptions between fingers and electrodes resulting in discomfort.

Risk of burning the skin by high-frequency surgical unit at the electrode contact point

→ Do not connect to a surgical device with high frequency simultaneously.

Combustible/explosive substances in the immediate surroundings could be ignited

→ Do not operate **tipstim® glove** close to combustible/explosive substances or flames of any type.

To avoid deviations in the output parameters by environmental conditions

→ Observe the predefined operating and storage conditions at all times.



tipstim® glove to be protected from strong sunlight and strong heat sources



tipstim® glove to be protected from moisture (IP 00 acc. to DIN EN 60529)



5°C min. 35°C max.

tipstim® glove only to be operated at an ambient temperature between 5°C and 35°C



30% 75%

tipstim® glove only to be operated at a relative humidity of 30-75%



700 hPa 1.060 hPa

tipstim® glove only to be operated at a relative pressure between 700-1060 hPa

tipstim® glove not to be used in dusty environment



Do not wash



Do not iron



Bleaching not allowed



Do not dry in tumble drier



Do not use chemicals to clean

Possible risk of infection for patients designated to use sterile products only

- Do not use **tipstim® glove** if sterile environmental conditions are required.

Risk by uncontrolled actions

- Do not use **tipstim® glove** with patients suffering from seizure disorders (e.g. epilepsy), increased epileptogenicity or severe cognitive impairments. **Exception:** explicit permission by a medical specialist.

Risk by improper use

- **tipstim® glove** only to be connected to devices that have been specified as compatible by the manufacturer.



Deviations in the output parameters

- Do not operate **tipstim® glove** in the vicinity of therapeutic shortwave or microwave devices as this will cause deviations in the output.

Pain or other health problems during treatment

- Stop using the device immediately, consult a medical specialist and notify the manufacturer without delay.

Danger of injury by damage to **tipstim® glove** or its accessories

- Do not crush **tipstim® glove**. Avoid squeezing or pulling the connection cables. Damaged parts must not be used.

Danger of injury by electrical shock when starting or ending therapy session

- Switch on the associated **tipstim®** pulse generator only after **tipstim® glove** has been put on and connected correctly. Always completely switch off the associated **tipstim®** pulse generator before taking off **tipstim® glove** or disconnecting the electrode cable.

Tissue damage around conductive implants

- Do not use **tipstim® glove** close to conductive implants.

Damage to surgical wounds, to injured skin and other skin irritations

- Do not use **tipstim® glove** close to fresh surgical wounds or damaged skin.

Damage to health in case of infectious diseases and fever

- Do not use **tipstim® glove**.

Danger of injury when operating machinery simultaneously

- Do not use **tipstim® glove**.

Danger of injury by high electrical currents in case of sensitivity disorders

- Talk to your medical specialist about which level of intensity to use.

Health impairments of stroke patients

- Please make sure to use **tipstim® glove** 2 weeks after stroke at the earliest.

Health impairments of patients suffering from polyneuropathy or peripheral nerve lesion in the region of the upper extremities

- Do not use **tipstim® glove**.

Impairment of the treatment success due to interaction caused by a simultaneous therapy with anticonvulsants (drugs for the treatment of epilepsy)

- **tipstim® glove** may only be used under medical supervision.

PREPARING A THERAPY SESSION

Before starting the therapy:

- Before putting on **tipstim® glove**, please make sure that your hand to be treated is clean, free of cream and dry.
- Always connect **tipstim® glove** to the **tipstim®** pulse generator.
- To do this, insert the plug of the electrode cable supplied into the connection point of the **tipstim®** pulse generator (see figure 1).
- Fully connect the 3 metal pins of the cable to the 3 snap adapters. Make sure there is no visible metal of the pin on view (see figure 2).
- Plug the 3 snap adapters to **tipstim® glove**. Please follow the colour sequence: red cable to button with red background, black cable to black button and yellow cable to yellow button (see figure 3).



fig. 1



fig. 2



fig. 3

■ Put on **tipstim® glove**. Make sure that the zip is located on the back of the top of the hand. Do not twist the fingers of **tipstim® glove** (seams of **tipstim® glove** must be located on either side of the finger).

Do not pull **tipstim® glove** too strongly as this will damage the electronic components inside **tipstim® glove** (see fig. 4-7). The zip at the back of the hand allows one to put on **tipstim® glove** more easily – especially for those with spasticity.



fig. 4



fig. 5



fig. 6



fig. 7

■ Make sure that all fingertips touch the finger tops of **tipstim® glove** and that the fingers fit closely. This is important to ensure correct stimulation of the fingertips.

If necessary readjust **tipstim® glove** to the correct settings by using the other hand (see figure 6).

If **tipstim® glove** cannot be closed completely, this is not critical for the therapy. It is important that all five fingers touch the finger tops of **tipstim® glove** and fit tightly.

■ Read the instructions for use of **tipstim®** pulse generator.

DURING THE THERAPY SESSION

■ For best results keep your hand and fingers relaxed by laying the hand, for instance, on a table. Do not move the hand during therapy. Strong hand/finger movements may lead to a loss in electrode contact and as a result to an uneven stimulation.

Note: In case there is no current noticeable at the beginning or in the further course of the therapy and intensity of **tipstim®** pulse generator cannot be increased (display is blinking and shows 2 mA or less and cannot be increased, an acoustic signal is audible and will be repeated after 30 seconds) there is no sufficient contact between at least one finger and the in-built electrodes. Please readjust **tipstim® glove** (see figures 4–5) to make sure that you have a tight fit.

If the problem continues then the likely cause is that the skin is very dry leading to an insufficient contact with the electrodes and so reducing the conductivity of **tipstim® glove**. Soak your fingertips in clear water for about 1 minute before starting the therapy. This process is generally suitable to improve conductivity. Repeat this process in case the electrical contact should be disrupted again during therapy. A short

interruption of the therapy session has no negative effect on the therapy results.

AFTER THE THERAPY SESSION

■ Always turn off the **tipstim®** pulse generator before taking the **tipstim® glove** off.

■ Gently pull off **tipstim® glove**.

■ Always store **tipstim® glove** and **tipstim®** pulse generator in the packing provided. Take care not to bend the cables!

Note: It might be the case that, after having finished the therapy session, you still feel a slight tingling sensation in your fingertips. This effect is harmless and will disappear after some time.

REPLACEMENT OF TIPSTIM® GLOVE AFTER 100 THERAPY SESSIONS (60 MINUTES EACH)

If you want to change your **tipstim® glove** for a new one please observe the following instructions:

- Loosen snap adapters carefully from **tipstim® glove**. Take care not to tear the **tipstim® glove**.
- Do not pull the cable, prize the cables off gently.
- Connect the new **tipstim® glove** as described previously in the instructions for use (preparing a therapy session).

STORAGE AND CARE

- Store **tipstim® glove** in a dry place.
- For cleaning follow the instructions on the label found on the inside of the **tipstim® glove**: Do not wash, use bleach, iron, dry-clean or tumble-dry the **tipstim® glove**.
- To protect the conductive material of **tipstim® glove** always wash hands before use. Also make sure the hand is clean, dry and free of sweat. Do not use any hand creams or lotions.
- Do not turn **tipstim® glove** inside out.

TECHNICAL INFORMATION

All textiles and yarns used for the manufacturing of **tipstim® glove** meet the Oeko-Tex 100 standard and do not contain any biological material of animal origin.

Material:	85% Polyamid, 15% Elasthan
Inlay:	100% Polyester
Electrode:	94% Polyamid, 6% Dorlastan
Pad:	100% Polyester
Weight:	approx. 50g

tipstim® glove is available in different sizes for the left or right hand. You will find a size chart under:



www.tipstim.com

THERAPY RECOMMENDATIONS AND EXPLANATIONS

■ Daily therapy times

Unless otherwise recommended by the medical expert therapy should be performed for 1 hour every day.

■ Total therapy time

Therapy time in weeks/months will be defined by your medical expert and depends on your disease's severity, the elapsed time since the origin of your disease and your individual therapeutic progress.

■ General notes

Since the hand is supplied by different nerves, fingers show a varying sensitivity. For this reason **tipstim**[®] pulse generator offers 2 different channels allowing an individual adaptation of the current intensity.

You should feel a relatively even and clear perception of the stimulation at all 5 fingers, however, stimulation must not be unpleasant or painful. For further information please refer to the instructions for use of **tipstim**[®] pulse generator. In everyday therapy the intensity used for channel 1 (left channel) of **tipstim**[®] pulse generator (stimulating thumb, forefinger,

middle finger) will generally be higher than the one chosen for channel 2 (right channel: ring finger, little finger).

Please note that there is no default or standard value for the current intensity. This may vary from patient to patient and day to day depending on such factors as electrical resistance of the skin, environmental conditions etc.

TROUBLESHOOTING

■ First read the instructions for use of **tipstim**[®] pulse generator (Debugging and repair by untrained users).

■ It may occur (very rarely) that your skin is too dry for a sufficient contact with the in-built electrodes (display is blinking and shows 2 mA or less and cannot be increased, an acoustic signal is audible). To solve this problem soak your fingertips in clear water for about 1 minute and start the therapy again.

■ If the fault should reoccur, please contact the manufacturer/supplier of **tipstim**[®] or your treating physician/therapist.

ENVIRONMENTAL PROTECTION AND WASTE DISPOSAL



tipstim[®] is not to be disposed of with normal/household waste. Only dispose using a reputable recycling company or return the device to the supplier. Please obey your local regulations regarding disposal.

WARRANTY

For **tipstim**[®] **glove**, the legal warranty or a warranty for the operating life of **tipstim**[®] **glove** stipulated by the manufacturer shall apply – whatever occurs first. The warranty claim is not applicable for defects, failures or damages which derive from noncompliance with these instructions for use and/or non-compliance with the medical expert's instructions. The warranty does not apply in the event of accidents, misuse and interventions and changes performed by non-authorized personnel.

Should you experience any problem with the medical device or its components please refer to the manufacturer or your local dealer.

WE WISH YOU A SUCCESSFUL
COURSE OF THERAPY!