Nalu™ Medical Inc.

ENGLISH

TD2 Therapy Disc

TD2 Therapy Disc - 34014-001

DESCRIPTION

The TD2 Therapy Disc is the externally worn transmitter module that powers and sends stimulation commands to the Nalu Implantable Pulse Generator. The Therapy Disc is positioned externally over the implant using an adhesive retention clip or a belt and is controlled using the Nalu Remote Control Application.

The service life for the Therapy Disc is 3 years.

INDICATIONS FOR USE

Spinal Cord Stimulation (SCS)

This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Peripheral Nerve Stimulation (PNS)

This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Nalu Neurostimulation System for PNS is not intended to treat pain in the craniofacial region.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

CONTRAINDICATIONS AND WARNINGS

For a complete list of contraindications and warnings associated with this product, see the Nalu Neurostimulation System User instructions for use.

Carefully examine all product packaging before use; do not use product if packaging is damaged or open.

HANDLING

When needed, clean the outside of the Therapy Disc with a damp cloth to prevent dirt and dust. Do not use abrasive or caustic cleaning products on your Therapy Disc.

INSTRUCTIONS FOR USE

For complete instructions, please refer to the Nalu Neurostimulation System User instructions for use.

Powering ON the TD2 Therapy Disc

1. If not already in the Base Station Charger, place the disc in the charger momentarily; once it blinks and buzzes remove the Therapy Disc from the Base Station Charger.
2. Listen, watch and feel.
3. The buzzer will beep and vibrate, and the white LED will blink to indicate battery level.

Following the white LED blinks, the green LED will blink to indicate the most recently used program. The number of green LED blinks corresponds to the current program.

Connecting the TD2 Therapy Disc with the Nalu Implantable Pulse Generator

1. Place the Therapy Disc over the implant.
2. Three (3) short beeps will sound, and the buzzer will vibrate when the Therapy Disc connects to the implant.

NOTE: The TD2 Therapy Disc starts stimulation at the most recently used program and stimulation level.

NOTE: If the Therapy Disc becomes disconnected from the implanted pulse generator after having been connected, the Therapy Disc will beep and vibrate once every second.

NOTE: Alerts for the Therapy Disc can be configured using the Nalu Remote Control Application or the Clinician Programmer.

CUSTOMER SERVICE – USA

In USA, to order replacement parts, or product inquiries, please contact Nalu's Customer Service.

Nalu Medical, Inc.
2320 Faraday Ave Ste 100
Carlsbad, CA 92008

Telephone: +1-800-618-3402
Customer Service:
info@nalumed.com
Technical Support:
support@nalumed.com
www.nalumed.com

Caution: Federal law restricts this device to sale by or on the order of a physician

℞ Only

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Refer to the following table for an explanation of applicable product label symbols:

Symbol	Title	Explanation	Standard	Reference
	Manufacturer	Medical device manufacturer, as defined in EU Directive 93/42/EEC	ISO 15223-1	5.1.1
	Date of manufacture	Date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Use-by date	Date after which the medical device is not to be used.	ISO 15223-1	5.1.4
	Batch code	Manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1	5.1.5
	Catalogue number	Manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1	5.1.6
	Do not use if package is damaged	Medical device should not be used if the package has been damaged or opened.	ISO 15223-1	5.2.8
BEST BEFORE	Best Before	This device is best used before this date	N/A	N/A
	Keep away from sunlight	A medical device that needs protection from light sources.	ISO 15223-1	5.3.2
	Keep dry	A medical device that needs to be protected from moisture.	ISO 15223-1	5.3.4
	Temperature limit	The temperature limits to which the medical device can be safely exposed.	ISO 15223-1	5.3.7
	Do not re-use	A medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1	5.4.3
	Refer to instruction manual/booklet.	Indicates the instruction manual/booklet must be read. (This symbol is blue and white on the device label)	ISO 7010:2011	M002
	Caution	User to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1	5.4.4
	MR Conditional	Medical device demonstrated safety in the MR environment within defined conditions.	ASTM F2503-13	Fig. 6
	MR Unsafe	Medical device poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503-13	Fig. 9
Rx Only	Prescription use only	Caution: Law prohibits dispensing without prescription	21 CFR 801.109	N/A
QTY	Quantity	Indicates the total number of products provided in a package.	N/A	N/A

Symbol	Title	Explanation	Standard	Reference
SN	Serial Number	Manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1	5.1.7
	Radio Transmitter	Device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device	IEC 60601-1-2:2007	5.1.1
EC REP	Authorized Representative in the European Community	Authorized representative in the European Community	ISO 15223-1	5.1.2
	Protected against electric shock	Device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation	IEC 60417	5333
IP22	Protected against access to certain hazardous parts	Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical	IEC 60529	N/A
IP68	Protected from dust and immersion in water	Protected from dust and against effects of immersion in water up to 1.5m depth for 30 mins occasionally	IEC 60529	N/A
FC	FCC	This symbol indicates that this equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.	47 CFR 2.926	N/A
	Do not throw in the trash	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Nalu Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Nalu Medical.	BS EN 50419 Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	Fig. 1
STERILE EO	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1	5.2.3
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1	5.2.6
	Stimulator length	Indicated the length of the device	N/A	N/A
	Humidity limitation	Indicates the range of humidity to which the device can be safely exposed	ISO 15223-1	5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the device can be safely exposed	ISO 15223-1	5.3.9