

nalu™

neurostimulation



ABOUT THE NALU NEUROSTIMULATION SYSTEM

The Nalu system consists of a fully-featured, battery-free, miniaturized implantable pulse generator (IPG) that is powered wirelessly by an externally worn Therapy Disc and controlled through a smartphone-based remote control app. Despite its small size, Nalu's micro-IPG delivers treatment capabilities similar to larger IPGs as well as unique advantages associated with advanced waveforms, extensive programming options, exceptional upgradability, and a system life of 18 years. The Nalu Neurostimulation System is currently FDA-cleared for **Spinal Cord Stimulation (SCS)** and **Peripheral Nerve Stimulation (PNS)** indications. To learn more, visit <http://nalumed.com>.

ABOUT NALU MEDICAL

Nalu is a Carlsbad, California-based medical technology company focused on developing and commercializing innovative and minimally invasive solutions for patients with chronic neuropathic pain. The Nalu Neurostimulation System delivers gentle electrical pulses to the nervous system to modulate pain signals to the brain. The Nalu system was designed to address major unmet needs in the treatment of chronic neuropathic pain and provide a differentiated value proposition for patients and physicians.



NALU PRODUCTS

Micro Implantable Pulse Generator (mIPG)

mIPG Specifications



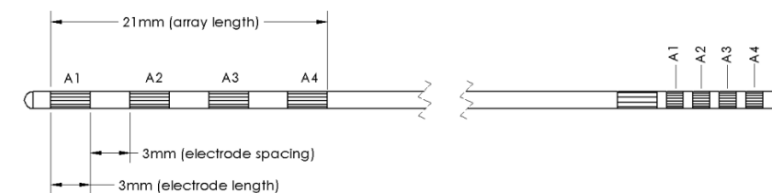
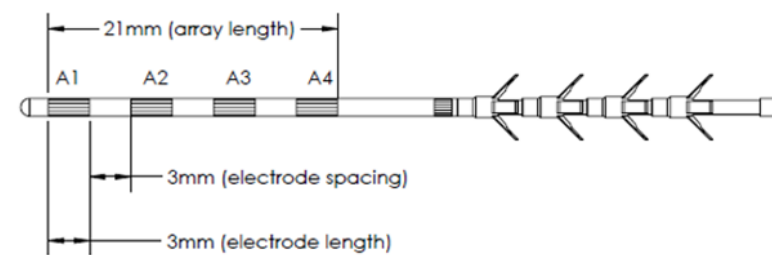
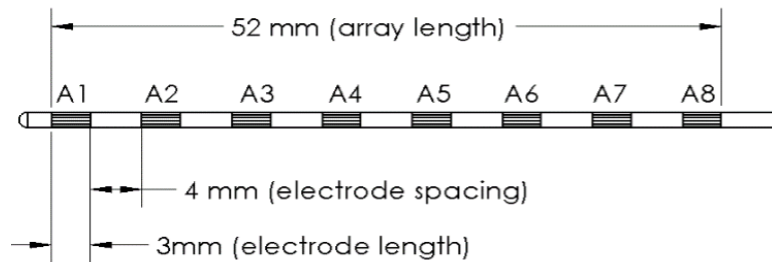
	(1 x 8) SCS	(2 x 8) SCS	(2 x 4) PNS	(1 x 4) PNS
IPG Kit	71003	71004	71020	71007
IPG Only	11003-002	11004-002	11007-002	11006-002
Contacts	8	16	8	4
IPG Housing Dimensions	2.8 cm (length), 1.1 cm (width), 4.9 mm (thick)			
Conditional MRI Labeling*	Whole body 1.5T Head & extremity 3T		Head & extremity 1.5T & 3T	
Volume	~1.5 cc			
Expected Service Life	18 years			
Current Delivery	Constant Current			
Current Sources	Multiple Independent Current Sources			
Parameters	<ul style="list-style-type: none">• Amplitude: 0 – 10.2 mA• Pulse Width: 12 – 2000 μs• Frequency Rate: 2 – 1499 Hz			
Pulse Pattern (on/off)	12 μs – 1000 μs			
Dosage	1 ms – 25 ms			
Programs / Areas	8 / 4			
Patient Remote	Smart Phone (Android or iOS), iPod			
Kit Includes	IPG, Pocket Tunneller (10 cm), Torque Wrench, IPG Insertion Tool (10 cm), Straw Tunneller			

*Review surgical manual for MRI Conditional details.

Leads

	Trial Lead, 1x8 SCS & PNS	Perm Lead, 1x8 SCS	Perm Lead, 1x8 PNS	Trial Lead, 1x4 PNS	Tined Lead, 1x4 PNS
Lead Kit	72003 (60 cm)	72001(40 cm) 72002 (60 cm)	72011 (40 cm) 72012 (60 cm)	72013 (40 cm)	72006 (25 cm) 72007 (40 cm)
Lead Only	12006-060 (60 cm)	12001-040 (40 cm) 12001-060 (60 cm)	12007-040 (40cm) 12007-060 (60 cm)*	12009-040 (40 cm)	12005-025 (25 cm) 12005-040 (40 cm)
Contacts	8	8	8	4	4
Lead Lengths	60 cm	40 cm, 60 cm	40 cm, 60 cm	40 cm	25 cm, 40 cm
Electrode Length	3 mm	3 mm	3 mm	3 mm	3 mm
Electrode Spacing	4 mm	4 mm	4 mm	3 mm	3 mm
Array Length	52 mm	52 mm	52 mm	21 mm	21 mm
Lead Diameter	1.3 mm	1.3 mm	1.3 mm	1.3 mm	1.3 mm
Kit Includes	<ul style="list-style-type: none"> • SCS/PNS Trial Lead • 4.5" Spoonbill Needle • Bent Stylet 	<ul style="list-style-type: none"> • SCS Perm Lead • Anchor • 4.5" Spoonbill Needle • Bent Stylet • Torque Wrench 	<ul style="list-style-type: none"> • PNS Perm Lead • Anchor • 4.5" Spoonbill Needle • Bent Stylet • Torque Wrench 	<ul style="list-style-type: none"> • PNS Trial Lead • 6" Spoonbill Needle • Straight Stylet 	<ul style="list-style-type: none"> • PNS Tined Lead • 14 cm Tearaway Introducer • Straight Stylet

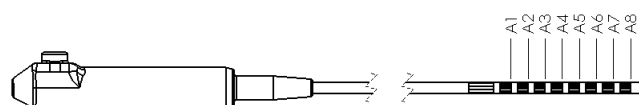
*Special Use Only



Lead Extensions*

Specifications	Lead Extension 1x4	Lead Extension 1x8
Extension Kit	72005	72004
Extension Only	12003-035	12002-030
Contacts	4	8
Length	35 cm	30 cm
Kit Includes	<ul style="list-style-type: none"> • Extension • Torque Wrench • Straw Tunneller 	

*MRI Unsafe



Lead Anchor

13001 31.5 mm (L) x 5.7 mm (W)



Spoonbill (Insertion) Needle

23001-045, 4.5"

23001-060, 6"



Introducer Assembly

23003-045, 10 cm

23003-060, 14 cm



Pocket Tunneler

23004



IPG Insertion Tool

23006



Straw Tunneller

23007 30 cm



Electrode Interfacing Cable (EIC)

- 34003 Electrode Interfacing Cable (EIC), 60 cm
- 34004 Electrode Interfacing Cable Extension, 180 cm



Lead Stylet

- | | |
|---------------------------|-----------------------|
| 23012-030 Straight, 30 cm | 23002-030 Bent, 30 cm |
| 23012-045 Straight, 45 cm | 23002-045 Bent, 45 cm |
| 23012-065 Straight, 65 cm | 23002-065 Bent, 65 cm |

Lead Blank

- 23013-050 50 cm

Torque Wrench

- 23005



Therapy Disc

- 34001-001



Trial Therapy Disc

- 34002



Adhesive Clip

- 74007-002 H100 Light Adhesive (box of 30)
- 74007-003 H300 Adhesive for Sensitive Skin (box of 30)
- 74007-001 H200 Strong Adhesive, H200 (box of 30)
- 74007-004 S200 Silicone Adhesive (box of 30) *Special Use Only



Limb Cuff and Relief Belt

- 34009 Limb Cuff
- 34011 Limb Cuff, Large
- 34007 Relief Belt



IPG and Lead Kits

Model	Description
71004	SCS/PNS IPG Kit Dual 8 (2 x 8) <i>Includes: IPG, Pocket Tunneller, Straw Tunneller, IPG Insertion Tool, & Torque Wrench</i>
71003	SCS/PNS IPG Kit Single 8 (1 x 8) <i>Includes: IPG, Pocket Tunneller, Straw Tunneller, IPG Insertion Tool, & Torque Wrench</i>
71007	PNS IPG Kit Single 4 (1 x 4) <i>Includes: IPG, Pocket Tunneller, Straw Tunneller, IPG Insertion Tool, & Torque Wrench</i>
71020	PNS IPG Kit Dual 4 (2 x 4) <i>Includes: IPG, Pocket Tunneller, Straw Tunneller, IPG Insertion Tool, & Torque Wrench</i>
72001	SCS Perm Lead Kit 8 contact, 40 cm <i>Includes: Lead, Anchor, Spoonbill Needle (4.5"), Bent Stylet, & Torque Wrench</i>
72002	SCS Perm Lead Kit 8 contact, 60 cm <i>Includes: Lead, Anchor, Spoonbill Needle (4.5"), Bent Stylet, & Torque Wrench</i>
72003	SCS/PNS Trial Lead Kit 8 contact, 60 cm <i>Includes: Lead, Spoonbill Needle (4.5"), & Bent Stylet</i>
72013	PNS Trial Lead Kit 4 contact, 40 cm <i>Includes: Lead, Spoonbill Needle (6"), & Straight Stylet</i>
72004	Extension Kit 8 contact <i>Includes: Extension, Torque Wrench, & Straw Tunneller</i>
72005	Extension Kit 4 contact <i>Includes: Extension, Torque Wrench, & Straw Tunneller</i>
72006	PNS Tined Lead Kit 4 contact, 25 cm <i>Includes: Tined Lead, Introducer Assembly (14 cm), & Straight Stylet</i>
72007	PNS Tined Lead Kit 4 contact, 40 cm <i>Includes: Tined Lead, Introducer Assembly (14 cm), & Straight Stylet</i>
72011	PNS Lead Kit 8 contact, 40 cm <i>Includes: Lead, Anchor, Spoonbill Needle (4.5"), Bent Stylet, & Torque Wrench</i>
72012	PNS Lead Kit 8 contact, 60 cm <i>Includes: Lead, Anchor, Spoonbill Needle (4.5"), Bent Stylet, & Torque Wrench</i>
71005	SCS IPG & Lead Kit - Dual 8 IPG + Dual 40cm leads Perm Kit <i>Includes: IPG, Pocket Tunneller, Straw Tunneller, IPG Insertion Tool, Torque Wrench, Lead (x2), Anchor (x2), Spoonbill Needle (4.5") (x2), & Bent Stylet (x2)</i>
71019	PNS IPG & Lead Kit - Dual 8 IPG + Dual 40cm leads Perm Kit <i>Includes: IPG, Pocket Tunneller, Straw Tunneller, IPG Insertion Tool, Torque Wrench, Lead (x2), Anchor (x2), Spoonbill Needle (4.5") (x2), & Bent Stylet (x2)</i>

Surgical Accessories and a la carte*

Model	Description
12001-040	SCS Perm Lead – 8 contact, 40 cm
12001-060	SCS Perm Lead – 8 contact, 60 cm
12005-025	PNS Tined Lead - 4 contact, 25 cm
12005-040	PNS Tined Lead - 4 contact, 40 cm
12006-060	SCS/PNS Trial Lead – 8 contact, 60 cm
12007-040	PNS Perm Lead - 8 contact, 40 cm
12007-060	PNS Perm Lead - 8 contact, 60 cm
12009-040	PNS Trial Lead – 4 contact, 40 cm
12002-030	Extension - 8 contact, 30 cm
12003-035	Extension - 4 contact, 35 cm

*Special Use Only

Model	Description
23001-045	Spoonbill Needle (4.5")
23001-060	Spoonbill Needle (6")
23002-030	Stylet (Bent, 30cm)
23002-045	Stylet (Bent, 45cm)
23002-065	Stylet (Bent, 65cm)
23003-045	Introducer Assembly (4.5")
23003-060	Introducer Assembly (6")
23012-030	Stylet (Straight, 30 cm)
23012-045	Stylet (Straight, 45 cm)
23012-065	Stylet (Straight, 65 cm)
23013-050	Lead Blank, 50 cm
13001	Anchor
23004	Pocket Tunneler (10 cm)
23004-015	Pocket Tunneler (15 cm)
23005	Torque Wrench
23005-003	Extended Torque Wrench
23006	IPG Insertion Tool (10 cm)
23006-015	IPG Insertion Tool (15 cm)
23007	Straw Tunneler
34003	Electrode Interfacing Cable (EIC)
34004	Electrode Interfacing Cable (EIC), Extension

Patient Kits and Accessories

Model	Description
74001	Patient Kit <i>Includes: MODEL_34001-001 Therapy Discs (2), Charger, Power Cords, USB Cable, Relief Belt, Equipment Bag, ID Card</i>
74002	Trial User's Kit <i>Includes: MODEL_34002 Trial Therapy Discs (2), Charger, Power Cords, USB Cable, Relief Belt, Equipment Bag</i>
PD-000242	Remote Control
34001-001	Therapy Disc
34002	Trial Therapy Disc
43001	Charger
74007-002	Adhesive Clips, H100 (box of 30)
74007-003	Adhesive Clips, H300 (box of 30)
74007-001	Adhesive Clips, H200 (box of 30)
74007-004	Adhesive Clips, S200 (box of 30)
34007	Relief Belt
34009	Limb Cuff
34011	Limb Cuff (Large)



1 OF THE TOP 100 TECHNOLOGY INTRODUCED IN THE **WORLD**



1ST PLACE IMPLANT & TISSUE REPLACEMENT DEVICE CATEGORY



BEST MEDICAL **DEVICE** IN THE FIELD OF TECHNOLOGY



BEST MED**TECH COMPANY** IN THE FIELD OF NEUROLOGY

INDICATIONS FOR USE

Product Safety Information - Brief Summary

Prior to using these devices, please review the latest Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Indications for use:

Spinal Cord Stimulation - The Nalu Neurostimulation 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 - The Nalu Neurostimulation 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 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: Patients contraindicated for this therapy are those who are unable to operate the system, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, and/or are pregnant.

Warnings/Precautions: Occupational exposure to high levels of non-ionizing radiation, electromagnetic interference (EMI), electromagnetic equipment/ environments, machinery or heavy equipment, theft detectors and metal screening devices, implanted cardiac or other neurostimulation systems, diathermy, magnetic resonance imaging (MRI), computed tomography (CT) scanning, radiofrequency (RF) ablation, psychotherapeutic procedures, other medical procedures, and tampering could result in system damage, inappropriate therapy, injury, unexpected stimulation, or painful stimulation. Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Nalu Neurostimulation System. Implanting clinicians should be experienced in implantable medical devices and should review the procedures described in the Instructions for Use.

Adverse Events: Undesirable changes in stimulation sensation and/or location with or without patient movement. Inadequate pain relief or increase in pain following system implantation. Surgical risks. Instructions for Use must be reviewed for detailed disclosure.

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