Fallbericht

Univ. Prof. Dr. Rudolf Likar, MSc

Vorstand der Abteilung für Anästhesiologie, allgemeine Intensivmedizin, Notfallmedizin, interdisziplinäre Schmerztherapie und Palliativmedizin
Klinikum Klagenfurt am Wörthersee
LKH Wolfsberg

Lehrabteilung der Medizinischen Universität Graz, Innsbruck, Wien

Lehrstuhl für Palliativmedizin SFU
SFU Fakultät für Medizin

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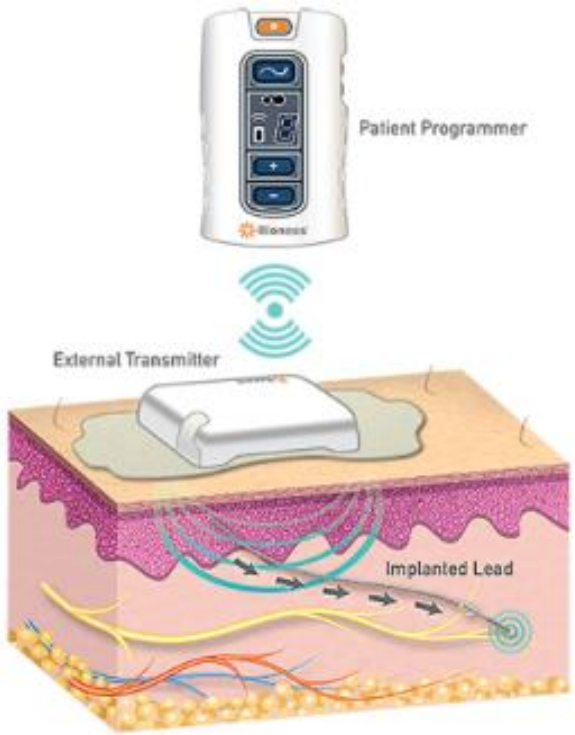
Bioness Implantation



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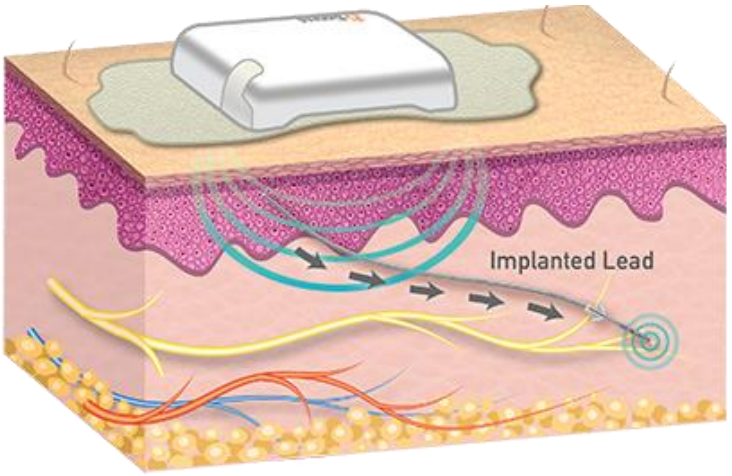
StimRouter Neuromodulation System



Minimally-invasive implant designed to treat **chronic pain of peripheral nerve origin,** below the cranial facial region. The minimally-invasive lead implant procedure is performed **under local anesthesia** through a small incision.

Powered externally through the skin to stimulate the target peripheral nerve with a small, focal electrical field - interrupting the pain signal to alleviate pain.

Puts **patients in control** of their pain with a handheld, wireless Patient Programmer.

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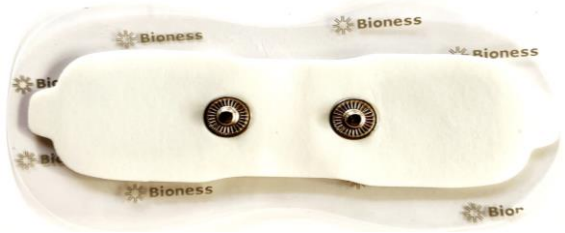
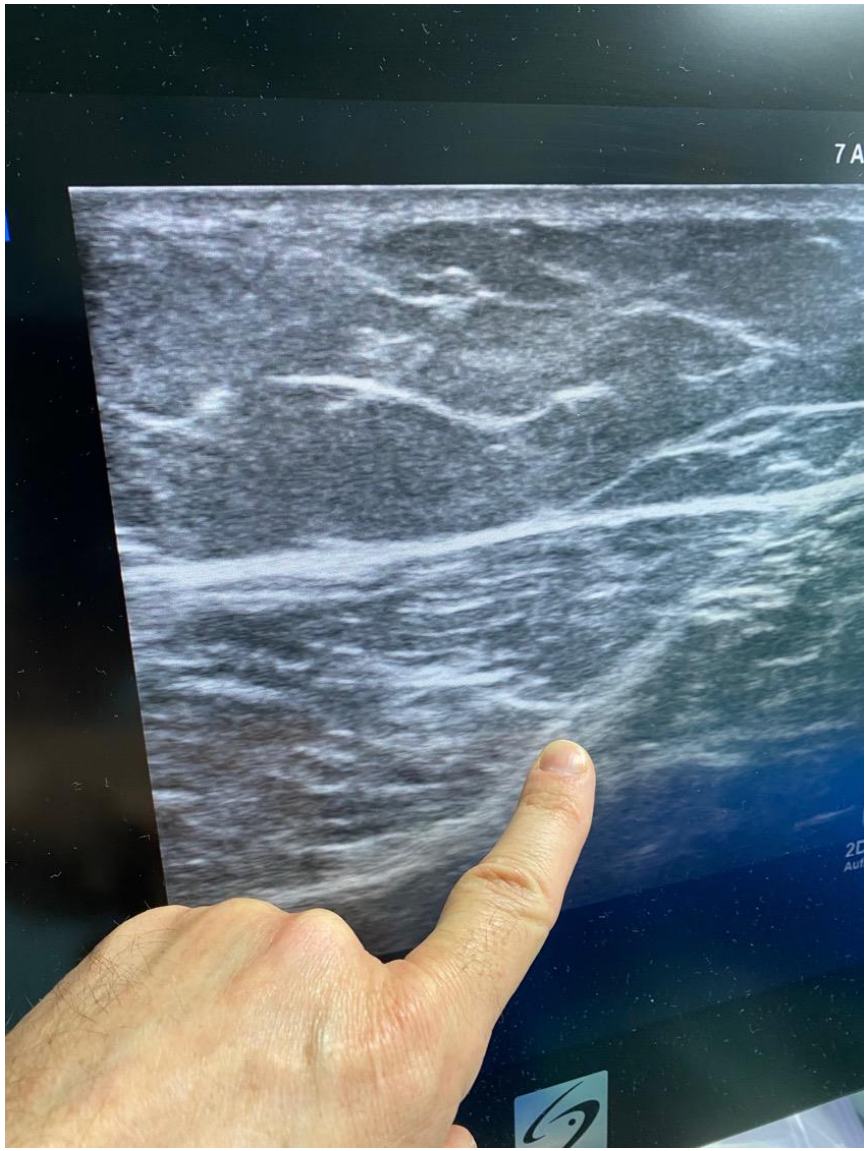
StimRouter-System
Komponenten

Externer Pulse Transmitter (EPT) überträgt E-Feld Stimulation

Wird nach Stimulation abgenommen und über Nacht aufgeladen



Gel Elektrode wird alle 2-5 Tage erneuert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7 Apr 202
Site
8xp/13-6 Nerv
TIW: 0,3

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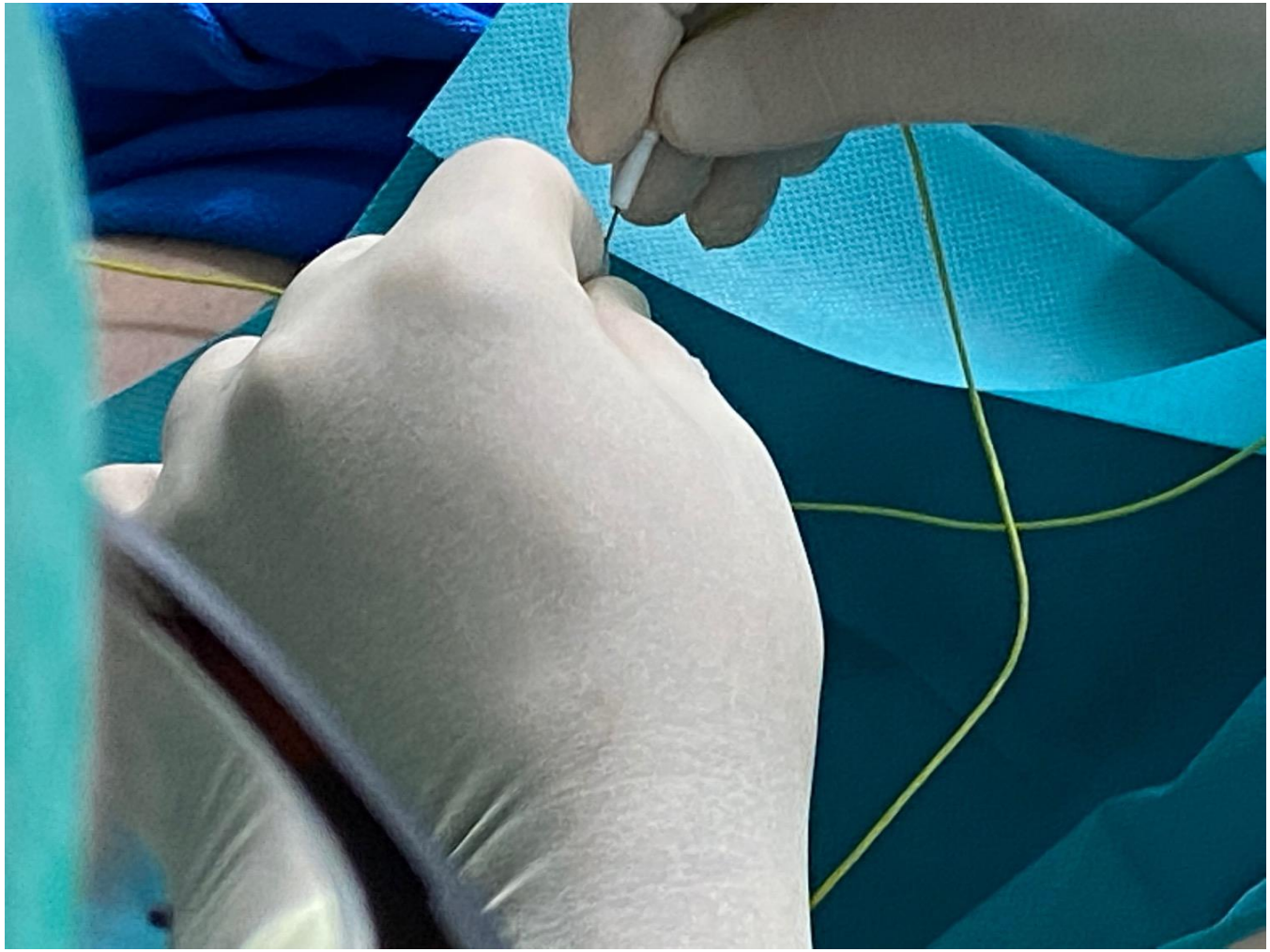

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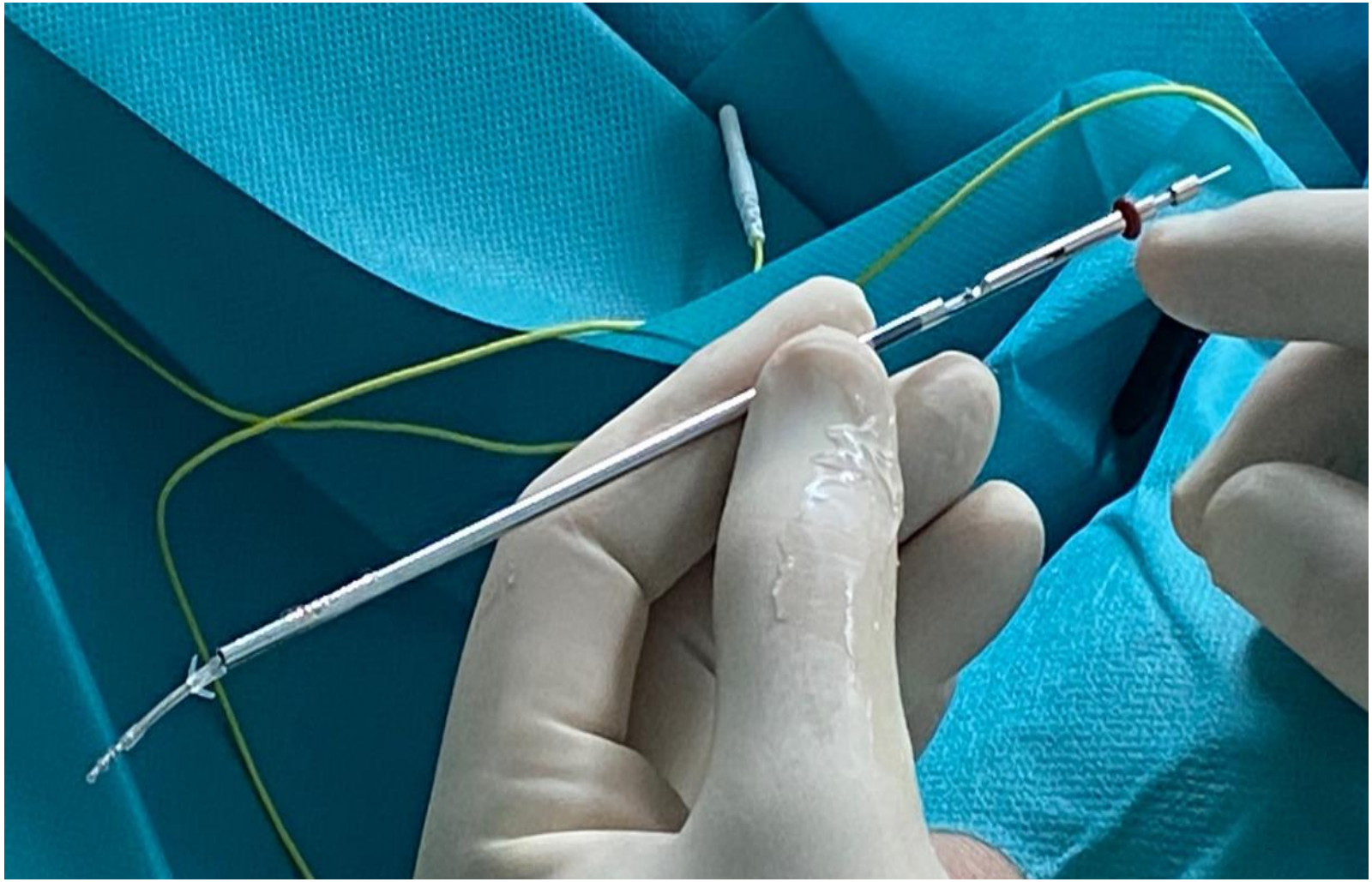

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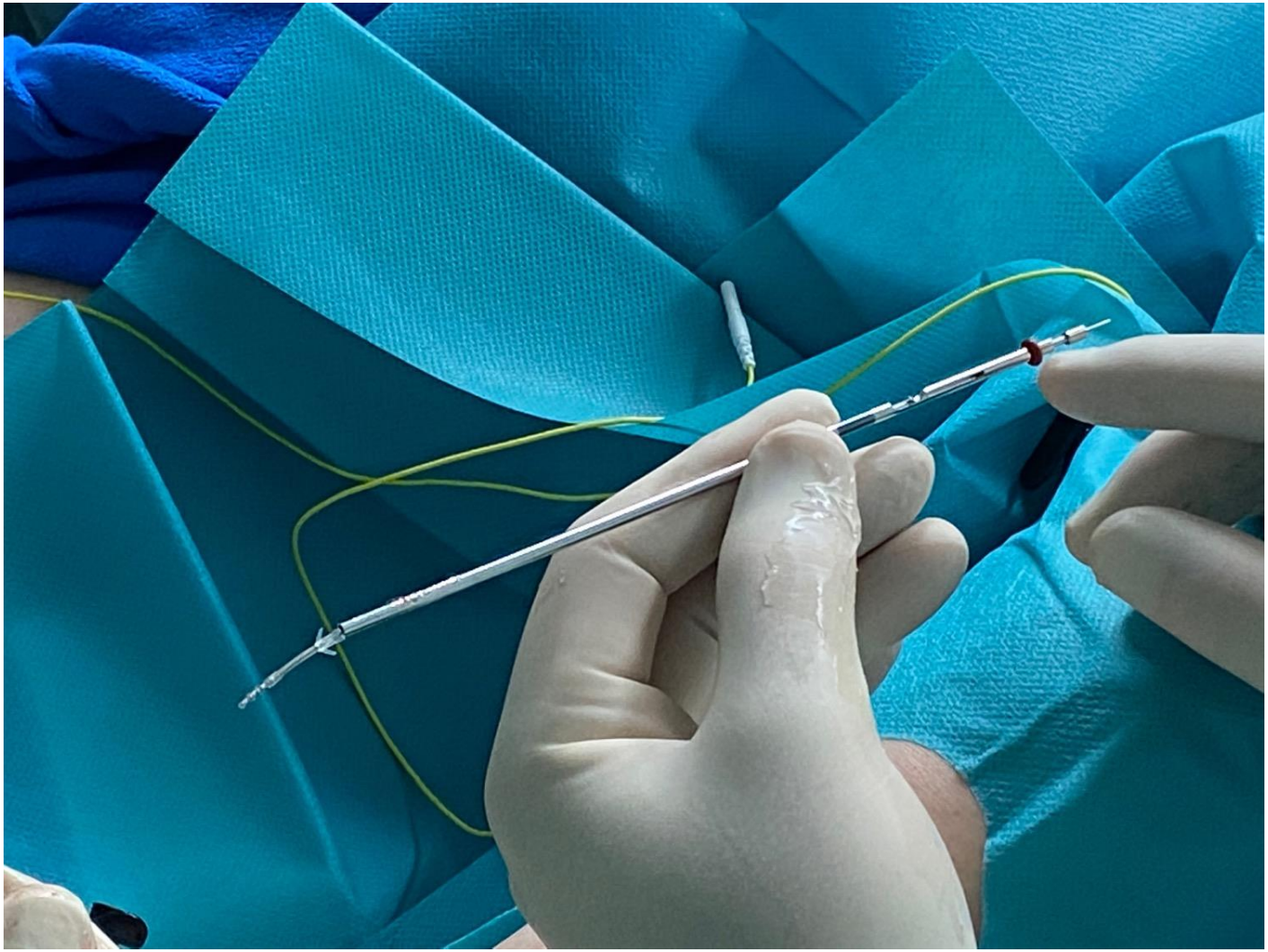
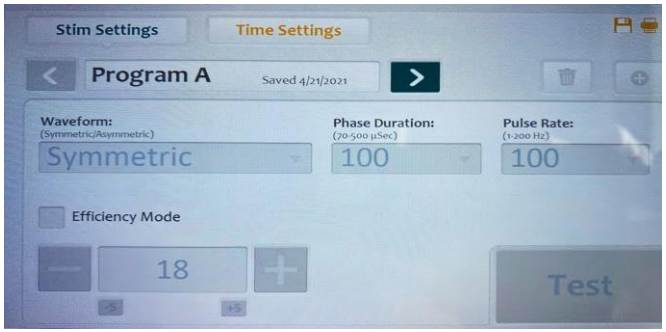
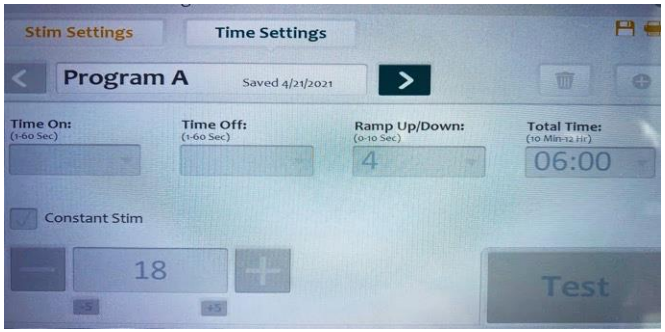
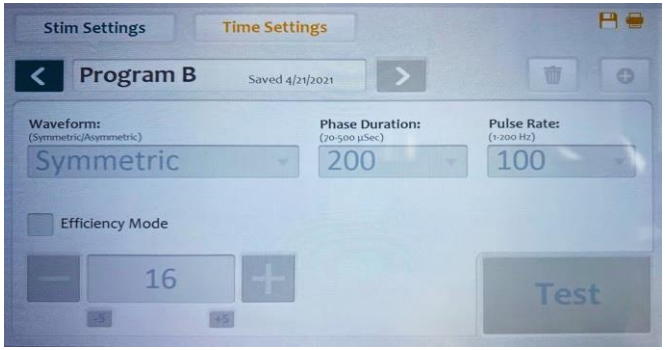
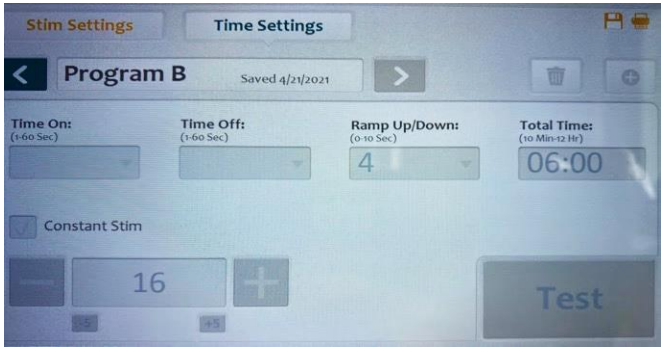


Bis zu 8 verschiedene Programme im Patienten-Gerät einstellbar









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Abstract

Peripheral neuropathic pain (PNP) and complex regional pain syndrome (CRPS) can be effectively treated with peripheral nerve stimulation.

In this clinical trial report, effectiveness of novel, miniature, wirelessly controlled microstimulator of tibial nerve in PNP and CRPS was evaluated.

In this pilot study the average preoperative visual analog scale (VAS) score in six patients was 7.5, with 1, 3 and 6 months: 2.6 (p=0.03), 1.6 (p=0.03), and 1.3 (p=0.02), respectively.

The mean average score in the six patients a week preceding the baseline visit was 7.96, preceding the 1, 3 and 6 month visits: 3.32 (p=0.043), 3.65 (p=0.045), and 2.49 (p=0.002), respectively. The average short-form McGill pain score before surgery was 23.8, and after 1, and 6 months it was 11.0 (p=0.45), 6.3 (p=0.043), and 4.5 (p=0.01), respectively.

Applied therapy caused a reduction of pain immediately after its application and clinical improvement was sustained on a similar level in all patients for six months.
No complications of the treatment were observed.

Intermittent tibial nerve stimulation by using a novel, miniature, wirelessly controlled device can be effective and feasible in PNP and CRPS.
It is a safe, minimally invasive, and convenient neuromodulative method.

Sokal P. Harat M. Zielinski P. et al. Tibial nerve stimulation with a miniature, wireless stimulator in chronic peripheral neur pain. Journal of Pain Research 2017:10 613-619.

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Characteristics of patient N=6

Patient	Characteristics
Patient 1	Female, 39 years old, diabetic PNP with diabetes since 2009, symmetrical feet pain paresthesias, and burning sensation in soles
Patient 2	Female, 62 years old with PNP in soles and toes after boreliosis in 2012
Patient 3	Male, 76 years old, idiopathic PNP: tingling and sharp sensation in sole and heel of left leg for 20 years
Patient 4	Male, 78 years old, idiopathic PNP of left leg with tingling in heel and sole
Patient 5	Male, 46 years old, spinal cauda equina injury after trauma due to motorbike accident in 1989 with CRPS and after failed SCS trial
Patient 6	Male, 55 years old, diabetic PNP lasting 4 years with diabetes in both feet with the predominance on the right side

Abbreviations: CRPS, complex regional pain syndrome; PNP, peripheral neuropathic pain; SCS, spinal cord stimulation.

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Parameters and duration of stimulation

Patient	Rate (Hz)	Pulse width (µs)	Amplitude (mA)	Duration time (hour/24 hours)
Patient 1	20	800	4.4–4.8	2
Patient 2	10–20	500–800	3.7–4.7	1
Patient 3	20	800	4.7	1
Patient 4	20	100	2.3–3.1	0.5
Patient 5	20	800	8.5	2.5
Patient 6	10–20	800–200	8.5	1

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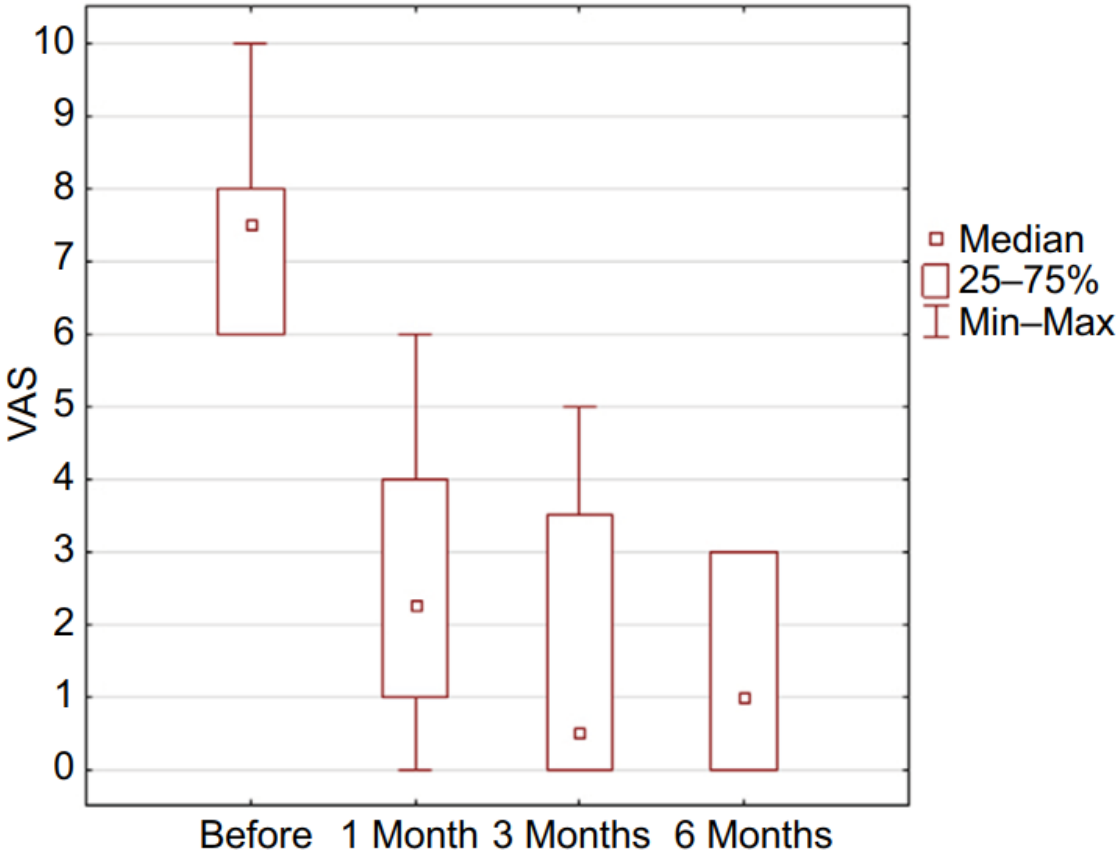
Results in VAS scale in control visits p=0.0023 using ANOVA Friedman test.

Abbreviations: ANOVA, analysis of variance; VAS, visual analog scale.



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Mean averages of 21 measurements of VAS taken three times a day during a week according to patients' diaries preceding control visit before surgery, after 1 month, after 3 months, and after 6 months in the treated leg

Abbreviation: VAS, visual analog scale.

Patient	Before	1 month	3 months	6 months
Mean	7.96	3.32	3.65	2.49
Patient 1	8.19	4.71	2.86	2.25
Patient 2	8.09	3.28	6.6	5.68
Patient 3	6.60	3.00	4.76	2.0
Patient 4	7.35	1.71	3.0	1.28
Patient 5	9.76	0.95	1.62	1.33
Patient 6	7.76	6.28	3.05	1.19

Sokal P. Harat M. Zielinski P. et al. Tibial nerve stimulation with a miniature, wireless stimulator in chronic peripheral neur pain. Journal of Pain Research 2017:10 613-619.

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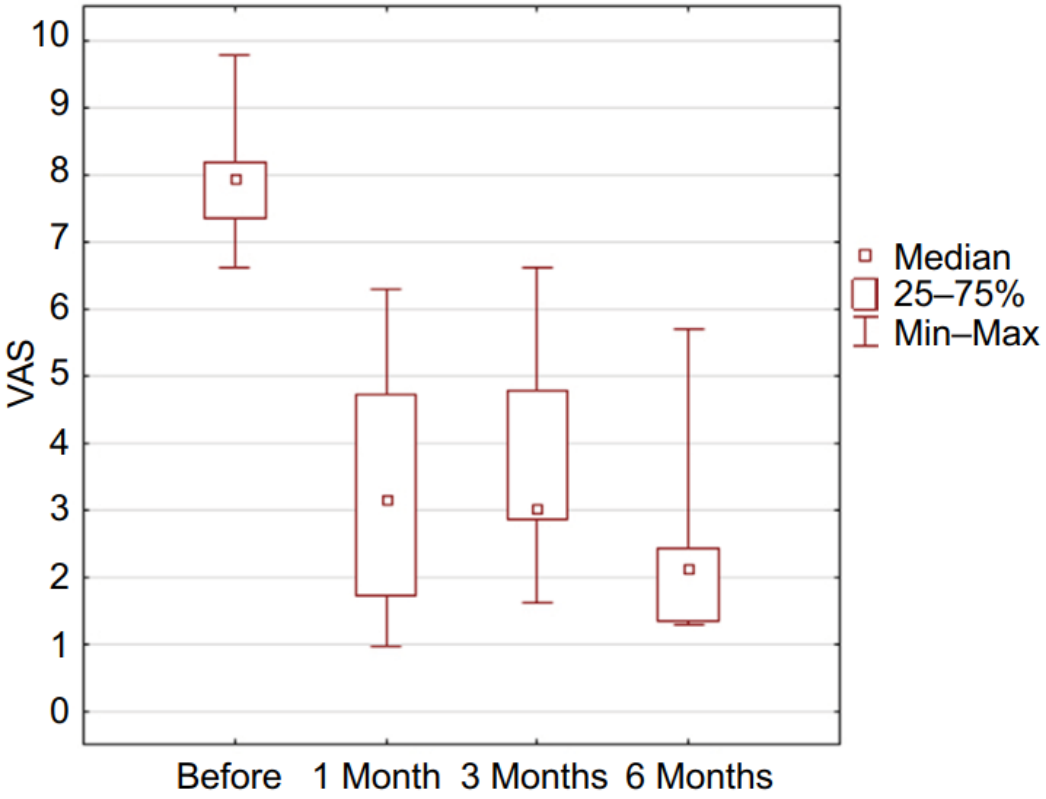
Results in mean VAS during the week preceding the controlled visit (p=0.0003) in ANOVA Friedman test.

Note: Statistical significance observed after 1 month; after 3 months, p=0.03; and after 6 months, p=0.02 in Dunn's multiple comparison.

Abbreviations: ANOVA, analysis of variance; VAS, visual analog scale.



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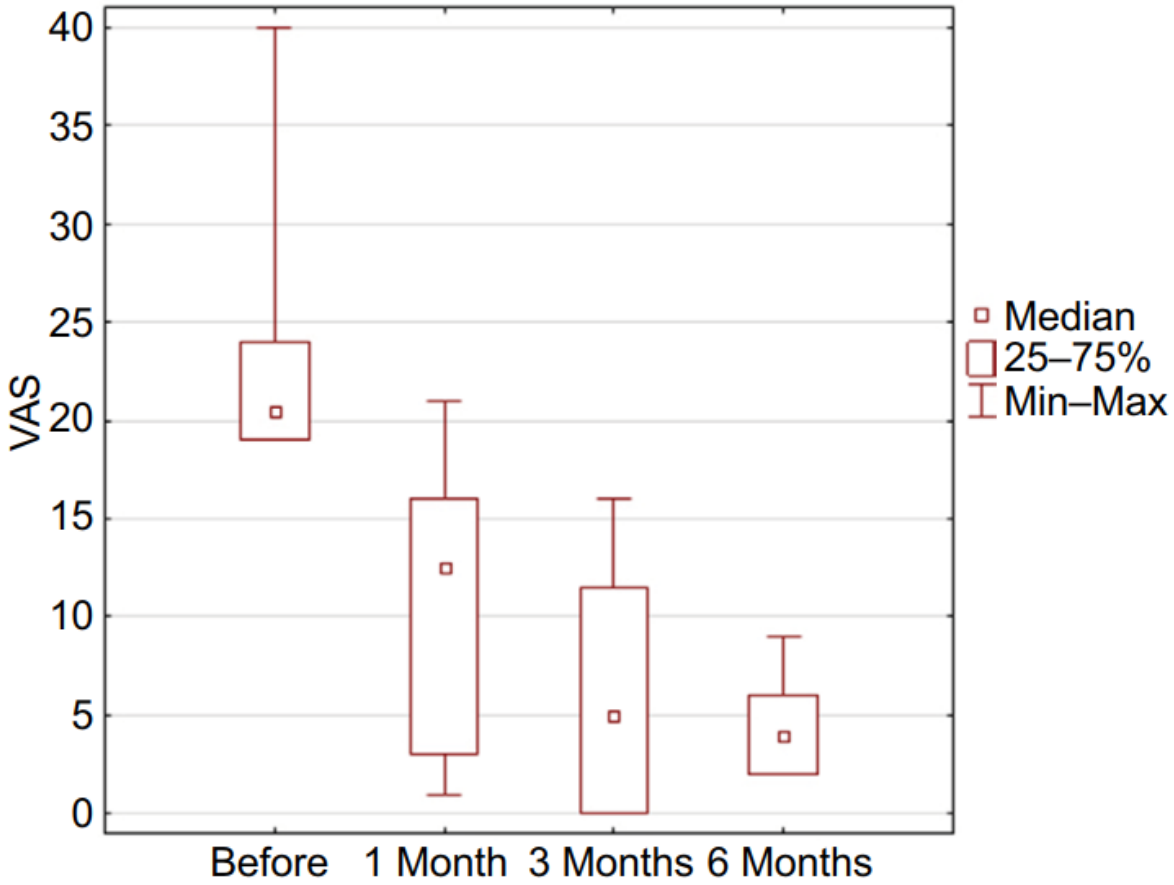
Results in McGill score (p=0.0023 in ANOVA Friedman test).

Note: Statistical significance after 3 months and after 6 months.
Abbreviations: ANOVA, analysis of variance; VAS, visual analog scale.



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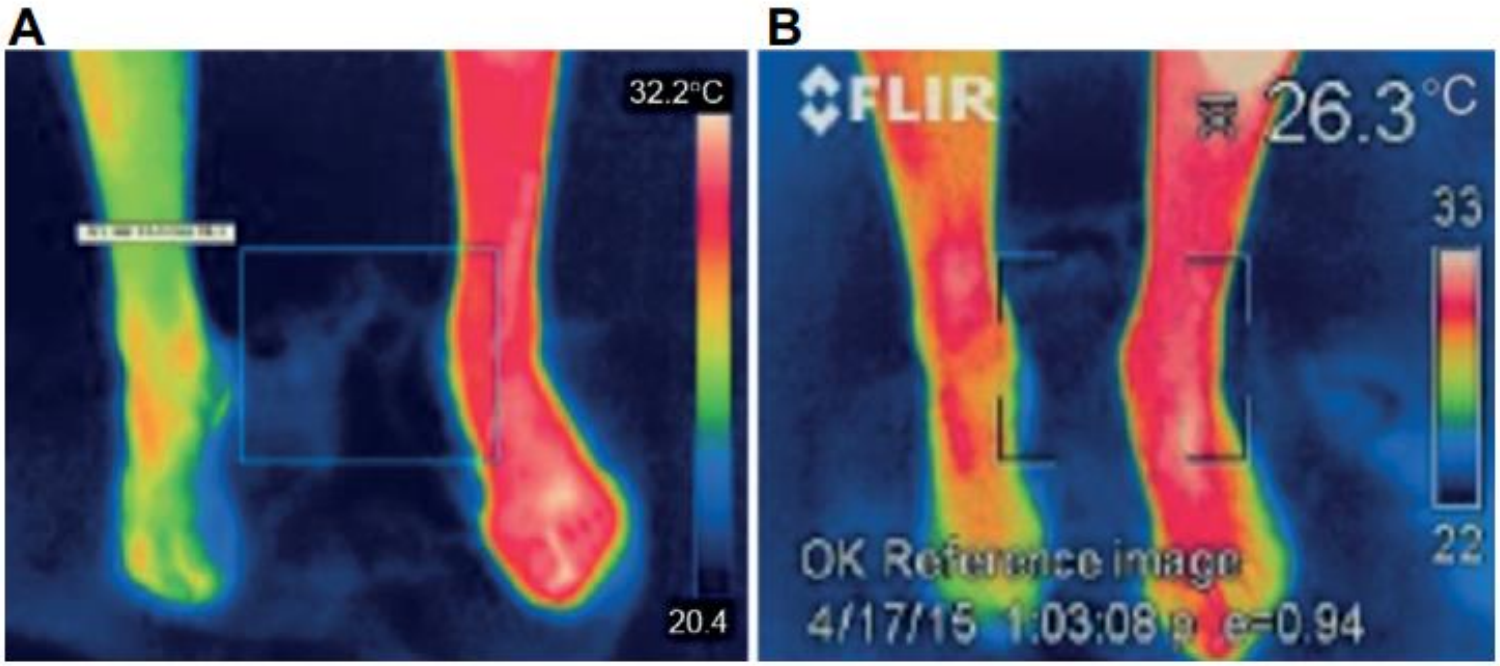
Thermographic effect of stimulation of the right leg in patient 5 demonstrated on the controlled visit after 1 month.

Note: (A) Shows both feet before stimulation and (B) after 30 min of stimulation



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Targeted Peripheral Nerves

Arm

Ulnar | Median | Radial | Axillary | Suprascapular

Trunk

Ilioinguinal | Intercostal

Pudendal | Iliohypogastric | Coccygea

Genitofemoral | Superior Cluneal

Leg

Saphenous | Tibial | Femoral

Femoral Cutaneous | Sural

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Common Clinical Applications

Failed surgery pain – knee, hip, back

Nerve compression, injury or trauma

Post-stroke shoulder pain

Foot/neuroma pain

CRPS

Back pain

Spinal cord injury pain

Post-amputation pain

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DANKE

FÜR IHRE AUFMERKSAMKEIT

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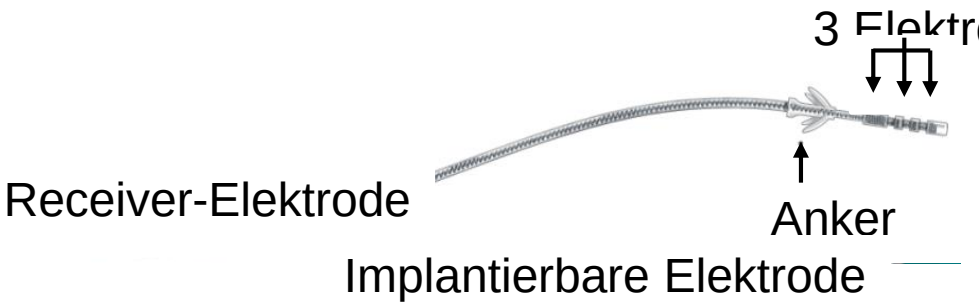
StimRouter-System
Komponenten



Stimulationssonde

Mit 3 Stimulationselektroden; integrierte Receiver-Elektrode;

mit Anker; 15cm lang, voll implantierbar

Patient Programmer

Steuert EPT-Stimulation

Bis zu 8 individuell verschiedene Stimulationsprogramme wählbar

StimRouter Lead

- Only component of the system that is implanted
- Flexible, durable 15cm lead with integrated receiver
- Anchoring mechanism designed to prevent migration

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External Pulse Transmitter (EPT)

- Transmits electrical field stimulation to receiving end of lead that is implanted under the skin
- Programmable: Stores up to 8 stimulation programs
- Rechargeable: Can operate ~2 days on single charge
- Attaches to disposable Electrode Patch
- Gel patch adheres to skin to properly position EPT

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Patient Programmer

- Wirelessly controls the EPT
- Turns on/off; Adjusts intensity +/-
- Allows patients to control stimulation, manage programs & intensity
- Tracks compliance & usage
- Visual and auditory indicators
- Rechargeable battery

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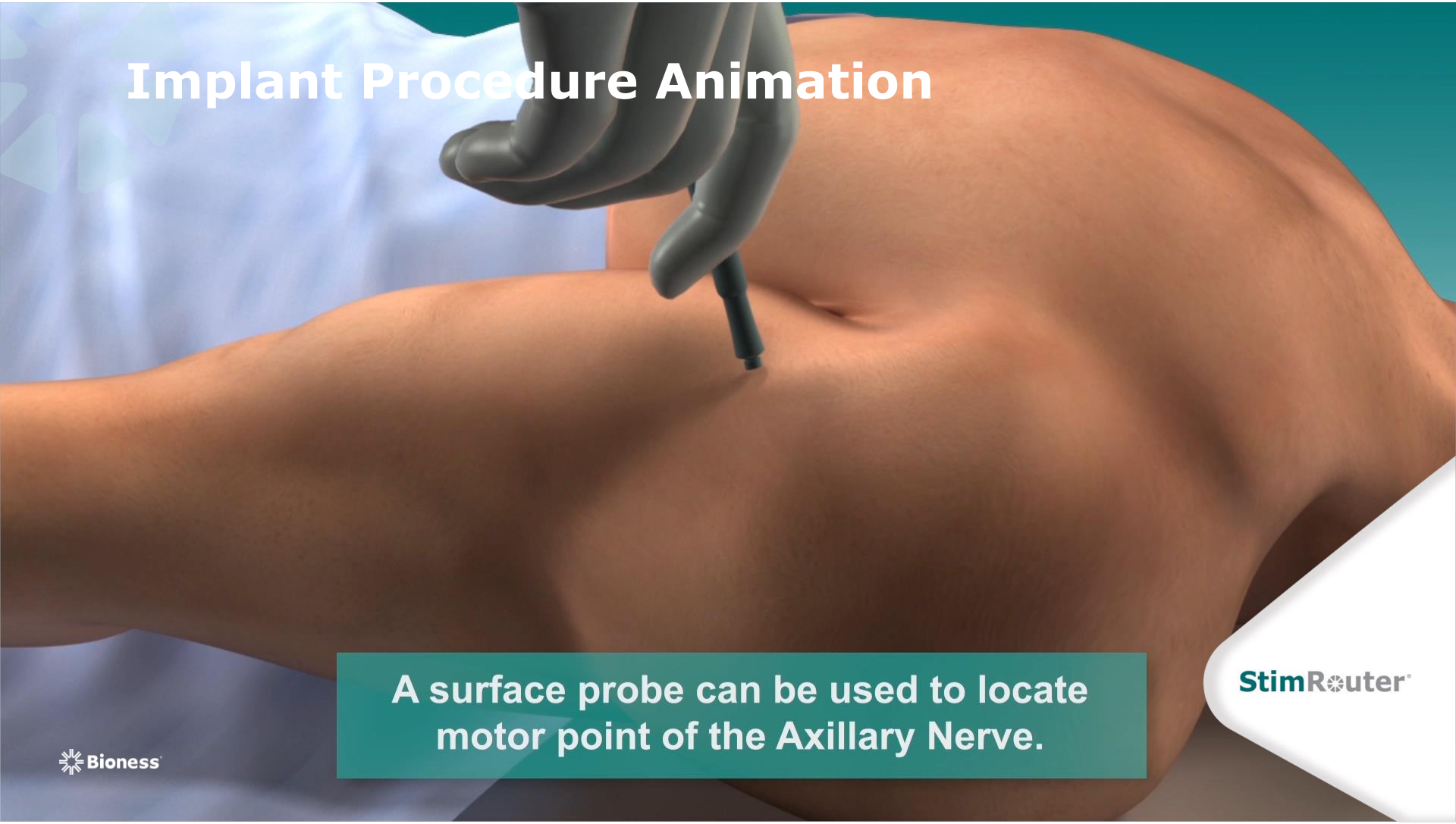
Implant Procedure Animation



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StimRouter-System Komponenten

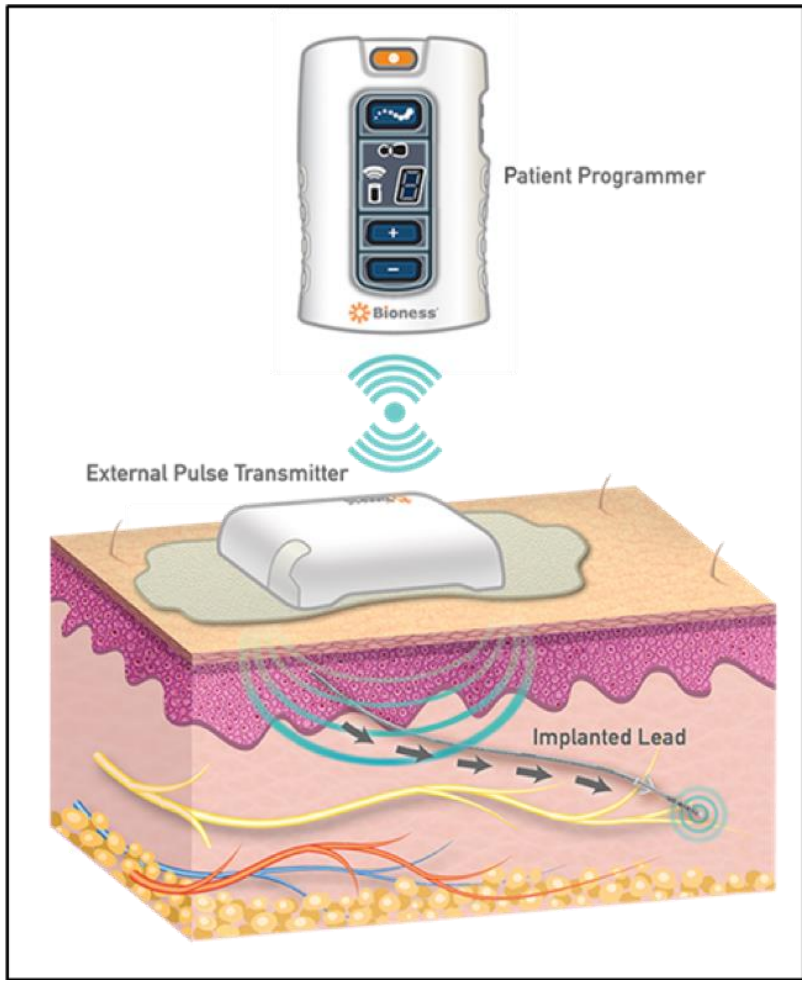
Externer Pulse Transmitter (EPT)

Wird nach Stimulation abgenommen und über Nacht aufgeladen

Gel Elektrode wird alle 2-5 Tage erneuert

Patient Programmer controls stimulation and commands EPT to run up to 8 customized stimulation programs

Lead contains 3 stimulation electrodes, integrated receiver and anchor; 15cm long, fully implanted


Patient Programmer
Bioness
External Pulse Transmitter
Implanted Lead

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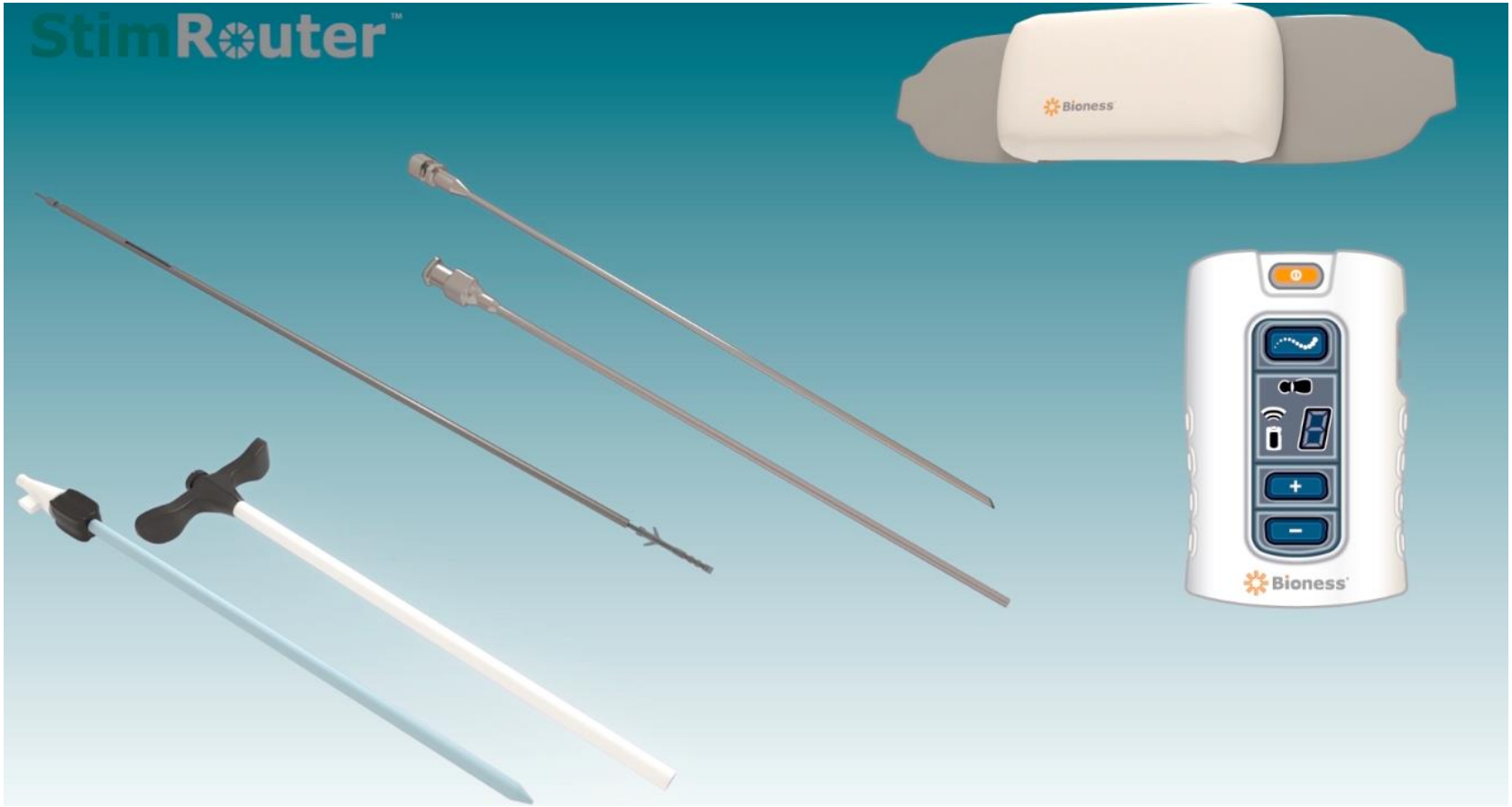

Insert the dilator into the introducer sheath; insert both pieces into the incision staying in the subcutaneous tissue in the trajectory pre-planned; mark the end location of the introducer for programming ease

Remove the dilator, break the wings to skin level, & insert the tail into the sheath

Hold onto the tail while slowly & steadily pulling apart the introducer wings until they are completely removed

Close with a suture and/or Dermabond

****Preferred technique: less trauma for the patient with no use of the tunneling tools, less risk of infection by decreasing incision number, and same day programming a guarantee.**


Biomass