

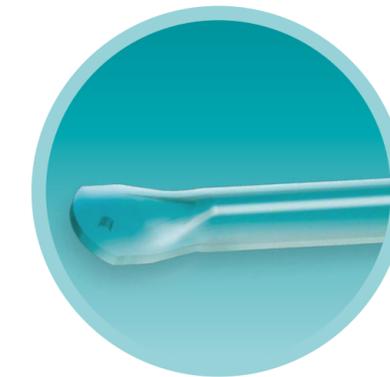
# NEUROCAP®

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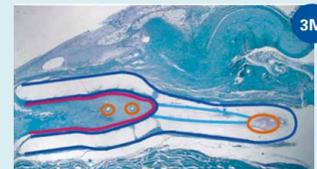
## Peripheral Nerve Capping Device

The ANIMAL study strongly underlines its effective mode of action in creating a full barrier with the surrounding tissues, preventing axonal sprouting and avoiding the formation of end-neuroma. 3, 6 and 12 months post implantation histology underlines NEUROCAP®'s action as effective barrier for unwanted nerve outgrowth.

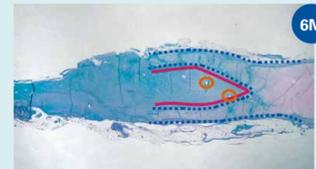
<b>Objective</b>	A randomized controlled study (N=42 animals) to assess the implantation effects of the NEUROCAP® device in a rat sciatic nerve model after 12 weeks, 6 months, and 12 months
<b>Participating centers</b>	• VA Portland (US) - Dr. Peterson
<b>Endpoints</b>	• <b>Procedural data, Adverse events, Clinical observations, Histopathology</b>
<b>Observations and final conclusions</b>	<ul style="list-style-type: none"> <li>• No adverse procedural observations, clinical observations, or other adverse events that attributed to the use of NEUROCAP® throughout the duration of the study.</li> <li>• Chaotic fascicles score increased in controls and decreased in the NEUROCAP® group over 12-mo</li> <li>• Inflammation score remained low in controls and decreased in NEUROCAP® group to 0.0 at 12-mo</li> <li>• Nerve outgrowth score significantly higher in control group compared to NEUROCAP® group</li> <li>• No neuromas in NEUROCAP® group at any time point (wrt control group: 20% at 3-mo; 38% at 6-mo; 100% at 12-mo)</li> <li>• NEUROCAP® treated nerves seem to become more organized with absence of neuroma formation (in contrast to the control nerves)</li> <li>• Publication in preparation</li> </ul>



NEUROCAP®  
Histological evaluation at 3, 6 and 12 months after implantation  
(10x total magnification)



At 3 months, the device blocks sprouting by acting as physical and mechanical barrier

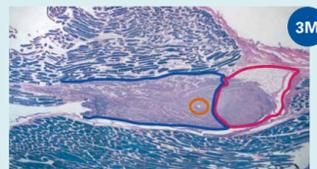


At 6 months, NEUROCAP treated nerve-end stump shows organized fibers



At 12 months, NEUROCAP treated nerve-end is organized and atrophied without neuroma

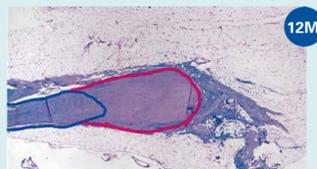
CONTROL GROUP  
Histological evaluation at 3, 6 and 12 months after implantation  
(10x total magnification)



Control with formation of a neuroma



Control with well-formed neuroma



Control with well-formed neuroma

## Evidence Based Performance

NEUROCAP® is available in a diameter range of 1,5 - 8 mm.

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The information presented in this brochure is intended to inform and demonstrate the product. Always refer to the package insert, product label and/or user instructions before using this product. NEUROCAP® is a registered trademark of and manufactured by Polyganics, The Netherlands.

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# NEUROCAP®

A UNIQUE DEDICATED DEVICE FOR THE MANAGEMENT OF END-NEUROMAS

# NEUROCAP®

SAFE AND EFFECTIVE MANAGEMENT OF SYMPTOMATIC NERVE-END NEUROMA

# NEUROCAP®

EVIDENCE BASED DATA TO STRENGTHEN AND BROADEN THE CLINICAL VALUE

## Neuromas are a highly disabling pathology

Symptomatic neuroma may develop after a nerve dissection following any trauma to a peripheral nerve, whether accidental or planned (i.e. surgery). Neuroma-induced neuropathic pain and morbidity seriously affect the patient's daily life and socioeconomic functioning. The incidence of symptomatic neuromas after peripheral nerve injury is estimated to be 3-5%, however certain surgeries (e.g. autograft procedures, amputations) may have up to a 30% incidence rate. On average, patients are undergoing 2.8 re-interventions after the initial treatment of a neuroma. Following treatment of a neuroma, 86% of patients experience none to minimal improvement

## NEUROCAP® design is straightforward, simple and effective

NEUROCAP® is intended to protect a peripheral nerve end and to separate the nerve from surrounding environment to reduce the development of a symptomatic end-neuroma. NEUROCAP® is a transparent tubular device with one open end and one closed end. Dislocation of the nerve stump is prevented by suturing the nerve end into the cap. A hole at the sealed end of the tube allows easy fixation of the nerve stump with a suture to the surrounding tissue. This allows an effective capping technique without the necessity of excessive manipulation or sacrificing other tissue. Currently, there is no gold standard for neuroma treatment; burying of the nerve stump is the most common procedure

NEUROCAP®'s unique features support important (clinical) needs:

- Made of inert and biodegradable lactide and caprolactone copolymers with an excellent safety track record of implementation in other medical devices
- Transparent and simple design for easy handling and optimal nerve positioning during the procedure
- Controlled mechanical strength and flexibility prevent (a) axonal sprouting (b) adhesion of the nerve-ends into muscle and scar tissue
- Predictable bioresorbability to support a sustainable encapsulation of the nerve stump
- Long-term pre- and clinical follow-up data (12 months) indicate an effective barrier function and considerable and lasting pain reduction in treated patients

## NEUROCAP® is the only clinically proven nerve capping device

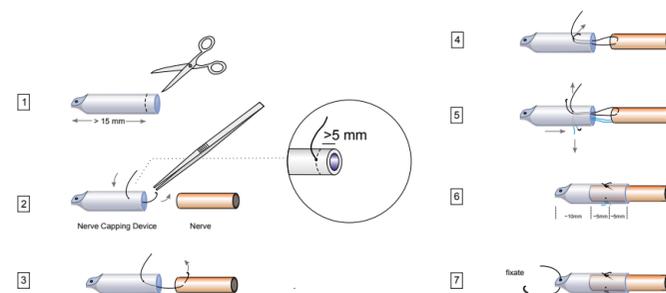
A strong body of evidence supports the effectiveness of NEUROCAP®.

- Pivotal clinical data of the STOP Neuroma trial (one-year clinical patient follow-up) confirms safety and performance of NEUROCAP® application in the treatment of symptomatic end neuroma in peripheral nerves (publication in progress).
- The PROTECT Neuro study, a multicenter post-market clinical follow-up study in both the US and Europe, is designed to strengthen and expand the clinical value of NEUROCAP® in the upper and lower extremities over a 2-year period of patient monitoring. Patient enrollment of this PMS study successfully concluded in summer 2018.
- The modes of action of the device, creating a full barrier with the surrounding tissues, preventing axonal sprouting and avoiding the formation of end-neuromas, is clearly demonstrated in a rat sciatic nerve model and is currently prepared for publication.



Superficial Radial Nerve neuroma (courtesy: Dr M. Bertleff, The Netherlands)

## NEUROCAP® Product Application



## STOP Neuroma Trial: this pivotal study reveals reduction of symptomatic pain over a year clinical follow up

<b>Objective</b>	A cohort study with a 12-month clinical follow up (N=10) to assess safety and performance of NEUROCAP® for the treatment of symptomatic end-neuroma
<b>Participating centers</b>	<ul style="list-style-type: none"> <li>• Medical center Lelystad / MC Groep (NL); M. Bertleff, MD, PhD</li> <li>• University Medical Center Groningen (NL); T. Middelberg, MD, PhD</li> <li>• Maastricht University Medical Center (NL); T. van Mulken, MD</li> </ul>
<b>Endpoints</b>	<p><b>Primary endpoint safety (6 wk FU)</b></p> <ul style="list-style-type: none"> <li>• Demonstrate device safety, defined as &lt; 8.3% serious adverse device effects</li> </ul> <p><b>Primary endpoints effectiveness (6 wk FU)</b></p> <ul style="list-style-type: none"> <li>• Reduction of pain caused by symptomatic neuroma (VAS; Elliot; DN4)</li> <li>• Improvement of quality of life</li> <li>• Reduction or stabilization of quantity/class of pain medication used to treat neuroma pain</li> </ul> <p><b>Secondary endpoints (3, 6, 12 mo FU)</b></p> <ul style="list-style-type: none"> <li>• &lt; 8.3% serious adverse device effects</li> <li>• Reduction of pain caused by symptomatic neuroma (VAS; Elliot; DN4)</li> <li>• Improvement of quality of life</li> <li>• ≤ 20% recurrence of symptomatic neuroma</li> <li>• Reduction of quantity/class of pain medication</li> <li>• Ease of use and placement of the device</li> </ul>
<b>Timelines</b>	<ul style="list-style-type: none"> <li>• Enrollment concluded: March-2017</li> <li>• Last patient, last visit (12-month follow up): March-2018</li> <li>• Final data: May/June-2018 (presented during FESSH-2018)</li> </ul>

Patient (gender-age)	Neuroma	NEUROCAP® size	Pre-op VAS (0-100 mm)	+ 6 wks VAS (0-100 mm)	+ 3 mths VAS (0-100 mm)	+ 6 mths VAS (0-100 mm)	+ 12 mths VAS (0-100 mm)
F27	SRN neuroma	2,5 mm	81	1	1	1	1
F66	SRN neuroma	3,0 mm	93	9	25	30	8
F42	Dorsal branch ulnar nerve and SRN	2,5 mm	79	6	1	3	6
F25*	Dorsal branch ulnar nerve	2,0 mm	64	1	1	72	60
F21	SRN neuroma	2,5 mm	80	26	27	27	30
M59**	SRN neuroma	3,0 mm	9	30	30	14	62
F41***	Radial nerve	3,0 mm	78	13	12	72	21
F33	SRN neuroma	1,5 mm	80	1	9	1	1
F37	Median nerve	1,5 mm	78	1	0	1	1
M41****	Sens. branch median nerve	1,5 mm	91	85	72	NA	NA
<b>MEDIAN (range)</b>	-	-	79 (9-93)	8 (1-85)	11 (0-72)	14 (1-72)	8 (1-62)

\* Non-device related AE at 6 months after external trauma (hit on operational site). Surgically treated between 6- and 12-month follow-up.

\*\* Uncertainty on first measurement, validation needed. However recurrent neuroma

\*\*\* Patient indicates variable pain rates, sometimes spontaneous and sometimes when carrying heavy load. Pain is much less frequent than before surgery

\*\*\*\* SAE after external trauma (bumped on table corner); severe seroma formation at operational site. Re-operated and Neurocap® removed; study exit after removal

## PROTECT NEURO post-market study: first preliminary results confirm the pivotal STOP Neuroma outcomes

<b>Objective</b>	A cohort study (N=73) to collect long-term performance data (24 months clinical follow-up) and the ease of use of NEUROCAP® for reduction of peripheral symptomatic end-neuroma formation in both upper and lower extremities
<b>Participating centers</b>	<ul style="list-style-type: none"> <li>• University of Pennsylvania (US), PA - Prof. dr. Levin, Principal Investigator</li> <li>• Buncke Clinic (US) - Dr. Buncke</li> <li>• VCU Richmond (US) - Dr. Isaacs</li> <li>• Geisinger Institute Danville (US) - Dr. Klerna</li> <li>• Thomas Jefferson Philadelphia (US) - Dr. Culp</li> <li>• Peachtree Clinic Atlanta (US) - Dr. McClelland</li> <li>• Stanford University (US) - Dr. Curtin</li> <li>• VA Portland (US) - Dr. Layman</li> <li>• Arizona Hand Center (US) - Dr. Champagne</li> <li>• University Lund (SV) - Prof. Dr. Dahlin</li> <li>• Birmingham Hand Center (UK) - Dr. Power</li> <li>• Centro di Mano Milano (IT) - Prof. Dr. Pajardi</li> <li>• CFCM Paris (FR) - Dr. Houvet</li> <li>• University Linköping (SV) - Dr. Nyman</li> <li>• University Göteborg (SV) - Dr. Sassu</li> <li>• Parc Sanitari de Joan de Deu (ES) – Dr. Aparicio</li> <li>• BG Trauma Center Frankfurt am Main (GR) – Prof. Dr. Sauerbier</li> <li>• Institut de la main de la Clinique Jeanne d'Arc (FR) – Dr. Loubersac / Dr. Gaisne</li> </ul>
<b>Endpoints</b>	<p><b>Primary endpoint (3, 6, 12, 24 mo FU)</b></p> <ul style="list-style-type: none"> <li>• Reduction of pain caused by symptomatic neuroma (VAS)</li> </ul> <p><b>Secondary endpoints (3,6,12 mo FU)</b></p> <ul style="list-style-type: none"> <li>• Elliot Neuroma score</li> <li>• Rate of recurrence of painful neuroma</li> <li>• Pain medication use</li> <li>• Level of disability (QuickDASH/Goals)</li> <li>• Ease of use and physician satisfaction</li> </ul>
<b>Timelines</b>	<ul style="list-style-type: none"> <li>• Patient enrollment concluded in July-2018</li> <li>• Last patient, last follow up: expected July-2020</li> <li>• Final data: available during Q3-2020</li> </ul>

Variable	Screening Mean ± SD (N = 73)	+3 mo FU Mean ± SD (N = 49)	+6 mo FU Mean ± SD (N = 34)	+12 mo FU Mean ± SD (N = 10)
<b>VAS</b>	70.6 ± 17.8	18.1 ± 21.7	26.5 ± 27.7	25.7 ± 23.0
<b>Quick DASH*</b>	56.0 ± 20.8	30.0 ± 23.7	26.7 ± 24.7	39.8 ± 31.0
<b>Goals**</b>	10.6 ± 2.7	4.9 ± 3.9	4.3 ± 3.9	6.5 ± 5.4
<b>Elliot</b>	12.5 ± 3.7	5.2 ± 4.3	6.2 ± 5.4	6.6 ± 5.1

\* QuickDASH Screening: n = 48; 3-months: n = 33; 6-months: n = 22; 12-months: n = 4

\*\* Goals Screening: n = 63; 3-months: n = 44; 6-months: n = 33; 12-months: n = 10