



allayTM HYDROGEL
CAP



Put Neuromas to Rest

Optimize peripheral nerve surgery with proven hydrogel technology designed to reduce the risk of neuroma formation

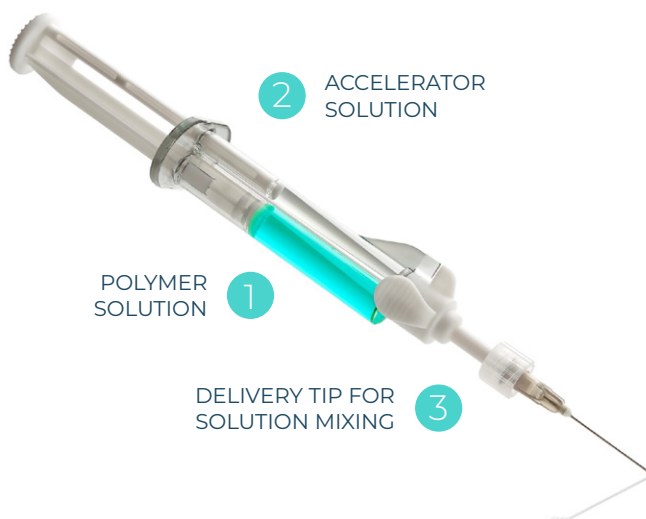
TULAVI



5+ million patients
treated with hydrogel
technology*

We are Redefining Peripheral Nerve Surgery

Introducing the first and only
fully absorbable hydrogel
technology specifically
indicated to reduce the risk
of symptomatic neuroma
formation.



Backed by science. Trusted in practice.

Built on Adaptive Hydrogel
Technology, now formulated
specifically for peripheral
nerves. The allay™ Hydrogel
Cap is designed to:

PROTECT
Transected Nerves
Creates a non-compressive,
hydrophilic, and flexible
hydrogel cap that conforms
to nerve ends



BLOCK
Axonal Escape
Provides a mechanical
barrier, preventing escape
of disorganized axons

REDUCE
Neuroma Formation
No neuroma formation
demonstrated across 9
preclinical studies, n>170¹



* Based on product volumes from four hydrogel companies across multiple specialties, developed by Incept LLC.

¹ Data on File at Tulavi Therapeutics.

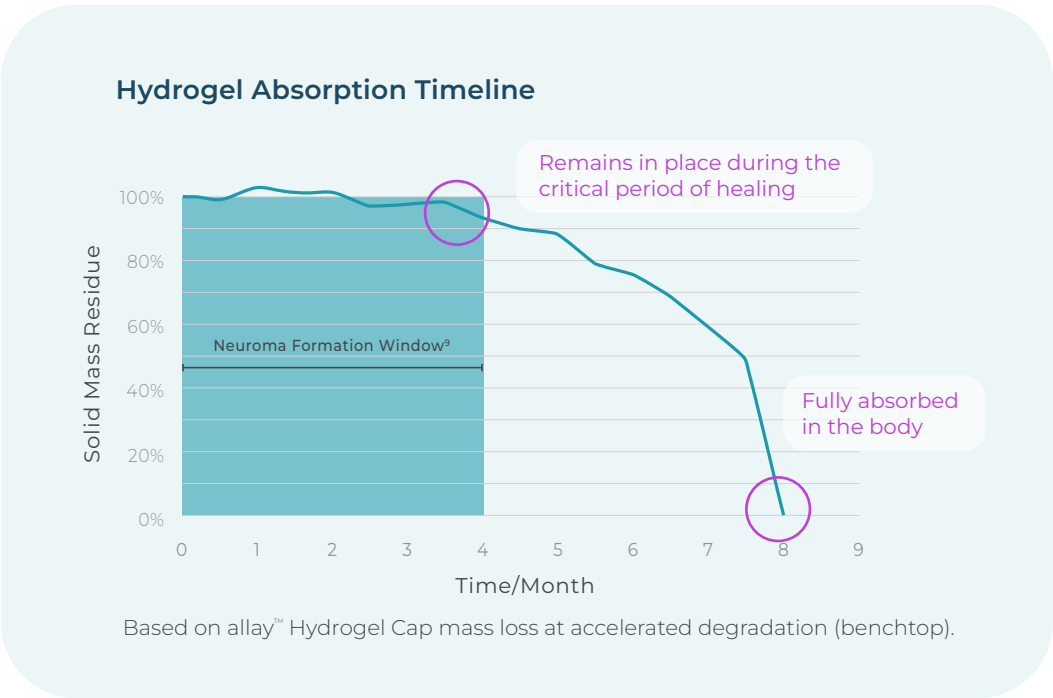
Clinical Solution

Fast & Intuitive Application

The allay™ Hydrogel Cap rapidly forms *in situ* to create a conformable and protective cushion.



Through the process of hydrolysis, the allay™ Hydrogel Cap is fully absorbed in approximately 8 months.⁸



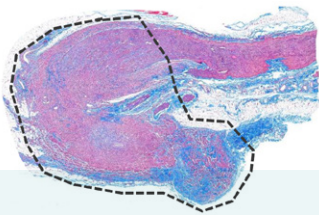
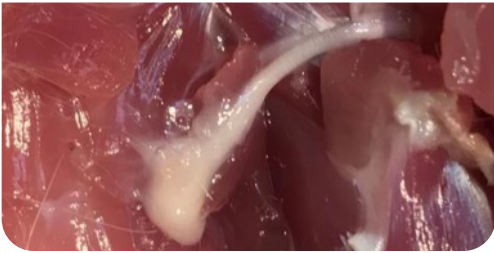
⁸ Data on File at Tulavi Therapeutics.
⁹ Oliveira KMC, et al. Time course of traumatic neuroma development. PLoS One. 2018 Jul 16;13(7):e0200548.

Proven Results

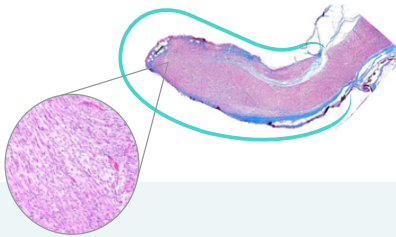
Demonstrated Neuroma Prevention

No Neuroma Formation Across 9 Preclinical Studies, N>170¹⁰

Untreated Nerve
Neuroma Formation
3 Months



allay™ Hydrogel Cap
No Neuroma
3 Months



Real-world Clinical Outcomes

“

After years of failed interventions, allay helped to provide this patient with relief that she had not seen in many years.”

**Saphenous Nerve Neuroma Excision,
Orthopedic Surgeon, North Carolina**

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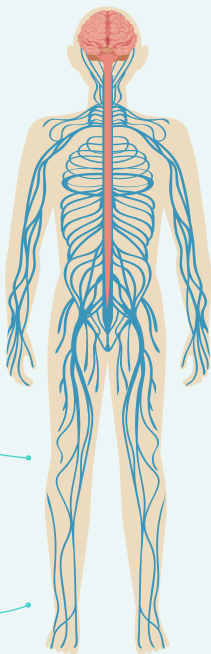
This approach saved me over two hours in the OR.”

**Plastic Hand and Peripheral
Nerve Microsurgeon**

“

Patient had painful neuromas from 3 amputated fingers, feels great now. I wouldn’t have even offered him the surgery without this great option.”

**Revision Digital Amputation,
Orthopedic Surgeon, Florida**



Scan to learn more
about clinical applications
and real-world outcomes

¹⁰ Data on File at Tulavi Therapeutics.

Unmet Clinical Need

Nerve Injury Often Leads to Painful Neuromas²

The problem may be bigger than you think:

600,000+ amputations occur each year ³	85% of patients experience chronic phantom or neuroma pain ⁴	1,900,000+ peripheral nerve surgeries occur each year ⁵	50% of patients experience persistent post-operative pain ⁶
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Designed to Optimize Nerve Recovery

The allay™ Hydrogel Cap remains in place for 8 months, protecting the nerve throughout the critical period of neuroma formation.^{5,7}



2 Yang H, Dong Y, Wang Z, Lai J, Yao C, Zhou H, Alhaskawi A, Hasan Abdullah Ezzi S, Kota VG, Hasan Abdulla Hasan Abdulla M, Lu H. Traumatic neuromas of peripheral nerves: Diagnosis, management and future perspectives. Front Neurol. 2023 Jan 11;13:1039529.

3 Rivera, J. A., Churovich, K., Anderson, A. B., & Potter, B. K. (2024). Estimating Recent US Limb Loss Prevalence and Updating Future Projections. Archives of Rehabilitation Research and Clinical Translation, 6(4), 100376.

4 Döring K, Trost C, Hofer C, Salzer M, Kelaridis T, Windhager R, Hobusch GM. How Common Are Chronic Residual Limb Pain, Phantom Pain, and Back Pain More Than 20 Years After Lower Limb Amputation for Malignant Tumors? Clin Orthop Relat Res. 2021 Sep 1;479(9):2036-2044.

5 Data on File at Tulavi Therapeutics.

6 Kehlet, H., Jensen, T. S., & Woolf, C. J. (2006). Persistent postsurgical pain: Risk factors and prevention. The Lancet, 367(9522), 1618–1625.

7 Oliveira KMC, et al. Time course of traumatic neuroma development. PLoS One. 2018 Jul 16;13(7):e0200548.

Single Solution. Treat Multiple Nerves & Sizes.

A single allay™ Hydrogel Cap Set enables surgeons to efficiently treat multiple nerves across a broad range of sizes.



Small Nerve Set

Nerve Sizes: 1, 2, 3 and 4 mm

Model # TL-5515-1



Large Nerve Set

Nerve Sizes: 5, 6 and 7 mm

Model # TL-5515-2

Additional Delivery Tips

One box includes 6 packages, each package contains one single use delivery tip

Model # TL-7627

allay™ NERVE CAP INDICATION FOR USE

The allay™ Nerve Cap is indicated for use in adults aged 22 years or older as a physical barrier to separate the peripheral nerve end from the surrounding environment to reduce the risk of the development of a symptomatic neuroma.

CONTRAINDICATIONS

The allay™ Nerve Cap is not designed, sold, or intended for use except as described in the indication for use and is contraindicated for use in:

- Areas of active surgical site infection.
- Areas of active blood flow.
- Areas of excessive movement or over a joint.
- Patients with a known allergy to poly(ethylene glycol) (PEG) or the color additives FD&C Yellow No. 5 Dye (tartrazine) or FD&C Blue No. 1 Dye (Brilliant Blue FCF).

PRECAUTIONS

- Only physicians who have adequate surgical training should use the allay™ Nerve Cap.
- The allay™ Nerve Cap system is provided sterile. Do not use if the packaging is open or damaged. Do not use if the Powder in the Powder Vial is not free flowing.
- The allay™ Nerve Cap is not intended for patients under 22 years of age.
- The safety and effectiveness of the allay™ Nerve Cap was based on non-clinical performance testing only.

- **For single use only.** The allay™ Nerve Cap is designed to be used as a single-use device. Discard open used and unused portions of the allay™ Nerve Cap system including any unused mixing tips and Cap Forms after the procedure. Do not re-sterilize or reuse as in situ formation will be adversely affected.
- **Use within 30 minutes of preparation of the Applicator.** Discard entire system if not used within 30 minutes.
- Store at room temperature.
- The allay™ Nerve Cap polymerizes rapidly so the injection should proceed uninterrupted without stopping. Stopping during injection may result in the tip clogging. A replacement tip is provided, should this occur.
- This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity [CFR 21 Part 201.20].

ADVERSE EVENTS

Potential complications that may be associated with any peripheral nerve surgery may include pain, infection, decrease or increase in nerve sensitivity, and complications associated with the use of anesthesia. Minor discomfort in the surgical site may occur for several days.



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