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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 12109384 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12109384 (the "12109384 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

{"answer": "As of April 26, 2026, here is a summary of United States Patent 12,109,384:

Title: Hemostasis valves and methods of use

Assignee: Inari Medical, Inc.

Inventors:

- Benjamin E. Merritt
- John C. Thress
- Paul Lubock

Filing Date: March 7, 2024

Issue Date: October 8, 2024

Abstract:

Devices, systems, and methods for sealing medical devices, particularly during intravascular access, are disclosed. Some aspects relate to a hemostatic valve for sealing a wide range of medical devices, such as catheters, wires, and embolectomy systems. The valve can include an elongate member having a first end, a second end, and a central lumen extending therebetween. A reinforcement structure...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more

asserted claims of the 12109384 Patent:

Analysis of Prior Art Cited in US Patent 12,109,384

Based on the patent details and the family history of US Patent 12,109,384, the following patents are identified as relevant prior art. The analysis focuses on references that were cited during the prosecution of this patent and its parent applications.

1. U.S. Patent No. 11,000,682 B2

- Full Citation: Merritt et al., U.S. Patent No. 11,000,682 B2, "Hemostasis valves and methods of use."
- Publication Date: May 11, 2021
- Filing Date: August 30, 2018
- Assignee: Inari Medical, Inc.
- Brief Description: This patent is a direct parent to the '384 patent and discloses a hemostasis valve with a pliable elongate member, a reinforcement structure (such as a braided mesh), and a tensioning mechanism. This mechanism uses at least one filament that can be actuated to constrict the elongate member's central lumen, creating a seal. The invention allows for sealing around various-sized medical instruments and is designed for single-handed operation.
- Potential Anticipation: As a direct parent in the same patent family, this document...

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

Based on an analysis of the claims and description of U.S. Patent No. 12,109,384, a strong case for obviousness under 35 U.S.C. § 103 could be constructed by combining prior art references that teach the core components of the invention: a constricting filament mechanism for sealing, a reinforced flexible tube, and a manual actuator. A Person Having Ordinary Skill in the Art (PHOSITA) in the field of medical devices, particularly intravascular catheters and valves, would have been motivated to combine these known elements to achieve the predictable result of a durable, reliable hemostasis valve.

Analysis of Key Claim Elements

The inventive concept of US 12,109,384, particularly as described in independent claim 1, centers on a specific combination of features in a hemostatic valve:

1. A Pliable, Elongate Tubular Member: A soft, collapsible tube forming the main lumen of the valve (e.g., elongate member 132).
2. A Filament-Based Tensioning Mechanism: At least one filament that extends around the tubular member to constrict and seal it (e.g., at least one filament 150). This is...

4. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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