

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN BALLOON DILATION
DEVICES, SYSTEMS, AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1449

NOTICE OF INSTITUTION OF INVESTIGATION

Institution of investigation pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on April 18, 2025, under section 337 of the Tariff Act of 1930, as amended, on behalf of Entellus Medical, Inc. of Plymouth, Minnesota, Stryker Corporation of Portage, Michigan, and Stryker Sales, LLC of Portage, Michigan. Supplements to the complaint were filed on April 25 and May 8, 2025. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain balloon dilation devices, systems, and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,083,878 (“the ’878 patent”); U.S. Patent No. 11,090,472 (“the ’472 patent”); and U.S. Patent No. 12,274,847 (“the ’847 patent”). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: Susan Orndoff, The Office of the Secretary, Docket Services Division, U.S. International Trade Commission, telephone (202) 205-1802.

SUPPLEMENTARY INFORMATION:

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2025).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on May 20, 2025, ORDERED THAT –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1-11, 14-15, and 19-30 of the '878 patent; claims 1-16, 18-22, 24-25, 27, and 29-30 of the '472 patent; and claims 1-4, 6-12, 15-20, and 22 of the '847 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “(a) balloon dilation devices; (b) systems containing the same for tracking, guiding, illumination, and/or navigating cavities, and (c) components thereof consisting of: (i) components of the balloon dilation device; and (ii) components for tracking, guiding, illuminating, and/or navigating used in balloon dilation devices and with systems containing the same”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Entellus Medical, Inc.
3600 Holly Lane North, Suite 40
Plymouth, Minnesota 55447

Stryker Corporation
1941 Stryker Way
Portage, Michigan 49002

Stryker Sales, LLC
1941 Stryker Way
Portage, Michigan 49002

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Fiagon GmbH
Neuendorfstraße 23b
16761 Hennigsdorf
Germany

Fiagon AG Medical Technologies
Neuendorfstraße 23b
16761 Hennigsdorf
Germany

Fiagon NA Corporation
3913 Todd Ln Building 100, Suite 101
Austin, Texas 78744

Fiagon NA, LLC
3913 Todd Ln Building 100, Suite 101
Austin, Texas 78744

Hemostasis, LLC
5000 Township Pkwy
White Bear Lake, Minnesota 55110

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa Barton', enclosed within a rectangular box.

Lisa Barton
Secretary to the Commission

Issued: May 20, 2025