

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
SHERMAN DIVISION**

SNYDERS HEART VALVE LLC,

Plaintiff,

v.

ST. JUDE MEDICAL, CARDIOLOGY  
DIVISION INC.; AND ST. JUDE  
MEDICAL S.C., INC.,

Defendants.

CIVIL ACTION NO. 2:16-cv-812

ORIGINAL COMPLAINT FOR  
PATENT INFRINGEMENT

**JURY TRIAL DEMANDED**

**ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Snyders Heart Valve LLC (“Snyders”) files this original complaint against St. Jude Medical, Cardiology Division, Inc. and St. Jude Medical S.C., Inc. (collectively, “Defendants” or “St. Jude”), alleging, based on its own knowledge as to itself and its own actions and based on information and belief as to all other matters, as follows:

**PARTIES**

1. Snyders is a corporation formed under the laws of the State of Texas, with a principal place of business in Tyler, Texas.

2. Defendant St. Jude Medical S.C., Inc. is a corporation organized under the laws of the state of Minnesota with a principal place of business at 6300 Bee Cave Road, Building 2, Suite 100, Austin, Texas 78746. Defendant St. Jude Medical S.C., Inc. can be served with process by serving its registered agent: C T Corp System, 1999 Bryan St., Suite 900, Dallas, TX 75201.

3. Defendant St. Jude Medical, Cardiology Division, Inc. is a corporation organized under the laws of Delaware with a principal place of business at 177 East County Road B, St.

Paul, Minnesota 55117. Defendant St. Jude Medical, Cardiology Division, Inc. can be served with process by serving: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

### **JURISDICTION AND VENUE**

4. This is an action for infringement of a United States patent arising under 35 U.S.C. §§ 271, 281, and 284–85, among others. This Court has subject matter jurisdiction of the action under 28 U.S.C. §1331 and §1338(a).

5. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b). Upon information and belief, St. Jude has transacted business in this district and has committed, by itself or in concert with others, acts of patent infringement in this district.

6. St. Jude is subject to this Court’s specific and general personal jurisdiction pursuant to due process and/or the Texas Long Arm Statute, due at least to St. Jude’s substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; and/or (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided to individuals in Texas and in this district.

### **DR. SNYDERS AND HIS INVENTION**

7. Robert V. Snyders, M.D. is an accomplished physician having practiced clinical medicine for over forty years. Dr. Snyders has over 30 years of experience in cardiovascular device design, prototyping and pre-clinical studies and has been awarded six United States patents and several international patents related to medical devices (asserted patents in bold):

- a. **U.S. Patent No. 6,821,297 (“Artificial heart valve, implantation instrument and method therefor”)**

**b. U.S. Patent No. 6,540,782 (“Artificial heart valve”)**

c. U.S. Patent No. 6,095,968 (“Reinforcement device”)

d. U.S. Patent No. 5,256,132 (“Cardiac assist envelope for endoscopic application”)

e. U.S. Patent No. 5,169,381 (“Ventricular assist device”)

f. U.S. Patent No. 4,690,134 (“Ventricular assist device”)

8. Dr. Snyders is the sole inventor of U.S. Patent Nos. 6,540,782 (the “’782 Patent”) and 6,821,297 (the “’297 Patent”) (collectively, the “Patents-in-Suit”).

9. Dr. Snyders’ named his valve the “Funnel Valve” due to its resemblance to that particular geometric shape. The Funnel Valve allowed rapid deployment of a bioprosthetic heart valve without the need for conventional, invasive surgery.

10. Dr. Snyders submitted his Funnel Valve design to Medtronic’s Chris Coppin, M.D., Ph.D., Senior Research Manager. In May 2000, Dr. Coppin noted that Dr. Snyders’ “funnel valve design is quite ingenious” and that “there is no other product on the market that even comes close to,” being able to “be deployed by minimally invasive means for urgent...use in patients that are too unstable for open heart surgery.”

11. In mid-2001, Dr. Snyders tested the Funnel Valve with several renowned physicians including Dr. Mehmet Oz, Dr. Paul DiGiorgi, Dr. Neel Joshi, and Dr. Alessandro Barbone at Columbia Presbyterian Medical Center. The physicians at Columbia Presbyterian determined that the funnel valve was “a promising design for potential transluminal valve replacement.”

12. The Funnel Valve also underwent tests at the Heineman Medical Research Laboratories in early 2002. During those tests, Dr. Mano Thubrikar, Ph.D., Associate Director,

Biomedical Engineering, determined that the Funnel Valve was “ingenious” and that it was the only valve he had “seen so far, which can be implanted using a catheter-based technology.”

### **ALLEGATIONS COMMON TO ALL CLAIMS**

13. St. Jude has made, had made, used, imported, provided, supplied, distributed, sold, and/or offered for sale artificial heart valves, including the Portico Valve.

Portico™ transcatheter aortic heart valve



The Portico™ transcatheter aortic heart valve is designed to be implanted in the native aortic heart valve without open-heart surgery and without concomitant surgical removal of the failed native valve. The valve is implanted using the Portico™ transfemoral delivery system. You receive the valve sterile and nonpyrogenic.

14. St. Jude has also made, had made, used, imported, provided, supplied, distributed, sold, and/or offered for sale systems for delivery of the artificial heart valves, including the Portico Transfemoral Delivery System (collectively with the heart valve products, the “accused products”).

Portico™

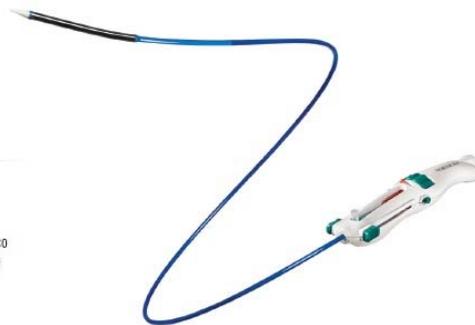
**TF** Transfemoral Delivery  
and Loading System

#### **INDICATIONS FOR USE**

The Portico transfemoral delivery system is intended for the delivery and placement of the Portico transcatheter aortic heart valve. The system may be used to deploy, reposition\* and retrieve\* the valve from the patient if necessary.

#### **PRODUCT BENEFITS**

- Delivery system enables self-expanding stent to be fully resheathed\* — allowing for repositioning of the valve (proximally or distally) at the implant site, or retrieving\* the valve if needed
- Facilitates gradual, controlled deployment — providing time to accurately assess final placement of the valve
- Annulus-first deployment allows optimal placement for overall valve performance
- Designed for enhanced flexibility and trackability



15. The accused products include a line of rapidly-deployable artificial heart valves that may be delivered to a patient’s damaged heart valve through an artery in order to avoid invasive, open-heart surgery. The accused products also include a line of catheter delivery systems used to deliver the artificial heart valves to the patient’s damaged heart valve through an artery.

16. Specifically, St. Jude’s accused products include at least the following model numbers:

<b><u>Bioprosthesis Model</u></b>	<b><u>Delivery System Model</u></b>
PRT-23 (Portico Transcatheter Aortic Valve - 23 mm)	PRT-DS-TF-18F (Portico Transfemoral Delivery System - 18F)
PRT-25 (Portico Transcatheter Aortic Valve - 25 mm)	PRT-DS-TF-18F (Portico Transfemoral Delivery System - 18F)
PRT-27 (Portico Transcatheter Aortic Valve - 27 mm)	PRT-DS-TF-19F (Portico Transfemoral Delivery System - 19F)
PRT-29 (Portico Transcatheter Aortic Valve - 29 mm)	PRT-DS-TF-19F (Portico Transfemoral Delivery System - 19F)

**ST. JUDE’S INFRINGEMENT OF U.S. PATENT NO. 6,540,782**

17. On April 1, 2003, United States Patent No. 6,540,782 (“the ’782 patent”) was duly and legally issued by the United States Patent and Trademark Office for an invention entitled “Artificial Heart Valve.” A copy of the ’782 Patent is attached as Exhibit 1 hereto.

18. Snyders is the owner of the ’782 patent with all substantive rights in and to that patent, including the sole and exclusive right to prosecute this action and enforce the ’782 patent against infringers, and to collect damages for all relevant times.

19. By making, having made, using, importing, providing, supplying, distributing, selling or offering for sale the accused products, St. Jude has directly infringed (literally and/or under the doctrine of equivalents) at least claim 1 of the ’782 patent.

20. St. Jude has infringed the '782 Patent by making, using, providing, supplying, distributing, selling, importing and/or offering for sale, directly or through intermediaries, artificial heart valves comprising a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and downstream region of the damaged valve, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors.

21. The accused products include a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band.

22. The valve element of the accused products moves in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

23. St. Jude has sold, supplied, provided, offered for sale, and/or distributed, directly or through intermediaries, the infringing heart valves to doctors who conduct transcatheter aortic valve replacement on patients with damaged heart valves using the patented apparatus.

24. St. Jude's infringement in this regard is ongoing.

25. Snyders has been damaged as a result of the infringing conduct by St. Jude alleged above. Thus, St. Jude is liable to Snyders in an amount that adequately compensates it for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

26. Snyders and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law for infringement of the '782 patent.

**ST. JUDE'S INFRINGEMENT OF U.S. PATENT NO. 6,821,297**

27. On November 23, 2004, United States Patent No. 6,821,297 ("the '297 patent") was duly and legally issued by the United States Patent and Trademark Office for an invention entitled "Artificial Heart Valve, Implantation Instrument, and Method Therefor." A copy of the '297 Patent is attached as Exhibit 2 hereto.

28. Snyders is the owner of the '297 patent with all substantive rights in and to that patent, including the sole and exclusive right to prosecute this action and enforce the '297 patent against infringers, and to collect damages for all relevant times.

29. By making, having made, using, importing, providing, supplying, distributing, selling or offering for sale the accused products, St. Jude has directly infringed (literally and/or under the doctrine of equivalents) at least claim 22 of the '297 patent.

30. St. Jude has infringed the '297 Patent by making using, providing, supplying, distributing, selling, importing and/or offering for sale, directly or through intermediaries, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising: a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the

downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region.

31. The accused products include a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame, said element having a convex upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

32. The accused products include an opening extending through at least one of said frame and the flexible valve element.

33. St. Jude has sold, supplied, provided, offered for sale, and/or distributed, directly or through intermediaries, the infringing heart valves to doctors who conduct transcatheter aortic valve replacement on patients with damaged heart valves using the patented apparatus.

34. St. Jude's infringement in this regard is ongoing.

35. Snyders has been damaged as a result of the infringing conduct by St. Jude alleged above. Thus, St. Jude is liable to Snyders in an amount that adequately compensates it for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

36. Snyders and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law for infringement of the '297 patent.

#### **ADDITIONAL ALLEGATIONS REGARDING INDIRECT INFRINGEMENT**

37. St. Jude has also indirectly infringed the Patents-in-Suit by inducing others to directly infringe the Patents-in-Suit. St. Jude has induced the end-users to directly infringe (literally and/or under the doctrine of equivalents) the Patents-in-Suit by directing or instructing doctors and technicians to insert the accused heart valves between a plurality of cusps of a damaged heart valve in an infringing manner. Such steps by St. Jude include, among other things, advising or directing doctors and technicians to use the accused products in an infringing manner; advertising and promoting the use of the accused products in an infringing manner; and/or distributing instructions and training videos that guide users to use the accused products in an infringing manner. Specifically, St. Jude's "Instructions for Use" for the Portico Transfemoral Transcatheter Aortic Valve Implantation System instructs the doctor to "Backload the Portico delivery system onto an 0.035' (0.89 mm)-compatible stiff guidewire while maintaining position across the aortic valve." The instructions further instruct the doctor to "[p]osition the delivery system so that the inner shaft marker band is aligned with the damaged aortic valve annulus plane," and "[b]egin deploying the valve by turning the deployment/re-sheath wheel in the

direction of the arrow on the handle.” Finally, the Portico instructions warn, “[t]he transfemoral implantation system should only be used by physicians who have undergone training on use of this product.” St. Jude’s inducement is ongoing.

38. St. Jude also indirectly infringes by contributing to the infringement of the Patents-in-Suit. St. Jude has contributed to the direct infringement of the Patents-in-Suit by the end-user of the accused products (doctors who place the accused heart valves into a patient’s damaged heart valve). The accused heart valves are specially designed to be used in an infringing way and have no substantial uses other than ones that infringe the Patents-in-Suit. St. Jude knows that the accused products constitute a material part of the invention of one or more of the claims of the Patents-in-Suit and are not staple articles of commerce suitable for substantial non-infringing use. St. Jude’s contributory infringement is ongoing.

39. St. Jude’s actions are at least objectively reckless as to the risk of infringing a valid patent and this objective risk was either known or should have been known by St. Jude.

40. St. Jude’s direct and indirect infringement of the Patents-in-Suit is, has been, and continues to be willful, intentional, deliberate, and/or in conscious disregard of Snyders’ rights under the Patents-in-Suit.

41. Snyders has been damaged as a result of the infringing conduct by St. Jude alleged above. Thus, St. Jude is liable to Snyders in an amount that adequately compensates it for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

42. Snyders and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law.

### **ST. JUDE'S KNOWLEDGE OF THE PATENTS-IN-SUIT**

43. St. Jude is, and has been, well aware of Dr. Snyder's pioneering work that led to the issuance of the Patents-in-Suit, as well as Dr. Snyder's application for, and the issuance of the Patents-in-Suit.

44. In June 2000, Dr. Snyders had a telephone call with St. Jude's, Mr. Jon Shear in which Mr. Shear indicated that he was interested in Dr. Snyders' Funnel Valve technology and that he knew about Dr. Snyders' patents in the area. Mr. Shear also requested more information about the Funnel Valve and Dr. Snyders sent him a "package" of information in response to his request.

45. Dr. Snyders had another telephone conversation with St. Jude's Mr. Shear in January 2002 in which Dr. Snyders discussed the results of his Funnel Valve studies.

46. In February 2002, Dr. Snyders had a conversation with St. Jude's Director of Marketing, veterinarian Roy Hosek regarding Dr. Snyders' Funnel Valve technology.

47. Also in February 2002, Dr. Snyders spoke with St. Jude's Janice Barstad regarding his Funnel Valve technology.

48. In November 2003, Dr. Snyders had a in depth conversation with St. Jude's Director of Research and Development, Cardiac Surgery, Will Sutton. In that conversation Dr. Snyders discussed his Funnel Valve technology and gave Mr. Sutton the '782 Patent number. Mr. Sutton indicated that he would locate the continuation in part patent (the '297).

49. St. Jude has had knowledge of the Patents-in-Suit since at least November 4, 2005, when St. Jude cited the '782 patent in their own patent application No. 11/183,537.

50. St. Jude also has had knowledge of the Patents-in-Suit at least as of the date when it was notified of the filing of this action.

**JFURY DEMAND**

Snyders hereby requests a trial by jury on all issues so triable by right.

**PRAYER FOR RELIEF**

Snyders requests that the Court find in its favor and against St. Jude, and that the Court grant Snyders the following relief:

a. Judgment that one or more claims of the '782 and '297 patents have been infringed, either literally and/or under the doctrine of equivalents, by St. Jude and/or all others acting in concert therewith;

b. A permanent injunction enjoining St. Jude and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in concert therewith from infringement, inducing infringement, or contributing to the infringement of the '782 and '297 patents;

c. Judgment that St. Jude accounts for and pay to Snyders all damages to and costs incurred by Snyders because of St. Jude's infringing activities and other conduct complained of herein;

d. That St. Jude's infringements be found to be willful, and that the Court award treble damages for the period of such willful infringement pursuant to 35 U.S.C. § 284;

e. That Snyders be granted pre-judgment and post-judgment interest on the damages caused by St. Jude's infringing activities and other conduct complained of herein;

f. That this Court declare this an exceptional case and award Snyders its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and

g. That Snyders be granted such other and further relief as the Court may deem just and proper under the circumstances.

Dated: October 25, 2016

Respectfully submitted,

s/ Matthew Antonelli

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