UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
and MEDTRONIC COREVALVE, LLC
Petitioner

v.

TROY R. NORRED, M.D.
Patent Owner

Case IPR2014-00111
Patent 6,482,228

# DECLARATION OF CARL T. RUTLEDGE, Ph.D.

**NORRED EXHIBIT 2197 - Page 1**
**Medtronic, Inc., Medtronic Vascular, Inc.,**
**& Medtronic Corevalve, LLC**
**v. Troy R. Norred, M.D.**
**Case IPR2014-00111**

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I, Carl T. Rutledge, declare as follows:

1. I am a citizen of the United States and a resident of Ada, Oklahoma. My post office address is 2009 East 11th Street, Ada, Oklahoma 74820-7006.

2. In 1966, I received a B.S. with honors in Physics and Mathematics form the University of Arkansas (Fayetteville). In 1969, I received a M.S. in Physics from the University of Arkansas (Fayetteville). In 1971, I received a Ph.D. in Physics from the University of Arkansas (Fayetteville).

3. I am currently employed as a Linscheid Distinguished Professor and Chairman in the Physics Department at East Central University in Ada, Oklahoma.

4. From 1981 until the present, I have been employed full-time as a Professor in the Physics Department at East Central University, where I have also taught Astronomy, Computer Science and Mathematics. From 1970 to 1981, I was employed as a Professor of Physics at Southern Arkansas University (Magnolia).

5. A copy of my current Curriculum Vitae is filed as Exhibit 2092.

6. I have been asked to review the work of Dr. Stephen Lombardo and assist in explaining the equations used in his mathematical model. I understand the purpose of the model was to confirm that a prosthetic aortic valve could be held in place by a stent that was within the size range tolerated by the adult human

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anatomy without rupturing the aorta using mainly the frictional forces between the stent and the aorta

7. In order to perform my work, I was provided with an electronic copy of Dr. Lombardo's model, Exhibit 2084, as well as a copy of his handwritten notes, Exhibit 2019.

8. Referring to Exhibit 2109, pressure is given in mm Hg, or millimeters of mercury. Standard air pressure at sea level will push a mercury column up a tube evacuated at the top to a height of 760 mm = 76 cm. (Standard mercury barometers operate on this principle.) 760 mm is called one atmosphere and corresponds in US units to 14.7 pounds/square inch, or 14.7 $lb/in^2$. This means 1 $lb/in^2$ = 760 mm Hg/14.7 = 51.7 mm Hg.

9. Maximum pressure to be exerted on the aorta is 300 mm Hg, or 30 cm Hg, as 10 mm = 1 cm, which is the most pressure a normal heart can supply.

10. An aortic rupture (bursting) pressure of 1200 mm or 120 cm Hg was used, which greatly exceeds the rupture data provided by Dr. Norred.

11. The coefficient of friction (cof) is found by dividing the tangential sliding force $F_t$ parallel to the surface by the normal force $F_n$ pushing down on the surface:

$$\text{cof} = F_t/F_n$$

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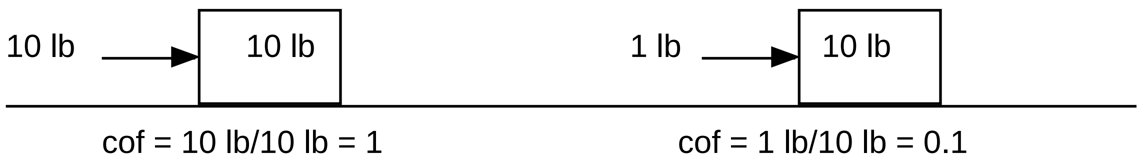
12. The larger the coefficient of friction, the harder it is to slide one object over another. For example, if it takes 10 lb ($F_t$) of horizontal force to slide a 10 lb ($F_n$) box across the floor, the coefficient of friction is 10/10 = 1 and the box is hard to slide. If it takes only 1 lb of force to slide the box, the coefficient of friction is only 1/10 or 0.1 and the box is 10 times easier to slide.




13. The minimum coefficient of friction between a stent and an artery wall was taken to be 0.2. Actually, since a stent will depress slightly into an artery wall due to its mesh shape, the coefficient of friction probably would be significantly larger, making the stent more securely locked in place. This is similar to the tread on a tire giving more traction in snow than a bald tire.

14. Aorta diameter was taken as 3.0 cm (a little over one inch, as 2.54 cm = 1 inch.).

15. Next the amount of force needed to hold the valve in place in the heart was calculated. The area of a circular valve of radius R is $A = \pi R^{2,}$ , where $\pi$ = 3.14.

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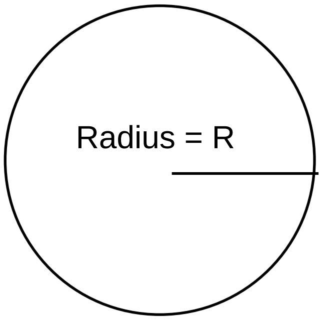


The force F on the valve is pressure P times area A, or F = PA. From here on we will use cm instead of mm.

16. The force = 30 cm Hg x 3.14 x (1.5 cm)2= about 200 cm Hg $cm^2$. This is about 6 pounds in US units.

17. The unit cm Hg $cm^2$ is a unit of force not commonly encountered but useful in these calculations. For perspective, 1 pound = 33 cm Hg $cm^2$.

18. If the force of the stent on the walls is 200 cm Hg $cm^2$, then the area A of the stent must be area = force/pressure, or A = F/P = 200 cm Hg $cm^2$/30 cm Hg = about 7 $cm^2$.

19. If we assume as a stent model sections of wire 0.1 cm width, 1.0 cm length and an angle of 60° (to make equilateral triangles as shown below) and let there be 20 sections of wire in each,

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then the area of each stent would be 20 pieces x 1 cm x .1 cm = 2 $cm^2$ each, so four stents such as this would be needed. These could be combined into a single stent.

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