

Corporation. I joined SCIMED full-time after graduation, and I remained with the company until 1996. During this time I rose from engineering intern to full-time R&D engineer to Director of R&D. Throughout my various roles at SCIMED, the focus of my work was on medical devices in the field of interventional cardiology, particularly catheter design.

4. Since 1997, I have served as an independent consultant for early stage medical device companies in the areas of product design and intellectual property development. Several of my consulting clients have developed successful products that are on the market and in hospitals today. A number of the products have been in the field of interventional cardiology, particularly catheters.

5. In addition to my work as an independent consultant, since 2000 I have engaged in a number of entrepreneurial ventures in the field of medical devices. In many of these ventures, I held chief responsibility for product design and development. Several of these products have been in the area of interventional cardiology. I have also done considerable work outside the area of interventional cardiology, including in treatments for orthopedics for extremities such as feet and ankles and treatment of spinal disorders. In 2006, I co-founded Entellus Medical, a company focused on treatments for chronic sinusitis. As Chief Technology Officer, I lead the product development and research teams. Entellus went public in 2015, and was acquired by Stryker in 2018.

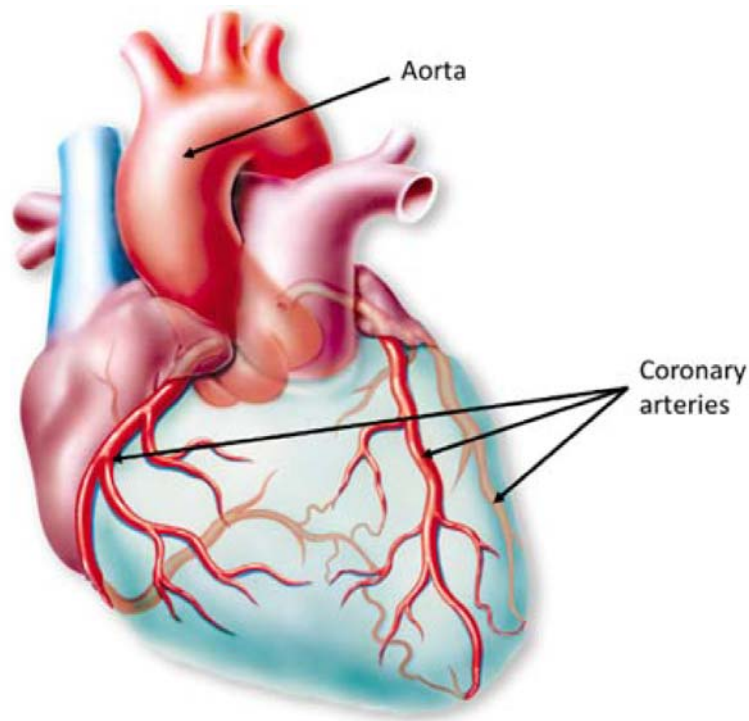
6. Between my work at SCIMED, my independent consulting, and my entrepreneurial ventures, I have been named as an inventor on over 140 issued U.S.

patents, as well as many corresponding patents in foreign countries. Numerous patent applications on which I am a named inventor are still pending.

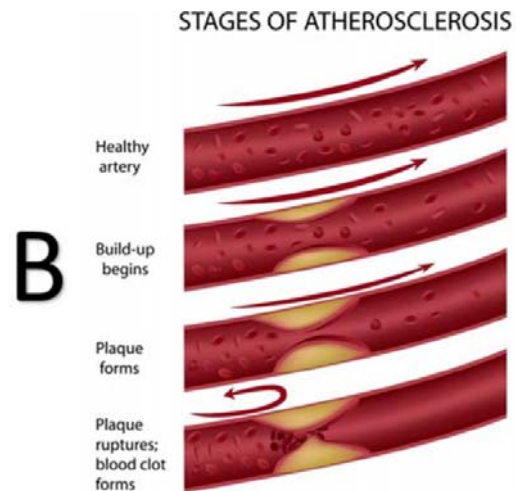
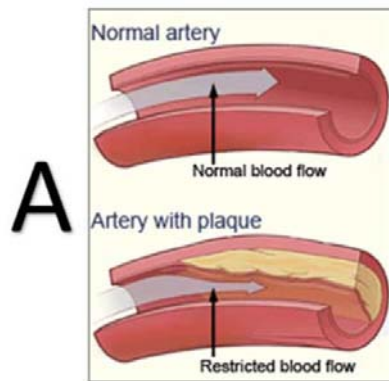
Background on the Technology: Coronary Catheters and Heart Disease

7. The technology involved in this case pertains to coronary catheter procedures. These are procedures for treating conditions in the blood vessels of the heart itself (coronary arteries). More specifically, this case pertains to a specialized catheter device used in some of the more challenging procedures, called a “guide extension catheter.”

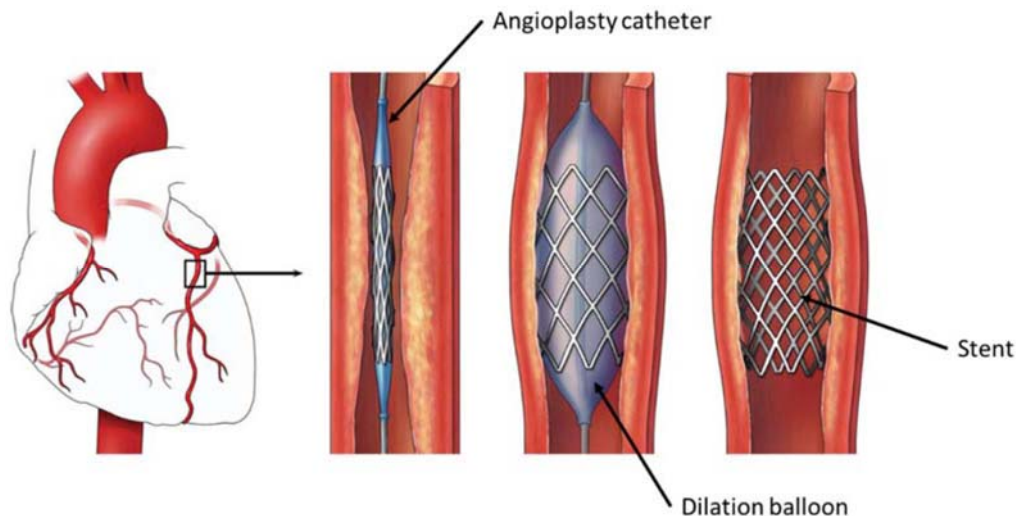
8. As the heart is essentially a large, muscular, pumping organ, it requires a lot of oxygenated blood to sustain itself. This blood circulates within the heart muscle via the coronary arteries (see diagram below). Over time, these blood vessels may become diseased (coronary artery disease, “CAD”) resulting in regions of narrowing or occluding. Starting in the 1970s, advances were made in treating this disease with catheter devices advanced into the coronary arteries from relatively accessible arteries in the leg or arm, e.g., the femoral artery in the leg or the radial artery in the arm.



9. CAD (also called atherosclerosis or plaque buildup) results in narrowed regions (lesions or stenoses) that can restrict the flow of blood to regions of the heart muscle (see below—A). Severe lesions can dramatically restrict the blood flow, starving the muscle of oxygen (ischemia), which can create severe chest pain and significantly limit a patient’s activity and quality of life. If the lesion completely blocks the flow of blood (typically from a subsequent blood clot within the lesion), this can lead to a heart attack (myocardial infarction). (See below—B). Severe lesions and complete blockages necessitate some sort of treatment to reopen the blocked region and re-establish normal or near normal blood flow. In the case of a complete blockage (myocardial infarction), the patient may die if the blocked vessel is not re-opened quickly, i.e., within hours of the blockage.



10. The most common treatment for CAD is with catheter devices that dilate the blockage from inside and place a support scaffold (stent) therein. The stent is inserted across the lesion in a collapsed state and then dilated with a balloon-tipped catheter called an angioplasty catheter (see below). It is therefore critical that these catheter devices are able to be positioned within the blockage, and positioned quickly, in order to successfully treat the patient.



11. One of the main pumping chambers of the heart is the left ventricle “LV.” The LV receives the oxygenated blood from the lungs and pumps it to the body via the

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