

ACCELERATING SUCCESS THROUGH STRATEGIC INNOVATION

## Value Genesis: Developing a Revolutionary Surgical Procedure and Device Architecture

**Client:** A world leader in heart valve implants and cardiac surgical products.

**Challenge:** The client had identified a potential opportunity to enter a market that was characterized in large part by low volume, non-consumers, although millions would benefit from treatment. People undergoing the existing cardiac procedure were subject to a highly invasive surgery that was usually only performed when the patient was already scheduled for an open-heart procedure, resulting in a low number of patients served.

Outside of the overly invasive procedure, patients could be treated via pharmaceutical options, however the success rate was not high. Patients were faced with limited options, which prompted the client to acquire new technology that held the potential for a minimally invasive procedure – thereby opening the market. However, the client faced the challenge of procedural, configuration and support system innovation in order to develop a market-ready product.

**Diagnosis:** The client had recently obtained access to technology that provided the potential for an alternative, market-expanding, means of performing a key procedure in the surgical area practiced at the time. Surgeons using the current technology faced an extremely invasive procedure that required rare expertise as well as lengthy patient recovery time.

An analysis of the market dynamics for advanced cardiac procedures identified that the number of procedures performed was limited by ability of surgeons to perform the procedure without extreme patient risk.

Needed was a fresh look at the drivers behind performing the advanced cardiac procedures from the perspective of patients, surgeons, and other stakeholders, and a reformulation of the treatment to make it both less traumatic and less risky.

**Methodology:** Value Genesis began with a look at the segmentation of the marketplace, identifying thought leaders in the field of cardiac surgery, as well as groups of more “common” physicians. An essential, but rare, set of

thought leaders were premier cardiac surgeons, proficient at non-invasive, surgical techniques. Subsequently, interviews were scheduled with a number of these leading surgeons, and other key stakeholders, to understand the different issues that each of these constituencies faced with the surgical challenge at hand.

Not only were critical needs and operating paradigms probed for in these interviews, but actual surgeries were also observed. Key observations were made in the operating room involving procedures and implement use, as well as the interrelationships among key support staff in the room and their equipment.

After substantial observations in the OR's, the cardiac procedure was broken down into constituent steps, which helped further identify potential risks and end-user needs, of both the patient and the medical staff.

Referencing specific observed needs, brainstorming and technical capabilities analysis sessions were conducted to generate ideas for alternative equipment, and simpler, less invasive procedures. These sessions led to a large number of concepts, which were then narrowed down to potential future product candidates.

**Results:** Value Genesis identified key difficulties and risks in a delicate cardiac procedure that was limited to being performed by highly capable surgeons. Subsequent observations made inside the operating room revealed opportunity for alternate approaches to treatment using an emerging technology.

Through brainstorming and technical analysis around the observed needs, a new minimally invasive procedure was conceived that could be performed by a wider set of surgeons. Creating an ancillary product and support procedures, which greatly reduced the potential for surgical error, further reduced risks associated with the treatment.

Further work with the client's research and development department resulted in acquisition of the enabling technology, comprehensive designs for the new products, surgical procedure testing and clinical trials.

Value Genesis identified a revolutionary procedure and surgical tool path to market for our client to address an underserved medical need and a major business opportunity.

