



# The ESI O-cluder

**Electroformed Stents Inc**  
**Richard Hines, President**  
**16525 Orchard Lane**  
**Stilwell, KS 66085**  
**913.710.1063**  
**Fax: 913.588.2609**  
**rick@estent.com**

## The ESI O-cluder ... Endovascular Eloquence



The ESI O-cluder is the latest innovation in minimally-invasive aneurysm treatment. A novel, eloquent, and industry-changing device, the ESI O-cluder overcomes many of the limitations of the current endovascular method of treating aneurysms: coiling. The thin, hourglass-shaped design of the ESI O-cluder provides superior treatment for most of the aneurysms that coils currently treat. Like coiling, the ESI O-cluder is delivered endovascularly and

works by reducing the circulation of fresh blood into the aneurysm, triggering a thrombus that allows the healing process to begin. The similarities between the ESI O-cluder and coiling, however, end there.

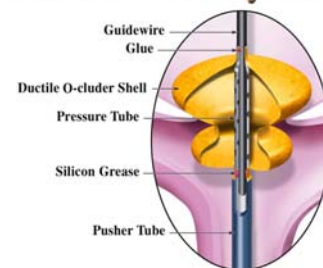
### Ease of Delivery

The ESI O-cluder, a small dumbbell or hourglass-shaped gold balloon, is compacted for endovascular delivery via catheter. After delivery, with one lobe inside the aneurysm and the other lobe contained in the artery, the compacted ESI O-cluder is pressure expanded, inflating the ESI O-cluder to its original shape. A simple mechanical collapse of the ductile gold lobes follows, forming a pop-rivet-like structure that captivates the neck of the aneurysm and reduces blood circulation into the aneurysm. Finally, a balloon catheter contours the collapsed ESI O-cluder to the arterial wall, fully opening the parent artery.

### Efficiency and Efficacy

The entire ESI O-cluder deployment procedure requires much less time than coiling, thereby reducing stress on the patient and physician, while also drastically reducing the cost. By minimizing the amount and number of objects inserted into the aneurysmal sac, the ESI O-cluder decreases the possibility of complications resulting from perforation of the aneurysmal sac, and by eliminating the danger of coils protruding into the parent artery, the ESI O-cluder prevents the formation of a partial blockage that may lead to clot and stroke.

#### O-cluder & Delivery Catheter

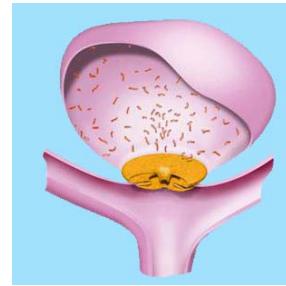


### Eliminates the Mass Effect

Furthermore, the ESI O-cluder reduces the mass effect by eliminating the permanent lump of coils contained within the aneurysm that maintains an undesirable pressure on the surrounding brain tissue. The design of the ESI O-cluder also allows for the removal of blood from the aneurysm through the catheter, reducing the size of the aneurysm. Moreover, as time passes, the thrombus may be slowly absorbed, further reducing pressure on the surrounding tissue.

### **Eradicates Recanalization**

Finally, and most importantly, the collapsed lobes of the ESI O-cluder completely cover the neck of the aneurysm, virtually eliminating recanalization: the reformation of the aneurysm at its neck. Recanalization occurs in approximately 15 percent of coiled aneurysms and in nearly 50 percent of coiled giant aneurysms. The virtual elimination of recanalization, the reduction of the mass effect, and the superior efficiency and affordability of the ESI O-cluder clearly places it well ahead of all other aneurysmal treatments.



### **Endovascular Background**

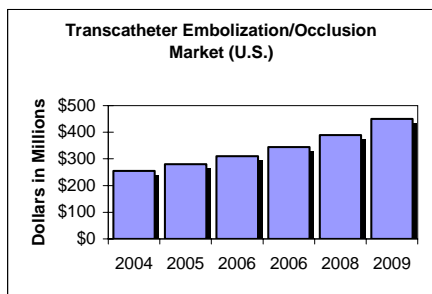
Neurovascular aneurysms, a weak bulging spot on the wall of a brain artery, pose a health risk because of their potential for rupture. When a neurovascular aneurysm ruptures, it bleeds into the compartment surrounding the brain, the *subarachnoid space*, causing a subarachnoid hemorrhage. Subarachnoid hemorrhage from a ruptured neurovascular aneurysm can lead to a hemorrhagic stroke, brain damage, and death.

### **Endovascular Market**

Annually, the incidence of subarachnoid hemorrhage in the United States exceeds 30,000 people. ESI believes that the O-cluder is capable of treating eighty percent of these aneurysms, presenting a U.S. market opportunity of \$100 million annually. Additionally, large and giant aneurysms, not adequately treated with current procedures, provide an opportunity for the O-cluder to demonstrate its superiority.

### **Endovascular Growth**

Transcatheter-based technologies for the endovascular treatment of neurovascular aneurysms have been in development worldwide for over twelve years, leading to remarkable progress in device technology. The industry expects these rapidly growing markets to drive procedural growth, projected at ten to twelve percent annually, over the next decade, opening the door for the development of improved endovascular embolization products and techniques.



### **Endovascular Opportunity**

Treating ruptured aneurysms is only the tip of the iceberg. A huge market potential exists for the treatment of silent aneurysms. Silent aneurysms, and their potential to rupture, are present in approximately four percent of the American population. Today, due to the limitations of the current aneurysm treatment options, medical professionals do not screen for silent aneurysms. As a result, the majority of silent aneurysms remain undetected. Only when silent aneurysms

result in a stroke or when other symptoms present are they treated, which is generally too late to avoid serious complications. ESI believes that the success of the O-cluder will lead to the acceptance of general screening for silent aneurysms, thereby furthering the market opportunity of the O-cluder.

### **ESI Strategy**

As ESI continues to build on our core technologies, our current strategy entails leading the ESI O-cluder through bench, animal and human testing, and the Food & Drug Administration (FDA) approval process in order to commercialize the device.

### **ESI Commitment**

ESI formed in 1998 to capitalize on our patented process for producing innovative endovascular medical devices through electroforming. At the core of ESI's philosophy exists a commitment to improve less-invasive medical devices and procedures by overcoming the limitations of current endovascular treatments. Through the continued refinement of existing products and procedures and the development of new technologies, ESI's broad product portfolio focuses on transcatheter-based technologies that represent an addressable worldwide endovascular market opportunity. ESI's Research and Development Facility, located directly between the Hogle Brain Imaging Center and the Breidenthal Animal Research Facility at the Kansas University Medical Center (KUMC) Biotechnology Incubator, provides convenient access to KUMC's doctors, facilities, and resources.

