FocalSeal-Synthetic Absorbable Sealant

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: FocalSeal-Synthetic Absorbable Sealant
Manufacturer: Focal, Inc
Address: Four Maguire Road, Lexington, Massachusetts 02173
Approval Date: May 26, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p990028a.pdf

What is it? The FocalSeal-L Sealant is a new type of surgical sealant surgeons use to seal air leaks on lungs following removal of cancerous lung tumors.

How does it work? FocalSeal-L Sealant is "painted" on the lung tissue. Once activated by light, the sealant is formed.

When is it used? Diagnosis of lung cancer often requires that patients have lung tumors surgically removed. After tumors are removed, air leaks can develop around the sutures or staples used in the surgical procedure. Currently, air leaks are closed by suturing, stapling tissue, or applying surgical mesh over the air leak. In some patients, lung tissue is so fragile surgeons do not try to use these usual closure methods. Surgeons can now use the FocalSeal-L Surgical Sealant in addition to these standard surgical closure methods.

What will it accomplish? Clinical studies showed that 39% of patients treated with FocalSeal-L Sealant and standard surgical closure techniques were air-leak free when they were discharged from the hospital compared to 11% percent of patients treated with standard techniques alone. The studies also showed that the amount of time required to stop air leaks was less than with standard techniques. Side effects were about the same although the patients treated with FocalSeal-L Sealant had a somewhat higher rate of infection (7.2% vs. 3.6%).

When should it not be used? FocalSeal-L Sealant should not be used when patients undergo total lung removal because of the possibility that there will be an additional risk of infection. In a clinical study in patients undergoing sleeve resection or bronchoplasty, there was an increased incidence of broncho-pleural fistulae. A broncho-pleural fistulae is an abnormal passageway that develops between the walls of the lung's air passages and the membrane surrounding the lung. A fistulae is an additional source of infection.

Additional information: Summary of Safety and Effectiveness is available at: http://www.fda.gov/cdrh/pdf/p990028.html A JAMA article in which FDA Commissioner Jane E. Henney, MD discusses this product is at: http://jama.ama-assn.org/issues/v284n6/ffull/jfd00006-1.html