FDA clears TransOral robotic surgery developed at Penn

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A minimally invasive surgical approach developed by head and neck surgeons at the University of Pennsylvania School of Medicine has been cleared by the U.S. Food and Drug Administration (FDA). The da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, California) has been cleared for TransOral otolaryngologic surgical procedures to treat benign tumors and select malignant tumors in adults.

Drs. Gregory S. Weinstein and Bert W. O'Malley, Jr., of the University of Pennsylvania School of Medicine's Department of Otorhinolaryngology: Head and Neck Surgery, founded the world's first TransOral Robotic Surgery (TORS) program at Penn Medicine in 2004, where they developed and researched the TORS approach for a variety of robotic surgical neck approaches for both malignant and benign tumors of the mouth, voice box, tonsil, tongue and other parts of the throat. Since 2005, approximately 350 Penn patients have participated in the world's first prospective clinical trials of TORS. These research trials compromise the largest and most comprehensive studies of the technology on record.

"TORS has dramatically improved the way we treat head and neck cancer patients, completely removing tumors while preserving speech, swallowing, and other key quality of life issues," said Bert O'Malley, Jr., MD, professor and chairman of Penn Medicine's Department of Otorhinolaryngology:Head and Neck Surgery. "It is very exciting that a concept conceived at PENN, evaluated in pre-clinical experimental models at PENN, tested in clinical trials at PENN, and then taught to key

surgeons and institutions both within the U.S. and internationally has been officially recognized by our federal governing agencies and peers around the world as a new and improved therapy for select neck cancers and all benign tumors."

45,000 Americans and approximately 500,000 people worldwide are diagnosed with head and neck cancers each year. Head and neck tumor treatments often involve a combination of surgery, radiation therapy, and chemotherapy. In many cases, surgery offers the greatest chance of cure; yet conventional surgery may require an almost ear-to-ear incision across the throat or splitting the jaw, resulting in speech and swallowing deficits for patients. In comparison, the minimally invasive TORS approach, which accesses the surgical site through the mouth, has been shown to improve long term swallowing function and reduce risk of infection while speeding up the recovery time. When compared to traditional surgeries, after their cancers have been removed successfully, patients have been able to begin swallowing on their own sooner and leave the hospital earlier. TORS outcomes are markedly improved when compared to standard chemotherapy, radiation or traditional open surgical approaches for oropharyngeal cancer.

"Based on our data and patient outcomes, coupled with the national and international enthusiasm and interest for TORS, we are changing the way oropharyngeal cancer and tumors will be treated now and in years to come," noted Gregory Weinstein, MD, FACS, professor and vice chair of the University of Pennsylvania School of Medicine's Department of Otorhinolaryngology: Head and Neck Surgery, director of the Division of Head and Neck Surgery and current president of The Society of Robotic Surgery. "We are already investigating new TORS treatments for other conditions such as sleep apnea, and collaborating with colleagues in Penn Neurosurgery to use TORS to remove skull base tumors and repair cervical spine disease."

The Penn TORS program developed an international training program that has trained numerous surgical teams from 12 different countries, many of whom have started establishing TORS programs at their respective institutions. With the FDA clearance of the da Vinci System for transoral otolaryngology, Penn Medicine will immediately expand its well established training program to include surgical teams from the United States.

Provided by University of Pennsylvania School of Medicine

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