



## **Natural Orifice Surgery Consortium for Assessment and Research® (NOSCAR®)**

A joint initiative supported by the  
American Society for Gastrointestinal Endoscopy and the  
Society of American Gastrointestinal and Endoscopic Surgeons

### **FOR IMMEDIATE RELEASE:**

### **NOSCAR® Announces NOTES® Multicenter Human Trials in the U.S.**

*First national human trial expected to begin later this year*

**OAK BROOK, Ill., July 10, 2009** – The Natural Orifice Surgery Consortium for Assessment and Research® (NOSCAR®), a joint effort of the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), announces the first Natural Orifice Transluminal Endoscopic Surgery® (NOTES®) multicenter human trial in the United States. Until now, NOSCAR research efforts have focused on basic research. The next phase will involve critical human trials. Continuing research commitments from industry partners Ethicon Endo-Surgery, Olympus America Inc. and Stryker Medical will provide funds to support the study in this emerging transdisciplinary therapy. The landmark study was announced at the 4<sup>th</sup> International Conference on NOTES in Boston where nearly 300 physicians and industry representatives gathered to learn the latest information about the science and technology of the medical platform.

“NOSCAR is taking a big step forward later this year with the commencement of the first NOTES multicenter human trial in the U.S. We are grateful to our partners at Ethicon Endo-Surgery, Olympus America Inc. and Stryker Medical for helping make the study possible,” said Michael L. Kochman, MD, NOSCAR Research Subcommittee co-chair.

The human studies are expected to begin later this year. NOSCAR leadership is currently finalizing the design for a prospective multicenter trial of NOTES cholecystectomy (gallbladder removal) versus conventional laparoscopic cholecystectomy. NOSCAR will be granting funds to selected institutions to conduct these trials. Institutions participating in the trial have demonstrated a strong commitment to developing the basic science that forms the foundation of NOTES and have already performed human NOTES cases under an Institutional Review Board protocol; approximately 200 patients will be enrolled in the clinical trial.

NOSCAR will make additional announcements regarding the participating institutions, study protocols and when studies will commence. ACI, a Clinical Research Organization based in Pennsylvania, has been retained to provide data collection and report preparation services for the study.

“We are delighted that the research and science to date has led us to the point where we can begin conducting human trials. The careful, responsible introduction of NOTES is our utmost concern; this study will provide the basis for such an introduction,” said Steven D. Schwaitzberg, MD, NOSCAR Research Subcommittee co-chair.

### **About NOSCAR**

Natural Orifice Transluminal Endoscopic Surgery® (NOTES®) might represent the next major advancement in minimally invasive therapy. To address this emerging technology, a working group consisting of expert laparoscopic surgeons from SAGES and a group of expert interventional endoscopists representing ASGE have joined together as the Natural Orifice Surgery Consortium for Assessment and Research® (NOSCAR®). The

growing capabilities of therapeutic flexible endoscopy have ushered in a new era in treatment of gastrointestinal conditions. Refinements in laparoscopic surgery have progressed to the point that complex surgical procedures, such as gastric bypass, can now be performed in a minimally invasive fashion. These trends have set the stage for the development of even less invasive methods to treat conditions in both the gut lumen and in the peritoneal cavity. It seems feasible that major intraperitoneal surgery may one day be performed without skin incisions. The natural orifices may provide the entry point for surgical interventions in the peritoneal cavity thereby avoiding abdominal wall incisions. For more information, visit [www.noscar.org](http://www.noscar.org).

#### **About the Society of American Gastrointestinal and Endoscopic Surgeons**

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) was founded in 1981 to foster, promote, support and encourage academic, clinical and research achievement in gastrointestinal endoscopic surgery. SAGES members are general and colorectal surgeons who perform endoscopy and laparoscopy as part of their practice as well as surgical residents, fellows, and other allied health personnel. The Society has grown from fewer than 50 original members to more than 5,500 from every state and over 80 countries. Visit [www.sages.org](http://www.sages.org) for more information.

#### **About the American Society for Gastrointestinal Endoscopy**

Founded in 1941, the mission of the American Society for Gastrointestinal Endoscopy is to be the leader in advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with nearly 11,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education. Visit [www.asge.org](http://www.asge.org) and [www.screen4coloncancer.org](http://www.screen4coloncancer.org) for more information and to find a qualified doctor in your area.

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