

# **Comprehensive Compliance Program – January 2020**

## PURPOSE OF THIS PROGRAM

The fundamental elements of our Compliance Program are described below. Note that our Compliance Program is constantly evolving to meet the changing needs and demands of the compliance environment and of Endologix. We continuously review and enhance our Compliance Program and reserve the right to continue to do so at any time in the future without notice.

Endologix conducts its business in compliance with all applicable federal and state statutes and regulations, as well as applicable industry guidelines that govern the medical device industry.

It is illegal to provide, offer, or agree to provide or offer, or accept, obtain, or agree to accept or attempt to obtain, a kickback or bribe. A kickback or bribe may be defined as any money, fee, payment, commission, credit, gift, gratuity, transfer of value, or compensation of any kind that is provided directly or indirectly, and that has as one of its purposes the improper obtaining or rewarding of favorable treatment in a business transaction. Endologix' position on kickbacks and bribes is clear – they are illegal and are not allowed.

An individual who is unsure whether a violation of any law, regulation or policy occurred must seek advice from their manager/supervisor or the Senior Director of Compliance. Complaints, suggestions for improvements or reports of alleged violations of law should be made via the company's Communication Channels (Open Door Reporting (Incident Management) or Hotline) to any member of Senior Management, Senior Director of Compliance, or Human Resources. They may be made anonymously if desired. Anonymity will be maintained during the investigation to the extent practicable and in the best interests of Endologix.

It is not sufficient simply to take note of the Compliance Program. Every individual is responsible for implementation of these standards and is called upon to review his or her own behavior in light of the standards and to determine where improvements are possible.

Problems must be actively addressed. There may be a duty both to provide and to obtain information. Compliance with these policies will be a part of every individual's performance evaluation.

Employees should be aware of the Federal Anti-Kickback Statute (AKS), and the constraints it places on the marketing and promotion of products reimbursable by any Federal health care programs. The AKS is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made in whole or in part to induce or reward referrals of Federal health care business. The AKS potentially implicates not only the offer or payment of anything of value for patient or business referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a Federal health care program. Endologix' products are regularly prescribed and utilized in medical procedures paid for under Federal health care programs. Violations of the AKS can



result in criminal sanctions, exclusion/debarment from government programs and/or civil fines to both the individual or entity that authorizes, offers or pays a kickback, <u>and</u> the individual or entity that solicits or receives the kickback.

### FUNDAMENTAL GUIDELINES OF THE COMPLIANCE PROGRAM

Endologix strives to obey the laws and regulations that govern its business. All individuals must respect and obey all laws, rules and regulations that apply to our business. All individuals should understand the laws and regulations which apply to them in the performance of their duties and ensure that Endologix complies with the laws, rules and regulations, as well as the codes and policies that govern how Endologix conducts business. Without reservation, Endologix adopts and advocates the AdvaMed Code of Ethics which facilitates our company's ethical interactions with Health Care Professionals in the United States, and the European MedTech Code of Ethical Conduct which is intended to provide guidance as to the minimum standards which apply to our business practices in Europe and, generally, elsewhere.

## **LEADERSHIP – SENIOR DIRECTOR OF COMPLIANCE**

Endologix has designated a Senior Director of Compliance to implement and manage the Compliance Program, which includes policies, procedures, training, monitoring, conducting investigations, and establishing best practices and preventative measures. The Compliance policies contain the procedures that Endologix has adopted to demonstrate the company's commitment to ethical, honest and responsible conduct when interacting with Health Care Professionals.

#### WRITTEN STANDARDS – COMPLIANCE POLICIES AND PROCEDURES

Endologix maintains Compliance policies which every individual will follow when conducting business transactions. The policies and procedures include guidelines for ethical standards and compliance with applicable laws which are critical to the company's ability to collaborate with Health Care Professionals.

#### **EFFECTIVE LINES OF COMMUNICATION**

Endologix encourages open and direct communication and discussion regarding any requests for guidance or clarity, and/or compliance concerns. Endologix provides a number of resources (Communication Channels) employees can use to ask a question, obtain guidance, or report a compliance concern. Resources for reporting concerns include talking with your direct supervisor, the Senior Director of Compliance, Human Resources, or utilizing the company's Hotline, an independent, third-party toll-free telephone number or Web portal that anyone can access 24 hours a day, 7 days a week. The Hotline handles calls in multiple languages.

Endologix does not tolerate any form of retaliation against an individual arising from a goodfaith report of a potential violation of our Compliance Program, a related policy, or of an integrity concern.



## TRAINING AND EDUCATION

Employees will undergo compliance training on the laws and industry guidelines regarding business transactions with Health Care Professionals.

#### ACCOUNTABILITY

Endologix supports ethical behavior and requires every individual to adhere to the policies in the Compliance Program and the Global Business Practice Standards as a condition of their employment.

#### **ASSESSMENT - AUDITING AND MONITORING, ENFORCEMENT OF PROGRAM**

Endologix will self-assess and monitor it's compliance with policies and procedures. The Senior Director of Compliance will conduct a periodic internal audit of the company regarding interactions with and/or payments to Health Care Professionals. If it is determined that a compliance violation has occured, reasonable steps will be taken to respond appropriately to the violation, prevent the occurrence of future violations of a similar nature, and support preventative measures and corrective actions.

## <u>REMEDIATION - INVESTIGATING AND MANAGING ALLEGED AND CONFIRMED</u> <u>INSTANCES OF NON-COMPLIANCE AND DISCIPLINARY STANDARDS</u>

Endologix has established a framework of standards of conduct for individuals relating to internal investigations and managing alleged and confirmed instances of non-compliance. Although each situation is considered on a case-by-case basis, Endologix consistently undertakes appropriate corrective action to address inappropriate conduct and to deter future violations. Endologix maintains a high standard of disciplinary measures in the event of non-compliance. Each individual will certify that s/he understands these standards of conduct for investigations, and subsequent disciplinary actions.