

Compliance Program Policy

INTRODUCTION

One Surgical, Inc. (“One Surgical”) recognizes the importance of conducting business in an ethical, lawful and socially responsible manner and strives to maintain the highest legal and ethical business standards in conducting its business. It is One Surgical’s policy that all personnel conduct themselves in a manner consistent with all applicable laws and regulations. In developing, implementing and applying its Compliance Program and Compliance Policies, One Surgical will be guided by applicable industry guidance such as the Advanced Medical Technology Association (“AdvaMed”) Code of Ethics for Interactions with Health Care Professionals and MedTech Europe Code of Ethical Business Practice (“EucoMed”).

To that end, One Surgical has adopted this Compliance Program and policies to implement the Compliance Program in order to facilitate ethical interactions with individuals or entities that are in a position to purchase, lease, order, or arrange for or recommend the purchase, lease, or order of One Surgical products, including, but not limited to, hospitals, ambulatory surgery centers, physicians, health care practitioners (e.g., physical therapists, occupational therapists), clinics, distributors, and any individual employed by such entities with responsibility or authority for purchasing, leasing, or ordering any One Surgical product (collectively, “Customers”). This policy applies to interactions with Customers who work in the U.S., even if the interaction occurs outside the U.S.

SCOPE

The Compliance Program and Compliance Policies apply to all One Surgical officers and directors, full-time employees, part-time employees, temporary personnel and all individuals who market or sell on behalf of One Surgical (collectively, “personnel”). One Surgical personnel do not include wholesalers or distributors whose only relationship with One Surgical is the purchase, distribution and/or shipping of such items or services. All One Surgical personnel are responsible for knowing and complying with these Compliance Policies and all applicable Federal and state laws, regulations and government guidance that applies to their work. The Compliance Program will be distributed to all One Surgical personnel on an annual basis. Newly hired staff will receive this Code as part of their initial orientation. It is the responsibility of each individual to be aware of those policies and procedures that pertain to his or her work and to follow those policies and procedures.

COMPLIANCE STRUCTURE

One Surgical has named a Compliance Officer who is responsible for the day-to-day direction and implementation of the Compliance Program. This includes developing resources (such as policies and procedures, training programs, and communication tools), and providing support (such as

operating a reporting mechanism, conducting program assessment, and providing advice). The Compliance Officer may delegate duties to other employees as appropriate.

The Compliance Officer is responsible for distributing standards, ensuring training is conducted, conducting, monitoring and responding to audits, investigating and resolving reports of potential non-compliance, and otherwise administering the Compliance Program. Concerns may also be reported anonymously by contacting One Surgical's Compliance Hotline at XXX-XXX-XXXX.

EDUCATION AND TRAINING

Education and training are conducted on an ongoing basis to ensure that staff throughout the Company are aware of the standards that apply to them. Attendance and participation in relevant compliance training programs is a condition of continued employment. Attendance records of education/training will be maintained per SOP-1004- Training System.

PERSONAL OBLIGATION TO REPORT

One Surgical is committed to ethical and legal conduct that is compliant with all relevant laws and regulations and to correcting noncompliance wherever it may occur. All personnel have an individual affirmative obligation to report any activity by any employee, subcontractor, or vendor that appears to violate applicable laws, rules, regulations, accreditation standards, the AdvaMed Code of Ethics, EuCoMed, or this Compliance Program. This duty to report potential non-compliance includes both first-hand knowledge and statements made by others regarding possible non-compliance.

Personnel are encouraged to report concerns first to their Manager if they are comfortable with it and think it appropriate under the circumstances. If this is uncomfortable or inappropriate, the situation should be reported to One Surgical's Compliance Hotline at XXX-XXX-XXXX. If a matter that poses serious compliance risk to the organization or if the matter reported involves a serious issue of patient safety is reported, and if the reporting individual doubts that the issue has been given sufficient or appropriate attention, the matter should be reported to higher levels of management until the reporter is satisfied that the full importance of the matter has been recognized.

INTERNAL INVESTIGATIONS OF REPORTS

One Surgical is committed to investigating all reported concerns promptly and confidentially to the extent possible. The Compliance Officer coordinates any findings from investigations and recommend corrective action or change, as needed. Cooperation with investigation efforts is expected of everyone.

DISCIPLINE

All violators of the Code will be subject to disciplinary action. The precise discipline will depend on the nature, severity, and frequency of the violation and will be implemented in accordance with policy.

MEASURING PROGRAM EFFECTIVENESS

We are committed to assessing the effectiveness of our Compliance Program through various efforts. Monitoring and auditing efforts support policies and compliance in general. Through these monitoring and auditing efforts, we are continuously assessing the effectiveness of the Program and finding ways to improve it.

CORRECTIVE ACTION

Where an internal investigation or auditing identifies a compliance weakness, appropriate corrective action will be initiated. Corrective action may include, as appropriate, notifying the appropriate governmental agency, instituting whatever disciplinary action is necessary, and implementing systemic changes to prevent a similar violation from recurring in the future.

ACKNOWLEDGEMENT PROCESS

All personnel are required to sign an acknowledgment confirming they have reviewed the Compliance Program, understand it represents mandatory policies of One Surgical and agree to abide by it. New employees are required to sign this acknowledgment as a condition of employment. Each employee is also required to participate in annual compliance training, and records of such training must be retained. Adherence to and support of the Compliance Program and participation in related activities and training is considered in decisions regarding, promotion, and compensation.

CONFLICT OF AUTHORITIES

One Surgical Compliance Policies supplement (and do not replace) laws, regulations and government rules. As a general matter, laws, regulations and other government rules control over the standards set forth in the Compliance Policies unless the Compliance Policies impose stricter requirements than these authorities. Questions regarding the application of any laws, regulations or government rules should be directed to the Compliance Officer.

QUESTIONS RELATING TO ONE SURGICAL COMPLIANCE POLICIES

The Compliance Program and Policies do not address every situation that may arise. The absence of a specific guideline, however, does not relieve One Surgical personnel of the responsibility for operating with the highest ethical standards of business conduct. Any questions concerning the Compliance Policies or any other legal or business ethics matter not specifically addressed in the Compliance Policies should be directed to the Compliance Officer, the point person at One Surgical for healthcare compliance matters.

Revision History

Revision	ECO #	Date Issued	Description	Issued By
A			Initial Release	

APPENDIX I: COMPLIANCE PROGRAM PERSONNEL ACKNOWLEDGEMENT

COMPLIANCE PROGRAM ACKNOWLEDGEMENT

I _____ have reviewed One Surgical’s Compliance Program and understand that it represents mandatory policies of One Surgical and that I must abide by it. I understand that failure to abide with the requirements in the compliance system will result in disciplinary action including possible termination.

I acknowledge that I have a personal obligation to report compliance concerns by any employee, subcontractor or vendor that I am aware of either first hand or based on statements made by others and that failure to report compliance concerns will be cause for disciplinary action. I acknowledge that One Surgical will maintain confidentiality regarding reports of compliance concerns and that One Surgical has a policy to not retaliate or discipline anyone who makes a compliance report in good faith.

Signature

Date