

Subject: Compliance Program	Policy Number: CP-001
Policy: Compliance Program Overview	Effective Date: 01/10/2022
	Revision 7/3/2018, Date(s): 01/10/2022

I. Introduction.

CrossRoads Extremity Systems, LLC (“CREX”) 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 CREX’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, CREX will be guided by applicable industry guidance such as the Advanced Medical Technology Association (“AdvaMed”) Code of Ethics for Interactions with Health Care Professionals.

To that end, CREX 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 CREX products, including, but not limited to, hospitals, ambulatory surgery centers, physicians, health care practitioners (e.g., physical therapists, occupational therapists), nurses, clinics, distributors, and any individual employed by such entities with responsibility or authority for purchasing, leasing, or ordering any CREX 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.

II. Scope.

The Compliance Program and Compliance Policies apply to all CREX officers and directors, full-time employees, part-time employees, temporary personnel, all individuals who market or sell on behalf of CREX (collectively, “personnel”), and distributors who operate as CREX sales agents or representatives. All CREX 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 CREX 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.

III. Compliance Structure.

We have 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 completing and returning a Compliance Report Form like the one attached to this Policy or through the general phone number (901) 221-8406 extension 120 directly to the Compliance Officer anonymously.

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IV. 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.

V. Personal Obligation to Report.

We are 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, 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.

If you are comfortable with it and think it appropriate under the circumstances, we encourage reporting concerns first with your Manager. If this is uncomfortable or inappropriate, the situation should be reported to the Compliance Officer, or by completing and returning a Compliance Report Form. 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.

CREX makes every effort to maintain the confidentiality of the identity of any individual who reports concerns of possible misconduct. There is no retribution or discipline for anyone who reports a concern in good faith. Anyone who deliberately makes a false accusation with the purpose of harming or retaliating against another person may be subject to discipline. Any person may report compliance concern(s) anonymously by completing the attached form and mailing to the Compliance Officer or calling (901) 221-8406 Extension 120.

VI. Internal Investigations of Reports.

CREX 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. The Compliance Officer will review compliance reports with leadership (CEO, at a minimum) at least annually.

VII. 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.

VIII. Measuring Program Effectiveness.

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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.

IX. 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.

X. Acknowledgment Process.

All personnel are required to sign an acknowledgment confirming they have reviewed the Compliance Program, understand it represents mandatory policies of CREX 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.

XI. Conflict of Authorities.

CREX 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.

XII. Questions Relating to CREX 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 CREX 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 CREX for healthcare compliance matters.

CROSSROADS EXTREMITY SYSTEMS, LLC

Compliance Report Form
Confidential: Attorney/Client Privileged Document

*Please complete the front of this form to report a compliance concern. You may mail at the address below to the Compliance Officer.
Please add additional pages if necessary.*

*Alternatively call (901) 221-8406 Extension 120 for the Compliance Officer to report anonymously.
Your call information will not be visible to the Compliance Officer*

Date: _____

Position: _____
(Unless anonymity requested)

Name: _____
(Unless anonymity requested)

Phone No.: _____
(Unless anonymity requested)

If you choose to report anonymously, please provide as much detail as possible so that we can properly investigate.

Description of Concern:

List anyone with whom you have discussed this concern and their response (if any):

List anyone else who might have knowledge that could help address this concern:

By identifying and reporting this concern, you have taken a positive step in promoting the best interest of CrossRoads Extremity Systems, our patients and your co-workers. Thank you! Return completed forms to the Compliance Officer or mail completed form to:

CrossRoads Extremity Systems
Compliance Officer
6423 Shelby View Drive, Suite 101
Memphis, TN 38134

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To be completed by the Compliance Officer

Description of Investigation (include all people interviewed, documents reviewed, or audit performed):

Conclusion:

Action (including follow-up date as applicable):

Date reported to the Compliance Committee: _____