

5. **Obligations of Sales and Marketing Personnel.** All sales and marketing personnel must be familiar with and understand the on-label uses of products for which they are responsible. They must also ensure that any third parties that they engage to promote Stryker products (e.g., promotional speakers) are familiar with and understand the on-label uses of any relevant products.
  
6. **Unsolicited Questions from HCPs Concerning Off-Label Uses of Stryker Products.** Field representatives shall not respond to questions from HCPs concerning unapproved or uncleared uses of Stryker products. All unsolicited requests by HCPs for the provision of information about the off-label use of Stryker products shall be directed to the Clinical Affairs department. Company responses will be prepared and disseminated by Clinical Affairs in accordance with guidance from the FDA or other authority. In recognition of the critical importance of patient safety, if a field representative is put in a situation in which an HCP initiates a discussion regarding the functionality (e.g., manner of use, device characteristics, or operating parameters) of a Stryker device for an off-label use *in an immediate patient care setting* (including immediately prior to a surgical procedure), the field representative may describe the functionality of the Stryker product for that use after notifying the HCP that the proposed use is off-label. The field representative may only describe information on device functionality on which the representative has been trained or which information has been provided to the field representative by the Company. Anecdotal information shall not be described. If an HCP initiates such a discussion other than in an immediate patient care setting, the field representative shall offer to direct the inquiry to Clinical Affairs. Under no circumstances shall a field representative participate in discussion about potential clinical outcomes of an off-label use or make reference to other information where the outcomes of such off-label use may be discussed.

7. **Compliance.** All employees and directors of Stryker Corporation are responsible for complying with this On-Label Promotion policy, and the President or executive in charge of each division, subsidiary or operating unit is responsible for ensuring that his or her employees know and comply with this policy. Violations of this policy will result in disciplinary action, up to and including dismissal. If you have questions about this policy, please contact Stryker's Chief Compliance Officer, General Counsel, or Vice President of Regulatory Affairs and Quality Assurance.




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**Joint Replacements**

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**Trauma, Extremities & Deformities**

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**Cranio-maxillofacial**

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**Spine**

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**Biologics**

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**Surgical Products**

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**Neuro & ENT**

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**Interventional Spine**

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**Navigation**

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**Endoscopy**

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**Communications**

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**Imaging**

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**Patient Care & Handling Equipment**

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**EMS Equipment**

# On-Label Product Promotion

## Corporate Policy Number Five



Copies of all Corporate Policies may be found on [www.stryker.com/corporatepolicies](http://www.stryker.com/corporatepolicies)

2825 Airview Boulevard  
 Kalamazoo, MI 49002  
 t: 269 385 2600 f: 269 385 1062

## Introduction:

The promotion of medical devices is highly regulated by the United States Food and Drug Administration (“FDA”) and regulatory bodies in other countries in which Stryker conducts business (“other authority”). The applicable laws and regulations are designed to make certain that the information that manufacturers provide to health care professionals and patients about the uses, benefits, and risks of medical devices is truthful, not misleading, and based on robust scientific evidence and sound clinical medicine. Among other things, these laws and regulations generally limit the promotion of a medical device to the cleared or approved uses of the device. As part of Stryker’s commitment to operating ethically and lawfully, Stryker and its agents must only promote its products for on-label uses. Executing on this commitment is consistent with Stryker’s business goals, as it supports the Company’s reputation for professionalism and our credibility among health care professionals and patients.

## Purpose:

Stryker’s Code of Conduct, Corporate Policy Number One, provides that the Company “will represent its products and services accurately and will comply with applicable regulatory and legal requirements governing the marketing and sale of its products and services.” The purpose of this On-Label Promotion Policy, Corporate Policy Number Five, is to provide further guidance and direction on the Company’s commitment to promoting its products and services in compliance with applicable regulatory and legal requirements by making it clear that Stryker employees, contractors, consultants, and other third parties acting on Stryker’s behalf may only promote Stryker products for on-label uses.

## Scope:

This policy applies to all employees, officers, and directors of Stryker Corporation and its domestic and foreign subsidiaries. In addition, where noted, this policy also applies to contractors, consultants and other third parties acting on Stryker’s behalf when those persons engage in the promotion of Stryker products on behalf of Stryker (e.g., distributors and promotional speakers).

## Details:

1. Definitions. For purposes of this policy:

- a. The term “health care professional” (“HCP”) means those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe products sold, leased, or distributed by Stryker.
- b. The term “on-label use” means any use for which the FDA or other authority has cleared or approved a product, or which is within the scope of an applicable 510(k) exemption or similar exemption under applicable laws or regulations outside the United States.

- c. The term “off-label use” means any use for which the FDA or a corresponding foreign regulatory authority has not cleared or approved a product, or which is outside the scope of an applicable 510(k) exemption or similar exemption under applicable laws or regulations outside the United States.
- d. The term “promotion” means any activity undertaken, organized, or sponsored by Stryker, the purpose of which is to encourage the prescription, purchase, recommendation, or use of Stryker products. “Promotion” includes any statements or express or implied claims directed to persons outside of Stryker, whether in oral, written, graphic or electronic form, about the effectiveness, safety, performance, instructions for use, or other characteristics of a Stryker product, when such claims or statements are prepared, disseminated, or made by Stryker or its agents (e.g., consultants, contractors, distributors and speakers), for the purpose of marketing or selling such product. Some examples of promotion include, but are not limited to:
  - Activities of sales representatives, including the presentation of detail aids or other printed materials to HCPs, emails from sales representatives to HCPs recommending the use of a Stryker product, and conversations between sales representatives and HCPs when the sales representative recommends the use of a Stryker product;
  - Presentations and trainings on Stryker products given by HCPs to other HCPs or to patients, when the presenting HCPs are paid by Stryker or are acting on behalf of Stryker;
  - Advertisements of Stryker products in medical journals; and
  - Information about Stryker products presented to the general public in the form of television or print advertisements, direct mail pieces, or internet websites or other electronic media.

2. **Standards for Promotion.** All promotion for Stryker products must be truthful, accurate, objective, balanced, scientifically sound, and consistent with the on-label use of the product. Promotion of Stryker products must not be misleading by omission, exaggeration, undue emphasis, or in any other way. These principles apply to contractors, consultants and other third parties engaged in the promotion of Stryker products on behalf of Stryker.

3. **Prohibition on Off-Label Promotion.** Promotion of a Stryker product for an off-label use is prohibited. Promotion of an off-label use is never acceptable, even when the off-label use is an accepted medical practice or standard of care. These principles apply to contractors, consultants and other third parties engaged in the promotion of Stryker products on behalf of Stryker.

a. **Examples of Prohibited Off-Label Promotion.** Examples of prohibited off-label promotion include, but are not limited to:

- Promoting a Stryker product for an unapproved or uncleared use when no Premarket Approval Application (“PMA”), 510(k) or applicable exemption applies (e.g., promoting an implant for use in a part of the body or in a manner that is not within its approved or cleared use);
- Promoting a Stryker product for a specific use within a general on-label use (e.g., promoting a laser for use in a stented coronary artery when the laser is only cleared for use in coronary arteries);
- Promoting two separately approved or cleared products for combined use when those products are not approved or cleared for use together (e.g., promoting a cleared Stryker device for use as an attachment to another cleared Stryker device, when the combination of the two devices has not been approved or cleared by the FDA or other authority);
- Promoting an unapproved or uncleared method of implantation, deployment, placement, insertion, removal, or other surgical technique for a Stryker product (e.g., promoting insertion of an implant from a posterior approach when the regulatory approval of the implant only covers insertion from an anterior approach);
- Promoting a Stryker product for a specific patient population that is not covered by the approval or clearance (e.g., promoting a fixation device for use in pediatric patients when the device is not specifically approved or cleared for pediatric use);
- Calling on physicians whose specialties are such that the Stryker device could only be reasonably expected to be used off-label by that physician (e.g., calling on a pediatric surgeon when the device is only approved for adult use); and
- Soliciting physician participation in a clinical study of an off-label use of a device, where the investigation is not properly authorized under applicable law.

4. **Approval of Promotional Materials.** Only materials that have been approved pursuant to the applicable regulatory procedures may be used in connection with the promotion of Stryker products. Both the alteration of Stryker-approved promotional materials and the use of home-made promotional materials that have not been reviewed and approved by Stryker are prohibited.