AVACEN Wellness Representative (WR) Marketing Guidelines Version 200811

A. Wellness Representatives (WRs) are only allowed to market the AVACEN device using the following indications, approved marketing materials, rules, and intended use:

1. **U.S. FDA-Clearance:** The AVACEN device is a non-invasive Class II medical device that is cleared by the FDA as a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied.

2. **E.U. CE Mark Approval:** A heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; the temporary relief of widespread pain associated with fibromyalgia; muscular relaxation; and the temporary increase of microcirculation.

3. **AVACEN Medical Approved Marketing Materials**
   Defined as all content and marketing materials found on AVACEN.com, including the AVACEN device User Guide. Representatives are not allowed to rephrase, reinterpret, or edit any AVACEN Medical Approved Marketing Materials. AVACEN.com website links to all marketing materials and content should be provided instead of using digital attachments to ensure the recipient receives the most recent version. For example, to ensure you have the most recent user guide, instead of reading or sharing an attachment, always visit and share this link: **USER GUIDE**

4. **Selling Restrictions:** The AVACEN device is not for sale in the U.S. or E.U. for any non-cleared or non- approved indications. For more details on Contraindications, Warnings and Precautions, please view the AVACEN User Guide.

5. **Individual Country Laws:** All Representatives must abide by the specific wellness or medical device marketing laws of each individual country.

6. **Intended-Use(s):** Use for medical devices means any use specified in the Labeling approved by the regulatory agency for the country in which the medical device is being sold. Labeling includes any written material which accompanies, supplements, or explains the product. Representatives are required to consistently monitor and memorize the most current AVACEN device Intended Use published by AVACEN Medical in the AVACEN User Guide.

B. Representatives are not allowed to prompt or solicit requests for information regarding NON-Intended uses of the AVACEN device. If an unsolicited request is received, the Representative must follow the guidelines stated below. The differences between Unsolicited and Solicited Requests are described below. Expanded explanations can be found using this FDA Guidance Document: Responding to Unsolicited Requests

1. **Unsolicited Requests** are those initiated by persons that are completely independent of the Representative. (This may include health care professionals, health care organizations, members of the academic community, and formulary committees, as well as consumers such as patients and caregivers). Requests concerning the use of the AVACEN device that are prompted in any way by a Representative or its representatives are not "unsolicited requests" and are considered "solicited requests".

2. **Solicited Requests** are requests for information concerning the use of the AVACEN device that are prompted in any way. Such solicited requests may be considered evidence of intent that a medical device be used for a use other than a specifically approved Intended-Use. Although not exhaustive, the following example illustrates what is generally considered to be a solicited request:

   Example: A Representative mentions a use of the AVACEN device that is not a specifically approved Intended- Use and invites a health care professional to request more information.

3. If an **Unsolicited Request** for use of the AVACEN device that is not a specifically approved Intended-Use is received, the response must be made privately through a one-on-one communication, which will be handled by AVACEN Medical Clinical Affairs. A text copy of this request and any related information that is discussed must be sent to AVACEN Medical Clinical Affairs department: **ClinicalAffairs@AVACEN.com**. Please include the name and contact information of the requestor.

   Representatives are not allowed to respond privately or publicly to any request to use the AVACEN device that is not specifically an approved Intended-Use. Please direct all requests to: **ClinicalAffairs@AVACEN.com**

4. If a Representative is ever unsure if or how they should respond, please email AVACEN Clinical Affairs at
   ClinicalAffairs@AVACEN.com

   Complaints: A complaint is any written, electronic, or oral communication that mentions deficiencies related to the quality, durability, reliability, safety, effectiveness, or performance of the AVACEN device. When a complaint is received, the Representative must inform AVACEN Medical by emailing the information to **CFC@AVACEN.com**. Please include all details of the complaint, including the contact information of both the customer and the Representative.

C. Marketing Examples of ambiguity, expressions of opinions, subjective, false and/or misleading statements:

The AVACEN device…

- is guaranteed to help…
- cured my friend's arthritis
- will help cancer patients boost their immune system
- will help people lose weight
- will speed up healing and reduces neuropathy

- will help migraine sufferers and reduce monthly migraines
- will help fibromyalgia patients and help patients recover after surgery
- will help with depression and anxiety
- will make people healthier and is good for overall health
- will make you feel better during the day and sleep better at night

D. FAQs

1. **Question**: Can I voluntarily share my personal experience with the device if it involves a Non- Intended-Use?

   Answer: No – Because voluntarily sharing personal Non- Intended-Use experience could cause a "Solicited Request for Information" – which is NOT allowed by regulatory agencies. If an Unsolicited Request for use of the AVACEN device that is not specifically and approved Intended- Use is received, the response must be made privately through a one-on-one communication, which will be handled by AVACEN Medical Clinical Affairs. A text copy of this request and any related information that is discussed must be sent to AVACEN Medical Clinical Affairs: **ClinicalAffairs@AVACEN.com**. Please include the name and contact information of the requestor.

E. Protected Health Information (PHI)

1. Purpose

This document describes the procedure for protecting and controlling Confidential Health Information, also known as Protected Health Information (PHI).

2. Scope

This document applies to all Representatives.

3. Definitions / Acronyms

3.1 **Protected Health Information (PHI)** means any information, whether oral or recorded in any form or medium that is individually identifiable information related to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provisions of health care to an
individual. PHI also includes the individual's:

- Name
- Address
- Telephone and Fax Numbers
- Electronic Email Addresses
- Date of Birth
- Social Security Number
- Medical record numbers
- Health plan beneficiary numbers

- Account numbers
- Certificate/license numbers;
- Vehicle identifiers and serial
- numbers, including license plate
- numbers;
- Device identifiers and serial
- numbers;
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers
- Finger and voice prints
- Full face photographic images and any comparable images.
- Any other information that can be used to identify the individual.

4. **The Definition Of HIPAA**

The Health Information Profitability and Accountability Act of 1996 (HIPAA) represents a federal law which prevents a health care provider from releasing individually identifiable PHI (protected health information) without the consent of an individual. The purpose of HIPAA is to protect the confidentiality, integrity and the availability of electronic protected health information (EPHI) when stored, maintained or transmitted.

5. **Requirements**

5.1 All Representatives must reasonably and appropriately safeguard the Protected Health Information (PHI) they receive to process orders and handle any order related communications and processes.

5.2 When written records are no longer needed for order related communications and processes, they will be shredded and only stored electronically.

5.3 Any discovery of a breach of Protected Health Information (PHI) must be sent to the AVACEN Medical Compliance Officer by sending an email to: **ClinicalAffairs@AVACEN.com** describing all breach details without unreasonable delay and in no case later than 60 calendar days after discovery.

F. Internet and Social Media Content

1. Representatives are not allowed to share any off-label results on the internet or any social media platforms.

2. This applies to all personal off-label results and the results of others.

3. The same Marketing Guidelines and off-label rules apply to all components of the internet and all social media platforms.

4. If a Representative becomes aware of any off-label content that is generated that may have been prompted by the company, please immediately email **ClinicalAffairs@AVACEN.com** with the off-label example, the location of the content, the platform and web address/URL.

