

# Off-Label Discussions

*What Does “Off-Label” Mean and What  
Can You Say to Doctors About Such  
Applications*

*Presented by UOC USA INC.*

# *What is Off-Label Use?*

- Any application of a product that isn't an indicated use as determined by the Food & Drug Administration ("FDA") for each cleared or approved product (included in the Instructions for Use and/or the 510(K) or Approval Documentation
- Sales personnel must ensure that they are well-versed on cleared and/or approved uses of all products that they represent

# *The Learned Intermediary*

- Doctors may utilize off-label applications pursuant to a legal theory that they are “learned intermediaries” or, in English, they are educated about medicine to the degree that they may use a product in a manner not cleared or approved by the FDA if their medical knowledge and experience supports such use.
- Manufacturers and their sales representatives ARE NOT CONSIDERED LEARNED INTERMEDIARIES
- Even if a doctor makes it clear that he/she wishes to use an off-label application without suggestion from a sales representative, the sales representative may not provide information or support regarding such application

# *What You Should Do If You Receive a Request for Off-Label Information*

- If a surgeon requests for assistance with an off-label application during a procedure, you may not provide the doctor with any information except to say that the proposed application is off-label
- If a surgeon requests information about an off-label application in an office or other non-operating room location, you may direct the surgeon to the corporate headquarters

# ***What You May Not Do***

- You may not suggest an off-label application for any product
- You may not assist the doctor in the use of a product off-label
- You may not discuss off-label applications even casually if the purpose of your discussion is to encourage the doctor in any way to utilize such an application
- You may not promote, educate about, or otherwise inform any medical professional in the continuum of care regarding an off-label application