## Japan Fair Competition Code for Medical Devices Industry (JFCC-MDI)

## Backgrounds

- This Code is an industry voluntary regulating rule in compliance with the Giveaways and Advertisements Law
- Authorized by Japan Fair Trade Commissioner on Nov. 16, 1998, effective since April 1, 1999
- Violation of this code will be a violation of the law
- Japan Healthcare are supported by each patients and the social insurance system bared by taxpayers. Thus purchasing and selection of medical devices under this system should not be influenced by inappropriate giveaways
- Industry has established "Japan Fair Trade Council for Medical Devices Industry" to monitor and implement the Code
- Public Servants are further restricted by "Public Servant Ethic Law"

AdvaMed Code of Ethics	Delta with JFCC-MDI
Member-Sponsored Meetings	HCPs attending sponsorship is NOT allowed if venue is overseas or LIMITED if venue is in conjunction with 3rd party conferences
3rd Party Conferences	<ul> <li>Conference Sponsor MUST be an established entity</li> <li>Grants/Funds can NOT be specific in usage</li> <li>Conference Sponsor MUST disclose prospectus (financials)</li> <li>HCPs attending sponsorship is NOT allowed</li> </ul>
Sales & Promotional Meetings	Contract negotiations and sales terms OK if selling direct to hospital
Consulting Arrangements	<ul><li>Standard 10,000 yen@case, Max 30,000 for Post Marketing Study</li><li>Survey compensation limited to 1,000 yen</li></ul>
Gifts to Physicians	<ul> <li>Limited to fair market value of 3,000 yen (not exchangeable to cash)</li> <li>Medical textbooks/magazines or anatomical models are restricted</li> <li>Free Samples and opportunities for product evaluations are restricted</li> <li>After-services beyond warrantee are restricted</li> <li>Social events are OK up to 1,000 yen per person, max. 20,000 yen</li> <li>Significant Life Events are OK within local practices</li> <li>Seasonal Gift exceeding 3,000 yen is OK within local practices</li> </ul>
Reimbursement & Technical Information	<ul> <li>Reimbursement information only on own products</li> <li>Frequency of In-services will be restricted from April 2009</li> </ul>
Charitable Donations	Educational grants only to teaching universities