



# Discussion Topics for the Committee

1. Assuming that the ongoing study of SA4Ag achieves its pre-specified primary efficacy objective in a population undergoing elective, posterior-approach, instrumented, multilevel spinal fusion surgery, please discuss the reasons why efficacy should or should not be generalized to other elective orthopedic surgical populations.
2. Assuming that the ongoing study of SA4Ag demonstrates safety in a population undergoing elective, posterior-approach, instrumented, multilevel spinal fusion surgery, please discuss the reasons why safety should or should not be generalized to other elective orthopedic surgical populations.