

Panel Questions
July 17, 2001 GPS Panel Meeting

1. Adverse events such as pain, infection, and itching were similar in the clinical study for both the CCS and the Biobrane-L (BIO) control. Please discuss whether the safety data for CCS provides a reasonable assurance that it is safe for the management of split thickness autograft donor sites in burn patients.
2. The primary effectiveness endpoint in the protocol was time to complete wound closure as measured by photographic assessment. The study was designed to evaluate a 9.5-day improvement in time to wound closure. The primary efficacy results are provided in the following table:

	<u>Median Days to Wound Closure</u>			<u>Mean Days to Wound Closure</u>		
	CCS	BIO	p-value	CCS	BIO	p-value
Photographic ITT	15.0	22.0	0.0006	18.0	22.4	<0.0001
Photographic PP	15.0	21.0	0.0009	17.8	22.1	<0.0001
Investigator ITT	12.0	16.0	<0.0001	13.2	18.4	<0.0001
Investigator PP	12.0	16.0	<0.0001	12.9	17.9	<0.0001

Do these data demonstrate that there is a reasonable assurance that in a significant portion of the target population, the use of CCS will provide clinically significant results?

3. Do you have any recommendations regarding the proposed labeling including indications, contraindications, warnings, precautions, instructions for use, etc.?