Risk Analysis
Elasto-Gel™ Sterile Products
Weight of Product

Introduction

Elasto-Gel™ Wound Dressings were formulated and designed by evaluating competitive products and based on past experience by the Director of Research in developing other products. Clinical evaluations produced a refined product. From the feedback of doctors and nurses, those properties that were important to them were determined. One of the factors that was important was the exudate absorbing capacity of the product. The weight of the product was also of concern, because many of the potential end-users of the product were elderly nursing home patients. Since both of the properties are inter-related in an inverse manor, we concluded that we should establish an acceptable weight range for each size of our product. For example, we established that for the 4x4 size, the weight should be 40 to 50 grams. This provides a product with a reasonable weight, high absorption capacity, and adequate protection against friction along with some pressure reduction.

Risk Analysis

Absorption: The absorption capacity of ***Elasto-Gel™*** is relatively high compared to competitive products and, in contrast, ***Elasto-Gel™*** does not fall apart or dissolve as it absorbs water. Therefore, it becomes relatively heavy, but at the same time it keeps the wound bed from becoming saturated and macerating the surrounding skin. We determined that in order for the doctors and nurses to be able to predict the performance of the dressing, it should be made with relatively consistent absorption capacity. Since the absorption capacity is directly proportional to the weight of the product, we established a target weight value of 45 grams for the product with a variation of plus or minus 10% for the most popular size 4x4. This value has been readily accepted by the practicing nurses and physicians for the many years that this product has been on the market. This has been an achievable production goal.

Weight of the Product: The weight of the product, when applied to the patient, becomes an important factor only when the patient is a young child or an elderly frail person. In these cases, if the patient has a very large wound and requires a relatively large dressing, the weight becomes important especially on the highly exudating wounds, such as a scald burn. In these cases, the dressing can become too heavy for the patient to support when it is saturated with the exudate, or if it is too light it may not have enough absorption capacity to contain the exudate.

Risk: Although it is important to be able to predict the performance of the product to a reasonable degree, variation in total absorption is not a serious risk to the patient because it is not very often that one would leave the dressing until total absorption capacity of the dressing was achieved. If it does reach total absorption capacity, the worst that happens is that the liquid leaks out from under the dressing and/or the dressing will need to be changed more frequently.

Because of the variation of weight has essentially no serious detrimental effects on the patient, but is only a convenience problem or nursing problem, we have established the rejection criteria for weight variation to be:

> If more than 10% of the production is outside the specifications then the lot will be rejected or if 90% is within the specifications at a 95% confidence level the lot will be accepted.