Xennovate Medical

Innovation to Reality™

TECHNICAL BRIEF

EVERLIFT™ HYDROCOLLOID REMOVAL-FORCE TEST RESULTS

In 2004 an outside consultant, Medical Device Designs Incorporated of Madeira Beach, Florida was engaged to quantitatively evaluate Xennovate Medical's design concept for reducing the removal force of a hydrocolloid, while concurrently minimizing the loss of adhesive force.

The consultant employed a study model developed by him during his development of a new hydrocolloid adhesive mass formula two decades earlier. His model employs the forearm of test subjects, and he has often demonstrated the value of using live skin over stainless steel, the so-called "standard" stainless steel test. In his opinion the stainless steel test does not effectively evaluate the adhesion effects on live skin.

His first test employed Xennovate Medical's standard integrated XenMed™ 18 formulation with a polyurethane film one mil thick on one side. A series of "sandwiches" were then made and samples were tested to determine the optimal location of the open netting material ("Tulle") in the sandwich. The test results unequivocally demonstrated that the netting needed to be as close to the skin as possible to maximize the reduction in removal force.

A second study was then conducted to quantify several manifestations of the design when the Tulle was merged with the XenMed at the skin surface. The standard of comparison, plain XenMed 18, was identical to the XenMed sandwich in all aspects except the Tulle on the skin-side surface of the XenMed 18. While a variety of Tulle's were employed, the optimum at the time was a Tulle design that had 32 openings per square inch with no elongation in the direction of removal. Multiple samples of that XenMed sandwich demonstrated reduced removal forces up to 33% (sample measured 70 gm/in compared to the standard of 105 gm/in). The measured amount of "lost" adhesive surface contact due to the Tulle is less than two percent (2%).

While we have not yet tested more alternatives, we have, since these tests were completed, created two new formulations with increasingly greater skin adhesion should our customers have an application requiring fine tuning the removal forces. Additionally, we could employ Tulle with 64 or more openings/inch to further reduce the removal force required for an established adhesion force. In short, we stand ready to work with our OEM customers to create customized solutions to their customers' problems.

Provided by David W Smith MD
Manager and CEO
January 2006