

# OPTIMIZATION OF COLD-FORM FOIL PACKAGING

## INTRODUCTION

Cold-form foils have been successfully deployed in pharmaceutical, medical device and *in vitro* diagnostic / point-of-care test kits for many years. As research scientists continue to create innovative solutions, demands on cold-form foils continue to grow and develop. It is critical, therefore, to have a solid understanding of the specific requirements that these foils need to meet, how the desired performance is realized, and how both requirements and material design impact the overall package design. In this white paper, we will look more closely at the interaction of cold-form foil requirements, package design, and manufacturing processes, with a view to understanding how all of these need to work together to achieve optimal package performance so that patients can receive the life-saving therapies they need.

## COLD-FORM FOIL REQUIREMENTS

In the early 1960's Karl Klein developed the first machine<sup>1</sup> to form materials comprising aluminum foil into cavities or blisters that could hold a solid drug. Since that time, this technology has been implemented in a variety of other applications, most notably in medical device and point-of-care test kits. In its simplest form, the cold-forming process transforms a flat flexible barrier material containing a layer of aluminum foil into shapes such as shown in Figure 1. Normally, this shaping process occurs at ambient temperatures (in contrast to thermoforming, which requires heat) and involves a form and plug into which the material is pressed.

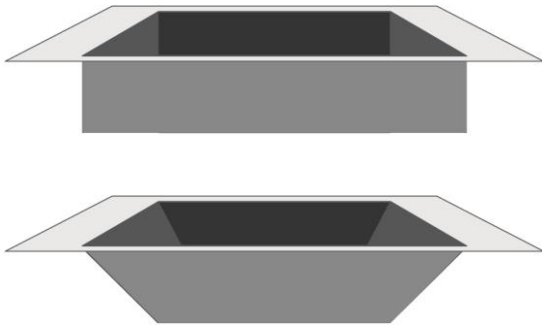


Figure 1 - Common cold-form foil shapes

Cold-form foil materials serve a number of very important purposes in the packaging of items such as drug capsules, sutures, and diagnostic fluids. While each specific application will have its own unique requirements, in nearly every case requirements such as oxygen and moisture barrier, physical product protection during manufacturing, distribution and use, sealability to a lid or other device component, and ease of manufacturability factor into the package design process. Other requirements that often arise involve opacity (to safeguard against UV exposure), chemical resistance, appearance, and ease of opening, to name a few. It is important to understand all the nuances of a particular product to make certain that your package is optimally designed for market success.

## MATERIAL, PROCESS AND DESIGN CONSIDERATIONS

The shaping of the flexible barrier material during the cold-forming process causes local stretching (and consequent thinning) of the film. The degree of thinning is strongly dependent on the depth of the form, the cross-sectional area (or footprint) of the form, and the draft angle at which the film is formed. The draw ratio, a value commonly used in cold-forming design discussions, is the quotient of final surface area after drawing ( $A_f$ ) over the starting cross-sectional area ( $A_i$ ).



*Figure 2: Hypothetical formed parts to demonstrate draft angle and draw ratio*

To better illustrate the concept of draw ratio and draft angle, two hypothetical forms were drawn with the same starting cross-sectional area and draw depth (see Figure 2). The upper part has a 90° draft angle, while the lower part has a draft angle of 45°. So just from a draft angle perspective, the lower part will experience less local stresses compared to the upper part. The draw ratio of the two parts are also significantly different. The upper part has a draw ratio of 1.80, while the lower part has a draw ratio of 1.26. Admittedly, the lower part has less formed volume. However, if the lower part were enlarged

overall such that the floor of the form had the same surface area as the upper part, the draw ratio is in fact further reduced (1.20). This underscores the value of shallower draft angles to minimize stress on the part during the forming process.

As the above example demonstrates, as the draw ratio increases, the average elongation of the film increases, which in turn increases the stresses applied to the film during the forming process. Also, depending on the design of the cavity, some areas of the film will undergo greater elongation and be subjected to more stress compared to other areas. In other words, applied stresses may not be uniform across the cavity. Failure to properly account for applied stresses during the cavity design process can lead to challenges during the product implementation phase.

Of course, both material design and process design also contribute to overall product success. From a material perspective, it is critical to design and select a flexible barrier material that will meet all of the requirements for a given application. In fact, as cold-forming geometries become more and more complex and demanding, film design considerations become critical for success. The material choices for the various layers of the overall structure (material type and thickness), the source and quality of those materials, and the adhesive chemistries to join the layers together are all vital to the design of the flexible barrier material. The various materials in the structure must be chosen to optimize energy transfer seamlessly and uniformly throughout the film as the laminate is stretched.

Careful design of the manufacturing process also greatly increases the probability of product success. The surfaces of the male and female elements of the forming tool must be chosen so as to minimize frictional forces that arise during the forming process. Coatings with a very low coefficient of friction, such as polytetrafluoroethylene, are commonly used. Attention must also be paid to processing parameters, such as clamping pressure and forming speed. Sufficient clamping pressure is required to immobilize the material in the forming tool, and forming speeds must be optimized as a function of the complexity of the form, draft angles, and draw ratios.

Inadequacies in material and process design will manifest themselves in various ways. Ideally, the elongation of the laminate film will be uniform across the entire formed area, such that highly thinned areas are avoided, as these may result in a significant loss of barrier properties. Additionally, poor material choice and design can also lead to issues such as foil pin-holing, material contraction after forming (a memory effect), or even material cracking or layer delamination. The latter two are clearly catastrophic failures. However, pin-holing of the aluminum foil layer will not be readily apparent during production unless parts are inspected off-line on a light table or in-line with an appropriate vision inspection system. While foil pin-holes do not impact the sterility of the package (assuming the other layers of the laminate structure are still intact – use ASTM F3039 dye penetration test to verify), they will impact the barrier properties of the package and may shorten shelf-life.

A material and process combination that are non-optimized will result in a formed cavity with variable residual thickness and areas of high stress. This is depicted schematically in Figure 3 for a competitive material, where the darker red color represents areas of greater thinning and higher stress. Some areas of the form will have a much thinner wall than other areas, impacting shelf-life. High-stress points increase the risk of cracking during forming, leading to defective product, scrap, and potentially more serious consequences. Figure 2 drives home the importance of thoughtful design of cold-form materials and processes.

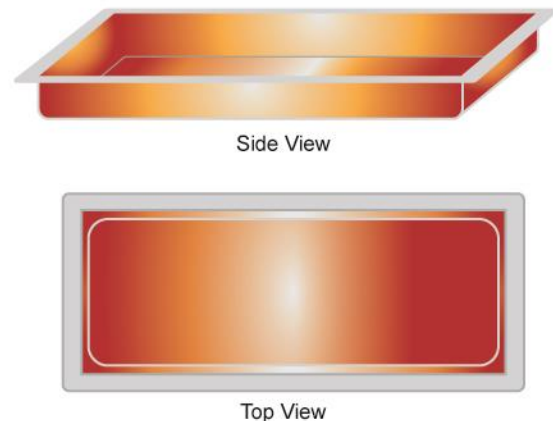


Figure 3: Stress concentration diagram for a non-optimized form-foil.

In developing the overall laminate structures of Rollprint's FormFoil™ product portfolio, all of the above considerations were factored into material choices for each layer. Particular attention was given to the choice of aluminum foil and adhesives. In the case of aluminum foil, a number of soft alloys were evaluated for depth of draw (at steep and shallow draft angles) and draw appearance after forming, leading to the selection of a small number of candidates with exceptional performance. This performance is driven largely by the small and consistent grain size of the aluminum alloys and the absence of micro-imperfections in the foil.

Similarly, a number of adhesive chemistries were tested with the goal of identifying chemistries that provide excellent adhesion and are soft enough to “flow” as required during forming. These

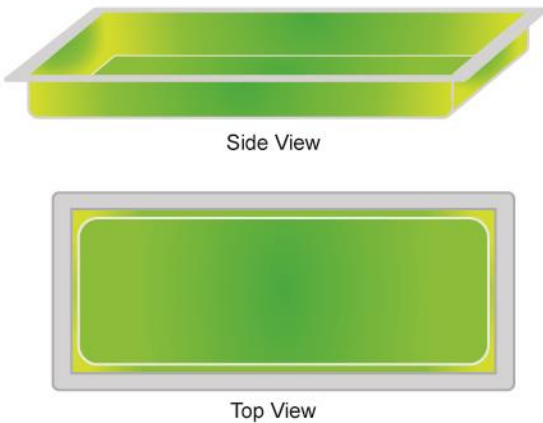


Figure 4: Stress concentration diagram for an optimized form-foil.

properties ensure efficient energy transfer between the layers. Furthermore, factors such as the application of adhesives during lamination (as well as other processing parameters) were also carefully evaluated and optimized to maximize the overall performance of the forming foil.

Figure 4 is a schematic representation of a cold-formed cavity using Rollprint’s FormFoil™ product. In comparing this figure to Figure 3 above, it is apparent that the part in Figure 4 has a much more uniform thickness and stress distribution. Part-to-part variation will be significantly reduced with an optimized material like FormFoil™, forming depths

are generally greater with a uniform and optimized cold-form foil, and the overall processability will be improved. And finally, this optimization opens the door for down-gaging opportunities for less demanding applications. FormFoil™ designed with 1.5 mil (38  $\mu\text{m}$ ) or 1.0 mil (25  $\mu\text{m}$ ) aluminum foil are now viable candidates to replace current materials that may have been over-designed to compensate for a non-optimal material design.

## CONCLUSION

As engineers and scientists actively working in the medical device and diagnostic fields, our aim is to improve the quality of life of the patients we serve. As we design flexible barrier materials for a wide array of applications in the 21<sup>st</sup> century, we seek to do so in ways that not only enhance patient outcomes but also promote stewardship over the resources available to us. Rollprint’s FormFoil™ product family seeks to achieve both of these goals through an in-depth understanding of the science and engineering at work in these products.

<sup>1</sup> Ron Pilchik, Pharmaceutical and Blister Packaging, Part I: Rationale and Materials, *Pharmaceutical Technology*, November 2000, p. 68-78