



TOOLING DESIGN BEST PRACTICES FOR ACLAR® FILMS

This guide allows you to optimize the barrier performance of your blister and increase the shelf life of your finished packaged. Aclar laminates do not require special tooling; however by following these best practices, you can maximize the performance of the Aclar film laminates you are considering. For additional information on thermoforming Aclar films, also reference our *Aclar® Films Thermoforming Guideline* available at www.aclar.com.

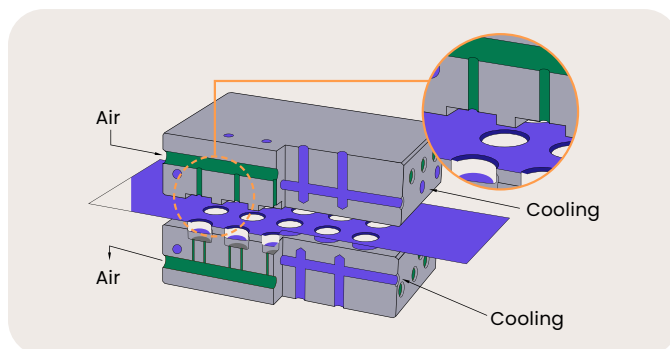


GENERAL RECOMMENDATIONS

For maximum flexibility, all thermoforming molds should be designed as dedicated molds¹ (Figure 1) and with features recommended for high-barrier materials. Dedicated molds provide more uniform thickness distribution and can be used successfully for both barrier and non-barrier materials.

- For cavities deeper than 6 mm or with a deep draw ratio greater than 3:1, use plug assist in combination with air pressure to improve thickness distribution and barrier performance.
- Use a dedicated cavity dimension for each pill size and pill shape. When standard cavities are used for multiple sizes or shapes, the large cavity design will increase the free volume of the cavity when smaller pills are packaged in it. This additional free volume will add moisture in the head space at time zero² and increase the rate of moisture transfer into the cavity.
- Air Flow channels³ can be designed utilizing existing best practices for conventional mold design.
- To achieve proper forming, calculate and design sufficient cooling capacity. Be sure to consider the thermal conductivity of the forming material, the mold, and the upper and lower line speeds in your design.
- Dimensional stability of the Aclar laminates must be considered in your design of formed parts. Ask your laminate supplier for their material specifications and/or include them in design approval.

Dedicated mold



Universal mold

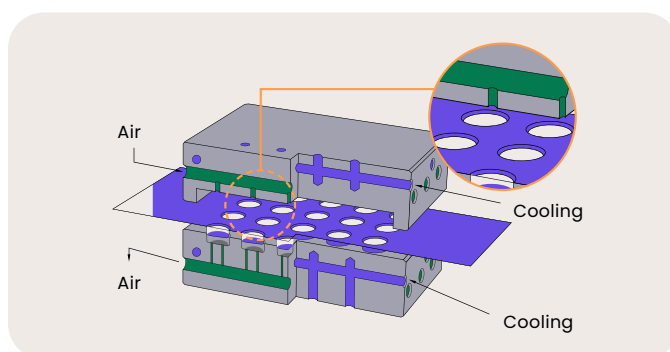
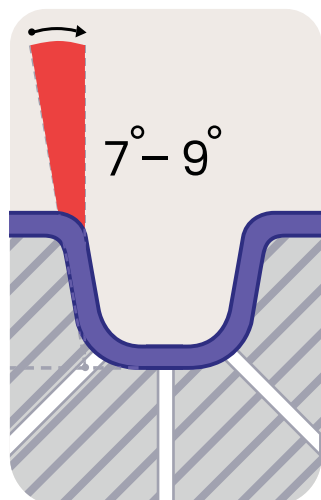


Figure 1

High barrier materials



Non barrier materials

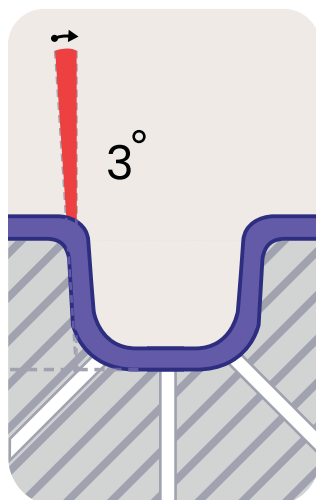


Figure 2

FORMING MOLD

To achieve optimized thickness distribution and optimum barrier properties, adhere to the following design recommendations:

- Draft angle⁴ of 7° to 9° (Figure 2). These higher draft angles will produce less thinning of the forming material than the lower draft angles (3° to 5°) typically used with non-barrier materials. Note that draft angle should be tailored to the size and shape of the cavity.
- Benefits of a higher draft angle:
 - Higher efficiency cavity filling when dedicated tube feeders are not used.
 - Blisters release more easily from mold when running at high speeds.
- The upper plate of the dedicated mold should be designed with an area of up to 1mm surrounding the opening of the cavity where the film is not restrained between the upper and lower forming tool. This allows more film to be available for forming.

- An adequate number of air evacuation ports⁵ that are appropriately sized and correctly placed are important for good forming and unrestricted air release (Figure 3).
- We recommend:
 - Number of Ports: 5 – 7 (dependent on cavity size)
 - Diameter: 0.5 mm – 0.7 mm
 - Placement: Center and corners of the bottom of the cavity
- The metal surface of the mold should have some texture (~ 0.7 ra) and should not be highly polished. The texturing allows for easier forming and release of the blister from the mold and combats the smooth, high coefficient of friction surface of Aclar® films.
- A radius instead of a chamfer⁶ should be used at the cavity entrance (Figure 4). Chamfers increase wall thinning and can decrease the barrier of the cavity. A 0.5 mm radius is recommended, and if sealing flange width allows, use a 1 mm radius.
- To avoid severe material thinning in the corners of the cavities, design smooth transitions from the cavity wall to the blister bottom with similar radii to that of the product shape. This ensures good material flow during forming resulting in uniform material thickness distribution in the cavity.
- Cavity dimensions must allow for proper clearance between the dosage and the lid stock to enable efficient product feeding and proper sealing of the lid stock to the blister. The recommendation is to design the cavity dimensions for the maximum dosage size based on product tolerances allowing for 0.5 mm of clearance between the dosage and the lid stock. (Figure 5).

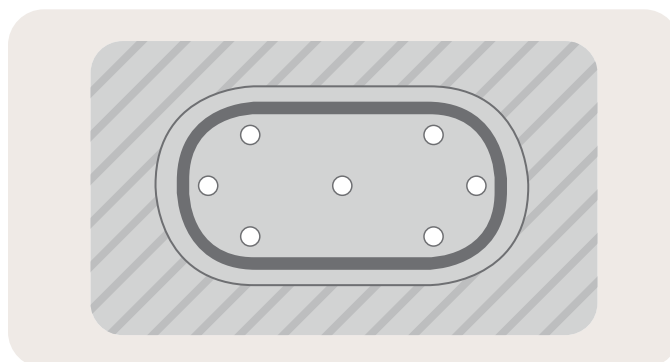


Figure 3



Figure 4

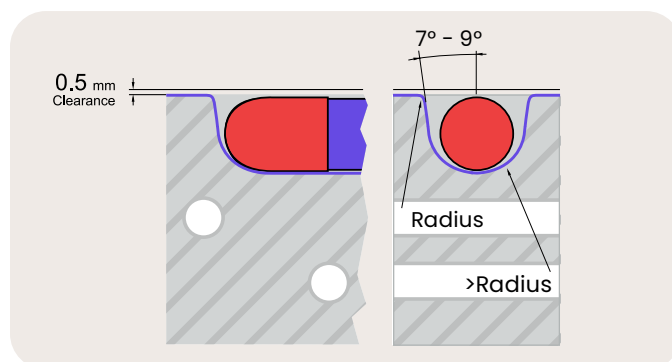


Figure 5

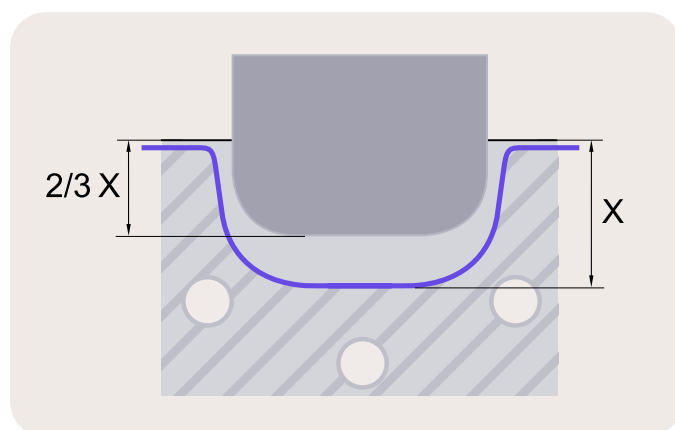


Figure 6

FORMING PLUGS

For cavities deeper than 6 mm or with a deep draw ratio greater than 3:1, pre-forming with plug assist is recommended.

There are a variety of plug materials available; we recommend the use of isolating materials with a low coefficient of friction such as Teflon®, Delrin®, or syntactic foam materials such as Scotchply®, Dosey® or Hytac®.

Special attention needs to be taken when designing the shape of the plug. In principle, the shape and size of the plug should be similar to that of the cavity. The size of the plug should be approximately 80% of the cavity size but practical tests may allow for further optimization. The optimum material thickness distribution typically occurs at a plug penetration of 2/3 of the cavity depth (Figure 6).

BLISTER CARD LAYOUT

The blister-card-layout has an effect on the lay-flatness and cartoning performance.

- Strengthening ribs or elements⁷ to reinforce the blister flatness may be designed into the blister card to make cartoning easier (Figures 7A and 7B).
- When designing the layout for blister cards made with Aclar laminate, the reinforcing ribs work best when designed perpendicular to the machine direction (MD). The ribs should have a width to depth ratio between 2:1 and 3:1 to avoid under forming. Sufficient air evacuation ports must also be included in the rib design to achieve full forming.

SEALING

- Two sealing systems are used for sealing pharmaceutical blister packaging:
 - Intermittent motion platen sealing
 - Continuous motion rotary sealing
- Aclar laminates can be sealed with either system. No special requirements are necessary in the design of the sealing device to accommodate Aclar® films.
- All high barrier packaging, including Aclar laminates, requires a sufficient seal flange width from pocket to pocket; pocket to edge; or to perforation to achieve a quality, tight seal.
- The recommended minimum seal flange width is 3 mm (Figures 7A and 8). If the blister card size does not allow for this; contact a Solstice technical representative to discuss your options for maintaining a quality, tight seal. Solstice will coordinate with you and your tooling supplier to recommend sealing alternatives for your blister card.

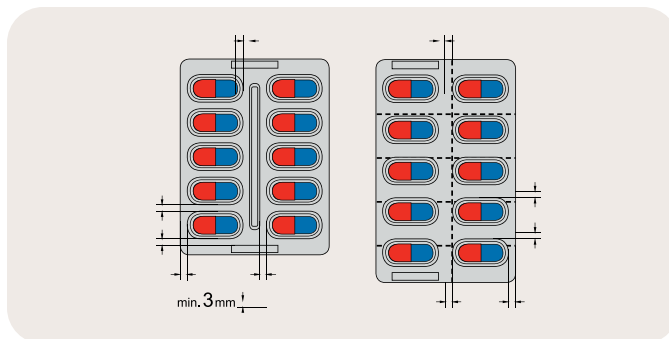


Figure 7A

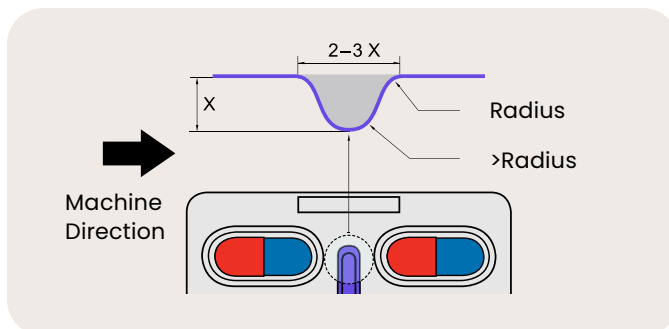


Figure 7B

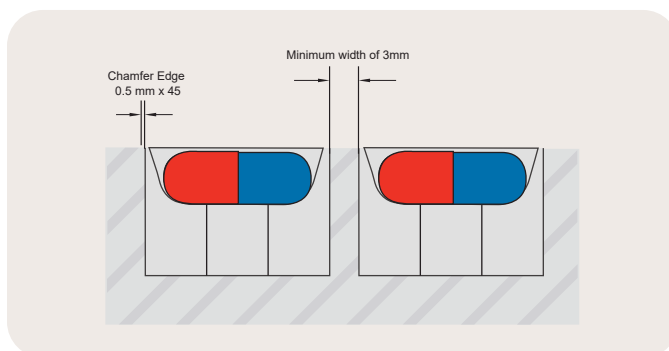


Figure 8

For additional information or to contact us, please visit: www.aclar.com

DEFINITIONS

¹**Dedicated and universal molds:** Dedicated or "matched" molds are dedicated to the format; the film is clamped around each individual cavity to provide controlled forming. The result is even sealing flange widths, homogenous blister cooling, reduced forming stress, and minimized risk of blister leakage.

Universal molds have an open air box as the upper forming plate and can be used with various formats. The disadvantages are nonuniform top-to-bottom cooling of the laminate and un-clamped flanges. The outcome is less control of forming – even less when plug assist is used. Sealing flanges will vary in width and stress can be introduced in the sealed area of the blister card resulting in micro-channels and ultimately blister leakage.

²**Time Zero:** Starts from the time the blister is sealed.

³**Air Flow Channels:** Passage ways which supply the high pressure forming air to the cavities.

⁴**Draft Angle:** The forming angle of the cavity side walls.

⁵**Air Evacuation Ports:** Design features around the bottom of the cavities and in reinforcing elements used to release trapped air.

⁶**Cavity Flange Radius/Chamfer:** Geometry at the blister entrance, either designed as a Radius (i.e. R 0.5) or a Chamfer i.e. 0.5 x 45°.

⁷**Strengthening Rib/Elements:** Design features in the blister card typically used to improve the mechanical stability and flatness of blister card and to avoid bowing of the blister card for easier cartoning.



For More Information Visit

solstice.com

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