



Case Study

Medicine Measuring spoons for special doses

How did a leading parallel-importer secure a new product license and additional market-share in record time?

As one of the largest manufacturers of spoons and scoops in the UK, Splice Cast Ltd were delighted to receive a call from a well-known pharmaceutical wholesaler with an urgent medicine-dosing challenge.

A large batch of product had been imported from Europe for re-labelling and distribution in the UK. Unfortunately, the off-the-shelf medicine spoon which the customer intended supplying in the pack did not meet MHRA requirements and their product license (PL) was withheld, pending submission of a suitable dose. With the medicine's sell-by date fast approaching, the customer needed a solution and they needed one fast.

The Challenge

Due to the bulk density of the medicinal preparation, none of Splice Cast's standard spoons provided the required dose. A custom dosing solution was required. The challenge was to get the new spoon designed, prototyped, approved and delivered within a timeframe of seven weeks...

The Solution

The PATHFINDER™ process is a logical series of steps which define the successful development of a new medical device. Closely following these stages in this project would ensure that the final product would be delivered "Right - first-time, on-time and within budget".

The initial step involved documenting the exact requirements on a design brief with details on project deadlines and product criteria such as the custom handle-branding, specific colour and the required CE-mark.

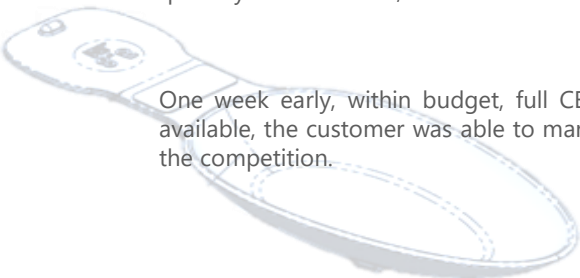
Next, the design team prepared and submitted detailed part drawings and a physical prototype in accordance with the customer's approved design brief. A physical prototype is an excellent way to evaluate a new product in real-life and allowed the customer's QA department to perform dose-repeatability trials and get regulatory approval on the new design prior to committing to the custom tooling.

Splice Cast use a system of tooling-inserts to allow derivatives of standard products to be produced very cost-effectively. Tooling for the new part was thus completed and first-off samples checked to ensure they met the required dose criteria.

Following customer-approval of the samples, full production commenced without delay and the initial order quantity was delivered, six weeks after the customer's initial enquiry!

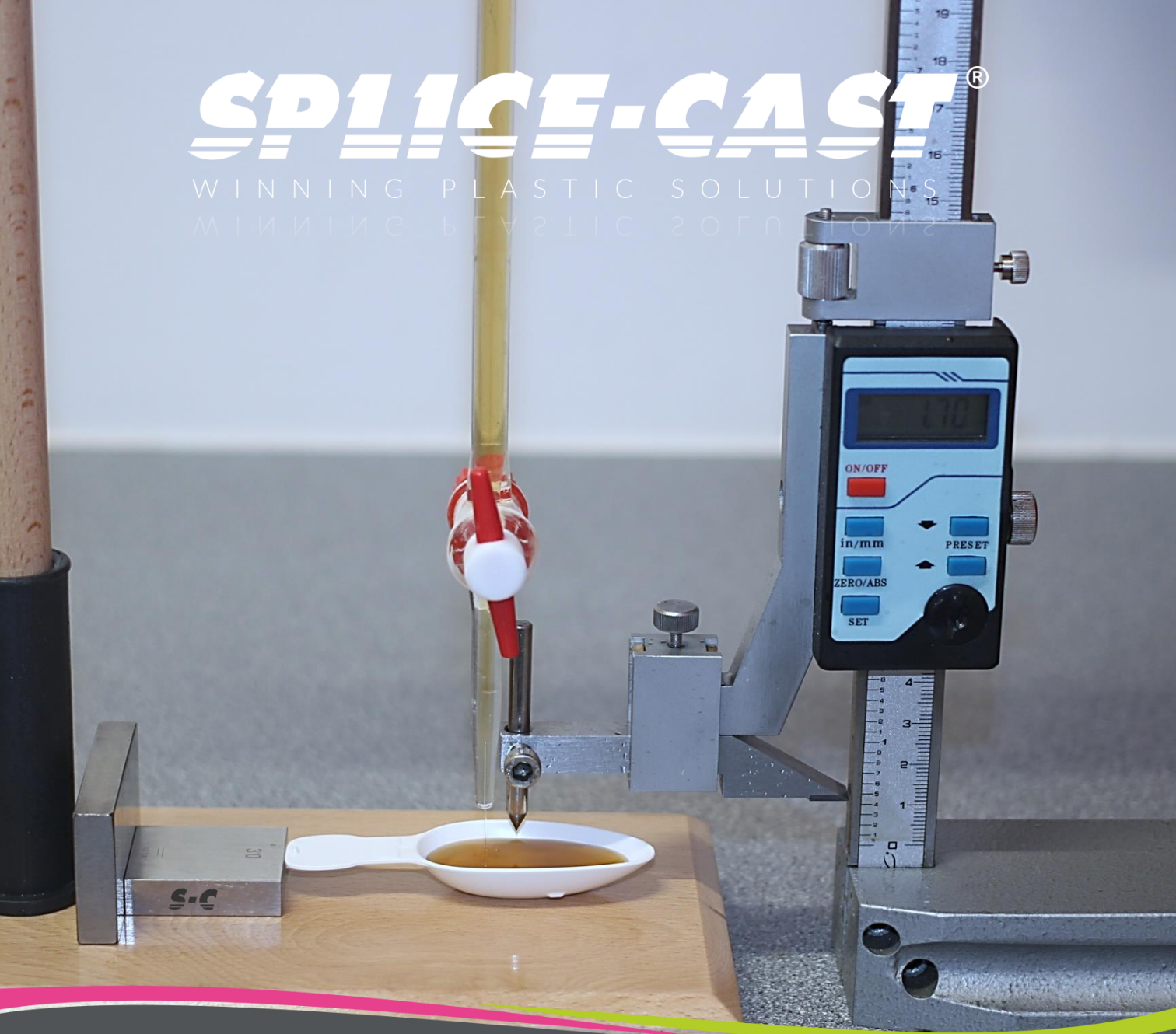
The Result

One week early, within budget, full CE-marking and MHRA approval... With an approved, licenced product available, the customer was able to market the product and secured additional market-share by being ahead of the competition.



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