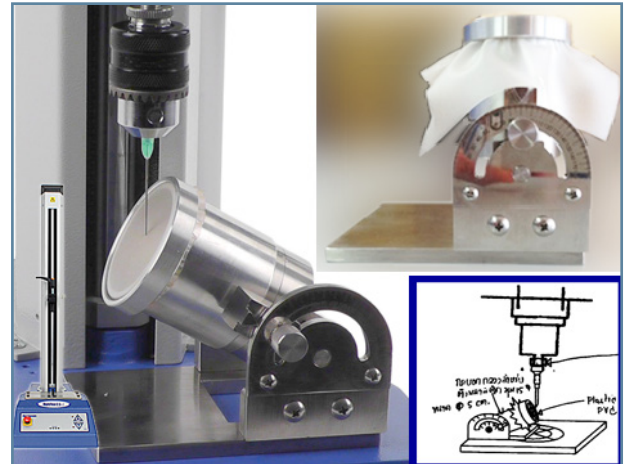


## Solutions@Mecmesin

### Dialysis Needle Sharpness Test for Patient Comfort

#### Specification

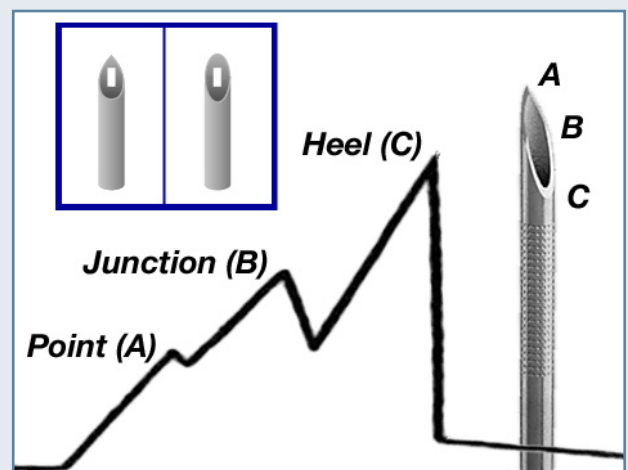
**Kawasumi Laboratories Inc.** was founded in 1957 as Japan's first manufacturer of disposable plastic medical devices for blood collection and transfusion purposes. Amongst the variety of hemodialysis and plasmapheresis products the company has developed is a range of 'painless' arteriovenous (AV) needles for dialysis. The design of this 'constant-site cannulation' (or 'buttonhole technique') needle is optimized to minimize tissue damage and hence reduce pain, prevent risk of damage to the fistula itself and guard against accidental needlestick. Silicone application technology and a unique bevel geometry are keys to achieving these patient comfort objectives. The 'constant-site cannulation' device has a "non-sharp" point as insertion occurs at a pre-existing site tunnel. Kawasumi Laboratories required a capability to test alternative prototype needle designs to evaluate, and hence control, the level of discomfort experienced by the patient.



MultiTest UTM and custom fixture to test needle insertion forces at adjustable angles

#### Solution

Mecmesin Asia worked with the customer to understand the nature of the process of insertion, to replicate the conditions and enable an accurate and repeatable test methodology. A custom fixture was produced to allow adjustment of the angle of insertion into the test sample, a standard specification of 15 degrees is normally used. A sheet of PVC, replicating the toughness properties of human skin, is located over a lower fixture with enough internal clearance to permit full passage through the membrane. A typical graph plotting force against distance shows a characteristic shape with salient features reflecting the passage of elements of the needle tip through the epidermis. Three peaks are observed: one at the moment of puncture / initial penetration; a further increase in force as the needle aperture (junction) travels through; and a final peak as the heel is reached. The force drops and levels out as the constant bore body of the cannula is finally inserted. The Emperor™ program calculates these peaks and also the average value during the cannula insertion segment. Comparing designs in order to minimize these forces gives Kawasumi's R&D laboratory valuable information to feedback into the design process, and quantitative data to promote their products to their own customers.



Elements of a needle tip and their influence on the insertion force graph

#### System

- MultiTest 2.5-i computer controlled system
- 50 N intelligent loadcell (ILC)
- Custom-designed fixture

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