Using Ultrasonic Technology to Manufacture Products

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This article was first published in *Medical Device Technology* magazine Vol. 17, Issue 7.

The use of ultrasonics in medical device manufacturing is gaining momentum as designers and engineers take advantage of the benefits it offers. A number of example medical applications are described that demonstrate the utility of ultrasonic processing in their manufacture.

An effective technology

The versatility of ultrasonics has been exemplified by the wide variety of applications that have evolved for this technology. These range from marking tablet formulations and cutting human tissue to assembly of dry-powder inhalers and nasal-spray nozzles. Table I summarises its commercial applications.

During the past two decades, the medical disposables market has undergone a number of changes in the types of device produced, the substrates selected and sterilisation procedures employed. There has also been a pronounced shift towards the use of single-use devices, which has forced design engineers to evaluate polymers such as poly(vinyl choride), polyamide (PA), polycarbonate and acrylonitrile butadiene styrene (ABS). As a result of these advances, there has been a marked resurgence in the use of ultrasonic processing for welding and cutting. The technology offers the following features.

- Process times of 0.1–1.0s are possible, making it suitable for mass-production operations.
- It is a highly reproducible process, which is important for the manufacture of quality-critical products.
- It is a clean process with little chance of product contamination compared with other cutting/welding techniques.
- With appropriate joint design, a hermetic seal is achievable, which is highly desirable for devices containing moisture-labile substances, where secure containment of unwanted materials is needed, and where evidence of tampering is important.

This overview will provide case histories of manufacturing medical products using ultrasonics and add to those examples discussed in a previous article.[1]

Table I: Applications of ultrasonic technology

Field	Application
Welding	Manufacture of medical devices, including, dry-powder inhalers, pouches, sachets and disposable razors.
Cutting/drilling	Cutting/drilling diverse materials, including ceramics and tissue.
Processing	Dispersion of solid materials in liquid media, crystallisation, filtration. Atomisation of solutions/suspensions.
Cleaning	Aqueous cleansing of metallic, glassy surfaces. Descaling the surfaces of teeth. Inactivation of microbes.

The welding process

The basic principles of ultrasonic assembly involves the application of a vibrating sonotrode to a thermoplastic–thermoplastic or thermoplastic–metal interface to induce a high degree of localised frictional heat. This will cause the thermoplastic to melt and form a molecular bond at the interface. The weldability of material is related to a number of physical properties such as its thermal conductivity, elastic modulus and melting temperature; for ultrasonic applications the ideal range is 100–275 °C.

Dispensing device. Ultrasonic welding was employed for the Integuseal (Kimberly-Clark)[2] (Figure 1), which has been introduced to help

Figure 1: Applicator device that applies a layer of polycyanoacrylate resin on the skin prior to surgery.

Figure 2: System allows catheters to be positioned easily around a patient's torso and limbs for drug administration.

prevent the spread of MRSA. The device consists of a glass-filled PA casing that houses up to three tubes of polycyanoacrylate resin; the housing is assembled using ultrasonic welding to give a hermetic seal around the housing. Once activated, the system is used to apply a layer of polycyanoacrylate resin across the surface of the skin prior to an invasive surgical procedure. The resin creates a "biobarrier" to pathogens because bacteria are unable to spread across the resin and into an open wound.

Locking device. A previous article[1] discussed the problems associated with the fixation of medical devices such as catheters with the Spinoza lock. Figure 2 highlights the PAD-lock system,[3] which also allows catheters to be positioned around a patient's torso and limbs for ease of drug administration whilst reducing discomfort to the patient. The lock consists of an ABS casing that houses polyacetal lockable latches. Each lock part has been designed and moulded individually using injection moulding. These component parts are then welded together into a single-unit device by ultrasonic welding. The positioning of the lock along a length of catheter is accomplished by compressing the latches, which release the clamping mechanism and allow the catheter to be pulled through. Recompression of the latches clamps the locking device into position around the catheter.

The cutting process

Ultrasonic cutting uses a knife blade attached to an ultrasonic source. The cutting action is a combination of the pressure applied to the sharp cutting edge and the mechanical vibration of the blade moving over a short distance (~100 µm).

Dental pouch. Figure 3 shows the FingaDent finger pouch.[4] This product was designed for regions of the world where fresh, clean water is a rare commodity and dental hygiene a luxury that many people cannot afford. The device consists of an outer sleeve composed of textured, nonwoven polypropylene and an inner polyethylene sleeve, which act as a biobarrier. The outer sleeve and the interstitial space, which occurs between the outer and inner layers, contain a fluoride based antibacterial oral cleaning fluid. By inserting a forefinger into the inner sleeve, the outer sleeve is then rubbed across the teeth. The rubbing action releases the oral cleaning fluid and this fluid combined with the textured surface clean the surfaces of teeth. The outer and inner sleeves are cut and bonded simultaneously to form a watertight bond using ultrasonics. Ultrasonics processing is one of the few processes that can interchangeably cut and/or weld textile and thermo-plastic materials.

Cutting and welding

Polyester films. The Dust bubble[5] (Figure 4) is used to reduce particulate matter generated during

Figure 3: The basic components of the finger-pouch device for dental applications.

Figure 4: Applications of this device include wound care as well as the reduction of particulate matter that is generated during drilling in device manufacture.

the drilling of surfaces. It has found use in the medical device and pharmaceutical industries where manufacture or building maintenance in clean-room environments is required. Consisting of two polyester films that have been cut and welded together using ultrasonics, the material is fixed onto an object and the drill bit actually drills through the polyester films. The particulate matter that is generated is trapped between the two films by the hermetic seal, thus reducing contamination. The California State School system in the United States now routinely uses the product to ensure containment of particulate material during routine facility maintenance.

Widening application range

The versatility and simplicity of ultrasonic energy can be harnessed to provide a clean solution for a number of cutting and welding applications. The use of this technology is appro- →

priate for a diversity of applications and should not only be limited to the mass production of plastic consumable products. mdt

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This article first appeared in *Medical Device Technology*, 17, 7, 30–31 (September 2006). www.medicaldevicesonline.com