F. JOHN FUCHS
WILLIAM J. CHIARELLA

Multiple frequency ultrasonics: the best of both worlds.

Expanding Ultrasonic Cleaning Technology

Critical surfaces of implants and other patient contact items must meet cleanliness standards surpassed only by those imposed in the semiconductor and disc drive industries. Achieving this desired level of cleanliness on a variety of surfaces requires specialized techniques including multifrequency ultrasonics.

Ultrasonic cleaning is no stranger in the field of life sciences. Since its very inception, over a half century ago, ultrasonic cleaning equipment has been a standard feature in biomedical research facilities and hospital surgical suites. As the need for cleanliness has increased over the past few decades, however, ultrasonics has played a major role in meeting that need. In fact, many advances in ultrasonic technology have been in direct response to the needs of this industry.

A Brief History

Ultrasonic cleaning was first employed in the laboratory to ensure cleanliness of apparatus used in research. In the hospital, it was found useful in cleaning surgical instruments prior to sterilization. Ultrasonics completely removed dried-on tissue, blood, and other contaminants from instruments with a minimum of time and effort.

While there were efforts to use ultrasonic energy to actually sterilize, these efforts were unsuccessful. Maintaining a sterile environment, although imperative to prevent infection, is not necessarily synonymous with cleanliness. In short, *dirt, although sterilized, is still dirt!* Cleanliness, then, remains important in addition to sterilization to assure the proper function of not only surgical instruments but the growing abundance of implants and other patient contact items.

With the advent of single-use instruments, one might think that the need to

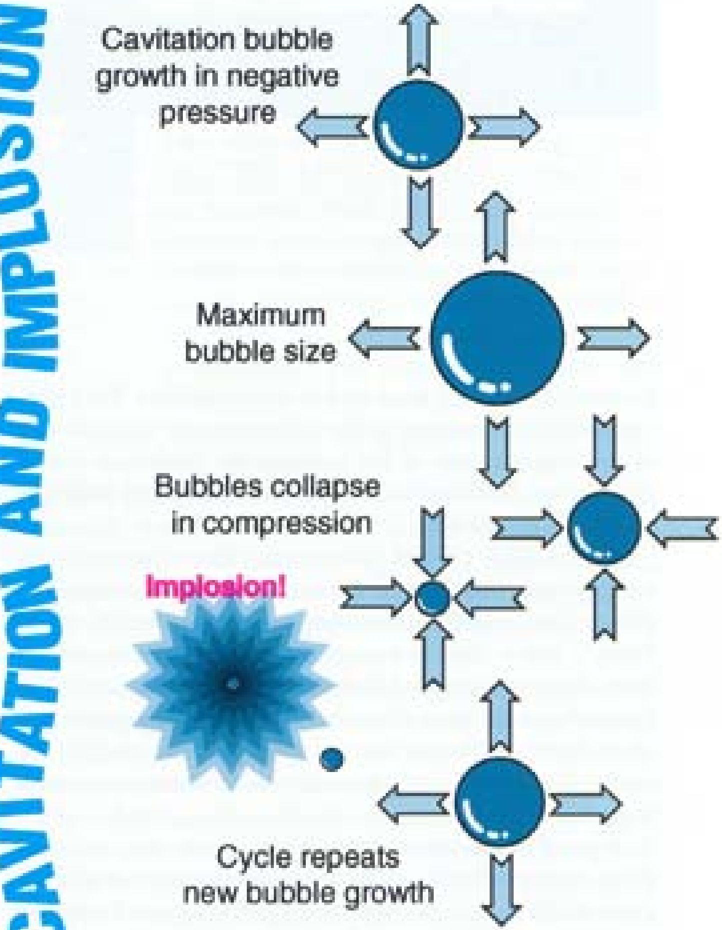

Figure 1. In an ultrasonic cleaning system, cavitation bubbles form and grow under the influence of negative pressure in the rarefaction portion of the sound wave. As the sound wave progresses, negative pressure is replaced by positive pressure in the compression portion of the sound wave, causing cavitation bubbles to implode, which releases mechanical energy in a "jet" or shock wave. This energy release enhances and facilitates cleaning processes.

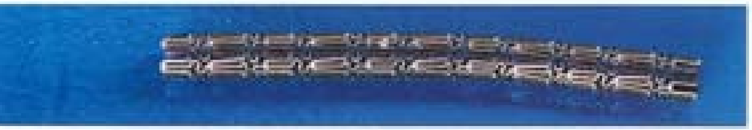

Photo 1. Just over ½ in. in length, this thin wall tubular stent has a complex pattern of laser cut openings. Each opening is approximately the same width as the diameter of a brush bristle. This part must be cleaned to remove residue from the laser cutting process as well as microscopic chips.

temperature and chemistry records, serve to thoroughly profile the cleaning process. This is of growing importance as the requirement to document all processes continues to increase.

Conclusion

Ultrasonic cleaning technology continues to grow to meet the on-going challenges of the life science and other industries with the implementation of digital waveform synthesis. Although many effects of digital waveform synthesis have been documented and are in commercial use, work to further understand and develop its capabilities is ongoing both in the laboratory and in practical field trials. This emerging science guarantees that tomorrow's digitally tailored waveforms will be able to meet the ever increasing cleanliness requirements generated by advances in other technologies by providing the ideal cleaning parameters for each application.

Photo 2. The back surface of a hip joint socket is approximately 2 in. in diameter. This surface has a "mossy" texture to allow the recipient's bone to permanently fuse to it. In this case, cleaning requires the removal of all foreign contamination that may hamper fusing.

itation does not occur. The thickness of the boundary layer (which may "hide" smaller particles) diminishes as the ultrasonic frequency increases (**Figure 3**).

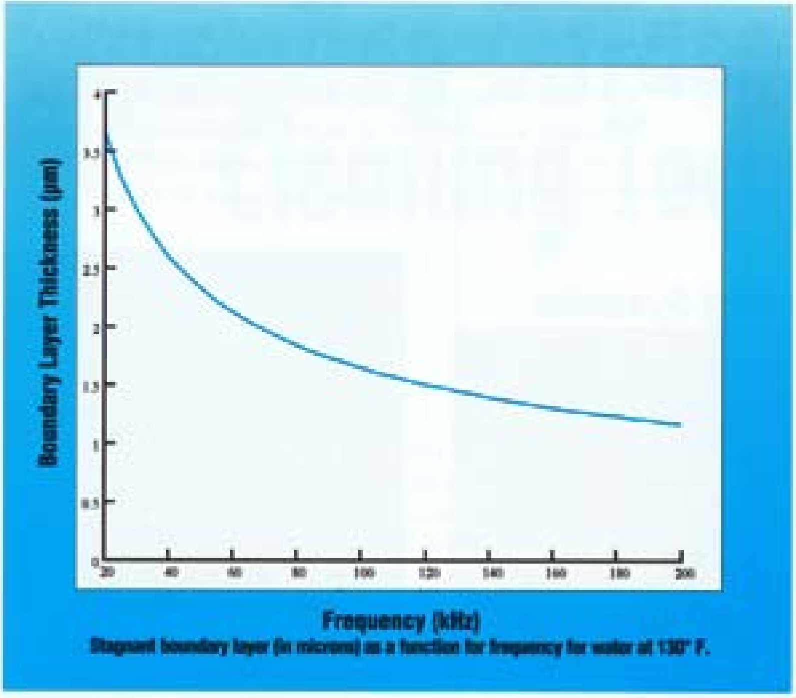

Figure 3. As ultrasonic frequency is increased, the thickness of the boundary or "stagnant" layer diminishes. Small particles and other contaminants trapped in the boundary layer cannot be effectively removed by ultrasonic cleaning. In some cases, a combination of frequencies, one for gross removal and a second, higher frequency for finish cleaning, may give superior cleaning results.

Since increasing ultrasonic power has very little effect on the thickness of the boundary layer, there is a compelling argument for using higher frequency when there is a need for penetrating an irregular surface or removing extremely small particles.

Best of Both Worlds

The "best of both worlds" requires the use of multiple frequency ultrasonics. Low frequency in the range of 25 to 40 kHz to provide aggressive removal of larger volumes of surface contamination and higher frequencies in the range of 65 to 200 kHz to penetrate irregular surfaces and remove extremely small particles.

Multi-frequency capability can be supplied through the use of discreet equipment functioning at the various frequencies or by using equipment capable of providing multiple frequencies in a single cleaning chamber. The ability to provide multiple frequencies in a single unit is, of course, desirable. The benefits of being able to program frequency changes throughout the cleaning process are presently under exploration as an enhancement to the benefits already seen from multi-frequency cleaning.

Each cleaning application is unique and requires its own set of ultrasonic parameters. The variety of items ranges from small stents with dimensions measured in fractions of millimeters to hip joints hundreds of times that size. The stent requires extreme cleanliness as it is inserted directly into the blood stream and, due to the techniques used in its fabrication and the required geometry, may exhibit both small and large particle contamination (**Photo 1**). The hip joint, on the other hand, requires cleanliness for a completely different reason. The surfaces of the hip which are to be attached to the patient's own bone must be free of all contaminants to allow the adhesive or the fusing effect as the bone grows into the porous surface to be effective (**Photo 2**).

Pacemakers and many other implanted devices offer a cleaning challenge to remove contaminants resulting from the finishing stages of the manufacturing process, which may include buffing and polishing. These steps, often performed in the interest of cosmetics, may make the finished surface an inherent particle generator. Other patient contact items including cannulae, endoscopes, heart/lung bypass and dialysis machines, and catheters present cleaning requirement and challenges, which are increasingly being met through the use of ultrasonic cleaning systems tailored for each.

On the Horizon

Ultrasonic cleaning is far from a "mature" technology. The generic ultrasonic cleaner, a catalog item for decades, is being displaced by a new generation of ultrasonic cleaning systems which utilize newly developed technology to provide better cleaning to meet today's challenges.

Life sciences, along with wafer fabrication for the electronics industry and disc drives for the computer industry, provide the biggest opportunities for this new technology. Digital generation and control of the ultrasonic waveform and frequency within a cleaning system offer the cleaning specialist the opportunity to prescribe a specific recipe for each cleaning task. Applications previously declared "impossible" due to lack of adequate cleaning or the potential for part damage due to ultrasonic cavitation erosion are being conquered today using this technology.

Finally, digital ultrasonics brings with it the ability to control and document the ultrasonic cleaning process in a way not previously possible. Digital readouts can provide a permanent record of ultrasonic cleaning parameters including time, intensity, waveform, and frequency. These, added to the traditional

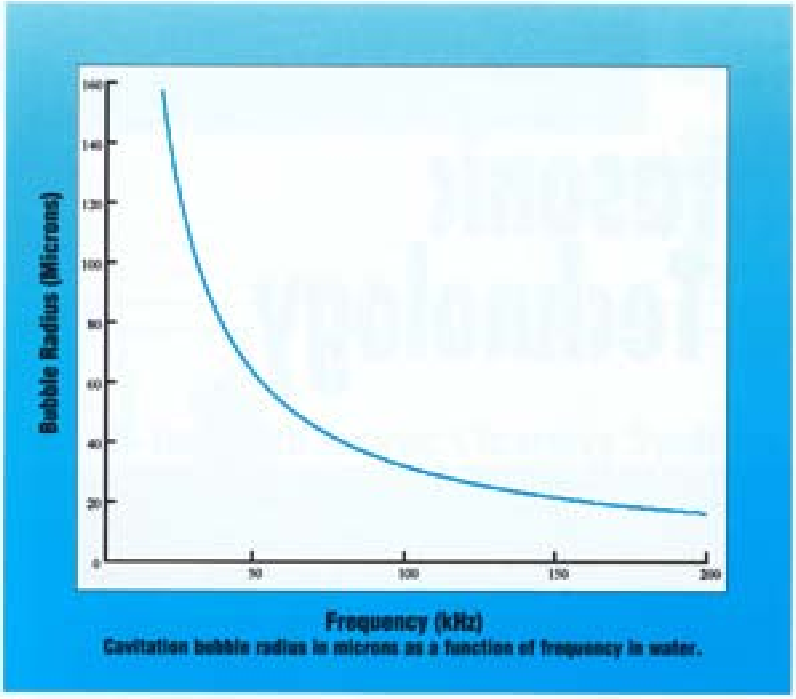

Figure 2. As ultrasonic frequency is increased, the size of cavitation bubbles produced in an ultrasonic system decreases. Although smaller bubbles result in less intense individual implosion events, there are more implosion events per unit of time. Higher ultrasonic frequency generally provides a more gentle but penetrating cleaning action and provides better removal of extremely small particles from a surface.

Instead, it has been increased and moved from the highly controlled environment of the laboratory and surgical suite to the manufacturer of the instruments. Single-use instruments must be cleaned and sterilized before they leave the manufacturer's facility.

Additionally, surgical instruments have become more complex and miniaturized. These changes have further complicated and enhanced the importance of effective cleaning. Today's micro- and arthroscopic surgery routinely utilizes instruments previously challenged in size and complexity only by watchmaker's tools. Clearances between moving parts are often less than the thickness of a human hair, making the complete elimination of particulate contamination extremely important to their function.

Beyond conventional instruments, there are countless other surgical items which come in direct contact with patients. These include fluids delivery tubing and the associated fittings and valves as well as monitors that measure blood pressure (even within the heart itself), body temperature, and a myriad of other parameters in real time. Add to these requirements the need of the drug industry to clean the equipment used to produce and package drugs of every description. All of these require not only sterility, but the ultimate in cleanliness as well.

Mechanisms of Cleaning

To understand the benefits of ultrasonics one must first understand the mechanism of cleaning. Soluble contaminants are removed by being dissolved by an appropriate solvating agent. This solvating agent could be a hydrocarbon solvent or an aqueous chemistry utilizing surfactants along with other cleaning agents. Insoluble contaminants must be removed by physical displacement using mechanical means.

Ultrasonic energy in a liquid creates cavitation "bubbles" which collapse in implosion, releasing considerable energy in the form of microscopic shock waves (**Figure 1**). The shock waves that result from the implosion of cavitation bubbles provide a micro-stirring effect which penetrates into porous surfaces and hidden areas to improve liquid exchange, which speeds dissolution of soluble contaminants.

In the case of insoluble contaminants, the liquid media acts as a coupling agent to deliver mechanical force to break ionic or adhesive bonds and displace particles from the surface to which they are attracted or attached. Again, this effect is very penetrating, reaching into areas which would be inaccessible using other techniques including brushing and wiping.

Ultrasonic parameters including frequency, power, and waveform can be tailored to produce a desired cleaning effect. The diameter of the cavitation bubbles produced in an ultrasonic field is inversely related to the ultrasonic frequency. As the ultrasonic frequency is increased, the size of the average cavitation bubble becomes smaller (**Figure 2**).

Smaller cavitation bubbles implode with less force than larger cavitation bubbles, resulting in a more gentle cleaning effect at the higher frequency. Although the effect resulting from each cavitation bubble collapse diminishes as frequency is increased, the number of cavitation events increases as there are more vibrations per unit of time. Smaller cavitation bubbles are also more able to penetrate irregular surfaces than the larger bubbles produced at lower frequencies. Provided the input power is maintained constant, the total energy delivered by the cavitation and implosion events remains constant as frequency is varied.

Lower frequency ultrasonics in the range of 25 to 40 kHz provides the most aggressive overall cleaning in the widest variety of applications. The ability of cavitation and implosion to remove very small particles is, however, enhanced at frequencies of 65 kHz and higher. Particles on the order of several microns and smaller in size do not present enough surface area to the shock wave, created by the implosion of a large cavitation bubble, for it to absorb enough energy to be sufficiently displaced for removal. In addition, there is a stagnant or "boundary" layer in the liquid immediately adjacent to the wetted surface where cav-