

# TODAY'S MEDICAL DEVELOPMENTS

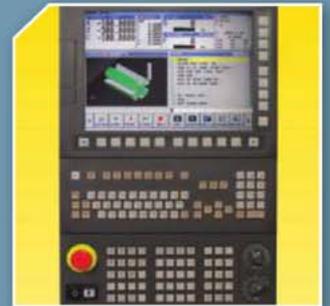
Dedicated to the Design & Manufacturing of Medical Equipment and Devices

## PRECISION medical implants

Micro gun-drilling machine from Precihole delivers a tabletop design to produce straight, accurate, deep holes for nails, screws, and other medical instruments.



MAZAK'S Integrex J-200S  
Multitasking Machine



FANUC'S  
Series 0i-F CNC



EDGE TECHNOLOGIES'  
FMB 20-100 Bar Feeder

EDITED BY ELIZABETH ENGLER MODIC

# Emerging technology in medical device manufacturing

**An innate ability to foster rapid prototyping, inexpensive product development, and low-volume, high-mix production makes sheet hydroforming ideal for medical device manufacturing.**

An emerging metal and composite forming technology is helping medical device manufacturers react quickly to product developments and develop new products in a short time frame. Sheet hydroforming, traditionally known for its contributions to the aerospace and lighting industries, effectively and intricately forms high-strength materials, such as titanium, using inexpensive tooling. Manufacturers say the process could revolutionize

the way medical devices are conceived, developed, and produced.

## Process

Sheet hydroforming uses pressurized fluid in a flexible bladder or diaphragm to shape sheet material with a single tool. It can produce a wide range of geometries from a variety of materials including aluminum, stainless steel, titanium, and even composites. Manufacturers of a wide range of medical

devices are discovering the advantages the process can provide, specifically in new part development. These include tooling cost savings, improved part development time, and increased forming capabilities over traditional methods. The sheet hydroforming process can replace many metal forming processes and consolidate multiple steps into a single operation.

## Tooling

Companies operating sheet hydroforming equipment can bypass the long lead times and increased expense of traditional tooling. This ability to go deeper into the part development process, while getting their products to market faster, is an incredible advantage in a highly competitive marketplace.

During fluid cell or deep draw types of hydroforming, the flexible diaphragm acts as a universal die half, conforming to any shape within the forming chamber. This eliminates the need for expensive, difficult-to-manufacture matched die sets. It is a fundamental shift in tooling that dramatically alters the investment required in both manufacturing time and expense.

For manufacturers developing new parts, which might be subjected to design reviews and subsequent changes, this freedom from precision male/female tool alignment is liberating. In addition to fast setup and changeover times, sheet hydroforming tools can be refined, or replaced altogether, at a



↑ This poured epoxy tool was a fast, economical option for this multi-bend part which features a stretch flange, a compression flange, and a return flange. Sheet hydroforming can replace press brake forming, consolidating multiple brake cycles into a single sheet hydroforming cycle.

fraction of the cost of mating dies. For new medical device parts in development, users can substitute various materials and material thicknesses, without altering the tooling in use.

## Alternative tooling materials

State-of-the-art materials, engineered to withstand the high forming pressures associated with sheet hydroforming, are allowing manufacturers to shape hundreds of parts on 3D-printed tooling before tool deformation occurs. Machining departments can be bypassed altogether, with tool drawings sent directly to the printer. Printed tools commonly reduce tooling costs by 50% to 80% and lead time by 60% to 80%, making the already economical hydroform tools even more attractive.

In addition to 3D printed materials, aluminum, and steel, medical device manufacturers developing new parts with minimal investment in tooling can use poured epoxies and hardwood as tool material.

## Improved part quality

Beyond the process' tool-related advantages are several benefits directly linked to part quality. First, because half of the tool is a flexible rubber diaphragm, marring part surface due to direct metal-on-metal contact is eliminated. The resulting smooth, scratch-free surface finish can eliminate labor costs by removing the need for polishing and post-forming.

In deep draw sheet hydroforming, material thinning is also improved when compared to traditional draw-forming methods, which use matched male/female die sets. In the traditional process, the material is stretched into the final shape, with considerable thinning occurring in areas that come into direct contact with the die halves. Sheet hydroforming, by contrast, results in less variation in the blank-to-finished part thickness, as the material is uniformly elongated. The forces applied during the

cycle are multi-directional, drawing the material around the tool and reducing the stretching and thinning associated with traditional draw forming. This benefits medical device manufacturers who are working with expensive materials because the starting thickness of the material can be reduced.

Uniform pressure applied by the diaphragm allows for the production of complex geometries that are cost prohibitive (or impossible) using traditional forming methods. Parts that require multiple forming steps, using elaborate progressive dies, can frequently be consolidated into a single tool and can be completed in a single press cycle. Other geometric challenges, such as negative angles, can be sheet hydroformed easily due to the expansion capabilities of the diaphragm.

## Reduced reliance on skilled labor

Powerful, intuitive control systems, such as those featured on the Triform line of deep draw sheet hydroforming presses manufactured by Beckwood Press Co., shift forming capabilities from experienced individuals, to the presses themselves.

"Traditional sheet hydroforming involved skilled operators, fully in-tune with the idiosyncrasies of the individual press," says Bob Blood, technical sales manager for Triform Sheet Hydroforming. "Because of this, sheet hydroforming was considered as much of an art as it was a science."

Modern systems allow for precise control over both the diaphragm pressure and, on deep draw models, punch position, at any point in the forming cycle. This infinite control over the forming process, along with the ability to save proven recipes for future access, leads to rapid new part development and greater part consistency due to the repeatable nature of the process.

Additional features, like Triform's In-Sight technology, give new part developers an inside look at the forming process.



↑ A series of five different fluid cell tools rests unsecured on a sheet hydroforming press table. Benefits of the fluid cell sheet hydroforming process include the ability to run multiple different parts in a single press cycle.

"In-Sight allows operators to pause the press at any point in the cycle and open the forming chamber for a visual inspection of the forming results. Depending on what is observed, the operator can choose to resume the cycle or abort the cycle in order to refine the programmed recipe," Blood says. "Users can pinpoint the specific problem area in the forming process, allowing for educated changes to be made to the diaphragm pressure, punch position, lubrication, or other process variables."

Advanced forming simulations To further enhance the sheet hydroforming process' new part development advantages, users can integrate a number of advanced forming simulation suites. Tool design, flat pattern design, and the optimal press recipe can all be determined and stored before a single tool is manufactured or a single flat pattern cut.

Simulation suites, like ESI's Pam-



↑ Sheet hydroforming can be an ideal forming solution for a wide range of parts and part sizes.

Stamp 2G, simplify and compress new part development time by allowing users to fail faster.

“If you can work out, through the simulation software, what doesn’t work, you’ll be able to more quickly zero in on what does,” Blood explains.

Added benefits of forming simulations include a lowering of the labor and material cost normally expended during new part development. Simulations also act as valuable tools in terms of the part quoting and sale processes, as companies can identify potential formability issues

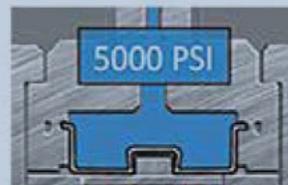
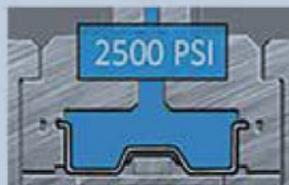
up front, allowing them to factor those time and cost additions into their planning.

Future of medical manufacturing Sheet hydroforming and the accompanying technologies are helping medical device manufacturers prepare for the future. With these technologies, device manufacturers can stay ahead of government regulations, implement a leaner manufacturing environment, and bring products to market faster while delivering higher profit margins.



↑ A deep drawn part cross section shows uniform wall thickness. Because the material is wrapping around the punch tool as it is raised into the diaphragm, material is elongated more uniformly when compared to traditional drawing methods.

## TWO SHEET HYDROFORMING PROCESSES

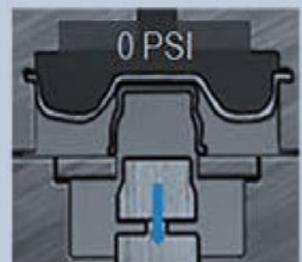
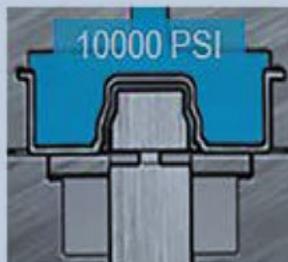
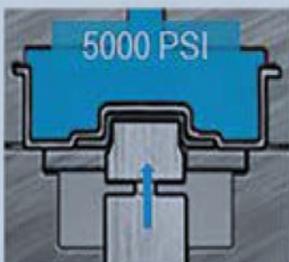


There are two types of sheet hydroforming processes: fluid cell and deep draw.

In fluid cell sheet hydroforming, the material is formed over a single tool, using the force of the diaphragm. The

sheet material is placed on an unsecured form block (male or female) that is placed on the press' working surface. The diaphragm is pressurized with hydraulic fluid, expanding as it exerts equal pressure on every point within the forming chamber.

Multiple parts can be hydroformed in a single fluid cell press cycle, as long as the tools and material blanks fit within the forming area. The fluid cell process is ideal for forming shallow contour parts, including those with flanges.



↑ **Top photo:** Fluid cell process **Bottom photo:** Deep draw

In deep draw sheet hydroforming, parts are formed using the same diaphragm-principle associated with the fluid cell process. However, the tooling related to the deep draw process is attached to a moveable punch

cylinder, which extends up into the diaphragm during the cycle. During deep draw sheet hydroforming, the diaphragm primarily acts to hold down the material while the tool extends atop the hydraulic cylinder.

Parts which require a controlled flow of the material, such as cans, boxes or those which have a greater tendency to wrinkle during the forming process, can benefit from the deep drawing action.