MedTech Fluid Management Optimization: The Design Engineer's Guide

Healthcare and medtech have undergone a dramatic stress test due to COVID-19. End-user expectations and requirements are high around innovation and usability. Policymakers and regulators are creating the conditions for accelerated innovation. Non-traditional manufacturers and agile market entrants are jumping into the medtech space. Healthcare-focused device and equipment companies are reallocating resources to address urgent supply needs, volatile external market factors and future viability.

Now is a uniquely appropriate time for medtech manufacturers to improve current products and systems and envision new ones. Design engineers are at the forefront of this effort. The demand continues for medical devices and diagnostic instruments that are increasingly sophisticated, yet smaller, faster and more reliable. Other trends already underway—such as broadened care delivery both at home and in ambulatory surgery settings—are accelerating during the pandemic and predicted to continue to grow, underscoring the need for simple to use, intuitive and effective solutions.

With all the form, fit and function considerations that medtech design engineers take into account, fluid management is an avenue for enhancement that is often underleveraged. Fluid handling is widely used in healthcare: liquid cooling of medical lasers, reagent dispensing in in vitro diagnostic equipment, precise drug delivery, managing fluids to and from

patients, safe removal of waste—the list goes on. Regardless of application, a thorough understanding of a few key concepts in fluidics design, particularly around connectors, can go a long way in creating devices and equipment that are more efficient, easier to use and superior to competitors' offerings.

FLUID MANAGEMENT OPTIMIZATION

Effective fluid management entails bringing together all the right components to optimize the system.

Key design and specification factors that must be considered by design engineers include required flow rates; pressure and temperature parameters; intended media and compatibility; tubing diameter and interfaces; potential shut-off valves; and, applicable sterilization processes. More complex projects might also include simultaneously managing lines for power and air along with fluids. Each of these design decisions should be considered in the context of flow rate and pressure drop, which affect the overall fluid loop performance.

FLOW RATE AND PRESSURE DROP

All components in a fluidic loop act as resistors by way of pressure drop—whether filters, sensors, tubing, fittings or connectors—with a pump working to

overcome this resistance and provide the desired flow rate. Any change within the system can affect valve and filter function, and even power requirements. In designing and enhancing fluid circuits, this fundamental truth is sometimes underestimated. From a design engineering standpoint, it is critical to understand allowable pressure drop across the fluid system.

Because connectors can substantially influence the flow performance of a system, it is important for the design engineer to better understand their impact. Connector shape and valve and termination types affect pressure drop. Pressure drops also vary by manufacturer, with some designs exhibiting less turbulence and resistance to flow than others. For example, comparison testing of 1/8-inch connectors showed that one type had a 23 percent better flow coefficient (CV=0.37 vs CV=0.30) than others of the same size. This higher flow capacity reduces pressure drop through the connector by an average of 34 percent, minimizing the burden on pumps and optimizing performance.

By comparing published Cv factors for various connectors, design engineers can determine the pressure drop across the connector and match the correct size to their application requirements. The following equation calculates the pressure drop for a given flow rate through a connector:

$$\Delta P = \left(\frac{Q}{C_v}\right)^2 \times S$$

Q = flow rate in gallons per minute
Cv = flow coefficient of the connector
ΔP = pressure drop in PSI (Δ between the upstream pressure and the downstream pressure)
S = specific gravity of fluid grams/cm^3

Connector design factors influencing realized pressure drop include:

- **Valved or non-valved:** Connectors that include an integral valve to stop flow upon disconnect generally have higher pressure drop across the connection than a comparable non-valved product.
- **Type of valve:** Connectors with non-spill or dry-break valving technology may have higher pressure drop than standard valve designs and may vary considerably by design.
- **Shape:** Connectors that cause the flow path to turn (e.g., 90-degree elbows) will have higher pressure drop.
- **Termination:** Connector threads, hose barbs, or other options can impact the pressure drop. Supplier partners can help you determine the relationship between a connector's flow performance and integration point in the fluid system to eliminate flow restrictions and optimize performance.

Considering the number of connection points used in a total system, this calculation and specifying decision significantly impact overall flow and efficiency. By understanding connector flow performance and pressure drop for all components in the fluid circuit, design engineers can specify pumps that deliver the desired performance, efficiency, and reliability.

USABILITY AND FUNCTIONALITY INTERSECTIONS

In fluid management, enhanced usability comes from thoroughly thinking through how both your customers and other end users are going to interact with the fluid pathway. Market factors like the growth of at-home care means many more patients and their caregivers are interacting with devices such as dialysis equipment, infusion pumps and ventilators.

Also, one piece of equipment can involve multiple fluid circuits. A blood analyzer, for example, uses multiple lengths of tubing and connectors to supply the machine with various reagents, buffers, cleaning chemicals, or to handle the waste product at the end of the process. Typically, lab technicians connect bottles that either supply the system with these chemicals or act as a collection reservoir to the machine via tubing with connectors on both ends. Sourcing the right connector can help facilitate quick and intuitive replacement of the bottles as they empty or fill. For example, valved connectors help eliminate spills and limit air from entering the system upon disconnect, creating a closed system and a cleaner, safer work environment. The connector and tubing materials selected by the design engineer must be compatible with the reagents, solvents and cleaners being used.

Although the fluid loop is just one aspect of overall equipment function, other considerations affect fluid circuit design, including but not necessarily limited to the following:

- What are the environments in which the equipment will operate?
- How will your end users manage internal and external tubing throughout the system?
- How do your end users connect or disconnect tubing or other parts through which liquids flow?
- Will your end users be properly trained to make secure, correct connections?

Critical factors in fluid management include:

- **The ability to connect/disconnect components in the system as appropriate.** This may include day-to-day connection and disconnection by patients and HCPs as well as technicians who build and maintain equipment. Force to connect contributes to product usability and varies greatly by connector choice.

  Connector types largely fall within two categories:

  1. Fittings: single metal or plastic parts that connect tubing using terminations like hose barbs, threads or other joining methods; and,

  2. Quick disconnect (QD) couplings: comprised of two mating pieces in an insert/body configuration.

  Latching mechanisms can impact the force needed to connect. Some QDs accommodate low-force, single-handed connections. Others require higher linear force or multi-step connection processes. Force to connect is also impacted by system pressure at the time of connection, valve design, and internal spring loading.

  While many QDs employ O-rings, some connectors offer multi-lobed seals, which require less force to connect, while also providing redundant protection against leakage and greater resistance to debris or foreign contaminants. Frictionless valves mitigate valve sticking due to seal compression set and also keep connection forces low.

  From an equipment servicing standpoint, fittings with hose barb terminations are intended to connect tubing, not disconnect it. The tubing is securely joined however, and maintenance technicians may need to cut "stuck" tubing to remove it from the hose barb, or cut the end of deformed tubing and then reconnect the shortened length. This is time consuming and can damage the hose barbs, so proper training is critical.

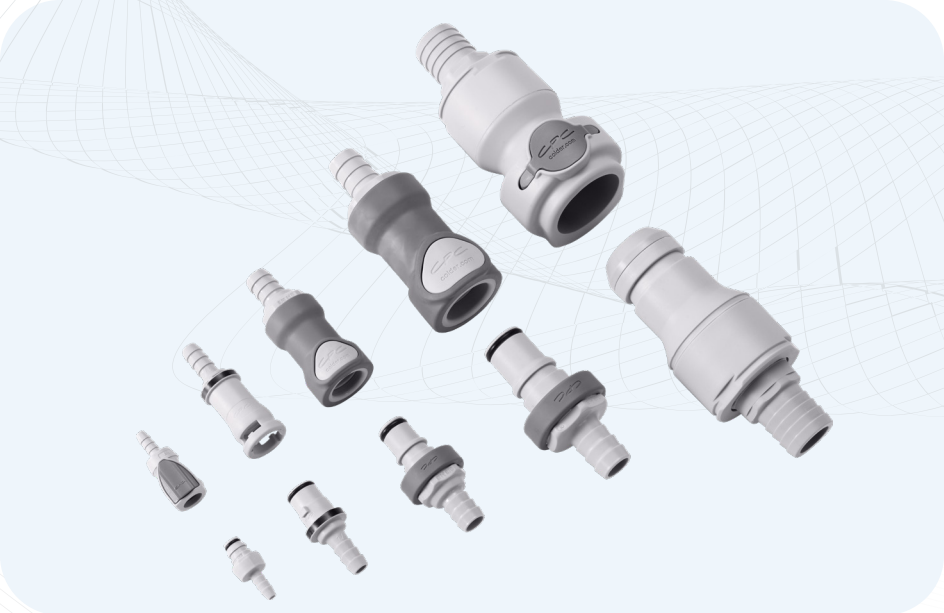
  If repeated connections and disconnections are required during both service and use, quick disconnects may be a more appropriate choice. Integrated non-spill shutoff valves also automatically stop flow, reducing spills or pressure loss during disconnection.

- **Avoidance of spillage and/or air introduction.** Leak-free performance is essential for applications where even a few drips of fluid or the introduction of air could impact equipment function. For example, an MRI scanner's critical components—powerful magnets and electronics— are cooled to near absolute zero via liquid hydrogen or liquid helium. Managing the fluid cooling loop is critical to the overall function of the device.

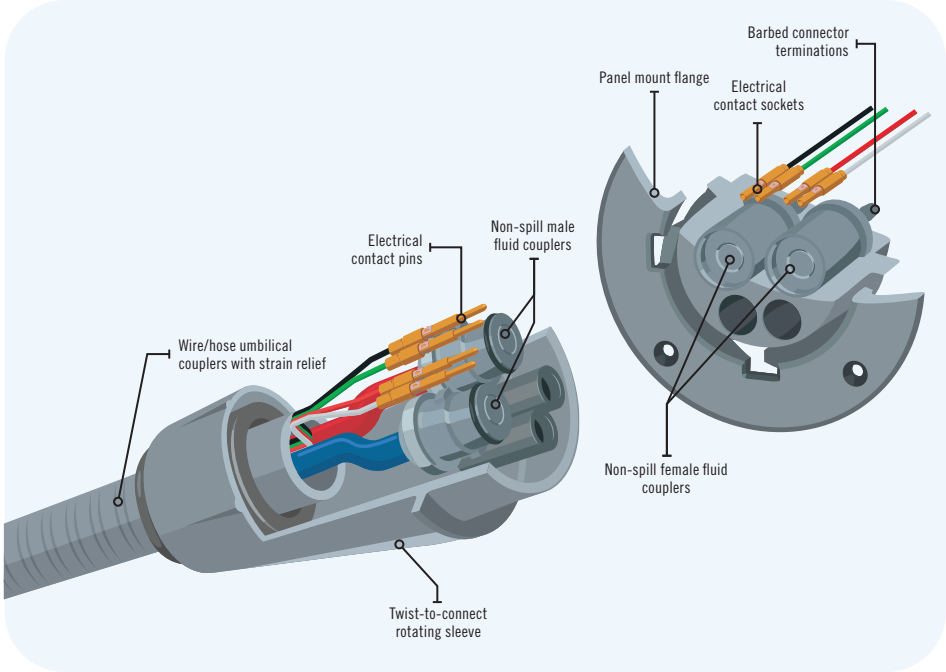
  On a smaller scale, consider chemotherapy infusion pumps. Currently, many chemo pumps use tube clamps to discontinue flow. The only thing holding the fluid in place is surface tension, but it takes very little force to break that tension leading to potential spillage.

  Connectors with integrated precision flush-face valves, on the other hand can help avoid spills, contamination or air inclusion upon connection.

  Again, connectors of the same size can deliver different performance. The volume of a drop of water is about .05ml. A traditional valved coupler often has >1ml spillage per connection cycle, while more advanced non-spill technologies can reduce this volume to as little as .02ml spillage per connection cycle at a similar flow size and system pressure. With air inclusion, traditional valved couplers may have >1cc inclusion per connection cycle while enhanced connectors can reduce this volume



Connectors with integrated precision flush-face valves are "non-spill" solutions that help avoid spills, contamination or air inclusion upon connection.



Hybrid connectors accommodate the transfer of liquid, air, power and signal into one connection device.

to ~0.01cc per connection cycle, depending on the connector's flow.

- **Speed and convenience.** Though reliability is the baseline, fluid loops are enhanced and streamlined by well-designed components within the system. For example, hybrid quick disconnects combine the transfer of fluids (liquids and air) with power and signal into a single connection device. By eliminating the need for multiple connections, the user interface is simplified between remote tools and a device. These connectors allow technicians to quickly change or replace modular tools, umbilicals or hand pieces.
  With connectors, even seemingly small design elements like swivel joints that help avoid kinks in tubing or thumb latches for single-handed connection and disconnection can enhance users' experiences with devices on a daily basis.

SPECIFICATIONS: TUBING AND CONNECTORS

The functional needs of a medtech fluid management application determine the parameters for tubing and connectors. Without the right match between tubing and connectors, vibration, tension, pressure spikes or poor fit can lead to problems. Your choice of the appropriate connectors for the tubing type and application is key for fluid handling in medical environments.

When determining flow requirements, the tubing's inner diameter (ID) size generally establishes the first consideration for the size of the connector. Device designers often default to using widely available fittings with familiar hose barb terminations, which provide adequate sealing performance for many applications.
One or more ridges grip inside the tubing. During installation, tubing expands over the hose barb termination. As the tubing relaxes to its original diameter, the barb grips and seals it. For equipment servicing, again it is important to remember that fittings with hose barb terminations connect tubing easily, but can be difficult to disconnect without cutting or stretching the tubing.

While the tubing diameter and durometer (hardness) largely determine proper fit of a connector with tubing, other factors to consider include:

- **Pull-off resistance.** When soft tubing is pulled, it grabs more tightly on sharp multi-barbed terminations. In contrast, a shallow or rounded hose barb mated with very stiff tubing could allow the tubing to disengage with minimal pulling. Because terminations exhibit different tensile strength characteristics for different tubing sizes and grades, it is important that you pair the right termination with the tubing material and its use.

- **Ease of installation.** For higher durometer tubing or hose, termination options such as push-to-connect or compression styles provide better performance with a lower assembly force than with hose barbs. Regardless of the termination style, quick disconnect couplings support fast disconnections simply by joining the male and female halves of the assembly, providing a leak-free connection without the use of tools.

- **Mounting options.** Tubing ports can be mounted to the back, side or front panel of a machine. Common mounting options include panel mount, or direct mounting into NPT thread or ports. If the tubing connection is located in a difficult-to-access location, the generous chamfer of blind mate connectors automatically guide to the correct mating position for easy and secure connections. For

connections that may be exposed to rough day-to-day handling by HCPs or patients, metal or high performance polymer products may be preferred for their strength. Plastic connectors are a lightweight, robust, cost-effective solution to connect tubing to equipment.

Other critical functional inputs include:

- **Media effects/chemical compatibility.** All components within the fluid circuit that come into contact with fluids must be evaluated by the design engineer for chemical compatibility. It's important, too, to consider the effects of media if fluids are not in circulation. For example, chemicals can degrade plastics in stagnant areas and dead volumes present the risk of biological growths. You must ensure media compatibility to avoid the degradation or corrosion of components in the fluid pathway, and potential debris that arises as a result.

  Remember to consider cleaning solutions and other environmental exposure. Also consider the effects of gamma ray, electron beam, ETO or autoclave sterilization on fluid loop materials if the device will be sterilized.

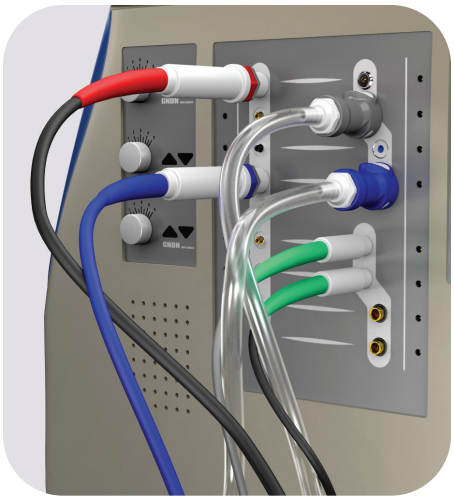
- **Temperature.** Temperature ranges must be considered not only during equipment operation, but also during maintenance, storage or shipping. For example, a standard polypropylene connector cannot withstand being autoclaved at 250°F for 30 minutes without degrading; however, a stainless steel version withstands high temperature and a longer list of disinfectants or reagent media.

SAFETY

Of course, designing for simple, intuitive and repeatable use of medtech equipment is critical. The process requires a thorough analysis of the application by the design engineer in order to create equipment that is compatible with the physical, chemical and biological environment, and be easy to use and help prevent user errors. You must carefully evaluate the potential for leaks, spills or misconnections.

Standards such as the ISO 80369 series define noninterchangeable connectors and can impact your connector selections for a wide range of medical device applications.

In connectors, enhancements range from simple physical characteristics to advanced technologies. Color-coded or mechanically keyed components aid in correct connections. Connectors equipped with radio frequency identification (RFID) technology allow data exchange at the point of connection by sending RFID signals between the two separated coupling halves. Data is stored



Medical equipment connections must be secure, convenient and designed to avoid misconnections.

on an RFID tag embedded in one half of the coupling while a reader is in the other half. When the two coupling halves are brought within a few centimeters of each other, the reader detects the tag, reads it, and sends the tag data to the control unit running the system. This technology can track batch numbers, expiration dates,

RFID-equipped connectors can verify correct line attachment and media, and track batch numbers and the number of uses.

and the number of uses for single- or limited-use products. It can also help verify secure connections, correct line attachment or appropriate media.

An ocular surgery system maker incorporated RFID-enabled connectors into the disposable lines used between the main console and surgical hand piece. In addition to handling fluids, these smart couplings convey information about batch and product integrity, confirm correct tool connections, and automatically adjust procedure settings based on the instrument installed all contributing to increased safety, procedure speed and accuracy.

STREAMLINING FUTURE PRODUCT DEVELOPMENT

Higher performing, more usable and differentiated products start with design engineers, whose work matters greatly in the overall product success and performance. Optimized fluid management is one way that medtech design engineers can deliver solutions that end users will value and prefer.

To solve a project's technical and design issues related to fluid management, collaboration with a partner with specialized knowledge can yield significant benefits such as:

- Shortening prototyping and go-to-market timelines.
- Leveraging the external expert's fresh perspectives and deep application/cross-application experience.
- Using the external specialist's robust validation and testing data, such as performance testing for flow and pressure drop and in-depth material characterization. ISO13485 certified supplier partners can support the design controls process.

With connector technologies, the possibilities are numerous and complex. Connectors are often a user's primary interface with medtech products. They play an important role in successful fluid management from providing reliable, leak-free performance to influencing overall perceptions of equipment design, ease of use and satisfaction. Through a deeper understanding of fluid management, your engineers will not only successfully move fluids from point A to point B, but also deliver more intuitive, compelling and functional designs.

About CPC

CPC quick disconnect fluid handling couplings help make clean, quick and safe medtech connections. Whether your application calls for non-valved or non-spill, low flow or high flow, reusable or disposable, our broad range of standard and custom-engineered components can meet your specifications. Medical equipment OEMs around the world choose CPC connectors because of our proven performance in operating rooms, life science labs and home healthcare settings.

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We Inspire Confidence at Every Point of Connection

	QUESTIONS	KEEP IN MIND
FLOW	What is your required flow and pressure drop?	When calculating, be sure to allow for the effect of shutoff valves and tubing connections.
TUBING	What's the diameter of the tubing you are using?	Be sure to know the inner and outer tubing diameter dimensions.
MEDIA	What media are you using?	The viscosity and corrosiveness of the fluid traveling through the connection can affect fluid flow, as well as the connector itself. Make sure all media are chemically compatible with the connector you choose, as well as all coupling materials, including o-rings, seals and springs.
TEMPERATURE	What is your minimum and maximum temperature range?	Standard ranges are from -40° C to 200° Fahrenheit/-40° to 93° Centigrade.
PRESSURE	What is the maximum pressure your connector will need to withstand?	This should be assessed by the design engineer, but quick-disconnect connectors rated to 250 psi (17 bar) will be able to handle most low-pressure applications.
TUBING CONNECTIONS	What tubing connection are you using?	The most common are hose barb, compression fittings and push-to-connect.
SHUTOFF OPTIONS	Do you need automatic or integral shutoff valves? Single, double or non-spill?	Fluid-filled connectors that don't come with an automatic shut-off could lead to spills.
MOUNTING OPTIONS	How is the connector going to be configured into your application?	Again, while this should be assessed by the design engineer, the most common configuration ways are via pipe thread, panel mount, in-line or elbow.
EASE OF OPERATION	Do users need a connector that's easy to operate?	Don't forget to think about who will be using your product, professionals and non-professionals.
RELIABILITY	Could a misconnection or failure occur? If so, how and how often and what are the consequences?	A misconnection could result in a range of potential issues. Consider the criticality of the connection and its requirements for reliability.
REGULATIONS	Are you subject to any federal, state and industry regulations? Are there any forthcoming regulations you should be aware of?	
SPECIAL REQUIREMENTS	Do you have any special requirements such as sterilization, NSF listed, USP Class VI approved materials, special packaging, color coding, keying, lot traceability, etc.?	Are there other devices or machines being used in the same environment that may need to be connected? If so, what are they and what are their functions? Taking these devices and machines into account on the front end can save time, reduce costs and improve safety.

These are common examples, provided for information only, of the numerous issues design engineers face in sourcing connectors and managing fluids.
All of your design decisions must be made based on the particular circumstances of your application.
For more information, email: info@cpcworldwide.com, phone: 651-645-0091.