

# 10 Essential Questions for Reevaluating Your Medical Device Assembly Process



Thank you for your interest in Nordson EFD's Dispensing Solutions.

For a confidential discussion of how we can help you improve your medical device dispensing systems, we invite you to contact our experienced Product Application Specialists at 800.556.3484 or [info@nordsonefd.com](mailto:info@nordsonefd.com).

# Is Your Medical Device Dispense Valve System Delivering All The Performance You Paid For?

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Medical device manufacturers that assemble devices and equipment must meet stringent FDA regulations for quality and product consistency, which makes rigorous process control essential. Fluids for medical device manufacturing can be extremely expensive. It is vital to have quality assembly equipment that generates consistent and accurate results, without fluid contamination, to avoid costly waste.

Is your current dispense valve system giving you accurate deposits with minimal maintenance – or are you applying inconsistent amounts of fluid and wasting too much time and money on downtime, rework, and cleanup?

This paper discusses some common problems encountered with typical fluid dispensing systems in the medical device industry, and offers helpful tips for improving your dispense valve performance.

We hope that you find this information helpful. If we can be of further assistance, please contact our experienced Product Application Specialists at 800-556-3484 or [info@nordsonefd.com](mailto:info@nordsonefd.com).

# 1. Are You Using the Best Dispense Valve for Your Fluid Application?

Best results will be obtained when the valve design is matched to the properties of the fluid being dispensed.



Diaphragm valves with inert wetted parts are a good choice when working with reactive fluids.



Needle Seat

Needle valves minimize dead volume when making very small shots of thin fluids.



Piston valves have snuffback to keep thick fluids from drooling.

For most medical device dispensing applications, a well-designed, general-purpose diaphragm or piston valve that can handle a range of fluid viscosities is a good choice.

In most situations, however, best results will be obtained with a valve style and configuration carefully matched to the specific properties of the fluid being dispensed.

## Difficult Fluids Such as Medical-grade Cyanoacrylate

Wetted internal parts, as well as any fittings and tubing that come in contact with the fluid, should always be carefully chosen for compatibility with the fluid being dispensed.

When working with the cyanoacrylates used in catheters and stents, for example, diaphragm valves with wetted parts made of inert, Ultra High Molecular Weight (UHMW) polymer are a good choice because they will not react with the fluid. Nylon or metal fluid fittings, however, should never be used with cyanoacrylates because they absorb moisture and will promote premature curing. Use polyethylene or polypropylene fittings instead. Chemically inert, polyethylene-lined or PTFE FEP tubing is a good choice for fluid feed lines.

## Thin to Medium Fluids

Thin fluids like solvents and watery adhesives have much different requirements, especially when very small deposits are needed. For these applications, needle valves are often recommended because shutoff occurs close to the valve outlet or dispense tip. This is an important design feature because it minimizes dead volume that can cause dripping or oozing.

When applying fluids in critical applications such as needle bonding, there is even a needle valve that “seats” the needle in the dispensing tip instead of the valve body. By virtually eliminating dead volume, this design makes it possible to produce even smaller and more consistent microdeposits.

## Thick Fluids

Thick materials like sealants or the RTV silicones used to bond pacemaker assemblies, for example, pose very different challenges than thinner fluids like adhesives or solvents.

When using thick fluids, a high-pressure valve with a balanced spool design will provide good control. Also look for a snuffback feature – it will prevent drooling and tailing, and help reduce the rework and cleanup often associated with these more challenging assembly materials.

## 2. Are You Using a Dispense Valve System – or Just a Dispense Valve?

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Taking a “system” approach to fluid dispensing and carefully evaluating all the details – even something as small as a fluid fitting – will help prevent many problems on your medical device assembly line.

A dispense valve system has four main components:

- The dispense valve
- A precision dispense tip
- A means of initiating the dispensing cycle
- A fluid reservoir

The greatest accuracy, reliability, and production yields will be obtained when all four components are engineered to work together as an integrated system. This approach will also simplify qualification and validation processes.

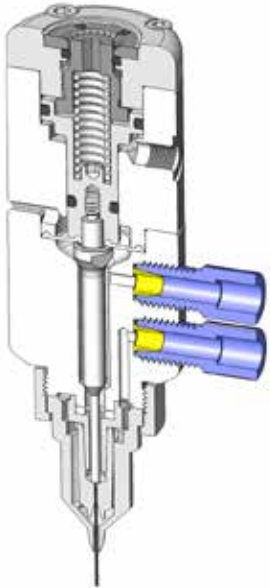


A valve paired with a dedicated valve controller will typically provide faster response time than a valve triggered by mechanical means or a remote PLC. A dedicated controller will also allow deposit size to be fine-tuned with much greater precision than other methods, and can be interfaced with the assembly line’s main PLC.

Tips should be of high quality to ensure unobstructed fluid flow, and matched to the specific fluid and volume being dispensed.

Fluid tanks should always be fitted with constant bleed regulators, to maintain steady fluid pressure and prevent variations in deposit size as the fluid level moves from full to empty.

### 3. Does your application require valves that must meet CIP or SIP standards?



Aseptic valves meet FDA regulations while providing accurate consistent shots.

Proper coating placement, coverage, and thickness are critical in medical applications. Manual tools and spray systems that allow only coarse adjustment may not provide the controlled, consistent coverage needed to achieve predictable process results and reliable device performance.

Aseptic valves feature a smooth fluid flow path that is free of any entrapment areas. FDA-compliant wetted parts make the valve suitable for CIP (Clean-In-Place) and SIP (Sterilize-In-Place) medical assembly processes.

Aseptic dispense valve wetted components can be made of 316L stainless steel or PTFE, to conform to biopharmaceutical regulations in medical assembly processes. Internal threads can be removed to provide a smooth, easily cleaned fluid flow path, free of entrapment areas and the valve fluid body can be made electro-polished to increase corrosion resistance.

Aseptic valve shot sizes can range from 0.5 microliter deposits to a continuous flow rate of 60 milliliters per second. These dispense valves close after each cycle with a fast, clean cut-off that eliminates drips.

Similarly, aseptic spray valves also feature a fluid flow path that is free of any entrapment areas—a critical consideration in sterile and aseptic fluid applications that use low- to medium-viscosity fluids. An aseptic spray valve works best with a small gauge dispensing tip to produce uniform round spray patterns. Alternatively, some aseptic spray valves can be fitted with fan air caps for a wider area of coverage.



The unique design of the aseptic spray valve is critical for sterile fluid applications.

#### Compatible Fluids

- Saline solutions
- Optical Monomers
- Pill coatings
- Stent coatings
- Silicone oils
- Solvents
- Reagents
- Pharmaceutical fluids

Aseptic valves and aseptic spray valves offer medical device manufacturers an accurate, cost-effective coating method that can increase yields, reduce production costs, and improve process control.

## 4. Is Your Dispensing Line Running as Fast as it Can?

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A dedicated valve controller at the dispensing station simplifies setup and helps valves cycle faster.

If your dispense valves are not cycling fast enough, the valve control system may not be compatible with the dispense valve.

Most automatic assembly machines use PLCs (Programmable Logic Controllers) to sequence machine functions, but a PLC's primary purpose is not to control dispense valves.

A PLC also may or may not offer online programming of dispensing functions. Without this capability, entire production lines have to be shut down just to make simple adjustments to deposit size, and even if a PLC can program valve functions, the valve may not be within the line of sight of the engineer or operator trying to adjust it.

A dedicated controller mounted at the dispensing station will simplify initial valve setup, make it faster and easier to purge the valve after refilling the fluid reservoir, and allow adjustments to be made and checked "on the fly" without shutting down the production line. A devoted valve controller with a fast-acting solenoid and a digital timer can be a simple and cost-effective way to achieve faster cycle times and more precise control of deposit size. The valve controller can also be interfaced with the PLC if desired.

Smaller details in the valve system can also make a big difference. A tapered polyethylene tip, for example, can shorten dispense time by reducing resistance and providing a faster flow rate than a straight metal tip of the same size. Using a fluid line with a larger internal diameter is another way to reduce cycle time in certain applications.

## 5. Would High-Speed Jetting Fit Your Application Needs?

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Jetting valves can dispense a wide range of fluids in volumes as small as 0.5 nanoliters at continuous speeds of up to 1500Hz, or 1500 shots per second, with exceptional process control.

Non-contact jetting systems are capable of dispensing a wide variety of fluids at speeds of up to 1500Hz, or 1500 shots per second. By combining high speed with exceptional accuracy, these systems allow medical products to be built more cost-effectively with consistently high quality.

Additionally, since jet valve systems are non-contact, it is possible to apply fluid in hard-to-access areas or onto uneven or delicate substrates where dispensing needles cannot be used.

Jetting can be used with a wide range of fluids. Applications include:

- Syringes
  - Lubricating interiors with silicone oil
  - Bonding needles with UV adhesive
- Blood bags
  - Sealing bags with cyanoacrylate
- Endoscopes
  - Bonding lenses with optical adhesives
- Test strips
  - Jetting or dispensing protein solution
  - Insulin/blood sugar test strips
  - Veterinarian test strips



## 6. Do Your Valves Leak and Drip?

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Using valves small enough to be mounted at the point of fluid application reduces the risk of drooling.

Leaking is a common problem with valves that have complex designs, or seals and O-rings that wear out over time.

The most reliable diaphragm designs entirely eliminate the need for seals and O-rings. The best valves will easily handle many different fluid applications, and provide tens of millions of cycles without maintenance.

Carefully choosing the valve seat materials will also prevent many problems. UHMW (Ultra High Molecular Weight) polyethylene, for example, provides exceptional wear characteristics and chemical compatibility with a wide range of medical assembly fluids, keeping the valve system working longer without downtime or maintenance.

When valves are too large or heavy to be mounted at the dispensing station, extra time must be spent on design and fixturing. If extra lines and fittings must be added to transfer the fluid from the valve (where cutoff takes place) to the point of deposit, it increases the risk of dripping and drooling.

Using a compact, fast-acting valve that is small enough to be mounted directly at the dispensing station will provide several advantages: greater flexibility in system design, a neater installation that takes up less space, and a cleaner cutoff.

## 7. Is It Difficult to Produce Consistent Shots?

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A digital controller allows for programmable settings that allow for consistent, repeatable deposits.

Valves that require time-consuming manual or mechanical adjustments to establish shot size can make it difficult to dispense a specific amount of fluid. When several valves are used on the same machine or production line without the proper control systems, it is nearly impossible to get each valve to produce an identical shot.

If your valves are taking too long to set up and you cannot obtain consistent results, a valve system with a dedicated controller is a more efficient approach to establish shot size and regulate valve operation. Another advantage of using a controller is that settings can be recorded and saved for the next time that specific job is run, or after maintenance has been performed.

Valve open time is the most precise way to adjust shot size. With a digital valve controller, open time can be adjusted in increments as small as 0.001 seconds, for exceptional control over the amount of material applied.

On production lines with multiple dispensing stations, using a dedicated valve controller at each station can make it simple to adjust each valve's open time independently, and obtain an identical shot from each valve.

## 8. Are You Cutting Corners on Your Dispense Tips?

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“Flash” inside hub of low-quality tip restricts fluid flow.



High-quality tip provides unobstructed fluid path.

Correct tip selection is very important to dispense valve performance. The best choice is using a tip with the largest possible internal opening for the intended application. This will prevent air bubbles from forming.

Tip quality has a surprisingly large effect on the accuracy and uniformity of fluid deposits – especially in critical applications where very small deposits are required.

Trying to save a few cents on lower-quality tips may result in costing more in the long run once factors such as fluid waste and additional operating time are factored. Even the most precise dispensing system will not produce consistent results if the tip – the last path the fluid travels before it reaches the part – is obstructed by debris from the molding or machining process.

Which of these components would you rather use?

## 9. Is Your Current Valve Setup Trapping Air?

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Tips should be selected based on the specific fluid and application.

Entrapped air can cause oozing and variations in shot size. Be sure to purge all air and fluid lines whenever setting up a system, refilling the fluid tank, or performing maintenance. Other recommendations include:

- Keeping air lines shorter than 5 feet to reduce the risk of trapped air and improve valve response time.
- Tip selection is very important, and can help prevent air entrapment. When using metal tips, use 21 gauge (0.020”) or larger if the application permits, as they will allow small air bubbles to purge through.
- Tapered polyethylene tips are a good choice in any size. They allow fluid to flow freely through the tip to purge and prevent air bubbles from collecting. Tapered tips typically range from 14 gauge to 27 gauge.
- Use a valve controller with a purge function that allows the user to bleed any air in the system quickly and easily.
- Use a fluid tank with a constant-bleed air regulator to prevent fluctuations in pressure and shot size.
- Install a filter/regulator between the plant air supply and the dispense valve to remove any residual moisture from the system – this is especially important when working with cyanoacrylates.



## 10. How Often Do Your Valves Require Maintenance?



Required maintenance can greatly vary between valve systems.

All valves will eventually require maintenance, but some designs require more frequent repair than others. Here are some things to consider:

- How often is maintenance required? While a well-engineered valve design will go tens of millions of cycles without any degradation in performance or accuracy, others may require maintenance after they have been shut down over the weekend, or even at the start of every shift.
- If valve maintenance is required, can it be performed on site, or does the valve have to be returned to the manufacturer?
- If service can be performed on site, how complicated is it? Can you simply remove the fluid head without dismounting the valve? Or does the valve have to be removed from the mounting fixture and taken apart? With some high-performance designs, routine maintenance is as simple as replacing the dispense tip.
- Spare parts provided by local machine shops may not always be readily available. This delay could lead to line downtime when replacement parts are needed. Using engineered products that have an abundant supply of replacement parts can add significant value.

If you're spending too much time and money keeping your valves up and running, it might be worth looking at a more reliable, low-maintenance design.

### Should You Replace Your Current Dispense Valve System?

In the middle of coping with day-to-day production challenges, it can be difficult to calculate just how much poor valve performance is really costing you.

However, doing so could save you money, increase production, reduce bottlenecks, and improve the overall quality of your products. It may be worth tracking valve-related problems for a week or so, then converting them into a yearly expenditure.

#### Some key points to analyze:

- How much time and labor are you spending on valve setup?
- How much are valve-related downtime and maintenance labor costing you per year?
- Is most of your valve maintenance scheduled, or do your valves break down unexpectedly?
- If your current valves make it hard to control shot size, how much are you spending on valve-related rework, rejects, and cleanup?
- Are your dispensing stations causing a bottleneck?
- Are you wasting expensive assembly fluid?
- Do you have any valve-related safety issues – spills, fumes, storage/ disposal of hazardous waste?

Depending on the responses you come up with, the most cost-effective solution may be to install a more accurate and reliable dispense valve system.

In many instances, the savings will pay for the new equipment in a surprisingly short time and continue to reduce operating expenses year after year.

# Thanks for Reading!

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We hope you found this information helpful.

If you are not satisfied with the performance of your current dispense valve system, we invite you to discuss your application with one of our experienced Product Application Specialists.

EFD offers dispensing solutions for the following applications:

- Catheters
- Pacemakers
- Contact lenses and packages
- Vial filling
- Syringe lubrication
- Stent coating
- Membranes
- Surgical and dental tools
- Diagnostic equipment
- Respiration devices
- Defibrillators
- Hearing aids
- Pills and medicines
- Needle Bonding
- Blood Collection Tubes

There is no cost or obligation for this service, and your information will be treated as confidential. Qualified applications may be eligible to try an EFD dispense valve system under our no cost-evaluation program.

For more information, visit Nordson EFD on the web at [www.nordsonefd.com](http://www.nordsonefd.com), [www.facebook.com/NordsonEFD](https://www.facebook.com/NordsonEFD) or [www.linkedin.com/company/nordson-efd](https://www.linkedin.com/company/nordson-efd) or contact us at [info@nordsonefd.com](mailto:info@nordsonefd.com), +1 401.431.7000 or 800.556.3484.





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