COMMAND
MEDICAL PRODUCTS

MANAGING TUBING ASSEMBLIES TO PREVENT OCCLUSIONS

PRACTICAL DESIGN, ASSEMBLY, AND TEST CONSIDERATIONS FOR MEDICAL TUBING SYSTEMS

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EXECUTIVE SUMMARY

Occlusion in medical tubing assemblies is a well-known risk, especially when small-diameter tubing is bonded to connectors or other components. Even a partial restriction can affect flow, dosing, or device function, so most device manufacturers want assurance that assembled tubing remains open and functional.

Preventing occlusion is not just a test activity. The biggest impact comes from how the tubing and connector are designed and how the bonding process is controlled. In practice, the key factors are adhesive placement, connector insertion depth, tubing support during bonding, and appropriate verification testing.

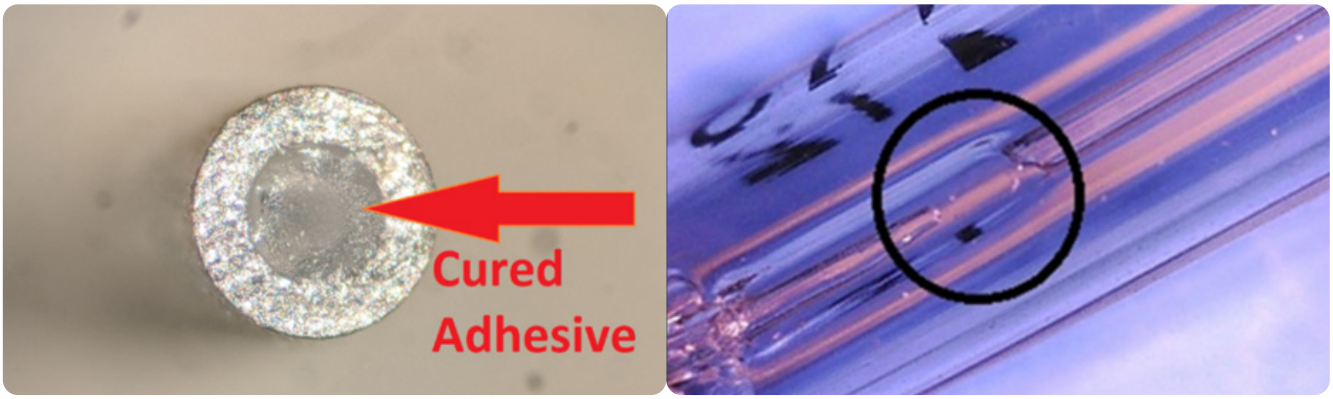
This paper summarizes practical methods used in medical tubing assembly to reduce occlusion risk and to verify lumen patency in a repeatable way.

INTRODUCTION

Most tubing occlusions occur at interfaces where tubing is bonded to a connector, spike, Y-piece, or similar component. These locations combine several risk factors at once: adhesive, mechanical insertion, and geometry changes. The smaller the tube ID is, the more sensitive it becomes to small variations. Experience shows that tubes below roughly 0.063 in ID become especially prone to restriction from adhesive or insertion effects.

In many cases, assemblies arrive for manufacturing with an occlusion requirement already noted on the drawing. At that point, the device designer is expected to both prevent occlusion and define how it will be evaluated. That makes it important to understand where occlusion comes from in real production.

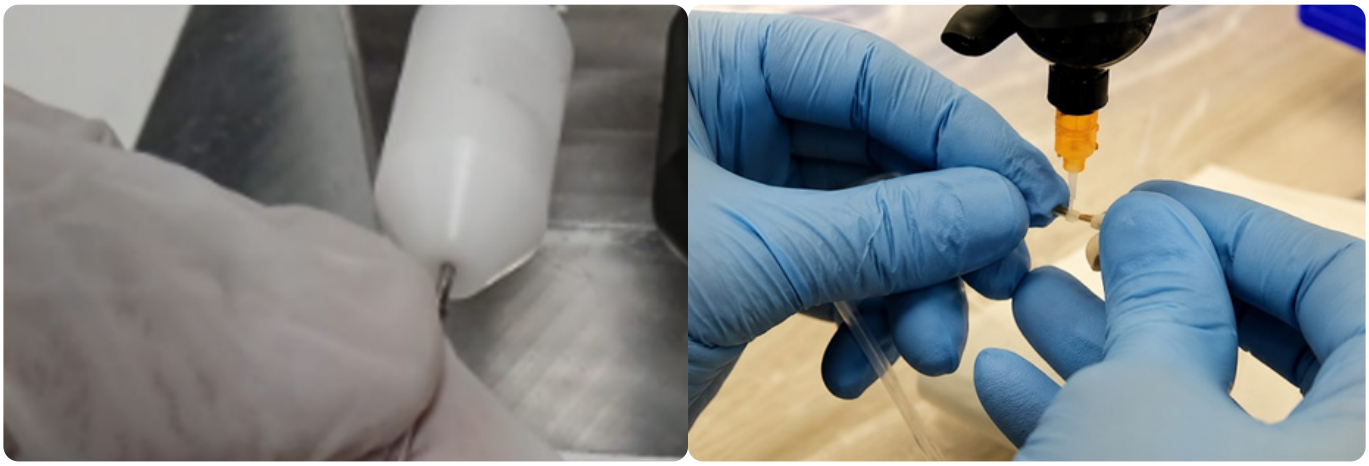
Figure 1.
Fully occluded tube (left) and inner tube diameter partially occluded (right)



Cross-sectional view showing a fully occluded tube, with adhesive that has migrated from the bonding area into the inner diameter of the tube. (Source: Images captured during internal process.)

A highly effective technique is keeping a small airflow through the tubing while bonding. One end of the tube is connected to low air pressure, adhesive is applied, and the connector is inserted while air continues to flow. This keeps adhesives from migrating into the lumen and helps the tube maintain its shape.

Figure 3. End of tube connected to air source (left) and adhesive dispensing onto component to be bonded to free end of tube (right)



One end of the small inner diameter (ID) tube connected to an air source. The opposite end is bonded to the component using adhesive while air is continuously flowing through the tube and exiting the component. (Source: Images captured during internal process.)

Some processes also use a post-bond pin check. A mandrel slightly longer than the connector barb is inserted through the bond area to confirm that adhesive has not entered the lumen. This works well as a detection method, although it does not prevent occlusion and must be done carefully to avoid dislodging adhesive.

Figure 4. Go/No Pin fully inserted in non-occluded bond (left) and Go/No Pin partially inserted in an occluded bond (right)

A Go/No go pin is inserted into the bonded tube/luer assembly to assess occlusion. If the pin can pass through without restriction, the part is considered non-occluded. If resistance is encountered and the pin cannot be fully inserted, the part is considered occluded. (Source: Images captured during internal process.)

WHERE OCCLUSIONS ACTUALLY COME FROM

The most common cause is adhesive entering the lumen during bonding. If the dispense location is too close to the tube end, or the volume is inconsistent, adhesive can wick inside as the connector is inserted. In practice, the "how much" and "where" of adhesive placement matter more than the adhesive itself.

Another frequent issue is connectors being pushed too deeply into the tube. This can collapse the tube wall locally or reduce the internal diameter at the barb interface. There have been cases where simply inserting a Y-connector too far created a measurable restriction.

If the tube is squeezed or supported improperly during bonding, it can deform before the adhesive cures, and that deformation tends to stay in place. It is also important to recognize that assemblies with several diameter changes naturally introduce some flow resistance. Even a clear, unobstructed assembly will not measure zero restriction due to friction and internal geometry.

PREVENTION STARTS IN DESIGN

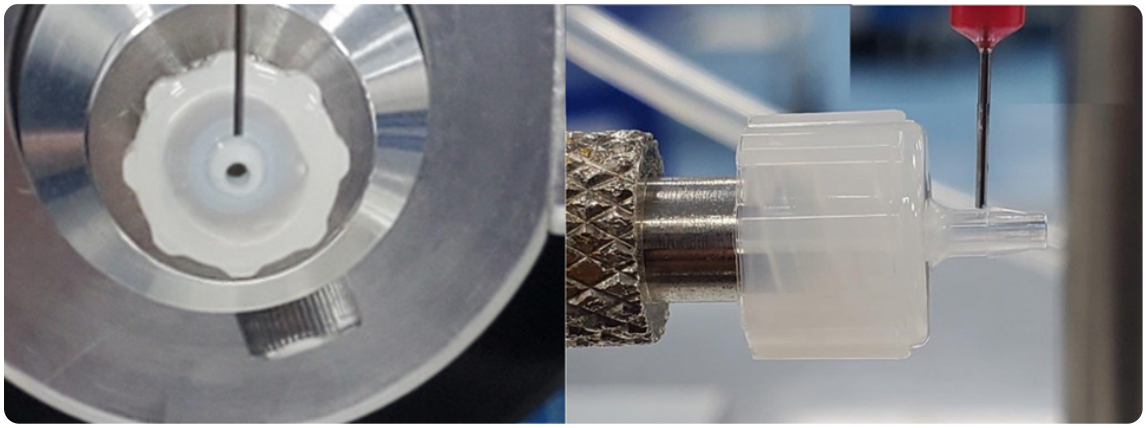
The best place to control occlusion is before the assembly ever reaches production. Connector insertion depth, adhesive zones, and tubing wall support should be defined in the design. Connector geometry needs to match the tubing wall thickness, so the tube is supported but not collapsed.

Device manufacturers are often asked to solve occlusions after the design is frozen. When possible, early discussion between the device designer and the device manufacturer avoids a lot of downstream testing and rework.

CONTROLLING OCCLUSION DURING ASSEMBLY

From a manufacturing standpoint, adhesive control is the single biggest factor. Consistent dispensing equipment, fixed tube and connector location, and defined distance from the tube end all help keep adhesive out of the lumen.

Figure 2. Luer barb centered with dispensing needle (left) and needle location along barb (right)



Luer placed onto a rotational device that ensures repeatability in the positioning of the adhesive dispensing needle, thereby ensuring that adhesive is consistently applied at a location that mitigates the risk of occlusion. (Source: Images captured during internal process.)

HOW OCCLUSION IS VERIFIED

In production, occlusion is usually checked using air pressure or airflow methods. A common approach is a back-pressure test. Air is applied to the assembly, and the downstream pressure response is observed. If the path is restricted, back pressure remains higher than normal.

Flow testing goes a step further by measuring actual airflow through the tubing. This is more sensitive to partial occlusion but requires the test setup to match the tubing size and length. Small-ID tubing especially needs a tester with the right flow range and resolution.

Leak testing can sometimes indicate occlusion as well, particularly if the test sequence includes venting or flow phases. Modern testers can combine leak, flow, and occlusion checks in one program.

AIR TESTS VS. REAL FLUID PERFORMANCE

One ongoing challenge is that device manufacturers typically test with air, while the device may use liquid with quite different properties. A certain airflow reduction does not directly translate to the same liquid flow reduction.

A practical way to bridge this gap is to build assemblies with known partial restrictions and let the device manufacturer test them with the actual fluid. Once acceptable performance is defined, the corresponding air-test limits can be set for production.

DEFINING ACCEPTABLE OCCLUSION

Because every tubing assembly exhibits inherent resistance, acceptance cannot be based on zero pressure or unrestricted flow. Instead, the baseline behavior of an unobstructed assembly should be measured first.
Acceptable occlusion is then defined as an allowable deviation from that baseline.

EQUIPMENT FIT MATTERS

Occlusion and flow testers are not one-size-fits-all. Systems designed for microbore tubing may lack capacity for larger assemblies, while systems sized for larger flow may not have enough resolution for small IDs. The tester configuration needs to match the tubing range being produced.

WHEN OCCLUSION RISK IS HIGHEST

Experience shows that occlusion control and testing are most critical when tubing ID is small, connectors are bonded, or assemblies include multiple components or transitions. Infusion and drug-delivery tubing sets are typical high-risk applications, particularly below about 0.063 in ID.

CONCLUSION

Occlusion in medical tubing assemblies is preventable with robust design and controlled bonding processes. The most effective measures are accurate adhesive placement, supported connector insertion, airflow during bonding, and verification testing matched to the tubing size and function.

Because acceptable restrictions depend on how the device uses the tubing, defining occlusion limits usually requires collaboration between the device manufacturer and the device designer. When design, assembly, and testing are aligned, occlusion risk can be reduced to low levels without adding unnecessary manufacturing complexity.

ABOUT MIGUEL BALLESTEROS

Miguel has more than 15+ years of experience driving operational performance, process optimization, and engineering execution within high-volume manufacturing environments. He has a strong background supporting operational excellence through root cause analysis, process optimization, Kaizen activities, and manufacturing reliability improvements.

ABOUT COMMAND MEDICAL PRODUCTS

Command Medical Products is a contract manufacturer of single use medical devices and custom medical kits, specializing in fluid management applications for infusion therapy, general surgery and laboratory and diagnostic markets.
Across its FDA registered, ISO 13485 certified facilities in Florida and Central America, Command provides precision tubing extrusion, advanced welding, ISO Class 7 clean room assembly, packaging and validation support.
Drawing on decades of medical manufacturing experience, Command combines disciplined quality systems and lean manufacturing with a transparent, highly collaborative approach, giving customers clear visibility, responsive communication and dependable execution throughout product development, manufacturing transfer, commercialization and ongoing production.
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