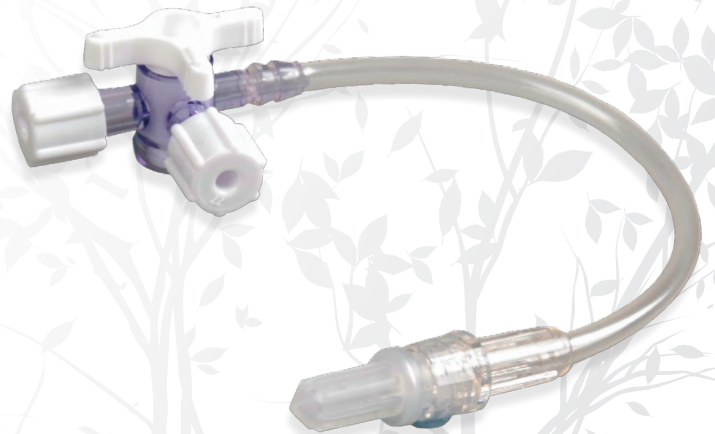


## Solvent Tube Bonding

**Background:** Joining of plastic composites is a practice of long-standing interest in the medical industry. An enormous number of medical disposable products are assembled using plastic joining solvents. Medical devices are becoming more complex and more sophisticated, both in performance specifications and structural complexity. Solvent bonding for assembly of plastic parts is an effective method of making permanent connections. This method produces aesthetic and clean looking joints with low weight and sufficiently strong connections.

Assembling with solvent bonds can be cost saving, but might be tricky in achieving desired performance.

Bonding of medical components involves a thorough understanding in design, material compatibility, performance testing, assembly methods and regulatory affairs.



### Potential difficulties:

- Entrapment of solvent in the joint may compromise the part structure
- Stress cracking and crazing
- High solvent evaporation time due to its entrapment in the polymer matrix
- Assembly hazards such as fire or toxicity and smell
- Rigid process control usually necessary
- Environmental, health, and safety considerations are necessary.

### Advantages:

- Homogenous distribution of mechanical loads (stress)
- Material integrity is maintained
- Ability to seal as well as bond
- Aesthetic design (smooth, blemish-free surface)
- Lower total product cost

### Solvent Bonding Best Practice Key Ingredients:

- Material selection of bonded parts
- Optimized solvent formula
- Rapid bonding cycle time
- Venting & Ventilation
- Solvent dispensing and dosing
- Tube pocket design
- Optimized tube pocket dimensions
- Annealing
- Tube quality and storage conditions

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## Material selection

- Determining factors to be generally observed- mechanical and physical properties of bonded-joint requirements.
- Polymer selection (1) – Solvent bonding is applicable only with amorphous polymers such as Polycarbonate, PVC or Polystyrene
- Stress cracking is more prevalent in low molecular weight polycarbonates;
- It is therefore recommended to select polycarbonates with higher molecular weight which have better resistance to solvent-induced cracking.

## Optimized solvent formula

- The most common solvents for bonding of medical plastic parts is based on Cyclohexanon or Methylene Chloride, usually mixed in different formulas and ratios with other ingredients. Recent concerns about Methylene Chloride health effects have led to a search for alternatives in many of these applications.
- Basically it is known that Cyclohexanone and other solvents might urge stress cracks.

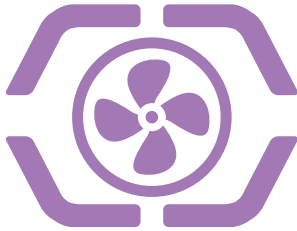


The use of 100% Cyclohexanone is not recommended. It can be mixed in a ratio of 50:50 with Methyl Ethyl Ketone(MEK) and the solvent cement can be further bodied up to 25% by weight with the parent plastic (of the tube) to increase viscosity. By most part PVC or PUR pellets are added to the solvent formula to the above ratio. That kind of bodied solvent cement can fill gaps (2), and provides less shrinkage and internal stress than if only pure solvent is used.

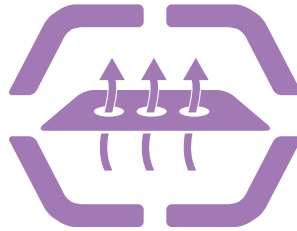
## Venting & Ventilation

- Good aeration to allow solvent vapors release from the product is critical. While the products are drying all ports should be open. It is not recommended to bond while ports are closed, as no vaporization is possible this way. Good ventilation is an essential requirement and exhaust hoods are highly recommended. This evaporation process also results in the continuous thickening of the solvent mix at solvent reservoir. That means that it must be replenished from time to time.
- Any kind of bonding agent has the potential of urging stress cracks if proper aeration and drying is not performed adequately.
- Products should be left for complete solvent evaporation for at least 24 hours (3). This is extremely important in order to avoid internal stress and crack evolvement. It is not recommended to test bonding strength, sterilize or pack the products during that period.

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**Ventilation**



**Ensure adequate venting**

- In case of a male luer lock connector bonding to a stopcock, over torque of the connector over the In case protectors (caps or covers) must be assembled before the end of the bonding and drying stage, it is strongly recommended to use Vented protectors in order to enable vaporization of the bonding agent vapors.

## Solvent dispensing and dosing

- Excess of bonding agent coming in contact with the body material may cause cracks and should be avoided. Solvent trapped inside a joint may lead to porosity and weakness. Only the minimum amount of solvent, to allow proper bonding should be used (2).
- It is advised to perform the bonding process by using a dispensing device. For other processes, attention must be taken to absorb the excess solvent from the tube very carefully, after dipping it in the solvent.
- If excess solvent is present, it is most important that it will not reach the stressed parts, so probably the best way is to aerate the products horizontally positioned.
- When bonding a tube (to a stopcock or another component) it is highly recommended to hold the tube below the stopcock (stopcock's male luer pointing downward) and leave it for at least two hours after the bonding in this position.

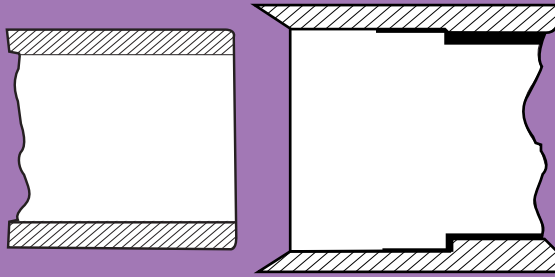


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## Fitment port design & Optimized fitment port dimensions

- The fitment port should be designed to comply with the tube's dimensions and material. Optimized joint geometry will reduce manufacturing cycle time, assembly forces and disqualification percentage. It will also reduce the risks for disconnections and cracking (4).
- Plastic injection molding of some fitment geometries might introduce residual internal stresses, that when comes in contact with organic solvent bonding agents might crack.
- Efforts to reduce stress concentrations formed at the bond-line ends of joints may include the use of tapered or beveled external scarf and radius fillets at the bond-line end.
- It is usually recommended to design a tapered excess solvent trap at the fitment port inlet to allow containment of excessive solvent (3). (see drawing 1)

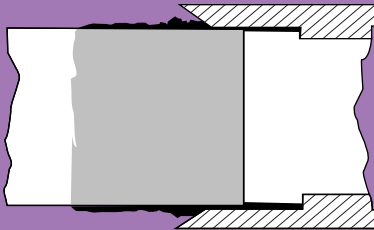
drawing 1



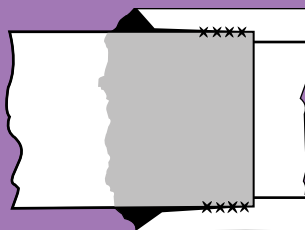
- Fillet at the edge of the bond achieved by internal taper on the inlet thickens the bond-line thus reducing shear stress concentration by separating the strain over a larger dimension.

(see drawing 2 and 3)

drawing 2

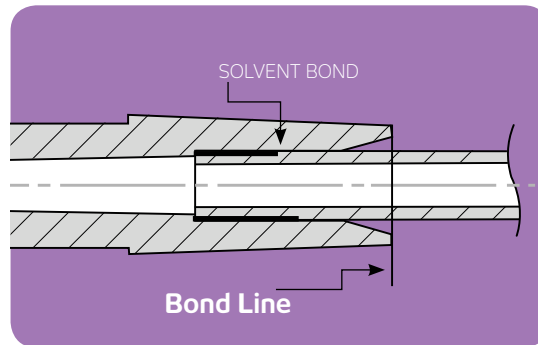
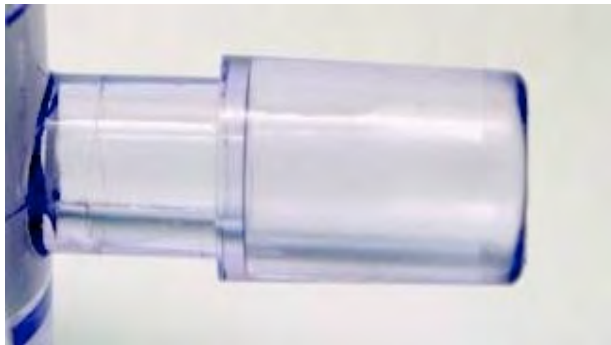


drawing 3



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- It is important to cut the tube square. A square cut provides the surface of the tube with the maximum bonding area and may leave larger area for excess of solvent which is poorly ventilated.



TUBE POKET DESIGN

## Annealing

- Stress cracking or crazing is the formation of microcracks on the surface of a plastic part that has residual internal stresses due to its molding or assembly process. The contact with a solvent will cause the stresses to release uncontrollably resulting in stress cracking of the part. When this is the problem annealing the plastic components (prior to their assembly) can reduce the level of residual stresses and improve the joint resistance to cracking.
- Temperature and time should be chosen according to the thickness and weight of the molded part (2).
- The annealing process should be conducted by a properly validated equipment and method that will ensure an exposure to an equal amount of heat for every component.
- It is recommended to use forced air circulation oven with tight temperature and time control when annealing plastic parts, otherwise temperature variation may occur and parts may be damaged or left un-annealed.
- The annealing temperature must be lower than the plastic's glass transition temperature (marked Tg in the plastic's data sheet).
- The annealing process might introduce undesired trade-offs like surface brittleness and deformations. If possible it is recommended to avoid the need for annealing by optimizing the joint's geometry, material and molding process (5).

## Tube Quality and Storage Conditions

- Medical grade PVC tubing is commonly used in medical devices because it is versatile but it is somewhat sensitive and usually requires special handling procedures that are important to maintain the dimensional tolerances and physical properties
- Commercially available PVC is highly branched and has low crystallinity. Since the reliability of bonds in medical device is of utmost importance it is recommended to use PVC with higher molecular weight (K-Value >100 with number average molecular weight up to 150,000) which has a number of advantages, such as more ordered structure, more linearity, higher degrees of crystallinity, and higher mechanical strength.
- It is important that bonded parts do not undergo physical or chemical changes whilst being stored. Hence it is advised that parts be stowed in orderly pattern- lengthwise /crosswise grid or other interlocking pattern, while maintaining good horizontal alignment in a packaging unit to eliminate all types of physical strain on the bonded area.



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- Moisture can alter the chemistry of both the surface and substrate of the bonds, thus compromising the performance of bonded joints.



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