Solvent Bonding ZYLAR 530 to Standard Medical Grade PVC Tubing Containing DEHP Plasticizer.

The strongest bonds are obtained by bonding ZYLAR 530 to PVC Tubing (DEHP Type) using a dopant solution of 5% G-20 HIFLO Polymer dissolved in cyclohexanone (See Appendix). The use of this bonding technique produces bonds of high strength resulting in tubing failure prior to bond failure in standard pull tests. Note: G-20 HIFLO Polymer is available from Cyro Industries Inc.

Strong bonds can also be obtained by bonding ZYLAR 530 to PVC tubing (DEHP Type) using 100% cyclohexanone. In this technique, the bonds, while strong (see attached test information), will fail prior to tubing failure in standard pull tests. Therefore, this bonding technique is recommended for less demanding applications involving bonding to PVC tubing.

Bonding of ZYLAR 530 to PVC Tubing Containing TOTM Plasticizer.

Customer evaluations have shown that it is difficult to solvent bond ZYLAR 530 to PVC tubing containing TOTM plasticizer. TOTM is a polymeric plasticizer that is used in higher concentration compared to the standard DEHP plasticizer for medical grade PVC tubing. Preliminary testing has been conducted which indicates that strong bonds can be obtained by the use of the following adhesive systems.

Recommended Adhesives for Bonding ZYLAR 530 to PVC Tubing Containing TOTM Plasticizer.

1. Loctite 3301 UV Cure Adhesive 19733.

2. Loctite 4014 (FDM-14) Instand Adhesive 17188. Note: Loctite Corporation should be contacted directly for the appropriate application and curing procedures for these adhesives.

The above listed recommendations are furnished in good faith. However, it is the responsibility of the medical device manufacturer to conduct adequate testing to insure that all materials and assembly procedures used in the device are appropriate for the application. Our bonding recommendations should be considered as starting points only for the more detailed end use testing by the device manufacturer.

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APPENDIX

TEST PROCEDURES AND RESULTS FOR BONDING ZYLAR 530 TO STANDARD MEDICAL GRADE PVC TUBING CONTAINING DEHP PLASTICIZER

1. Experimental Procedure

ZYLAR 530 male luers and standard medical grade PVC tubing (DEHP type) were obtained from a medical device manufacturer. The bonding studies were conducted using 100% cyclohexanone, cyclohexanone/THF combinations, and 3, 5, and 10% G-20 HIFLO dopant solutions.

The bonding technique used was as follows: the PVC tubing (2" in length) was dipped into the solvent formulation to an appropriate depth to insure full coverage of the bond area when assembled to the luers. Time in the solvent formulation was about 1 – 2 seconds and then the tubing was removed, blotted on a paper towel to remove excess solvent and immediately mated to the luer. The mated unit was manually held together for several seconds to allow the initial setting of the bond to occur. Five assemblies were prepared for each solvent formulation. An accelerated aging test procedure was followed. The ZYLAR 530 luer/PVC tubing assemblies were air dried for several hours and then placed in a 60° C oven for one week. The assemblies were then placed in a freezer for one day, followed by three days in the 60° C oven.

Pull tests were performed using a tensile tester. The test speed used was two inches per minute. Pounds of force needed to produce failure (either bond or tubing failure) were recorded.

2. Results and Recommendations (see Table 1)

The strongest bonds as judged by tubing failure rather than bond failure occurred with the use of 5 and 10% G-20 HIFLO dopant solution. We recommend the use of the 5% dopant solution due to its lower viscosity.

All of the various solvent bonding systems used resulted in bond failure rather than tubing failure. We recommend the 100% cyclohexanone system for bonding ZYLAR 530 to PVC tubing (DEHP type). This system is only recommended for less demanding medical applications. Its use would be at the discretion of the medical device manufacturer.

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PROCEDURE FOR PREPARATION OF CYROLITE G-20 HIFLO DOPANT SOLUTION

I. Formulation for preparation of 1,000 grams of 5% Cyrolite G-20 HIFLO Dopant solution:

950G Cyclohexanone (1010 ml. by volume)
50g Cyrolite G-20 HIFLO pellets

II. Procedure

Weigh 950 grams cyclohexanone into clean container large enough to hold dopant solution. An alternate approach is to measure 1010 ml. by volume of cyclohexanone and place into the container.
Add 50 grams of Cyrolite G-20 HIFLO pellets to the cyclohexanone, seal the container, an immediately place on a device that will agitate the pellet/cyclohexanone mixture sufficiently to allow the pellets to dissolve. An example would be a paint shaker.
The amount of time necessary to dissolve the pellets will depend on the amunt of agitation. Very gentle agitation will require 24 hours. The vigorous agitation of a paint shaker will reduce this time considerably (probably to several hours).

III. Notes

a) Please note that the final dopant solution will be translucent in appearance. It will never be totally clear. However, once it has been used to bond a medical device to PVC tubing, the final bond appearance is clear.

b) Once the dopant solution has been prepared, it can be stored for future use. The container should be sealed to prevent loss of solvent by evaporation. It is suggested that the dopant solution be used so that it is not stored for longer than six months.

c) Precautions

i. Do not apply an external heat source to the dopant solution during the solution process. The dopant solution should be stored at room temperature.

ii. Be sure and follow the manufacturer's recommendations for the safe handling of cyclohexanone. This information can be found on the MSDS.

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TABLE 1

Bond Strength of ZYLAR 530 Male Luers to PVC Tubing (DEHP Type)

Solvent Bonding Formulation	Type of Failure	Force to Failure, lbs. Average Value *
100 % Cyclohexanone	Bond	16.8
50/50 Cyclohexanone/THF	Bond	16.0
100% THF	Bond	12.8
3% Cyrolite G-20 HIFLO in Cyclohexanone	Bond	17.9
5% Cyrolite G-20 HIFLO in Cyclohexanone	Tubing	16.6
10% Cyrolite G-20 HIFLO in Cyclohexanone	Tubing	16.7

Notes:

- ✓ Instron test speed in pull tests = 2°/minute
- ✓ Aged one week at 60℃, one day in freezer, three days at 60℃
- ✓ *Average value for five assemblies tested to failure
- ✓ Cyrolite G-20 HIFLO is manufactured by Cyro Industries
- ✓ Cyrolite G-20 HIFLO has passed USP Class VI tests – contact Cyro Industries for verification

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