



May 6, 2002

Todd E. Clark
Environmental Specialist III-C
Duval County Health Department
Environmental Health/Engineering Division
900 University Blvd. N, Suite 300
Jacksonville, Florida 32211

Dear Mr. Clark,

As we discussed by phone last week, I am confirming that it is the position of Saint-Gobain Performance Plastics that our Tygon Brand tubing is not intended for implantation. Typically, this tubing is used for the transmission of body fluids which is accomplished by threading it through a peristaltic pump.

The Food and Drug Administration defines implantation as a period of time greater than 29 days. Specific clearance to market products for this purpose must be obtained from the FDA. It is not Saint-Gobains' intent now, or in the future, to manufacture, label, market or sell the Tygon tubing for this purpose. We have not tested it to these parameters and cannot verify its performance if used in such an unapproved manner.

Our labeling clearly does not state acceptability of use for long term implant, or for body piercing of any type. I hope this clarifies our position.

Very truly yours,

Joanne Moon
General Manager, Health Markets
Saint-Gobain Performance Plastics
700 Warner Boulevard
Taunton, Ma 02780