

**Subject:** Theraworx Catheter Compatibility Test

9 March 2017

**Objective:** Conduct a Compatibility Test between Theraworx and various Catheters.

**Catheters tested:**

1. Coloplast Self-Cath, Female Lot# 3297668
2. Coloplast Self-Cath, Male Lot# 4254416
3. Convatec Gentle Cath, Male Lot# 487525
4. Bard Touchless, Pre-Lubricated, Unisex Lot# NGAW4610
5. Covidien-Dover Red Rubber Lot# 5118R12QX

**Test Conditions**

1. Three of each Catheter are cut to approximately 5 inches in length and weighed.
2. Catheters are placed in closed 16 ounce jars, partially submerged in 200ml of Theraworx Formula.
3. The Catheters in Theraworx are subjected to 37°C (98.6°F) for 5 days.
4. Control Catheters are placed in Distilled Water under same conditions.
5. Upon completion of test, Catheters are photographed, rinsed in Distilled Water, dried @ 50°C for 1 hour and weighed to a hundredth of a gram.

**Results**

**Coloplast Self-Cath Male & Female**

Weight: No change for either the Water Control or the Theraworx solution.

Subjective: Catheters had a slight affinity for the Theraworx solution, having absorbed some color.

**Convatec Gentle Cath Male**

Weight: No change for either the Water Control or the Theraworx solution.

Subjective: No changes observed.

**Bard Touchless, Pre-Lubricated**

Weight: From 0.03 to 0.08 grams lost from those immersed in the Theraworx solution. The changes in weight are likely attributed to the loss of catheter lubricant due to the surface-active nature of the Theraworx solution.

No weight loss for the Water Controls.

Subjective: Catheters had a slight affinity for the Theraworx solution, having absorbed some color.

**Covidien-Dover Red Rubber**

Weight: There was from 0.01 to 0.04 grams gained in both the Water Control and the Theraworx solution.

**Discussion**

37°C was selected for the storage temperature since it is the same as the average internal body temperature.

Although Compatibility Tests are typically conducted for at least three months @ 40°C to achieve a two-year shelf life, conducting this test for that length of time would be excessive since catheters are employed for just a few days. Immersing the catheters in Theraworx solution likely correlates to an even longer test.

#### Summary

Overall, all catheters exhibited compatibility with Theraworx solution. The few hundredths grams weight gain or loss was insignificant. Although there was some color affinity for two of the catheter brands, I do not judge that as an incompatibility issue. Had any catheter gained or lost weight in tenths of a gram or swelled or otherwise distorted that would constitute incompatibility.