



## Technical Paper Latex vs. Non-latex Comparative PAC Balloon Performance

### **Hypothesis:**

The non-latex balloon on the ICU Medical pulmonary artery catheters has identical elasticity performance characteristics as latex balloons on both ICU Medical and Edwards Lifesciences PA catheters. Durability characteristics (burst testing, cycle testing) will show non-latex balloons to be more durable.

## Methodology:

Representative samples of ICU Medical (model 41239-06, 41240-05) and Edwards (model 131F7, K9FC146F7) PAC catheters with latex and non-latex balloons were tested for balloon deployment pressure, passive deflation rate, balloon burst pressure, and inflation cycles to failure. Balloons were also evaluated for balloon conformance to the body of the catheter before and after a single inflation. Results are shown in the table below.

	Balloon Deploy Pressure (PSI) <sup>1</sup>	Deflation Rate (seconds) <sup>2</sup>	Balloon Burst Pressure (PSI) <sup>3</sup>	Inflation Cycle Test to Failure <sup>4</sup>
ICU Medical - latex	11.7	0.66	21.6	163
ICU Medical - non-latex	13.9	0.52	17.1	500+
Edwards - latex	14.1	1.41	16.22	215.6
Edwards - Non-latex	14.7	1.6	21.4	500+

## Definitions:

1. Balloon Deploy Pressure: pressure required to overcome balloon inertia and begin the inflation process (felt at the syringe barrel).
2. Deflation Rate: time required for passive deflation of the balloon.
3. Balloon Burst Pressure: maximum pressure applied before balloon burst occurs.
4. Inflation Cycle Testing: number of inflation cycles completed before balloon failure (leak).

## Observations:

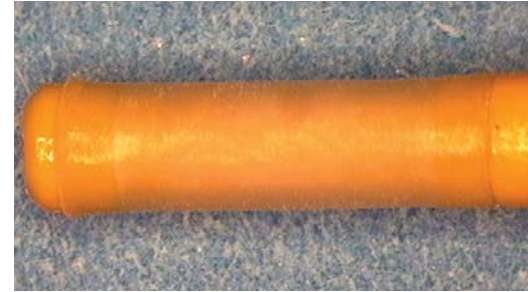
- The ICU Medical PAC balloon matches or exceeds the deployment and deflation characteristics (elasticity) of latex balloons from either ICU Medical and Edwards Lifesciences.
- The ICU Medical non-latex PAC balloon is as durable as the Edwards non-latex balloon but without sacrificing elasticity as does the

Edwards product.

- Edwards non-latex PAC balloon is more durable than the latex equivalents. Material rigidity contributes to this durability but degrades elasticity and performance.

## Balloon Conformity:

### ICU Medical PAC Balloons Without Latex

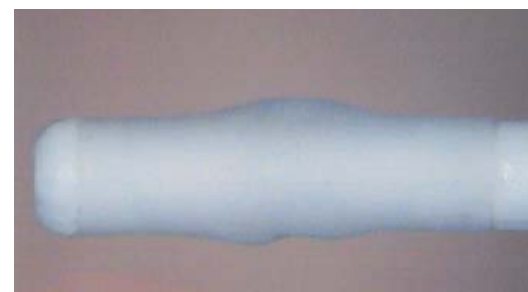


Balloon conformity before inflation.



Balloon conformity after 1 inflation.

### Edwards Lifesciences PAC Balloons Without Latex



Balloon conformity before inflation.



Balloon conformity after 1 inflation.

## Conclusions:

- ICU Medical's PAC balloon without latex demonstrates performance characteristics equivalent to latex balloons.
- ICU Medical's PAC balloon without latex is safer to use:
  - Better balloon/body conformity than the Edwards balloon without latex pre and post inflation.
  - Durability of the ICU balloon without latex meets or exceeds that of other balloon materials.