

Latex vs. Non-latex Comparative PAC Balloon Performance

PURPOSE

In response to risks associated with latex allergies, many manufacturers offer products with non-latex components. The objective of this study was to compare the elasticity and durability characteristics of the non-latex balloon on the ICU Medical pulmonary artery catheters (PAC) to the latex balloons on both ICU Medical and Edwards Lifesciences PA Catheters.

MATERIALS AND METHODS

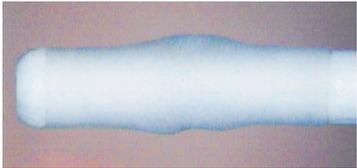
Representative samples of ICU Medical (models 41239-06, 41240-05) and Edwards (models 131F7, K9FC146F7) PA Catheters with latex and non-latex balloons were tested for balloon deployment pressure, passive deflation rate, balloon burst pressure, and inflation cycles to failure. Balloons were also evaluated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

RESULTS

The ICU Medical PAC balloon matched or exceeded the deployment and deflation characteristics (elasticity) of latex balloons from either ICU Medical or Edwards. The ICU Medical non-latex PAC balloon was as durable as the Edwards non-latex balloon, but did not sacrifice elasticity as shown with the Edwards product. The Edwards non-latex balloon was more durable than the Edwards latex equivalents. Material rigidity contributed to the durability of the Edwards non-latex balloon, but degraded elasticity and performance. Results are shown in the table below.

TABLE

ICU Medical latex and non-latex PAC balloons vs. Edwards latex and non-latex PAC balloons				
	Balloon Deploy Pressure (PSI) ¹	Deflation Rate (seconds) ²	Balloon Burst Pressure (PSI) ³	Inflation Cycle Test to Failure ⁴
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+

BALLOON CONFORMITY	ICU Medical PAC Balloons Without Latex	Edwards PAC Balloon Without Latex
Balloon conformity before inflation		
Balloon conformity after 1 inflation		

CONCLUSION

ICU Medical's PAC balloon without latex demonstrated performance characteristics equivalent to latex balloons. In addition, ICU Medical's PAC balloon without latex showed better balloon/body conformity than the Edwards balloon without latex pre- and post-inflation. Durability of the ICU Medical non-latex balloon met or exceeded that of other balloon materials.

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).