

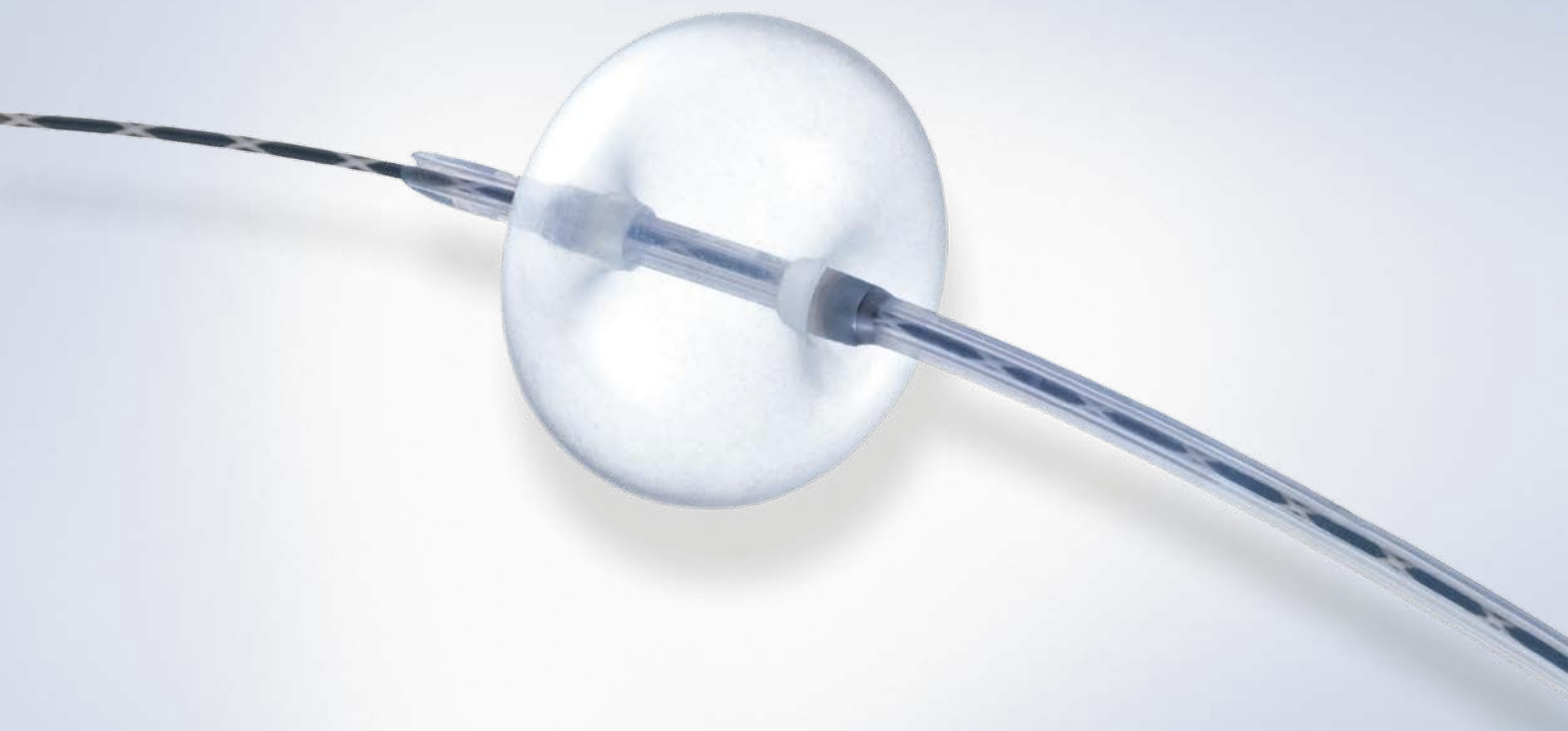
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# MULTI-3 V PLUS

Technical Report



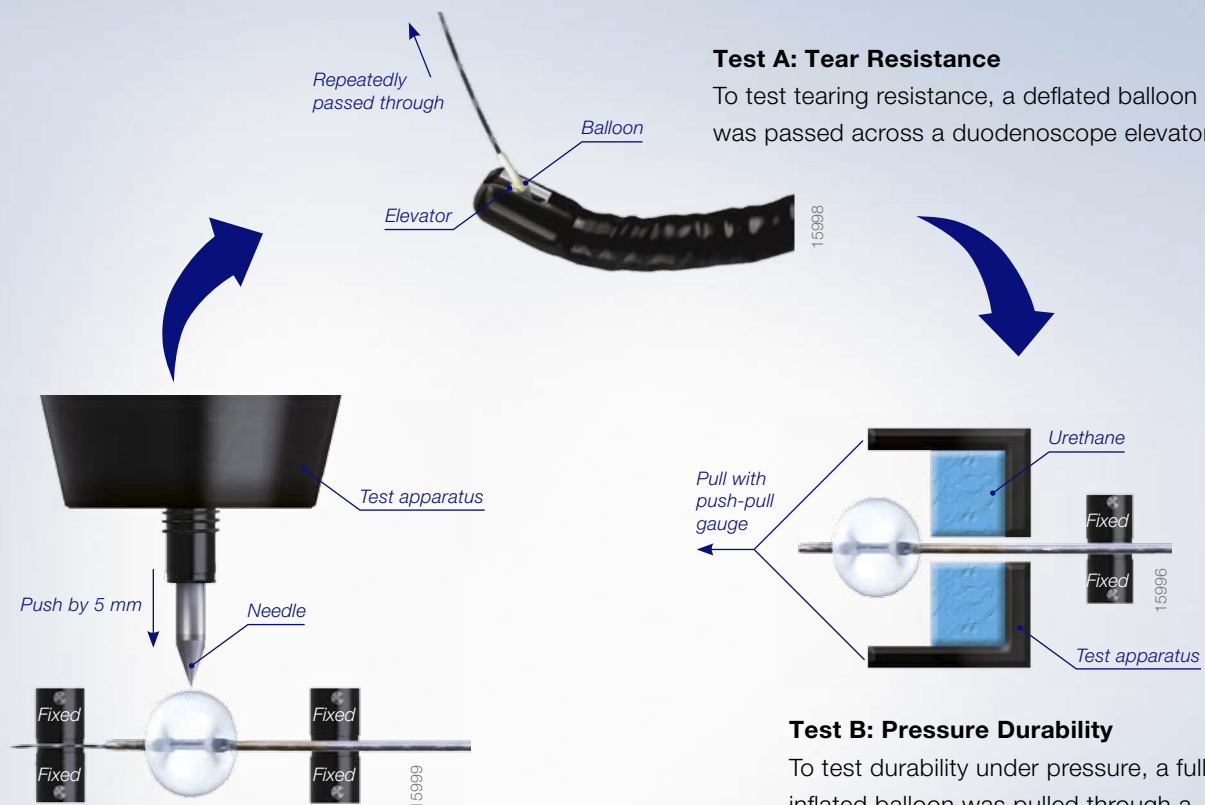
# SETTING THE GOLD STANDARD FOR DURABILITY

## Olympus Multi-3V Plus Extraction Balloon

### Test Methods

To analyze durability performance, the Olympus Multi-3V Plus, and two competitor extraction balloons were tested side-by-side in a laboratory setting. Each balloon brand was evaluated using three durability tests, performed in the following order: Test A—tearing resistance against the duodenoscope elevator; Test B—durability under pressure; and Test C—puncture resistance.

Sample groups comprised of five extraction balloons (n=5) each were used to evaluate each balloon brand. Each extraction balloon in the group was evaluated under identical conditions with three different durability tests repeated in order for five cycles or until rupture. The balloons were inflated to their maximum size according to manufacturer specifications.



#### Test A: Tear Resistance

To test tearing resistance, a deflated balloon was passed across a duodenoscope elevator.

#### Test B: Pressure Durability

To test durability under pressure, a fully inflated balloon was pulled through a small urethane channel at a constant force. The urethane channel was designed to simulate passage through the papilla.

#### Test C: Puncture Resistance

To test puncture resistance, pressure was applied to the surface of a fully inflated balloon by depressing a stylus into the balloon 5 mm.

The balloon was held in place between two fixtures by the balloon catheter at one end and by a wire passed beyond the tip of the balloon at the other end.

### Comparative Results<sup>1</sup>


The table below shows the durability test results for each balloon brand. For example, Sample 1 from the Olympus Multi-3V Plus group successfully completed all three tests for four cycles, but ruptured during the puncture resistance test (Test C) in the fifth cycle.


Comparative Results																
Group	Sample	Cycle 1			Cycle 2			Cycle 3			Cycle 4			Cycle 5		
		A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
Olympus Multi-3V Plus 15-20 mm	1															X
	2															
	3										X					
	4															X
	5															X
Competitor A	1		X													
	2		X													
	3		X													
	4		X													
	5		X													
Competitor B	1						X									
	2		X													
	3	X														
	4		X													
	5		X													

Test A: Tear Resistance

Test B: Pressure Durability

Test C: Puncture Resistance

 = Successful completion

 = Rupture

### Discussion

The test methods used to produce this Technical Report were intended to evaluate the limits of three competitive extraction balloon brands. The samples from the Olympus Multi-3V Plus group successfully completed multiple durability test cycles. All of the samples in Competitor A group failed the durability test (Test B) under pressure in the first test cycle.

Only one sample in Competitor B group passed the first cycle of tests, but that balloon failed during the second cycle. In addition, Competitor B also had a balloon that ruptured during its first tear resistance test (Test A) against the duodenoscope elevator. The most common failure point for Competitor B balloon was its puncture resistance test (Test C).

Among the competitors tested, the Olympus Multi-3V Plus extraction balloon stood out as the most durable based on its ability to pass across the duodenoscope elevator without tearing, hold up under pressure, and resist punctures from a sharp object.

### Conclusion

The Olympus Multi-3V Plus extraction balloon is the gold standard for extraction balloon durability.

# MULTI-3V PLUS

Specifications				
Model	B-V232P-A/B	B-V242Q-A/B	B-V432P-A/B	B-V442Q-A/B
<b>Maximum Balloon Diameter</b>	15 mm	15 mm	20 mm	20 mm
<b>Sheath Diameter</b>	Tip: 4.5 Fr, Distal end: 5.5 Fr, Proximal end: 7 Fr	Tip: 4.5 Fr, Distal end: 5.5 Fr, Proximal end: 7 Fr	Tip: 4.5 Fr, Distal end: 5.5 Fr, Proximal end: 7 Fr	Tip: 4.5 Fr, Distal end: 5.5 Fr, Proximal end: 7 Fr
<b>Sheath Design</b>	Over-the-wire	Distally wire-guided	Over-the-wire	Distally wire-guided
<b>Working Length</b>	190 cm	195 cm	190 cm	195 cm
<b>Minimum Channel Size</b>	2.8 mm	3.2 mm	3.2 mm	3.2 mm
<b>Compatible Guidewire</b>	0.035 inch	0.035 inch	0.035 inch	0.035 inch
<b>Radiopaque Band</b>	One band at the distal end and one band at the proximal end	One band at the distal end and one band at the proximal end	One band at the distal end and one band at the proximal end	One band at the distal end and one band at the proximal end
<b>Syringes*</b>	8.5/11.5/15 mm	8.5/11.5/15 mm	15/18/20 mm	15/18/20 mm
<b>Lumen</b>	Triple lumen	Triple lumen	Triple lumen	Triple lumen
<b>Injection Port</b>	A: Above type, B: Below type	A: Above type, B: Below type	A: Above type, B: Below type	A: Above type, B: Below type

(\*3 per balloon package)

1 Data on file at Olympus

Specifications, design, and accessories are subject to change without any notice or obligation on the part of the manufacturer.

**OLYMPUS**

**OLYMPUS EUROPA SE & CO. KG**  
 Postbox 10 49 08, 20034 Hamburg, Germany  
 Wendenstrasse 14-18, 20097 Hamburg, Germany  
 Phone: +49 40 23773-0, Fax: +49 40 233765  
 www.olympus-europa.com

