THE PROVEN SOLUTION IN DISSECTION[1]

Preperitoneal distention balloons for laparoscopic inguinal hernia repair

Twenty-four years of clinical use — and more than 1 million balloons deployed worldwide since 2013.[1,2]

Preperitoneal distention balloons have a history of success, proven performance, and quality.[1]

Benefits of balloon dissection compared to telescopic dissection:

- Four times lower conversion rate from TEP to TAPP/open[3,†]
- Eight minute shorter average operating time[3,‡]
- Significantly reduced postoperative pain at six hours[4,§]
- Lower rate of seroma[4,Ω]
- Lower incidence of scrotal edema[4,††]



†2.5 percent versus10.6 percent, p = 0.002.
‡55 minutes versus 63 minutes, p = 0.004.
§3.4 (±1.2) pain score on VAS versus 4.3 (±1.2) pain score, p < 0.021.
Ω17.9 percent versus 64.3 percent, p < 0.001.
††One patient versus nine patients, p < 0.01.

Medtronic
Further, Together

SAFE[4,8] EFFICIENT[7] **EASY[7]**

The preperitoneal distention balloon separates tissue planes, forming a discrete cavity.



‡‡39 out of 50 hernia surgeons surveyed in the US by Ipsos agreed; 28 out of 48 hernia surgeons surveyed in Europe by Ipsos agreed.

§§35 out of 50 hernia surgeons surveyed in the US by Ipsos agreed; 25 out of 48 hernia surgeons surveyed in Europe by Ipsos agreed.

Balloon dissection is the preferred method for development of the preperitoneal space in TEP inguinal hernia repair.[5]



A majority of hernia surgeons agree that dissection using a preperitoneal balloon is safe and effective[‡‡] and easier to perform [§§] than manual dissection.[6]

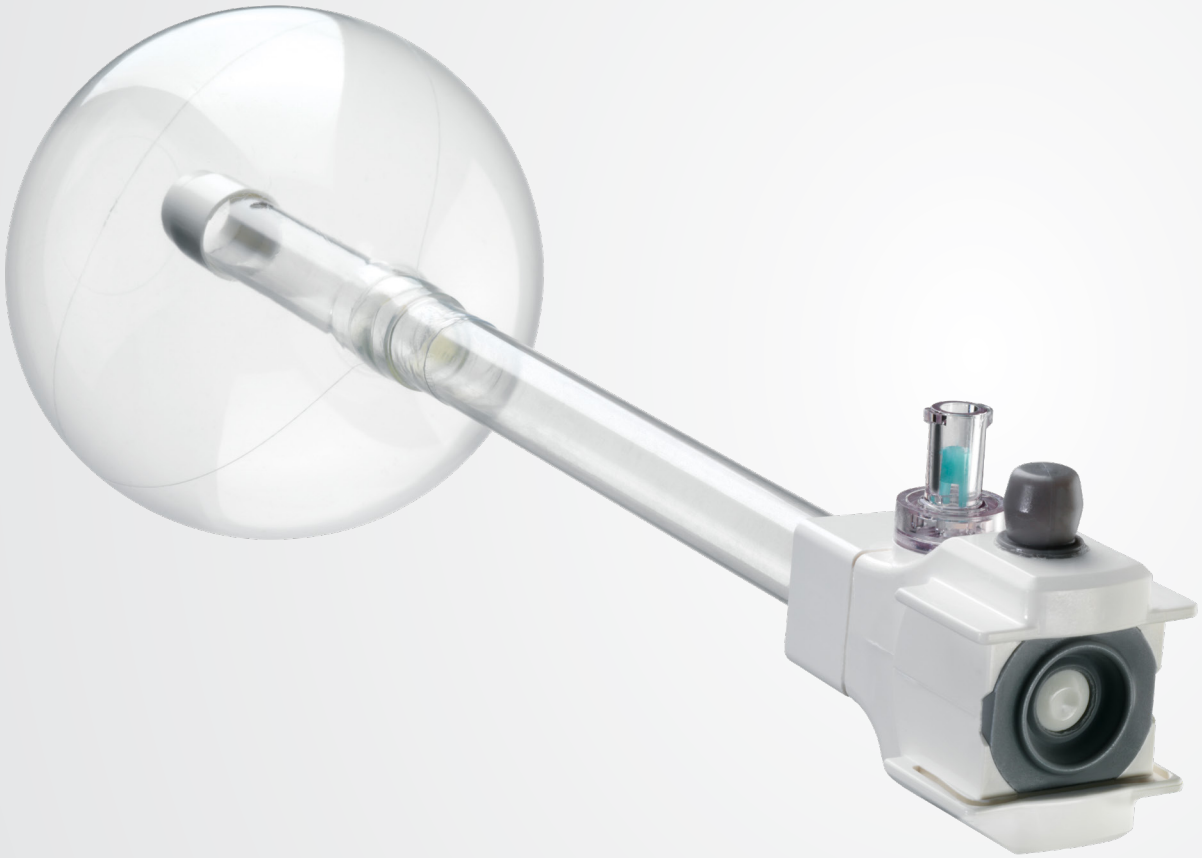
A SURGEON'S **PERSPECTIVE**

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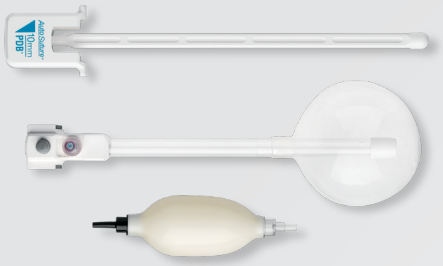


"As a high-volume surgeon performing about 400 laparoscopic inguinal hernia repair procedures each year, I carefully choose the surgical techniques and products that will result in the best outcomes for my patients. I have been using Medtronic dissection balloons for about 14 years in all of my laparoscopic inguinal hernia repair cases.

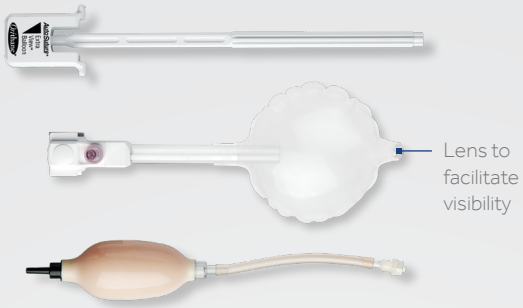
In my opinion, the key benefit of Medtronic dissection balloons is that they provide a clear view of the working space. The balloon dissects the preperitoneal space under direct visualization, allowing me to see the tissue planes. The risk of tears in the peritoneum is extremely low when using a dissection balloon because of the benefit of dissection under direct visualization. It is easy to use, and it saves me time in the OR compared to telescopic dissection. The balloon also helps to prevent early postoperative complications such as seroma and scrotal edema."



PDB™ System



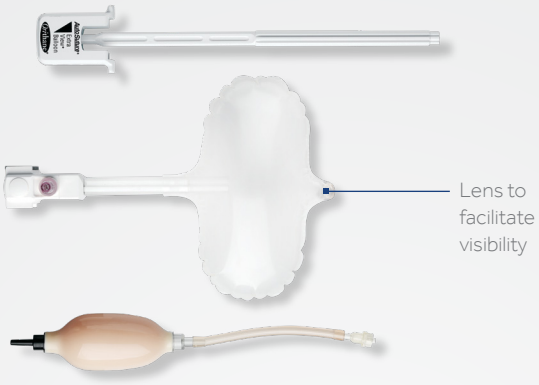
OMSPDB1000 – PDB™ round distention balloon



OMSXB1 – Extra View™ round distention balloon



OMSPDBS2 – PDB™ oval distention balloon



OMSXB2 – Extra View™ oval distention balloon

Extra View™ Balloons

Please refer to the instructions for use for complete indications, contraindications, warnings and precautions.

1. Based on internal analysis of IBM Cognos sales data. April 2018.
2. U.S. Food & Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K935426 Preperitoneal Distention Balloon System 510(k). Accessed April 17, 2018.
3. Bringman S, Ek A, Haglind E, et al. Is a dissection balloon beneficial in totally extraperitoneal endoscopic hernioplasty (TEP)? A randomized prospective multicenter study. *Surg Endosc.* 2001;15(3):266-270.
4. Misra M.C., Kumar S, Bansal V.K. Total extraperitoneal (TEP) mesh repair of inguinal hernia in the developing world: Comparison of low-cost indigenous balloon dissection versus direct telescopic dissection: A prospective randomized controlled study. *Surg Endosc.* 2008;22(9)1947-1958.
5. Sherwinter D, Garg M. The effect of balloon positioning on pre-peritoneal dissection in laparoscopic inguinal hernia repair. *Hernia* 20(1): S89.
6. Based on internal report, Spacemaker™ Plus enhancement: evaluation and price optimization, based on research conducted by Ipsos in the US, UK, Germany and France, October 2013.
7. PDB™ System [instructions for use]. Mansfield, MA: Medtronic; 2011.
8. Koksal N, Altinli E, Sumer A, et al. Impact of Herniorraphy Technique on Testicular Perfusion: Results of a Prospective Study. *Surg Laparosc Endosc Percutan Tech.* 2010; 20:3

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