Clinical evidence

Proven track record: HARMONIC® technology has successfully ligated vessels in VATS lobectomy since 2008

2008-2014	**Six-year clinical retrospective** with HARMONIC® technology in VATS[1]	**82** patients **97** PA branches sealed **21** PVs sealed	"Its narrow profile and thin blades make it ideal for ligation of pulmonary vasculature, particularly where the size and necessary clearance of mechanical staplers prohibit safe dissection."
2014	**Pilot study:** Benchtop burst pressure comparison of 4 advanced energy devices[2]	**14** patients **49** PA branches sealed	Strong seals with HARMONIC ACE® Shears
2015	**Benchtop burst pressure comparison** of HARMONIC ACE®+ Shears to stapler (white reload)[3]	**43** patients **90** PA branches sealed with HARMONIC ACE®+ **47** PA branches sealed with stapler	Mean BP • HARMONIC ACE®+, 333 mmHg • Stapler, 114 mmHg P<0.001
2016	**Preclinical animal survival** with HARMONIC ACE®+7[4]	**10** animals **21** PA branches sealed	All animals survived 30 days without hemothorax and no postoperative bleeding.
2017	**Phase 1 clinical trial** with HARMONIC ACE®+7[5]	**10** patients **14** PA branches sealed	PA branch sealing of vessels ≤7mm in diameter with HARMONIC ACE®+7 was effective in open lobectomy.
2018	**Phase 1 clinical trial** with HARMONIC ACE®+7[6]	**20** patients **31** PA branches sealed	PA branch sealing of vessels ≤7mm in diameter with HARMONIC ACE®+7 was effective in VATS lobectomy.
2019	**Phase 2 clinical trial** with HARMONIC ACE®+7[7]	**150** patients **239** PA branches sealed	PA branch sealing: HARMONIC ACE®+7 during VATS lobectomy for vessels ≤7mm in diameter was effective. The use of HARMONIC ACE®+7 is a reasonable sealing method for small PA branches.

PA = pulmonary artery
PV = pulmonary vein
BP = burst pressure

1 White A, Kucukak S, Lee DN2, Swanson SJ. | Ann Thorac Surg. 2016 Apr;101(4):1334-7. **2** Liberman M, et al. Pilot study of pulmonary arterial branch sealing using energy devices in an ex vivo model. J Thorac Cardiovasc Surg. 2014 Dec;148(6):3219-23. **3** Liberman M, et al. Pulmonary Artery Sealing Using the HARMONIC® ACE Shears for Video-Assisted Thoracoscopic Surgery Lobectomy. Ann Thorac Surg. 2015 Sep;100(3):898-903. **4** Goudie E, Liberman M, et al. Pulmonary Artery Sealing with an Ultrasonic Energy Device in Video-Assisted Thoracoscopic Surgery Lobectomy: An Animal Survival Study. Ann Thorac Surg. 2016 Oct;102(4):1088-94. **5** Goudie E, Liberman M, et al. Pulmonary artery sealing with ultrasonic energy in open lobectomy: A phase I clinical trial. J Thorac Cardiovasc Surg. 2017 Jun;153(6):1600-1607. **6** Goudie E, Liberman M, et al. Phase 1 Trial Evaluating Safety of Pulmonary Artery Sealing with Ultrasonic Energy in VATS Lobectomy. Ann Thorac Surg. 2018 Jan;105(1):214-220. **7** Liberman M, et al. Prospective, multicenter, international phase 2 trial evaluating ultrasonic energy for pulmonary artery branch sealing in video-assisted thoracoscopic surgery lobectomy. J of Thoracic and Cardiovascular Surgery. Sep 2019. DOI 10.1016/j.jtcvs.2019.09.061.

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