

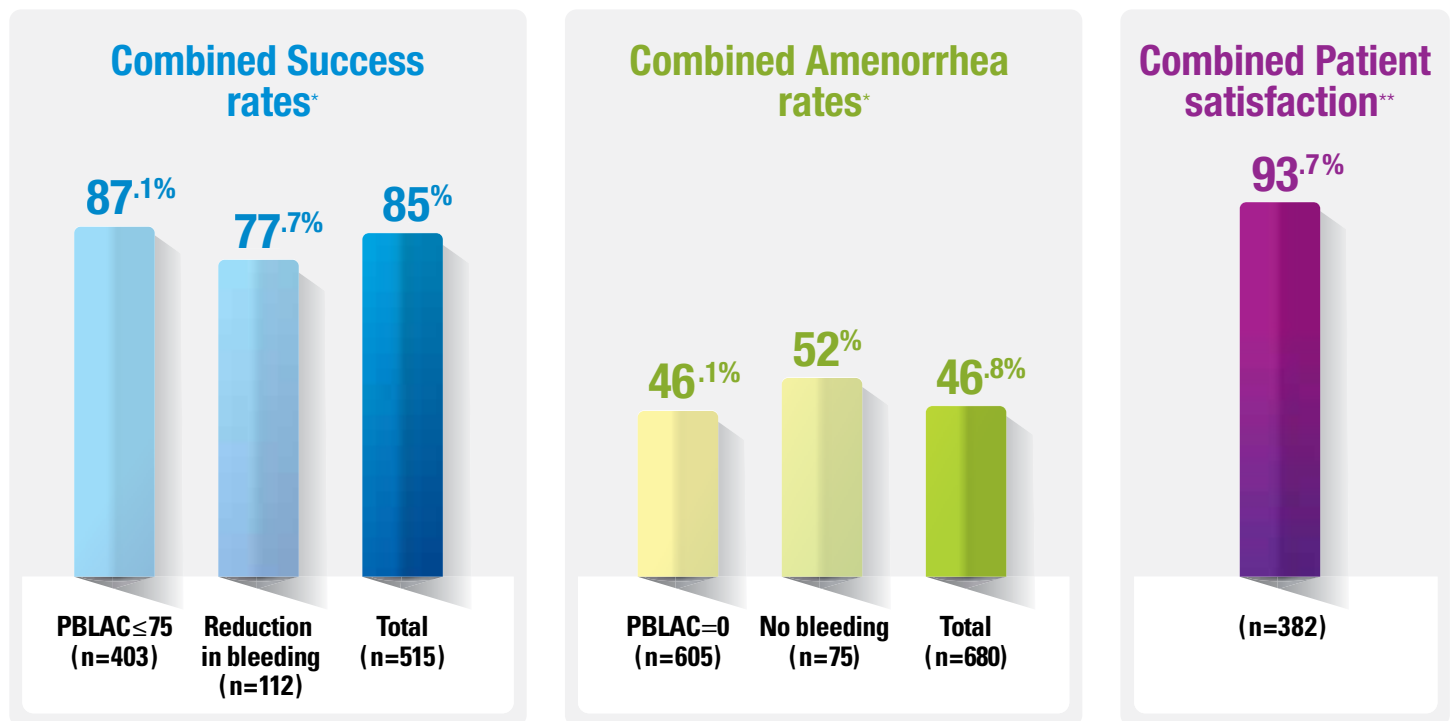
# NovaSure Endometrial Ablation Aggregate Data

After 14 years of treating AUB with minimally invasive, safe, non-hormonal treatment, the NovaSure endometrial ablation system has time tested and durable results. The proven high rate of success, amenorrhea and patient satisfaction are not only a testament to the **2 million women treated** but also are confirmed through long-standing, extensive, prospective clinical data.

The below data is representative of:

- Over 700 subjects
- 10 peer-reviewed publications
- A proven record of safety and efficacy

*"The definition of treatment success is necessarily subjective and perhaps best based on a woman's satisfaction level and willingness to continue a particular therapy"*



\*1-year rates based on an intent-to-treat population

\*\*1-year rates based on an evaluable.

**METHODOLOGY:** Ten prospective studies, six single-arm NovaSure trials and four randomized controlled trials were reviewed for amenorrhea rate, success rate and patient satisfaction. The follow-up period for these measures was 12 months. Studies were chosen based on similar protocols and endpoints.

**REFERENCES:** 1. Marjoribanks J, Lethaby A, Farquhar C. Surgery versus medical therapy for heavy menstrual bleeding. Cochrane Database of Systematic Reviews 2006, Issue 2. Art. No.: CD003855. DOI: 10.1002/14651858.CD003855.pub2.

#### NovaSure Aggregate Data - Bibliography

- Cooper J, Gimpelson R, Laberge P, Galen D, Garza-Leal JG, Scott J, Leyland N, Martyn P, Liu J. A randomized, multicenter trial of safety and efficacy of the NovaSure system in the treatment of menorrhagia. J Am Assoc Gynecol Laparosc. 2002 Nov;9(4):418-28.
- Gallinat A, Nugent W. NovaSure impedance-controlled system for endometrial ablation. J Am Assoc Gynecol Laparosc. 2002 Aug;9(3):283-9.
- Busund B, Erno LE, Grønmark A, Istre O. Endometrial ablation with NovaSure GEA, a pilot study. Acta Obstet Gynecol Scand. 2003 Jan;82(1):65-8.
- Fulop T, Rákóczi I, Barna I. NovaSure impedance controlled endometrial ablation: long-term follow-up results. J Minim Invasive Gynecol. 2007 Jan-Feb;14(1):85-90.
- Baskett TF, Clough H, Scott TA. NovaSure bipolar radiofrequency endometrial ablation: report of 200 cases. J Obstet Gynaecol Can. 2005 May;27(5):473-6.
- Clark TJ, Samuels N, Malick S, Middleton L, Daniels J, Gupta J. Bipolar Radiofrequency Compared With Thermal Balloon Endometrial Ablation in the Office: A Randomized Controlled Trial. Obstet Gynecol. 2011 May;117(5):1228.
- Abbott J, Hawe J, Hunter D, Garry R. A double-blind randomized trial comparing the Cavaterm and the NovaSure endometrial ablation systems for the treatment of dysfunctional uterine bleeding. Fertil Steril. 2003 Jul;80(1):203-8.
- Bongers MY, Bourdrez P, Mol BW, Heintz AP, Brölmann HA. Randomised controlled trial of bipolar radio-frequency endometrial ablation and balloon endometrial ablation. BJOG. 2004 Oct;111(10):1095-102.
- Penninx JP, Mol BW, Engels R, van Rumste MM, Kleijn C, Koks CA, Kruitwagen RF, Bongers MY. Bipolar radiofrequency endometrial ablation compared with hydrothermablation for dysfunctional uterine bleeding: a randomized controlled trial. Obstet Gynecol. 2010 Oct;116(4):819-26. doi: 10.1097/AOG.0b013e3181f2e3e3.
- Athanatos D, Pados G, Venetis CA, Stamatopoulos P, Rouso D, Tsolakidis D, Stamatopoulos CP, Tarlatzis BC. Novasure impedance control system versus microwave endometrial ablation for the treatment of dysfunctional uterine bleeding: a double-blind, randomized controlled trial. Clin Exp Obstet Gynecol. 2015;42(3):347-51.

**NOTE:** Please refer to the IFU for risk information.