

# MyoSure® Tissue Removal System

## Efficacy - one year follow-up

### Twelve Month Outcomes for Patients Undergoing Hysteroscopic Morcellation of Uterine Polyps and Myomas in an Office or Ambulatory Surgical Center

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#### Abstract

**Study Objective:** To examine efficacy of hysteroscopic removal of polyps and myomas on health-related quality of life and symptom severity at 1-year post-procedure.

**Design:** Randomized, prospective, comparative setting clinical trial. (Canadian Task Force classification II-2)

**Setting:** Nine outpatient obstetrics and gynecology practices and hospitals in the U.S.

**Patients:** Women 18 to 55 years of age with polyps and/or Type 0 or I myomas  $\geq 1.5$  cm and  $\leq 3.0$  cm.

**Interventions:** Treatment of polyps and fibroids with the MyoSure device.

**Measurements and Main Results:** A total of 118 lesions (76 polyps, 42 myomas) were removed. Among the 118 pathologies removed, 53 were removed in an office setting (28 myomas, 25 polyps) and 55 were removed in an ambulatory surgical center (ASC) setting (14 myomas, 41 polyps). The mean percentage of pathology removed was 95.9 +/- 6.8% for fibroids and 99.9 +/- 0.7% for polyps. Symptom severity as measured by the UFS-QOL scale improved significantly ( $p < .01$ ) between baseline (mean score of 67.5 +/- 15.4) and 12 months postprocedure (mean score of 22.3 +/- 22.6). Health related quality of life as measured by the HRQOL scale also improved significantly ( $p < .01$ ) between baseline (mean score 38.7 +/- 23.3) and 12 months post-procedure (mean score of score 83.9 +/- 24.4). Both the office and ASC groups demonstrated a statistically significant ( $p < .01$ ) improvement in UFS-QOL and HRQOL. Conclusion: For women with intrauterine polyps and/or myomas who suffered from abnormal uterine bleeding, hysteroscopic morcellation with the MyoSure device provided significant, durable health related quality of life improvements up to 12 months post-procedure. These findings held for patients treated in both office-based setting and ambulatory surgical centers.

#### Safety

- No bleeding adverse events
- Low fluid deficit (mean fluid deficit of 461.0 cc)

#### Effectiveness

- 99.9% of polyps and 95.9% of fibroids removed

#### Satisfaction

- 89.2% patient satisfaction
- Significant UFS-QOL reduction and improvement in HRQOL
- 95.9% of patients would consider similar treatment again
- 100% of patients would recommend similar treatment

