TruClear™

PREMIER SURGICAL
Accessible Support, Advancing Surgery

Clinical Findings on intrauterine tissue removal with the **TruClear™ System**

Gentle Resection

Clinical implementation of the hysteroscopic morcellator for removal of intrauterine myomas and polyps. A retrospective descriptive study.

Hamerlynk TW, Dietz V, Schoot BC. Gynecol Surg. 2011;8(2):193-196.

This study concludes that the TruClear™ system is a fast, safe, and easy method for removal of polyps and smaller type 0 and 1 myomas. It also notes that there was no significant intraoperative or postoperative bleeding documented during the study.

Evaluation of hysteroscopic polypectomy and submucosal fibromyomectomy with the use of TruClear™ system morcellator in comparison with conventional resectoscopy. The Greek experience.

Mathiopoulos D, Vlachos S, Tsiaousi I, Giatrakou M. Gynecol Surg. Paper presented at: 20th Annual Congress ESGE. 2011. 10. 9, S61.

This study showed the TruClear™ system reduced the operating time and was safer in comparison to conventional resectoscopy, particularly when treating myomas. The system was evaluated based on the following criteria: operating time, fluid loss, visibility, normal saline usage, serious complications (perforation and bleeding), and learning curve.

Hysteroscopic Morcellation Compared with Electrical Resection of Endometrial Polyps. A Randomized Controlled Trial

Paul P. Smith, MBChB (Hons), Lee J. Middleton, MSc, Mary Connor, MD, and T. Justin Clark, MD (Hons)

This study concludes that in comparison to electrosurgical resection during hysteroscopic polypectomy, morcellation was significantly quicker, less painful, more acceptable to women, and more likely to completely remove endometrial polyps compared with electrosurgical resection.

The icon of hysteroscopic future or merely a marketing image? A systematic review regarding safety, efficacy, advantages, and contraindications.

Noventa M, Ancona E, Quaranta M, et al. Repro Sci. 2015;22(10):1289-1296. doi: 10.1177/1933719115578929.

A review of all available evidence pertaining to the use of intrauterine morcellators (IUM) was conducted to compare IUM systems to traditional resectoscopy and outpatient operative hysteroscopy, inclusive of 1,185 patients. The available evidence allows us to consider IUM devices – such as the TruClear™ system – as a safe, effective, and cost-effective tool for the removal of intrauterine lesions such as polyps, myomas (type 0 and type 1), and placental remnants. Evidence regarding the TruClear™ 5.0 system suggests that it may represent the best choice for office hysteroscopy.

Therapeutic Hysteroscopy in an Outpatient Office-Based Setting Compared to Conventional Inpatient Treatment: Superior? A Cohort Study.

Smits, R.M, Kuijsters, N.P., Braam, L., van Vliet, H.A., Schoot, B.C. Gynecological Surgery. 2016:13(4);339-44. doi:10.1007/s10397-016-0974-0

Overall, office-based hysteroscopic procedures (including hysteroscopic tissue removal with the TruClear™ system) with the use of sedation and analgesia are safe, with a low complication rate, not painful and lead to substantially shorter operation and admission times. Office-based hysteroscopic procedures could lead to lower healthcare costs. Cost-effectiveness analysis and randomized controlled trials should be performed to give a definite answer on this topic.

Targeted Pathology Removal

Histopathological outcomes following operative intrauterine morcellation of endometrial polyps: a cohort study.

AlHili MM, Hopkins MR, Shannon LK, Famuyide AO. J Minim Invasive Gynecol. 2010;17(6), S38.

This study concludes that diagnosis of morcellated intrauterine specimens, from the TruClear™ system, is no different from those obtained via hysteroscopic resection and is within the Mayo Clinic's standard of 3–5 percent alteration.

Hysteroscopic enucleation of type ii submucosal uterine leiomyomas using a TruClear™ system hysteroscopic morcellator: case report and review of the literature.

Pakrashi T, Ressler IB, Sroga JM, DiPaola KB, Thomas MA, Lindheim SR. J Laparoendosc Adv Surg Tech. 2013;23(4):378-382.

This case report describes the surgical principles that guided a complete enucleation of a Type II leiomyoma using the TruClear™ system. Postoperatively, sonohysterography showed complete closure of the dead space with only a slightly distorted endometrial cavity. This report is an example of how the TruClear™ system may allow for complete enucleation during hysteroscopic resection of Type II leiomyoma(s) at the hands of an experienced surgeon.

Long-term outcomes after intrauterine morcellation vs hysteroscopic resection of endometrial polyps.

AlHili MM, Nixon KE, Hopkins MR, Weaver AL, Laughlin-Tommaso SK, Famuyide AO. J Minim Invasive Gynecol. 2012;20(2):215-221.

This study concludes that compared with electrical resection, intrauterine tissue removal using the TruClear™ system may be associated with lower recurrence of endometrial polyps. However, the incidence of recurrent abnormal uterine bleeding (AUB) is independent of polypectomy method. This article also notes that there were no reports of inability to establish a histopathologic diagnosis among all pathology specimens evaluated.

An alternative approach for removal of placental remnants: hysteroscopic morcellation.

Hamerlynck TW, Blikkendaal MD, Schoot BC, Hanstede MM, Jansen FW. J Minim Invasive Gynecol. 2013;20(6):796-802.

This study concludes that hysteroscopic tissue removal seems to be an effective technique for the management of placental remnants, with complete removal in 94.3 percent of patients. The TruClear™ system may also reduce the need for additional removal procedures.

Descriptive study of a new diagnostic-therapeutic hysteroscopic morcellation system.

Pampalona JR, Bastos MD, Mancebo Moreno G, et al. Progresos de Obstetricia y Ginecologia. 2013;56(9):482-488.

The new tissue removal system is a safe and effective diagnostic-therapeutic technique for the outpatient management of endometrial polyps. Completed in an outpatient setting, a prospective study between June 2011 and January 2012 performed polypectomies on 100 patients using the TruClear™ system. The polypectomy procedure was 100 percent successful in all patients and none of the patients were referred on for future surgery. Tolerance was moderate to good in 91.3 percent of the patients.

A comparison of hysteroscopic mechanical tissue removal with bipolar electrical resection for the management of endometrial polyps in an ambulatory care setting: preliminary results.

Pampalona JR, Bastos MD, Mancebo Moreno G, et al. J Minim Invasive Gynecol. 2015;22(3):439-455.

This study was designed to compare efficacy, pain, and the learning curve associated with the treatment of polypectomies using the TruClear™ system versus bipolar electrical resection in an ambulatory care setting. If a successful procedure is predicated on access to cavity, visualization, and complete resection and excision of endometrial polyp, the TruClear™ system shows a higher success rate than the Versapoint™* bipolar electrosurgery system at 92 percent and 77 percent, respectively.

Hysteroscopic polypectomy in an office setting: specimen quality assessment for histopathological evaluation.

Franchini M, Zolfanelli F, Gallorini M, Giarro G, Fimiani R, Florio P. Eur J Obstet Gynecol Reprod Biol. 2015;189:64-67.

A retrospective review of consecutive polyp histopathological slides and respective reports from November 2012 to March 2013 was conducted. It included all hysteroscopic tissue removal procedures using either mechanical instruments, a bipolar electrode or the TruClear™ system. Of the 90 reviewed polyp slides, it was shown that the hysteroscopic tissue removal of endometrial polyps in an office setting using the TruClear™ system provides adequate tissue for histological diagnosis, despite the effects of tissue fragmentation.

Efficient Procedure

The intra uterine morcellator: a new hysteroscopic operating technique to remove intrauterine polyps and myomas.

Emanual MH, Wamsteker K. J Minim Invasive Gynecol. 2005;12(1):62-66.

When compared with conventional monopolar resection, the TruClear™ system was faster in operating time, and appears easier to use. This article suggests it results in fewer fluid-related complications and a shorter learning curve.

Hysteroscopic morcellator for removal of intrauterine polyps and myomas: a randomized controlled pilot study among residents in training.

Van Dongen H, Emanuel MH, Woterbeek R, Trimbos JB, Jansen FW. J Minim Invasive Gynecol. 2008;15(4):466-471.

This study showed operating time was reduced more than eight minutes when using the TruClear™ system compared to conventional resectoscopy. Subjective surgeon and trainer scores for convenience of technique on a visual analog scale were in favor of the TruClear™ system. In conclusion, the TruClear™ system offers a good alternative to conventional resectoscopy for residents in training.

New developments in hysteroscopy.

Emanuel MH. Best Pract Res Clin Obstet Gynaecol. 2013;27(3):421-429.

Diagnostic and operative hysteroscopy have become standards in gynaecologic practice, and many hysteroscopic procedures have replaced old, invasive techniques, such as dilatation and curettage. The publication notes that the introduction of hysteroscopic tissue removal (e.g., TruClear™ system) opens the option of hysteroscopic surgery for the majority of patients — without the need for extensive training and experience for the gynaecologists.

Hysteroscopic morcellation compared with electrical resection of endometrial polyps.

Smith PP, Middleton LJ, Connor M, Clark TJ. Obstetrics & Gyne. 2014;123(4):745-751.

This study evaluated whether mechanical hysteroscopic tissue removal using the TruClear™ system or bipolar electrosurgical resection is more favorable for removing endometrial polyps in an office setting — in terms of feasibility, speed, pain, and acceptability. It concluded that, in comparison to electrosurgical resection during hysteroscopic polypectomy, mechanical tissue removal was significantly quicker, less painful, more acceptable to women, and more likely to completely remove endometrial polyps.

Hysteroscopic tissue removal systems: a randomized in vitro comparison.

Meulenbroeks D, Hamerlynck TW, Saglam-Kara S, Van Rijssel NK, Van Vliet HA, Schoot BC. J Minim Invasive Gynecol. 2017 Jan 1;24(1):159-164. doi: 10.1016/j.jmig.2016. 08. 829.

An in vitro comparison of the removal of analogue polyp tissue demonstrated that the larger TruClear™ INCISOR™* Plus device,† MyoSure™* Classic and MyoSure™* Lite devices were significantly faster than the TruClear™ INCISOR™* device‡ for removal of one polyp, only the TruClear™ INCISOR™* Plus device was consistently faster than the TruClear™ INCISOR™* device for the removal of more than one polyp. The performance of the MyoSure™* Lite decreased significantly during removal of three consecutive tissue samples, making it slower than the TruClear™ INCISOR™* Plus device. For the removal of myoma tissue, the resection rate of the TruClear™ ULTRA Plus device§ was significantly higher than that of the MyoSure™* XL, with a decrease in MyoSure™* XL's resection rate seen with an increase in the fibroid volume.

Hysteroscopic evacuation of retained products of conception.

Tam, T., Placek, J., Juarez, L. J Obstet Gynaecol. 2016 Nov;36(8):1004-1005.

A case review of a 40-year-old, gravida 1, para 0, infertile patient with endometriosis and adenomyosis sent to the Emergency Department for vaginal bleeding. Operative hysteroscopy utilizing the TruClear™ Hysteroscopic Tissue Removal System was performed to successfully evacuate gestational products.

Hysteroscopic Morcellation Versus Loop Resection for Removal of Placental Remnants: A Randomized Trial.

Hamerlynck TW, van Vliet HA, Beerens AS, Weyers S, Schoot BC. J Minim Invasive Gynecol. 2016 Nov - Dec;23(7):1172-1180. doi: 10.1016/j.jmig.2016. 08. 828

This study compares mechanical hysteroscopic resection with the TruClear™ system with loop resection for the removal of placental remnants with respect to procedure time, adverse events, tissue availability, histology results, short-term effectiveness, and postoperative adhesions. Mechanical hysteroscopic tissue resection demonstrated a faster alternative than loop resection. Both techniques are safe and show high rates of complete removal and tissue availability and low rates of de novo intrauterine adhesions.

PS-TRU-Clinical-Summary / 01

Hysteroscopic Morcellation: Review of the Manufacturer and User Facility Device Experience (MAUDE) Database

Karina Haber, MD*, Eleanor Hawkins, MD, Mark Levie, MD, and Scott Chudnoff, MD, Journal of Minimally Invasive Gynecology, Volume 22, Issue 1, 110 - 114

The objective of this study is to investigate the number and type of adverse events associated with hysteroscopic morcellation of intrauterine disease. The suction-based, mechanical energy, rotating tubular cutting system was developed to overcome adverse events that occur during traditional resectoscopy. On the basis of acknowledged limited information from the MAUDE database, it seems that life-threatening complications such as fluid overload, uterine perforation, and bleeding do occur with hysteroscopic morcellation but less frequently than with traditional electrocautery.

† TruClear™ INCISOR™* Plus device is now known as TruClear™ soft tissue shaver plus.
‡ TruClear™ INCISOR™* device is now known as TruClear™ soft tissue shaver mini
§ TruClear™ ULTRA Plus device is now known as TruClear™ dense tissue shaver plus.

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