

A clear advantage in uterine tissue removal

System



Setting the standard in hysteroscopic morcellation

Bring clarity, precision and efficiency to hysteroscopic morcellation with the TRUCLEAR° System. Featuring fast, efficient resection, advanced fluid management and pathology-optimized morcellators, the TRUCLEAR System offers a complete technology platform for the removal of a range of intrauterine abnormalities. It is the only system designed for visual D&C, hysteroscopic adhesiolysis and evacuation of retained products of conception (RPOC) in addition to fibroid and polyp removal.

With over eight years of clinical experience, the TRUCLEAR System continues to set the standard for effective and safe tissue resection.



"The development of the TRUCLEAR System represents a major breakthrough in hysteroscopic surgery."

Dr. Justin Clark, Birmingham Women's Hospital, Birmingham, United Kingdom

Designed for optimum performance

Clear Operative Field

- 100% continuous flow and suction helps maintain a clear operative field
- No tissue floating within the uterine cavity

Safe Gentle Resection

- Simple, mechanical design means there is no risk of energy discharge-induced scarring and a reduced risk of air or gas emboli compared to conventional resection
- Localized treatment reduces endometrial damage, which may help preserve the chances of pregnancy
- Proprietary suction control technology minimizes fluid use

Efficient Procedure

- Continuous cutting and tissue removal means only a single insertion is necessary
- Single insertion means fewer procedural steps

Effective Pathology Removal

- Targeted pathology removal under continuous visualization ensures efficient cut and capture
- Tissue capture allows evaluation of the entire pathology





"With the TRUCLEAR System, I can address a whole spectrum of abnormalities with one high-performing system."

Dr. Charles E. Miller, Advocate Lutheran General Hospital, Park Ridge, IL

Multiple procedures, one high-performance system

The TRUCLEAR^o System is specifically indicated to remove more intrauterine abnormalities than any other morcellation system. As the only pathology-optimized, hysteroscopic morcellator, the TRUCLEAR System enables more efficient procedures and enhanced performance for a full spectrum of conditions, including:

Diagnostic Visual D&C and Endometrial Biopsy

Provides direct visualization of the uterine cavity, facilitating removal of targeted endometrial tissue, hyperplastic endometrium or other intrauterine tissue for pathology analysis

Myomectomy

Brings speed, efficiency and precision to the removal of myomas

Helps ensure patient safety through advanced fluid management

Retained Products of Conception Evacuation

Minimizes endometrial damage and reduces risk of intrauterine adhesions by evacuating RPOC under direct visualization

Captures tissue for histological confirmation

May reduce the need for additional procedures as the system has demonstrated complete removal in over 94% of patients²

Polypectomy

May improve the efficiency of polyp removal by reducing polypectomy procedure time by half¹

Minimizes patient discomfort

Hysteroscopic Adhesiolysis

Removes intrauterine adhesions under direct visualization

Designed to reduce damage to surrounding healthy endometrium

1. M.H. Emanuel and K. Wamsteker (2005). "The Intra Uterine Morcellator: A New Hysteroscopic Operating Technique to Remove Intrauterine Polyps and Myomas." The Journal of Minimally Invasive Gynecology 12(1), 62-66.

 Tjalina W.O. Hamerlynck, MD; Mathijs D. Blikkendaal, MD, Benedictus C. Schoot, MD, PhD; Miriam M.F. Hanstede, MD and Frank Willem Jansen, MD, PhD. (2013) "An Alternative Approach for Removal of Placental Remnants: Hysteroscopic Morcellation." JMIG December 2013 20(6), 796-802.

More options mean more control in every procedure

The TRUCLEAR° System blends high-performance morcellators and scopes with advanced fluid management for efficient and effective pathology removal. The system includes:

The TRUCLEAR 5.0 Hysteroscope Set:

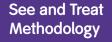
- Smallest instrumentation available today, facilitating gentle, effective procedures*
- Perfect for in-office procedures and patients with a stenotic cervix as little or no dilation is required
- Longer scope means access to the entire uterus, including cornua and fundal wall
- Used with the TRUCLEAR INCISOR^o Plus Rotary 2.9 morcellator

The TRUCLEAR 8.0 Hysteroscope Set:

- Large working channel offers capability to use additional hysteroscopy instruments
- Option to use TRUCLEAR Obturator for gentle introduction of the sheath into the uterine cavity
- For use with the TRUCLEAR Rotary 4.0 and the new TRUCLEAR ULTRA Reciprocating 4.0 morcellators

TRUCLEAR Disposable Morcellators:

- · Simultaneous tissue cutting and aspiration to reduce procedure time
- Proprietary suction control feature to minimize fluid loss
- Three pathology-optimized disposable morcellators:
 1) TRUCLEAR INCISOR Plus Rotary 2.9 for soft tissue
 2) TRUCLEAR Rotary 4.0 for soft tissue
 - 3) TRUCLEAR ULTRA Reciprocating 4.0 for dense tissue



Offering a clear view of the uterine cavity and a large working channel, TRUCLEAR Hysteroscopes allow you to treat uterine conditions at the same time as diagnosis.

"The operative port allows for the introduction of rigid scissors for septal resection; TRUCLEAR morcellators for removal of polyps, fibroids, or to perform curettage; and tubal catheterization for the evaluation and treatment of proximal tubal occlusion in conjunction with the use of the C arm."

Dr. Daniel B. Williams, Houston Fertility Institute, Houston, TX



TRUCLEAR ULTRA Reciprocating 4.0

"Because operative hysteroscopy requires precise inflow and outflow measurement to ensure patient safety, accuracy and precision are key in fluid management; and that's what I've found in Smith & Nephew's Fluid Management System."

Dr. Robert Gustofson, Colorado Center for Reproductive Medicine, Denver, CO TRUCLEAR[®] Hysteroscopic Fluid Management System enhances visualization and helps ensure patient safety

Maintaining proper fluid levels is essential for successful outcomes. The TRUCLEAR Fluid Management System features:

High flow rate

- Maximum flow rate of 700 ml/min optimizes visualization
- Allows intrauterine pressure to be maintained at the desired level

High-speed response

- Proprietary software allows agile response to intrauterine changes
- Scale continuously monitors fluid deficit for accurate measurements

Controlled suction

• Provides suction flexibility in order to maintain clear visualization

Reliable warning systems for safety

• Audible alarms indicating over pressure, under pressure and fluid deficit thresholds





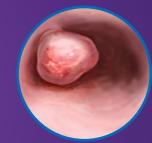
Insert the hysteroscope into the uterus



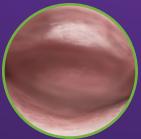
uterus with

Performing hysteroscopic morcellation: a simple procedure

The procedure uses a morcellator inserted through a hysteroscope that simultaneously cuts and aspirates tissue.



Locate intrauterine abnormality



Remove the morcellator and hysteroscope from uterus



Place morcellator against pathology -TRUCLEAR^o Morcellator will simultaneously aspirate and cut tissue

Get a clear advantage in your procedures

To learn more about the TRUCLEAR° System, contact your local sales representative.

Ordering information

| Part # | Product Description | Unit of Measure | |
|----------|---|-------------------------|--|
| 72202709 | TRUCLEAR Hysteroscopic Morcellator | Inclusive of: | |
| 7209808 | TRUCLEAR Control Unit | Each | |
| 7209820 | TRUCLEAR Footswitch | Each | |
| 7209807 | TRUCLEAR Handpiece | Each | |
| 72202707 | TRUCLEAR 8.0 Hysteroscope Set | Inclusive of: | |
| 7209208 | TRUCLEAR Operative Hysteroscope 8.0 | Each | |
| 7209383 | TRUCLEAR Sheath 9.0 | Each | |
| 7209384 | TRUCLEAR Obturator | Each | |
| 72203606 | TRUCLEAR Calibration Insert 4.0 | Each | |
| 72202720 | Hysteroscopic Fluid Management System | Inclusive of: | |
| 7210164 | Hysteroscopic Fluid Management System Control Unit | Each | |
| 7210165 | Hysteroscopic Fluid Monitor System Stand | Each | |
| 7210166 | Hysteroscopic Roller Base | Each | |
| 72203420 | Hysteroscopic Vacuum Regulator | Each | |
| 72202710 | US Country Kit (Manual and Power Cord)* | Each | |
| 72202734 | TRUCLEAR System | Includes all the above* | |
| 72203554 | TRUCLEAR 5.0 Hysteroscope Set | Inclusive of: | |
| 72202976 | TRUCLEAR Operative Hysteroscope 5.0 | Each | |
| 72202977 | TRUCLEAR Sheath 5.6 | Each | |
| 72203506 | TRUCLEAR Calibration Insert 2.9 | Each | |

| Part# | Product Description | Unit of Measure | |
|---------------------|--|-----------------|--|
| Disposable Products | | | |
| Morcellators | | | |
| 72203012 | TRUCLEAR ULTRA Reciprocating 4.0 | Each | |
| 7209509 | TRUCLEAR Rotary 4.0 | Each | |
| 72202536 | TRUCLEAR INCISOR° Plus Rotary 2.9 | Each | |
| Tube Sets | | | |
| 7209827 | Hysteroscopic Procedure Kit (Includes Inflow Tube Set, Outflow Tube Set, IUR Non-sterile Kit) | Inclusive | |
| 7209824 | IUR Non-sterile Kit (Includes 4 jumper tubes and tissue trap) | Each | |
| 72203257 | Single Jumper Procedure Kit | Each | |
| 7209822 | Hysteroscopic Inflow Tube Set | Box of 10 | |
| 72200869 | Y-Adaptor, Inflow Tube Set | Box of 10 | |
| 7209823 | Hysteroscopic Outflow Tube Set | Box of 5 | |
| 72200024 | 3000cc Hi-Flow Canisters | Box of 36 | |
| Other | | | |
| 7211067 | TRUCLEAR Calibration Insert 4.0, Disposable | Each | |
| 72203004 | Gynecology Instrument Tray | Each | |
| 72203303 | Vacuum Pump (US) | Each | |

*Does not include TRUCLEAR Calibration Insert 4.0, 72203606

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