

Clinical evidence for using powered instruments in sinus surgery

Improve patient outcomes⁶⁻⁸
Reduce operative time^{6,7}
Faster healing with less scarring^{7,8}



1 in 8

Americans suffer from chronic rhinosinusitis (CRS)¹

Symptoms include difficulty with nosebreathing, excess nasal discharge, facial pain, and loss of smell.

CRS can negatively affect health and quality of life significantly. 1-3

Some patients have rated CRS as more disabling than other serious conditions, such as angina, emphysema, and lower back pain.³

Annual costs to society has been reported to be over \$4 billion.⁴

When medical treatments fail, **endoscopic sinus surgery may be an option**.⁴ Surgical success rates for CRS have been reported to be near 70% in cases with nasal polyps and closer to 90% in cases without.^{†,5}



Why use powered instruments to supplement manual?

The goal of sinus surgery is to **restore ventilation and drainage while preserving non-diseased mucosa**. Procedures are performed using manual instruments alone or together with a powered microdebrider.

The Straightshot™ M5 Microdebrider is an electric shaver that resects tissue and bone. The Straightshot™ M5 microdebrider is compatible with our straight and curved blades with 360 degree-rotating blade tips. It simultaneously suctions fluid from the surgical site, **improving visibility**.

This brochure presents study results showing differences between using powered and manual instruments for sinus surgery. As always, surgeons should weigh potential benefits and risks to make the best decision for each patient.



Normal mucosa helps warm and humidify the air, and contains thousands of cilia that facilitate drainage. The microdebrider resects tissue more precisely and causes less mucosal damage than traditional instruments.⁶⁻⁸





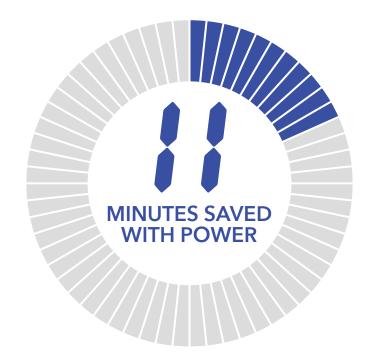
Integrated Power Console (IPC™ system)



3



Using a microdebrider with rotating blades, powered FESS can remove polyps, bone, and diseased tissue in a more time-efficient manner than manual instruments alone.^{6,7}



Cornet et al: Comparative study of manual instruments vs. manual instruments with the addition of the microdebrider, in 60 patients; prospective randomized double-blind controlled trial⁶

Median operating time-microdebrider: 30 min

Median operating time-traditional instruments: 41 min

Saafan et al: Comparative study of manual instruments vs. microdebrider in 200 patients⁷

Powered endoscopy: 83 +/- 15 min

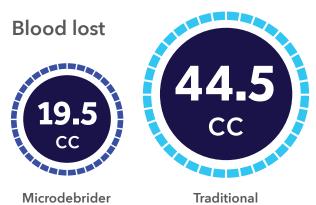
Conventional instruments: 94 +/- 18 min



Reduced surgical bleeding

A longer operation means greater blood loss potential. With manual instruments, surgeons constantly have to remove a cutting instrument and insert a suction instrument to clear fluid/blood that obstructs visualization.

Powered instruments enable simultaneous cutting and suction. Microdebriders have been shown to reduce procedure time, reduce surgical bleeding, and improve visibility at the operative site.⁶⁻⁸



Krouse et al: Retrospective chart review of microdebrider vs. traditional techniques in 475 patients⁸

Microdebrider group: 19.5 cc blood lost Traditional group: 44.5 cc blood lost



Shorter healing times

As the edge dulls, a manual instrument requires more effort to use and can pull excessive tissue. Our laser-cut microdebrider blades ensure a sharp edge for every patient. The powered microdebrider with laser-cut blades facilitates more precise removal of diseased tissue, causes less mucosal damage, and contributes to faster healing with less scarring.⁶⁻⁸

Krouse et al: (Average healing time) Chart review of microdebrider vs. traditional techniques in 475 patients⁸ *Microdebrider: 39 days on average*

Traditional instruments: 55 days on average

Saafan et al: (Average time to mucosalization) Comparative study of manual instruments vs. microdebrider in 200 patients⁷

Powered instrument mean: 2.7 weeks (avg.)
Conventional instrument mean: 3.3 weeks (avg.)



4



Since 1997, Medtronic ENT has developed a broad range of powered surgery tools for performing minimally invasive ENT procedures with greater precision and speed.

Straightshot™ M5 Microdebrider

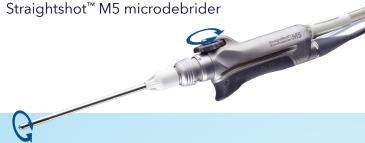
The award-winning15 Straightshot™ M5 microdebrider features:

- Widest variety of application-specific blades and burs¹⁵
- Blade tips that **rotate 360°**

RAD™ 40 Automated EM tracking blade

- **Built-in suction** to enhance visualization
- Factory-calibrated blades for surgical navigation with our Fusion™ system







Inferior turbinate blade

30K high-speed burs

Integrated Power Console (IPC[™] system)

This versatile system offers:

- Easy-to-use touchscreen interface
- Two irrigation pumps
- Multi function foot pedal
- Powers up to four handpieces at a time:
 - Straightshot™ M5 and Straightshot™ M4
 - Endo-Scrub™ 2 lens cleaning sheaths
 - Skeeter[™] otologic drill
 - Midas Rex[™] Legend[™] drills
 - Midas Rex[™] microsaws

The Endo-Scrub™ 2 and IPC™ difference

Designed to improve the ability to operate in the presence of bleeding 9-13



Fogging and accumulated debris can decrease visualization and necessitate removing the scope during a surgical procedure for cleaning.



Endo-Scrub™ 2 lens cleaning sheaths ensures that fluid is evacuated from the sheath to keep the lens from fogging.



Integrated Power Console (IPC[™] System)









The importance of training

Premium Training and Education

Studies indicate the benefits of powered FESS. When properly used by an experienced surgeon, research has shown that complication rates are comparable between the microdebrider and traditional instruments.⁶

Medtronic offers advanced training and education opportunities for surgeons and OR staff.

- Education and training in ENT, cranial, spinal, and orthopaedic surgical products and techniques
- Quarterly OR personnel training
- Support for hundreds of courses worldwide

Dr. Glen Nelson Surgeon Education and Training Center

At our newest bioskills lab, surgeons and staff broaden their skills through hands-on experience with personalized curricula in the latest devices and techniques.

- Powered surgical products, including IPC[™]
 (Integrated Power Console), Straightshot[™] M5
 microdebrider, Indigo[™] otologic drill, Midas
 Rex[™] Legend[™] systems
- StealthStation™ ENT navigation system
- Fusion™ ENT surgical navigation system
- Nerve monitoring with NIM[™] systems
- NuVent™ sinus dilation system

Learn more at www.medtronic.com/NelsonEducationCenter or call (800) 874-5797.

References

- 1. Albu S. Chronic Rhinosinusitis-An Update on Epidemiology, Pathogenesis and Management. *J Clin Med.* 2020 Jul 18;9(7):2285. doi: 10.3390/jcm9072285.PMID: 32708447; PMCID: PMC7408732.
- 2. Hoehle LP, Phillips KM, Bergmark RW, Caradonna DS, Gray ST, Sedaghat AR. Symptoms of chronic rhinosinusitis differentially impact general health-related quality of life. *Rhinology*. 2016 Dec 1;54(4):316-322. doi: 10.4193/Rhino16.211. PMID: 27665614.
- 3. Becker DG. Sinusitis. J Long Term Eff Med Implants. 2003; 13(3):175-194.
- 4. Bhattacharyya N, Orlandi RR, Grebner J, Martinson M. Cost burden of chronic rhinosinusitis: a claims-based study. *Otolaryngol Head Neck Surg*. 2011 Mar;144(3):440-5. doi: 10.1177/0194599810391852. Epub 2011 Feb 3. PMID: 21493210.
- 5. Smith KA, Orlandi RR, Oakley G, Meeks H, Curtin K, Alt JA. Long-term revision rates for endoscopic sinus surgery. *Int Forum Allergy Rhinol*. 2019 Apr;9(4):402-408. doi: 10.1002/alr.22264. Epub 2018 Dec 20. PMID: 30570840; PMCID: PMC6438735.
- 6. Cornet ME, Reinartz SM, Georgalas C, et al. The microdebrider, a step forward or an expensive gadget? *Rhinology*. 2012; 50:191-198.
- 7. Saafan ME, Rageb SM, Albirmawy OA, et al. Powered versus conventional endoscopic sinus surgery instruments in management of sinonasal polyposis. *Eur Arch Otorhinolaryngol.* 2013; 270(1):149-155. DOI: 10.1007/s00405-012-1969-8. E-pub April 10, 2012.
- 8. Krouse JH and Christmas DA. Powered instrumentation in functional endoscopic sinus surgery II: a comparative study. *ENT Journal*. 1996; 75(1): 42-45.
- 9. Jho H-D. Endoscopic pituitary surgery. Pituitary. 1999; 2:139-154.
- 10. Gross CW, Becker DG. Power instrumentation in endoscopic sinus surgery. *Oper Tech Otolaryngol Head Neck Surg*. 1996; 7(3):236-241.
- 11. Lui WM, Leung GKK, Hui Y, Lee KK, Fan YW. Endonasal endoscopic removal of growth hormone-secreting pituitary adenomas. HKMJ. 2001; 7(2):189-192.
- 12. Kennedy DW. Functional endoscopic sinus surgery: concepts, surgical indications, and instrumentation. In: Kennedy DW, Bolger WE, Zinreich SJ, eds. *Diseases of the Sinuses: Diagnosis and Management*. 1st ed. Philadelphia, PA: PMPH USA; 2001:197-210.
- 13. Bolger WE, Kennedy DW. Surgical complications and postoperative care. In: Kennedy DW, Bolger WE, Zinreich SJ, eds. Diseases of the Sinuses: Diagnosis and Management. 1st ed. Philadelphia, PA: PMPH USA; 2001:303-316.
- 14. Straightshot[™] M5 Microdebrider Design Awards, 2019.
- 15. Internal verification for: "Widest variety of application-specific blades and burs."

IPC™ System:

The IPC System is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone in Head & Neck/ENT, Oral/ Maxillofacial and Plastic/Reconstructive/Aesthetic surgical procedures.

Risks may include electrical shock, component damage, substandard performance, increased emissions, or decreased immunity. Do not operate the IPC[™] system in the presence of Magnetic Resonance Imaging devices. The IPC[™] system should not be used adjacent to or stacked with other equipment. All service must be performed by Medtronic qualified personnel only. Repair and/or modification to the IPC™ system by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.

Verify reusable device was cleaned and sterilized prior to use

Always keep the cutting area of the tool away from fingers and loose clothing to prevent laceration of user and cross-contamination through compromised glove.

For complete use and safety information see the IFU at https://manuals.medtronic.com/manuals/

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Rx only. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications.

For further information, please call Medtronic ENT at 800.874.5797 or consult Medtronic's website at www.medtronic.com/ent.

Medtronic

Medtronic **ENT**

6743 Southpoint Drive N Jacksonville, FL 32216 Toll free: (800) 874-5797

Fax: (800) 678-3995

International Telephone Numbers Europe HQ Switzerland 41-21-802-7000 India 91-22-33074700 Latin America HQ 305-500-9328

Adriatic Region 385-1-488-1120 Argentina 54-11-4898-5700 Australia 1-800-668-670 Telephone: (904) 296-9600 Baltic Region 37-1-67560226 Belgium 32-2456-09-09 Brazil 55-11-2182-9200 Canada 1-800-268-5346 Chile 56-2-2655-5110 China 86-10-5869-8989 Colombia 57-1-742-7300 Czech Republic 420-233-059-111 France 33-470-679-800 Germany 49-2159-8149-209

Greece 30-210-67-79-099

Hungary 36-188-90600

Hong Kong 852-2919-1300

Israel 972-9-972-4400 Italy 39-02-24137-324 Japan 81-3-6774-4611 Korea 82-2-3404-3600 Lebanon 961-1-370-670 Luxembourg 32-2456-09-09 Malaysia 60-37-953-4800 Mexico 52-55-11-02-90-30 Netherlands 31-45-566-8800 Poland 48-22-4656900 Russian Fed. 7-495-580-73-77 Singapore 65-6436-5000 South Africa 27-11-260-9300 Spain 34-91-625-05-40 Taiwan 886-2-2183-6000 Thailand 662-232-7400 UK 44-1923-205-166