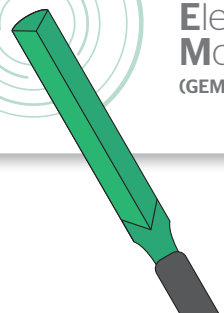
Megadyne™

Value analysis summary

MEGADYNE™ Telescoping Soft Tissue Dissectors

Intelligently delivered by
Geometric
Electron
Modulation
(GEM) Technology



ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
Shaping the future of surgery

MEGADYNE™ Telescoping Soft Tissue Dissectors

Executive overview

The MEGADYNE™ Telescoping Soft Tissue Dissectors are powered by patented Geometric Electron Modulation (GEM) Technology. This intelligent technology delivers the efficiency and hemostasis surgeons want with significantly **less thermal damage**[1] than standard monopolar electrosurgery.

Experience less thermal damage[1] plus...

Less instrument exchange vs. scalpel

- This **multifunctional tool** can be used for incision, dissection and coagulation, which may increase surgical efficiency[2]
- Can eliminate the need for a surgical scalpel in the OR, **removing a risk for sharps injuries**[3]

Less need to exchange electrodes[4]

- **Telescoping shaft** for access to deep surgical cavities[5]

Less surgical smoke vs. stainless steel blades

- **99.6% less surgical smoke**[6]
- **97% reduction in BaP,** a known carcinogen, and 75% reduction in phenanthrene, a known irritant[6]

1 In ACE Mode vs. standard monopolar electrosurgery: In a preclinical porcine model on abdominal wall dermis that measured thermal damage via histology ($p<0.05$). (075571-190301) **2** (075573-190306) **3** In a clinical study vs. cold steel scalpel that demonstrated noninferior wound healing/scar formation via the Patient Scar Assessment Scale (PSAS) ($p<0.0001$). Lee BJ, et al. Advanced Cutting Effect System versus Cold Steel Scalpel: Comparative Wound Healing and Scar Formation in Targeted Surgical Applications. Plast Reconstr Surgery Glob Open. 2014;2(10). (075570-190305) **4** (100922-190429) **5** (100925-190429) **6** In a preclinical porcine model vs. uncoated stainless steel blades at 60W analyzed via spectrophotometer and HPLC UV ($p<0.001$). Kisch T, et al. Electrocautery Devices with Feedback Mode and Teflon-Coated Blades Create Less Surgical Smoke for a Quality Improvement in the Operating Theater. Medicine, 2015;94(27) (075563-200224)

MEGADYNE™ Telescoping Soft Tissue Dissectors

Areas of procedural focus

For use in cutting and coagulation of soft tissue, such as:

- Orthopedics (hip, knee, spine)
- Plastics
- Breast

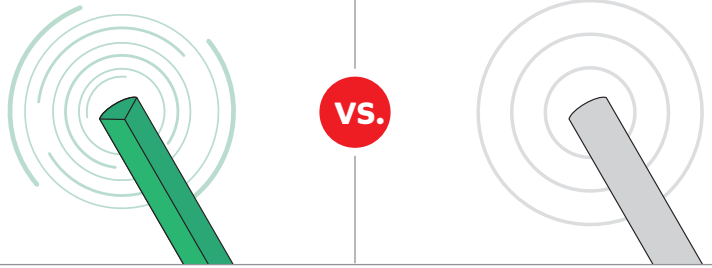
MEGADYNE™ Telescoping Soft Tissue Dissectors

The GEM difference

The patented intelligent Geometric Electron Modulation (GEM) Technology can deliver the **efficiency and hemostasis you want with significantly less thermal damage**[1] than standard monopolar electrosurgery.

GEM Technology

- **Power delivered fluctuates** based on tissue impedance, which was designed for less thermal damage[2]
- Achieves a **scalpel-like cutting effect** with significantly less thermal damage[3]



Standard monopolar electrosurgery

- **Constant power** delivers the same amount of energy regardless of tissue impedance
- Associated with **significantly more thermal damage** than MEGADYNE™ Soft Tissue Dissectors powered by GEM Technology[1]

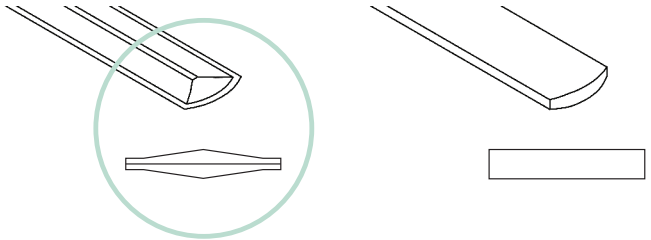
Achieving the GEM effect

Two components are required to obtain the GEM effect:

1

A tapered blade

Tapered blade edges focus energy to allow plasma formation at low voltages with the least amount of energy required.



2

A generator that modulates power

The generator modulates the power to maintain the voltage as close as possible to the minimum voltage required for cutting targeted tissue at the surgical site.

MEGADYNE™ Electrosurgical Generator in GEM Mode

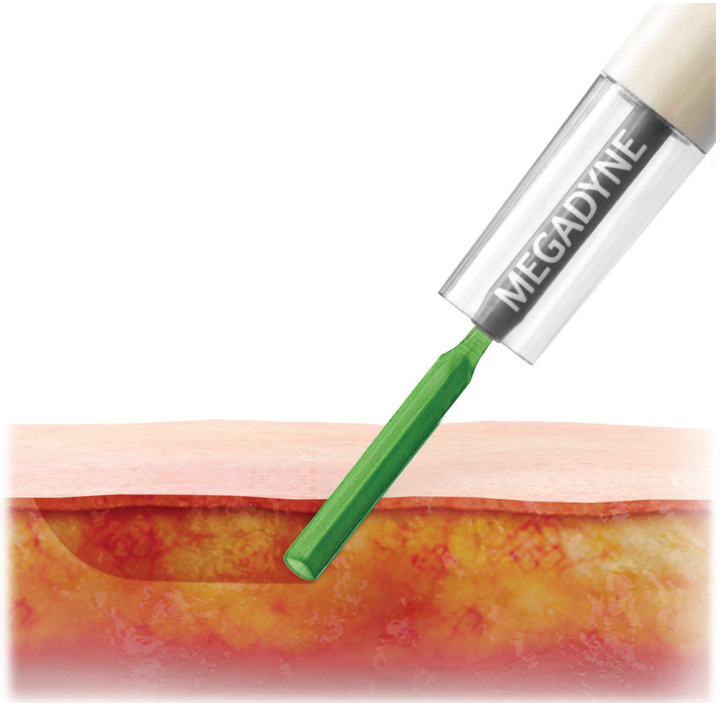
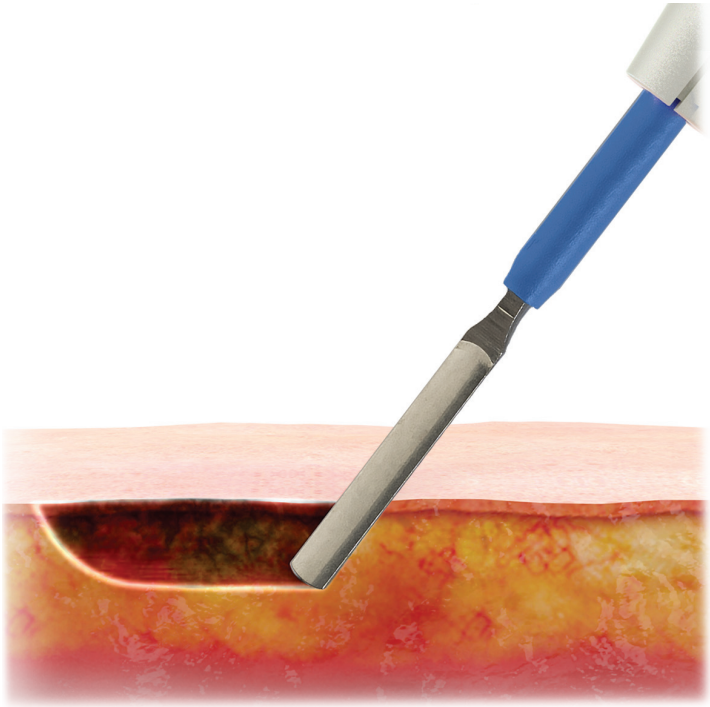
MEGADYNE™ MEGA POWER™ Electrosurgical Generator in ACE Mode

1 In ACE Mode vs. standard monopolar electrosurgery: In a preclinical porcine model on abdominal wall dermis that measured thermal damage via histology ($p<0.05$). (075571-190301) **2** Based on proprietary GEM Technology and preclinical porcine testing on abdominal wall dermis that measured thermal damage via histology ($p<0.05$). GEM Technology and test results are achieved when used on the Megadyne Mega Power generator in GEM Mode only. (083164-190305)
3 Based on proprietary GEM Technology and preclinical porcine testing on abdominal wall dermis that measured thermal damage via histology ($p<0.05$). GEM Technology and test results are achieved when used on the Megadyne Mega Power generator in GEM Mode only. (083165-190306)

MEGADYNE™ Telescoping Soft Tissue Dissectors

Significantly less thermal damage[1]

Power is optimized to deliver the minimum energy required to cut tissue, resulting in less thermal damage:[1]

GEM Technology	Standard monopolar electrosurgery
	

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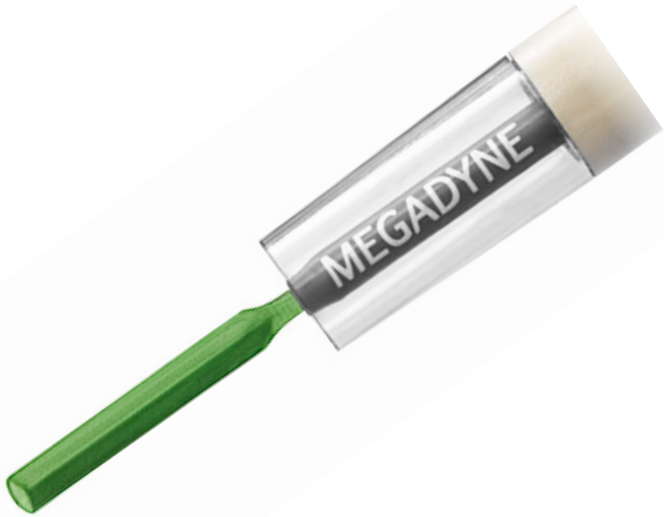
MEGADYNE™ Telescoping Soft Tissue Dissectors

Less instrument exchange vs. scalpel and less risk of sharps injuries[1]

Multifunctional tool for incision, dissection and coagulation; may eliminate need for a surgical scalpel in the OR.[1]



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MEGADYNE™ Telescoping Soft Tissue Dissectors

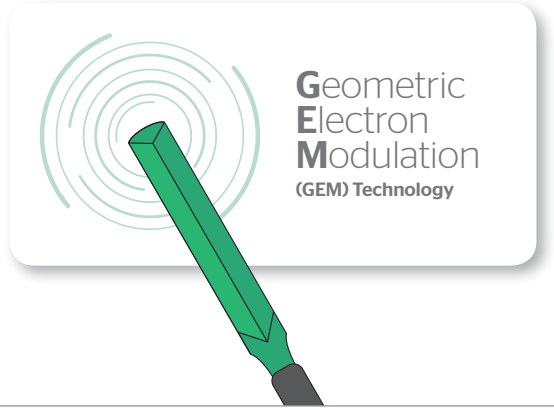
Less need to exchange electrodes[1]

Telescoping shaft for access to deep surgical cavities and less electrode exchange[2]

1 (100922-190429) **2** (100925-190429)

MEGADYNE™ Telescoping Soft Tissue Dissectors

Less surgical smoke vs. stainless steel blades



99.6%

Less surgical smoke[1]

97%

Reduction in BaP, a known carcinogen[1]

75%

Reduction in phenanthrene, a known irritant[1]

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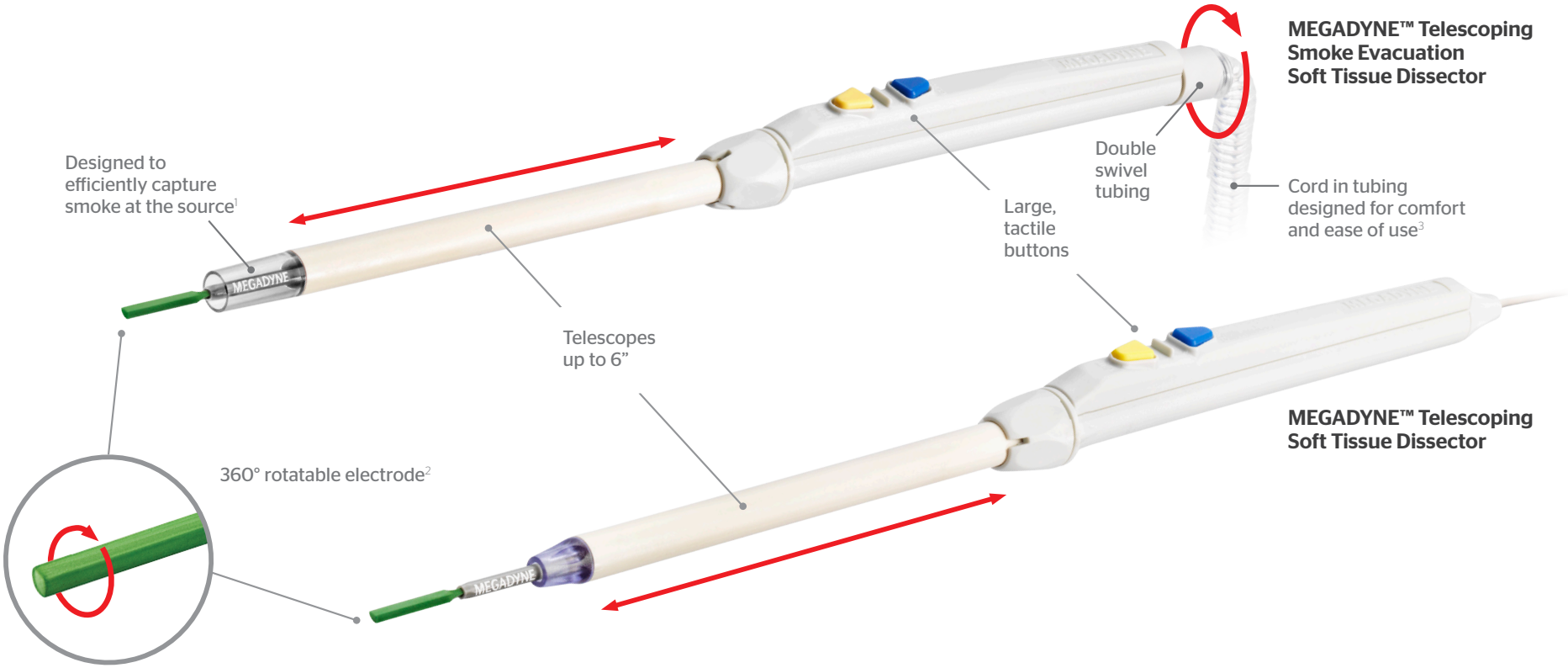
MEGADYNE™ Telescoping Soft Tissue Dissectors

Design features



1 (075017-181017) **2** (100924-181017) **3** (075014-181016)

MEGADYNE™ Telescoping Soft Tissue Dissectors

Economic value

This multifunctional tool may increase surgical efficiency and eliminate the need for a surgical scalpel in the OR.[1]

- Scalpel blades are responsible for 8% of all sharps injuries, producing more than 30K injuries per year.[2]
- The economic impact of scalpel blade injuries is estimated between $2.2M and $154M per year.[3]
- Sharps injuries are associated with occupational transmission of more than 20 life-threatening infectious pathogens.[4]

1 In a clinical study vs. cold steel scalpel that demonstrated noninferior wound healing/scar formation via the Patient Scar Assessment Scale (PSAS) ($p<0.0001$). Lee BJ, et al. Advanced Cutting Effect System versus Cold Steel Scalpel: Comparative Wound Healing and Scar Formation in Targeted Surgical Applications. Plast Reconstr Surgery Glob Open. 2014;2(10). (075570-190305) **2** Injuries incurred by hospital-based healthcare personnel. *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program*, Centers for Disease Control and Prevention, 2008. (078294-170808) **3** Injuries incurred by hospital-based healthcare personnel; estimates in US dollars (includes direct costs associated with the initial & follow-up treatment of the exposed). *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program*, Centers for Disease Control and Prevention, 2008. (078291-170808)
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MEGADYNE™ Telescoping Soft Tissue Dissectors

System components and codes

The MEGADYNE™ Telescoping Soft Tissue Dissectors are available in two blade types, and all blades come pre-installed in the pencil.

The MEGADYNE™ Electrosurgical Generator in GEM Mode or the MEGADYNE™ MEGA POWER™ Generator in ACE Mode is required to obtain the scalpel-like cutting effects[1] of GEM technology.

MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector

Code	Blade length	Blade type	Soft tissue dissector	Tubing length	Connector type	Quantity per sales unit
ME7251ST	2.5 inches	Standard 	Telescoping smoke evacuation	10 feet	Universal	6
ME725M1ST	2.5 inches	Modified 	Telescoping smoke evacuation	10 feet	Universal	6

MEGADYNE™ Telescoping Soft Tissue Dissector

Code	Blade length	Blade type	Soft tissue dissector	Cord length	Connector type	Quantity per sales unit
ME7251T	2.5 inches	Standard 	Telescoping non-smoke evacuation	10 feet	Universal	6
ME725M1T	2.5 inches	Modified 	Telescoping non-smoke evacuation	10 feet	Universal	6

1 In ACE Mode vs. standard monopolar electrosurgery: Based on proprietary GEM Technology and preclinical porcine testing on abdominal wall dermis that measured thermal damage via histology ($p<0.05$). GEM Technology and test results are achieved when used on the MEGADYNE™ MEGA POWER™ Electrosurgical Generator in ACE Mode only. (083163-190306, 083164-190305, 083165-190306)

MEGADYNE™ Telescoping Soft Tissue Dissectors

Ordering information

How to order

All purchase orders are made to Johnson & Johnson Health Care Systems, Inc. (JJHCS).

If you want to order direct, you may order electronically (online) at:

- **https://us.jjcustomerconnect.com** or **1-866-565-4283**
- **Electronic Data Interchange (EDI) Helpline: 1-800-262-2888**

Or, to place a non-electronic (manual) order, contact Johnson & Johnson Health Care Systems, Inc. at 1-800-255-2500 between 8:30 a.m. and 6:30 p.m. (Eastern Standard Time) or fax us at 1-732-562-2212.

Customer support

For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of a 510(k) clearance letter, or complaints, please contact our Customer Support Center by calling 877-ETHICON (384-4266). Our support center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions.

For more information, visit: **ethicon.com**

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