

Megadyne™

# Value analysis summary

MEGADYNE™ Smoke Evacuation Portfolio



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## MEGADYNE™ Smoke Evacuation Portfolio

# Executive overview

The MEGADYNE™ Smoke Evacuation Portfolio delivers **all-around flexibility** by providing **multiple smoke evacuation** pencils and a versatile smoke evacuator. <sup>1</sup>



### MEGADYNE™ Telescoping Smoke Evacuation Pencil

The **adjustable length** of the MEGADYNE™ Telescoping Smoke Evacuation Pencil helps position the smoke evacuation tip closer to the surgical site, which may provide more **efficient smoke evacuation**.<sup>2-4\*</sup>



### MEGADYNE™ Smoke Evacuator

MEGADYNE™ Smoke Evacuator is designed to have effective and quiet performance for **open and laparoscopic procedures**.<sup>1,5,6\*\*</sup>

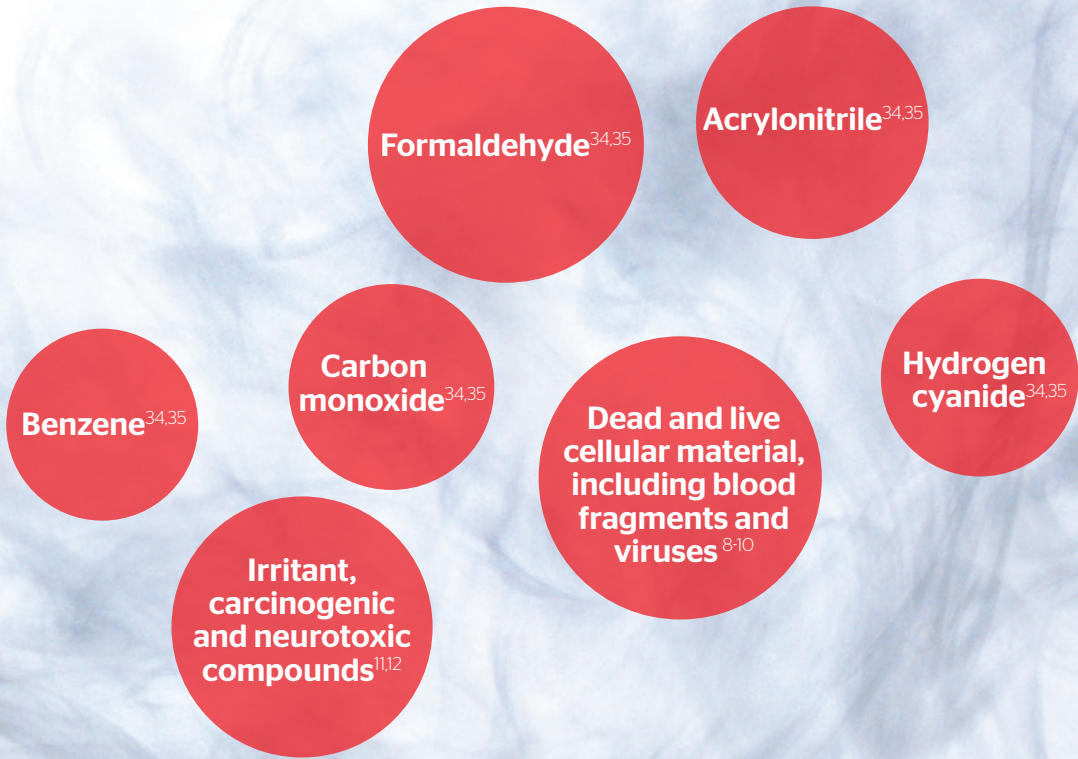
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\*May provide more efficient smoke evacuation by capturing smoke at the source.

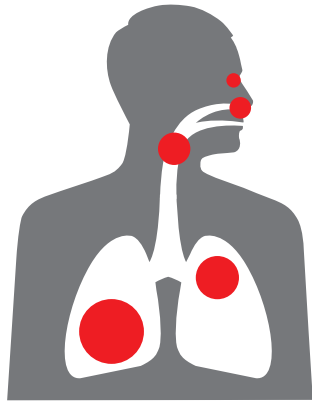
\*\*Efficiently captures and filters 99.999% of particulates and microorganisms of 0.1 to 0.2 microns and performs quiet at 50 +/- 10 dBA per IEC 60601-1 at 1 m, with [59.2 dBA in open mode] [and/or] [51.9 dBA in lap mode] at 1 m

# What's in electrosurgery smoke?



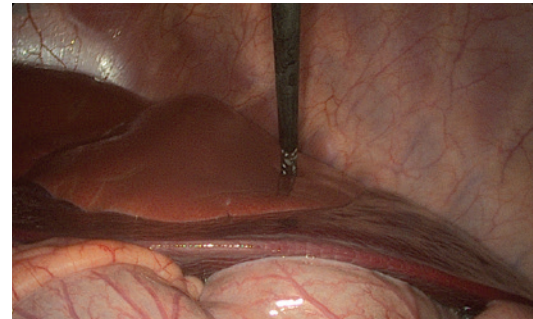
# The effects of surgical smoke on health and visibility

Potential **health risks** of surgical smoke

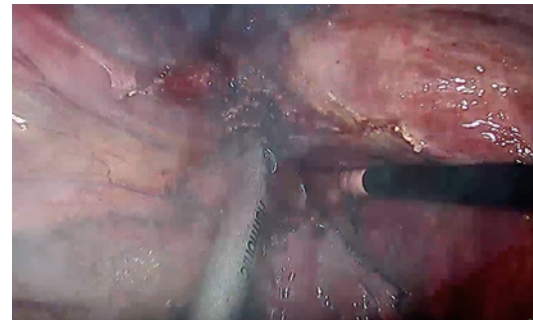


CDC\*: "Exposure to surgical smoke can cause both acute and chronic health effects ranging from eye, nose and throat irritation to emphysema, asthma or chronic bronchitis"<sup>13\*</sup>

How smoke **impacts visibility**



**Surgical site without smoke**



**Surgical site with smoke**

## MEGADYNE™ Smoke Evacuation Portfolio

# MEGADYNE™ Smoke Evacuator

MEGADYNE™ Smoke Evacuator is designed to have effective and quiet performance for **open and laparoscopic procedures.**<sup>14-16\*</sup>

Filter is designed to capture particulate and microorganisms of 0.1-0.2 microns at 99.999% efficiency<sup>16</sup>



Enables automatic activation with electrosurgical generators that deliver monopolar, bipolar, ultrasonic, and advanced bipolar energy<sup>16</sup>

Designed to be intuitive and simple to use<sup>16</sup>

### 3 ways to activate

#### Connect cable

Automatically detects energy device activation to trigger smoke evacuation



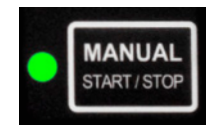
#### RF sensor

Automatically detects monopolar device activation to trigger smoke evacuation



#### Manual start/stop button

Push button to start or stop smoke evacuation



#### Flexible

- Allows users to adjust run time
- Supports continuous smoke evacuation under Manual Mode<sup>16</sup>

#### Comprehensive

- Has an adjustable flow rate to accommodate insufflation air flow to maintain peritoneum pressure in laparoscopic procedures<sup>16</sup>

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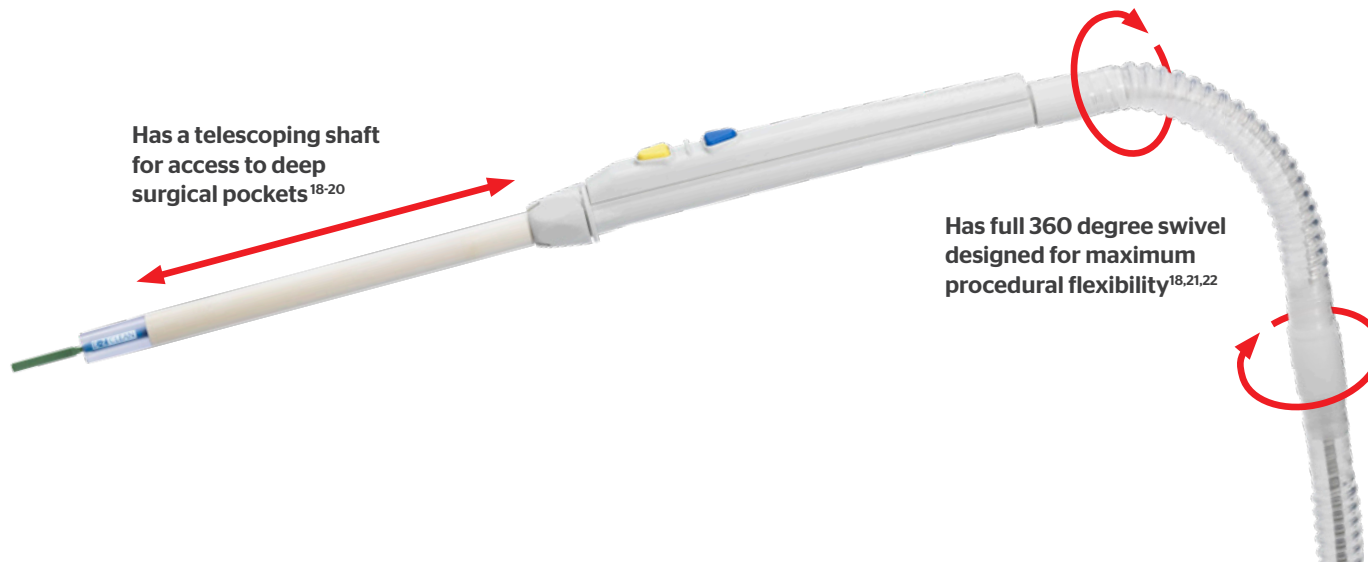
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\*Efficiently captures and filters 99.999% of particulates and microorganisms of 0.1 to 0.2 microns and performs quiet at 50 +/- 10 dBA per IEC 60601-1 at 1 m, with [59.2 dBA in open mode] [and/or] [51.9 dBA in lap mode] at 1 m



## MEGADYNE™ Smoke Evacuation Portfolio

# MEGADYNE™ Telescoping Smoke Evacuation Pencil



Secure telescoping shaft length at any position from fully extended to fully retracted

Fully compatible with more than 16 different smoke evacuators from 12 manufacturers<sup>28 # ¥</sup>

### Visibility

- The adjustable length of the Megadyne™ Telescoping Smoke Evacuation Pencil helps position the smoke evacuation tip closer to the surgical site, which may provide more efficient smoke evacuation.<sup>18,23,24\*</sup>

### Surgeon comfort

- Cord in tubing may enhance comfort and ease of use<sup>25</sup>
- Features tactile buttons for high user feedback.<sup>18,26</sup>

### Efficiency

- The adjustable shaft of the Megadyne™ Telescoping Smoke Evacuation Pencil minimizes the need to exchange electrodes of varying lengths.<sup>25</sup>
- E-Z Clean electrodes with PTFE produce 68% less smoke compared to uncoated stainless steel blades.<sup>27\*\*</sup>

\*May provide more efficient smoke evacuation by capturing smoke at the source.

\*\*In a preclinical porcine model at 60W vs. uncoated stainless steel blades at 60W (p<0.001).

#The following devices are not recommended for compatibility: ConMed Airseal IFS, 1000 and AER Defense, Stryker Neptune S1, Bovie Smoke Shark 1.

¥Third party trademarks are the property of their respective holders. Inclusion of the third party trademarks herein is not to be taken as an endorsement of the MEGADYNE™ Telescoping Smoke Evacuation Pencil by those third parties

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## References:

1. As Per Instructions For Use (133887-200303, 131252-200127, 131119-200124)
2. Ethicon, 14012019, Design Claims Memo for Telescoping Pencils, Dec 2019, Data on File (131500-200727)
3. Ethicon, 6020195-01, Sub-Assy, Megadyne Telescoping Smoke Evacuation Pencil, 10 foot, Dec 2019, Data on File (131500-200727)
4. Ethicon, 6020196-01, Sub-Assy, Megadyne Telescoping Smoke Evacuation Pencil, 15 foot, Dec 2019, Data on File (131500-200727)
5. Ethicon, ENG-RPT-704 Filter Physical characteristics comparison with predicate device filter, Oct 2019, Data on File ((131252-200127)
6. Ethicon, ENG-RPT-753, MESE1 competitive sound test report, Feb 2020, Data on File (131252-200127)
7. (131695-200204)
8. OSHA: Surgical Suite – Common Safety and Health Topics (E932) (119490-200214)
9. CDC NIH: Control of Smoke from Laser/Electric Surgical Procedures (E933) (119490-200214)
10. NIOSH: Control of Smoke from Laser/Electric Surgical Procedures (E934) (119490-200214)
11. Al Sahaf, Chemical composition of smoke produced by high-frequency electrosurgery Ir J Med Sci; 2007;176:229 (121417-190822)
12. Gates. Operating room nursing and lung cancer risk in a cohort of female registered nurses, J Work Environ Health;2007;33(2):140-147 (121417-190822)
13. NIOSH Study Finds Healthcare Workers' Exposure to Surgical Smoke Still Common. Nov 3, 2015 available at <https://www.cdc.gov/niosh/updates/upd-11-03-15.html> [accessed 19.02.2020] (132927-200819)
14. Ethicon, ENG-RPT-704 Filter Physical characteristics comparison with predicate device filter, Oct 2019, Data on File (131252-200127)
15. Ethicon, ENG-RPT-753, MESE1 competitive sound test report, Feb 2020, Data on File (131252-200127)
16. As Per Instructions For Use (131252-200127, 131337-200128, 131317-200128, 131256-200127, 131392-200129, 131334-200128)
17. As Per Instructions For Use (131337-200128, 131119-200124)
18. Ethicon, 14012019, Design Claims Memo for Telescoping Pencils, Jan 2019, Data on File (131625-200203, 131496-200721, 131500-200727, 131758-200205)
19. Ethicon, 6010145-01, Nozzle/Collet Assy, Megadyne Telescoping Pencil, Sept 2019, Data on File (131625-200203)
20. Ethicon, 5800138-01, Lock Nut, Extension, Megadyne Telescoping Pencil, Sept 2019, Data on File (131625-200203)
21. Ethicon, 5800134-01, Straight Swivel, Female, Ultra Vac 2, Nov 2016, Data on File (131496-200721)
22. Ethicon, 5800141-01, Swivel Insert, Male, Megadyne Telescoping Smoke Evacuation Pencil, Nov 2019, Data on File (131496-200721)
23. Ethicon, 6020195-01, Sub-Assy, Megadyne Telescoping Smoke Evacuation Pencil, 10 foot, Dec 2019, Data on File (131500-200727)
24. Ethicon, 6020196-01, Sub-Assy, Megadyne Telescoping Smoke Evacuation Pencil, 15 foot, Dec 2019, Data on File (131500-200727)
25. As Per Instructions For Use (131437-200721, 131621-200721)
26. Ethicon, X4010343, Dome Switch, 6mm, Aug 2019, Data on File (131758-200205)
27. Kisch 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:e1104 (125295-200205)
28. Ethicon, ENG-RPT-710 Universal Smoke Connector Compatibility Summary Report, March 2020, Data on File (144286-200622)
29. Ethicon, ENG-RPT-418, Zip Pen Product Specification Verification Test Report, Feb 2018, Data on File (131696-200204)
30. Ethicon, ENG-RPT-403, Zip Pen Flow Evaluation Test Report, Dec 2014, Data on File (138067-200423)
31. (131695-200204)
32. Kisch 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:e1104 (125295-200205)
33. Ethicon, ZIP PEN™ Instructions for Use, Data on File (123063-190912)
34. Pierce JS, Lacey SE, Lippert JF, Lopez R, Franke JE, Laser-generated air contaminants from medical laser applications: a state-of-thescience review of exposure characterization, health effects, and control;2011;8:447;446
35. Barrett WL, Garber SM, Surgical smoke:a review of the literature,Surg Endosc;2003;17:979-98

**Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.**

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