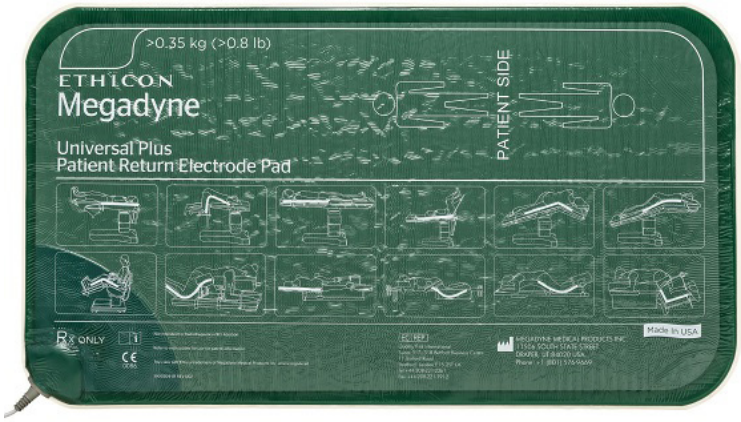
EVALUATION

Capacitive Electrosurgical Return Electrodes—Megadyne™ Mega Soft™ Universal and Mega Soft™ Universal Plus

A Report Excerpted from *Health Devices* | December 2020



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EVALUATION

Capacitive Electrosurgical Return Electrodes—Megadyne™ Mega Soft™ Universal and Mega Soft™ Universal Plus

A Report Excerpted from *Health Devices* | December 2020

This report focuses on our Evaluations of the Megadyne™ Mega Soft™ Universal and Mega Soft™ Universal Plus capacitive electrosurgical return electrodes.

A summary of our findings is presented below and on the next 2 pages. Our detailed Evaluation results for the Mega Soft™ Universal begin on page 6 and for the Mega Soft™ Universal Plus on page 13. Our Evaluation Background, which provides supplementary information, including how the technology is used and what factors we test for, starts on page 20.

RATINGS: CAPACITIVE ELECTROSURGICAL RETURN ELECTRODES

Model	Rating	Where Marketed	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership (Estimated) over Two Years
Megadyne™ Mega Soft™ Universal Last updated May 2020	★★★★☆	Worldwide	Excellent	Excellent	Excellent	Not evaluated	Good	Not evaluated	Good	Not evaluated	Excellent: $2,300*
Megadyne™ Mega Soft™ Universal Plus Last updated May 2020	★★★★☆	Worldwide	Excellent	Excellent	Excellent	Not evaluated	Good	Not evaluated	Good	Not evaluated	Excellent: $2,300*

* Based on prices for the United States, a major market for the product.

Summary of Findings: Capacitive Electrosurgical Return Electrodes

MEGADYNE™ MEGA SOFT™ UNIVERSAL

Where Marketed

As of the time of publication, this product is sold worldwide.

Findings

Our rating is based on the following findings:

Performance—Excellent. The Megadyne™ Mega Soft™ Universal reusable patient return electrode is indicated for use with any size patient.

Safety—Excellent. The Mega Soft™ Universal prevents patient burns in a variety of clinical situations.

Workflow—Excellent. The Mega Soft™ Universal is easy to set up and can be used with patients regardless of their skin condition (for example, it has no adhesive, so there is no potential for skin damage during removal).

Patient Experience—Not evaluated. The patient experience is not a factor when selecting a capacitive electrosurgical return electrode.

Interoperability—Good. The Mega Soft™ Universal met our required criteria for device interoperability. See the product description on the Full Text tab for a list of compatible generators.

Cybersecurity—Not evaluated. Cybersecurity is not applicable when selecting a capacitive electrosurgical return electrode.

Maintenance—Good. The Mega Soft™ Universal met our required criteria for device maintenance; it is intended to last 24 months with appropriate use and cleaning.

User Experience—Not evaluated. User experience is covered in our workflow and maintenance testing.

Cost of Ownership—Excellent; $2,300 (estimated) over two years for a single-corded electrode including an electrosurgical unit compatibility connector cable. Note that this calculation is based on prices for the United States, a major market for the product. A Mega Soft™ Universal reusable electrode has the potential to save a facility at least 52% in acquisition cost with a sufficient volume of electrosurgery patients when compared to the cost of disposable conductive return electrodes.

Considerations for Challenging Environments

There is no significant concern for use of this product in challenging environments. The Mega Soft™ Universal is not associated with any environmental, installation, training, or servicing burdens.

MEGADYNE™ MEGA SOFT™ UNIVERSAL PLUS

Where Marketed

As of the time of publication, this product is sold worldwide.

Findings

Our rating is based on the following findings:

Performance—Excellent. The Megadyne™ Mega Soft™ Universal Plus reusable patient return electrode is indicated for use with any size patient.

Safety—Excellent. The Mega Soft™ Universal Plus prevents patient burns in a variety of clinical situations.

Workflow—Excellent. The Mega Soft™ Universal Plus is easy to set up and can be used with patients regardless of their skin condition (for example, it has no adhesive, so there is no potential for skin damage during removal).

Patient Experience—Not evaluated. The patient experience is not a factor when selecting a capacitive electrosurgical return electrode.

Interoperability—Good. The product met our required criteria for device interoperability. See the product description on the Full Text tab for a list of compatible generators.

Cybersecurity—Not evaluated. Cybersecurity is not applicable when selecting a capacitive electrosurgical return electrode.

Maintenance—Good. The Mega Soft™ Universal Plus met our required criteria for device maintenance; it is intended to last 24 months with appropriate use and cleaning.

User Experience—Not evaluated. User experience is covered in our workflow and maintenance testing.

Cost of Ownership—Excellent; $2,300 (estimated) over two years for a single-corded electrode including an electrosurgical unit compatibility connector cable. Note that this calculation is based on prices for the United States, a major market for the product. A Mega Soft™ Universal Plus reusable patient return electrode has the potential to save a facility at least 52% in acquisition cost with a sufficient volume of electrosurgery patients, when compared to the cost of disposable conductive return electrodes.

Considerations for Challenging Environments

There is no significant concern for use of this product in challenging environments. The Mega Soft™ Universal Plus is not associated with any environmental, installation, training, or servicing burdens.

Megadyne™ Mega Soft™ Universal

PRODUCT DESCRIPTION

1. The Mega Soft™ Universal is a capacitive electrosurgical return electrode intended to disperse monopolar radio-frequency (RF) current from a patient's target tissues back to one electrosurgical unit (ESU)—or two, if a dual-corded capacitive electrode is in use.

2. Major components:

    a) The Mega Soft™ Universal pad—A 1.8 kg (4 lb) capacitive electrosurgical return electrode that consists of a flexible conductive mesh encased between layers of insulating gel (total thickness of 3.2 mm [0.125 in]). The insulation is intended to form a dielectric barrier that allows the conductive mesh to form a capacitive circuit with the patient lying on top of the pad. The pad itself is reusable for 24 months and is very large—52 × 92 cm (20 × 36 in)—offering approximately 40 times the surface area of a standard dual-foil conductive electrosurgical return electrode. It is nonadhesive and does not require the skin preparation and hair clipping that conductive electrosurgical return electrodes require. The electrode typically has one single cord attached to a reinforced corner of the pad for connection to one ESU; a dual-corded version of the pad is available for connection to two ESUs being used simultaneously. The pad is two-sided. The Mega Soft™ Universal does not require any disposable components.

    b) Connector cables—Megadyne™ offers several connector cables in two different lengths (2.4 and 4.4 m [8 and 14.4 ft]) that attach the pad's cord(s) to a variety of ESUs. Furthermore, Megadyne™ offers ESU-specific cables to satisfy the ESUs that only accept dual-foil electrodes.

    c) As of the time of publication, Megadyne™ claims Mega Soft™ compatibility with the following ESUs, with Megadyne™ completing specific generator-compatibility letters upon hospital request:

        (1) Bowa

            (a) Arc 300

            (b) Arc 350

            (c) Arc 400

        (2) ConMed System 5000

        (3) Erbe*

            (a) ICC 350

            (b) VIO 200S

            (c) VIO 300D

            (d) VIO dV

        (4) Eschmann TD830

        (5) Medtronic**

            (a) Force FX-C

            (b) ForceTriad

            (c) Pulsar

            (d) Pulsar II

            (e) Valleylab Force 2

            (f) Valleylab FT10

            (g) Valleylab FX8

        (6) Olympus ESG-400

3. Cleaning requirements:

    a) The Mega Soft™ Universal should be cleaned, rinsed, and dried after use. Megadyne™ has a list of over 40 cleaning/disinfection solutions approved for use with Mega Soft™ return electrodes, including mild bleach, quaternary ammonium, phenol, and alcohol solutions.

* Both Erbe and Megadyne™ report that Megadyne's™ capacitive return electrodes should not be used with certain Erbe specialty modes—High Cut and Endo Cut—as doing so may result in a different electrosurgical effect than intended.

** Some Medtronic generator instructions for use explicitly warn against the use of a return electrode that does not engage their generators' return-electrode contact-quality monitor.

Figure 1. MEGADYNE™ MEGA SOFT™ Universal Reusable Patient Return Electrode

b) Note that alcohol-based solutions may cause staining or hardening of the electrode's outer skin and that cleaning solutions with peroxide should not be used.

4. The Mega Soft™ Universal can be used in any open or minimally invasive surgery that requires the application of radio-frequency monopolar electrosurgery for cutting or control of bleeding. Dedicated specialized radio-frequency ablation equipment should not be used. Clinical applications include:
   a) Cardiac catheterization labs
   b) Cardiothoracic surgery
   c) Dermatologic surgery
   d) Emergency medicine
   e) Endoscopy
   f) Gastrointestinal surgery
   g) General surgery
   h) Gynecology
   i) Labor and delivery
   j) Neurosurgery
   k) Oncologic surgery
   l) Ophthalmology
   m) Orthopedic surgery
   n) Otolaryngology
   o) Plastic/reconstructive surgery
   p) Podiatry
   q) Thoracic surgery
   r) Urology
   s) Vascular surgery
   t) Specialty surgery

5. Optional components:
   a) Repair kit—The outer skin of the electrode's insulating materials should "self-heal" in the event of a small puncture. However, should surgical staff note a larger puncture or tear in the skin when performing visual inspection prior to use, the electrode should be removed from service and fixed using the designated repair kit materials; this will help avoid accidental patient contact with the conductive mesh beneath the insulating layer or with any contaminated, difficult-to-disinfect surfaces.
   b) Additional or replacement connector cables as needed

SIGNIFICANT FINDINGS

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the product. For more details, see the ECRI's Testing section of our Evaluation Background on this technology.

Performance—Excellent

Major Advantage

1. Compatible patient size:
   a) The electrode is indicated for use with any patient 0.36 kg (0.8 lb) or larger. This lower weight limit is below that of the average "very low birth weight" patient, which is defined as a neonate smaller than 1.5 kg (3.3 lb) (CDC 2018). This also accounts for electrode positioning scenarios wherein clinical staff are unable to maximize the patient-electrode contact area.
   b) An electrode that encompasses use with neonatal, pediatric, and adult patients without requiring the purchase and stocking of multiple catalog items is advantageous.

Notable Findings

1. Use of multiple generators may present radio-frequency leakage burn risk:
   a) Regardless of whether capacitive or conductive return electrodes are used, using two simultaneously activating electrosurgical generators on the same patient may expose the patient to a leakage current great enough to cause a burn via contact with a grounded object or solution (i.e., not as a result of return electrode contact).*

* The term leakage current refers to electrical current that is not intended to be applied to the patient. This current normally flows harmlessly, and within an allowable standard limit, from imperfectly insulated conductive portions of a device to earth/ground via the power cord grounding conductor. However, if there is an excessive amount of current, a break in the grounding path, or some other failure, this current can flow through a person in contact with the device, possibly causing injury.

b) The standard leakage current limit (ANSI/AAMI/IEC 2017) is written for a single generator and conductive return electrode, and not for a large capacitive pad or for two generators used on one patient at a time. Facilities need to be aware that, with both conductive and large capacitive return electrodes, the use of two ESUs on one patient can potentially quadruple the resulting power delivered to the tissues from leakage current, with the potential to burn a patient. (See our article Using Multiple Electrosurgical Units on One Patient: What to Do When You Can't Avoid It for further discussion.)

c) Hospitals intending to use multiple ESUs on a single patient, with any type of return electrode(s), should take particular care to ensure that the patient is not touching any grounded object or solution in order to avoid a potential burn.

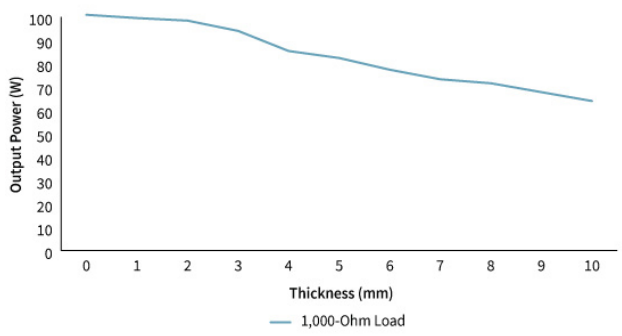

Figure 2. Generator output power when set at 100 W with a 1,000-ohm simulated patient load with increasing blanket thickness between patient and Mega Soft™ Universal reusable patient return electrode.

2. Generator output with the interposition of blankets:

a) A connected generator is able to output within 20% of its set power with an approximately 5 mm (0.2 in) thick blanket interposed between patient and electrode (see Figure 2).

b) The product instructions for use (IFU) tell clinicians to position a patient directly on the electrode in order to maximize contact area, but specify that a loose sheet and draw sheet may be placed over the electrode, which is a likely clinical scenario. While excessive materials between patient and electrode may result in diminished electrosurgical output, two sheets (approximate thickness 2 mm [0.08 in]) are a reasonable clinical expectation and will not substantially impact generator output.

Safety—Excellent

Major Advantage

1. Prevention of electrode burns:

a) We activated an ESU set at 100 W pure cut for 10 seconds while touching the active electrode to the surface of metallic (i.e., conductive) disks with diameters varying from 20 to 200 mm (0.8 to 7.9 in) that were resting on surrogate tissue on the surface of the Mega Soft™ Universal electrode. During this, ECRI did not measure any noticeable rises in either the relative energy density factor* or the surface temperature of the disks, indicating that the surrogate tissue was not damaged.

b) Return electrodes should provide protection from return-site burns; we were not able to elicit any burns to our surrogate patient tissue during testing.

Minor Advantage

1. Prevention of electrode burns when damaged:

a) We observed the electrode gel resealing itself (termed "self-healing") after being punctured with a suture needle and sliced with a scalpel. Energized tissue placed on top of the damaged portion of the electrode did not burn in areas of contact with the damage.

b) Change in electrode uniformity after damage:

(1) Before inflicting the damage described in 1.a., we measured the coupling uniformity—or the current through an energized object coupled to both the pad and the generator's rated surrogate patient load—over 30 sections across the surface of the electrode. We observed that the current through this coupled object was approximately 13% lower in the affected areas before the damage.

(2) While the electrode gel may reseal itself when damaged, it is important to note that the electrode may no longer uniformly disperse current across its surface;

* The energy density factor is the square of current density multiplied by delivery time. It is used as an estimation of the likelihood of skin burns from electrosurgical current through a conductive material (Pearce et al. 1983).

its performance is impacted, and it should be repaired as soon as possible.

c) Despite the minimal burn risk, clinicians should still take care to examine the electrode for damage before every use and repair the device as required. If not repaired, areas of electrode damage could worsen and serve as a path for fluid ingress.

d) Incidental electrode damage is unlikely to result in a patient burn, though users should be aware that significant damage (e.g., larger tears or damage at the connector cord attachment) would necessitate replacement.

Workflow—Excellent

Major Advantage

1. Electrode setup:

a) Preparation when using the Mega Soft™ Universal entails inspecting the electrode for damage, draping the electrode, and positioning the patient on top of it, as dictated by the needs of the procedure. It can be used with a patient no matter the condition of their skin. On a five-point scale from strongly disagree to strongly agree, 90% of product testers indicated that they strongly disagreed with (gave scores of one to) the following statement: "I found the prep required to be overly complex." Additionally, users were able to prep a surrogate patient in approximately 46 seconds, compared with the 1 minute 53 seconds that the same users took to prepare a patient with a conductive return electrode.

b) In contrast, when using a conductive return electrode, clinicians must do the following:

(1) Find an appropriate location to adhere the electrode, since it could, upon removal, potentially damage patients with sensitive skin such as burn patients or diabetic or elderly patients

(2) Clip any hair

(3) Clean and dry the area before affixing the electrode per Association of periOperative Registered Nurses (AORN) recommended practices, as well as the electrode and ESU manufacturers' IFU

Additionally, in case the patient is moved, or the ESU's return-electrode contact-quality monitor alarms, the return electrode must be monitored in case of loss of contact with the patient's skin.

c) The Mega Soft™ Universal electrode simplifies clinician workload during patient prep, while also minimizing the risk of burns associated with standard conductive return electrodes. We should note, however, that during ECRI's user testing, the reusable electrode took significantly more time to disinfect, rinse, dry, and store (2 minutes 12 seconds) than it does to remove and dispose of a conductive return electrode (21 seconds).

Patient Experience—Not Evaluated

While the capacitive pad provides some cushioning for patient comfort, the patient may only briefly be aware of the product before induction of anesthesia, and their experience is not a factor when selecting this product.

Interoperability—Good

The Megadyne™ Mega Soft™ Universal met our required criteria for device interoperability. See the product description for a list of compatible generators.

Cybersecurity—Not Evaluated

Cybersecurity is not applicable when selecting a capacitive electrosurgical return electrode.

Maintenance—Good

The Megadyne™ Mega Soft™ Universal reusable patient return electrode met our required criteria for device maintenance; it is intended to last 24 months with appropriate use and cleaning.

User Experience—Not Evaluated

User experience is covered in our workflow and maintenance testing.

ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR THE MEGADYNE™ MEGA SOFT™ UNIVERSAL

The costs reported in this table represent typical purchase costs reported to ECRI's PriceGuide database. These figures are provided as a guide only and may vary significantly. Note that these figures are based on the United States, a major market for the product.

Factor	Typical Cost	Assumptions
Purchase Costs		
Capital cost	$2,300	Cost of one single-corded capacitive electrosurgical return electrode (catalog no. 0845M2K02). Based on median price paid in ECRI's PriceGuide database.
Typical accessories	$0	One connector cord (catalog no. M2K02)—required for use with ESUs—is included in the purchase price. Median price paid in ECRI's PriceGuide database: $41.
Warranty	$0	Included in purchase price.
Clinical staff training	$0	Included in purchase price.
Biomedical staff training	$0	Not required for use or maintenance of the device.
Infrastructure modifications	$0	Infrastructure modifications are not required for use of an ESU return electrode.
Total purchase cost	$2,300	—
Annual Operational Costs		
Consumables	$0	No consumables required for use of the device.
Expected part replacement—averaged throughout life of product	$0	Parts are expected to last the two-year lifetime of the device. In the event that the electrode's outer skin is punctured, a repair kit is available for $13 (per ECRI's PriceGuide database), but is not typically included in estimating the total cost of ownership of this device. Replacement cables are also available for purchase.
Service	$0	No anticipated service requirements associated with the device.
Annual license fee	$0	No annual license fee required.
Average annual operational cost	$0	—
Estimated Total Cost of Ownership (for an estimated life of two years)	**$2,300**	—

CONSIDERATIONS FOR CHALLENGING ENVIRONMENTS: MEGADYNE™ MEGA SOFT™ UNIVERSAL

As of the time of publication, this product is marketed worldwide.

Category	Remarks
Physical Environment Ability to operate successfully in a variety of adverse conditions	No significant challenges or concerns. The Mega Soft™ Universal is not affected by typical ranges in the physical environment.
Installation Installation requirements compared to other equipment in the same category	No significant challenges or concerns. The Mega Soft™ Universal does not require installation. It may need to be safely stored (e.g., unstretched and away from contact with sharps) in the OR when not in use.
Training and Operation Whether the product can be learned and used without undue burden	No significant challenges or concerns. The Mega Soft™ Universal requires minimal training and offers a patient positioning guide as part of its outer skin.
Servicing Whether the product can be serviced without undue burden	No significant challenges or concerns. The Mega Soft™ Universal does not require servicing.

DISCUSSION OF KEY MANUFACTURER CLAIMS

These claims are drawn from labeling and promotional materials in the United States, a major market for the product.

Megadyne™ Claim	Category	ECRI Perspective
Mega Soft™ Reusable Patient Return Electrodes eliminate the need for small disposable sticky return pads.	Performance	**ECRI partially agrees.** The electrode can be used in most procedures in which a conductive return electrode would be used, but it cannot be used: with high-powered radio-frequency tumor ablation; with certain high-voltage Erbe ICC and VIO generator modes; in conjunction with laparoscopic electrode shielding technologies; or with some orthopedic (e.g., Jackson frame) tables that may require the table to flip for patient access.
Enhanced patient protection—eliminates adhesive-related injuries.	Safety	**ECRI agrees; we consider this a significant benefit.** The patient lies on top of the electrode; it does not need to be adhered to the patient for use, and thus does not pose a risk of damaging sensitive skin, as may occur during removal of adhesive electrodes.
Enhanced patient protection—can be used with jewelry, tattoos, piercings and implants—they will not concentrate energy and increase temperature.	Safety	**ECRI agrees; we consider this a significant benefit.** We did not observe any increase in current concentration or surface temperature when the electrode was used in conjunction with metallic objects. In the case of conductive dual-foil pad use, no metal should be between the active and return electrodes within the monopolar patient circuit to avoid the risk of burns as a result of current concentration.
Enhanced patient protection—Mega Soft™ has been used in over 100 million procedures; 0 pad-site burns.	Safety	**ECRI agrees; we consider this a significant benefit.** We were not able to cause a burn to surrogate patient tissue during our testing, and we are not aware of any burns as a result of use of this electrode in clinical practice.
Ease of use—no skin prep required and no shaving.	Workflow	**ECRI agrees; we consider this a significant benefit.** ECRI testing indicates that the Mega Soft™ Universal patient return electrode simplifies clinician workflow during patient prep, while also minimizing the risk of burns associated with standard conductive return electrodes.
Ease of use—can be used for all patient sizes.	Performance	**ECRI agrees; we consider this a significant benefit.** The electrode is indicated for use with patients as small as 0.36 kg (0.8 lb) with no weight limit.
Ease of use—may be used with a sheet and draw sheet between patient and pad.	Performance	**ECRI agrees, but this is not a purchasing advantage.** We would expect this of a capacitive electrosurgical return electrode. Our testing shows that with two blankets interposed between patient and electrode, the generator output is within 2% of its set power.
Ease of use—compatible with most isolated electrosurgical generators.	Interoperability	**ECRI agrees, but this is not a purchasing advantage.** We would expect this of a capacitive electrosurgical return electrode. The electrode is compatible with most available electrosurgical generators; Megadyne™ will provide a letter of compatibility as needed.
Reduced cost and waste with increased efficiencies—reduces costs vs. sticky pads.	Total Cost of Ownership	**ECRI agrees; we consider this a significant benefit.** If used for a sufficient volume of monopolar electrosurgery procedures over the course of two years, the Mega Soft™ Universal electrode has the potential to save facilities at least 52% when compared to the acquisition cost of conductive return electrodes for the same number of procedures.
Reduced cost and waste with increased efficiencies—reduces SKUs and ordering hassles.	Total Cost of Ownership	**ECRI partially agrees.** Each pad features one associated SKU, and the stocking of many pads for varying patient sizes is not required. ECRI did not interview hospital sourcing personnel regarding the hassles of ordering as part of this Evaluation.
Reduced cost and waste with increased efficiencies—reduces waste and waste-disposal costs.	Total Cost of Ownership	**Unknown.** ECRI did not consider disposal costs as part of its pricing comparison.
Reduced cost and waste with increased efficiencies—saves time: less than half the steps in the operating room vs. sticky pads.	Workflow	**ECRI partially agrees.** In a simulated procedure setup, users took an average of 46 seconds to set up and prepare a patient with the Mega Soft™ Universal electrode. For comparison, the same users took an average of 1:53 to prepare a surrogate patient with a conductive electrode. This is a significant time saving at the beginning of a procedure. However, in a simulated procedure breakdown, users took an average of only 21 seconds to remove and dispose of a conductive electrode, whereas the Mega Soft™ Universal electrode required approximately 2:12 to disinfect, rinse, dry, and store. While preparation with the Mega Soft™ Universal is significantly less cumbersome when compared to a conductive electrode, users should be aware of added OR workflows at the end of a procedure.
Reduced cost and waste with increased efficiencies—reusable for 24 months.	Total Cost of Ownership	**Unknown.** It is unclear if hospitals precisely follow the disinfection, storage, and handling protocols outlined in the product IFU, which outline the care required for the product to last 24 months. Anecdotally, ECRI members indicate that pad reorder is typically not required until after the product expiration date has passed.
Flexible for easy handling in the OR.	Workflow	**ECRI agrees.** The 1.8 kg (4 lb) double-sided pad is fairly easy to maneuver and cannot be set up incorrectly, but should still be properly maintained per the product IFU (e.g., cradled "like a baby," not pulled by the cord).

Cost of Ownership—Excellent; $2,300 (Estimated) over Two Years

If we assume that an operating room hosts four procedures per day that require monopolar electrosurgery for 260 working days of the year, the cost of using disposable dual-foil conductive return electrodes (the average of the median costs of the five most popular electrodes in ECRI's PriceGuide database is $2.35) over two years is approximately $4,900. A Mega Soft™ Universal reusable patient return electrode has the potential to save a facility at least 52% in acquisition cost with a sufficient volume of electrosurgery patients. See Electrosurgical Return Electrodes: Weighing the Clinical and Cost Factors for further discussion.

RECALLS AND HAZARDS

There are no ECRI *Health Devices Alerts* records associated with any version of the Megadyne™ Mega Soft™ electrode as of March 2020.

Megadyne™ Mega Soft™ Universal Plus

PRODUCT DESCRIPTION

1. The Mega Soft™ Universal Plus is a capacitive electrosurgical return electrode intended to disperse monopolar radio-frequency (RF) current from a patient's target tissues back to one electrosurgical unit (ESU)—or two, if a dual-corded capacitive electrode is in use.

2. Major components:
    a) The Mega Soft™ Universal Plus pad—A 3.6 kg (8 lb) capacitive electrosurgical return electrode that consists of a flexible conductive mesh encased between layers of insulating gel (total thickness of 6.4 mm [0.25 in]). The insulation is intended to form a dielectric barrier that allows the conductive mesh to form a capacitive circuit with the patient lying on top of the pad, as well as to increase patient comfort. The pad itself is reusable for 24 months and is very large—52 × 92 cm (20 × 36 in)—offering approximately 40 times the surface area of a standard dual-foil conductive electrosurgical return electrode. It is nonadhesive and does not require the skin preparation and hair clipping that conductive electrosurgical return electrodes require. The electrode typically has one single cord attached to a reinforced corner of the pad for connection to one ESU; a dual-corded version of the pad is available for connection to two ESUs being used simultaneously. The Mega Soft™ Universal Plus does not require any disposable components.
    b) Connector cables—Megadyne™ offers several connector cables (2.4 and 4.4 m [8 and 14.4 ft]) that attach the pad's cord(s) to a variety of ESUs. Furthermore, Megadyne™ offers ESU-specific cables to satisfy the ESUs that only accept dual-foil electrodes.
    c) As of the time of publication, Megadyne™ claims Mega Soft™ compatibility with the following ESUs, with Megadyne™ completing specific generator compatibility letters upon hospital request:
        (1) Bowa
            (a) Arc 300
            (b) Arc 350
            (c) Arc 400
        (2) ConMed System 5000
        (3) Erbe*
            (a) ICC 350
            (b) VIO 200S
            (c) VIO 300D
            (d) VIO dV
        (4) Eschmann TD830
        (5) Medtronic**
            (a) Force FX-C
            (b) ForceTriad
            (c) Pulsar
            (d) Pulsar II
            (e) Valleylab Force 2
            (f) Valleylab FT10
            (g) Valleylab FX8
        (6) Olympus ESG-400

3. Cleaning requirements
    a) The Mega Soft™ Universal Plus should be cleaned, rinsed, and dried after use. Megadyne™ has a list of over 40 cleaning/disinfection solutions approved for use with

* Both Erbe and Megadyne™ report that Megadyne's™ capacitive return electrodes should not be used with certain Erbe specialty modes—High Cut and Endo Cut—as doing so may result in a different electrosurgical effect than intended.

** Some Medtronic generator instructions for use explicitly warn against the use of a return electrode that does not engage their generators' return-electrode contact-quality monitor.

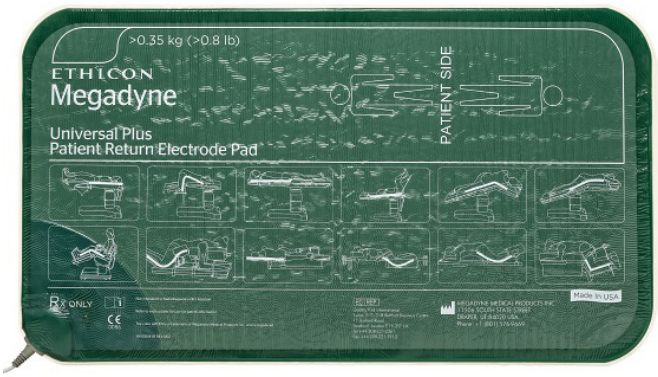

Figure 1. MEGADYNE™ MEGA SOFT™ Universal Plus Reusable Patient Return Electrode © Ethicon, Inc. 2018. Reproduced with permission.

Mega Soft™ return electrodes, including mild bleach, quaternary ammonium, phenol, and alcohol solutions.

b) Note that alcohol-based solutions may cause staining or hardening of the electrode's outer skin and that cleaning solutions with peroxide should not be used.

4. The Mega Soft™ Universal Plus can be used in any open or minimally invasive surgery that requires the application of radio-frequency monopolar electrosurgery for cutting or control of bleeding. Dedicated specialized radio-frequency ablation equipment should not be used. Clinical applications include:
   a) Cardiac catheterization labs
   b) Cardiothoracic surgery
   c) Dermatologic surgery
   d) Emergency medicine
   e) Endoscopy
   f) Gastrointestinal surgery
   g) General surgery
   h) Gynecology
   i) Labor and delivery
   j) Neurosurgery
   k) Oncologic surgery
   l) Ophthalmology
   m) Orthopedic surgery
   n) Otolaryngology
   o) Plastic/reconstructive surgery
   p) Podiatry
   q) Thoracic surgery
   r) Urology
   s) Vascular surgery
   t) Specialty surgery

5. Optional components:
   a) Repair kit—The outer skin of the electrode's insulating materials should "self-heal" in the event of a small puncture. However, should surgical staff note a larger puncture or tear in the skin when performing visual inspection prior to use, the electrode should be removed from service and fixed using the designated repair kit materials in order to avoid accidental patient contact with the conductive mesh beneath the insulating layer or with any contaminated, difficult-to-disinfect surfaces.
   b) Additional or replacement connector cables as needed

SIGNIFICANT FINDINGS

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the product. For more details, see the ECRI's Testing section of our Evaluation Background on this technology.

Performance—Excellent

Major Advantage

1. Compatible patient size:
   a) The electrode is indicated for use with any patient 0.36 kg (0.8 lb) or larger. This lower weight limit is below that of the average "very low birth weight" patient, which is defined as a neonate smaller than 1.5 kg (3.3 lb) (CDC 2018). This also accounts for electrode positioning scenarios wherein clinical staff are unable to maximize the patient-electrode contact area.
   b) An electrode that encompasses use with neonatal, pediatric, and adult patients without requiring the purchase and stocking of multiple catalog items is advantageous.

Notable Findings

1. Use of multiple generators may present RF leakage burn risk:
   a) Regardless of whether capacitive or conductive return electrodes are used, using two simultaneously activating electrosurgical generators on the same patient may expose the patient to a leakage current great enough to cause a burn via contact with a grounded object or solution (i.e., not as a result of return electrode contact).*

*The term leakage current refers to electrical current that is not intended to be applied to the patient. This current normally flows harmlessly, and within an allowable standard limit, from imperfectly insulated conductive portions of a device to earth/ground via the power cord grounding conductor. However, if there is an excessive amount of current, a break in the grounding path, or some other failure, this current can flow through a person in contact with the device, possibly causing injury.

b) The standard leakage current limit (ANSI/AAMI/IEC 2017) is written for a single generator and conductive return electrode, and not for a large capacitive pad or for two generators used on one patient at a time. Facilities need to be aware that, with both conductive and large capacitive return electrodes, the use of two ESUs on one patient can potentially quadruple the resulting power delivered to the tissues from leakage current, with the potential to burn a patient. (See our article Using Multiple Electrosurgical Units on One Patient: What to Do When You Can't Avoid It for further discussion.)

c) Hospitals intending to use multiple ESUs on a single patient, with any type of return electrode(s), should take particular care to ensure that the patient is not touching any grounded object or solution in order to avoid a potential burn.

2. Generator output with the interposition of blankets:

a) A connected generator is able to output within 20% of its set power with an approximately 6 mm (0.24 in) thick blanket interposed between patient and electrode (see Figure 2).

b) The product instructions for use (IFU) tell clinicians to position a patient directly on the electrode in order to maximize contact area, but specify that a loose sheet and draw sheet may be placed over the electrode, which is a likely clinical scenario. While excessive materials between patient and electrode may result in diminished electrosurgical output, two sheets (approximate thickness 2 mm [0.08 in]) are a reasonable clinical expectation and will not substantially impact generator output.

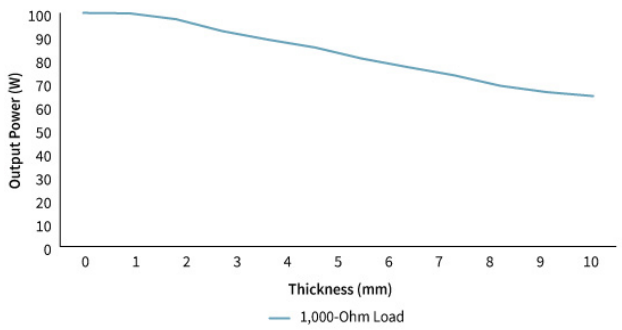

Figure 2. Generator output power when set at 100 W with a 1,000-ohm simulated patient load with increasing blanket thickness between patient and Mega Soft™ Universal Plus reusable patient return electrode.

Safety—Excellent

Major Advantage

1. Prevention of electrode burns:

a) We activated an ESU set at 100 W pure cut for 10 seconds while touching the active electrode to the surface of metallic (i.e., conductive) disks with diameters varying from 20 to 200 mm (0.8 to 7.9 in) that were resting on surrogate tissue on the surface of the Mega Soft™ Universal Plus. During this, ECRI did not measure any noticeable rises in either the relative energy density factor* or the surface temperature of the disks, indicating that the surrogate tissue was not damaged.

b) Return electrodes should provide protection from return-site burns; we were not able to elicit any burns to our surrogate patient tissue during testing.

Minor Advantage

1. Prevention of electrode burns when damaged:

a) We observed the electrode gel resealing itself (termed "self-healing") after being punctured with a suture needle and sliced with a scalpel. Energized tissue placed on top of the damaged portion of the electrode did not burn in areas of contact with the damage.

* The energy density is the square of current density multiplied by delivery time. It is used as an estimation of the likelihood of skin burns from electrosurgical current through a conductive material (Pearce et al. 1983).

b) Change in electrode uniformity after damage:

(1) Before inflicting the damage described in 1.a., we measured the coupling uniformity—or the current through an energized object coupled to both the pad and the generator's rated surrogate patient load—over 30 sections across the surface of the electrode. We observed that the current through this coupled object was approximately 14% lower in the affected areas before the damage.

(2) While the electrode gel may reseal itself when damaged, it is important to note that the electrode may no longer uniformly disperse current across its surface; its performance is impacted, and it should be repaired as soon as possible.

c) Despite the minimal burn risk, clinicians should still take care to examine the electrode for damage before every use and repair the device as required. If not repaired, areas of electrode damage could worsen and serve as a path for fluid ingress.

d) Incidental electrode damage is unlikely to result in a patient burn, though users should be aware that significant damage (e.g., larger tears or damage at the connector cord attachment) would necessitate replacement.

Workflow—Excellent

Major Advantage

1. Electrode setup:

a) Preparation when using the Mega Soft™ Universal Plus entails inspecting the electrode for damage, draping it, and positioning the patient on top of it, as dictated by the needs of the procedure. It can be used regardless of the condition of the patient's skin. On a five-point scale from strongly disagree to strongly agree, 100% of product testers indicated that they disagreed with (gave scores of one or two to) the statement "I found the prep required to be overly complex." Additionally, users were able to prep a surrogate patient in approximately 44 sec, compared with the 1 min 53 sec that the same users took to prepare a patient with a conductive return electrode.

b) In contrast, when using a conductive return electrode, clinicians must do the following:

(1) Find an appropriate location to adhere the electrode, since it could, upon removal, potentially damage patients with sensitive skin such as burn patients or diabetic or elderly patients

(2) Clip any hair

(3) Clean and dry the area before affixing the electrode per Association of periOperative Registered Nurses (AORN) recommended practices, as well as the electrode and ESU manufacturers' IFU

Additionally, in case the patient is moved, or the ESU's return-electrode contact-quality monitor alarms, the return electrode must be monitored in case of loss of contact with the patient's skin.

c) The Mega Soft™ Universal Plus simplifies clinician workload during patient prep, while also minimizing the risk of burns associated with standard conductive return electrodes. We should note, however, that the reusable electrode takes significantly more time to disinfect, rinse, dry, and store (2 min 10 sec) than it does to remove and dispose a conductive return electrode (21 sec).

Patient Experience—Not Evaluated

While the capacitive pad provides some cushioning for patient comfort, the patient may only briefly be aware of the product before induction of anesthesia, and their experience is not a factor when selecting this product.

Interoperability—Good

The Megadyne™ Mega Soft™ Universal Plus met our required criteria for device interoperability. See the product description for a list of compatible generators.

Cybersecurity—Not Evaluated

Cybersecurity is not applicable when selecting a capacitive electrosurgical return electrode.

Maintenance—Good

The Megadyne™ Mega Soft™ Universal Plus met our required criteria for device maintenance; it is intended to last 24 months with appropriate use and cleaning.

User Experience—Not Evaluated

User experience is covered in our workflow and maintenence testing.

ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR THE MEGADYNE™ MEGA SOFT™ UNIVERSAL PLUS

The costs reported in this table represent typical purchase costs reported to ECRI's PriceGuide database. These figures are provided as a guide only and may vary significantly. Note that these figures are based on the United States, a major market for the product.

Factor	Typical Cost	Assumptions
Purchase Costs		
Capital cost	$2,300	Cost of one single-corded capacitive electrosurgical return electrode (catalog no. 0847M2K02). Based on median price paid in ECRI's PriceGuide database.
Typical accessories	$0	One connector cord (catalog no. M2K02)—required for use with ESUs—is included in the purchase price. Median price paid in ECRI's PriceGuide database: $41.
Warranty	$0	Included in purchase price.
Clinical staff training	$0	Included in purchase price.
Biomedical staff training	$0	Not required for use or maintenance of the device.
Infrastructure modifications	$0	Infrastructure modifications are not required for use of an ESU return electrode.
Total purchase cost	$2,300	—
Annual Operational Costs		
Consumables	$0	No consumables required for use of the device.
Expected part replacement—averaged throughout life of product	$0	Parts are expected to last the two-year lifetime of the device. In the event that the electrode's outer skin is punctured, a repair kit is available for $13 (per ECRI's PriceGuide database), but is not typically included in estimating the total cost of ownership of this device. Replacement cables are available for purchase.
Service	$0	No anticipated service requirements associated with the device.
Annual license fee	$0	No annual license fee required.
Average annual operational cost	$0	—
Estimated Total Cost of Ownership (for an estimated life of two years)	**$2,300**	—

CONSIDERATIONS FOR CHALLENGING ENVIRONMENTS: MEGADYNE™ MEGA SOFT™ UNIVERSAL PLUS

As of the time of publication, this product is marketed worldwide.

Category	Remarks
Physical Environment Ability to operate successfully in a variety of adverse conditions	No significant challenges or concerns. The Mega Soft™ Universal Plus is not affected by typical ranges in the physical environment.
Installation Installation requirements compared to other equipment in the same category	No significant challenges or concerns. The Mega Soft™ Universal Plus does not require installation. It may need to be safely stored (e.g., unstretched and away from contact with sharps) in the OR when not in use.
Training and Operation Whether the product can be learned and used without undue burden	No significant challenges or concerns. The Mega Soft™ Universal Plus requires minimal training and offers a patient positioning guide as part of its outer skin.
Servicing Whether the product can be serviced without undue burden	No significant challenges or concerns. The Mega Soft™ Universal Plus does not require servicing.

DISCUSSION OF KEY MANUFACTURER CLAIMS

These claims are drawn from labeling and promotional materials in the United States, a major market for the product.

Megadyne™ Claim	Category	ECRI Perspective
Mega Soft™ Reusable Patient Return Electrodes eliminate the need for small disposable sticky return pads.	Performance	**ECRI partially agrees.** The electrode can be used in most procedures in which a conductive return electrode would be used, but it cannot be used: with high-powered radio-frequency tumor ablation; with certain high-voltage Erbe ICC and VIO generator modes; in conjunction with laparoscopic electrode shielding technologies; or with some orthopedic (e.g., Jackson frame) tables that may require the table to flip for patient access.
Enhanced patient protection—eliminates adhesive-related injuries.	Safety	**ECRI agrees; we consider this a significant benefit.** The patient lies on top of the electrode; it does not need to be adhered to the patient for use, and thus does not pose a risk of damaging sensitive skin, as may occur during removal of adhesive electrodes.
Enhanced patient protection—can be used with jewelry, tattoos, piercings and implants—they will not concentrate energy and increase temperature.	Safety	**ECRI agrees; we consider this a significant benefit.** We did not observe any increase in current concentration or surface temperature when the electrode was used in conjunction with metallic objects. In the case of conductive dual-foil pad use, no metal should be between the active and return electrodes within the monopolar patient circuit to avoid the risk of burns as a result of current concentration.
Enhanced patient protection—Mega Soft™ has been used in over 100 million procedures; 0 pad-site burns.	Safety	**ECRI agrees; we consider this a significant benefit.** We were not able to cause a burn to surrogate patient tissue during our testing, and we are not aware of any burns as a result of use of this electrode in clinical practice.
Patient Comfort—Pressure Reduction.	Performance/ Safety	**Unknown.** ECRI is not aware of any clinical or peer-reviewed evidence supporting the claim of pressure reduction from the Mega Soft™ Universal Plus. The pad is thicker than the Universal electrode and would logically provide more padding; however, a patient is likely already situated on top of a padded procedure table. On a five-point scale from strongly disagree to strongly agree, 100% of product testers indicate that they agreed with (gave scores of 4 or 5 to) the statement "If I were a patient, I would find this pad comfortable." For reference, 80% of users agreed regarding the Universal pad, and only 30% of users agreed regarding a conductive (i.e., dual-foil) pad.
Ease of use—no skin prep required and no shaving.	Workflow	**ECRI agrees; we consider this a significant benefit.** ECRI testing indicates that the Mega Soft™ Universal Plus patient return electrode simplifies clinician workload during patient prep, while also minimizing the risk of burns associated with standard conductive return electrodes.
Ease of use—can be used for all patient sizes.	Performance	**ECRI agrees; we consider this a significant benefit.** The electrode is indicated for use with patients as small as 0.36 kg (0.8 lb), with no weight limit.
Ease of use—may be used with a sheet and draw sheet between patient and pad.	Performance	**ECRI agrees, but this is not a purchasing advantage.** We would expect this of a capacitive electrosurgical return electrode. Our testing shows that with two blankets interposed between patient and electrode, the generator output is within 3% of its set power.
Ease of use—compatible with most isolated electrosurgical generators.	Interoperability	**ECRI agrees, but this is not a purchasing advantage.** We would expect this of a capacitive electrosurgical return electrode. The electrode is compatible with most available electrosurgical generators; Megadyne™ will provide a letter of compatibility as needed.
Reduced cost and waste with increased efficiencies—reduces costs vs. sticky pads.	Total Cost of Ownership	**ECRI agrees; we consider this a significant benefit.** If used for a sufficient volume of monopolar electrosurgery procedures over the course of two years, the Mega Soft™ Universal electrode has the potential to save facilities at least 52% when compared to the acquisition cost of conductive return electrodes for the same number of procedures.
Reduced cost and waste with increased efficiencies—reduces SKUs and ordering hassles.	Total Cost of Ownership	**ECRI partially agrees.** Each pad features one associated SKU and the stocking of many pads for varying patient sizes is not required. ECRI did not interview hospital sourcing personnel regarding the hassle of ordering as part of this Evaluation.
Reduced cost and waste with increased efficiencies—reduces waste and waste-disposal costs.	Total Cost of Ownership	**Unknown.** ECRI did not consider disposal costs as part of its pricing comparison.
Reduced cost and waste with increased efficiencies—saves time: less than half the steps in the operating room vs. sticky pads.	Workflow	**ECRI partially agrees.** In a simulated procedure setup, users took an average of 44 seconds to set up and prepare a patient with the Mega Soft™ Universal Plus electrode. For comparison, the same users took an average of 1:53 to prepare a surrogate patient with a conductive electrode. This is a significant time saving at the beginning of a procedure. However, in a simulated procedure breakdown, users took an average of only 21 seconds to remove and dispose of a conductive electrode, whereas the Mega Soft™ Universal Plus electrode required approximately 2:10 to disinfect, rinse, dry, and store. While preparation with the Mega Soft™ Universal Plus is significantly less cumbersome when compared to a conductive electrode, users should be aware of added OR workflows at the end of a procedure.

DISCUSSION OF KEY MANUFACTURER CLAIMS (CONTINUED)

Megadyne™ Claim	Category	ECRI Perspective
Reduced cost and waste with increased efficiencies—reusable for 24 months.	Total Cost of Ownership	**Unknown.** It is unclear if hospitals precisely follow the disinfection, storage, and handling protocols outlined in the product IFU, which outline the care required for the product to last 24 months. Anecdotally, ECRI members indicate that pad reorder is typically not required until after the product expiration date has passed.
Flexible for easy handling in the OR.	Workflow	**ECRI agrees.** The 3.6 kg (8 lb) single-sided pad is lighter than previous versions of the Mega Soft™ pad, though some test users felt it was heavy and difficult to handle, particularly to flip it over for disinfection. Additionally, users were concerned that since the pad is not double-sided like its predecessor, it might be accidentally placed upside down, draped, and used against IFU. The electrode should be properly maintained per the product IFU (e.g., cradled "like a baby," not pulled by the cord).

Cost of Ownership—Excellent; $2,300 (Estimated) over Two Years

If we assume that an operating room hosts four procedures per day that require monopolar electrosurgery for 260 working days of the year, the cost of using disposable dual-foil conductive return electrodes (the average of the median costs of the five most popular electrodes in ECRI's PriceGuide database is $2.35) over two years is approximately $4,900. A Mega Soft™ Universal Plus reusable patient return electrode has the potential to save a facility at least 52% in acquisition cost with a sufficient volume of electrosurgery patients. See Electrosurgical Return Electrodes: Weighing the Clinical and Cost Factors for further discussion.

RECALLS AND HAZARDS

There are no ECRI *Health Devices Alerts* records associated with any version of the Megadyne™ Mega Soft™ electrode as of March 2020.

Evaluation Background: Capacitive Electrosurgical Return Electrodes

OVERVIEW

Monopolar electrosurgery involves the generation of a circuit through a patient's body. When a surgeon activates an electrosurgical unit (ESU), it generates a high-frequency current. This current enters a patient at the point of application of an active electrode at the operative site, passes through the patient, then leaves the patient and returns to the generator via an electrode with a much larger surface area. This return electrode may disperse the current via either a conductive or capacitive function; in this article, we are describing a capacitive electrode.*

Capacitive electrosurgical return electrodes are large, reusable pads that are placed beneath the patient.** In electrosurgery, they disperse monopolar radio-frequency (RF) current from a patient's target tissues back to one ESU—or two, if a dual-corded capacitive electrode is in use.

To be considered in this clinical category, a product typically:

1. Consists of a conductive plate or mesh encased in insulating materials. See Principles of Operation for a description of how this setup forms a capacitive circuit with a patient and how it safely returns electrosurgical current from the patient to the ESU while the desired surgical effect is created at the surgical site.
2. Does not rely on direct contact with, or adhesion to, a patient's skin in order to function
3. Is reusable

The use of capacitively coupled return electrodes was suggested as early as 1938. In 1960, the Birtcher Corporation sold the Safetrode, a large (65 × 39 cm [25.5 × 15.5 in]) reusable return electrode.*** However, the use of these electrodes in general surgery never gained much traction due to general safety concerns regarding the durability of the electrode's outer casing—since damage or wear could potentially allow direct conductive connection with a patient—as well as the fact that these electrodes do not engage one of the major safety features of a modern ESU, the return-electrode contact-quality monitor (RECQM); potential users perceived this as being less safe than a conductive return electrode that would engage the RECQM.† See the Safety section for more discussion on this concern.

Capacitive return electrodes are currently available from only a single manufacturer, Megadyne™ Medical Products. In 2000, Megadyne™ began marketing the first version of their large capacitive return electrode, the Mega 2000. This electrode consisted of a large sheet of conductive fabric enclosed in an insulating material and used a nonadhesive, disposable protective sheath that required changing daily. It measured 50.5 × 91.2 cm (20 × 36 in), was indicated for patients over 11.3 kg (25 lb), and had an expected product life of 18 months.

Capacitive electrosurgical return electrodes are an evolving technology. Megadyne™ continues to add features that may increase device utility with regard to patient size, positioning, and comfort, as well as clinician handling. These features include:

1. Reduction in pad weight compared to some of the previous versions
2. Expanding the indicated patient population to include patients smaller than 0.45 kg (1 lb)
3. Extending product life to 24 months
4. Enhancing the insulating gel for added patient comfort compared to some previous versions, as well as protection against pad puncture from surgical sharps and destructive cleaning materials
5. Adding a patient positioning guide to the face of the product
6. Adding the option of a pad with dual generator connections for multiple ESUs in one procedure

* The other type, a conductive return electrode, often referred to as a "sticky pad," is a flat, disposable, adhesive-pad electrode that includes a conductive gel or adhesive that is in contact with the patient. The electrode can be single or dual foil. In a dual-foil electrode, the conductive surface is divided into two parts, with each part connected independently (via the same cable) to the ESU; this allows the generator to detect impedance differences between the two halves and enables return-electrode contact-quality monitoring, which halts ESU activation when the impedance is out of the expected range or if the impedance changes too much from its initial value.

** A capacitive electrode has approximately 40 times the surface area of a standard dual-foil conductive return electrode.

*** Pearce JA. Electrosurgery. New York: Wiley; 1986.

† An RECQM is an alarm that activates when it detects poor conductive electrode-patient contact or a return discontinuity. It requires a dual-foil conductive return electrode and can assess the quality of the electrode-to-skin contact; if the impedance between the foils of the electrode and the patient's skin exceeds certain critical limits that indicate degraded contact (e.g., due to peeling or detachment), the monitor will alarm and deactivate the ESU's output.

7. No longer requiring the use of a disposable sheath for each procedure, reducing the amount of waste associated with each pad

The major components are a conductive plate or mesh encased in an insulating gel, along with cords to facilitate connection of the capacitive return electrode to one or two ESUs.

Clinical applications consist of any open or minimally invasive surgery that requires the application of non-ablative radio-frequency monopolar electrosurgery for cutting or control of bleeding. Facilities and clinical departments that would use this product include:

1. Cardiac catheterization labs
2. Cardiothoracic surgery
3. Dermatologic surgery
4. Emergency medicine
5. Endoscopy
6. Gastrointestinal surgery
7. General surgery
8. Gynecology
9. Labor and delivery
10. Neurosurgery
11. Oncologic surgery
12. Ophthalmology
13. Orthopedic surgery
14. Otolaryngology
15. Plastic/reconstructive surgery
16. Podiatry
17. Thoracic surgery
18. Urology
19. Vascular surgery
20. Specialty surgery

The types of people who use the product include surgeons, physician assistants, circulating nurses, registered nurse first assistants, registered nurses, and surgical technologists. These products are referred to by a number of names; common synonyms include capacitive pad, gel pad, Mega Soft™, and reusable dispersive electrode.

OTHER CURRENTLY AVAILABLE CAPACITIVE ELECTROSURGICAL RETURN ELECTRODES

Note that, as of the time of publication, Megadyne™ is the only manufacturer of capacitive electrosurgical return electrodes.

Megadyne™ Medical Products Inc. [184531]

- Mega 2000
- Mega Soft™

ECRI'S TESTING

Our testing looks at what we believe are the important considerations when choosing a capacitive electrosurgical return electrode, as described below.

Performance

1. The impact that the introduction of the capacitive element into the monopolar electrosurgical circuit has on the ESU output at the surgical site; this impact should be negligible
2. Applicability for a wide patient population, from neonatal to bariatric patients
3. Performance when attached to two ESUs for one patient
4. Impact on electrosurgical output when interposed with an electric warming blanket or other potential barrier
5. The ability of the pad to uniformly pass current across its surface

Safety

1. Prevention of burns in varying situations—specifically:
    a) When the contact area between patient and pad is diminished
    b) When an alternate current pathway is introduced, such as one that might unintentionally transfer electrical current from the active electrode path, through insulating materials, to adjacent conductive material or tissues
    c) When the electrode is punctured during use
    d) When the electrode is interposed with conductive materials that might be in the vicinity of the surgical area
2. Uninterrupted function of an ESU's continuity monitor
3. Minimization of the risk of pressure-related skin injury

Workflow

1. Ease of patient preparation
2. Ease of device handling
3. Presence of device odor that might be unpleasant for staff or patients

Patient Experience

Not evaluated; the patient experience is not a factor when selecting a capacitive electrosurgical return electrode.

Interoperability

We assess the electrode's compatibility with a variety of available ESUs.

Cybersecurity

Not evaluated; cybersecurity is not applicable when selecting a capacitive electrosurgical return electrode.

Maintenance

1. Ease of cleaning
2. Ease of storage
3. Quality of construction

User Experience

Not evaluated; aspects of user interaction with the device are covered in our workflow and maintenance testing.

Cost of Ownership

We estimate the total cost of ownership over the product's expected life, including acquisition cost for the electrode and any required connector cables.

TECHNOLOGY BACKGROUND

Principles of Operation

1. Capacitive electrosurgical return electrodes consist of a conductive plate or mesh encased in insulating materials.
2. These insulating materials should separate the patient from the electrode, acting as a thin dielectric barrier, as well as provide a secondary cushioning effect for the patient. If any linens, cushions, or other materials are used on top of the capacitive return electrode, they also become part of the dielectric barrier.
3. The barrier between two conductive materials—the patient and the conductive plate or mesh—allows the formation of a capacitor, which is an electrical circuit element used to temporarily store a charge.
4. When the active electrode is applied at the surgical site, the ESU induces an oscillating voltage between the conductive materials—these are the patient and the conductive plate or mesh—alternating approximately 400,000 times per second (the frequency depends on the specific ESU). During this oscillation, several things happen:
    a) Electrical charge accumulates and diminishes in cycles, both where the patient is in contact with the dielectric barrier and on the electrode's conductive plate, in equal and opposing polarities.
    b) The dielectric material polarizes; electrical charge does not move through it.
    c) As charge moves to and from the surfaces of the patient's skin, there is a loss of energy that produces a minimal amount of heat within the skin.
5. In surgical use, even though electrical charge does not move through it, this type of electrode allows current flow across the electrode-patient capacitor such that electricity is safely returned from the patient to the ESU while the desired surgical effect is created at the surgical site.

Normal Operating Procedure

1. Clinicians inspect the capacitive pad for damage (e.g., punctures, peeling, cracked insulation) to the outer skin, cables, and connectors. Damaged outer skin should be repaired before use, according to the manufacturer's instructions for use (IFU), and damaged connectors replaced.
2. The capacitive pad is placed on the operating surface and smoothed to avoid any wrinkling, folding, or stretching. If a warming device is used, the capacitive pad should be placed on top of it, or staggered to maximize patient contact.
3. The patient is placed on top of the electrode in a way that maximizes contact area, and that minimizes materials (e.g., linens) between patient and pad so as not to diminish the intended electrosurgical effect at the site of active electrode application. No patient skin preparation (e.g., hair clipping, removal of jewelry and other metallic objects) is needed for system operation.

4. The capacitive pad is connected to the procedure room's powered-on ESU (or ESUs if two generators are being used with a dual-cord capacitive pad) via the appropriate connector cable into the return electrode socket. The ESU's RECQM icon should indicate correct installation.
5. The surgical team proceeds with monopolar electrosurgery as the procedure requires.
6. After the procedure, the ESU is turned off and the connector cable removed from the return electrode socket. The capacitive pad can be cleaned with an appropriate cleaning solution, rinsed to remove any chemical residue, allowed to dry, and then stored.

Safety

ECRI has not investigated any ESU burn incidents that resulted in the conclusion that a patient burn resulted from use of a capacitive electrosurgical return electrode. However, some ESU manufacturer IFU issue warnings against return electrodes that disable the RECQM, which will only function with conductive dual-foil return electrodes. By design, the large capacitive return electrode negates the need for an RECQM—significant partial detachment of the electrode (e.g., peeling) is unlikely due to the fact that it is positioned under the patient, and detachment would only diminish the power output at the surgical site.* As such, there is minimal risk of a return-site burn. However, a facility should be aware that using a capacitive return electrode may go against their chosen generator's IFU.

Additionally, facilities using Erbe generators should be aware that both Erbe and Megadyne™ report that Megadyne's™ capacitive return electrodes should not be used with certain Erbe modes (High Cut and Endo Cut), as doing so may result in a different electrosurgical effect than intended. This is a long-standing issue, which ECRI reported on as far back as 2000, when we evaluated the Megadyne™ Mega 2000 (the predecessor to the Mega Soft™ capacitive return electrode).

* Surgical teams should always check the electrosurgical return electrode and cables for any issues before increasing the generator's power output.

ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR A CAPACITIVE ELECTROSURGICAL RETURN ELECTRODE

The costs reported in this table represent typical quotation and purchase costs reported to ECRI's PriceGuide database. These figures are provided as a guide only and may vary significantly.

Factor	Typical Cost	Assumptions
Purchase Costs		
Capital cost	$2,300	Cost of one single-corded capacitive electrosurgical return electrode. Based on median price paid in ECRI's PriceGuide database
Typical accessories	$0	One connector cord—required for use with ESUs—included in purchase price. Median price paid in ECRI's PriceGuide database: $41.
Warranty	$0	Included in purchase price.
Clinical staff training	$0	Included in purchase price.
Biomedical staff training	$0	Not required for use or maintenance of the device.
Infrastructure modifications	$0	Infrastructure modifications are not required for use of an ESU return electrode.
Total purchase cost	$2,300	—
Annual Operational Costs		
Consumables	$0	No consumables required for use of the device.
Expected part replacement—averaged throughout life of product	$0	Parts are expected to last the expected two-year lifetime of the device. In the event that the electrode's outer skin is punctured, a repair kit is available for $13, but is not typically included in estimating the total cost of ownership of this device. Replacement cables are available for purchase.
Service	$0	No anticipated service requirements associated with the device.
Annual license fee	$0	No annual license fee required.
Average annual operational cost	$0	—
Estimated Total Cost of Ownership (for an estimated life of two years)	**$2,300**	—

Cost

If we assume that an operating room hosts four procedures per day that require monopolar electrosurgery for 260 working days of the year, the cost of using disposable dual-foil conductive return electrodes (the average of the median costs of the five most popular electrodes in ECRI's PriceGuide database is $2.35) over two years is approximately $4,900. A Mega Soft™ reusable patient return electrode has the potential to save a facility at least 52% in acquisition cost with a sufficient volume of electrosurgery patients. See Electrosurgical Return Electrodes: Weighing the Clinical and Cost Factors for further discussion.

RECALL AND HAZARD ANALYSIS

The are no ECRI *Health Devices Alerts* records associated with capacitive electrosurgical return electrodes. We are not aware of any associated patient burns when the electrodes are used according to the manufacturer's instructions.

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About ECRI

ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on patient safety, evidence-based medicine, and health technology decision solutions, ECRI is the trusted expert for healthcare leaders and agencies worldwide. The Institute for Safe Medication Practices (ISMP) is an ECRI affiliate. Visit ecri.org and follow @ECRI_Org.

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