



**Medtronic**

# Aquamantys<sup>®</sup> System

HELPING SURGEONS ACHIEVE HEMOSTASIS



# Advanced Energy

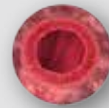
Medtronic Advanced Energy is dedicated to developing technology that provides benefits to surgeons and their patients. Our Aquamantys® System uses proprietary Transcollation® technology, a combination of radio frequency (RF) energy and saline, to provide hemostatic sealing of soft tissue and bone during surgery.

The Aquamantys System delivers Transcollation technology through an electro-surgical generator and handheld disposable devices. These products are used across a wide range of specialties, including spine surgery, orthopaedic reconstruction, orthopaedic trauma and surgical oncology. Aquamantys products are currently used in all of the top 18 hospitals listed in the *U.S. News & World Report* 2013-2014 Honor Roll of "America's Best Hospitals."<sup>1</sup>

## Unique Technology

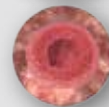
The combination of saline and RF energy in Transcollation technology allows the device temperature to stay at approximately 100°C – nearly 200°C less than traditional devices. The lower device temperature produces a tissue effect without the associated smoke and charring found in other methods.

## Hemostatic Sealing of Soft Tissue and Bone to Reduce Blood Loss



### Step 1

RF energy and saline are applied to tissue



### Step 2

Heat-induced shrinkage occurs

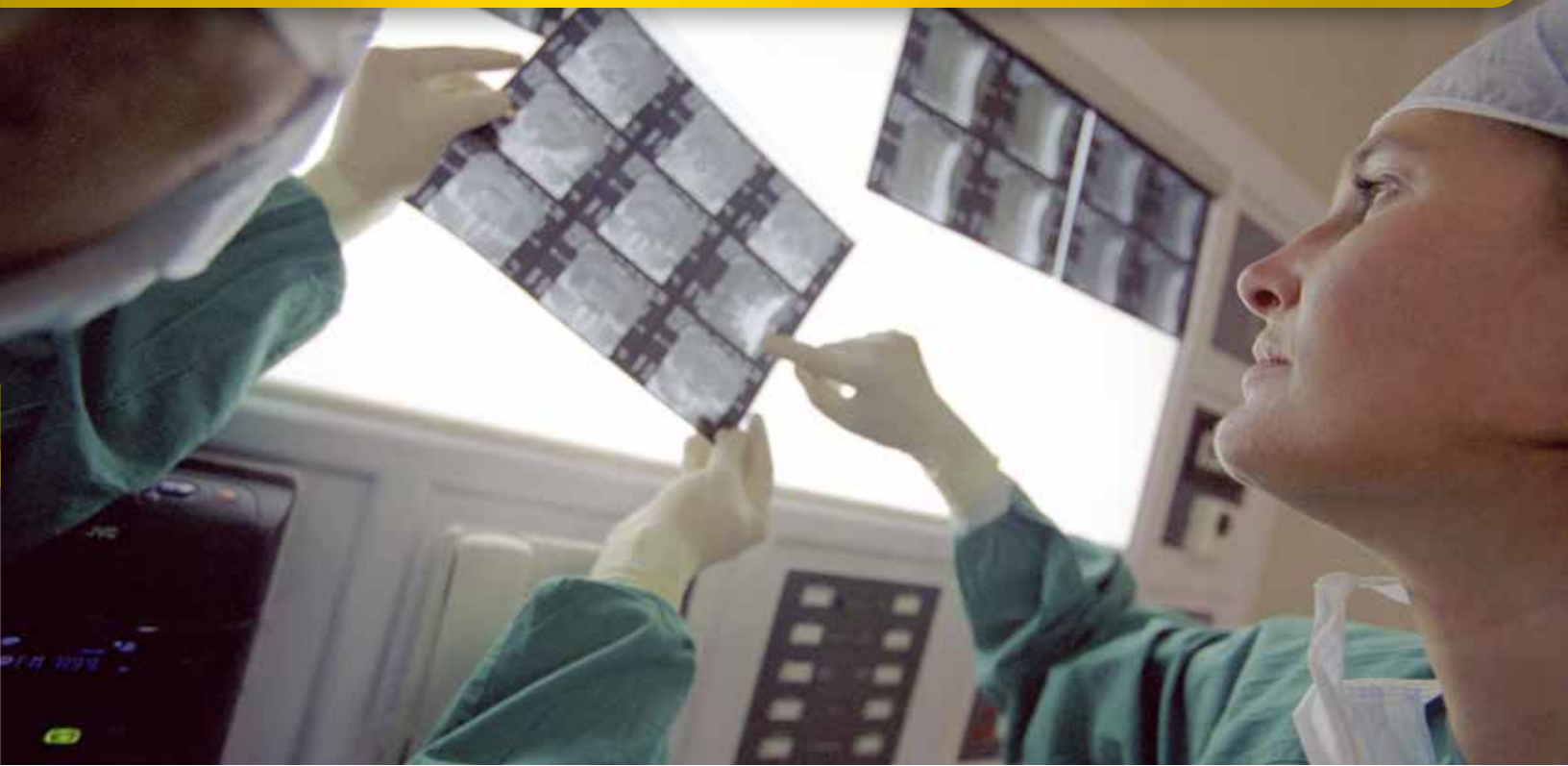


### Step 3

Vessels up to 1 mm in diameter may be occluded



# Surgical Applications



Below is a list of surgical applications in which Transcollation® technology is commonly used.

1. Shoulder



2. Thoracic



3. Spine



4. Surgical Oncology



5. Hip



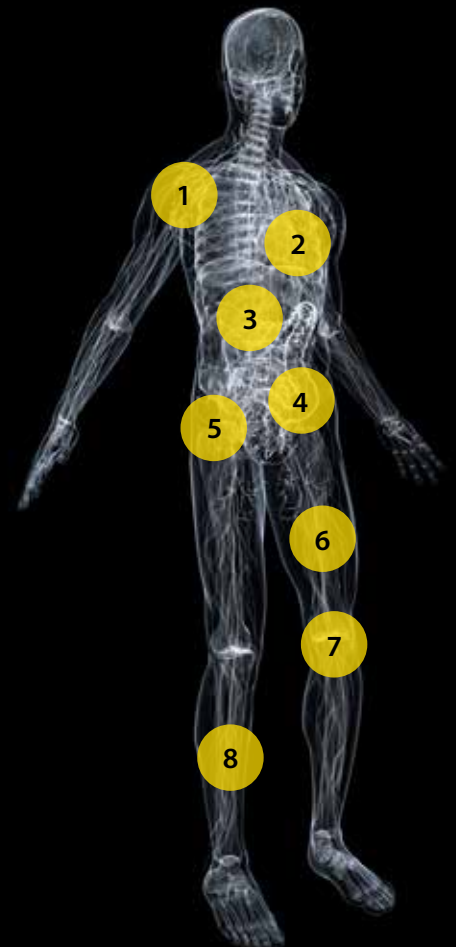
6. Musculoskeletal Oncology



7. Knee



8. Trauma



# Product Overview

## Aquamantys® System

The Aquamantys System addresses the need of surgeons to achieve hemostasis during surgery. It consists of a multi-use pump generator and single-use disposable handpieces.



### Aquamantys Generator

Delivers Transcollation® technology, with power settings from 20-200 watts and 3 different flow rate settings



### 2.3 Bipolar Sealer

Medium-sized electrodes provide more precise application for hemostatic sealing



### 6.0 Bipolar Sealer

Large-sized electrodes provide hemostatic sealing of bleeding soft tissue and bone



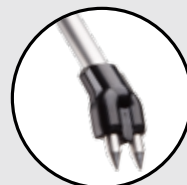
### 9.5 XL Bipolar Sealer

Cone-shaped electrode design aids in blunt dissection and hemostatic sealing



### MBS Malleable Bipolar Sealer with Light

Malleable shaft and built-in light allow access to difficult-to-reach anatomy and provide illumination during surgery



### Endo DBS 8.7 Dissecting Bipolar Sealer

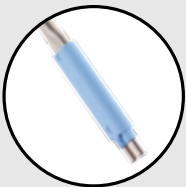
Laparoscopic length device enables minimally invasive procedures, with cone-shaped electrodes to aid in blunt dissection

Please note that some devices are available on both Aquamantys and Aquamantys3 platforms. See ordering information for details (page 11).

# Product Overview

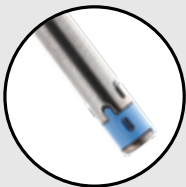
## Aquamantys<sup>®</sup>3 System

The Aquamantys3 System is the only multifunctional advanced energy platform that combines Transcollation<sup>®</sup> technology with monopolar cutting functionality.



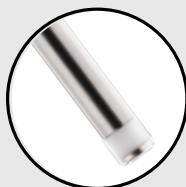
### SBS 5.0 Sheathed Bipolar Sealer

Retractable sheath enables simultaneous retraction and electrode use near sensitive tissue such as dura and nerve roots (sheath closed) and hemostatic sealing of soft tissue and bone (sheath open)



### Mini EVS 3.4 Epidural Vein Sealer

3.4mm tip size for small epidural access points, and insulated shaft enables simultaneous retraction and electrode use near sensitive tissue such as dura and nerve roots



### EVS Epidural Vein Sealer

Insulated shaft enables electrode use near sensitive tissue such as dura and nerve roots



### 8.2L Bipolar Sealer with Cutting

Combines Transcollation technology with monopolar electro-surgical cutting



### BSC 9.1 Bipolar Sealer with Cutting

Combines the benefits of Transcollation technology with monopolar electro-surgical cutting



### Aquamantys3 Generator

Combines Transcollation technology and electro-surgical cutting with a touch screen interface and automatic hand-piece recognition for optimized settings

# Benefits

## Clinical

- Reduces transfusion rates by minimizing intra-operative blood loss<sup>2-5</sup>
- Prevents and stops epidural bleeding near critical structures<sup>6,\*</sup>
- May reduce post-operative pancreatic leaks following distal pancreatectomy<sup>7,\*</sup>

## Economic

- Reduces transfusion rates;<sup>2-5</sup> reduced transfusions in turn may lower costs to the hospital<sup>8,\*\*</sup>
- Decreases surgical time<sup>9,\*</sup>
- May reduce the need for other hemostatic agents<sup>5,\*</sup>

## Patient

- Reduces transfusion rates;<sup>2-5</sup> reduced transfusions contribute to reduced hospital length of stay<sup>8,\*\*</sup>
- Helps to maintain hemoglobin levels<sup>2,10,\*</sup>
- May decrease complications and reduce post-operative patient morbidity<sup>4,\*</sup>



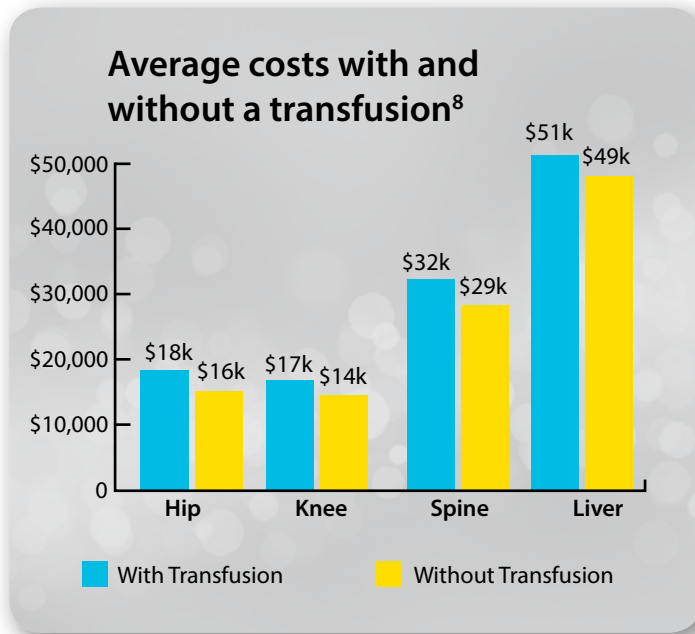
# Economic Value

Transcollation® technology is an important evolution in providing hemostasis for patient care. We recognize that healthcare providers have several options for managing patient blood loss perioperatively in conjunction with budget management. Clinical studies have shown that using the Aquamantys® System results in reduced blood loss and transfusion rates.<sup>2-5</sup>

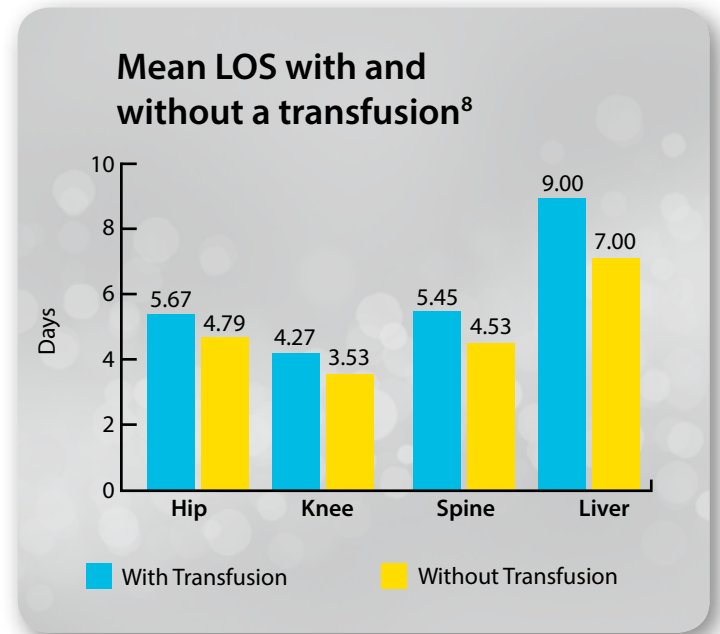
Transfusions have been directly linked to additional hospital costs and length of stay (LOS).<sup>8,\*\*</sup> Tables 1 and 2 below represent hospital national-average costs and LOS for surgery with and without a transfusion based on MedPAR data.

Medtronic is committed to delivering improved clinical outcomes while saving money for hospitals. We can work with your institution to create a customized economic analysis. Contact your local sales representative for additional information.

**Table 1**



**Table 2**



# Clinical Publications and Results

Numerous authors have reported on the clinical outcomes associated with the use of Transcollation® technology in orthopaedic reconstruction, spine, and surgical oncology procedures. These studies have shown the use of Transcollation technology to be associated with reduction in blood loss and transfusion rates.<sup>2-5</sup> The following list outlines some relevant study results.

## Knee

**Aquamantys bipolar sealer in primary total knee arthroplasty: experience with 3,172 consecutive knee replacements.** Sah A, Dearborn J. Poster presentation at American Academy of Orthopaedic Surgeons Annual Meeting. 2012; San Francisco, CA.

This study of sample size 3,172 in the bipolar sealer group and 667 in the electrocautery group demonstrated several benefits in the bipolar sealer group, including significantly lower knee drainage output (807 mL vs. 1290 mL;  $p < 0.0001$ ), a statistically higher hematocrit at discharge (31.5 vs. 30.2;  $p < 0.001$ ), and a reduction in transfusions from 10% to 3%.

**Hemostasis using a bipolar sealer in primary unilateral total knee arthroplasty.** Marulanda GA, Krebs VE, Bierbaum BE, et al. *Am J Orthop* (Belle Mead NJ). 2009; 38(12):E179-183.

This multi-center prospective randomized trial demonstrated that the amount of blood loss and decrease in post-operative hemoglobin were significantly lower in the bipolar sealer group ( $p = 0.0073$  and  $p = 0.0417$  respectively).

**Reductions in blood loss with use of a bipolar sealer for hemostasis in primary total knee arthroplasty.** Marulanda GA, Ragland PS, Seyler TM, Mont MA. *Surg Technol Int*. 2005;14:281-286.

Marulanda et al. in a 50 patient study demonstrated a significant reduction in post-operative and total blood loss in the bipolar sealer group ( $p = 0.05$  and  $p = 0.02$ , respectively), as well as an absence of tissue charring and smoke production.

## Hip

**Bipolar sealing in revision total hip arthroplasty for infection: efficacy and cost analysis.** Kamath AF, Clement RC, Derman PB, Garino JP, Lee GC. *J Arthroplasty*. 2012;27(7):1376-1381.

This study reviewing infected hip revision procedures demonstrated significantly lower total blood loss (998 mL vs. 1330 mL;  $p = 0.038$ ), change in hemoglobin (2.32 units vs. 3.99 units;  $p = 0.013$ ) and OR time (134 min vs. 157.5 min;  $p = 0.039$ ) in the bipolar sealer group with a cost-neutral to cost savings of \$1300 based on OR space allocation.

**Comparison of unilateral and rapidly staged bilateral resurfacing arthroplasty.** Gross TP, Lu F, Webb L. *Acta Orthop Belg*. 2011; 77(2):203-210.

This study demonstrated that when a bipolar sealer is used as part of a comprehensive blood management program, the following benefits may be observed: (1) may be more effective for preventing blood transfusion than a cell saver; and (2) may contribute to minimizing cost and complications associated with intra-operative blood loss and transfusions.

**Reductions in blood loss with a bipolar sealer in total hip arthroplasty.** Marulanda GA, Ulrich SD, Seyler TM, Delanois RE, Mont MA. *Expert Rev Med Devices*. 2008;5(2):125-131.

Marulanda et al. demonstrated a statistically significant difference in intra-operative ( $p = 0.002$ ) and post-operative ( $p = 0.001$ ) blood loss using the Aquamantys® System. They also demonstrated a reduction in both allogeneic and autologous transfusion rates from 28% to 23% and 24% to 12% respectively. Transfusions overall were significantly reduced from 53% to 20% ( $p = 0.005$ ).



# Clinical Publications and Results

## Spine

### **Hemostasis with a bipolar sealer during surgical correction of adolescent idiopathic scoliosis.**

Mankin KP, Moore CA, Miller LE, Block JE. *J Spinal Disord Tech.* 2012; 25(5):259-263.

During posterior spinal fusion surgery for deformity, this study showed a significant decrease in estimated blood loss in the bipolar sealer group whether measured in total ( $435 \pm 192\text{mL}$ , compared with  $1009 \pm 392\text{ mL}$  in the control group;  $p < 0.001$ ) or per level fused ( $39 \pm 17\text{ mL}$ , compared with  $95 \pm 33\text{ mL}$  in the control group;  $p < 0.001$ ). In turn, this decreased blood loss resulted in a significantly reduced risk of transfusion ( $p = 0.014$ ).

### **Bipolar sealing technology to control bleeding in pediatric spine surgery: a retrospective study.**

Snyder BD, Hedequist D, Shannon E. Poster presentation at Pediatric Orthopaedic Society of North America Annual Meeting. 2007; Hollywood, FL.

This 42 patient study in severe neuromuscular scoliosis demonstrated a reduced operative blood loss, a decrease in the amount of blood transfused, and reduction in overall operative time when the bipolar sealer was used as an adjunct to the author's conventional blood management strategy.

### **Use of bipolar sealer device reduces blood loss and transfusions in posterior spinal fusion for adolescent idiopathic scoliosis.**

Gordon Z, Son-Hing JP, Poe-Kochert C, Thompson GH. *J Pediatr Orthop.* 2013;33(7):700-706.

In this retrospective study of 100 patients undergoing posterior spinal fusion for idiopathic scoliosis, baseline characteristics between groups were similar except for the number of levels fused, which was larger in the bipolar sealer group. The results showed that bipolar sealer patients experienced statistically significantly lower total peri-operative blood loss including post-op drain output, intra-operative cell saver transfusion volume, intra-operative or post-operative transfusion rate, and total blood volume transfused.

## Surgical Oncology

### **Hepatic resection in 170 patients using saline-cooled radiofrequency coagulation.**

Geller DA, Tsung A, Maheshwari V, Rutstein LA, Fung JJ, Marsh JW. *HPB (Oxford).* 2005;7(3):208-213.

In a study of 170 patients at the University of Pittsburgh Medical Center, Geller et al. reduced transfusion rates for liver resections to 3.5% when using Transcollation® technology compared to published averages of 15-33% for large institutions.

### **Novel method of stump closure for distal pancreatectomy with a 75% reduction in pancreatic fistula rate.**

Blansfield JA, Rapp MM, Chokshi RJ, et al. *J Gastrointest Surg.* 2012; 16(3):524-528.

In this retrospective study of 62 patients who underwent distal pancreatectomies between 2002-2011, the results demonstrated a 75% decrease in post-operative leak rates. When Transcollation technology was used, 10% of patients experienced leaks, compared with 36% of patients with traditional stump closure methods.

### **Open partial nephrectomy using saline-enhanced monopolar radiofrequency device: evaluation of novel surgical technique with TissueLink DS3.0 dissecting sealer.**

Ilbeigi P, Ahmed M, Szobota J, Munver R, Sawczuk IS. *Urology.* 2005;65(3):578-582.

In a study of 22 open partial nephrectomies with hilar occlusion, data showed a 30-35% ( $p = 0.07$ ) reduction in blood loss in the 11 cases treated with Transcollation technology.

# Top Hospitals

All of the top 18 hospitals in *U.S. News & World Report's* 2013-2014 Honor Roll of "America's Best Hospitals" are using Transcollation® technology<sup>1</sup>

*Please note that facilities on this list currently use Transcollation technology in at least one specialty but not necessarily in all specialties.*

**Johns Hopkins Hospital**

Baltimore, MD

**Massachusetts General Hospital**

Boston, MA

**Mayo Clinic**

Rochester, MN

**Cleveland Clinic**

Cleveland, OH

**UCLA Medical Center**

Los Angeles, CA

**Northwestern Memorial Hospital**

Chicago, IL

**New York-Presbyterian University Hospital of Columbia and Cornell**

New York, NY

**UCSF Medical Center**

San Francisco, CA

**Brigham and Women's Hospital**

Boston, MA

**UPMC-University of Pittsburgh Medical Center**

Pittsburgh, PA

**Hospital of the University of Pennsylvania**

Philadelphia, PA

**Duke University Medical Center**

Durham, NC

**Cedars-Sinai Medical Center**

Los Angeles, CA

**NYU Langone Medical Center**

New York, NY

**Barnes-Jewish Hospital/Washington University**

St. Louis, MO

**Indiana University Health Center**

Indianapolis, IN

**Thomas Jefferson University Hospital**

Philadelphia, PA

**University Hospitals Case Medical Center**

Cleveland, OH



# Ordering Information



## Description

## Catalog Number

Aquamantys® 6.0 Bipolar Sealer .....	23-112-1
Aquamantys 2.3 Bipolar Sealer.....	23-113-1
Aquamantys EVS Epidural Vein Sealer.....	23-121-1
Aquamantys MBS Malleable Bipolar Sealer with Light.....	23-301-1
Aquamantys SBS 5.0 Sheathed Bipolar Sealer.....	23-312-1
Aquamantys 9.5 XL Bipolar Sealer.....	23-313-1
Aquamantys Mini EVS 3.4 Epidural Vein Sealer.....	23-314-1
Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer.....	23-317-1
Aquamantys Pump Generator .....	40-402-1



## Description

## Catalog Number

Aquamantys3 8.2L Bipolar Sealer with Cutting .....	25-102-1
Aquamantys3 BSC 9.1L Bipolar Sealer with Cutting.....	25-105-1
Aquamantys3 BSC 9.1S Bipolar Sealer with Cutting.....	25-106-1
Aquamantys3 6.0 Bipolar Sealer.....	23-305-1
Aquamantys3 2.3 Bipolar Sealer.....	23-306-1
Aquamantys3 MBS Malleable Bipolar Sealer with Light .....	23-307-1
Aquamantys3 9.5 XL Bipolar Sealer.....	23-316-1
Aquamantys3 Pump Generator .....	40-404-1



## References

1. U.S. News & World Report - Best Hospital Rankings, 2013-2014. <http://health.usnews.com/best-hospitals>. Data on file at Medtronic Advanced Energy.
2. Marulanda GA, Ulrich SD, Seyler TM, Delanois RE, Mont MA. Reductions in blood loss with a bipolar sealer in total hip arthroplasty. *Expert Rev Med Devices*. 2008;5(2):125-131.
3. Marulanda GA, Ragland PS, Seyler TM, Mont MA. Reductions in blood loss with use of a bipolar sealer for hemostasis in primary total knee arthroplasty. *Surg Technol Int*. 2005;14:281-286.
4. Mankin KP, Moore CA, Miller LE, Block JE. Hemostasis with a bipolar sealer during surgical correction of adolescent idiopathic scoliosis. *J Spinal Disord Tech*. 2012;25(5):259-263.
5. Geller DA, Tsung A, Maheshwari V, Rutstein LA, Fung JJ, Marsh JW. Hepatic resection in 170 patients using saline-cooled radiofrequency coagulation. *HPB (Oxford)*. 2005;7(3):208-213.
6. Santiago P. Controlling epidural bleeding and improving visibility during spinal surgery with a novel bipolar sealing technology: a case report. Company funded, non-peer-reviewed Medtronic white paper, 2009.
7. Blansfield JA, Rapp MM, Chokshi RJ, Woll NL, Hunsinger MA, Sheldon DG, Shabahang MM. Novel method of stump closure for distal pancreatectomy with a 75% reduction in pancreatic fistula rate. *J Gastrointest Surg*. 2012;16(3):524-528.
8. Covance report; 2008 MedPAR database based on ICD-9-CM Codes for 100% of Medicare beneficiaries.
9. Snyder BD, Hedequist D, Shannon E. Bipolar sealing technology to control bleeding in pediatric spine surgery: a retrospective study. Poster presentation at Pediatric Orthopaedic Society of North America Annual Meeting. 2007;Hollywood, FL.
10. Marulanda GA, Krebs Ve, Bierbaum BE, et al. Hemostasis using a bipolar sealer in primary unilateral total knee arthroplasty. *Am J Orthop (Belle Mead NJ)*. 2009;38(12):E179-183.

\* Performance has not been specifically established in all procedures.

\*\* Performance has not been specifically established with the Aquamantys® System.

Rx only. For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions For Use (IFU) that accompany Aquamantys and Aquamantys3 disposable devices and/or the Aquamantys and Aquamantys3 System User Guide.

For further information, please call 866-777-9400 or 603-742-1515.

You may also consult our website:

[www.medtronicadvancedenergy.com](http://www.medtronicadvancedenergy.com)

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Baltic Regional Office 37-1-67560226  
Belgium 32-2456-09-09  
Canada 1800-217-1617  
China 86-21-50800998  
Czech Republic 420-2-9657-9580  
France 33-470-679-800  
Germany 49-2159-8149-209  
Greece 30-210-67-79-099  
Hong Kong 852-2919-1312  
Hungary 36-30-5052987  
India 91-22-26836733  
Israel 972-9-972-4400  
Italy 39-02-24137-324  
Japan 81-6-4795-1506  
Korea 82-2-3404-3600  
Lebanon 961-1-370-670  
Luxembourg 32-2456-09-009

Netherlands 31-45-566-8800  
Poland 48-22-465-6942  
Russian Federation 7-495-580-73-77  
Singapore 65-6776-6255  
South Africa 27-11-466-1820  
Spain 34-91-625-05-40  
Taiwan 886-2-2183-6000  
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