AQUACEL® Ag Surgical

AQUACEL® Ag Surgical Cover Dressing (SCD)

Value Analysis Committee Product Information Kit

Hydrofiber® TECHNOLOGY

ConvaTec

The right dressing can make a difference

AQUACEL® Ag SCD reduces periprosthetic joint infection (PJI) and improves patient outcomes

PJI following total joint arthroplasty (TJA) is one of the most devastating postsurgical complications and continues to be a challenge for many healthcare organizations as the demand for TJA rises.[1,2]
PJI treatment often requires prolonged hospital stays, intravenous (IV) antibiotics, and additional surgical procedures. In addition, wound infection contributes to delayed healing, increasing the burden to patients and the cost of their healthcare.[3] Although much work has been done to guide clinical practice in the prevention and treatment of PJI, wound management is often overlooked. Dressing technology plays a vital role in preventing PJI following TJA and should be given due attention.[4]

AQUACEL® Ag SCD is an occlusive, skin-friendly surgical dressing infused with ionized silver for greater antimicrobial protection. The Hydrofiber® technology employed in AQUACEL® Ag SCD allows it to micro-contour to the wound bed—minimizing voids where bacteria can grow while maintaining the optimum moisture balance for healing. AQUACEL® Ag SCD is flexible, absorbent, and waterproof, so patients can shower shortly after the dressing is properly applied.

Over the next 18 years,

the demand for primary total hip arthroplasty (THA) is estimated to grow by 174%, and the demand for primary total knee arthroplasty (TKA) by 673%[5]

Recent clinical studies confirm that use of AQUACEL® Ag SCD significantly reduces the incidence of PJI after TJA[6] and increases patient satisfaction.[4] These are important outcomes to consider given the demand for more stringent reporting from the Centers for Medicare and Medicaid Services (CMS) and the impact that reporting has on Hospital Compare (http://www.hospitalcompare.hhs.gov) and the Value-Based Purchasing (VBP) Program.[7a,b]

New initiatives, including the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS: http://www.hcahpsonline.org) survey[8] and in-patient quality reporting (IQR) of hospital risk-standardized complication and readmission rates (RSCRs and RSRRs) following elective primary THA and TKA,[9] have been implemented as new standards for tracking patient satisfaction and quality of care. Adherence to these reporting guidelines will directly affect Medicare payments and the reputations of healthcare facilities.

With the projected rise in TJA over the next 18 years, an increased emphasis on patient satisfaction, strict monitoring of RSCRs and RSRRs, and the onset of VBP, improving postoperative surgical dressings is a simple and cost-effective measure that can have a profound impact on the financial success of acute care facilities.

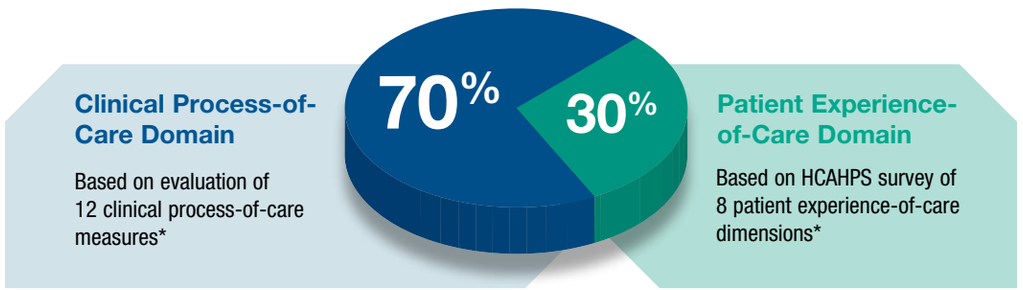
Overview of In-Patient Quality Reporting

- National Quality Forum (NQF: http://www.qualityforum.org/qps/) measure #1550 estimates hospital RSCRs following elective primary THA and TKA, including wound infection and PJIs[9]
- NQF measure #1551 estimates hospitals' 30-day all-cause RSRRs following elective primary THA and TKA[9]

Value-Based Purchasing: Changing the way hospitals are paid for services to Medicare beneficiaries[7a]

- National pay-for-performance system[10]
- VBP-eligible hospitals are scored based on achievement and improvement in clinical measures and patient satisfaction
- Directly impacts incentive payments for acute care hospitals
- 2% penalty applied if IQR is not submitted

Weighted Value of VBP Domains for CMS Acute Care Hospital Evaluation[7a]



*A detailed listing of the 12 clinical process-of-care measures and 8 patient experience-of-care dimensions is available at:
1) http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html,
2) http://www.healthcare.gov/news/factsheets/2011/04/valuebasedpurchasing04292011b.html, and
3) http://www.hcahpsoneline.org/home.aspx

Product Overview

AQUACEL® Ag SCD: Not all silver dressings are created equal

Combining flexible, skin-friendly hydrocolloid technology; patented, micro-contouring Hydrofiber® technology with ionic silver; and waterproof polyurethane film, AQUACEL® Ag SCD helps improve outcomes by creating an optimum healing environment and providing broad-spectrum antimicrobial activity.

Why purchase AQUACEL® Ag SCD for an orthopedic surgical unit?

To Reduce Incidence of PJI	To Improve Patient Outcomes	To Reduce Costs
New research supports that AQUACEL® Ag SCD can reduce the incidence of PJI by as much as 76% compared to standard gauze dressing[6]	Reducing infection decreases the need for lengthy hospital stays, treating infections with IV antibiotics, and revision surgeries. AQUACEL® Ag SCD also promotes healing and reduces the average surgical dressing wear time[4]	Treating PJI is one of the most resource-consumptive procedures in orthopedic surgery with costs as high as $100,000 per case.[11-13] Additionally, new CMS guidelines limit and/or eliminate reimbursement for hospital-acquired infections

What are the competitive advantages of implementing AQUACEL® Ag SCD?

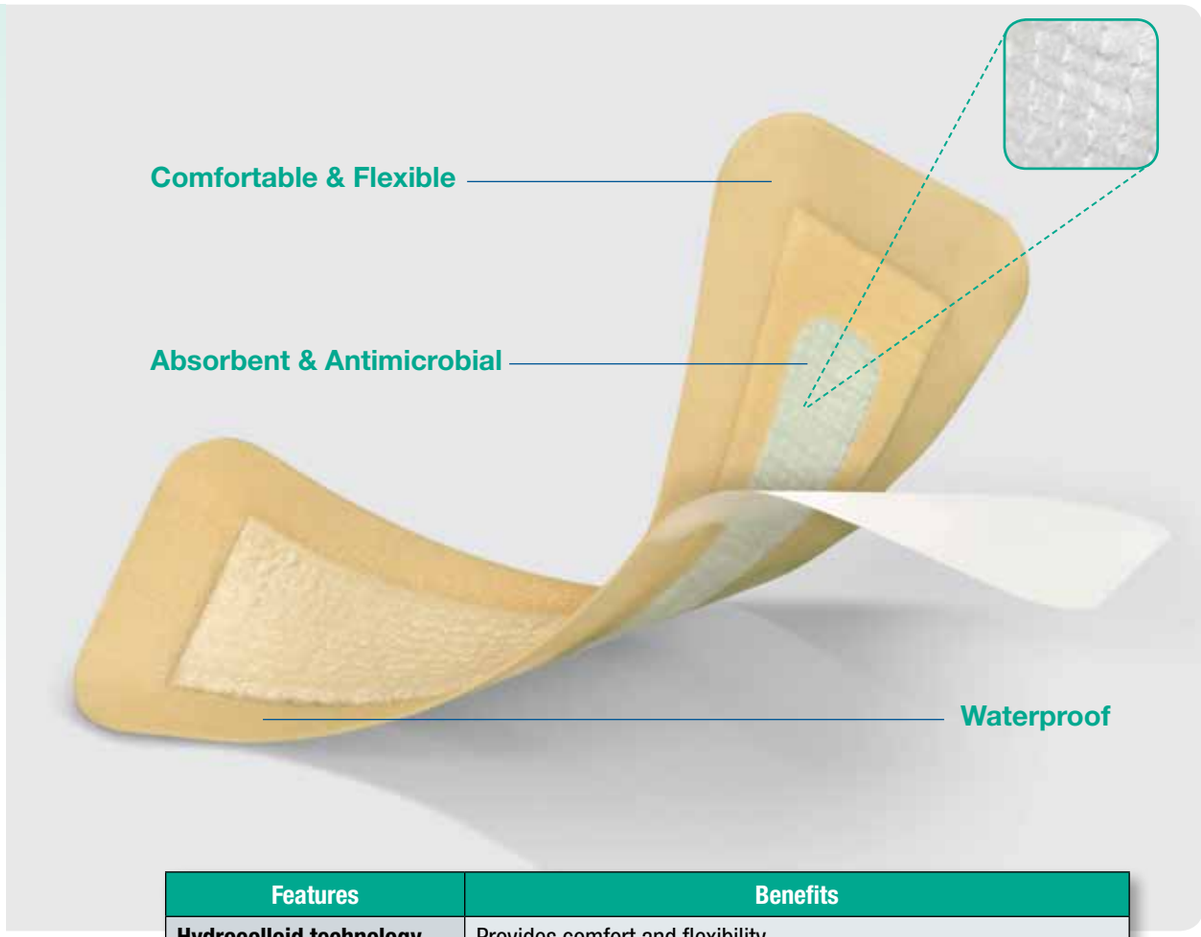
Antimicrobial Protection	Flexible and Skin-Friendly	Waterproof
Hydrofiber® technology with ionic silver micro-contours to the wound bed—providing sustained antimicrobial activity for up to 7 days*[14-16]	Protects periwound skin by helping reduce risk of maceration and blistering; allows for pain-free removal	Polyurethane film provides a waterproof barrier that allows patients to shower after surgery

*As demonstrated in vitro

In one of the largest clinical studies to date, AQUACEL Ag SCD was proven to reduce the incidence of PJI by as much as 76% compared with standard gauze dressing[6]

Product Illustration

AQUACEL® Ag. Surgical



Features	Benefits
Hydrocolloid technology	Provides comfort and flexibility
Hydrofiber® technology	Micro-contours to wound bed, eliminating voids where bacteria can grow; locks in wound exudate and removes it from wound bed*[14-16]
Ionic silver infusion	Releases ionic silver in a controlled manner, providing sustained antimicrobial activity for up to 7 days*[14-16]
Polyurethane film	Creates a waterproof barrier that helps prevent viral and bacterial infection*[14]

*As demonstrated in vitro

AQUACEL® Ag SCD with ionic silver is indicated for moderate to high exuding wounds that are infected or at risk of infection

Premarket Notification 510(k) K091034
Response to FDA Request for Additional Information October 16, 2009

Section 4: Indications For Use Statement

510(k) Number: K091034

Device Name: AQUACEL® Ag Surgical

Under the supervision of a healthcare professional:
AQUACEL® Ag Surgical may be used for the management of wounds healing by primary intent (e.g., traumatic and elective post operative wounds/incisions) and as an effective barrier to bacterial penetration to help reduce infection.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091034

Premarket Notification 510(k) K091034
Response to FDA Request for Additional Information October 16, 2009

Section 5: 510(K) Summary

Device:	**AQUACEL® Ag Surgical**
Applicant:	ConvaTec Inc.
Contact:	Patricia Kearins Manager, US Regulatory Affairs 908-904-2180 fax: 908-904-2235 email: patricia.kearins@convatec.com
Date:	October 16, 2009
Trade Name:	AQUACEL® Ag Surgical
Classification Name:	Dressing, Wound, Drug
Device Class:	Unclassified
Product Code:	FRO
Predicate Devices:	AQUACEL® Ag Hydrofiber® Dressing, K080383 DuoDERM® Extra Thin Dressing, K891696 (currently Class 1, 510(k) exempt)

DEC 1 6 2009

AQUACEL® Ag Surgical Dressing with Silver is a one piece post-operative dressing comprised of an inner (wound contact) non-woven pad which is held in place by two layers of skin-friendly hydrocolloid adhesive and an outer top layer of polyurethane film. The non-woven pad is comprised of Hydrofiber® dressing and ionic silver stitchbonded with nylon and elastane yarn for dressing extensibility (so the dressing will stretch and be used on flexing joints and limbs) and dressing recovery from extension (after limb movement the dressing will return to its original shape and size without the application of any additional force to the skin).

The one-piece dressing design provides ease of application and removal and provides a waterproof, bacterial, and viral barrier covering to the wound. The benefits provided by this dressing meet the clinical need for improved management of surgical wounds which have wound drainage and are at risk of infection.

AQUACEL® Ag Surgical combines the absorbency/retention properties of AQUACEL® Ag Hydrofiber® Dressing with the gentle skin-friendly properties of DuoDERM® Extra Thin adhesive.

Premarket Notification 510(k) K091034
Response to FDA Request for Additional Information October 16, 2009

AQUACEL® Ag Surgical dressing is a soft, sterile, non-woven pad composed of hydrocolloid fibers. This conformable and highly absorbent dressing absorbs wound fluids, creating a soft gel which maintains a moist environment and supports the body's healing process.

AQUACEL® Ag Surgical dressing is available under the supervision of a healthcare professional and is indicated for the management of wounds healing by primary intent (e.g., traumatic and elective post-operative wounds/incisions) and as an effective barrier to bacterial penetration to help reduce infection.

Since AQUACEL® Ag Surgical dressing is based on the AQUACEL® Ag Hydrofiber® technology, the safety and effectiveness of AQUACEL® Ag Surgical has been demonstrated by the literature and clinical data provided in previous 510(k)s (i.e., K080383). In summary, a careful and thorough review of the literature suggests that Hydrofiber® dressings have been used safely and effectively in clinical trials for the management of surgical incisions healing with primary intent. All the studies which have been reviewed suggest that, compared to a standard dressing, using a dressing with AQUACEL® leads to less dressing changes.

Thus we believe that, similar to previously cleared Hydrofiber®-based products (reference K080383), AQUACEL® Ag Surgical can be used safely and effectively for the management of wounds healing by primary intent (e.g., traumatic and elective post operative wounds/incisions).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

ConvaTec Inc.
% Ms. Patricia Kearins
Manager, US Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

DEC 1 6 2009

Re: K091034
Trade/Device Name: Aquacel® Ag Surgical
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 02, 2009
Received: December 03, 2009

Dear Ms. Kearins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 - Ms. Patricia Kearins

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

AQUACEL® Ag Surgical

New research indicates that AQUACEL® Ag SCD plays an important role in reducing the incidence of PJI and improving the patient experience

The AQUACEL® Ag Surgical Dressing With Ionic Silver Reduces the Rate of Acute Periprosthetic Joint Infection Following Total Joint Arthroplasty[6]

Cai J, Karam J, Parvizi J, Smith EB, Sharkey PF

Methodology

This retrospective study was conducted at Philadelphia's Rothman Institute by performing chart reviews to compare the overall incidence of PJI in 2 groups of patients who had undergone TJA. The study group of 903 patients received an AQUACEL® Ag SCD (applied in sterile conditions in the operating room) that remained in place for 5 days. The control group of 875 patients received a standard dressing of sterile gauze applied over the incision site and secured with adhesive tape in the operating room.

Results

AQUACEL® Ag SCD reduced the incidence of PJI by 76%. The study group had an incidence of acute PJI of 0.4% (4/903) compared with the control group treated with standard dressing, which had a 1.7% (15/875) incidence of acute PJI.

Conclusion

According to Dr. Peter Sharkey, "the systematic use of AQUACEL® Ag SCD would be an effective measure to prevent the occurrence of acute PJI following TJA."

Real-world clinical experience reveals benefits of AQUACEL® Ag SCD compared with tape and gauze dressing[4]

Overview

As part of an initiative to improve infection control protocols at NorthShore University HealthSystem, Dr. Kudrna and colleagues assessed the clinical efficacy of AQUACEL® Ag SCD to reduce postsurgical complications compared with standard surgical dressing.

Methodology

A group of 482 patients undergoing primary THA who received AQUACEL® Ag SCD were compared to a retrospective matched cohort of 482 patients who received a standard surgical dressing consisting of gauze and Elastoplast® tape. The rates of blistering, number of dressing changes, and overall incidence of surgical-site infections (SSIs) were carefully reviewed for both groups.

Results

No SSIs occurred in the AQUACEL® Ag SCD group (0%) compared with a 1.6% incidence of SSIs in the standard dressing group. A marked reduction in surgical-site blistering was also achieved in the AQUACEL® Ag SCD group (0.2% vs 11.4% in the standard dressing group). Additionally, the number of dressing changes (2.2 for AQUACEL® Ag SCD vs 5.1 for standard dressing) as well as the average wear time of the surgical dressing to wound healing (9.3 days for AQUACEL® Ag SCD vs 13.4 days for standard dressing) were considerably lower in the AQUACEL® Ag SCD group.

Conclusion

Dr. James Kudrna and his team of researchers found that "…the use of AQUACEL® Ag Surgical Dressing compared to a standard surgical dressing…diminished the rate of wound complications, blister formation, and surgical site infections…"

Interim analysis of a new study indicates that AQUACEL® Ag SCD reduces wound complications and improves patient satisfaction[4]

Overview

In an ongoing prospective randomized study, Dr. Springer and associates are evaluating the use of AQUACEL® Ag SCD compared to a tape-and-gauze dressing (Primapore™) used as the current standard surgical dressing at OrthoCarolina.

Methodology

The study involves 150 patients undergoing THA and 150 undergoing TKA that are being randomized prospectively to 1 of the 2 surgical dressings (AQUACEL® Ag SCD or Primapore). Outcomes for the study include wound complications, number of dressing changes, blister rates, overall patient and nursing satisfaction, and an economic analysis of the cost-effectiveness of the surgical dressings.

Results

Although the study continues, interim analysis of the first 150 patients that underwent TKA demonstrated fewer dressing changes and a significant ($P<.02$) reduction in overall wound complications associated with AQUACEL® Ag SCD compared with Primapore. In addition, no patients in the AQUACEL® Ag SCD group required additional surgical procedures, whereas 2 patients receiving the Primapore did. Patient satisfaction, defined as patients' perception of hygiene, sterility, and comfort, was also more favorable toward AQUACEL® Ag SCD than Primapore.

Competitive Product Comparison

AQUACEL® Ag Surgical

Competitive Product Overview

In vitro studies have shown that AQUACEL® Ag SCD offers distinct advantages over other silver-impregnated dressings. The Hydrofiber® technology locks in wound exudate and safely removes it from the wound bed and surrounding area.[14] This protects those surfaces from potential maceration. Hydrofiber® transforms into a clear, soft gel once it absorbs fluid, allowing it to micro-contour to the wound bed and fill "dead space" where bacteria can proliferate.[17] This gelling feature also allows AQUACEL® Ag SCD to respond effectively to different wound conditions, maintaining a favorable wound-healing environment and providing increased silver ion availability "on demand."[14]

Product Comparison—A Qualitative Assessment of Key Product Attributes

	AQUACEL® Ag SCD	Mepilex® Ag Border	Silverlon®	Acticoat® 7
Silver-impregnated	✔	✔	✔	✔
Sustains antimicrobial activity for up to 7 days	✔	✔	✔	✔
Waterproof	✔	✔		✔
Fully occlusive	✔			
Hydrofiber® technology	✔			
Micro-contours to wound bed, locking in fluid and sequestering bacteria	✔			
Responds to changing wound conditions by forming a cohesive gel	✔			
Proven to reduce PJI by 76% vs standard dressing[6]	✔			

In vitro studies have demonstrated that AQUACEL Ag SCD conforms to a simulated wound surface better than Meplilex Ag dressing, providing greater control over the growth and spread of bacteria under the dressing[17-19]

AQUACEL® Ag Surgical

AQUACEL® Ag SCD
Available Sizes and Product Order Codes

SKU	UPC	Dressing Size	For Incisions Up to	Dressings per Box
412009	76845511116	3.5” x 3.75” (9cm x 9.5cm)	1.5” (4cm)	10
412010	76845511119	3.5” x 6” (9cm x 15cm)	3.5” (9cm)	10
412011	76845511122	3.5” x 9.75” (9cm x 24.8cm)	6.5” (17cm)	10
420670	768455125111	3.5” x 12” (9cm x 30cm)	8.5” (22cm)	10
412012	76845511125	3.5” x 13.75” (9cm x 34.9cm)	10.5” (27cm)	10

Ordering Information

Convatec Products Website: **www.convatec.com**

Customer Service: **1-800-422-8811**

References: **1.** Kurtz SM, Lau E, Watson H, Schmier JK, Parvizi J. Economic burden of periprosthetic joint infection in the United States. *J Arthroplasty*. 2012;27:61-65 e61. **2.** Bongartz T, Halligan CS, Osmon DR, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. *Arthritis Rheum*. 2008;59:1713-1720. **3.** Drew P, Posnett J, Rusling L. The cost of wound care for a local population in England. *Int Wound J*. 2007;4:149-155. **4.** Wound complications and deep periprosthetic infection after total joint arthroplasty. The role of surgical dressing? White Paper. 2012. Data on file, Convatec. **5.** Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am*. 2007;89:780-785. **6.** Cai J, Karam JA, Parvizi J, Smith EB, Sharkey PF. The AQUACEL® Ag surgical dressing with ionic silver reduces the rate of acute periprosthetic joint infection following total joint arthroplasty. Poster presented at: 22nd Annual Meeting of the American Association of Hip and Knee Surgeons; November 2-4, 2012; Dallas, TX. **7a.** CMS issues final rule for first year of hospital value-based purchasing program. Centers for Medicare and Medicaid Services. http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3947. Accessed on October 16, 2012. **7b.** Frequently Asked Questions Hospital Value-Based Purchasing Program. Centers for Medicare and Medicaid Services. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/downloads/HVBPFAQ022812.pdf. Accessed on October 16, 2012. **8.** The HCAHPS Survey – Frequently Asked Questions. Centers for Medicare and Medicaid Services. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/downloads/HospitalHCAHPSFactSheet201007.pdf. Accessed on October 16, 2012. **9.** Hospital-level Risk-Standardized Complication Rates following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE). http://www.qualitynet.org. Accessed on October 16, 2012. **10.** What makes a positive patient experience? IHI explores how to improve a patient’s time in the hospital. Institute for Healthcare Improvement. http://www.ihi.org/knowledge/pages/publications/whatmakespositiveptexperience.aspx. Accessed on October 16, 2012. **11.** Parvizi J, Pawasarat IM, Azzam KA, Joshi A, Hansen EN, Bozic KJ. Periprosthetic joint infection: the economic impact of methicillin-resistant infections. *J Arthroplasty*. 2010;25:103-107. **12.** de Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. *Am J Infect Control*. 2009;37:387-397. **13.** Lavernia C, Lee DJ, Hernandez VH. The increasing financial burden of knee revision surgery in the United States. *Clin Orthop Relat Res*. 2006;446:221-226. **14.** Jones SA, Bowler PG, Walker M, Parsons D. Controlling wound bioburden with a novel silver-containing Hydrofiber dressing. *Wound Repair Regen*. 2004;12:288-294 **15.** Bowler PG, Jones SA, Walker M, Parsons D. Microbicidal properties of a silver-containing hydrofiber dressing against a variety of burn wound pathogens. *J Burn Care Rehabil*. 2004;25:192-196. **16.** Bowler PG. Progression toward healing: wound infection and the role of an advanced silver-containing Hydrofiber dressing. *Ostomy Wound Manage*. 2003;49:2-5. **17.** Antimicrobial activity of silver-containing wound dressings using a shallow wound microbial model. *Scientific Background Report* WHR13307 MA143. 2010, Data on File, ConvaTec, Skillman NJ. **18.** The antimicrobial activity of silver-containing wound dressings on a simulated colonized wound surface. *Scientific Background Report*. WHR13415 MA162. 2011, Data on File, ConvaTec, Skillman NJ. **19.** Observed antimicrobial activity of Mepilex® Border Ag dressing using two in vitro models. *Scientific Background Report*. WHR13405 MA160. 2011, Data on File, ConvaTec, Skillman NJ.

To find out more about AQUACEL® Ag Surgical Cover Dressings, visit www.convatec.com or call 1-800-422-8811.

Hydrofiber® TECHNOLOGY

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