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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{4}

AQUACEL® Ag SCD is an occlusive, skin-friendly surgical dressing infused with ionized silver for greater antimicrobial protection. The Hydrofiber\textsuperscript{®} 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.

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 PJs\textsuperscript{9}
- NQF measure #1551 estimates hospitals’ 30-day all-cause RSRRs following elective primary THA and TKA\textsuperscript{9}

Value-Based Purchasing: Changing the way hospitals are paid for services to Medicare beneficiaries\textsuperscript{7a}

- National pay-for-performance system\textsuperscript{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

Recent clinical studies confirm that use of AQUACEL® Ag SCD significantly reduces the incidence of PJI after TJA\textsuperscript{4} and increases patient satisfaction.\textsuperscript{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.\textsuperscript{7a,b}

New initiatives, including the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS: http://www.hcahpsonline.org) survey\textsuperscript{8} and in-patient quality reporting (IQR) of hospital risk-standardized complication and readmission rates (RSCRs and RSRRs) following elective primary THA and TKA,\textsuperscript{3} 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.

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\%.\textsuperscript{5}

Weighted Value of VBP Domains for CMS Acute Care Hospital Evaluation\textsuperscript{7a}

Clinical Process-of-Care Domain

Based on evaluation of 12 clinical process-of-care measures* 70\%

Patient Experience-of-Care Domain

Based on HCAHPS survey of 8 patient experience-of-care dimensions* 30\%

* A detailed listing of the 12 clinical process-of-care measures and 8 patient experience-of-care dimensions is available at:
2) http://www.healthcare.gov/news/factsheets/2011/04/valuebasedpurchasing04292011b.html, and
3) http://www.hcahpsonline.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?**

<table>
<thead>
<tr>
<th>To Reduce Incidence of PJI</th>
<th>To Improve Patient Outcomes</th>
<th>To Reduce Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>New research supports that AQUACEL® Ag SCD can reduce the incidence of PJI by as much as 76% compared to standard gauze dressing⁶</td>
<td>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 time⁴</td>
<td>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</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Antimicrobial Protection</th>
<th>Flexible and Skin-Friendly</th>
<th>Waterproof</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrofiber® technology with ionic silver micro-contours to the wound bed—providing sustained antimicrobial activity for up to 7 days¹⁴-¹⁶</td>
<td>Protects periwound skin by helping reduce risk of maceration and blistering; allows for pain-free removal</td>
<td>Polyurethane film provides a waterproof barrier that allows patients to shower after surgery</td>
</tr>
</tbody>
</table>

*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 dressing⁶

**AQUACEL® Ag SCD with ionic silver is indicated for moderate to high exuding wounds that are infected or at risk of infection**
510(k) Clearance

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) or radical and as an effective barrier to bacterial penetration to help reduce infection.

Prescription Use

AND/OR

Over-The-Counter Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Device: AQUACEL® Ag Surgical
Applicant: Convatec Inc.
Contact: Marla Kropf
Manager, US Regulatory Affairs
833-753-6666 Ext. 2680
email: marlakropf@convatec.com
Date: October 18, 2009
Trade Name: AQUACEL® Ag Surgical
Classification: Dressing, Wound, Drug
Device Class: Unclassified
Product Code: RAO
Produce Device: AQUACEL® Ag Hydrogel Dressing, K008382
Dressing (DRI-0005) 12 X 12" (Dry Use: ensuing from external airflow; after 30 minutes the dressing will return to its original shape and characteristics will be lost if exposed to vapors or any additional force to the drape).

AQUACEL® Ag Surgical Dressing, with Silver is a sterile, non-woven, porous, non-latex, antibacterial dressing with the ability to eliminate bacteria. The non-woven, porous, non-latex, antibacterial dressing is a soft gel, hydrophilic dressing, which contains silver ions and is designed to eliminate bacteria. AQUACEL® Ag Surgical Dressing is a sterile, non-woven, porous, non-latex, antibacterial dressing with the ability to eliminate bacteria. The non-woven, porous, non-latex, antibacterial dressing is a soft gel, hydrophilic dressing, which contains silver ions and is designed to eliminate bacteria.

AQUACEL® Ag Surgical Dressing contains the antibacterial properties of 250μg AQUACEL® Ag Hydrogel Dressing with the added antibacterial properties of OxidESC® 125 μg silver

Page 2 - Ms. Patricia Kropf

For the purposes of any questions or comments, please contact the following.

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Mark N. McKenna
Division of Surgical, Orthopedic and Retina Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Clinical Information

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

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

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.

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

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. 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. 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.”

Product Comparison—A Qualitative Assessment of Key Product Attributes

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

In vitro studies have demonstrated that AQUACEL Ag SCD conforms to a simulated wound surface better than Mepilex Ag dressing, providing greater control over the growth and spread of bacteria under the dressing.
References:
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.

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