Records processed under FOIA Request # 2015-8413 Released by CDRH on 02-01-2016 K121275 Page 1/2



JUL 25 2012

## SECTION 5: 510(K) SUMMARY

| | |
|---|---|
| **Device:** | **AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber** |
| **Applicant:** | ConvaTec Inc. |
| **Contact:** | Katrina Fiedler<br>Associate Director, US Regulatory Affairs<br>908-904-2541<br>Fax: 908-904-2235<br>Email: katrina.fiedler@convatec.com |
| **Date:** | April 25, 2012 |
| **Trade Name:** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber |
| **Classification Name:** | Dressing, Wound, Drug |
| **Device Class:** | Unclassified |
| **Product Code:** | FRO |

**Predicate Device**: AQUACEL™ Ag Hydrofiber™ Dressing, K080383

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a one piece wound dressing comprised of two layers of soft, sterile non-woven material. The non-woven pads are comprised of Hydrofiber™ dressing and ionic silver stitchbonded together with regenerated cellulose fibers and designed to provide additional absorbency and tensile strength properties. 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 EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; partial thickness (second degree) burns; diabetic foot ulcers, (venous stasis



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); surgical wounds left to heal by secondary intention such as dehisced surgical incisions; surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular); traumatic wounds; wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites; oncology wounds with exudate, such as fungoids-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; painful wounds and infected wounds.

Since AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is largely based on the AQUACEL™ Ag Hydrofiber™ technology, the safety and effectiveness of AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber 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 wounds.

Thus we believe that, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is substantially equivalent to the previously cleared Hydrofiber™-technology based products (reference K080383) and that AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber can be used safely and effectively for the management of wounds.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Convatec, Incorporated
% Ms. Katrina Fiedler
Associate Director, US Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K121275
Trade/Device Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 25, 2012
Received: April 27, 2012

Dear Ms. Fiedler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016



## SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

Device Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber

For Over-the-Counter Use:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds;
- Infected wounds

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___

(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)

Daniel Kane for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) Number K12(275

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

K121275

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Convatec, Incorporated
% Ms. Katrina Fiedler
Associate Director, US Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K121275
Trade/Device Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 25, 2012
Received: April 27, 2012

Dear Ms. Fiedler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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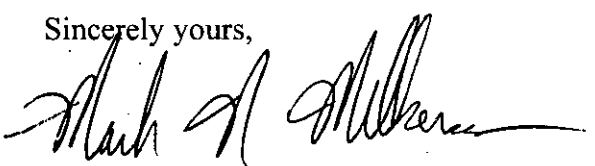
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016



## SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

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- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
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- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds;
- Infected wounds

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___

(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 for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



510(k) Number K120275

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 27, 2012

CONVATEC INC
200 HEADQUARTERS PARK DRIVE
SKILLMAN, NEW JERSEY 08558
ATTN: KATRINA FIEDLER

510k Number: K121275

Received: 4/27/2012

Product: AQUACEL AG EXTRA HYDROFIBER DR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

'lease note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

**Grayson, Giovanna ***

**From:** Grayson, Giovanna *
**Sent:** Friday, April 27, 2012 1:13 PM
**To:** 'katrina.fiedler@conatec.com'
**Subject:** ack letter
**Attachments:** image002.png

**DEPARTMENT OF HEALTH & HUMAN SERVICES**
**Public Health Service**
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 27, 2012
FIEDLER
KATRINA
CONVATEC INC
200 HEADQUARTERS PARK DRIVE
SKILLMAN, NEW JERSEY 08558
ATTN: KATRINA FIEDLER

510k Number: K121275
Received: 4/27/2012
Product: AQUACEL AG EXTRA HYDROFIBER DR

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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Sincerely,

510(k) Staff


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

**Grayson, Giovanna ***

**From:** Microsoft Outlook
**To:** 'katrina.fiedler@conatec.com'
**Sent:** Friday, April 27, 2012 1:13 PM
**Subject:** Relayed: ack letter

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'katrina.fiedler@conatec.com'

Subject: ack letter

---

Sent by Microsoft Exchange Server 2007



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-04-2016

K121275
SUBSTANTIVE



FDA CDRH DMC
APR 27 2012
Received KZ

ConvaTec

200 Headquarters Park Drive
Skillman, NJ 08558 USA
www.convatec.com

April 25, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: 510(k) Premarket Notification – Traditional
AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber

Dear Sir/Madam:

In accordance with Section 510(k) of the Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, subpart E, this Traditional Premarket Notification is being submitted for AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber by ConvaTec Inc. One copy of the 510(k) is enclosed (hard copy format including the Premarket Review Submission Cover Sheet and a detailed Table of Contents) along with an electronic copy on an accompanying compact disk.

This 510(k) seeks prescription and over-the-counter use clearance for AQUACEL™Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber, a variation of AQUACEL™ Ag Hydrofiber™ Dressing (previously cleared for prescription and over-the-counter use via K080383*). *A copy of the clearance letter for the predicate device Premarket Notification, K080383, follows this cover letter. Claims to be used in advertising are contained in Section 13 of this application.

AQUACEL™Ag EXTRA™ Hydrofiber Dressing with Silver and Strengthening Fiber has the classification name: *dressing, wound, drug*, product code: FRO, and the device is unclassified.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016



ConvaTec

The Establishment Registration for the manufacturing site is as follows:

Establishment Registration number is (b)(4) [redacted]
(b)(4) [redacted]

The Owner/Operator number is: 2241599
ConvaTec Inc.
200 Headquarters Park Drive
Skillman, New Jersey 08558 USA

ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market this device. We consider this information to be confidential commercial information and, therefore, exempt from public disclosure.

For additional general information, please see the "Design and Use of the Device" table attached to this letter for the submitted device, as described and recommended in the FDA guidance document entitled Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, issued August 12, 2005.

We understand that the submission to the government of false information is prohibited by U.S.C. 1001331(q). To the best of my knowledge, this notification is accurate in all its details.

We trust you will find the enclosed satisfactory; however, should you have any questions, please contact me via telephone at (908) 904-2541or by fax at (908) 904-2235 or via E-mail at katrina.fiedler@convatec.com.

Sincerely,

Katrina Fiedler

Katrina Fiedler, RAC-US, ASQ CQA
Associate Director, US Regulatory Affairs
ConvaTec Inc.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION<br>**MEDICAL DEVICE USER FEE COVER SHEET** | PAYMENT IDENTIFICATION NUMBER: (b)(4)<br>Write the Payment Identification number on your check. |
|---|---|

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) | 2. CONTACT NAME |
|---|---|
| CONVATEC INC<br>200 Headquarters Park Drive<br>Skillman NJ 08558<br>US | Katrina Fiedler<br>2.1 E-MAIL ADDRESS<br>katrina.fiedler@convatec.com<br>2.2 TELEPHONE NUMBER (include Area code)<br>908-904-2541 |
| 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)<br>*****4330 | 2.3 FACSIMILE (FAX) NUMBER (Include Area code)<br>908-904-2335 |

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

| Select an application type: | 3.1 Select a center |
|---|---|
| [X] Premarket notification(510(k)); except for third party | [X] CDRH |
| [ ] 513(g) Request for Information | [ ] CBER |
| [ ] Biologics License Application (BLA) | 3.2 Select one of the types below |
| [ ] Premarket Approval Application (PMA) | [X] Original Application |
| [ ] Modular PMA | Supplement Types: |
| [ ] Product Development Protocol (PDP) | [ ] Efficacy (BLA) |
| [ ] Premarket Report (PMR) | [ ] Panel Track (PMA, PMR, PDP) |
| [ ] Annual Fee for Periodic Reporting (APR) | [ ] Real-Time (PMA, PMR, PDP) |
| [ ] 30-Day Notice | [ ] 180-day (PMA, PMR, PDP) |

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 27-Mar-2012

Form FDA 3601 (01/2007)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

## CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

| Date of Submission | User Fee Payment ID Number | FDA Submission Document Number *(if known)* |
|---|---|---|
| 04/25/2012 | (b)(4) [redacted] | |

**SECTION A — TYPE OF SUBMISSION**

| PMA | PMA & HDE Supplement | PDP | 510(k) | Meeting |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Regular (180 day) | ☐ Original PDP | ☒ Original Submission: | ☐ Pre-510(K) Meeting |
| ☐ Premarket Report | ☐ Special | ☐ Notice of Completion | ☒ Traditional | ☐ Pre-IDE Meeting |
| ☐ Modular Submission | ☐ Panel Track (PMA Only) | ☐ Amendment to PDP | ☐ Special | ☐ Pre-PMA Meeting |
| ☐ Amendment | ☐ 30-day Supplement | | ☐ Abbreviated (Complete section I, Page 5) | ☐ Pre-PDP Meeting |
| ☐ Report | ☐ 30-day Notice | | ☐ Additional Information | ☐ Day 100 Meeting |
| ☐ Report Amendment | ☐ 135-day Supplement | | ☐ Third Party | ☐ Agreement Meeting |
| ☐ Licensing Agreement | ☐ Real-time Review | | | ☐ Determination Meeting |
| | ☐ Amendment to PMA & HDE Supplement | | | ☐ Other *(specify)*: |
| | ☐ Other | | | |

| IDE | Humanitarian Device Exemption (HDE) | Class II Exemption Petition | Evaluation of Automatic Class III Designation (De Novo) | Other Submission |
|---|---|---|---|---|
| ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ Original Submission | ☐ 513(g) |
| ☐ Amendment | ☐ Amendment | ☐ Additional Information | ☐ Additional Information | ☐ Other *(describe submission)*: |
| ☐ Supplement | ☐ Supplement | | | |
| | ☐ Report | | | |
| | ☐ Report Amendment | | | |

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

**SECTION B — SUBMITTER, APPLICANT OR SPONSOR**

| | | | |
|---|---|---|---|
| Company / Institution Name: ConvaTec Inc. | Establishment Registration Number *(if known)*: 2243969 | | |
| Division Name *(if applicable)*: | Phone Number *(including area code)*: 1-908-904-2541 | | |
| Street Address: 200 Headquarters Park Drive | FAX Number *(including area code)*: 1-908-904-2235 | | |
| City: Skillman | State / Province: New Jersey | ZIP/Postal Code: 08558 | Country: USA |
| Contact Name: Katrina Fiedler | | | |
| Contact Title: Associate Director, US Regulatory Affairs | Contact E-mail Address: katrina.fiedler@convatec.com | | |

**SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

| | | | |
|---|---|---|---|
| Company / Institution Name: | | | |
| Division Name *(if applicable)*: | Phone Number *(including area code)*: | | |
| Street Address: | FAX Number *(including area code)*: | | |
| City: | State / Province: | ZIP Code: | Country: |
| Contact Name: | | | |
| Contact Title: | Contact E-mail Address: | | |

FORM FDA 3514 (12/10) Page 1 of 5 Pages

PSC Publishing Services (301) 443-6740 EF



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE**

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site
- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*
- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager
- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*
- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*
- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment
- [ ] Response to FDA correspondence:
- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address
- [ ] Other Reason *(specify)*:

**SECTION D2 — REASON FOR APPLICATION - IDE**

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access
- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor
- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final
- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing
- [ ] Other Reason *(specify)*:

**SECTION D3 — REASON FOR SUBMISSION - 510(k)**

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology
- [ ] Other Reason *(specify)*:

FORM FDA 3514 (12/10) Page 2 of 5 Pages



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**SECTION E** **ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1 | FRO | 2 | | 3 | | 4 | |
| 5 | | 6 | | 7 | | 8 | |

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

| | *510(k) Number* | | *Trade or Proprietary or Model Name* | | *Manufacturer* |
|---|---|---|---|---|---|
| 1 | K080383 | 1 | AQUACEL Ag Hydrofiber Dressing | 1 | ConvaTec Inc. |
| 2 | | 2 | | 2 | |
| 3 | | 3 | | 3 | |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

**SECTION F** **PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name

Absorbent Antimicrobial Wound Dressing; AQUACEL Ag EXTRA; Wound Dressing; Dressing; Wound; Drug;Unclassified

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|---|---|---|
| 1 | AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber | 1 | |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FDA document numbers of all prior related submissions *(regardless of outcome)*

| | | | | | |
|---|---|---|---|---|---|
| 1 K080383 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

**SECTION G** **PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code: FRO

C.F.R. Section *(if applicable)*:

Device Class

- [ ] Class I
- [ ] Class II
- [ ] Class III
- [x] Unclassified

Classification Panel

General and Plastic Surgery Devices

Indications *(from labeling)*

SEE ATTACHED, FORM 3514

**FORM FDA 3514 (12/10)** Page 3 of 5 Pages



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

| *Note:* Submission of the information entered in Section H does not affect the need to submit device establishment registration. | FDA Document Number *(if known)* |
|---|---|

**SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

| | | |
|---|---|---|
| ☒ Original<br>☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number<br>(b)(4) [redacted] | ☒ Manufacturer ☐ Contract Sterilizer<br>☐ Contract Manufacturer ☐ Repackager / Relabeler |
| (b)(4) [redacted] | | |
| ☒ Original<br>☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☒ Contract Sterilizer<br>☐ Contract Manufacturer ☐ Repackager / Relabeler |
| (b)(4) [redacted] | | |
| ☒ Original<br>☐ Add ☐ Delete | Facility Establishment Identifier (FEI) Number | ☐ Manufacturer ☒ Contract Sterilizer<br>☐ Contract Manufacturer ☐ Repackager / Relabeler |
| (b)(4) [redacted] | | |

FORM FDA 3514 (12/10) Add Continuation Page Page 4 of 5 Pages



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**SECTION I** **UTILIZATION OF STANDARDS**

**Note:** Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---|---|---|---|---|
| 1 | | | N/A | | |
| 2 | | | N/A | | |
| 3 | | | N/A | | |
| 4 | | | N/A | | |
| 5 | | | N/A | | |
| 6 | | | N/A | | |
| 7 | | | N/A | | |

**Please include any additional standards to be cited on a separate page.**

**Public reporting burden for this collection of information** is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

**FORM FDA 3514 (12/10)** Page 5 of 5 Pages



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**FORM 3514**

**SECTION G – PRODUCT CLASSIFICATION - INDICATIONS (from labeling)**

For Over-the-Counter Use: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for: Abrasions, Lacerations, Minor cuts, Minor scalds and burns.

Under the supervision of a healthcare professional: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds
- Infected wounds



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


ConvaTec

200 Headquarters Park Drive
Skillman, NJ 08558 USA
www.convatec.com

April 25, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: 510(k) Premarket Notification – Traditional
AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber

Dear Sir/Madam:

In accordance with Section 510(k) of the Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, subpart E, this Traditional Premarket Notification is being submitted for AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber by ConvaTec Inc. One copy of the 510(k) is enclosed (hard copy format including the Premarket Review Submission Cover Sheet and a detailed Table of Contents) along with an electronic copy on an accompanying compact disk.

This 510(k) seeks prescription and over-the-counter use clearance for AQUACEL™Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber, a variation of AQUACEL™ Ag Hydrofiber™ Dressing (previously cleared for prescription and over-the-counter use via K080383*). *A copy of the clearance letter for the predicate device Premarket Notification, K080383, follows this cover letter. Claims to be used in advertising are contained in Section 13 of this application.

AQUACEL™Ag EXTRA™ Hydrofiber Dressing with Silver and Strengthening Fiber has the classification name: *dressing, wound, drug*, product code: FRO, and the device is unclassified.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ConvaTec

The Establishment Registration for the manufacturing site is as follows:

Establishment Registration number is (b)(4) [redacted]
(b)(4) [redacted]

The Owner/Operator number is: 2241599
ConvaTec Inc.
200 Headquarters Park Drive
Skillman, New Jersey 08558 USA

ConvaTec requests that the Food and Drug Administration hold as confidential information our intent to market this device. We consider this information to be confidential commercial information and, therefore, exempt from public disclosure.

For additional general information, please see the "Design and Use of the Device" table attached to this letter for the submitted device, as described and recommended in the FDA guidance document entitled Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, issued August 12, 2005.

We understand that the submission to the government of false information is prohibited by U.S.C. 1001331(q). To the best of my knowledge, this notification is accurate in all its details.

We trust you will find the enclosed satisfactory; however, should you have any questions, please contact me via telephone at (908) 904-2541or by fax at (908) 904-2235 or via E-mail at katrina.fiedler@convatec.com.

Sincerely,

Katrina Fiedler

Katrina Fiedler, RAC-US, ASQ CQA
Associate Director, US Regulatory Affairs
ConvaTec Inc.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


ConvaTec

**Design and Use of the Device**

| Question | YES | NO |
|---|---|---|
| Is the device intended for prescription use (21 CFR 801 Subpart D)?[A] | X | |
| Is the device intended for over-the-counter use (21 CFR 801 Subpart C)[A]? | X | |
| Does the device contain components derived from a tissue or other biologic source? | | X |
| Is the device provided sterile? | X | |
| Is the device intended for single use? | X | |
| Is the device a reprocessed single use device? | | X |
| If yes, does this device type require reprocessed validation data? | | |
| Does the device contain a drug? | | X |
| Does the device contain a biologic? | | X |
| Does the device use software? | | X |
| Does the submission include clinical information? | | X |
| Is the device implanted? | | X |

[A]A device may be intended for both prescription and over the counter use. If so, the answer to both of these questions is yes.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


## SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

Device Name: AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber

For Over-the-Counter Use:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds;
- Infected wounds

Prescription Use ___X____ AND/OR Over-The-Counter Use ___X____

(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)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


## SECTION 5: 510(K) SUMMARY

| | |
|---|---|
| **Device:** | **AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber** |
| **Applicant:** | ConvaTec Inc. |
| **Contact:** | Katrina Fiedler<br>Associate Director, US Regulatory Affairs<br>908-904-2541<br>Fax: 908-904-2235<br>Email: katrina.fiedler@convatec.com |
| **Date:** | April 25, 2012 |
| **Trade Name:** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber |
| **Classification Name:** | Dressing, Wound, Drug |
| **Device Class:** | Unclassified |
| **Product Code:** | FRO |

**Predicate Device**: AQUACEL™ Ag Hydrofiber™ Dressing, K080383

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a one piece wound dressing comprised of two layers of soft, sterile non-woven material. The non-woven pads are comprised of Hydrofiber™ dressing and ionic silver stitchbonded together with regenerated cellulose fibers and designed to provide additional absorbency and tensile strength properties. 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 EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; partial thickness (second degree) burns; diabetic foot ulcers, (venous stasis



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ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); surgical wounds left to heal by secondary intention such as dehisced surgical incisions; surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular); traumatic wounds; wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites; oncology wounds with exudate, such as fungoids-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; painful wounds and infected wounds.

Since AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is largely based on the AQUACEL™ Ag Hydrofiber™ technology, the safety and effectiveness of AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber 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 wounds.

Thus we believe that, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is substantially equivalent to the previously cleared Hydrofiber™-technology based products (reference K080383) and that AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber can be used safely and effectively for the management of wounds.



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## SECTION 6: TRUTHFUL AND ACCURACY STATEMENT

As required by 21 CFR 807.87(k), I certify that, in my capacity as Associate Director, US Regulatory Affairs for ConvaTec Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Katrina Fiedler

Katrina Fiedler
Associate Director, US Regulatory Affairs

April 25, 2012

April 25, 2012



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## SECTION 7: CLASS III SUMMARY AND CERTIFICATION

The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is not a Class III Device. This section is not applicable.



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Form Approved: OMB No. 0910-0396**
**Expiration Date: August 31, 2012**

# CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

*TO BE COMPLETED BY APPLICANT*

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

*Please mark the applicable checkbox.*

☐ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

| Clinical Investigators | | |
|---|---|---|
| | | |
| | | |
| | | |

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

| NAME | TITLE |
|---|---|
| (b)(6) [redacted] | ASSOC. DIRECTOR, CLINICAL AFFAIRS |
| FIRM/ORGANIZATION: CONVATEC | |
| SIGNATURE (b)(6) [redacted] | DATE *(mm/dd/yyyy)*: 23RD APRIL 2012 |

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Office of Chief Information Officer
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Rockville, MD 20850

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## SECTION 9: DECLARATION OF CONFORMITY AND SUMMARY REPORTS

To date, no performance standards or special controls have been issued by the Food and Drug Administration for this type of device.

As required under Section 514 of the Food, Drug and Cosmetic Act, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is manufactured in accordance with 21 CFR Part 820, Quality System Regulations.

FDA Form 3654, Standards Data Report for 510(k)s is not included in this submission.



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## SECTION 10: EXECUTIVE SUMMARY

This 510(k) seeks clearance with substantial equivalence for AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber.

### Description of Device

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a sterile one-piece wound dressing which is designed for the management of wounds and based largely on the technology of AQUACEL™ Ag Hydrofiber™ dressing. By combining the absorbency/retention properties of two layers of AQUACEL™ Ag Hydrofiber™ with the addition of strengthening fibers, a new dressing range has been developed to meet the user needs of extra absorbency and extra tensile strength.

### Indications for Use

For Over-the-Counter Use:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

Under the supervision of a healthcare professional:

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);



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- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds;
- Infected wounds

**Device Comparison Tables**

Tables of Similarities and Differences are provided on the following pages for both the proposed AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber compared to the respective predicate, AQUACEL™ Ag Hydrofiber™ Dressing (K080383).



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| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| **Manufacturer** | ConvaTec Inc. | ConvaTec Inc. | | |
| **Intended Use** | External Wound Dressing<br>- absorbs wound exudate<br>- protects wounds<br>- for the management of painful wounds<br>- provides a moist wound healing environment | External Wound Dressing<br>- absorbs wound exudate<br>- protects wounds<br>- for the management of painful wounds<br>- provides a moist wound healing environment | The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Strengthening Fiber and AQUACEL™ Ag Hydrofiber®™ dressing have the same identical intended use. | There are no differences in intended use. |
| **Indications for Use** | Over-the-Counter Use,<br>- abrasions<br>- lacerations<br>- minor cuts<br>- minor scalds and burns<br><br>Under the supervision of a healthcare professional AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:<br>- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;<br>- Partial thickness (second degree) burns;<br>- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);<br>- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;<br>- Surgical wounds that heal by primary | Over-the-Counter Use,<br>- abrasions<br>- lacerations<br>- minor cuts<br>- minor scalds and burns<br><br>Under the supervision of a healthcare professional, AQUACEL™ Ag Hydrofiber™ Dressing may be used for the management of:<br>- Wounds as an effective barrier to bacterial penetration to help reduce infection<br>-Partial thickness (second degree) burns;<br>- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);<br>- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;<br>- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular); | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Strengthening Fiber and AQUACEL™ Ag Hydrofiber™ dressings are both indicated for use under the supervision of a healthcare professional for the management of listed wounds and over- the-counter | There are no differences in indications for use. |


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| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| | intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);<br>- Traumatic wounds;<br>- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;<br>- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;<br>- Painful wounds;<br>- Infected wounds | - Traumatic wounds;<br>- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;<br>- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;<br>- Management of painful wounds<br>- Infected wounds | | |
| **Mode of Action** | The absorbent pad absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL™ Ag EXTRA™ Hydrofiber ™ Dressing with Silver and Strengthening Fiber kills wound bacteria held in the absorbent pad and provides an antimicrobial barrier to protect the wound bed.<br>By physically having two layers of silver Hydrofiber™ material, | The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL™Ag Hydrofiber™ dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. | The mode of action is the same due to both dressings incorporating Hydrofiber™ technology. | There are no significant differences in mode of action.<br><br>AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a dual layer dressing and incorporates strengthening fibers for added absorbency and tensile strength. |


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| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is able to provide additional absorbency.<br>The addition of strengthening fibers enables the dressing to maintain a higher tensile strength which aids in removal of the dressing from the wound. | | | |
| **Characteristics** | Sterile<br>Absorbs exudates (including bacteria ) or blood<br>Forms a soft conformable gel<br>Antimicrobial properties from ionic silver<br>May require a secondary dressing<br>Two Hydrofiber™ layers of construction<br>Contains stitchbonded strengthening fibers | Sterile<br>Absorbs exudates (including bacteria ) or blood<br>Forms a soft conformable gel<br>Antimicrobial properties from ionic silver<br>May require a secondary dressing<br>Single Hydrofiber™ layer construction | Both dressings contain sodium carboxymethyl-cellulose (Hydrofiber™ technology).<br><br>Both dressings have antimicrobial properties from ionic silver, and the Hydrofiber components include the same ratio of 1.2% w/w.<br><br>Both dressings are sterile, absorb exudate or blood and form a soft conformable gel.<br><br>Both dressings contour to the wound surface. | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber incorporates stitchbonding which enables the dressing to maintain a higher tensile strength in both wet and dry conditions.<br><br>AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber comprises of two layers of Hydrofiber™ technology. |


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| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| **Components** | Two layers of non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber™) impregnated with (b)(4) ionic silver which allows for a maximum of (b)(4) of silver for a 4 inch by 4 inch dressing, stitch-bonded together with Tencel® (regenerated cellulose; the same base material as Hydrofiber™).<br><br>The two Hydrofiber™ layers are nominally 77gsm (grams per square meter) basis weight each. | Non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver which allows for a maximum of 12 mg of silver for a 4 inch by 4 inch dressing.<br><br>The Hydrofiber™ material is nominally (b)(4) grams per square meter) weight. | Both dressings include sodium carboxymethylcellulose (Hydrofiber™ technology) as primary component.<br><br>The Hydrofiber™ technology in each dressing is impregnated with the same level of ionic silver (1.2%) on a w/w basis. | (b)(4) [redacted] |


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| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| **Changing Frequency** | Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds.<br>For partial thickness (second degree) burns, the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days or until clinically indicated.<br>For donor sites, the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days. | Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds.<br>For partial thickness (second degree) burns, the AQUACEL™ Ag Hydrofiber™ Dressing may be left in place for up to 14 days or until clinically indicated.<br>For donor sites, the AQUACEL™ Ag Hydrofiber™ Dressing may be left in place for up to 14 days. | The changing frequency is the same for both dressings. | There are no differences in the changing frequency. |
| **Contraindications** | Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components. | Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components. | Same | None |
| **Storage Conditions** | Store at room temperature (10°C – 25°C/50°F – 77°F). Keep dry. | Store at room temperature (10°C – 25°C/50°F – 77°F). Keep dry. | Same | None |
| **Packaging Materials** | Primary packaging - Aluminum /PE/ Laminate pouches manufactured by Amcor Flexibles. Secondary packaging - cardboard cartons. | Primary packaging - Aluminum /PE/ Laminate pouches manufactured by Amcor Flexibles. Secondary packaging - cardboard cartons. | Same | None |


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**Summary of Performance Testing**

(b)(4)

[redacted]



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## SECTION 11: DEVICE DESCRIPTION

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a sterile one-piece wound dressing, based on the well established absorptive and retentive properties of Hydrofiber™ technology.

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber has the additional design characteristics of increased tensile strength (through the introduction of Tencel® strengthening fibers) and greater absorptive capacity (due to the two layers of Hydrofiber™ technology).

This conformable and highly absorbent dressing absorbs wound fluids and creates a soft gel which maintains a moist environment that supports the body's healing process.

**Overview of Technology**

ConvaTec has developed a number of dressings containing Sodium Carboxymethylcellulose fibers in different textile structures. Collectively, this technology is referred to as Hydrofiber™ technology. AQUACEL™ Ag dressing, a non-woven fibrous Hydrofiber™ dressing with ionic silver (1.2% w/w), has gained wide spread acceptance in the management of acute and chronic wounds where the wound is clinically infected or there is a risk of infection.

By incorporating two thinner thickness layers of AQUACEL™ Ag Hydrofiber™ and stitching bonding these layers together, a new extension to the AQUACEL™ Ag dressing range has been developed to help meet the key customer requirements of additional absorption and additional tensile strength.

**Product Components**

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is comprised of a stitchbonded (the two layers of non-woven fabric are stitched together with Tencel® (regenerated cellulose) yarn so that they are effectively bonded together) absorbent pad. The dressing is essentially a combination of two thinner layers of silver Hydrofiber™ which is stitched together.



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(b)(4)

[redacted]

The pad component is composed of two layers of Hydrofiber™ which are stitchbonded together using Tencel® yarn. The stitches run in the warp (longitudinal) direction and in the weft (latitudinal) direction. The stitching accounts for nominally (b) [redacted] w/w of the pad.

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a pad dressing comprised of two thinner layers of the same base material as used in AQUACEL™ Ag dressing. AQUACEL™ Ag contains 1.2% w/w of ionic silver and has been shown to be effective against wound pathogens in both *in vitro* testing and clinical practice since its launch in 2002. Silver is an antiseptic agent which is widely used in wound care. Originally it was used mainly as a topical agent within a cream or ointment, but more recently it has been used within silver-containing wound dressings. The historical use of silver-containing products has not raised significant patient safety issues, with silver dressings gaining significant acceptance in wound management.

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is supplied sterile, and is available in a range of sizes, details of which can be seen in Table 1 below. Dressings are packed in light-resistant foil pouches, which also act as a moisture barrier.



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| Overall Dressing Dimensions | Pack Count | Product Code |
|---|---|---|
| 5cm x 5cm / 2 x 2inches | 10 | 420675 |
| 10cm x 10cm / 4 x 4 inches | 10 | 420676 |
| 10cm x 12cm / 4 x5 inches | 10 | 420677 |
| 15cm x 15cm / 6 x 6 inches | 5 | 420678 |
| 20cm x 30cm / 8 x 12 inches | 5 | 420679 |

**Table 1: Dressing and component dimensions**

**Mechanism of Action for the Silver Hydrofiber™ Dressing**

(b)(4)

[redacted]



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Wound Repair and Regeneration

# A comparative study of the cytotoxicity of silver-based dressings in monolayer cell, tissue explant, and animal models

Andrew Burd, MD, FRCS[1]; Chi H Kwok, MPhil[1]; Siu C Hung, MPhil[1]; Hui S Chan, PhD[2]; Hua Gu, MPhil[1]; Wai K Lam, PhD, FRSC(UK), FACB(US)[2]; Lin Huang, PhD[1]

(b)(4) Copy writed material

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[redacted]



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(b)(4) Copy writed material

[redacted]



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(b)(4) Copy writed material

[redacted]



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[redacted]



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(b)(4) Copy writed material

[redacted]



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(b)(4) Copy writed material

[redacted]



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## SECTION 12: Substantial Equivalence Discussion

**AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber**

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber incorporates the absorbency/retention properties of AQUACEL™ Ag Hydrofiber™ Dressing. Thus, by design, the components of the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber are substantially equivalent to:

- AQUACEL™ Ag Hydrofiber™ Dressing (previously cleared via 510(k), K080383)

Tables of Similarities and Differences are provided on the following pages for both the proposed AQUACEL™ Ag EXTRA™ Hyrdofiber Dressing with Silver and Strengthening Fiber compared to the respective predicate, AQUACEL™ Ag Hydrofiber™ Dressing and outlines the product characteristics and specifications which form the basis of the substantial equivalence discussion.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| **Manufacturer** | ConvaTec Inc. | ConvaTec Inc. | | |
| **Intended Use** | External Wound Dressing<br>- absorbs wound exudate<br>- protects wounds<br>- for the management of painful wounds<br>- provides a moist wound healing environment | External Wound Dressing<br>- absorbs wound exudate<br>- protects wounds<br>- for the management of painful wounds<br>- provides a moist wound healing environment | The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Strengthening Fiber and AQUACEL™ Ag Hydrofiber®™ dressing have the same identical intended use. | There are no differences in intended use. |
| **Indications for Use** | Over-the-Counter Use,<br>- abrasions<br>- lacerations<br>- minor cuts<br>- minor scalds and burns<br><br>Under the supervision of a healthcare professional AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of:<br>- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;<br>- Partial thickness (second degree) burns;<br>- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);<br>- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;<br>- Surgical wounds that heal by primary | Over-the-Counter Use,<br>- abrasions<br>- lacerations<br>- minor cuts<br>- minor scalds and burns<br><br>Under the supervision of a healthcare professional, AQUACEL™ Ag Hydrofiber™ Dressing may be used for the management of:<br>- Wounds as an effective barrier to bacterial penetration to help reduce infection<br>-Partial thickness (second degree) burns;<br>- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);<br>- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;<br>- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular); | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Strengthening Fiber and AQUACEL™ Ag Hydrofiber™ dressings are both indicated for use under the supervision of a healthcare professional for the management of listed wounds and over- the-counter | There are no differences in indications for use. |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| | intent such as dermatological and surgical incisions (e.g. orthopedic and vascular);<br>- Traumatic wounds;<br>- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;<br>- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;<br>- Painful wounds;<br>- Infected wounds | - Traumatic wounds;<br>- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;<br>- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;<br>- Management of painful wounds<br>- Infected wounds | | |
| **Mode of Action** | The absorbent pad absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL™ Ag EXTRA™ Hydrofiber ™ Dressing with Silver and Strengthening Fiber kills wound bacteria held in the absorbent pad and provides an antimicrobial barrier to protect the wound bed.<br>By physically having two layers of silver Hydrofiber™ material, | The dressing absorbs wound fluid and creates a soft, conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL™Ag Hydrofiber™ dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound bed. | The mode of action is the same due to both dressings incorporating Hydrofiber™ technology. | There are no significant differences in mode of action.<br><br>AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a dual layer dressing and incorporates strengthening fibers for added absorbency and tensile strength. |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is able to provide additional absorbency.<br>The addition of strengthening fibers enables the dressing to maintain a higher tensile strength which aids in removal of the dressing from the wound. | | | |
| **Characteristics** | Sterile<br>Absorbs exudates (including bacteria ) or blood<br>Forms a soft conformable gel<br>Antimicrobial properties from ionic silver<br>May require a secondary dressing<br>Two Hydrofiber™ layers of construction<br>Contains stitchbonded strengthening fibers | Sterile<br>Absorbs exudates (including bacteria ) or blood<br>Forms a soft conformable gel<br>Antimicrobial properties from ionic silver<br>May require a secondary dressing<br>Single Hydrofiber™ layer construction | Both dressings contain sodium carboxymethyl-cellulose (Hydrofiber™ technology).<br><br>Both dressings have antimicrobial properties from ionic silver, and the Hydrofiber components include the same ratio of 1.2% w/w.<br><br>Both dressings are sterile, absorb exudate or blood and form a soft conformable gel.<br><br>Both dressings contour to the wound surface. | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber incorporates stitchbonding which enables the dressing to maintain a higher tensile strength in both wet and dry conditions.<br><br>AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber comprises of two layers of Hydrofiber™ technology. |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | (b)(4) [redacted] |
| **Components** | Two layers of non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber™) impregnated with 1.2% ionic silver which allows for a maximum of (b)(4) [redacted] of silver for a 4 inch by 4 inch dressing, stitch-bonded together with Tencel® (regenerated cellulose; the same base material as Hydrofiber™).<br><br>The two Hydrofiber™ layers are nominally (b)(4) [redacted] grams per square meter) basis weight each. | Non-woven dressing composed of sodium carboxymethylcellulose (Hydrofiber™) and 1.2% ionic silver which allows for a maximum of 12 mg of silver for a 4 inch by 4 inch dressing.<br><br>The Hydrofiber™ material is nominally (b)(4) [redacted] grams per square meter) weight. | Both dressings include sodium carboxymethylcellulose (Hydrofiber™ technology) as primary component.<br><br>The Hydrofiber™ technology in each dressing is impregnated with the same level of ionic silver (1.2%) on a w/w basis. | |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

| Parameter | Proposed Device | Predicate Device | Similarities | Differences |
|---|---|---|---|---|
| **Trade Name** | AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber | AQUACEL™ Ag Hydrofiber™ Dressing | | |
| **510(k) Number** | New | K080383 | | |
| **Changing Frequency** | Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds.<br>For partial thickness (second degree) burns, the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days or until clinically indicated.<br>For donor sites, the AQUACEL™Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days. | Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds.<br>For partial thickness (second degree) burns, the AQUACEL™ Ag Hydrofiber™ Dressing may be left in place for up to 14 days or until clinically indicated.<br>For donor sites, the AQUACEL™Ag Hydrofiber™ Dressing may be left in place for up to 14 days. | The changing frequency is the same for both dressings. | There are no differences in the changing frequency. |
| **Contraindications** | Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components. | Do not use on patients who are sensitive to or who have had allergic reactions to the dressing or its components. | Same | None |
| **Storage Conditions** | Store at room temperature (10°C – 25°C/50°F – 77°F). Keep dry. | Store at room temperature (10°C – 25°C/50°F – 77°F). Keep dry. | Same | None |
| **Packaging Materials** | Primary packaging - Aluminum /PE/ Laminate pouches manufactured by Amcor Flexibles. Secondary packaging - cardboard cartons. | Primary packaging - Aluminum /PE/ Laminate pouches manufactured by Amcor Flexibles. Secondary packaging - cardboard cartons. | Same | None |


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Convatec, Division of ER
Squibb & Sons, LLC
% Ms. Marilyn Konicky
Associate Director
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K080383
Trade/Device Name: AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing
AQUACEL® Hydrofiber® Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO, NAC
Dated: February 8, 2008
Received: February 12, 2008

Dear Ms. Konicky:

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 such 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); good manufacturing practice requirements as set



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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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

## SECTION 4: INDICATIONS FOR USE STATEMENT, CONTINUED

**510(K) Number (if known):** K080383

**Device names:** AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing

For Over-the-Counter Use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

**Indications for Use:**

Under the supervision of a healthcare professional, AQUACEL® Ag Hydrofiber Dressing may be used for the management of:

- Wounds as an effective barrier to bacterial penetration **of the dressing as this may** help reduce infection
- Partial thickness (second degree) burns
- Diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness)
- Surgical wounds left to heal by secondary intention **such as dehisced surgical incisions**[1]
- **Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular)**[1]
- Traumatic wounds
- Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided **and donor sites**[1]
- Oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma
- Management of painful wounds
- **Infected Wounds**[1]

[1]**Clarified / New Indication, not previously included in this format under K013814 or K063271**

**Prescription Use** __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-the-Counter Use** __X__ (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)**

**(Division Sign-On)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080383



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

## SECTION 4: INDICATIONS FOR USE STATEMENT

**510(K) Number (if known):** K080383

**Device name:** AQUACEL® Hydrofiber® Wound Dressing

For Over-the-Counter Use, AQUACEL® Hydrofiber® Wound Dressing may be used for:

- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

**Indications for Use:**

Under the supervision of a healthcare professional, AQUACEL® Hydrofiber® Wound Dressing may be used for the management of:

- Leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- Surgical wounds (post-operative, donor sites, dermatological)
- Partial thickness (second degree) burns
- Traumatic or surgical wounds left to heal by secondary intention **such as dehisced surgical incisions**[1]
- ***Surgical wounds that heal by primary intent, such as dermatological and* surgical incisions (e.g., orthopedic and vascular)**[1]
- **Traumatic wounds**[2]
- Local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites
- Management of painful wounds

[1] **Clarified / New Indication, not previously included in the format under K943258, K982116, or K063271**
[2] **Indication re-positioned within Indications for Use statement**

**Prescription Use** __X__ **AND/OR** (Part 21 CFR 801 Subpart D)

**Over-the-Counter Use** __X__ (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)**

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080383



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## SECTION 13: Proposed Labeling

This section includes the proposed labeling for AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber (cartons/labels, OTC package insert, Rx only package insert), proposed advertising claims, and copies of the package inserts for the predicate device (AQUACEL™ Ag Hydrofiber™ dressing).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## OTC Proposed Package Insert

OVER-THE-COUNTER
STERILE

AQUACEL™ Ag EXTRA™

Hydrofiber™ Dressing with Silver and Strengthening Fiber

**INSTRUCTIONS FOR USE**

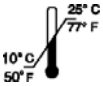
Do Not Use if Packaged is Damaged
*MISC 2215*

Do Not Reuse
*MISC 2026*

Gamma Sterilized
*MISC 2017*

Order Number
*MISC 2125*

Keep Dry
*MISC 2184*



Store at Room Temperature
*MISC 2047a*

Consult Instructions for Use
*MISC 2217*

Lot Number
*MISC 2063*

Expiration Date
*MISC 2060*

**PRODUCT DESCRIPTION**
Aquacel Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber is a soft, sterile, non-woven dressing made from two layers of silver Hydrofiber which are stitched together. This highly absorbent dressing conforms to the wound, absorbs wound fluid and creates a soft gel. The silver in the dressing helps reduce the risk of wound infection. [1,2]

This dressing should be used with a cover dressing (one that adheres to the skin).

**INDICATIONS**
***For Over-the-Counter use, AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber may be used for:***
- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**CONTRAINDICATIONS**
Do not use AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber if you are sensitive to the dressing, or its components, or have had an allergic reaction to the dressing.

**PRECAUTIONS AND OBSERVATIONS**
- **Caution:** Sterility is guaranteed unless pouch is damaged or opened prior to use.
- This device is for single-use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.
- Should you see irritation (reddening, inflammation), maceration (whitening of skin), hypergranulation (excess tissue formation), sensitivity or allergic reaction, call a healthcare professional.
- Call a healthcare professional if (1) signs of infection occur (increased pain, bleeding, wound drainage), (2) there is a change in wound color and/or odor, (3) the wound does not begin to show signs of healing and (4) any other unexpected symptoms occur.
- The dressing may be used on infected wounds only under the care of a healthcare professional.
- During the body's normal healing process, unnecessary material is removed from the wound which could make the wound appear larger after the first few dressing changes. If the wound continues to get larger after the first few dressings changes, consult a healthcare professional.
- Because AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber provides a moist environment that supports the growth of new blood vessels, occasionally the delicate newly formed blood vessels may produce a blood stained wound fluid.
- This wound dressing should not be used with other wound care products, other than those listed in **DIRECTIONS FOR USE** Section without first checking with a healthcare professional.
- If you have difficulty removing the dressing, the dressing should be fully saturated with sterile saline or sterile water and allowed to soak into the dressing.
- AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber should not be used with oil-based products such as petrolatum.
- Management of cavity wounds should only be performed under the guidance of a medical professional.

**DIRECTIONS FOR USE**
- Before applying the dressing, clean the wound area with an appropriate wound cleanser such as normal saline or Shur-Clens™ Wound Cleanser.
- Apply the dressing to the wound and then cover with a moisture holding dressing (i.e., DuoDERM™ Extra Thin, Versiva™ XC™), gauze, or other appropriate dressing. See individual package inserts for complete instructions for use. AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber should overlap ½ inch (1 cm) onto the skin around the wound.
- All wounds should be checked often. Remove the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber when leakage, excessive bleeding, or suspicion of infection occurs. The AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber is designed to remain in place no longer than seven days. The dressing should be changed when it is soaked with wound fluid or if the cover dressing is leaking or the cover dressing's edges are bunching or rolling up.

**FOR DRY WOUNDS**
- Place the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber on the wound and then wet with sterile saline or sterile water over the wound area only.
- Cover the dressing with a moisture holding dressing such as DuoDERM Extra Thin.

Store at room temperature (10ºC - 25ºC/50ºF - 77ºF). Keep dry.

If further information or guidance is needed, please contact ConvaTec Professional Services.

[1] The biocompatibility of AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber has been demonstrated through appropriate *in vivo* and *in vitro* tests.
[2] Antimicrobial activity has been demonstrated by relevant *in vitro* microbiological assays.

Made in UK

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™ indicates trademarks of ConvaTec Inc. AQUACEL Ag, EXTRA, the AQUACEL Ag logo, Hydrofiber, Shur-Clens, DuoDERM, and Versiva XC are registered trademarks in the United States.

**< END ENGLISH >**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

## Rx only Proposed Package Insert

**<BEGIN ENGLISH>**

RX Only

STERILE

AQUACEL™ Ag EXTRA™

Hydrofiber™ Dressing with Silver and Strengthening Fiber

**INSTRUCTIONS FOR USE**

Do Not Use if Packaged is Damaged
*MISC 2215*

Do Not Reuse
*MISC 2026*

Gamma Sterilized
*MISC 2017*

Order Number
*MISC 2125*

Keep Dry
*MISC 2184*

Store at Room Temperature
*MISC 2047a*

Consult Instructions for Use
*MISC 2217*

Lot Number
*MISC 2063*

Expiration Date
*MISC 2060*

**PRODUCT DESCRIPTION**
AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing is a soft, sterile dressing made from two layers of 1.2% ionic silver impregnated sodium carboxymethylcellulose stitched together with strengthening fibers which allows for a maximum of 18.48mg of silver for a 4 inch x 4 inch dressing. The silver in the dressing kills wound bacteria held in the dressing, and provides an antimicrobial barrier to protect the wound bed. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). Moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection.[1,2]

**INDICATIONS**
***Under the supervision of a healthcare professional, AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber may be used for the management of:***



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- Wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention such as dehisced surgical incisions;
- Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g., orthopedic and vascular);
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma;
- Painful wounds
- Infected wounds

**CONTRAINDICATIONS**
AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

**PRECAUTIONS AND OBSERVATIONS**
- **Caution:** Sterility is guaranteed unless pouch is damaged or opened prior to use.
- This device is for single-use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.
- When dressing sinus, tracking/tunneling or undermining wounds use AQUACEL Ag dressing with strengthening fibers (ribbon).
- During the body's normal healing process, non-viable tissue is removed from the wound (autolytic debridement), which could initially make the wound appear larger. If the wound continues to grow larger after the first few dressing changes, consult a healthcare professional. The wound should be inspected during dressing changes. Consult a healthcare professional if you see a) signs of infection (increased pain, increased redness, wound drainage), b) bleeding, c) a change in wound color and/or odor, d) irritation (increased redness and/or inflammation), e) maceration (skin whitening), f) hypergranulation (excessive tissue formation), g) sensitivity (allergic reaction), h) no signs of healing.
- If you have difficulty removing the dressing, it should be soaked with water or sterile saline until it removes easily. (For partial thickness burns, please refer to the Partial Thickness Burns section of this package insert)
- Because AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber provides a moist environment that supports the growth of new blood vessels, the delicate newly formed blood vessels may occasionally produce blood stained wound fluid.
- AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber is not compatible with oil-based products, such as petrolatum.
- Secondary dressings should be used as stated in the **DIRECTIONS FOR USE** Section**.**
- This wound dressing should not be used with other wound care products, other than those listed in **DIRECTIONS FOR USE** Section without first consulting a healthcare professional.

***In addition, for leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology), diabetic ulcers, pressure ulcers/sores, partial thickness (second degree burns), donor sites and surgical, oncology or traumatic wounds left to heal by primary or secondary intention:***
- Treatment of wounds listed above should be under the supervision of a healthcare professional.
- Appropriate supportive measures should be taken where indicated (e.g. use of graduated compression bandaging in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers, systemic antibiotics and frequent monitoring in the treatment of wound infection, control of blood glucose for diabetic ulcers, etc.).
- For oncology wounds, a secondary dressing of high absorbency may be required.
- In partial thickness (second degree) burns, consider alternate (surgical) procedures if the wound has not reepithelialized after 14 days.
- AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber is not intended for use as a surgical sponge.
- **The use of AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber has not been studied in wounds due to herpes simplex or impetigo.**

**DIRECTIONS FOR USE**
- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
- AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber should overlap 1cm (1/2 inch) onto the skin surrounding the wound.
- When using AQUACEL Ag EXTRA Hydrofiber Dressing in deep wounds, only fill the wound up to 80%, as AQUACEL Ag EXTRA Hydrofiber Dressing with Strengthening Fibers will expand to fill the wound space on contact with wound fluid.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- This primary dressing should be used with a secondary cover dressing. Apply the dressing to the wound and cover with a moisture retentive dressing (e.g. DuoDERM™ Extra Thin, CarboFlex™, Versiva™ XC) gauze, or other appropriate dressing. See individual cover dressing package inserts for complete instructions for use.
- All wounds should be inspected frequently. Remove the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber when clinically indicated (i.e., leakage, excessive bleeding, increased pain) or after a maximum of seven days.
- In donor sites, AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days.

**FOR PARTIAL THICKNESS BURNS (SECOND DEGREE BURNS):**

- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
- The AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber should overlap 5 cm (2 inches) onto the skin surrounding the burn or other adjacent AQUACEL Ag Hydrofiber Dressing.
- The AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber should be covered with sterile gauze and secured with medical tape or a retention bandage.
- Remove the gauze cover dressing periodically and inspect the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber while it remains in place on the burn.
- In this indication, adherence to the wound bed of the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber is a desired characteristic.
- Adherence of the dressing over joints could interfere with movement.
- Remove the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber when clinically indicated (e.g, excessive bleeding, clinical signs of infection).
- For partial thickness burns (second degree burns), AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days or until clinically indicated. If the burn is infected, frequent inspection of the wound may be necessary.
- As the burn wound reepithelializes, the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber will detach or be easily removed.

**FOR DRY AND MINIMALLY-EXUDING WOUNDS**

- Place the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber in the wound and then wet with sterile saline over the wound area only. The vertical absorption properties of AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber will help to maintain the moist area over the wound only and reduce the risk of maceration.
- Cover the dressing with a moisture retentive dressing such as DuoDERM Extra Thin to avoid drying out of the dressing and subsequent dressing adherence to the wound.

| | **7-day sustained activity test (simulated wound model)** | **Zone of inhibition test (Spectrum of activity)** |
|---|---|---|
| ***Staphylococcus aureus*** | ✓ | ✓ |
| ***Pseudomonas aeruginosa*** | ✓ | ✓ |
| ***Candida albicans*** | ✓ | ✓ |
| ***MRSA*** | | ✓ |
| ***VRE*** | | ✓ |
| ***Serratia marscesens*** ***(abtc resistant)*** | | ✓ |
| ***P. aeruginosa*** ***(abtc resistant)*** | | ✓ |
| ***Enterobacter cloacae*** | | ✓ |



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| | | |
|---|---|---|
| ***Klebsiella pneumoniae*** | | ✓ |
| ***Escherichia coli*** | | ✓ |
| ***Enterococcus faecalis*** | | ✓ |
| ***Streptococcus pyogenes*** | | ✓ |
| ***Bacteroides fragilis*** | | ✓ |
| ***Peptostreptococcus anaerobius*** | | ✓ |
| ***Clostridium ramosum*** | | ✓ |
| ***Clostridium clostridioforme*** | | ✓ |
| ***Clostridium cadaveris*** | | ✓ |
| ***Clostridium perfringens*** | | ✓ |
| ***Prevotella corporis*** | | ✓ |

This product is for single use only and is supplied sterile.

Discard any unused portion of the product after dressing the wound.

If the immediate product packaging is damaged, do not use.
Store at room temperature (10ºC - 25ºC/50ºF - 77ºF). Keep dry.
[1] The biocompatibility of AQUACEL Ag EXTRA Hydrofiber Dressing has been demonstrated through appropriate in vivo and in vitro tests.
[2] Antimicrobial activity has been demonstrated by relevant in vitro microbiological assays.

If further information or guidance is needed, please contact ConvaTec Professional Services.

Made in UK

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**< END ENGLISH >**



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


**Proposed Carton Label**

**Front of Carton•**

- AQUACEL™ Ag EXTRA™
- Product Size
- Statement of Identity (Hydrofiber™ Dressing with Silver and Strengthening fiber) Intended Action (For the Management of Exuding Wounds; contains 1.2% Silver)
- Product Count
- Product Graphic
- Sterilized using irradiation Symbol
- Reference Number (order code)

**Back of Carton**

- A text statement and graphical symbol illustrating: Keep dry.
- A text statement and graphical symbol illustrating: Do Not Reuse.
- A text statement and graphical symbol illustrating recommended storage condition: Store at Room Temperature (10°C -25°C/50°F - 77°F)
- A text statement and graphical symbol illustrating: Consult Instructions for Use.
- ConvaTec Logo
- ConvaTec Inc. US address
- 1-800-422-8811
- 2012 ConvaTec Inc.
- Copyright statement
- TM/R statement
- ConvaTec Limited, Deeside, CH5 2NU, UK
- Website address
- Made in UK
- Artcode reference

**Bottom of Carton**

- Lot Number and Expiration Date



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**Proposed Advertising Claims**

All Claims below cleared under 510(k) references K013814; K08063271; and K080383

- Absorbent Antimicrobial Wound Dressing provides a moist wound healing environment which is supportive of the wound healing process by aiding autolytic debridement and allowing for non-traumatic application and removal of the dressing without damaging newly formed tissue.
- By virtue of its gel blocking properties Absorbent Antimicrobial Wound Dressing absorbs exudate containing bacteria and locks it within its fibers.
- Provides an antimicrobial barrier to the wound bed.
- Soft and comfortable.
- Absorbs and wicks away fluid.
- Can be cut to suit various wound shapes without linting.
- Presence of silver protects the dressing from bacterial contamination. Presence of silver protects against bacterial comtamination and penetration in the dressing.
- When used for burns or wounds, silver prevents colonization in the dressing and acts to kill micro-organisms which can cause infection.
- Provides 7 days of antimicrobial control in the dressing.
- AQUACEL™ / AQUACEL ™ Ag dressing helps to reduce the pain of burns, donor sites, acute and chronic wounds through the gelling action of Hydrofiber™ technology.
- The moist environment provided through the Hydrofiber™ technology reduces pain while the dressing is in place. The moist environment also reduces pain during dressing changes by providing non-traumatic removal of the dressing without damaging new formed tissue.
- The gelling action of Hydrofiber™ technology in AQUACEL™and AQUACEL™ Ag dressings reduce wound pain while the dressing is *in situ*, and helps reduce the pain and trauma upon dressing removal.
- AQUACEL™ and AQUACEL™Ag dressings reduce pain while the dressing is in place.
- AQUACEL™ and AQUACEL™ Ag dressings create a moist wound environment to reduce the pain associated with frequent dressing changes.
- Designed to avoid frequent painful dressing changes and therefore reduce the need for analgesia. ( A Phase III, Prospective, Comparative Evaluation of AQUACEL™ Ag Dressing and Silver Sulfadiazine in the Management of Partial Thickness Burns, ConvaTec Final Study Report CW-0142-02-A075, dated June 9 2005)
- The gelling properties of Hydrofiber™ technology protects the incision site and provides for non-traumatic removal of the dressing.
- Absorbs and wicks away drainage.
- Soft and conformable to the incision site.
- In *in vitro* studies on surgical incisions, silver prevents colonization in the dressing and acts to kill micro-organisms, including MRSA and VRE which can cause infection.
- Provides an antimicrobial barrier to the incision site.

New proposed claims specific to AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and strengthening Fiber are detailed below:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- AQUACEL ™Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber absorbs more exudate than AQUACEL™ Ag Hydrofiber™ Dressing
- AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is stronger than AQUACEL™ Ag Hydrofiber™ Dressing.



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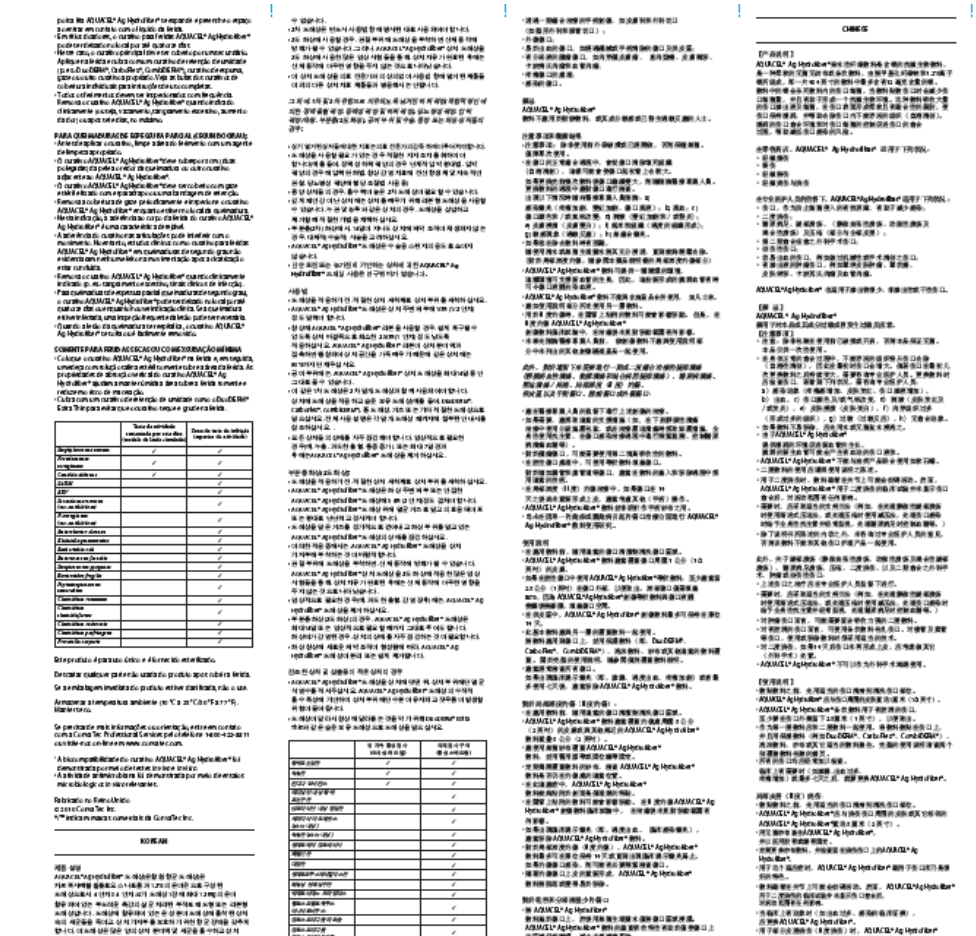



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Over-the-Counter / De venta libre / En vente libre / Vendas livre / 일반의 약품 / 非處方藥

STERILE / ESTÉRIL / STÉRILE / ESTÉRIL / 무균 제품 / 無菌

AQUACEL® Ag

**AQUACEL® Ag with Hydrofiber® / AQUACEL® Ag Apósito con Hydrofiber® / Pansement AQUACEL™ Ag Hydrofiber™ / AQUACEL® Ag Hydrofiber® Estéril / AQUACEL® Ag Hydrofiber® 드레싱 / AQUACEL® Ag Hydrofiber® 敷料**

**Silver Impregnated Antimicrobial Dressing / Apósito antimicrobiano con impregnación argéntica / Pansement antimicrobien imprégné d'argent / Curativo antimicrobiano impregnado de prata / 은 함침 항균 드레싱 / 含銀抗菌敷料**

**INSTRUCTIONS FOR USE / INSTRUCCIONES DE USO / MODE D'EMPLOI / INSTRUÇÕES DE USO / 사용 설명서 / 使用說明**

ConvaTec

## ENGLISH

**PRODUCT DESCRIPTION**
AQUACEL® Ag Hydrofiber® Dressing (silver impregnated antimicrobial dressing) is a soft, sterile, non-woven dressing. This highly absorbent dressing, conforms to the wound, absorbs wound fluid and creates a soft gel. The silver in the dressing helps reduce the risk of wound infection. [1,2]

This dressing should be used with a cover dressing (one that adheres to the skin).

**INDICATIONS**
**For Over-the-Counter use, AQUACEL® Ag Hydrofiber® Dressing may be used for:**
- Abrasions
- Lacerations
- Minor cuts
- Minor scalds and burns

**CONTRAINDICATIONS**
Do not use AQUACEL® Ag Hydrofiber® Dressing if you are sensitive to the dressing, or its components, or have had an allergic reaction to the dressing.

**PRECAUTIONS AND OBSERVATIONS**
- **Caution:** Sterility is guaranteed unless product is damaged or opened before use. Single use only.
- Should you see irritation (reddening, inflammation), maceration (whitening of skin), hypergranulation (excess tissue formation), sensitivity or allergic reaction, call a healthcare professional.
- Call a healthcare professional if (1) signs of infection occur (increased pain, bleeding, wound drainage), (2) there is a change in wound color and/or odor, (3) the wound does not begin to show signs of healing and (4) any other unexpected symptoms occur.
- The dressing may be used on infected wounds only under the care of a healthcare professional.
- During the body's normal healing process, unnecessary material is removed from the wound which could make the wound appear larger after the first few dressing changes. If the wound continues to get larger after the first few dressings changes, consult a healthcare professional.
- Use of the ribbon dressing in the treatment of cavity wounds should only be performed under the guidance of a medical professional.
- Because AQUACEL® Ag Hydrofiber® Wound Dressing provides a moist environment that supports the growth of new blood vessels, occasionally the delicate newly formed blood vessels may produce a blood stained wound fluid.
- This wound dressing should not be used with other wound care products, other than those listed in **DIRECTIONS FOR USE** Section without first checking with a healthcare professional.
- If you have difficulty removing the dressing, the dressing should be fully saturated with sterile saline or sterile water and allowed to soak into the dressing.
- AQUACEL® Ag Hydrofiber® Dressing should not be used with oil-based products such as petrolatum.

**DIRECTIONS FOR USE**
- Before applying the dressing, clean the wound area with an appropriate wound cleanser such as normal saline or Shur-Clens® Wound Cleanser.
- Apply the dressing to the wound and then cover with a moisture holding dressing (i.e., DuoDERM® Extra Thin, DuoDERM® CGF®, DuoDERM® CGF® Border Dressing), foam dressing, gauze, or other appropriate dressing. See individual package inserts for complete instructions for use. AQUACEL® Ag Hydrofiber® Wound Dressing should overlap ½ inch (1 cm) onto the skin around the wound.
- All wounds should be checked often. Remove the AQUACEL® Ag Hydrofiber® Wound Dressing when leakage, excessive bleeding, or suspicion of infection occurs. The AQUACEL® Ag Hydrofiber® Wound Dressing is designed to remain in place no longer than seven days. The dressing should be changed when it is soaked with wound fluid or if the cover dressing is leaking or the cover dressing's edges are bunching or rolling up.

**FOR DRY WOUNDS**
- Place the AQUACEL® Ag Hydrofiber® Dressing on the wound and then wet with sterile saline or sterile water over the wound area only.
- Cover the dressing with a moisture holding dressing such as DuoDERM® Extra Thin.

This product is for single use only and is supplied sterile.

Discard any unused portion of the product after dressing the wound.

If the inner package is damaged, do not use the dressing.

Store at room temperature (10ºC - 25ºC/50ºF - 77ºF). Keep dry.

If further information or guidance is needed, please contact ConvaTec Professional Services at 1-800-422-8811 or visit us online at www.convatec.com.

[1]The biocompatibility of AQUACEL® Ag Hydrofiber® Dressing has been demonstrated through appropriate *In vivo* and *In vitro* tests.
[2]Antimicrobial activity has been demonstrated by relevant *In vitro* microbiological assays.

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www.convatec.com

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## SPANISH

**DESCRIPCIÓN DEL PRODUCTO**
El apósito AQUACEL® Ag con Hydrofiber® (apósito antimicrobiano con impregnación argéntica) es un apósito suave, estéril, no tejido. Este apósito de gran absorción, se adapta a la herida, absorbe el líquido de la herida y forma un gel suave. La plata en el apósito ayuda a reducir el riesgo de infección de la herida.[1,2]

Este apósito debe usarse con un apósito de cobertura (uno que se adhiera a la piel).

**INDICACIONES**
***Para uso como producto de venta libre, el apósito AQUACEL® Ag con Hydrofiber® puede usarse para:***
- abrasiones
- laceraciones
- cortes menores
- escaldaduras y quemaduras menores

**CONTRAINDICACIONES**
No use el apósito AQUACEL® Ag con Hydrofiber® si tiene sensibilidad al apósito o a sus componentes, o ha tenido una reacción alérgica al apósito.

**PRECAUCIONES Y OBSERVACIONES**
- **Precaución:** La esterilidad está garantizada, a menos que el producto sea dañado o abierto antes del uso. Para un solo uso.
- Si viera irritación (enrojecimiento, inflamación), maceración (blanqueamiento de la piel), hipergranulación (formación excesiva de tejido), sensibilidad o reacción alérgica, llame a un profesional de atención de la salud.
- Llame a un profesional de atención de la salud si (1) hay signos de infección (aumento del dolor, de la hemorragia o de la supuración de la herida), (2) hay un cambio de color/olor, (3) la herida no da muestras de cicatrización y (4) ocurre cualquier otro síntoma inesperado.
- Puede usarse el apósito en heridas infectadas solamente bajo el cuidado de un profesional de la salud.
- Durante el proceso normal de cicatrización del organismo, se elimina el material innecesario de la herida, lo cual podría hacer que la herida parezca más grande después de los primeros cambios de apósito. Si la herida continúa agrandándose después de los primeros cambios de apósito, consulte a un profesional de atención de la salud.
- El uso del apósito en forma de cinta para el tratamiento de heridas cavitadas solo debe realizarse con la orientación de un médico profesional.
- Debido a que el apósito para heridas AQUACEL® Ag con Hydrofiber® proporciona un ambiente húmedo que promueve el crecimiento de nuevos vasos sanguíneos, ocasionalmente, los delicados vasos sanguíneos recién formados pueden producir un líquido de la herida manchado con sangre.
- Este apósito para heridas no debe usarse con otros productos para el cuidado de heridas, excepto los indicados en la Sección
- **INSTRUCCIONES DE USO** sin consultar primero a un profesional de la salud
- Si tiene dificultades para quitar el apósito, debe saturarlo completamente con agua o solución fisiológica estériles y permitir que estas empapen el apósito.
- El apósito AQUACEL® Ag con Hydrofiber® no debe usarse con productos con base oleosa como el petrolato.

**INSTRUCCIONES DE USO**
- Antes de aplicar el apósito, limpie el área de la herida con un limpiador de heridas adecuado como un limpiador de heridas salino normal o Shur-Clens®.
- Aplique el apósito a la herida y luego cúbrala con un apósito que retenga la humedad (p. ej., DuoDERM® Extra Thin, DuoDERM® CGF®, DuoDERM® CGF® Border Dressing), apósito de espuma, gasa u otro apósito adecuado. Consulte las instrucciones completas de uso en el prospecto del envase. El apósito para heridas AQUACEL® Ag con Hydrofiber® debe superponerse 1 cm (½ pulgada) sobre la piel que rodea la herida.
- Todas las heridas deben vigilarse con frecuencia. Retire el apósito para heridas AQUACEL® Ag con Hydrofiber® cuando haya filtración, sangrado excesivo o se sospeche que hay infección. El apósito para heridas AQUACEL® Ag con Hydrofiber® está diseñado para que permanezca colocado no más de siete días. Se debe cambiar el apósito cuando se empape con líquido de la herida, si hay filtración en el apósito de cobertura, o si sus bordes se fruncen o se enrollan.

**PARA HERIDAS SECAS**
- Coloque el apósito AQUACEL® Ag con Hydrofiber® sobre la herida y luego humedézcalo con agua o solución salina estériles únicamente sobre el área de la herida.
- Cubra el apósito con un apósito que retenga la humedad como DuoDERM® Extra Thin.

Este producto debe usarse una sola vez y se suministra estéril.

Deseche toda parte sin usar del producto después de vendar la herida.

No use el producto si el interior del envase está dañado.

Almacene a temperatura ambiente (10 °C - 25 °C/50 °F - 77 °F). Mantenga el producto seco.

En caso de necesitar más información u orientación, comuníquese con los Servicios Profesionales de ConvaTec llamando al 1-800-422-8811 o visítenos en Internet en www.convatec.com.

[1]La biocompatibilidad del apósito AQUACEL® Ag con Hydrofiber® ha sido demostrada mediante pruebas in vivo e in vitro adecuadas.

[2]La actividad antimicrobiana ha sido demostrada mediante análisis microbiológicos in vitro pertinentes.

**Fabricado por:**
ConvaTec Limited, Deeside, CH5 2NU, UK

ConvaTec Inc.
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www.convatec.com

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## FRENCH

**DESCRIPTION DU PRODUIT**
Le pansement AQUACEL™ Ag Hydrofiber™ (pansement antimicrobien imprégné d'argent) est un pansement doux, stérile et non tissé. Ce pansement très absorbant épouse la forme de la plaie, absorbe le liquide de plaie et crée un gel mou. L'argent contenu dans le pansement aide à réduire le risque d'infection de la plaie.[1,2]

Ce pansement doit être utilisé avec un pansement de recouvrement (un qui adhère à la peau).

**INDICATIONS**
En vente libre, le pansement AQUACEL™ Ag Hydrofiber™ peut être utilisé pour des :
- abrasions;
- lacérations;
- coupures mineures;
- échaudures et brûlures mineures.

**CONTRE-INDICATIONS**
N'utilisez pas le pansement AQUACEL™ Ag Hydrofiber™ si vous êtes sensible au pansement ou à ses composants ou si vous avez eu une réaction allergique au pansement.

**PRÉCAUTIONS ET OBSERVATIONS**
- **Mise en garde :** la stérilité est garantie sauf si le produit est endommagé ou a été ouvert avant usage. À usage unique.
- En cas d'irritation (rougeur, inflammation), de macération (blanchiment de la peau), d'hypergranulation (formation excessive de tissu), de sensibilité ou de réaction allergique, consultez un professionnel de la santé.
- Consultez un professionnel de la santé si (1) des signes d'infection surviennent (douleur accrue, saignement, drainage de plaie), (2) la couleur et/ou l'odeur de la plaie changent, (3) la plaie ne commence pas à montrer des signes de guérison, et (4) tout autre symptôme imprévu survient.
- Le pansement ne peut être employé sur des plaies infectées que sous la supervision d'un professionnel de la santé.
- Lors du processus de cicatrisation normal du corps, les matières superflues se détachent de la plaie, ce qui peut donner à la plaie une apparence plus étendue à la suite des premiers changements de pansement. Si la plaie continue à s'agrandir après les premiers changements de pansement, consultez un professionnel de la santé.
- Utilisez le pansement en forme de ruban uniquement sous la supervision d'un professionnel de la santé en cas de traitement de plaies cavitaires.
- Le pansement AQUACEL™ Ag Hydrofiber™ pour plaies offre un environnement humide qui favorise la croissance de nouveaux vaisseaux sanguins. Ces vaisseaux délicats nouvellement formés peuvent parfois produire un liquide de plaie sanguinolent.
- Ce pansement ne doit pas être utilisé avec des produits de soin de plaies autres que ceux répertoriés dans la section **MODE D'EMPLOI**, sans d'abord consulter un professionnel de la santé.
- Si vous éprouvez des difficultés à retirer le pansement, imbibez-le entièrement de solution saline stérile ou d'eau stérile et laissez-celle-ci pénétrer dans le pansement jusqu'à saturation.
- Le pansement AQUACEL™ Ag Hydrofiber™ est incompatible avec les produits à base d'huile, comme le pétrolatum.

**MODE D'EMPLOI**
- Avant d'appliquer le pansement, nettoyez la plaie à l'aide d'un nettoyant de plaie approprié, par exemple une solution saline normale ou le nettoyant de plaie Shur-Clens®.
- Appliquez le pansement sur la plaie et recouvrez-le d'un pansement permettant la rétention de l'humidité (c.-à-d. DuoDERM® Extra Thin, DuoDERM® CGF®, pansement de bord DuoDERM® CGF®), pansement de mousse, gaze ou autre pansement de type approprié. Consultez les feuillets contenus dans l'emballage respectif de ces produits pour leur mode d'emploi complet. Le pansement AQUACEL™ Ag Hydrofiber™ doit recouvrir sur 1 cm (½ po) la peau entourant la plaie.
- Toutes les plaies doivent être vérifiées souvent. Retirez le pansement AQUACEL™ Ag Hydrofiber™ en cas de fuite ou de saignement excessif ou si on soupçonne une infection. Le pansement AQUACEL™ Ag Hydrofiber™ est conçu de manière à ne pas rester en place plus de sept jours. Le pansement devrait être remplacé lorsqu'il est saturé de liquide de plaie ou lorsque le pansement de recouvrement fait ou que ses rebords se retroussent ou s'enroulent.

**POUR LES PLAIES SÈCHES**
- Placez un pansement AQUACEL™ Ag Hydrofiber™ sur la plaie et mouillez ensuite avec une solution saline stérile uniquement sur la zone de la plaie.
- Couvrez le pansement d'un pansement permettant la rétention de l'humidité tel que DuoDERM™ Extra Thin.

Ce produit ne doit être utilisé qu'une seule fois et a été stérilisé avant emballage.

Jetez toute portion non utilisée du produit après avoir pansé la plaie.

N'utilisez pas le pansement si son emballage immédiat est endommagé.

Entreposez à température ambiante (10 à 25 °C/50 à 77 °F). Gardez au sec.

Pour plus de renseignements ou des conseils, veuillez communiquer avec les services professionnels de ConvaTec.

[1] La biocompatibilité du pansement AQUACEL™ Ag Hydrofiber™ a été démontrée par des essais *In vivo* et *In vitro* appropriés.

[2] L'activité antimicrobienne a été démontrée par des essais microbiologiques *In vitro* pertinentes.

**Fabriqué par :**
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www.convatec.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

## PORTUGUESE

### DESCRIÇÃO DO PRODUTO

O AQUACEL® Ag Hydrofiber® (curativo antimicrobiano impregnado de prata) é um curativo não-tecido, estéril, macio e altamente absorvente que se adapta à ferida, absorve fluidos e cria um gel macio. A prata no curativo ajuda a reduzir o risco de infecções.[1,2]

Este curativo deve ser usado com cobertura (aderente à pele).

### INDICAÇÕES

***Sem receita, o curativo AQUACEL® Ag Hydrofiber® pode ser usado para as seguintes finalidades:***
- Abrasões
- Lacerações
- Pequenos cortes
- Pequenas queimaduras

### CONTRAINDICAÇÕES

Não utilizar o AQUACEL® Ag Hydrofiber® se for sensível ao curativo ou aos seus componentes, ou se houver reação alérgica.

### PRECAUÇÕES E OBSERVAÇÕES

- **Cuidado:** a esterilidade é garantida a menos que o produto esteja danificado ou seja aberto antes do uso. Apenas para uso único.
- Se forem observadas irritação (vermelhidão, inflamação), maceração (branqueamento da pele), hipergranulação (formação excessiva de tecido), sensibilidade ou reação alérgica, consulte um profissional de saúde.
- Contate um profissional de saúde se houver: (1) sinais de infecção (piora da dor, sangramento, drenagem da ferida), (2) alteração na cor e/ou odor da ferida, (3) ausência de sinais de cicatrização e (4) outros sintomas inesperados.
- O curativo pode ser usado em feridas infeccionadas somente sob os cuidados de um profissional de saúde.
- Durante a cicatrização normal, o organismo remove o material desnecessário da ferida. Com isso, ela pode parecer maior após as primeiras trocas de curativo. Se a ferida continuar a crescer após as primeiras trocas de curativo, consulte um profissional de saúde.
- O curativo em fita só deve ser usado no tratamento de feridas com cavidade sob a orientação de um profissional de saúde.
- Como o curativo AQUACEL® Ag Hydrofiber® proporciona um ambiente úmido que favorece o crescimento de novos vasos sanguíneos, às vezes esses delicados vasos recém-formados podem produzir um líquido sanguinolento no ferimento.
- Este curativo não deve ser utilizado com outros produtos para tratamento de feridas, com exceção dos produtos listados na seção.
- **INSTRUÇÕES DE USO**, sem consultar antes um profissional de saúde.
- Se houver dificuldade em remover o curativo, ele deve ser irrigado com solução salina estéril ou água estéril em abundância para que se umedeça completamente.
- O curativo AQUACEL® Ag Hydrofiber® não deve ser usado com produtos a base de óleo, como vaselina.

### INSTRUÇÕES DE USO

- Antes de aplicar o curativo, limpe a área da ferida com uma substância apropriada, como soro fisiológico ou a solução limpadora de feridas Shur-Clens®.
- Aplique o curativo na ferida e cubra com um curativo retentor de umidade (p. ex.: DuoDERM® Extra Thin, DuoDERM® CGF®, curativo com borda DuoDERM® CGF®), curativo de espuma, gaze ou outro curativo apropriado. Consulte as instruções de uso de cada tipo de curativo. O curativo para feridas AQUACEL® Ag Hydrofiber® deve sobrepor 1 cm (meia polegada) da pele ao redor da ferida.
- Todas as feridas devem ser observadas frequentemente. Remova o curativo para feridas AQUACEL® Ag Hydrofiber® se houver vazamento, sangramento excessivo ou suspeita de infecção. O curativo para feridas AQUACEL® Ag Hydrofiber® é projetado para permanecer no local por no máximo sete dias. O curativo deve ser trocado quando saturado com fluidos da ferida, se a cobertura estiver vazando ou se as bordas da cobertura estiverem amassadas ou enrolando.

### PARA FERIDAS SECAS

- Coloque o curativo AQUACEL® Ag Hydrofiber® na ferida e, em seguida, umedeça com solução salina estéril ou água estéril somente sobre a área da ferida.
- Cubra com um curativo absorvente de umidade como o DuoDERM® Extra Thin.

Este produto é para uso único e é fornecido esterilizado.

Descartar qualquer parte não usada do produto após cobrir a ferida.

Não utilize o produto se a embalagem interna estiver danificada.

Armazenar a temperatura ambiente (10 °C a 25 °C/50 °F a 77 °F). Manter seco.

Se precisar de mais informações ou orientação, entre em contato com a ConvaTec Professional Services pelo telefone 1-800-422-8811 ou visite-nos on-line em www.convatec.com.

[1] A biocompatibilidade do curativo AQUACEL® Ag Hydrofiber® foi demonstrada por meio de testes *in vivo* e *in vitro*.

[2] A atividade antimicrobiana foi demonstrada por meio de ensaios microbiológicos *in vitro* relevantes.

**Fabricado por:**
ConvaTec Limited, Deeside, CH5 2NU, UK

ConvaTec Inc
Skillman, NJ 08558
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## KOREAN

### 제품 설명

AQUACEL® Ag Hydrofiber® 드레싱 (은함침 항균 드레싱)은 부드러운 촉감의 살균 처리된 부직포 드레싱입니다. 흡수력이 매우 탁월한 이 드레싱은 굴곡진 창상에도 유연하게 적용되며 상처분비물을 흡수하고 부드러운 젤을 형성합니다. 드레싱에 함유되어 있는 은 성분이 상처의 감염 위험성을 낮추는데 도움이 됩니다.[1,2]

이 드레싱은 (피부에 부착되는) 덮개 드레싱과 함께 사용하여야 합니다.

### 적응증

***AQUACEL® Ag Hydrofiber® 드레싱은, 일반 의약품으로 사용하는 경우, 다음과 같은 상처에 사용할 수 있습니다:***
- 찰과상
- 열상
- 가볍게 베인 상처
- 가벼운 화상 및 데인 상처

### 금기 사항

이 드레싱 또는 그 구성 성분에 민감하거나 드레싱에 알레르기 반응을 경험한 적이 있는 사람은 AQUACEL® Ag Hydrofiber® 드레싱을 사용하지 마십시오.

### 주의 사항 및 관찰 사항

- 주의: 사용 전 포장이 파손되었거나 개봉되어 있다면 그 드레싱은 더 이상 무균 상태가 아닙니다. 1회용.
- 자극(발적, 염증), 짓무름(피부 백색화), 과립증 비후(과도한 조직 형성), 민감성 또는 알레르기 반응이 보이는 경우, 의료 전문가에게 연락하십시오.
- (1) 감염의 징후(통증 증가, 출혈, 상처 배농물)가 나타나거나, (2) 상처의 색 및/또는 냄새에 변화가 생기거나, (3) 치유의 징후가 전혀 나타나지 않거나 (4) 기타 예상치 못한 증상이 나타날 경우, 의료 전문가에게 연락하십시오.
- 이 드레싱은 의료 전문가의 감독 하에서만 감염된 상처에 사용할 수 있습니다.
- 인체의 정상적인 창상 치유 과정 중에, 불필요한 조직이 제거되는데, 이로 인해 처음 몇 번 드레싱을 교체할 때 상처가 더 커보일 수 있습니다. 처음 몇 번 드레싱을 교체한 후에도 상처가 지속적으로 점점 더 커지는 경우, 의료 전문가와 상의하십시오.
- 창상 치료에 리본 드레싱을 사용하는 것은 의료 전문인의 지도 하에서 시행되어야 합니다.
- AQUACEL® Hydrofiber® 상처 드레싱은 새로운 혈관의 성장을 위한 습윤 환경을 제공하기 때문에, 새로이 형성된 연약한 혈관들로 인해 상처 분비액에 피가 섞여 나올 수도 있습니다.
- 이 상처 드레싱을 의료 전문가와의 상의없이 사용법 항에 열거된 제품들 이외의 다른 상처 치료 제품들과 병용하지 마십시오.
- 드레싱이 벗겨지지 않는 경우, 드레싱을 멸균 식염수 또는 멸균된 물로 충분히 적신 뒤 충분히 스며들게 한 뒤에 드레싱을 떼어내면 쉽게 벗겨낼 수 있습니다.
- AQUACEL® Ag Hydrofiber® 드레싱은 바셀린과 같은 유성 제품들과 병용할 수 없습니다.

### 사용법

- 드레싱을 적용하기 전, 일반 식염수 또는 Shur-Clens® Wound Cleanser와 같은 적절한 상처 세척제로 상처 부위를 세척하십시오.
- 상처에 드레싱을 적용하고 나서, 습윤 보유 드레싱(예컨대, DuoDERM® Extra Thin, DuoDERM® CGF®, DuoDERM® CGF® Border Dressing), 폼 드레싱, 거즈 또는 기타 적절한 드레싱으로 덮으십시오. 전체 사용 설명은 각 제품 패키지에 첨부된 안내서를 참조하십시오. AQUACEL® Ag Hydrofiber® 상처 드레싱은 상처 주변 피부에 ½ 인치 (1 cm) 정도 겹쳐야 합니다.
- 모든 상처들의 상태를 자주 점검해야 합니다. 누출, 과도한 출혈 또는 감염이 의심될 경우, AQUACEL® Ag Hydrofiber® 상처 드레싱을 제거하십시오. AQUACEL® Ag Hydrofiber® 상처 드레싱은 7일 이내에 교체하도록 되어 있습니다. 드레싱이 상처 분비물을 빨아들였거나, 덮개 드레싱이 누출되거나, 덮개 드레싱의 가장자리가 주름이 잡히거나 말려 올라간 경우에는 드레싱을 교체해야 합니다.

### 건조한 상처인 경우

- AQUACEL® Ag Hydrofiber® 드레싱을 상처에 덧댄 뒤, 상처 주위에만 멸균 식염수 또는 멸균된 물을 적셔주십시오.
- DuoDERM® Extra Thin과 같은 습윤 보유 드레싱으로 드레싱을 덮으십시오.

본 제품은 1회용 제품이며, 멸균된 상태로 제공됩니다.

상처에 본 제품의 드레싱을 적용한 후, 사용하고 남은 부분은 모두 버리십시오.

내부 포장이 훼손된 경우 드레싱을 사용하지 마십시오.

실온(10ºC - 25ºC/50ºF - 77ºF)에서 보관하십시오. 건조하게 보관하십시오.

보다 자세한 정보 또는 지침이 필요한 경우, ConvaTec Professional Services 전화:1-800-422-8811번으로 연락하시거나, 저희 웹사이트: www.convatec.com을 방문하십시오.

[1] AQUACEL® Ag Hydrofiber® 드레싱의 생체 적합성은 적절한생체내 및 체외 시험들을 통해 입증되었습니다.

[2] 항균 작용 역시 적절한 체외 미생물학적 분석에 의해 입증되었습니다.

**제조원:**
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## CHINESE

### 產品描述

AQUACEL® Ag Hydrofiber®
敷料（含銀抗菌敷料）是一種柔軟、無菌、無紡布敷料。這種高吸收性敷料非常適合傷口的形狀，可吸收傷口液體，產生一種軟凝膠。敷料中所含的銀有助於降低發生傷口感染的風險。[1,2]

這種敷料應該與（粘附在皮膚上的）覆蓋敷料一起使用。

### 適應症

***做為非處方藥，AQUACEL® Ag Hydrofiber® 敷料可用於：***
- 磨損
- 破口
- 輕微的切傷
- 輕微的燙傷和灼傷

### 禁忌

對該敷料或其成分敏感，或已發生過敏反應的人士，請勿使用 AQUACEL® Ag Hydrofiber® 敷料。

### 注意事項和觀察結果

- 注意事項：除非使用前產品破損或已被開，否則保證無菌。僅限單次使用。
- 如果您發現刺激（變紅、發炎）、皮膚浸漬（皮膚變白）、超米粒組織（過度的組織形成）、敏感現象或過敏反應，請致電醫療專業人員。
- 出現以下情況時，請致電醫療專業人員：(1) 感染徵兆（疼痛加劇、流血、傷口流液）；(2) 傷口顏色和／或氣味改變；(3) 傷口無癒合徵兆；以及 (4) 出現任何其他意外症狀。
- 只有在醫療專業人員的治療下，才可將該敷料用於被感染的傷口。
- 在傷口的正常癒合過程中，不必要的物質會被去除，使得更換完前幾次敷料後傷口可能看上去變大。如果更換完前幾次敷料後傷口繼續變大，則請諮詢醫療專業人員。
- 請僅在醫療專業人員的指導下，在腔性傷口的治療中使用帶狀敷料。
- AQUACEL® Hydrofiber® 創傷敷料可提供一種潮濕的環境，而這種環境可支援新血管的生長。因此，這些新形成的脆弱血管有時可令傷口液體沾染血液。
- 未事先諮詢醫療專業人員前，該創傷敷料不應與使用說明部分中未列出的其他創傷護理產品合併使用。
- 如果您在除去該敷料時有困難，應使用無菌生理鹽水或無菌水將其充分浸透，以便讓鹽水或水滲透到敷料中。
- AQUACEL® Ag Hydrofiber® 敷料不應與含油產品一同使用，如凡士林。

### 使用說明

- 在應用敷料前，請用適當的傷口清潔劑清洗傷口區域，如生理鹽水或 Shur-Clens® 傷口清潔劑。
- 將敷料應用到傷口上，然後用保濕敷料（即，DuoDERM® 超薄 [DuoDERM® Extra Thin]、DuoDERM® CGF®、DuoDERM® CGF® 有邊敷料 [DuoDERM® CGF® BorderDressing]）、泡沫敷料、紗布或其他適當的敷料覆蓋。關於完整的使用說明，請參閱個別包裝說明。AQUACEL® Ag Hydrofiber® 創傷敷料應當覆蓋傷口周圍 ½ 英吋（1 公分）的皮膚。
- 應當經常檢查所有傷口。如果出現滲漏、過度出血、懷疑發生感染情況，應當移除 AQUACEL® Ag Hydrofiber® 創傷敷料。AQUACEL® Ag Hydrofiber® 創傷敷料最多可在原位保持七天。如果敷料滲透傷口液體，或覆蓋的敷料滲漏或其邊緣皺起或捲起，應當更換敷料。

### 對於乾性傷口

- 將 AQUACEL® Ag Hydrofiber® 料施於傷口上，然後用無菌生理鹽水或無菌水僅將傷口區域浸濕。
- 用 DuoDERM® 超薄 [DuoDERM® Extra Thin] 之類的保濕敷料覆蓋。

該產品僅供單次使用，且為無菌包裝。

在包紮傷口後，應當丟棄該產品的任何未用部分。

如果內部包裝出現損壞，切勿使用敷料。

在室溫 (10ºC - 25ºC/50ºF - 77ºF) 下存放。保持乾燥。

如果需要進一步的資訊或指導，請致電 1-800-422-8811 與康復寶的專業服務部聯絡，或參觀我們的網站 www.convatec.com。

[1] AQUACEL® Ag Hydrofiber® 敷料的生物相容性已透過適當的體內外測試進行證實。

[2] 抗菌活性已透過相關的體外微生物測驗進行證實。

**製造商：**
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Skillman, NJ 08558
1-800-422-8811

www.convatec.com

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Do Not Reuse / No reutilice el apósito / Ne pas réutiliser / Não reutilizar / 재사용하지 마십시오 / 切勿重複使用

STERILE R

Gamma Sterilized / Esterilizado con rayos gamma / Stérilisé aux rayons gamma / Esterilizado por raios gama / 감마 살균 처리/ γ 射線殺菌

REF

Order Number / Número de pedido / Référence de commande / Número de encomenda / 주문 번호 / 訂購編號

Keep Dry / Mantenga el producto seco / Garder au sec / Manter seco / 건조하게 보관하십시오 / 保持乾燥

Store at Room Temperature / Guárdelo a temperatura ambiente / Entreposer à température ambiante / Armazenar à temperatura ambiente / 실온에서 보관하십시오 / 室溫存放

Attention: See Instructions for Use / Atención: Consulte las instrucciones de uso / Attention : consulter le mode d'emploi / Atenção: ver instruções de uso / 주의: 사용 설명서를 참조하십시오 / 注意：請參閱使用說明

LOT

Lot Number / Lote / Lot / Lote / 로트 번호/ 批號

Expiration Date / Fecha de vencimiento / Date de péremption / Data de validade / 유효 기한 / 失效日期

1260183

## SECTION 14: Sterilization and Shelf Life

**AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber**

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is labeled as a sterile device and is sterilized by a traditional method of sterilization as defined in: Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, issued August 30, 2002. Accordingly, the following information is provided to support the sterilization of the device.

**Sterilization Method** (b)(4) [redacted]

(b)(4) [redacted]

**Sterility Assurance Level** (b)(4) [redacted]

**Sterilization Validation** (b)(4) [redacted]

**Method** (b)(4) [redacted] 7

**Contract Sterilizer** (b)(4) [redacted]

**Packaging** (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted]

**Sterilization:**

(b)(4) [redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


(b)(4)

[redacted]

**Shelf Life:**

The proposed shelf-life for AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is two years, when stored between 5°C and 25°C.

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is composed of the same base material as AQUACEL™ Ag (K080383) with the addition of strengthening fiber. AQUACEL™ Ag has been on the market for more than ten years. AQUACEL™ Ag dressings have a shelf life of 2 years based on documented stability testing. Experience of use in the market has not indicated any safety or effectiveness issues relating to stability.

The stitchbonding materials used in the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber are constructed from the same base material as Hydrofiber™ (regenerated cellulose) and are utilized in a number of other medical devices and wound dressings manufactured by ConvaTec. The shelf-life of dressings and devices containing this material is at least 2 years.

**Shelf-Life Justification:**

(b)(4)

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


(b)(4) [redacted]

**Additional Proposed Shelf-Life Studies**

(b)(4) [redacted]

**Reporting**

Stability reports containing the on-going confirmatory stability data will be written over the course of the (b)(4) [redacted] study in support of the product shelf life. The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber product will be continuously monitored over the course of (b)(4) [redacted] study and any significant changes over time will be reported as appropriate.

Shelf life reports will be written during the course of (b)(4) [redacted] study to confirm the shelf life and storage conditions for the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber product.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## SECTION 15: Biocompatibility

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber consists of the following materials, all of which are intended for prolonged contact with breached or compromised skin (per ISO 10993 Biological evaluation of medical devices):

- Sodium Carboxymethylcellulose Hydrofiber® with silver
- Tencel® yarn (regenerated cellulose)

The processes used to chemically produce, silverize and textile the Hydrofiber™ with silver material for the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber are identical to those processes used to manufacture AQUACEL™ Ag Hydrofiber® dressing.

(b)(4)

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


Results are reported in the following documents:

**PRODUCT: AQUACEL™ SILVER (AQUACEL™ Ag)**
**Corresponding AQUACEL™ Ag Surgical Component: Hydrofiber™ Ag**

(b)(4)

[redacted]

**PRODUCT:MULTIDERM (Versiva® Dressing) (Exempt)**
**Corresponding AQUACEL™ Ag EXTRA™ Component: Lyocell yarn**

(b)(4)

[redacted]

The referenced materials have not changed in composition. For more information on the Hydrofiber™ component, we refer the reader to the premarket notification listed below:

- AQUACEL™® Ag Hydrofiber™ Dressing (K080383)

This review supports the conclusion that no further safety testing is necessary.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


## SECTION 16: Software

The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a wound dressing and contains no software. This section is not applicable.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## SECTION 17 Electromagnetic Compatibility and Electrical Safety

The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a wound dressing and contains no electromagnetic or electrical components. This section is not applicable.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

## SECTION 18: PERFORMANCE DATA – BENCH

(b)(4)

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## SECTION 19: Performance Testing - Animal

No animal performance data has been generated for this product. Safety and efficacy has been demonstrated on the components of this product as cleared by the following premarket notifications:

K080383 – AQUACEL™ Ag Hydrofiber™ Dressing cleared May 2, 2008



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016


## SECTION 20: Performance Testing - Clinical

(b)(4) Testing

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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## SECTION 21: Other

Not applicable.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

K121275

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

# COVER SHEET MEMORANDUM

**From:** Reviewer Name Suzanne Schwartz, M.D.

**Subject:** 510(k) Number K121275

**To:** The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc )

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

| | | |
|---|---|---|
| ☐ | NO | NSE for lack of predicate |
| ☐ | NI | NSE for new intended use |
| ☐ | NQ | NSE for new technology that raises new questions of safety and effectiveness |
| ☐ | NU | NSE for new intended use AND new technology raising new questions of safety and effectiveness |
| ☐ | NP | NSE for lack of performance data |
| ☐ | NS | NSE no response |
| ☐ | NL | NSE for lack of performance data AND no response |
| ☐ | NM | NSE pre-amendment device call for PMAs (515i) |
| ☐ | NC | NSE post-amendment device requires PMAs |
| ☐ | NH | NSE for new molecular entity requires PMA |
| ☐ | TR | NSE for transitional device |

| Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.): | | YES | NO |
|---|---|---|---|
| Indications for Use Page | *Attach IFU* | ✓ | |
| 510(k) Summary /510(k) Statement | *Attach Summary* | ✓ | |
| Truthful and Accurate Statement. | *Must be present for a Final Decision* | ✓ | |
| Is the device Class III? | | | ✓ |
| If yes, does firm include Class III Summary? | *Must be present for a Final Decision* | | |
| Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) | | | ✓ |
| Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC | | | ✓ |
| Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html) | | | ✓ |
| Is this device intended for pediatric use only? | | | ✓ |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | | ✓ | ✓ |
| Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? | | | ✓ |
| Is clinical data necessary to support the review of this 510(k)? | | | ✓ |
| For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was | | | |

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

| Regulation Number | Class* | Product Code |
|---|---|---|
| unclassified | | FRO |

*(If unclassified, see 510(k) Staff)

**Additional Product Codes:** [redacted]

**Review:** David Krome (Branch Chief) PRSB (Branch Code) July 25, 2012 (Date)

**Final Review:** Erin J. Keith for MXM (Division Director) 7/25/12 (Date)

Records processed under FOIA Request # 2015-8413; Released by CDRH on 02-01-2016

**DEPARTMENT OF HEALTH AND HUMAN SERVICES** **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review**
**Traditional/Abbreviated**

# K121275

Date: July 24, 2012
To: The Record
From: Suzanne B Schwartz, MD

Office: ODE
Division: DSORD

510(k) Holder: ConvaTec
Device Name: AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber
Contact: Katrina Fiedler, RAC
Phone: 908.904.2541
Fax: 908.904.2235
Email: Katrina.fiedler@convatec.com

## I. Purpose and Submission Summary

The 510(k) holder would like to introduce AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber into interstate commerce.

## II. Administrative Requirements

| | Yes | No | N/A |
|---|---|---|---|
| Indications for Use page (Indicate if: Prescription or OTC) | Rx & OTC | | |
| Truthful and Accuracy Statement | ✓ | | |
| 510(k) Summary or 510(k) Statement | ✓ | | |
| Standards Data Report Form – Form 3654<br>1: No standard used - No Standards Form Required<br>2: Declaration of Conformity - Yes Standards Form Required<br>3: Standard but no declaration - Yes Standards Form Required | 1 | | |

## III. Device Description

| | Yes | No | N/A |
|---|---|---|---|
| Is the device life-supporting or life sustaining? | | ✓ | |
| Is the device an implant (implanted longer than 30 days)? | | ✓ | |
| Does the device design use software? | | ✓ | |
| Is the device sterile? | ✓ | | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

| | Yes | No | N/A |
|---|---|---|---|
| Is the device reusable (not reprocessed single use)?<br>Are "cleaning" instructions included for the end user? | | ✓ | |

As per the Sponsor's language:
"AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a one piece wound dressing comprised of two layers of soft, sterile non - woven material. The non - woven pads are comprised of Hydrofiber™ dressing and ionic silver stitchbonded together with regenerated cellulose fibers and designed to provide additional absorbency and tensile strength properties. 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 EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is a sterile one–piece wound dressing which is designed for the management of wounds and based largely on the technology of AQUACEL™ Ag Hydrofiber™ dressing. By combining the absorbency/retention properties of two layers of AQUACEL™ Ag Hydrofiber™ with the addition of strengthening fibers, a new dressing range has been developed to meet the user needs of extra absorbency and extra tensile strength."

"AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is comprised of a stitchbonded (the two layers of non - woven fabric are stitched together with Tencel® (regenerated cellulose) yarn so that they are effectively bonded together) absorbent pad. The dressing is essentially a combination of two thinner layers of silver Hydrofiber™ which is stitched together.

(b)(4)

[redacted]

**IV. <u>Indications for Use:</u>**

"AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is indicated for the management of wounds and can be used over - the - counter for minor wounds such as abrasions, lacerations, minor cuts, minor scalds and burns. Under the supervision of a healthcare professional, AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; partial thickness (second degree) burns; diabetic foot ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); surgical wounds left to heal by secondary intention such as dehisced surgical incisions; surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular); traumatic wounds; wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites; oncology wounds with exudate, such as fungoids - cutaneous tumors, fungating carcinoma,



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; painful wounds and infected wounds."

**There are no differences in intended use or indications for use between the subject device and the predicate, Aquacel Ag Hydrofiber dressing cleared under K080383.**

## V. Predicate Device Comparison

**Mode of action**: Same for both dressings due to both incorporating Hydrofiber technology. The difference between the predicate and the new device, manufactured by the same Sponsor, is that the (b)(4) [redacted]

Mode of Action for the subject device – "The absorbent pad absorbs wound fluid and creates a soft conformable gel, which maintains a moist wound environment to support the healing process. The dressing aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging newly formed tissue. The silver in the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber kills wound bacteria held in the absorbent pad and provides an antimicrobial barrier to protect the wound bed. By physically having two layers of silver Hydrofiber material, AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber is able to provide additional absorbency. The addition of strengthening fibers enables the dressing to maintain a higher tensile strength which aids in removal of the dressing from the wound."

**Similarities among Technological Characteristics:**

- Both contain sodium carboxymethyl-cellulose (Hydrofiber technology)
- Both have antimicrobial properties from ionic sliver, and the Hydrofiber components include the same ratio of 1.2% w/w
- Both dressings are sterile, absorb exudate or blood and form a soft conformable gel
- Both dressings contour to the wound surface

**Differences among Technological Characteristics:**

(b)(4) [redacted]

(b)(4) [redacted]

**Changing Frequency:**
Same for both dressings.
"Dressing may be left in place for up to 7 days; the dressing may require more frequent changes when used on heavily exudating wounds.

For partial thickness (second degree) burns, the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days or until clinically indicated.

For donor sites, the AQUACEL Ag EXTRA Hydrofiber Dressing with Silver and Strengthening Fiber may be left in place for up to 14 days."

**Contraindications:**
Same for both subject and predicate device, as stated: "Do not use on patients who are sensitive to



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

or who have had allergic reaction to the dressing or its components."

**Storage Conditions:**
Same for both subject and predicate device, as stated: "Store at room temperature (10°C - 25°C/50°F - 77°F). Keep dry."

**Packaging Materials:**
Same for both subject and predicate device, as stated: "Primary packaging – Aluminum/PE/ Laminate pouches manufactured by Amcor Flexibles. Secondary packaging – cardboard cartons.

## VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). There is no specific labeling required for this device. All claims previously cleared under 510(k) references K013814; K08063271; and K080383.

There are no differences in labeling between the subject device and the predicate, Aquacel Ag Hydrofiber dressing cleared under K080383 for either the Rx or OTC use.

## VII. Sterilization/Shelf Life/Reuse

"AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is labeled as a sterile device and is sterilized by a traditional method of sterilization as defined in: Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, issued August 30, 2002. Accordingly, the following information is provided to support the sterilization of the device.

Sterilization Method (b)(4) [redacted]

(b)(4) [redacted]

Sterility Assurance Level (b)(4) [redacted]

Sterilization Validation (b) [redacted]

Method (b)(4) [redacted]

Contract Sterilizer (b)(4) [redacted]

Packaging (b)(4) [redacted]

**Sterilization:**

**Sterilization:**

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4)

[redacted]

***Reviewer Comments:*** ***Sterilization and validation are acceptable.***

**"Shelf Life:**

The proposed shelf-life for AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is two years, when stored between [redacted] (b)(4)

AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber is composed of the same base material as AQUACEL™ Ag (K080383) with the addition of strengthening fiber. AQUACEL™ Ag has been on the market for more than ten years. AQUACEL™ Ag dressings have a shelf life of 2 years based on documented stability testing. Experience of use in the market has not indicated any safety or effectiveness issues relating to stability.

The stitchbonding materials used in the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber are constructed from the same base material as Hydrofiber™ (regenerated cellulose) and are utilized in a number of other medical devices and wound dressings manufactured by ConvaTec. The shelf-life of dressings and devices containing this material is at least 2 years.

(b)(4) [redacted]

(b)(4)

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

**Additional Proposed Shelf-life Studies:**

(b)(4)

[redacted]

**Reporting:**

Stability reports containing the on-going confirmatory stability data will be written over the course of the [redacted] study in support of the product shelf life. The AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber product will be continuously monitored over the course of (b)(4) [redacted] study and any significant changes over time will be reported as appropriate.

Shelf life reports will be written during the course of the [redacted] study to confirm the shelf life and storage conditions for the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber product."

***Reviewer Comments:* Shelf-life stability testing reports are acceptable. This product may not be reused and is stated as such in the labeling and package insert.**

## VIII. Biocompatibility

In accordance with ISO10993:2003, the AQUACEL Ag EXTRA Dressing is classified as:
- Surface Device,
- Contact: Breached or Compromised Surface
- Class C: Permanent Contact (as patient lifetime could exceed 30 days, i.e., continuous use across several dressing changes)

ISO10993:2003 calls for Cytotoxicity, Sensitization, Irritation, Sub-acute/Sub-chronic Toxicity and Genotoxocity for this classification of device.

"AQUACEL ™ Ag EXTRA™ Hydrofiber ™ Dressing with Silver and Strengthening Fiber consists of the following materials, all of which are intended for prolonged contact with breached or compromised skin (per ISO 10993 Biological evaluation of medical devices):

- Sodium Carboxymethylcellulose Hydrofiber® with silver
- Tencel® yarn (Lyocel - regenerated cellulose)

The processes used to chemically produce, silverize and textile the Hydrofiber™ with silver material for the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber are identical to those processes used to manufacture AQUACEL™ Ag Hydrofiber Dressing.

During the final AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber conversion process, two layers of Hydrofiber™ with silver material are stitched together (stitchbonded) Tencel® (regenerated cellulose) yarn.

The stitchbonded layers of Hydrofiber™ with silver are then cut and packaged into appropriate sizes. These stitchbonding and packing processes do not affect the

biocompatibility of the components within the AQUACEL™ Ag EXTRA™ Hydrofiber™ Dressing with Silver and Strengthening Fiber.

Hydrofiber™ dressings have been evaluated in previous pre-clinical evaluations as they are components of the products listed below and therefore no further testing is required on these components. Biocompatibility testing in accordance with ISO 10993 and US Good Laboratory Practices has been performed on the listed materials.

Results are reported in the following documents:

(b)(4)

[redacted]

(b)(4)

[redacted]

***As such, the biocompatibility testing provided for the subject device is acceptable.***

## IX. Software

Not applicable

| Version: | | |
|---|---|---|
| Level of Concern: | | |
| | Yes | No |
| Software description: | | |
| Device Hazard Analysis: | | |
| Software Requirements Specifications: | | |
| Architecture Design Chart: | | |
| Design Specifications: | | |
| Traceability Analysis/Matrix: | | |
| Development: | | |
| Verification & Validation Testing: | | |
| Revision level history: | | |
| Unresolved anomalies: | | |

## X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

## XI. Performance Testing – Bench

*In vitro* studies have been conducted comparing performance along the following parameters:

(b)(4)

[redacted]

(b)(4)

(b)(4)





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***Reviewer Comments:*** ***The testing reports were reviewed. These performance results are acceptable.***

(b)(4)

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

[redacted]

***Reviewer Comments:*** ***The test reports were reviewed. These performance data are acceptable.***

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

***Reviewer Comments:*** ***The test reports were reviewed. These performance data are acceptable.***

(b)(4)

[redacted]

**XII. Performance Testing – Animal**

"No animal performance data has been generated for this product. Safety and efficacy has been demonstrated on the components of this product as cleared by the following premarket notifications:

K080383 – AQUACEL™ Ag Hydrofiber™ Dressing cleared May 2, 2008"

***Reviewer Comments:*** ***This is acceptable.***

**XIII. Performance Testing – Clinical**

(b)(4)

[redacted]

(b)(4) Testing

[redacted]





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## XIV. Substantial Equivalence Discussion

| | Yes | No | |
|---|---|---|---|
| 1. Same Indication Statement? | ✓ | | If **YES** = Go To 3 |
| 2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | | If **YES** = Stop **NSE** |
| 3. Same Technological Characteristics? | ✓ | | If **YES** = Go To 5 |
| 4. Could The New Characteristics Affect Safety Or Effectiveness? | | | If **YES** = Go To 6 |
| 5. Descriptive Characteristics Precise Enough? | ✓ | | If **NO** = Go To 8<br>If **YES** = Stop **SE** |
| 6. New Types Of Safety Or Effectiveness Questions? | | | If **YES** = Stop **NSE** |
| 7. Accepted Scientific Methods Exist? | | | If **NO** = Stop **NSE** |
| 8. Performance Data Available? | | | If **NO** = Request Data |
| 9. Data Demonstrate Equivalence? | | | Final Decision: **SE** |

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

## XV. Deficiencies

**There are no issues to be resolved. Hence no deficiencies or requests for additional information needed to be sent to Sponsor.**

## XVI. Contact History

**July 19, 2012:** I requested Sponsor to provide enlarged font copies of packaging insert and labeling for subject device and predicate, RX and OTC. Sponsor provided these electronically via email latere that day.





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**XVII. Recommendation**

Regulation Number:
Regulation Name: None
Regulatory Class: Unclassified
Product Code: FRO, wound dressing with a drug

Reviewer — Date: July 24 2012

Branch Chief — Date: July 25, 2012

I concur
SE
E



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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# PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

| **If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):** | | YES | NO |
|---|---|---|---|
| 1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC) | | | ✓ |
| 2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)? | | | ✓ |
| 3. Does this device type require a PMA by regulation? (Please see management.) | | | ✓ |
| **Questions 4-8 are intended to help you start your review:** | | YES | NO |
| 4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc) | | | ✓ |
| 5. a. Did the firm request expedited review? (See management.) | | | ✓ |
| b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html) | | | |
| 6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device? | Please list document number and/or date, here: | | ✓ |
| 7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)? | Please list document number, here: | | ✓ |
| 8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html) | | | ✓ |

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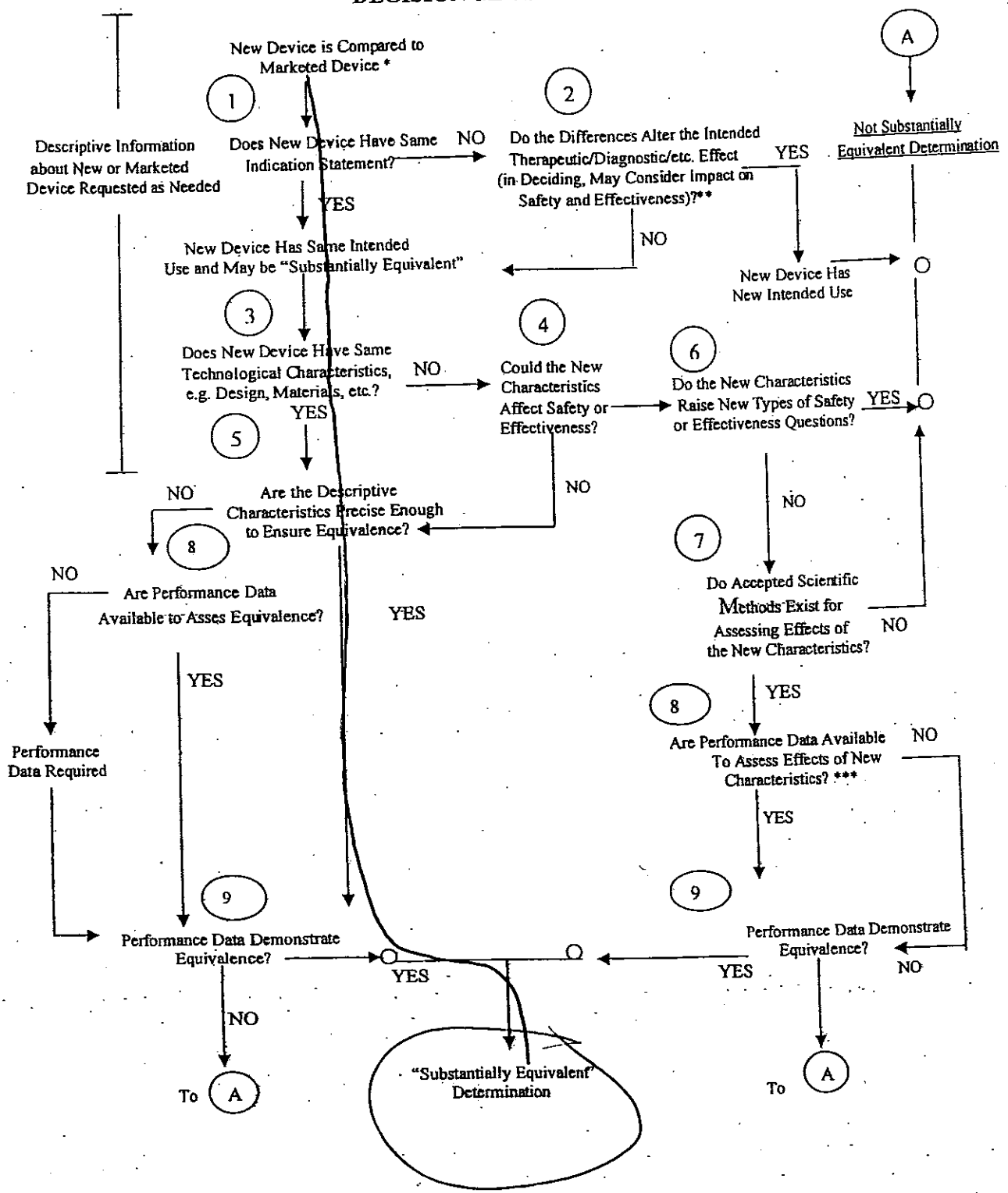
# 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS




* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118