

# Wound Market Consulting

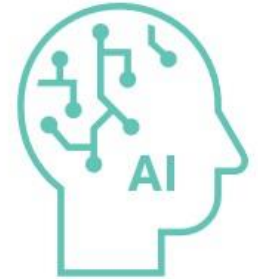
## The International Wound Care Market Specialists

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### ARTIFICIAL INTELLIGENCE & MACHINE LEARNING (AI/ML) – ENABLED DEVICES:

Technology that incorporates artificial intelligence (AI), and machine learning (ML) is advancing **FAST** across health care and is increasingly becoming important in the development of medical devices. AI/ML can provide valuable insights generated from vast amounts of data collected during the delivery of care. The US Food and Drug Administration (FDA) have stated that ensuring these innovative devices are safe, and effective and reach their potential is central to the FDA 's public health mission.



Recent advances in AI/ML devices that incorporate large language models (LLMs) allow AI/ML to analyse, translate, summarise and even predict very large datasets from real-world experience to assist health care providers and improve patient outcomes. The FDA's traditional methods for evaluating medical devices were not designed for AI and ML technologies and devices, so since 2019 the agency has been reviewing its approach to premarket reviews to AI/ML software and AI/ML based medical devices culminating most recently in the publication "Artificial Intelligence and Medical Products; How Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH), and the Office of Combination Products (OCP) are working together", to ensure learning is shared and alignment of AI in medical products.

In this article the FDA published a list (recently updated on the 19<sup>th</sup> October 2023) of AI/ML devices that have met the FDA premarket requirements marketed in US, of those 692 devices registered since 2008 only one wound care device is listed, DeepView Wound Imaging System.

For more information click [here](#).

#### AI DEVICE DEVELOPMENTS - UPDATE - SPECTRAL AI

Wound Market Consulting reported in September 2023 that Spectral AI had received their ISO certification. Spectral AI recently obtained the final stage of UK Conformity Assessed (UKCA) authorisation and Class I medical device classification from the FDA for its predictive software DeepView SnapShot Solution wound imaging system, for aiding burn wound care diagnosis. It integrates optical technology and algorithms from over 263 clinically validated data points to determine healthy and damaged tissue underneath the surface of the wound. Spectral claim that DeepView SnapShot allows clinicians to incorporate the wounds' healing potential before they determine the appropriate course of treatment. For more information click [here](#).

Look out for our next newsletter where we review other AI/ML medical devices in Europe.

### GERMAN STATUTORY HEALTH INSURANCE

The transition period for "other wound care product"s i.e. those products not covered by the legal definition of wound dressing that protects the wound and absorbs fluid will end at the beginning of December 2024. In order for these products to be reimbursable by the statutory health insurance (GKV), manufacturers must provide separate proof of benefits for their products by December 2024. During the 8<sup>th</sup> Wound Dialogue of the German Medical Technology Association (BvMed) in Berlin it was noted that it is not easy to collect proof of benefit and it was agreed by the majority at the meeting that other endpoints of treatment other than wound closure are also relevant.

### WOUND CARE CONFERENCES:

<b>Sweden:</b> 	<b>Wound Nurses in Sweden:</b> 10 <sup>th</sup> – 11 <sup>th</sup> April 2024. Click <a href="#">here</a> .	<b>United Kingdom:</b> 	<b>EWMA &amp; Society of Tissue Viability:</b> 1 <sup>st</sup> – 3 <sup>rd</sup> May 2024. Click <a href="#">here</a> .	<b>Netherlands:</b> 	<b>V&amp;VN Nursing Wound Congress:</b> 14 <sup>th</sup> May 2024 Click <a href="#">here</a> . Spain	<b>Spain:</b> 	<b>Spanish Association of Vascular Nursing &amp; Wounds:</b> 6 <sup>th</sup> – 7 <sup>th</sup> June 2024 Click <a href="#">here</a> .
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## INTERESTING TECHNOLOGIES IN DEVELOPMENT

### OPTIVIEW – TRANSPARENT DRESSING WITH HYDROCORE TECHNOLOGY

Medline recently launched a new addition to their existing portfolio, OptiView Transparent Dressing with Hydrocore Technology. The new clear design allows clinicians to view, inspect and monitor the skin and wounds quickly whilst the dressing remains in place. Existing procedures require the removal of dressings sometimes multiple times per day that may comprise the dressing adhesive and underlying skin. OptiView allows clinicians to identify changes to skin texture, colour and wound integrity early but can remain in place up to seven days. Medline report that OptiView's Hydrocore Technology incorporates a gel core that helps redistribute pressure and heat away from the skin to create a cooling effect, providing additional benefits to the patient.

To find out more, click [here](#).

### REPONEX PHARMACEUTICALS A/S SECURES EPO PATENT FOR WOUND HEALING DRUG RNX-022

Reponex Pharmaceuticals A/S recently received the patent for their hydrogel-based wound compound from the European Patent Office (EPO). The patent was granted for their drug RNX-022, a novel method of applying a hydrogel compound to wounds that accelerates the wound healing process. The topically applied hydrogel compound is comprised of ranolocyte-macrophage colony-stimulating factor (GM-CSF), sucralfate, and hyaluronan within a hydrogel base. The combination is reported to stimulate cell proliferation required for tissue regeneration and wound healing.

For more information click [here](#).

### FORCE REPAIR – COST EFFECTIVE 3D-PRINTED WOUND DRESSING

Force Repair is collaboration of 14 partners from 8 different EU countries working to develop a smart and multifunctional biomaterial for chronic wound treatment. The collaboration brings together experience and knowledge in biological, cellular and immunology mechanisms, biomaterial design and 3D additive printing. Based in Germany, Force Repair are in the process of developing their 3D-printed cost effective wound dressings that aim to treat infection and inflammation and promote wound healing. The hyaluronic acid based self hydrogel (HA-Ag-DH) printable dressing has been developed using advanced technologies including nanocarriers, antibiotics and anti-inflammatory drugs together with active pro-regenerative ingredients. Force Repair claim the dressing will offer a regenerative effect for a minimum of 15 days, thus reducing the frequency of dressing changes.

For more information click [here](#).

## HYDROGEL + CHITOSAN

### WYSS INSTITUTE FOR BIOLOGICAL INSPIRED ENGINEERING, HARVARD.

Use of hydrogels in clinical practice ranges from the delivery of drugs, lenses, 3D scaffolds and to wound dressings. However, bonding the hydrogel polymers to one another has always been challenging. Researchers at the Wyss Institute of Biological Inspired Engineering, Harvard have created a simple method that instantly bonds layers of polymeric materials (either the same or different) using a thin film of chitosan. Chitosan is a fibrous sugar-based material derived from the outer skeletons of shellfish. This approach to bonding layers has already been successfully applied to multiple medical problems including sealing of vascular injuries and the prevention of unwanted surgical adhesions. Bonded chitosan films offer numerous opportunities for the development of medical devices including in re-regenerative medicine.

For more information click [here](#).

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- ADVICE ON BORDERLINE CLASSIFICATIONS

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