

Medical Device Innovation a Responsible Journey

... not a Destination

The geko™ Wound Therapy device Story



Overview of Session

At the end of this session, the participants will be familiar with:

- The responsible introduction of technology: the geko™ device approach
- A case example of how innovation was introduced and disseminated, including partnerships
- Building evidence from the grassroots

The geko™ device Innovation Journey

2010 onwards
.....in UK

Intellectual Property secured

Research &
Development

Health Canada Approval

2011

Pilot Testing
Commercialization

Perfuse Medtec Inc. sole
Canadian distributor

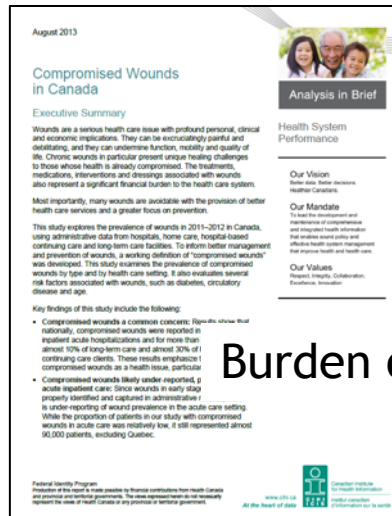


www.gekowound.ca

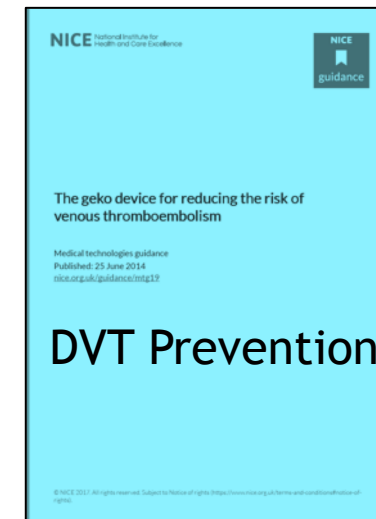
Where to start?

Identify a market with a need

Identify where it will be impactful: sport recovery & sport injury, reduce edema post cardiac surgery, refractory angina, wound care, DVT prevention



Burden of wounds



Testimonials -2014



**Hayley Wickenheiser
Sochi Olympics 2014**



**Hayley Wickenheiser and
Perfuse Medtec Inc. Team Members
Wounds Canada, May 2018**

Partnership with CHCA - 2015



PRE-SUMMIT WORKSHOP

TIME: 08:30—11:30

LOCATION: GOVERNOR GENERAL BALLROOM I (LEVEL 4)

(Separate registration is required for this event)

HEALTH CARE INNOVATION

Breaking down the barriers between the health system and technology innovators to effect health system change.

Innovations in health technology can significantly improve the care and well-being of patients everywhere and drive economic growth. Health care stakeholders and innovators across the country are posing these challenging questions:

1. What conditions are needed for successful adoption of new innovations in the health care sector?
2. How can innovators get new concepts adopted by the health care sector?
3. How are other countries meeting the challenges of health care innovation?

WORKSHOP OUTCOMES

- Learn how the MaRS Excellence in Clinical Innovation Technology Evaluation (EXCITE) program facilitates innovation adoption in Canada and worldwide.
- Discover a real-life model of disruptive technology in community-based wound care and the process that is being undertaken to accelerating adoption new innovations.
- Explore the exciting journey of the Geko™, a neuromuscular electrostimulation device that assists wound healing in difficult to manage diabetic foot and venous leg ulcers.

Session Moderator

Nadine Henningsen, Executive Director, Canadian Home Care Association

Guest panelists

Adel Aziziyeh
Project Coordinator,
MaRS EXCITE

Heather Binkle
Director Client Services, Ontario
Association of Community Care
Access Centres

Connie L. Harris,
RN, ET, IIVCC, MSc, CNS
Wound & Ostomy / Clinical Lead
Wound OBP, Quality and Professional
Practice Team, CarePartners

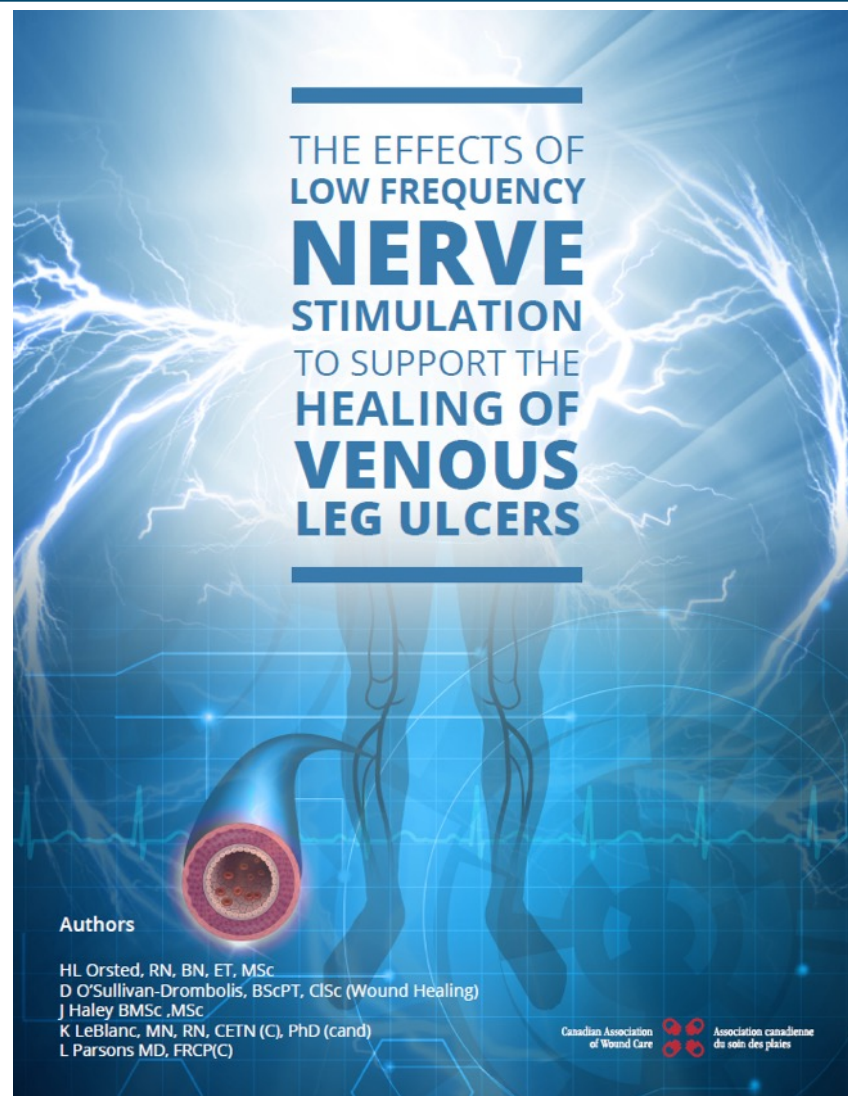
Dorace Ramage, RN,
Education Consultant,
Perfuse Medtec Inc.



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Partnership with Wounds Canada (CAWC)- 2016



Capacity Building: The Team

- Employ wound healing and research experts to improve upon eligibility criteria & data collection for evaluations
- Collaborate with professional associations (LTC, Canadian Home Care Association, Wounds Canada etc.)
- Develop relationships with professionals (ET nurses, Physicians and Surgeons, Allied Health)
- Employed marketing specialists to spread the word



Product Development

- Intellectual Property secured in UK - 2011



Summarizing the Evidence

Annotated Bibliography


The geko™ Device

Purpose: To provide a brief summary of the evidence to date for the geko™ device, particularly as it relates to haemodynamics, oedema reduction, wound healing and recovery.

Inclusion: Published papers, PhD thesis in public domain, Posters presented at Scientific Meetings and geko™ evaluations done in Canada which are currently in press or underway.

Exclusion: Published or Unpublished Case Studies with subjects <3 which can be viewed on geko™ website <http://gekodevices.com/en-uk/studies/studies-trials/>

Health Canada Registration:

 Santa Health Canada Canada		LNF#: 86311 Therapeutic Products Directorate Medical Devices Bureau Direction des produits thérapeutiques Bureau des matériels médicaux
Medical Device Licence "AMENDÉE" Licence Number: 86311 First Issue Date: 2011/06/10 Amended Date: 2017/11/02		Homologation d'un instrument médical "MODIFIÉE" No d'homologation: Première date de délivrance: Date de modification:
Device Class/Classe de l'instrument: 2 This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device: La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:		
Licence Name/Nom de l'homologation: MUSCLE STIMULATORS		
Licence Type/Type d'homologation: Group Family / Famille de groupes		
Reason for Amendment/Raison de la modification ADDITION OF A DEVICE		
Manufacturer Name & Address/Nom du fabricant & adresse SKY MEDICAL TECHNOLOGY LIMITED ALSO TRADING AS FIRSTKIND LIMITED HAWK HOUSE PEREGRINE BUSINESS PARK HIGH WYCOMBE, BUCKINGHAMSHIRE GREAT BRITAIN HP13 7DL		
Carry Agree, A Director, Medical Devices Bureau/Directrice générale, Bureau des matériels médicaux		
Application Number: Numéro de la demande: 272462		Manufacturer ID: Identificateur du fabricant: 133443

The geko™ Device: Annotated Bibliography June 6, 2018 © Perfuse Medtec Inc. 2018

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DR. BOB KIAII

CARDIAC SURGEON, LHSC





 @SMasottiCTV

STEFANIE MASOTTI

CTV NEWS

CTV NEWS
WINDSOR

CAC
Journal

perfuse
Medtec

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Great results!!!!

**THE RESPONSIBLE THING....
REPEAT IT....**

Community Evaluations - MH and SW CCAC 2015-2016

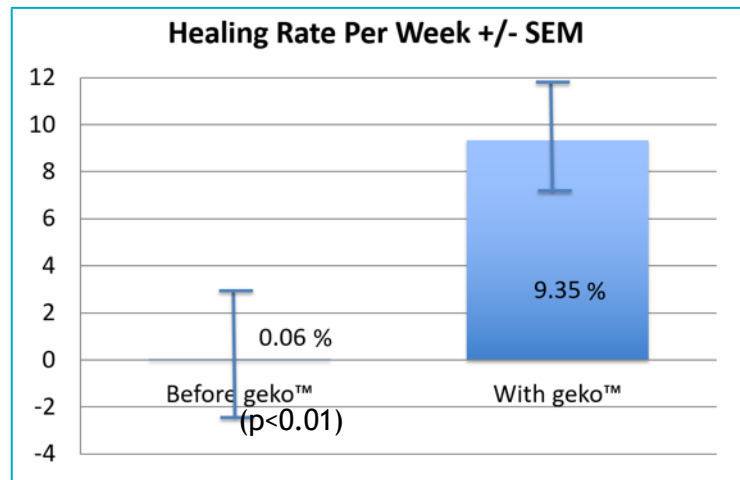
Problem: 16 patients with Non-healing VLU & DFU

Challenges:

- Dermatitis &/or folliculitis
- Suboptimal compression and offloading

Successes:

- Added as special access product in SW CCAC
- Added to formulary in MH CCAC
- Results published in International Wound Journal



Great results!!!!

**THE RESPONSIBLE THING....
REPEAT IT....**

LTC Evaluation -Revera 2016

Problem: 9 residents Non-healing VLU, DFU & PI in LTC

Challenges:

- Declined optimal compression therapy for VLU; DFU not effectively offloaded, not non-weight bearing.

Successes:

- Many wounds closed
- Best New Long-Term Care Product or Service of the year
- Revera invested financially in FirstKind
- Recently accepted for publication in IWJ

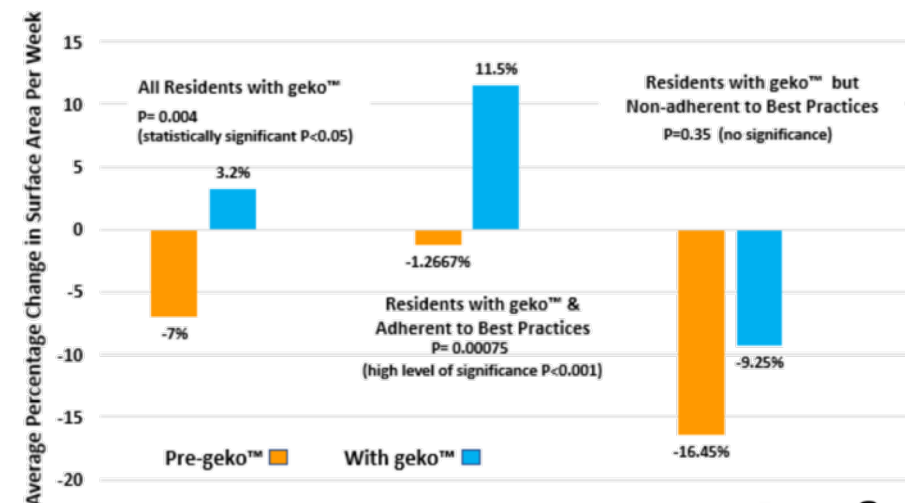
Best New Long-Term Care Product or Service of the Year

The geko device, distributed by Perfuse Medtec and piloted by Revera, significantly improves wound healing



Week 8 Rt. closed

Week 12 closed



Great results!!!!

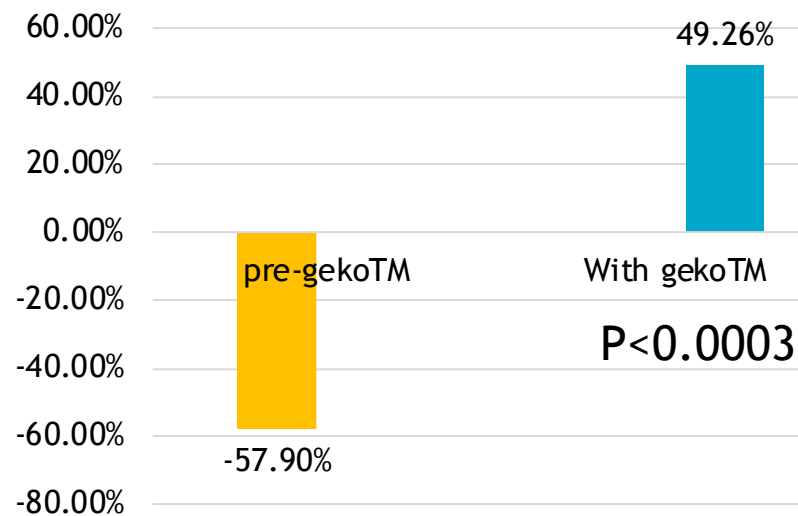
**THE RESPONSIBLE THING....
REPEAT IT....
WITH A TWIST**

Community Evaluations - WW CCAC 2016 - 2017

Question: Will the geko™ device speed healing in 10 patients with new lower leg wounds?

Challenges: Changes in staffing; introduction of new wound pathways both delayed enrollment

Successes: led to further evaluation of early adoption



Estimated Cost Savings

- It's not just about efficacy anymore
- Preliminary numbers suggest \$2,500 in savings per patient when adding the geko™ device to the treatment plan (WW LHIN)
- More robust analysis is underway (comparison with Canadian Bandaging Trial data)



Progression from low level to high level evidence

- The geko™ device is an extremely low risk device, yet there have been barriers to uptake.
- The biggest risk would be financial. Perfuse Medtec Inc. bore that risk.
- However, as the device is purchased, more evidence is needed including use for other applications (e.g. orthopedics, CVA, post-op SSI)
- Better evidence that bloodflow is being enhanced and, is it systemic?
- Higher level evidence in the form of randomized controlled trials in somewhat homogenous populations (to allow for proper comparisons).

Randomised Controlled Trial

LHSC 2016-2017

KIDNEY TRANSPLANT



200 randomized patients geko™ vs standard of care

Initial Results:

- Edema calf $p < 0.0001$ (no change in measurement with geko™ vs. 7.5% increase with IPC)
- Edema thigh $p < 0.001$ (no change in measurement with geko™ vs. 6 % increase with IPC)
- Urine output in first 6 days $p < 0.05$ (9 litres more urine with geko™)
- Complex wound infections were fewer in the geko™ group $p < 0.05$ (34% vs. 22% with geko™)
- Patient Satisfaction - patients were more satisfied with the geko™ device

VERY RELEVANT TO HOME CARE SETTING AND POST-OPERATIVE MANAGEMENT


Response to audit: New Evaluation MH LHIN 2018 - 2019



Plan:

- Use a validated VLU risk assessment tool to determine whether a patient has a low, moderate or high risk of not healing at 24 weeks with best practices, and start geko™ within first 10 days
- Quality of Life: Pre- and Post and Qualitative interviews

The journey continues.....



December 19, 2018
Perfuse MedTec Inc. Webinar Hosted by
Canadian Home care Association
Development of
ON-LINE LEARNING COURSES

Successes

- The steps followed to evaluate the geko™ device were integral in formulating the current MH LHIN, Home and Community Care New Product Innovation Evaluation Process
- MH LHIN winner of Spotlight on Innovation Award at CHCA in 2016
- MH LHIN Quality Award for Rochelle Duong in 2017

SPOTLIGHT on INNOVATION

Modernizing Home Care A Process to Evaluate and Adopt Innovation

Facilitating consistent access to, and use of, innovative wound care products can have a tremendous positive impact on the efficiency and effectiveness of home care service delivery and patient quality of life. The Mississauga-Halton Community Care Access Centre (MH CCAC) has successfully achieved this goal by using a structured collaborative approach to testing, measuring and adopting the geko™ device for rapid wound healing.

Embracing Innovation

The Ontario Health Innovation Council, established in November 2013 by the ministries of Research and Innovation, Health and Long-Term Care, and Government and Consumer Services, identified the need to expand the adoption of innovative new technologies in all health care settings, including home care. In their 2013 report, *The Catalyst*, the Council recommended the following:

- evidence-based review of emerging health technology innovations, and
- coordinated pathways for the adoption and diffusion of innovative health technologies.

Innovative health technologies offer many opportunities to improve patient experience, achieve better outcomes and reduce health care costs. One specific area where technologies can have significant impact is in the care and management of wounds. Canada spends \$3.9 billion on wound care annually, which represents 3 percent of total public health care costs (OACAC et al., 2010). In the home care sector, 50 percent of nursing visits involve wound care and approximately 36 percent of home care patients have a chronic wound (CIHI, 2011). Ineffective wound management negatively impacts patients and their families, who may experience pain, disability, discomfort, depression, anxiety, embarrassment, social isolation, hospitalization, financial burden and death (Stratton et al., 2009). For the MH CCAC, the cost of managing wounds in the home is significant. In 2014/15, the MH CCAC spent at least \$240,000 managing the most challenging wounds: arterial leg ulcers (ALUs), venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs). The actual amount spent is likely higher since this value does not include medical supplies, rehabilitation and personal support worker services.

Thank you to our SPOTLIGHT on INNOVATION sponsor Perfuse Medtec Inc., the distributor of geko™. A true wound care innovation, these self-contained devices increase venous return by over 100 percent, arterial flow by over 75 percent and microcirculatory flow by 400 percent. The geko™ device activates nature's mechanism of blood flow by using a micro-pump to create a vacuum effect on the skin, drawing blood into the wound and stimulating the blood pumping action. For more information on the geko™ device and its application, visit www.gekowound.ca.

Perfuse
Medtec

Congratulations to our 2017 Quality Award Winner Rochelle Duong!

Geko is a device used to close venous leg and foot ulcers. Results from a trial revealed that 78% of patients experienced accelerated weekly percentage healing rates. Rochelle introduced, initiated and implemented the new product to the LHIN and continues to monitor for success.



Successes



Ontario

Local Health Integration
Network

Réseau local d'intégration
des services de santé

**Home and
Community
Care**

1. Erie St. Clair
2. South West
6. Mississauga Halton

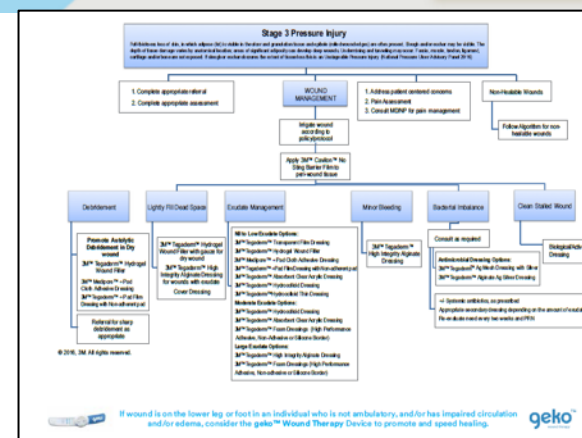
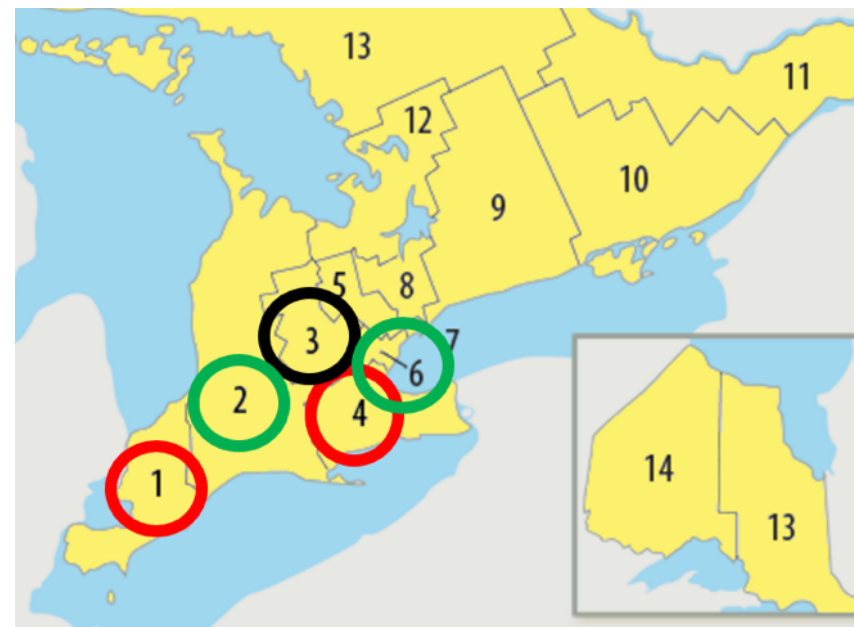
By Physician
or ET Nurse

4. Hamilton Haldeman
- Niagara Brant
3. Waterloo Wellington

Pending

Long Term Care

Revera
*innovators
in aging*



Overview of Session

At the end of this session, the participants will be familiar with:

- The responsible introduction of technology: the geko™ device approach
- A case example of how innovation was introduced and disseminated, including partnerships
- Building evidence from the grassroots

Contact us: info@perfusemedtec.com