

# Medical Device Innovation a Responsible Journey

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... not a Destination

## The geko™ Wound Therapy device Story



# Overview of Session

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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
- Development of on-line learning modules that recognize the challenges of traditional in-service training.

# 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



# 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



August 2013

### Compromised Wounds in Canada

Executive Summary

Wounds are a serious health care issue with profound personal, clinical and economic implications. They can be excruciatingly painful and debilitating, and they can undermine function, mobility and quality of life. Chronic wounds in particular present unique healing challenges to those whose health is already compromised. The treatments, medications, interventions and dressings associated with wounds also represent a significant financial burden to the health care system.

Most importantly, many wounds are avoidable with the provision of better health care services and a greater focus on prevention.

This study explores the prevalence of wounds in 2011–2012 in Canada, using administrative data from hospitals, home care, hospital-based continuing care and long-term care facilities. To inform better management and prevention of wounds, a working definition of “compromised wounds” was developed. This study examines the prevalence of compromised wounds by type and by health care setting. It also evaluates several risk factors associated with wounds, such as diabetes, circulatory disease and age.

Key findings of this study include the following:

- Compromised wounds a common concern: Roughly 1.5 million compromised wounds were reported in inpatient acute hospitals and for more than almost 10% of long-term care and almost 30% of continuing care clients. These results emphasize compromised wounds as a health issue, particularly in acute inpatient care.
- Compromised wounds likely under-reported, if acute inpatient care: Since wounds in early study properly identified and captured in administrative data under-reporting of wound prevalence in the acute care setting. While the proportion of patients in our study with compromised wounds in acute care was relatively low, it still represented almost 60,000 patients, excluding Quebec.

Analysis in Brief

Health System Performance

Our Vision  
Better care. Better medicine. Healthier Canadians.

Our Mandate  
To lead the development and maintenance of comprehensive and integrated health information that enables sound policy and effective health system management that improves health and health care.

Our Values  
Integrity, Collaboration, Excellence, Innovation

Federal Identity Program  
Provision of this logo is made possible by financial contributions from Health Canada and provincial and territorial governments. The above government logos do not necessarily represent the views of Health Canada or any provincial or territorial government.

www.ohri.ca  
All the Heart of Care

Canadian Centre for Health Information  
National Canadian Institute for Health Care



Burden of wounds

NICE National Institute for Health and Care Excellence

NICE guidance

The geko device for reducing the risk of venous thromboembolism

Medical technologies guidance  
Published: 25 June 2014  
nice.org.uk/guidance/mtg19

## DVT Prevention

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# 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, IIWCC, MSc, CNS  
Wound & Ostomy / Clinical Lead  
Wound OBP, Quality and Professional  
Practice Team, CarePartners

**Dorace Ramage, RN,**

Education Consultant,  
Perfuse Medtec Inc.



[www.gekowound.ca](http://www.gekowound.ca)



# Capacity Building: The Team

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



[www.gekowound.ca](http://www.gekowound.ca)

# Product Development

- Intellectual Property secured in UK - 2011



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# 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:

 Santé Health Canada Canada		LNFB: 96311	Therapeutic Products Directorate Medical Devices Bureau Direction des produits thérapeutiques Bureau des matériels médicaux
<b>Medical Device Licence</b>		<b>Homologation d'un instrument médical</b>	
* AMENDÉ *		* MODIFIÉE *	
Licence Number:	86311	No d'homologation:	
First Issue Date:	2011/06/10	Première date de délivrance:	
Amended Date:	2017/11/02	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 / Familles 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 Agent, A/Contraire, Medical Devices Bureau/Direction des produits, 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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The geko™ Device: Annotated Bibliography June 6, 2018 © Perfuse Medtec Inc. 2018

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# Evidence: 2013 - 2014

## Mini Evaluations:

Will the geko™ device help with:

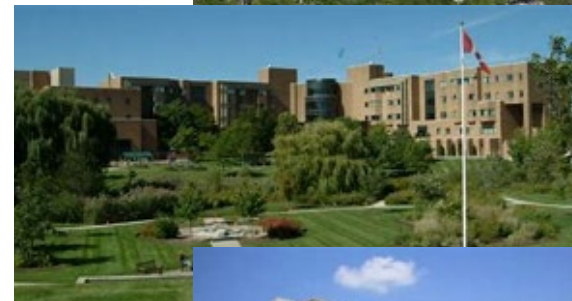
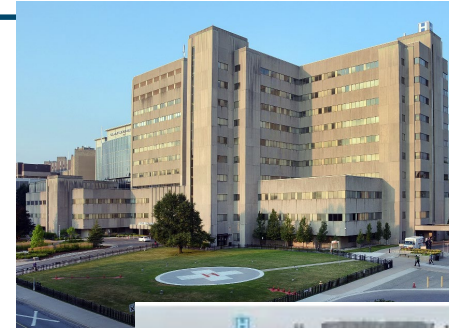
- post op cardiac edema?
- wound care in a rehabilitation hospital?
- DFU, Mixed Venous/Arterial, PAD wounds

## Clinical Trial:

Blood flow in occluded & non-occluded coronary arteries

## Successes:

- Success with edema reduction and wound healing
- Evolution to more powerful device



# Community Evaluations- ESC & HNHB CCAC 2014-15

**Problem:** Provide us with your most difficult patients “Train Wrecks”

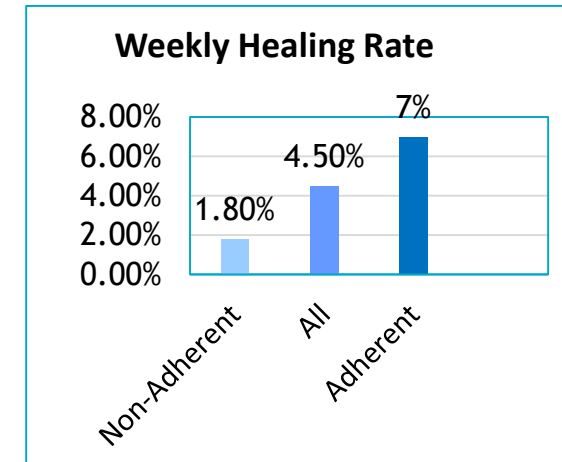
1<sup>st</sup> patient VLU & pressure ulcers for 6 months - VLU healed in 3 weeks



## Challenges:

- Other patients took longer
- Dermatitis &/or folliculitis
- Changing to newest device mid-evaluation

## Successes:



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:

IWJ International Wound Journal  
Explore this journal >

ORIGINAL ARTICLE

**Evaluation of a muscle pump-activating device for non-healing venous leg ulcers**

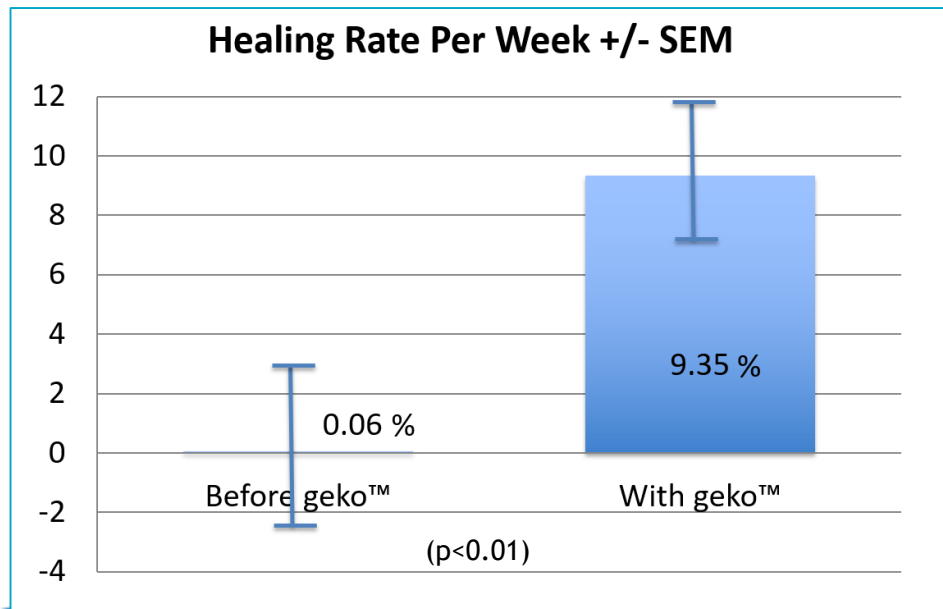
Connie Harris, Rochelle Duong, Gwen Vanderheyden, Beth Byrnes, Renee Cattryse, Ava Orr, David Keast

First published: 2 August 2017 Full publication history

DOI: 10.1111/iwj.12784 View/save citation

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published before inclusion  
in an issue



Great results!!!!

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

# LTC Evaluation - Revera 2016

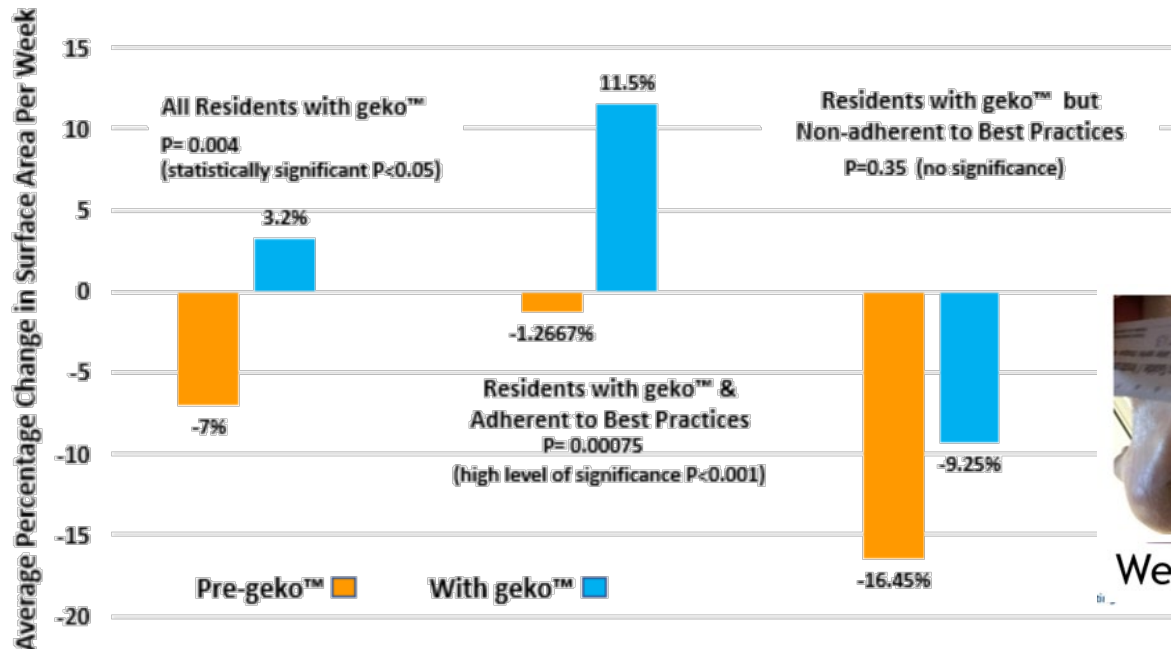


**Problem:** 9 residents Non-healing VLU, DFU and pressure injuries in LTC setting

**Challenges:**

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

**Successes:**



Week 8 Rt. closed    Week 12 closed



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Great results!!!!

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

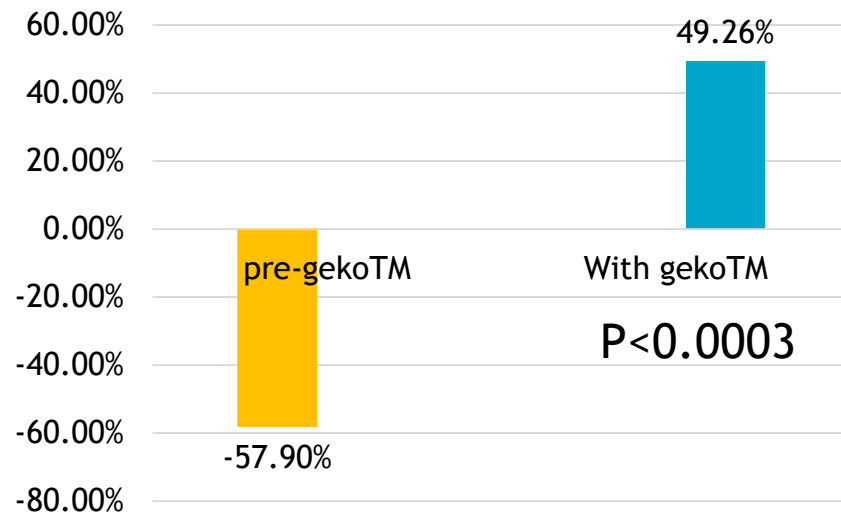


# Community Evaluations - WW CCAC 2016 - 2017

**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:**



# Estimated Cost Savings

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



# Progression from low level to high level evidence

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- 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).

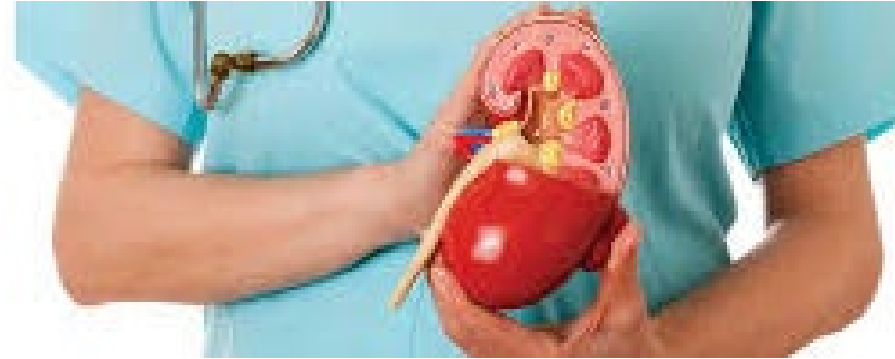
# Randomised Controlled Trial LHSC 2016-2017



London Health Sciences Centre

*Caring for You. Innovating for the World.®*

## 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)
- Edema thigh  $p < 0.001$  (no change in measurement with geko™ vs. 6 % increase)
- 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

# The journey continues.....

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# Response to audit: New Evaluation MH LHIN 2018 - 2019

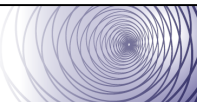


## Plan:

- 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

# 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.
- 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 (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, *Catalyst Towards an Ontario Health Innovation Strategy*, the council recommended the following:

- actions to support strategic, value-based procurement;
- 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 application is wound care. Annually Canada spends \$3.9 million (3 percent of total public health care expenditures) on wounds. In home care, 50 percent of nursing visits involve wound care and approximately 35 percent of home care patients have a chronic wound (CIMA, 2012).

Chronic wounds impact patients and their families, who may experience pain, disability, depression, anxiety, hospitalization, financial burden and death (Graham et al., 2001). For the MH CCAC, the cost of managing wounds in the home is significant. In 2014/15, the MH CCAC spent at least \$260,000 managing the most challenging wounds: arterial leg ulcers (ALUs), venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs). This amount does not include medical supplies, rehabilitation and personal support worker services.

Thank you to our SPOTLIGHT ON INNOVATION sponsor Perfuse Medical Inc. The structured innovation, trial and commercial device increase sales revenue by two to five percent and microcirculatory flow by one percent. The geko™ device captures a muscle pump force per session to help wounds and reduces edema. It requires 100 percent of continuous walking.

For more information on the geko™ device and its application, visit [www.gekowound.ca](http://www.gekowound.ca)



## 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.

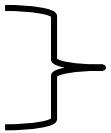


# Successes



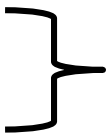
## Home and Community Care

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

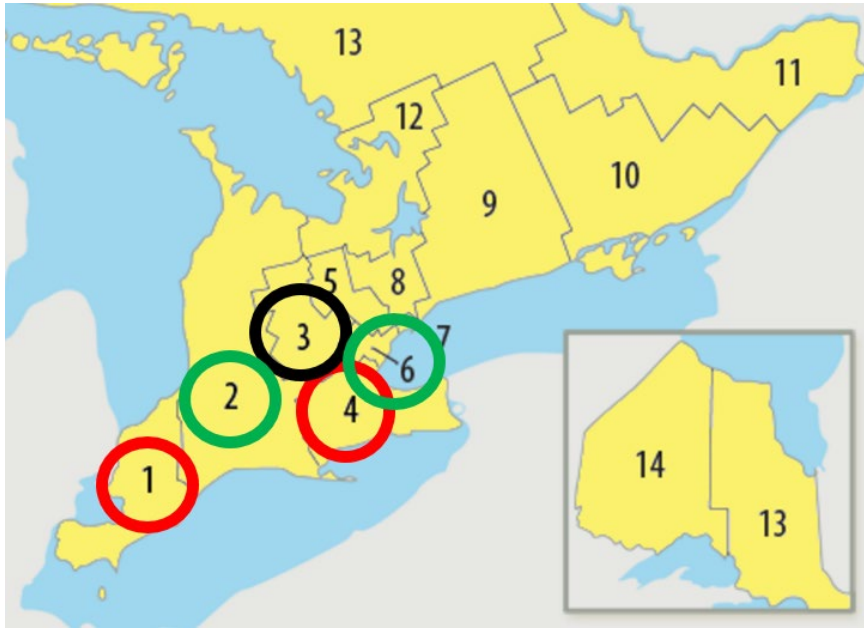


By Physician or ET Nurse

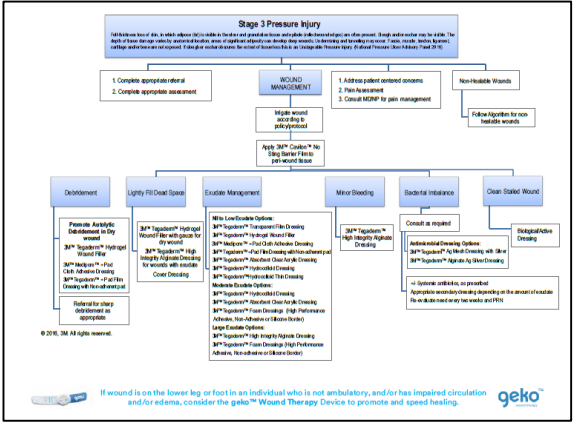
- 4. Hamilton Haldeman
- Niagara Brant
- 3. Waterloo Wellington



Pending



## Long Term Care





# Summary:

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## 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
- Development of on-line learning modules that recognize the challenges of traditional in-service training.

Contact us: [info@perfusemedtec.com](mailto:info@perfusemedtec.com)