

A LANCING DEVICE LIKE NO OTHER

Give fingers a break when checking blood sugar.

Genteel[®] helps to remove the obstacles for those with Type 1 or Type 2 diabetes, young or old, that prevent prescribed blood glucose testing.

Mission: Provide the most comfortable, pain-free, innovative lancing devices and lancets for the healthcare marketplace

Vision: Become the market leader for lancing devices and lancets used for the retrieval of blood used for monitoring, calibration and testing

www.mygenteel.com.au

PAIN FREE

Eliminates severe puncture marks, swelling, bruising and numbness

CHECK MORE OFTEN

Removes the obstacles of pain and trauma so people can start checking blood sugar levels as doctors prescribe

STOP SQUEEZING

With its vacuum, Genteel[®] brings blood to the surface and forms the perfect drop. Re-poking and squeezing is a thing of the past

TEST ANYWHERE

Gives fingers a break using vacuum and depth control. Palms match fingers!



Dr. Jacobs and Genteel®

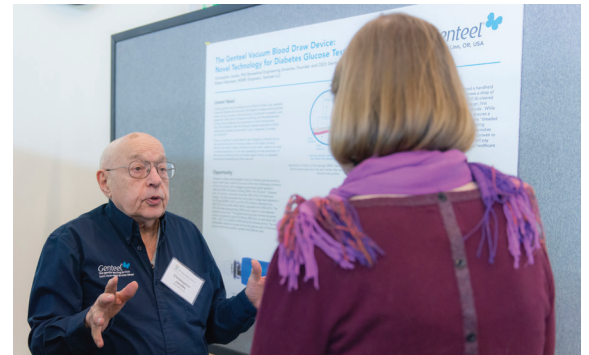
I've been a biomedical engineer for 40 years, holding patents on the variable rate cardiac pacemaker, heart-lung machine, and many medical devices still in use today in hospitals around the world.

It began with the journey of one man, ten years ago, who changed my life, and became the "everyman" to all those who suffer from this potentially debilitating, deadly disease.

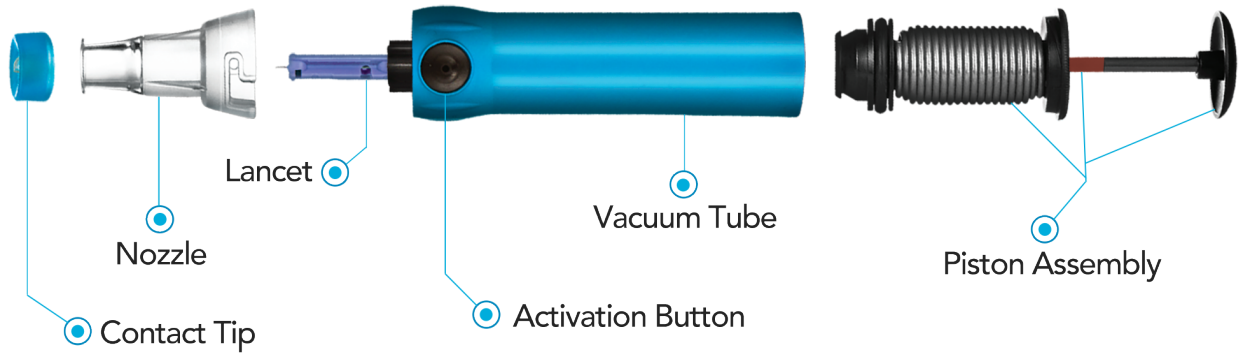
In early 2006, a friend, with Type 2 diabetes, called to say he was at his "wit's end" with the pain of lancing his fingertips, and begged me to help. "I'm just not testing," he said, "even though I know the consequences. There has to be something you can do!" I was moved by his distress, compelled by our friendship, and undone by the irresistible siren song that lies at the heart of every engineering challenge. The gauntlet was thrown, and I made a promise that was to consume me for the next ten years of my life, analyzing the interconnection between blood capillaries and pain nerves, limitations of current devices, and existing technologies that could bring painless lancing to reality.

I kept refining my initial editions of the device, until Genteel® evolved into the precision instrument it is today, with the ability to optimize blood draw with no discomfort. This technology holds 8 US patents, and over 22 international patents, both issued and pending. Genteel® LLC is now a reality, and my friend, who started the ball rolling 10 years ago, could not have envisioned that his private pain would lead to a life changing product that benefit countless others who walked in his footsteps every day.

Dr. Jacobs presenting Genteel® at Oregon Health and Science University, Portland

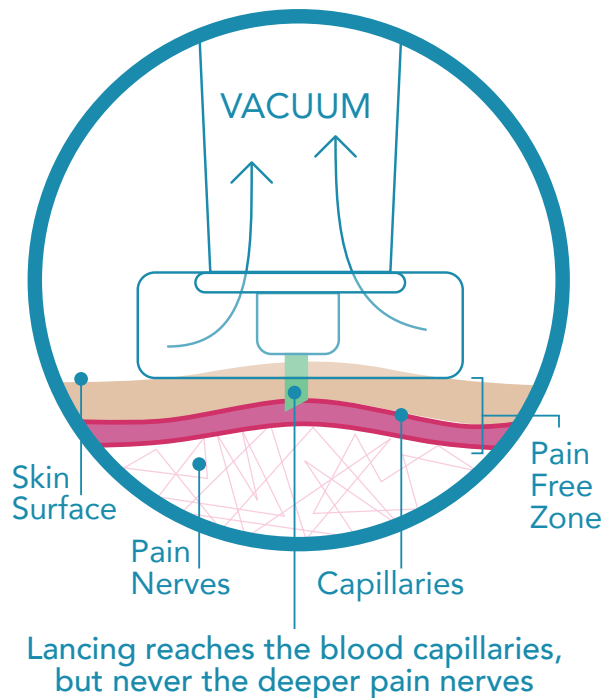


Genteel® Exhibiting at Children with Diabetes, Friends for Life Conference Anaheim, CA



Product Information

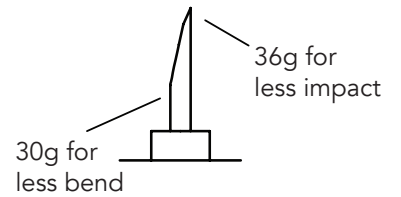
Contact Tips	<ul style="list-style-type: none">• provides precise and customizable lancing depth• adjustable lancing depths for different parts of the body
Vacuum	<ul style="list-style-type: none">• removes the need for re-pokes or squeezing, allows fingers to heal• vacuum makes getting blood from any body location convenient and easy
Activation Button	<ul style="list-style-type: none">• allows the user to keep vacuum activated as long as needed, bringing more blood to the surface
Lancets	<ul style="list-style-type: none">• for use with Butterfly Touch Lancets



Why Butterfly Touch Lancets Are So Different

Traditional lancet designs face a conflicting objective in gauge or needle size used to puncture the skin. With a fine or very high gauge, the advantage is a less invasive puncture, but is offset by greater needle vibration, which can cause more pain. With a larger gauge, to combat vibration, puncture size becomes more invasive, again causing pain.

Genteel®'s Butterfly Touch Lancets use "Variable Gauge" technology to combat this issue. Its large diameter base (30 gauge) maintains rigidity and eliminates vibration, then tapers to an extremely fine tip (36 gauge) to provide the least invasive puncture possible. Using Butterfly Touch Lancets in conjunction with the Genteel® device can eliminate the discomfort of traditional lancets and lancing devices.



Product Information

Gauge	<ul style="list-style-type: none"> • 30g base to 36g tip • variable gauge helps reduce pain while those with thicker skin still get enough blood.
Needle	<ul style="list-style-type: none"> • tri-bevel needle tip minimizes discomfort
Compatibility	<ul style="list-style-type: none"> • best used with Genteel® • works with most lancing devices • square shaft base





Endorsements



Albert Einstein College of Medicine

Richard Bernstein MD., Director Emeritus, Peripheral Vascular Disease Clinic, Albert Einstein College of Medicine, Bronx Municipal Hospital Center

"As a pioneer of and leading advocate for frequent blood sugar testing, I have been aware of, use, and now refer patients to your Genteel[®] Lancing Device. This is because I know firsthand how the device can reduce pain during lancing, with the additional benefit of using both alternate sites, when appropriate, as well as fingertips to measure blood sugar. In my experience, both as an individual with diabetes and a practicing clinician, I can speak to the discouraging effects lancing pain has on testing frequency. Now, with that pain eliminated, my patients are more encouraged to increase their checks, helping to maintain better control of their blood sugar. As such, I am an advocate of any device, such as Genteel[®], that can alleviate pain and discomfort, especially if such a device is easy to use and affordable."



OHSU

Andrew Ahmann, MD., Professor of Medicine, Diabetes and Clinical Nutrition School of Medicine, Oregon Health and Science University

"Blood sugar checking is performed millions of times a day by children and adults, so the long-term benefit of your invention is tremendous. After personally using your device, as well as from feedback from my patients and staff, I firmly believe that because Genteel[®] is able to consistently reduce lancing discomfort, frequency and compliance will improve."



University Health System
Texas Diabetes Institute

Jennifer Wimpee RD, LD, CDE., Registered Dietitian and Certified Diabetes Educator, Endocrinology/Pediatric Specialty Services, Texas Diabetes Institute

"I love the Genteel[®] lancet device! I have shown it to several of my patients. I see relief on the faces of my patients and the parents when they see that they can use other sites for testing. I also have had our physicians prick alternate sites with the device and they are amazed at how little it hurts and sometimes they don't feel it at ALL! I'm excited for my pediatric patients, from 9 months to 18 years, to have less painful blood sugar checks."



KAISER PERMANENTE[®]

Lori L Piana RN, BS, CDE CMT Insulin Specialist Kaiser Permanente Nursing Department of Population Health

"Genteel[®]'s technology, which allows painless blood draws, is not only of extreme benefit to my patients, but would be extremely useful to us here in the Kaiser Permanente Clinic, as we do approximately 20 finger sticks a week."



Nina Jain, MD., Medical Director of Pediatric Diabetes Program at UNC Co-director of the Pediatric and Adolescent Clinic for Genter Wellness

"We are very interested in demonstrating Genteel[®]'s technology to as many additional patients as possible to help them overcome barriers to monitor their blood sugar as often as necessary."

Customer Tips



Common User Mistakes	Possible Solutions
Not Enough Blood or No Blood Appearing As A Drop On Skin	<ul style="list-style-type: none"> • hold finger on Activation Button longer • remove finger from Activation Button, then lift Genteel off the skin (<i>not before, or at the same time</i>) • use a more aggressive contact tip, repeat above.
Blood In Nozzle	<ul style="list-style-type: none"> • remove finger from Activation Button before lifting Genteel off the skin.
It Hurts	<ul style="list-style-type: none"> • use a less aggressive contact tip or change body site • don't push the device too hard into the skin, use just enough pressure to create a seal gently on the skin surface
Alternate Site Accuracy	<ul style="list-style-type: none"> • palm readings are within meter accuracy of fingers • use alternate sites only if your blood sugar is in steady state, and not after doing an activity that will cause you blood sugar to change rapidly.

Genteel[®]'s Contact Tips

Genteel[®] comes with 6 Contact Tips which determine the level of lancet penetration. From shallowest, Blue, to deepest violet



Accreditations



FDA
FDA 510(k)
clearance on
May 12, 2016

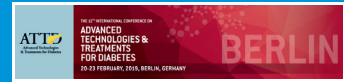
CE
CE marking
acquired
July 17, 2016

8
United States
Patents

22
International
Patents



ASSESSING THE BENEFITS OF A PAINLESS LANCING DEVICE IN A SUBSET OF PATIENTS FEARFUL OF FINGER PRICKING



R. WARRIER ¹, S. BADARUDEEN ², A. SHANKAR ¹, G. KRISHNAN ¹, L. RAMACHANDRAN ¹, K. THAMPIRAJ ¹, S. JOTHYDEV ¹, J. KESAVADEV ¹

1. JOTHYDEV'S DIABETES & RESEARCH CENTRE

Trivandrum, Kerala, India

www.jothydev.net, www.research.jothydev.com,
jothydev@gmail.com

2. MED CENTRE HEALTH ORTHOPAEDICS

& SPORTS MEDICINE,
LEXINGTON - KY, USA.

BACKGROUND & AIMS

- ▶ Self-monitoring of blood glucose (SMBG) has been recommended as the gold standard of glucose monitoring.
- ▶ There are a few patients including children and adults who are fearful of finger pricking, due to either real pain or needle phobia.
- ▶ Pricking the fingertips for glucose monitoring is in fact, more painful than the insulin shots, the latter being virtually painless with the new slender tiny needles.
- ▶ Genteel® is a novel vacuum-based lancing device that claims to be relatively painless by decreasing the depth of lancet penetration and thus decreasing the nociceptive stimuli while lancing.
- ▶ A randomized crossover trial was conducted over 6 months, comparing Genteel® versus conventional lancing device.

METHODS

- ▶ Study subjects: T1DM and T2DM patients on multiple daily insulin injections and fearful about finger pricking for glucose monitoring
- ▶ n=15, age 39.27±18.41y, 40% males, 52.33% T2DM

RESULTS

- ▶ Subjects reported significantly lower pain scores using Genteel® (p<0.0001), and also higher SMBG testing frequency (p=0.0002).
- ▶ The difference in pain scores with Genteel® was also significant when compared with the subject's initial perceived pain score prior to randomization (p<0.0001).
- ▶ Effect size 'r' was determined to be 0.660 (pain score) and 0.602 (SMBG frequency), suggestive of a large effect size difference between the 2 groups.

Parameters Assessed	Genteel Lancing Device	Conventional Lancing Device	p value	Effect size r
Painscore*	5.00±0.00	1.78±0.43	<0.0001	0.660
SMBG testing frequency**	0.66±0.23	0.28±0.16	0.0002	0.602

* To the question 'is pain a limiting factor for regular SMBG monitoring', subjects graded from 1 to 5 (1=very painful and a very strong limiting factor for performing SMBG; 5=not at all a limiting factor) ** [SMBG frequency (Genteel vs. Conventional)]/Total number of SMBG performed

CONCLUSIONS

- ▶ Our results demonstrate the utility of Genteel as a relatively painless lancing device for all ages with fear of pricking and could be a good alternative to the traditional ones.
- ▶ Structured SMBG will invariably improve the glycemic control and long-term outcomes.

REFERENCES

- ▶ Heinemann L. Finger pricking and pain: a never ending story. *Journal of Diabetes Science and Technology*. 2008;2(5):919-21.
- ▶ Shlomowitz A, Feher MD. Anxiety associated with self monitoring of capillary blood glucose. *British Journal of Diabetes*. 2014;14(2):60-3.