



# Drug-Free Pain Relief with Nanotechnology

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## Introduction

This white paper will cover health statistics of chronic pain in the United States and the approach Signal Relief employs to reduce pain. It will discuss the novel product in the Signal Relief portfolio, the Signal Relief Patch, designed to greatly improve comfort in those experiencing pain.

## Chronic Musculoskeletal Pain

In 2019, the National Center of Health Statistics reported that 20.4% of adults in the United States have chronic pain and 7.4% have high impact chronic pain (pain that limits life or work activities).<sup>1</sup> Data from the National Health Interview Survey showed that chronic pain is higher in women, persons over the age of 65, and non-Hispanic white adults. The prevalence of chronic pain also increases with age and as the place of residence becomes more rural.<sup>1</sup> While the underlying cause of chronic pain can vary (e.g., inflammation, underlying disease or condition, injury, medical treatment, etc.), it is associated with a decrease in quality of life and depressive and anxiety disorders.<sup>2,3</sup>

First-line therapy for chronic pain includes the use of over-the-counter analgesics such as acetaminophen and ibuprofen or COX-2 inhibitors such as celecoxib. When these treatments are ineffective in managing pain, opioids have dominated the treatment paradigm. After the publication of two small studies in the early 1980s demonstrating that opioids were not addictive, opioids became a welcome relief for the management of chronic pain. Unfortunately, this misinformation led to the long-term use of opioids that laid the foundation of our current opioid crisis.<sup>4</sup> In a recent survey, 22.1% of adults with chronic pain reported using opioids over the past three months.<sup>5</sup> Since 1991 the number of drug overdose deaths has quadrupled, and 70% of the 70,630 deaths in 2019 involved an opioid.<sup>6</sup> It is estimated that 4-6 percent of those who misuse opioids transition to heroin<sup>7-9</sup> and approximately 80% of people who use heroin first misused opioids.<sup>7</sup> The Center for Disease Control (CDC) has initiated an extensive program to help curb the crisis through public education, state funding, and information tracking strategies.<sup>10</sup> The National Institute of Health started the Helping to End Addiction Long-term

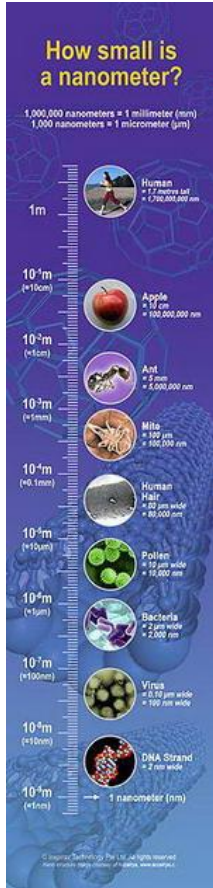


Figure 1. Nano Scale

(HEAL) initiative to provide funding to researchers addressing questions around addiction and to support the development of alternative non-opioid therapies for pain management.<sup>11</sup>

Therefore, there is an urgent need for safe and effective non-opioid options for pain management. Nanotechnology and nanomaterials have the potential to offer non-pharmacologic therapy for these patients without the adverse effects associated with systemic use. Lately, substantial research has been conducted investigating the production, toxicology, and potential medical applications of nanotechnologies. Many studies have found various nanotechnologies to be a promising option in the treatment of pain.<sup>12-15</sup>

### Nanotechnology: Nano-Capacitors

Nanotechnology utilizes materials at a nanometer scale. For perspective, the nanoscale is one thousand times smaller than the microscopic scale and one billion times smaller than the world of meters that we live in (Figure 1). A capacitor is a device that stores electrical energy in an electric field. It is a passive electronic component with two terminals that are close together but do not touch with non-conductive/dielectric material in between (Figure 2). Unlike standard capacitors with only two conductive plates, the Signal Pain Patch uses arrays of billions of nano-capacitors embedded in a dielectric binder material to create a thin, flexible

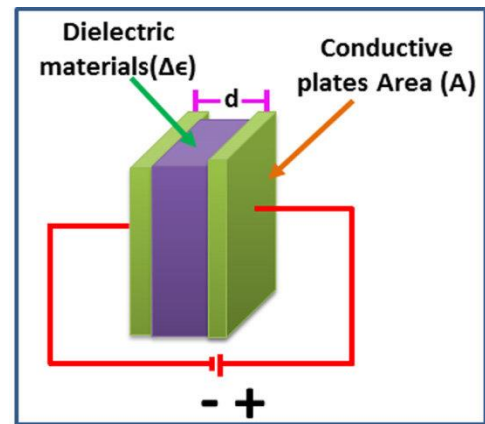


Figure 2. Capacitor

patch (Figure 4 and Figure 3).

### How Signal Pain Patch Uses Nano-Capacitor Technology

These arrays interact with the tiny electrical signals from the body's nervous system that are generated when the body is in pain. The energy from these pain signals is collected by the patch via a process called Neuro Capacitive Coupling. Capacitive coupling is the transfer of energy within an electrical network or between distant networks by means of displacement current between circuit(s) nodes, induced by the electric field. Displacement current density has the same units as electric current density, and it is a source of the magnetic field just as actual current is. However, it is not an electric current of moving charges, but a time-varying electric field (Figure 5). Nano-capacitors in the Signal

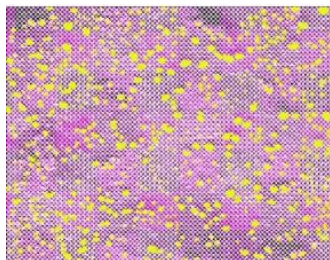


Figure 4. Nano-Capacitor Array

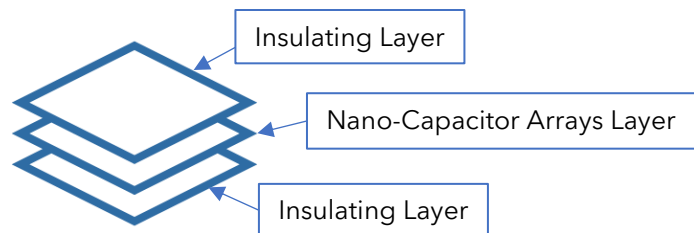


Figure 3. Signal Pain Patch Construction

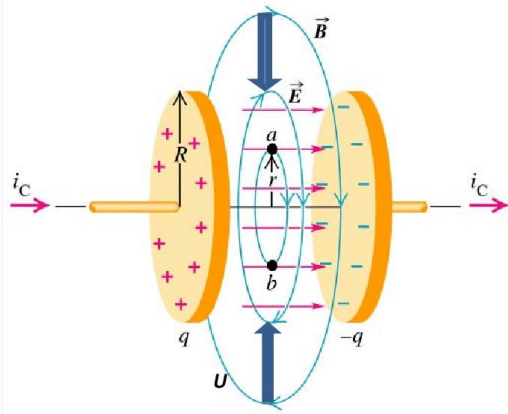


Figure 5. Displacement Current

Relief Patch exploit the body's natural electromagnetic field by emitting and absorbing electromagnetic energy. Thereby, the intensity of the pain signals reaching the brain is reduced, effectively relieving the pain.

This is not the first time that manipulation of neural electrical activity has been used to treat pain. TENS (Transcutaneous electrical nerve stimulation) is an FDA-approved treatment that works by blasting the nervous system with a static sensory white noise which is used to drown out the pain message or distract the brain from sensing pain.<sup>16</sup> The nano-capacitors function in a seemingly opposite direction. These nano-capacitors allow the absorption of energy which results in a decrease in pain messaging to the brain, resulting in attenuation of pain sensation.<sup>17</sup>

## Development History

Nano-capacitors utilized within the Signal Relief Patch were originally developed to replace military antenna systems with no additional power supply. Since development, it was incidentally found that these nano-capacitors may help control pain by working with the body's electrical system. The idea came to the developer of the antenna systems when he was severely injured in a motorcycle accident. Not wanting to take opioids for months he decided to try a prototype based on the antenna system to see if it could disrupt the pain signal and accelerate his recovery. Within 3 weeks and having taken only 2 of the 600 opioids prescribed he was pain-free and back to normal activity. The currently produced patch, in figure 6, below has undergone safety testing with SGS and passed all categories and is manufactured by an ISO compliant FDA registered manufacturer.



Figure 6. Signal Relief Patch

## Clinical Evidence

A clinical study is currently underway evaluating the efficacy of the Signal Relief Patch in patients suffering from osteoarthritis. Additional trials are being designed to gain important clinical evidence to support the performance characteristics of the Signal Relief Patch in general musculoskeletal pain. A pilot study with similar nano-capacitor arrays tested in human subjects showed promising results with a

decrease in mean **Brief Pain Inventory** scores by 71%.<sup>18</sup> 27% of participants reported that their pain did not return after patch removal and 55% reported that it took longer than one day for their pain to return after patch removal. In addition, no adverse events were reported with patch use. Of the 66 patients that participated in the trial, only one reported no pain relief with patch use.

## Conclusion

The Signal Relief Patch has the potential to offer patients and providers a safe and effective alternative to systemic pharmacologic therapies. The urgent need for non-opioid pain treatment compels further investigation into the role that nano-capacitors can play in the alleviation of pain. As our treatment paradigms evolve with time, nanotechnologies will likely diffuse across medical disciplines offering solutions to the many barriers to ideal therapy. Further research is required to fully illuminate the solutions that nanotechnologies can offer in the pain management treatment paradigm.

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