

**Document # 03-1223** 

**Product Launch: Gladiator MD™ Product Line** 

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# Help Your Patients... Accelerate Their Healing and Recovery

Gladiator Therapeutics patented SemiCera® technology delivers clinical strength FIR therapy, resulting in active healing at the cellular level.



# **Gladiator MD Product Line**



**Shoulder Device** 



**Knee Device** 



**Wrist Device** 



**Ankle/Elbow Device** 



**Abdomen/Back Device** 



**Mini Device** 

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# **EXECUTIVE SUMMARY**

Gladiator Equine is an innovator in Far Infrared technology. With unique patents on composition and design, their ceramics deliver a clinical strength therapy that has been proven in independent peer reviewed studies to accelerate the healing process. Use of this technology will allow patients to recover quicker and stay healthier.

## **Technology**



### Patented SemiCera® Ceramic Emitters

These powerful ceramic emitters are made from rare minerals and metal oxides.

Due to their design and composition, they are able to produce clinically significant far infrared therapy.

They are non-powered and do not require an electrical outlet or battery. They simply use the horse's ambient body heat to activate them.

### **Gladiator Therapeutics Stimulates the Healing Process**

### <u>Introduction</u>

The exchange of information within the human cell is extremely complex, as well as the signaling processes throughout the physical body (intracellular and intercellular).

All molecules vibrate. Science has shown the frequencies created by these vibrations in our bodies are in the infrared range at the temperature of life.

Gladiator technology emits infrared in that specific range to activate the signaling within each individual cell as well as activating the microtubules (pathways) that allow cells in various parts of the body to communicate freely.

In doing so, our technology increases the efficiency of all biological processes due to the proper molecular vibration from the specific Far Infrared being emitted.

## Wound Healing

Gladiator technology activates and boosts the body's healing processes, for accelerated healing that has been clinically proven to be *68% faster than healing without technological interventions*.

How it Works...

Body heat activates the patented ceramic, which emits photons that travel throughout the body of the horse, producing a vibrational energy that initiates cellular respiration and stimulates stem cells.

During cellular respiration, the animal's cellular energy source receives signals when energy is required for development, healing, and regeneration. A biological reaction occurs breaking down the energy source so it can be released and used by the cells to perform the biological process of healing.

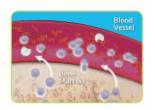
It also promotes wound healing and faster surgical recovery from accelerated hyperacute fibronectin response.

This response actively signals the horse's body to send stem cells from surrounding healthy tissue and bone marrow.

Subsequently, a scaffolding of microtubules is formed across the wound bed creating highways for cells to migrate and aggregate, creating buds to begin filling in the wound bed.

Finally, capillary sprouts produce a microvascular network supporting the development of granulation tissue to complete the healing process.

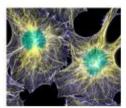
The healing process is illustrated below:



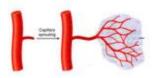
 Adjacent uninjured tissue and stem cells originating in the bone marrow circulate to the injury site.



 Scaffolding consisting of new collagen fibres, proteoglycans and elastin fibres are formed facilitating cell migration.



 Cells adhere to each other or to the scaffolding structure and aggregate to fill in the injured site.



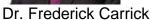
 Capillary sprouts form a microvascular network in the granulation tissue to produce a scar.

# **Technology Elevator Pitch**

Due to its unique composition and design, Gladiator is the only company with a Far Infrared Device that provides deep tissue therapy for treating chronic conditions with extended use without risk of tissue damage. This device is made of patented mineral-based ceramics that continually emit infrared light. Far infrared in the body creates cellular signaling to accelerate the healing process. It has documented therapeutic benefits to regenerate muscles and nerves, repair bone, revascularize tissue, and produce collagen and cartilage. Its energy is self-sustaining so it can be used anywhere at any time. As opposed to other technologies to treat aches and pains, or for faster recovery, the Gladiator has few contraindications and is pain free.

### Clinical Evidence







Dr. Kiminobu Sugaya

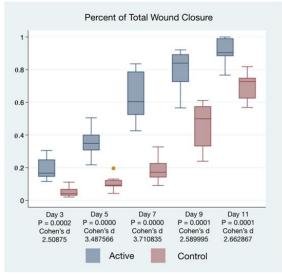
Leading researchers at the University of Central Florida conducted independent studies on wound healing using Gladiator technology.

Results were published in peer reviewed medical journal in August 2021:

Life, Cell Biology & Tissue Engineering
 Poster presentation accepted for Military Health System Research Symposium (MHSRS),
 Orlando FL 2021

## Key Findings:

- Gladiator technology initiated cell signaling earlier than normal biological processes
- Sped up the development of the cellular matrix, aggregation of cells and formation of capillaries, thus accelerating the healing process
- Wounds healed 68% faster compared to no technology intervention



A. H&E Stain Analysis Region

Control

Active

(see Appendix for study abstract)

# **PRODUCT OVERVIEW- Gladiator MD Shoulder Device**

# **Application**

The Gladiator MD Shoulder Device is a therapeutic device with SemiCera technology which has been proven beneficial for:

- Healing soft tissue injuries such as sprains and strains
- Surgical recovery after arthroscopy, rotator cuff or other shoulder surgery
- Inflammation and pain reduction for more productive rehabilitation

# **Key Features & Benefits**

Feature	Benefit
High powered SemiCera ceramics	-Stimulates healing and angiogenesis at the cellular level
	- Assists in healing minor tears of soft tissue and cartilage, potentially eliminating the need for surgery
	-Provides an active healing solution complementary to other treatment protocols
	-Reduces need for pain medication, or injections
	-Increases blood flow to tissue for optimal perfusion before and after surgery
	-Allows for more productive physical rehabilitation due to less inflammation
Non-powered technology	-Requires no electrical outlet or power supply so it can be used anytime, anywhere
	-Scientifically proven to be safe, even with unlimited use as the device does not create heat or damage tissue
Medical grade textiles	Material is safe to come in contact with skin without risk of irritation
Breathable & washable device	Reduces risk of contamination and infection
Adjustable Velcro closure	Accommodates variation in patient size and keeps the device securely in place

### Instructions for Use

- 1. Attach longer torso strap on one end of the device with clip attachment.
- 2. Position the device over the shoulder with Gladiator logo facing up on the shoulder.
- 3. Grasp the torso strap and wrap around your body, fasten clip on opposite end.
- 4. Grasp smaller arm strap and wrap around forearm.
- 5. Faster Velcro on other side.
- 6. Ensure the device stays in place but is not tight as to restrict circulation.
- 7. The device can be utilized for as long as the user can support it for comfort and daily living activities.

### Note:

A thin layer of clothing may be worn over the treatment area. It is safe to utilize 24 hours a day.

## **Product Specifications**

Model # 1150

Size: 15.5" x 7.5" x 2.25"

### Materials:

Breathable Medical Grade Textiles Rare Earth Minerals & Metal Oxides Silicone rubber

Latex Free Made in USA

# PRODUCT OVERVIEW- Gladiator MD Knee Device

# **Application**

The Gladiator MD Knee Device is a therapeutic device with SemiCera technology which has been proven beneficial for:

- Healing soft tissue injuries such as sprains and strains
- Surgical recovery after arthroscopy, ACL or other knee surgery
- Inflammation and pain reduction for more productive rehabilitation

# **Key Features & Benefits**

Feature	Benefit
High powered SemiCera ceramics	-Stimulates healing and angiogenesis <sup>1</sup> at the cellular level
	- Assists in healing minor tears of soft tissue and cartilage, potentially eliminating the need for surgery
	-Provides an active healing solution complementary to other treatment protocols

	-Reduces need for pain medication, or injections
	-Increases blood flow to tissue for optimal perfusion before and after surgery
	-Allows for more productive physical rehabilitation due to less inflammation
Non-powered technology	-Requires no electrical outlet or power supply so it can be used anytime, anywhere
	-Scientifically proven to be safe, even with unlimited use as the device does not create heat or damage tissue
Medical grade textiles	Material is safe to come in contact with skin without risk of irritation
Breathable & washable device	Reduces risk of contamination and infection
Adjustable Velcro closure	Accommodates variation in patient size and keeps the device securely in place

### **Instructions for Use**

- 1. Slide the device over the knee with the wider opening at the top of the leg.
- 2. Opening should fit comfortably over the knee cap.
- 3. Fasten the Velcro straps so that the device stays in place but is not tight as to restrict circulation.
- 4. The device can be utilized for as long as the user can support it for comfort and daily living activities.

### Note:

A thin layer of clothing may be worn over the treatment area. It is safe to utilize 24 hours a day.

## **Product Specifications**

Model # 1250

Size: 13.6"x 8.8" x 1.5"

### Materials:

Breathable Medical Grade Textiles Rare Earth Minerals & Metal Oxides Silicone rubber

Latex Free Made in USA

<sup>\*</sup>See package insert for more use instructions.

# **PRODUCT OVERVIEW- Gladiator MD Wrist Device**

## **Application**

The Gladiator MD Wrist Device with SemiCera technology is a therapeutic device which has been proven beneficial for:

- Carpal tunnel syndrome
- Pre & post operative treatment
- Sprains & strains

## **Key Features & Benefits**

Feature	Benefit
High powered SemiCera ceramics	- Increases blood flow to wrist relieving symptoms of nerve compression
	-Alleviates numbness, tingling, and pain
	-Improves dexterity
	-Reduces need for pain medication, or injections, or surgery
	-Allows person to quickly resume normal work and daily activities
Non-powered technology	-Requires no electrical outlet or power supply so it can be used anytime, anywhere
	-Scientifically proven to be safe, even with unlimited use as the device does not create heat or damage tissue
Medical grade textiles	Material is safe to come in contact with skin without risk of irritation
Breathable & washable device	Reduces risk of contamination and infection
Adjustable Velcro closure	Accommodates variation in patient size and keeps the device securely in place

### **Instructions for Use**

- 1. Slide the device over the hand.
- 3. Position one securing strap above the wrist and the other between the thumb and pointer finger.
- 4. Fasten the Velcro straps so that the device stays in place but is not tight as to restrict circulation.
- 5. The device can be utilized for as long as the user can support it for comfort and daily living activities.

### Note:

A thin layer of clothing may be worn over the treatment area. It is safe to utilize 24 hours a day.

## **Product Specifications**

Model # 1200

Size: 6" x 3.75" x 2"

### Materials:

Breathable Medical Grade Textiles Rare Earth Minerals & Metal Oxides Silicone rubber

Latex Free Made in USA

# PRODUCT OVERVIEW- Gladiator MD Ankle/Elbow Device

## **Application**

The Gladiator MD Ankle/Elbow Device, with SemiCera technology, is designed to be worn on the ankle to treat the foot area or elbow. It is ideal for elbow injuries or the feet where circulation and healing are compromised such as with the following:

- Diabetic foot ulcers/Blisters
- Venous stasis ulcers
- Surgical wounds
- Pressure injuries
- Neuropathy

Secondarily, it can be used to reduce inflammation and pain to treat the elbow for pre- or postoperative procedures, and soft tissue injuries.

### **Key Features & Benefits**

Feature	Benefit
High powered SemiCera ceramics	-Reduces need for pain medication or injections
	-Increases circulation and reduces inflammation where blood flow is compromised.
	-Relieves pain and stiffness.
	-Offers alternative option to manage symptoms before surgical intervention is considered.
Non-powered technology	-Requires no electrical outlet or power supply so it can be used anytime, anywhere

	-Scientifically proven to be safe, even with unlimited use as the device does not create heat or damage tissue
Medical grade textiles	Material is safe to come in contact with skin without risk of irritation
Breathable & washable device	Reduces risk of contamination and infection
Adjustable Velcro closure	Accommodates variation in patient size and keeps the device securely in place

### **Instructions for Use**

- 1. Position the device over the treatment site with the flat side of the device closest to the body. Secure with Velcro straps.
- 2. Ensure the device stays in place but is not tight as to restrict circulation.
- 3. If experiencing sensitivity, move the device adjacent to the treatment area.
- 4. The device can be utilized on the treatment area for as long as the user can support it for comfort and daily living activities.

### Note:

A thin layer of clothing may be worn over the treatment area. It is safe to utilize 24 hours a day.

## **Product Specifications**

Model # 1225

Size: 6.5" x 3.5" x 1"

### Materials:

Breathable Medical Grade Textiles Rare Earth Minerals & Metal Oxides

Silicone rubber

Latex Free Made in USA

# PRODUCT OVERVIEW- Gladiator MD Abdomen/Back Device

### Application

The Gladiator MD Abdomen/Back Device with SemiCera technology is a therapeutic device which has been proven beneficial for systemic wellness, healing soft tissue injuries, and surgical recovery. Worn on the abdomen or back, it is particularly well suited for the following:

- Cellular regeneration for systemic recovery
- Wound healing
- Back pain
- Gastrointestinal conditions

### **Key Features & Benefits**

Feature	Benefit
High powered SemiCera ceramics	-Relieves muscle pain and stiffness, lessening the need for pain medication
	-Improves muscular relaxation
	-Reduces inflammatory toxins
	-Increases blood flow to tissue and organs in the torso for better systemic wellness
	-Lowers risk of injury before and after movement
Non-powered technology	-Requires no electrical outlet or power supply so it can be used anytime, anywhere
	-Scientifically proven to be safe, even with unlimited use as the device does not create heat or damage tissue
Medical grade textiles	Material is safe to come in contact with skin without risk of irritation
Breathable & washable device	Reduces risk of contamination and infection
Adjustable Velcro closure	Accommodates variation in patient size and keeps the device securely in place

### Instructions for Use

- 1. Wrap the device around the abdomen by attaching the strap with clip at the opposite end.
- 2. Leave in this position to treat the body systemically or to treat the abdominal area.
- 3. Rotate the device to treat the back area.
- 4. Fasten and adjust the so that the device stays in place but is not tight as to restrict circulation.
- 5. The device can be utilized for as long as the user can support it for comfort and daily living activities.

#### Note:

A thin layer of clothing may be worn over the treatment area. It is safe to utilize 24 hours a day.

## **Product Specifications**

Model # 1100

Size: 23.8"x 8.8"x 1"

### Materials:

Breathable Medical Grade Textiles Rare Earth Minerals & Metal Oxides Silicone rubber

Latex Free

# **PRODUCT OVERVIEW- Gladiator MD Mini Device**

## **Application**

The Gladiator MD Mini Device is a therapeutic device which has all of the benefits of other devices with SemiCera technology. It is designed for flexibility as it can be used anywhere on the body. Some common applications for its use are:

- Pre-operative treatment
- Post-operative treatment
- Sprains and strains
- Pain reduction

## **Key Features & Benefits**

Feature	Benefit
High powered SemiCera ceramics	-Relieves muscle pain and stiffness, lessening the need for pain medication
	-Improves muscular relaxation
	-Reduces inflammation
	-Lowers risk of injury before and after movement
Non-powered technology	-Requires no electrical outlet or power supply so it can be used anytime, anywhere
	-Scientifically proven to be safe, even with unlimited use as the device does not create heat or damage tissue
Medical grade textiles	Material is safe to come in contact with skin without risk of irritation
Breathable & washable device	Reduces risk of contamination and infection

### **Instructions for Use**

- 1. Place the Gladiator Mini over the treatment area on the body
- 2. If you plan to be up and around the mini should be secured with the enclosed strap
- 3. Fasten and adjust the strap so that the device stays in place but is not tight as to restrict circulation.

### Note:

A thin layer of clothing may be worn over the treatment area. It is safe to utilize 24 hours a day.

## **Product Specifications**

Model # 1050 Size: 12" x 9.5"

Materials:

Rare Earth Minerals & Metal Oxides

Silicone rubber

Latex Free Made in USA

# SALES OBJECTIVE & STRATEGY

### **Positioning Statement**

Gladiator MD with SemiCera ceramics have the only proven active healing technology to provide both protection and healing at the cellular level.

### Strategy

Offer patients an alternative or complementary therapy with proven science.

### **Elevator Pitch**

The Gladiator devices with patented SemiCera technology offer the most advanced therapy in the market. With proven efficacy to reduce inflammation and accelerate healing, our devices offer an advanced therapy that will last a lifetime.

## Competition

Gladiator has created a unique position in the market by being the only proven high efficacy FIR device with patented technology. The company continues to conduct clinical trials to validate the technology and discover new applications.

The landscape for competing technologies is as follows:

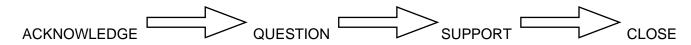
Product Type	Therapy Summary	Advantages
Gladiator SemiCera FIR ceramic technology	<ul> <li>Activates the body's own repair processes through cell signaling</li> <li>Reduces inflammation by stimulating lymphatic system</li> </ul>	<ul> <li>Efficacy proven with peer reviewed published studies</li> <li>Documented accelerated healing rate</li> <li>Non-powered and portable for use anytime anywhere.</li> </ul>
Competitive Product Type	Therapy Summary	Disadvantages

FIR, infused textile and powder products	<ul><li>Reduces inflammation</li><li>Increases circulation</li></ul>	Lack of efficacy and scientific proof
Electric stimulation	<ul><li>Electricity stimulates blood flow</li><li>Regenerates nerves</li></ul>	<ul> <li>May irritate or worsen wounds, infections, rashes, or burns</li> <li>Not appropriate for certain patient populations</li> </ul>
Cold laser	<ul> <li>Sends wavelengths of low-level light</li> <li>Reduces swelling and promotes healing of joints and soft tissue</li> </ul>	<ul> <li>Requires an office visit</li> <li>Limited treatment time to 20 minutes, 2-3 days per week</li> </ul>

The key selling points to remember when selling against competitive technology is the following:

- 1. Gladiator Therapeutics is the only company that has proven efficacy with reputable researchers and published results in peer reviewed journals.
- 2. The SemiCera ceramics have unique patents on design and composition. Others have a generic "ceramic powder" with questionable efficacy. Many competitors utilize third party FIR studies to infer that their products have similar results, however the studies are not utilizing their products.
- 3. Gladiator Clinical Strength Technology has the following benefits over the competition.
  - a. Faster healing which can result in other reduced medical costs
  - b. Reduces pain and discomfort from normal activity

## **Objection Handling**



Objection #1 "It costs too much"

Response:

Sales Rep	I understand that cost is a concern. What specifically are you comparing it to?
Customer	I have bought other healing technology devices for less.
Sales Rep	The Gladiator technology has been scientifically proven to be clinically effective to reduce inflammation and accelerate the healing process. Other devices utilize less effective ceramic powders or infused textiles. The Gladiator devices will stimulate the body's own cellular signaling processes to accelerate healing, reduce inflammation and repair tissue much faster.  Also, the ceramics will last for years and there are no parts to break or replace over time. This device may also reduce other expenses such as pain medication, or other interventions.

Objection #2 "All Infrared Product Claim to Accelerate Healing and Reduce Inflammation" Response:

Sales Rep	Yes, it is true that there are some similarities in statements made by other
	companies. How do you determine which products to buy?
Customer	I would look for any scientific evidence that each company could provide or see
	what products my peers have had success with.

### Sales Rep

Great, well let me start by telling you about the scientific evidence. Our technology has been studied by leading researchers in the medical industry and the findings have been published in four different peer reviewed journals. That means that the study protocols were found to be sound by other leading scientists and that the findings were unique and not seen elsewhere. Let me give you a copy of one of the leading studies that clearly shows advanced healing using our technology. If you are looking to provide the most advanced therapy on the market, Gladiator products can keep you healthy and active. There are numerous case studies and testimonials on the Gladiator website that illustrate success healing injuries. You can also visit the website at Gladiatortherpeutics.com.

# PRODUCT SUPPORT

## Warranty

All product is warrantied for 30 days for a same product exchange for manufacturers defects.

## **Cleaning Instructions**

The Gladiator device is designed to be patient dedicated. The device can be wiped down with an antimicrobial cleanser or disinfectant.

### **General Use Instructions**

### Contraindication

- Persons with Hemophilia should not use the device as it has not been thoroughly tested for this condition.
- Pregnant women should only use under the supervision of a physician.

### Use Recommendations

- Do not leave device underneath any body part where the nodules may create a pressure point.
- Device should not be used for a 48-hour period after surgery or if there is active bleeding from surgery or trauma.
- Use of silver impregnated dressings will reduce efficacy of the device.
- As treatment progresses there may be increased sensitivity of the treatment area. Adjust device above or below the treatment area until it is comfortable for use.
- Never place ice therapy on the device.
- Maintain proper hydration when using the device.
- Use of this device will not interact with any medication.

### FAQ's

### General FAQs

What research supports the effectiveness of this technology?

Dr. Carrick and Dr. Sugaya, respected researchers from the University of Central Florida College of Medicine (UCF COM) in Orlando, Florida, have conducted several independent studies demonstrating the technology's ability to accelerate wound healing. These studies revealed a significant 68% increase in the healing rate when compared to no intervention. Their findings were published in peer reviewed medical journal Life in 2021.

2. How does the technology use quantum physics and far-infrared technology to achieve these results?

Gladiator Equine products utilize a uniquely constructed, highly patented ceramic device to emit far-infrared into the horse's body. This causes vibration at the cellular level and thus increases cell signaling allowing the necessary regenerative and healing properties of the body to be optimized. The technology requires no external power source as it utilizes the body's natural heat to activate production of far-infrared.

3. How do Gladiator products work?

Gladiator products utilize non-powered far-infrared (FIR) technology to reduce soreness and inflammation. This technology is self-sufficient and non-invasive, requiring no external power source. When far-infrared rays penetrate the skin, they heat up the body's tissues, leading to beneficial effects such as improved blood flow, reduced inflammation, muscle relaxation, and faster wound healing.

4. Do Gladiator products generate heat?

No, Gladiator products do not produce heat as they are self-powered and autonomous.

5. What are the benefits of using Gladiator products?

<u>Pain Reduction:</u> Gladiator lightweight and portable devices can be applied to any part of the body, reducing pain effectively.

<u>Ceramic Technology:</u> All devices incorporate patented ceramic technology, ensuring their legitimacy and innovation.

Non-invasive & Non-toxic: These devices are non-invasive and do not require medication; simply place them on the affected area.

<u>Energy Source:</u> Gladiator devices are cordless and do not need batteries; they use the body in conjunction with ceramic technology for power.

<u>Improved Circulation & Reduced Inflammation:</u> These products enhance blood flow, reducing inflammation and associated pain.

Accelerated Healing: Speeds up muscle and soft tissue healing.

<u>Safety:</u> Gladiators' simple design and innovative technology make all their products safe, with no side effects and no risk of overexposure.

6. Are there specific conditions or injuries where this technology is particularly effective?

This technology is effective for all conditions involving inflammation, wound healing, and cellular recovery.

7. Are there any potential side effects or risks associated with the use of this technology?

There are no known side effects associated with this technology. Maintaining proper hydration during use is recommended. Gladiator Technology conducted extensive tests during the product development process to ensure its safety for both humans and animals.

8. How does this patented technology compare to existing methods or technologies in terms of effectiveness and cost?

Gladiator Therapeutics' devices offer a unique combination of protection and therapy. While many lower-priced products primarily serve as protective layers, Gladiator devices provide clinical-strength therapy that promotes cellular-level healing and recovery. They represent groundbreaking and innovative approaches to pain and inflammation associated with healing, utilizing non-powered FIR technology to activate cellular regeneration and accelerate healing, thus enhancing recovery, overall well-being, and complementing existing medical regimes.

9. Are there any legal or ethical considerations surrounding the use of this technology?

During the product development process, Gladiator Technology conducted extensive tests to ensure the product is safe for both humans and animals, prioritizing the principle of "doing no harm."

10. Does the product ever get hot/cold in extreme heat or cold conditions?

The product may become too hot to touch in extreme heat, so it should be allowed to cool down before use. Do not use on a horse if it has been left out all day in extremely hot weather.

11. How can you tell when it is working?

Therapeutic devices typically begin working within 5-10 minutes of application. Horses usually do not feel the device working, except in rare instances when healing causes nerve sensations. In such cases, slight adjustments to the device near the treatment area can resolve any sensitivity. The effectiveness of Gladiator products can be observed through reduced soreness and inflammation, faster wound healing, and overall improvements in well-being.

12. Are Gladiator products easy to use?

Yes, Gladiator products are autonomous and non-invasive, requiring no external power source, making them suitable for use in any environment around the world.

13. Could it ever be worn too long?

There are no time limits for wearing the devices, as they do not generate heat or damage tissues. The longer they are worn, the faster healing occurs for wound applications.

14. Do the ceramics ever wear out?

The ceramics do not wear out and will last a lifetime. With proper maintenance and care, your Gladiator Equine products will continue to provide healing benefits for years.

15. Is there anything that should not be placed near the device that could deactivate it?

The device cannot be deactivated, but if placed in a cold environment, it may require ambient body heat to begin emitting.

16. What is the difference in the amount of ceramics used?

After extensive clinical research, Gladiator Therapeutics has determined the optimal number of ceramics for each treatment application, ensuring optimized efficacy.

17. Is it ever not safe on any parts of the body?

The device is safe for use on the entire body. When treating the eye area, the ceramic emitters should be placed above or to the sides of the eye. The infrared therapy will penetrate the skin and travel through the body to reach the eye area.

18. Why should customers choose Gladiator Therapeutics over other alternatives?

Gladiator Therapeutics has conducted studies validating the efficacy of their products with outstanding results. Other companies rely on third-party studies that reference the technology in general and are not conducted on their proprietary devices. Not all products have the same composition, design, and efficacy.

### Wound Care FAQs

1. What type of wound care dressings do you recommend for use with the device?

Persons using the device should continue to utilize the wound care dressing that is recommended by their healthcare practitioner. The only restriction is that advanced wound care dressings containing silver will reduce the effectiveness of the device.

2. Do you suggest any difference in dressing changing protocols while using the Gladiator device?

There are no changes to the manufacturers' dressing changes protocols.

3. Can the Gladiator device be used on infected wounds?

The Gladiator device is safe for use on infected wounds.

4. What types of wounds can the Gladiator device treat?

The device is recommended for the following wound types:
Diabetic Foot Ulcers/Blisters
Venous Stasis Ulcers
Pressure Injuries
Surgical Wounds (after a 48 hr. post-op waiting period)

5. Does the device contain any ingredients that could cause an allergic reaction?

The Gladiator device has passed biocompatibility testing by an independent lab to comply with the FDA. The material does not initiate a response or cause a reaction when introduced to human tissue.

6. How is the Gladiator device cleaned and disinfected?

For general cleaning for home use the device can be cleaned with antimicrobial detergent. The silicone is non-Reactive and does not react to disinfectant or sterilization chemicals. The silicone rubber does not support bacterial growth, which also supports infection prevention.

7. What should I expect to feel or see when using the device?

The technology works at a cellular level and sensation and response to therapy will vary by individual. The longer the technology is worn the quicker the results. In some patients the nerves will become more active as healing occurs and may cause some sensitivity. If these instances it is appropriate to move the device adjacent to the treatment area.

### Pre & Post Surgery FAQs

1. How long must I wait after surgery to wear the device?

The recommended wait time after surgery is 48 hours.

2. Is it beneficial to wear the device prior to surgery?

The shoulder device will reduce inflammation and increase overall circulation in the tissue which will be beneficial to a person's overall recovery.

3. How long should I wear the device each day?

The device can be worn all day without risk of tissue damage.

4. Will the device reduce pain?

Yes, the device will reduce pain while in use and for a period of time afterwards. Many people report that they can reduce pain medication as a result.

For general alconing for home use the device can be alconed with entimistable
For general cleaning for home use the device can be cleaned with antimicrobial detergent. The silicone is non-Reactive and does not react to disinfectant or sterilizatio chemicals. The silicone rubber does not support bacterial growth, which also supports infection prevention.

# **Appendix**

Life (Basel) 2021 Aug 26;11(9):878. doi: 10.3390/life11090878.

# Accelerated Wound Healing Using a Novel Far-Infrared Ceramic Blanket

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PMID: 34575027

PMCID: <u>PMC8469926</u> DOI: 10.3390/life11090878

# **Abstract**

<u>Introduction:</u> Wounds are associated with ranges of simple to complex disruption or damage to anatomical structure and function. They are also associated with enormous economic and social costs, increasing yearly, resulting in a severe impact on the wellbeing of individuals and society. Technology that might accelerate wound healing is associated with many benefits to injured people.

<u>Methods:</u> BALBc mice underwent symmetrical excisional wounds through the panniculus carnosus. They were divided into a treatment group placed on an autonomous ceramic far-field infrared blanket (cIFRB) and a control group maintained under standard conditions. We also expanded and cultured adipose tissue-derived mesenchymal stem cells (MSCs) on cIFRB and compared them to standard conditions subjected to a scratch injury to compare survival, proliferation, and wound healing.

<u>Results:</u> The wound healing of the cIRFB treatment group was significantly faster than the control group of mice. The wound-healing effect of mesenchymal stem cells on cIRFB was also increased and associated with significant migration to the wound area.

<u>Conclusions:</u> Wound healing is improved in a mouse model exposed to cFIRB. The ceramic blanket also promotes survival, proliferation, increased migration, and wound healing of MSCs without affecting their survival and proliferation. The utilization of cFIRB in cellular biology and medical applications may be promising in many situations currently explored in animal and human models. This technology needs no direct or battery power source and is entirely autonomous and noninvasive, making its application possible in any environment.

# **Company Information**

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