

InjuryShield™

Medical

Biocompatible / Made in U.S.A

Patent Pending

10612 Providence Road; D343 • Charlotte, NC 28277
888.608.1141 • 704.817.3777 • Fax: 704.943.0894

InjuryShield™ is a thermoplastic-based, self-contained injury protection and splinting system that is biocompatible, radiolucent, latex-free, and available in near limitless sizes and shapes.

Designed to succeed where other protective products fail, InjuryShield™ is self-securing and conforms to nearly any injury, providing immobilization and wound protection.



InjuryShield™ Provides:

Bone/ Joint Stability
Wound/ Injury Protection

InjuryShield™ Facts:

Class 1 or Class 2 medical product
Resistant to moisture and oxidation
Biocompatible • Biodegradable
Latex-Free • Radiolucent
Low-Cost • Lightweight

The InjuryShield™ Solution:

Create a Custom Splint in Minutes
Needs only 2 minutes and 60C of heat
Transitions from rigid to malleable
Can be applied to most any injury site
Available in multiple sizes and shapes
Re-usable • Easy-to-use

Stabilizing Injuries Quickly and Easily by Innovating with Versatile, Low-Cost, Easy-To- Use Materials and Processes

Quickly stabilizing injuries in emergency settings and in the field has traditionally required complex and cumbersome equipment. A repurposed class of lightweight and easily manipulated materials may be the solution.

This white paper discusses materials and processes that provide a quick, simple, and low-cost method for stabilizing and protecting a vast array of injuries and wounds, including cranial, pelvic, and dental. The market for medical instruments and supplies will be discussed as well as expected industry performance over the next five years followed by an overview of state-of-the-art splinting systems and novel methods for stabilizing injuries via low-temperature thermoplastics.

***US Market for Medical,
Instruments:***

**\$100 Billion
5.3% Annual Revenue
Growth**

The Medical, Dental, and Veterinary Instruments and Supplies Market Overview

The US market for *medical, dental, and veterinary instruments*, to include orthopedic products, non-electrical diagnostic and surgical equipment, and other medically impactful devices, currently stands at just beyond US \$100B with expected annual revenue growth through 2020 of 5.3%. The orthopedic product and dental instrument segments alone represent at least 28% of the industry. Hospitals, clinics, and physicians, represent the largest consumers of industry products, accounting for about 57% of the total industry market. These health facilities require medical instruments and supplies to provide emergency, inpatient, and outpatient care as well as to conduct research.

Success by new companies within these areas will be strongly dependent upon providing novel, low-cost solutions to ongoing and expensive challenges.

According to industry analysts at Freedonia, demand for *disposable medical supplies* in the United States is forecast to total \$54.1 billion in 2020, representing annual gains of 4.2% from \$44.1 billion in 2015. Demand for wound management products – the second largest discrete product group segment – is expected to reach to \$12.1 billion in 2020

Due to market maturity, an aging and growing population, **increasing expenditure on personal first aid kits and medical supplies**, and high profit margins, this industry has remained resilient through international market downturns. To maintain this strength, innovation in product design and adoption to healthcare reform must be achieved. This includes continued investment in R&D from both the public and private sectors while reducing overall costs in manufacturing and distribution. The baby boomer demographic is set to become the industry's largest market, with over 50M people aged 65 and older in the US alone by 2020.



Medical care for animals, including nonsurgical and emergency care for personal pets, has also increased steadily, enabling the veterinary services market to reach US \$36B in 2015 with revenues expected to rise annually by over 4% through 2020.

Demand for medical products from emerging markets continues to increase with GDP and as citizens demand export growth of 4.8% through 2020.



Combining medical instruments with the dental and veterinary markets, addressable, non-surgical, treatable conditions in humans and animals include bone fractures, sprains and strains, ACL/MCL/PCL damage, other acute joint injuries and syndromes affecting motion, sports/ athletic/ performance injuries, oral and maxillofacial injuries, bruxism, and chronic pain and disability from disease. Methods for temporary and short-term care of these conditions include pain management through medication but also medical devices and instruments including casts, slings, braces, and splints.

The Challenge

By definition, splints are used for support or immobilization of a limb or joint for healing, reduction of pain, or prevention of further injury. Current splints and methods (e.g., gutter splints, spica splints, sugar-tong splints), while generally simple to apply, can be cumbersome and ineffective for small fractures (wrists, fingers) and difficult-to-access injuries (cranial, pelvic,

Traditional Splints:

- Bulky
- Require expertise
- Difficult to apply to several injuries effectively
- Not easily removed for cleaning and bathing



Thermoplastics can stabilize injuries and quickly protect areas of trauma in the field or emergency room

jaw). They have varying materials, angles, and sizes. Many are composed of a strong plastic material, pre-shaped or in an extended “spoon” shape. Very rarely do they fit without some manipulation (e.g., cutting, filing). Although hospitals usually have at least two different types of splints and several sizes of each, certain situations require the practitioners to be inventive when splinting, employing other items, such as tongue depressors and rods, to provide additional support as needed.

Even considering the advancements in medical care over the past hundred years, current methods and products for immobilization rely on decades-old (and in many cases, centuries-old) technologies and materials: gauze, foam/ cotton padding, stockinette, elastic, flexible metal, plaster, and fiber-glass. This requires maintenance of several inventory items and requires the provider to both assess the situation and determine the preferred method and materials for immobilization. The number of steps and quantity of material required for even a simple splint requires an inordinate amount of time and attention from even highly trained medical personnel, stealing attention from the overall care of the subject.

In terms of wound and injury protection, emergency medicine struggle with traditional wraps and bandages. The minimally injured struggle with prolonged immobilization, preventing quick and efficient healing. Additionally, dirt and other elements penetrate the edges of bandaging leading to infection and long-term consequences.

The Progress

Technological progress in splinting has been made in the dental industry by means of thermoplastic materials. **Thermoplastics**, a type of plastic polymer, become soft when heated and return to original rigidity when cooled. They can endure this process several times without adverse effects. Certain thermoplastics have been used safely and successfully as low-cost, biodegradable splinting materials by the medical community for over 70 years.



Because of their compatibility with organic tissues, dentists and oral surgeons have employed specialized thermoplastics for temporary crowns, bite impressions, and bruxism guards for several years. The originally rigid material is slightly heated in hot water until pliable and then applied to the site and formed in position by hand. As the material cools, it returns to its rigid state. If applied incorrectly, it may be removed, reheated, and reapplied without degradation.

As splint material for both human and animal subjects, thermoplastics can both stabilize injuries prior to surgery and quickly immobilize and protect areas of trauma in the field or emergency room.

Two types of thermoplastic splints have seen recent development: low temperature thermoplastics are made malleable in hot water and then placed directly on the subject for quick, often temporary, immobilization; whereas high temperature thermoplastics are made with a cast (too hot for direct contact with an injury) and take longer to cure but are more appropriate for long-term immobilization such as lower back and hip injuries. Both types can be made in a fashion that is removable by the user (e.g., for cleaning and subject bathing) but typically the high temperature thermoplastics are more appropriate for long-term, temporarily removable splints.



Being lightweight, easy to apply and remove, and biologically compatible, some forms of thermoplastic are sold and marketed through medical device suppliers as both dental and orthopedic products. However, *thermoplastics currently sold as general orthopedic solutions have been fabricated without optimized chemistry that results in the following:*

- Lack of biocompatibility;
- Requires high heat and/ or prolonged heating to become pliable;
- Requires long periods of time to cure;
- High cost in non-bulk quantities;
- Requires professional training; and/ or
- Lack of patent protection.

The use of traditional and cumbersome materials and products for stabilizing injuries and addressing trauma is pervasive and entrenched. A game-changing material and design is needed.

A New Solution: InjuryShield™

Continuing the proven pathway of thermoplastics for dental and other applications, the team of Kate Liddle and Mike Murdock are leading the charge toward a novel, lightweight, low-cost solution for injury care using biocompatible materials. Developed from the same Class 2 medical device used for two decades in dentistry, **InjuryShield™ is a patent-pending, low-temperature thermoplastic-based device stored and transported as a rigid, opaque sheet.** Similar to other thermoplastic splint materials, InjuryShield™ is a non-electric, non-mechanical medical device/instrument that requires only low heat to activate and mold.

Its novelty is based partly in its ease of use: InjuryShield™ becomes clear and moldable when heated to 60°C in a small amount of liquid for approximately two minutes. The user molds the product to the injury site, where it is then allowed to cool and transition back to its original rigidity and opacity. The color change assists the user in the preparation process. Overall, it is easy to use and requires little user training—in fact, simple instructions allow for self-teaching.

InjuryShield™ is fully capable of multi-use injury care—it remains biocompatible, radiolucent, latex-free, can be manufactured in near limitless sizes and shapes, and is *Made in the USA*. Designed to succeed where other injury care devices fail, it is self-securing and fully conforms to nearly any injury/ wound site. The user can easily increase the strength and size of InjuryShield™ by applying additional layers, which adhere to one another in the cooling process. InjuryShield™ can be re-heated and re-formed without loss of chemical or physical integrity. Removal is possible via shears or force. It can be cleaned with alcohol or cold sterilized and will function in concert with other splints and bandages.

InjuryShield™ Specific Advantages:

- Versatility in Application
- Ease of Use
- Low-temperature activation (60°C)
- Fast activation time (< 2 minutes)
- Re-usable/ Re-formable
- Moisture/ Oxidation Resistant
- Low Cost

The size and shape of **InjuryShield™** can be easily modified to fit the varying sizes of bones and joints. Clinics will not have to maintain a large variety of splints or other immobilization devices in storage. **First Aid kits will be revolutionized** by the addition of this versatile injury and wound protection device. Because of the firm shape and often large mass of standard splints, medical personnel must use significant padding and securing materials to ensure the limb is stable yet incapable of secondary damage from rubbing. InjuryShield™ can be easily molded to any appendage, at any size, and at a low mass. It can be placed around a light area of padding for a customized shape, resulting in a reduction of secondary damage. InjuryShield™ can be reformed and reused when bandage changes are performed, greatly reducing the financial burden for the patient. Emergency medicine practitioners require low-cost, sustainable, lightweight, and readily deployable technologies as both immediate and short-term solutions.

InjuryShield™ is an excellent choice for securing other medical components and bandages to the body. As an example, it can be used as a protective cover on catheters and biological agents. In this case, InjuryShield™ provides a viable alternative to heavy bandaging or metal/ plastic/ epoxy components for smoother edges, lighter mass, and a more stable protective device.

InjuryShield™, capable of Class 1 and Class 2 medical device versions, is currently available in several forms, the most common being 4"x4" sheets and 3" and ½" ovals. The team is currently designing pathways for larger sizes (requires changes to the manufacturing processes), integration of biologics (e.g., antibiotics, drug therapy) directly into the material, and formulations unique to the specific requirements of other markets.

The Product Team

Kate Liddle and Mike Murdock are the entrepreneurial/manufacturing team for InjuryShield™. Each boasts more than 20 years of experience in manufacturing and distribution, sales and marketing in dental, medical and other industries. They have worked together successfully in separate businesses for more than 15 years. MakeITMarketUSA.com™ (MIMUSA) was formed in December 2013 in North Carolina to manufacture core products for All Dental ProdX (ADP) after Ms. Liddle (ADP founder and partner) moved product tooling to the US. Dr. Brandon Conover, CEO of Practical Scientific Solutions, serving as technical advisor to the MIMUSA team, brings several years of experience in biomedical devices, product engineering, and technology development within medical and military verticals. For veterinary applications the team receives advisory assistance from Dr. Dana A. Vamvakias, DVM, CCRT, cVMA, who brings extensive experience and training in small animal medicine, working dog medicine, and emergency medicine. Dr. Vamvakias is certified in Canine Rehabilitation Therapy and Veterinary Medical Acupuncture. For military applications (i.e., combat medical and dental), the team receives advisory assistance from SGM Kyle Sims, Medical Combat Developer, US ARMY Special Operations Command (USASOC), Fort Bragg NC. The MIMUSA team has strived to give back to their local communities and to be a force of positive change around the world. Unfortunately, the cost of many medical products—from prophylactic to diagnostic to therapeutic—is prohibitive for clinics and medical providers in many communities. Oftentimes, simple injuries and traumas that are treated quickly in well supplied hospitals lead to lifelong deformities or worse in less visible corners of the world. Because of low cost and ease of use, InjuryShield™ may be an ideal solution for clinics in underserved areas of the world to address injuries and provide a better quality of life.

References

IBISWorld, Medical Inst. & Supply Manuf. in the US, Nov. 2015, Report 33911a, Sarah Turk.
IBISWorld, Veterinary Services in the US, Jan. 2016, Report 54194, Sarah Turk.
IBISWorld, Medical Device Manufacturing in the U Jan. 2016, Report 33451b, Jack Curran.
Hoover's, Medical Equipment & Supplies Manufacturing Industry Report, 2016.
Glazer, H. S. and K. Liddle, "The Chairside Night 'n Day Guard," Dental Materials & Technology, Oral Health Journal, July 2011.
Goldstein, M. B., "Thermoplastics: Various applications of Bite Buddy and Temp Tabs thermoplastic wafers," Dental Products Report, Sept. 2005.