

Brain-Pad Reaches Agreement with FTC on Advertising while Confirming its Ability to Continue to Advertise its Products Protections to the Base of the Skull and TMJ

Brain-Pad is pleased today that the Federal Trade Commission has announced that it has approved an agreed upon consent order concerning the company's product claims and has placed the consent order for public comment. Brain-Pad and the FTC have been working together for months, and in that time, Brain-Pad has voluntarily altered its packaging and advertising claims to reflect the parties' agreement.

Brain-Pad believes in its products' ability to help reduce the risk of jaw impact concussions and has worked, and will continue to work, to analyze the science and support behind its products. There is much scientific debate over how best to reduce the risk of concussions across a wide variety of sports.

As Brain-Pad made clear to the FTC, Brain-Pad does not claim, nor can anyone claim, that their protective devices **prevent** concussions. It is clear concussions occur under a varied set of circumstances and conditions.

Brain-Pad is, however, confident that the claims that it does make about its products are true, where many of its business competitors have no science and no technology behind their claims. Brain-Pad is proud to do its part, both now and in the future, to help improve the sports environment, through education and protection, for youth and professional athletes.

Though Brain-Pad remains confident that its science and independent testing and research supports all of its prior claims, and Brain-Pad disagrees with the FTC, Brain-Pad believes that it is better to work with the regulating bodies' in advancing the protection from injury as science and consumer knowledge continues to develop. Accordingly, despite its disagreement with the FTC's allegations, Brain-Pad has agreed to modify its advertising to avoid a protracted legal battle and to further this collective goal. Thus, Brain-Pad has agreed to settle with the FTC. Settling does not mean Brain-Pad agrees with the FTC's allegations; we do not.

OVERVIEW: Even with heightened attention on sports injuries, the prevalence of injuries caused by direct and/or indirect impacts to the jaw or chin are often overlooked, and often times, outright ignored.

Protective equipment exists today that greatly reduces the forces transmitted to the base of the skull and TMJ. In nearly two decades and including three independent biomechanical studies, the relative effectiveness of the dual arch mouth guard (more properly identified as a "jaw-joint protector" as opposed to a "mouth guard" for protecting teeth) was well established.

The first study was sponsored by NFL Charities and the National Operating Committee for Standards in Athletic Equipment (NOCSAE) in 1993. The following two studies were performed by Wayne State in 2005 and, in a study fully funded by the NFL with Biokinetics, in 2011.

The latest tests in 2011 validated using an impact force standard for all head-contact sports, including football. The tests used two different head forms with articulated jaws with instrumentation above the Condyle and into the Temporal Mandibular Joint (TMJ) measuring linear force.

The results of all three tests were unequivocal in demonstrating that the Brain-Pad® dual-arch jaw-joint protector™ was the most effective device to significantly reduce forces transmitted through the lower jaw TMJ into the base of the skull. A dual-arch jaw joint protector is defined as a dual channel mouth guard that repositions the jaw bone slightly down and forward while stabilizing and securing the lower jaw.

These same tests also showed that some single-arch mouth-guards actually increased the forces transmitted through the lower jaw to the base of the skull due to the “lubricating” effect of the upper arch only mouth guard design.

Brain-Pad Protection: Brain-Pad® was founded in 1995 by a dental surgeon in Philadelphia who treated professional boxers in his practice. Brain-Pad has been protecting athletes, first in combat arts and mixed martial arts and then in helmeted contact sports, for more than 16 years. The company has sold literally millions of Brain-Pad® Jaw-Joint Protectors™ and, in fact, is either mandated or highly recommended for use in mixed martial arts and boxing competitions.

The Brain-Pad Jaw-Joint Protector™ is a dual arch mandibular orthotic that positions the jaw in a slightly down and-forward position and achieves stabilization through its design, reducing and redirecting force from the impact to the jaw away from the TMJ and base of skull. The Brain-Pad appliance and the molars – which are the strongest bones in the skull – primarily absorb the impact forces.

As a result of the early work done by Brain-Pad, Dr. Voight Hodgson, the technical director of NOCSAE and a professor at Wayne State University, became interested in jaw interaction and the implication of impact to this region of the head looking at the mandible impacting the fossa and the transfer of force and impact to the basal skull and brain region. Another major concern of Dr. Hodgson was chinstrap loading and the detrimental forces affecting a number of cranial nerves that control sensory and motor functions. Brain-Pad believes that its Brain-Pad Jaw-Joint Protector addresses both of these issues.

Examining The Data: In 2003, a benchmark was established with a study conducted by Biokinetics of Canada, authored by Dr. Elliot Pellman. The study established 9.3 ± 1.9 m/sec of velocity impact as creating concussive forces. In 2005, at Wayne State University, using the head form with an articulated jaw, Brain-Pad revisited this and found similar results as in 1993 study, with impact forces delivered directly to the facemask and chin.

Brain-Pad found that on a 60-inch drop directly to the facemask, more than 500 pounds of force was transmitted through the chin cup slamming the jaw bone directly up into the base of the skull just below the brain. When wearing a Brain-Pad® jaw-joint protector™, impact forces were cut by 40 percent. Then in 2011, in a study fully-funded by the NFL and which made use of a new head form with an articulated jaw, was performed at Biokinetics in Canada. It was shown that the Brain-Pad® Jaw-Joint Protector™ was measurably superior at withstanding and reducing a 9.5m/sec impact, more than other leading retail mouth guards. In fact, the study showed, when compared to wearing no mouth guard at all, those single arch mouth guards actually increased velocity impact forces rather than decreased them.

Any product, such as the Brain-Pad® Jaw-Joint Protector™, that reduces impact forces to the thin base of the skull and TMJ can only be a benefit to the athlete.

What To Do Now: With debilitating injuries on the minds of all coaches and parents, the only acceptable result is that protective sports equipment must bring about a reduction of velocity impact forces.

We have, in our scientific community, a great understanding of linear impact forces, which were greatly aided by the auto industry's crash-test programs. However, lateral, angular and rotational forces are not understood as well. Current helmet testing protocols and equipment date from the late 1960s and should be updated to observe more than just skull fractures.

It is time for athletes, coaches, trainers, sports medicine doctors, sports equipment manufacturers, regulating agencies, and state and federal governments to work together to understand the potential causes and detrimental effects of all injuries and to establish realistic standards of design to reduce, as much as possible, the incidence of injuries. Brain-Pad firmly believes the steps it has taken in tandem with the Federal Trade Commission review are steps in the right direction.