Scrambler Therapy® - Healthcare and Insurance System

Scrambler Therapy® if correctly used is a control tool for severe chronic neuropathic and cancer pain. Scrambler Therapy® is very effective, non-invasive.

ROME, ITALY, October 15, 2018 /EINPresswire.com/ -- About Scrambler Therapy® Technology efficacy and safety issues
The Scrambler Therapy Device is based on 5 artificial neurons which were developed to non-invasively transmit information recognizable as "self" and "no-pain" to the central nervous system (CNS). A proprietary algorithm dynamically generates this specific strings of "no-pain" information, achieving both an immediate and complete analgesia and a re-modulation of the pain system with high level of safety and a long-term efficacy.

To determine and understand efficacy and safety issues, one needs to consider that, different synthetic action potentials, adequately modulated and assembled in information-strings, can build millions of different sequences that interact with C-fiber surface receptors, and can determine many different physiological responses. The creation and selection of this information is therefore decisive in the clinical response, being related to the different efficacy degrees in the immediate control of pain, but also in the short, medium and long term efficacy and to the treatment safety.

More specifically, the remodulation of the pain system is a dynamic process that requires significant variability of the strings of "no-pain" information, and this dynamic information must be always effective in an environment very changeable for many type of neurological damage and various characteristics of the pain. In this context, extensive preliminary work has been necessary to verify the selection and interconnection of strings of information that are effective and safe in an array of pain syndromes.

Before being placed on the market, a long series of clinical trials have been performed on ST: from 1999 to 2006 approximately 2,400 cases, treated at the University of Rome Tor Vergata and related to chronic and non-cancer and oncological pain resistant to other treatments, have been analysed.

For all these reasons, it is quite clear that the concept of similarity that only considers the parameters of frequency, pulse width and intensity (used for other devices) is not applicabile to Scrambler Therapy® Technology. Any variation to the original OEM technology and/or to the algorithm (together they control the synthesis of the information), inevitably alters the well-known consolidated efficacy and safety parameters, producing unknown or potentially harmful effect.

About the FDA 510(k) clearance and CE mark
Both FDA 510(k) clearance (# K142666 or Delta International Services & Logistics) and 0476 CE mark are exclusively referred to the device based on scrambler therapy technology and labeled as Scrambler Therapy® Technology MC-5A.

Placement on the market.

In Europe Scrambler Therapy followed the ordinary new medical device procedure, that requires the applicant to demonstrate the efficacy and safety of the new device in its clinical use by specific clinical trials conducted in a broad range of cases.

In the U.S., FDA has various ways for the approval and clearance of medical devices. The 510(k) procedure calls for indication of one or more medical devices of the same reference category (in our case electro-analgesia) and FDA assesses the degree of similarity between reference devices and the new one. If the device undergoing FDA clearance has substantially the same technology and clinical (efficacy and safety) features like the indicated reference device (normally a standard TENS) the clearance process is rapidly achieved and no specific clinical trials are requested.
If the device technology and clinical features are different from the ones of reference predicate device, FDA calls for specific clinical trials that must demonstrate that the new device has equal or higher efficacy and safety features than the ones already authorized. This is the reason why the FDA in the clearance lists the referenced predicate devices. This was the procedure followed to market ST in the US. In this case, however the FDA does not mean to say that the predicate devices have the same technology and clinical features of ST (in fact, FDA requested specific clinical trials) but simply that ST according to clinical trials forwarded has efficacy and safety features equal or higher than authorized reference devices.
With the new 510 (k) #K142666 only for Scrambler Therapy® Technology MC-5A device, any potential confusion between TENS and ST device has been definitively dispelled.

Consequently, the FDA classified Scrambler Therapy as a non-invasive electro-analgesia device, but in the review process acknowledged its unique feature, that drastically differentiates it from conventional TENS devices. Then allowed for marketing only in the context of clinical trials, similar to those performed in Europe. For this reason, it is correct to refer to this new methodology by clearly and uniquely defining it only as Scrambler Therapy®, both in the scientific literature and in clinical practice.

About RCTs double blind issues
ST treatment is very operator-dependent, for this reason only partial double blind or single blind RCTs can be carried out. Attempts to do a complete double blind automatically determines substantial changes in the standard treatment protocol. These changes prevent the operator to follow the normal procedures registered in the healthcare authorizations and can erase or certainly extremely reduce the efficacy of the treatment consequently invalidating the scientific data.
This methodology problem is present (even more broadly) in many other medical validated treatments such as for example spinal cord stimulator (SCS).
To date, from a merely scientific point of view, to avoid the introduction of Bias which makes the clinical outcomes unreliable the available solutions are:
- RCT vs sham / TENS partially double blind (ST operator cannot be blind)
- RCT vs validated protocol therapies
- Double Blind with single arm sham to analytically determine the placebo effect. The following treatment of the same patients with the normal procedure will guarantee the trial's ethicality and provide further comparable results.
More info: https://www.scramblertherapy.org/RCTsdoubleblind.htm

Intellectual property
Scrambler Therapy® scientific research and development technology have been developed in

Italy by Professor Giuseppe Marineo. The official "Scrambler Therapy"® scientific and clinical information website is at https://www.scramblertherapy.org/english.htm

About Delta International Service & Logistics (DIS&L)
DIS&L is the only company authorized to sign international exclusive agreements, provide maintenance and distributor support for method usage training and other logistics needs.
More info:
Worldwide: https://www.st-team.eu
U.S. DIS&L Division - https://www.st-team.eu/scrambler-therapy-in-u.s..htm

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