Properties and Characteristics of an Optimum/Ideal Non-active Surgical Implant

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Abstract

Essence of properties and characteristics rendering a non-active surgical implant optimum or ideal has hitherto been lacking and requires further consideration.

Definitions governing medical devices given in leading geo-political regulatory domains are insufficient to specify

constitute logic rules and are not conducive to determine optimum / ideal characterisation (because they are goal-oriented). Equally, the position concerning voluntary, non-majoritarian goal-oriented standards in NASI is devoid of fundamental attributes of such product. Consequently, it is opined the vast majority of NASI placed on the market (PoM) manifest immaculately by spontaneous assumption of implant potential during their conception.

We propose the concept of implant potential as: the extent of qualities of an implant determining its suitability, safety, performance and usefulness throughout its service and total implant life without undesirable physiological loss, malfunction or detriment to an organ or organ system of the body.

Consequently, it is necessary to understand physiological function from which optimum implant potential may be deduced. Physiological function may be as: activity natural to or purpose of a person or thing. Consequently, optimum physiological function is highest conduciveness of such function to a favourable physiological outcome. It is therefore conjectured NASI by implant potential might improve such products, evaluation of their suitability and (criteria for) regulatory compliance.

Consequently, it is possible to deduce implant rules from implant potential, thereby promoting uniform, assessment and comparison. If successful, such approaches connote obvious

article explores fundamentals of NASI, their properties and characteristics and proposes implant rules based on implant potential, from which concepts of optimum physiological function and implant potential, respectively, are proponed. might even improve standards published by standard organisations.

Implant rules

Initially, it might seem obvious what constitutes a NASI and its role in medicine, yet, closer examination of the subject indicates critical investigation of these matters is lacking [4-6] and requires further consideration. Among factors which might be considered, it is necessary to establish understanding of physiology as it relates to NASI treatments.

Physiology is the study of the function of living organisms a branch of biology concerned with normal function of living organisms and their parts and a way in which a living organism or bodily functions.

a NASI designed to remedy disordered physiological (function) can do so optimally if it adheres to certain rules (Figure 1).

Present regulatory position of NASI may be illustrated by studying

According to EN ISO 14630, an implant is as): implant potential. following rules allow improved (Table

Definition non-active surgical implant EN ISO 14630

3.6 EN ISO 14630 ‘non-active surgical implant’: Surgical implant, the operation of which does not depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

Definition surgical implant EN ISO 14630

3.8 EN ISO 14630 ‘surgical implant’: Device that is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place the procedure, or any medical device that is intended to be partially introduced into the human body by means of surgical intervention and that is intended to remain in place the procedure for at least 30 days, meaning a NASI (by deduction is as and) must be:

Definition non-active surgical implant EN ISO 14630

3.6 and 3.8 (merged) EN ISO 14630 ‘non-active surgical implant’: Surgical implant, the operation of which does not depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity, that is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place the procedure, or any medical device that is intended to be partially introduced into the human body by means of surgical intervention and that is intended to remain in place the procedure for at least 30 days.

It is argued these while they might be suited for the respective ISO/TR (ISO/TR 14283) and standard (ISO 14630) [9], also directives on medical devices do not conduce precise properties and characteristics necessary for design rules on such products. Further, it is opined temporality used to discriminate implants allowing into regulatory classes is irrelevant in determining

Neutrality	Disambiguous or indifferent, not evoke responses affecting comfort, well-being or quality of life of recipient, including physiologic motion and articulation
Attrition	Wear over time, if any, consistent and concurrent with native implant environment
Depreciation	Functional loss over time, if any, consistent and concurrent with native implant environment

Table 2: Properties and characteristics of optimum / ideal NASI.

It is not the purpose of this article to argue only autologous NASI can substitute, however implied.