A Comment on the CE Marking of Iliac Artery Stents

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In this journal a study to evaluate the clinical outcomes of an iliac stent is published. The stent already had a CE (Conformité Européen) mark and was therefore freely available within Europe for clinical use. For an iliac stent to have a CE mark and therefore be freely available on the market the European Medical Devices Directive describes the essential requirements that must be met. In brief these are:

1. A device that does not compromise the clinical condition or safety of the patient, the safety and health of users or, where possible, any third party.
2. The device must achieve its intended purpose as designated by the manufacturer and
3. Any risks associated with the use of the device are judged by informed clinical opinion to be acceptable when weighed against the benefits to the patients and compatible with a high level of protection of health and safety.

It also introduces controls covering the safety, performance, specification, design, manufacture, labelling and packaging of devices. In order to comply with the directive the manufacturer may either (a) compile the relevant scientific literature currently available on the intended purpose of the device and the techniques employed, together with, if appropriate, a written report containing an evaluation of the compilation, or (b) provide the results and conclusions of a specifically designed clinical investigation. The clinical investigation is only required if the device introduces completely new concepts, or represents a modification of a device that contains a novel feature or modifies an important physiological effect, or where the device incorporates materials previously untested in humans, or where a device which may already be CE marked, is proposed for a new purpose or function.

This author questions whether the process is sufficient to achieve the essential requirements.

Many manufacturers choose a compilation of the scientific literature to obtain a CE mark for iliac stents. This is despite the literature accompanying the market release of a new stent invariably detailing new and unique advantageous features of the device. This leaves the clinician in a quandary for whilst an iliac stent may have a CE mark based on a compilation of relevant literature, such a route often does not show equivalence in all areas of interest (i.e. technology, critical performance, design, principles of operation, population involved, conditions of use and clinical purpose). Since there are no standard criteria by which the various notified bodies throughout Europe judge the performance of the new devices, there can be no surprise that manufacturers choose their body to suite their own needs.

Many new devices are released without any data on long-term efficacy or safety being available. And once the CE marking process, as described by the European Medical Devices Directive, has been completed there is currently no enforceable standardised mechanism for obtaining relevant clinical outcomes on these new devices. Most stents are produced using either nitinol or stainless steel. Each new stent has a unique feature, usually in the form of the design of the stent rather than then metal used, which may potentially result in adverse clinical outcomes. The Directives do not mandate a pre-market clinical investigation and reliance is placed upon the manufacturers to conduct a post-marketing trial. This does not always happen which means that a substantial number of patients could be treated with new stents without any specific supporting clinical literature.

Whilst I applaud the progress that has been made in the evaluation of medical devices following the introduction of the European Medical Devices Directive there appear to be shortcomings in the process that need to be addressed.

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