Class I Devices

Case Studies in Medical Devices Design

Peter J. Ogrodnik

Class 1 Devices

Case Studies in Medical Devices Design

Peter J. Ogrodnik

ELSEVIER

AMSTERDAM • BOSTON • HEIDELBERG • LONDON
NEW YORK • OXFORD • PARIS • SAN DIEGO
SAN FRANCISCO • SINGAPORE • SYDNEY • TOKYO

Academic Press is an imprint of Elsevier

Academic Press is an imprint of Elsevier
32 Jamestown Road, London NW1 7BY, UK
525 B Street, Suite 1800, San Diego, CA 92101-4495, USA
225 Wyman Street, Waltham, MA 02451, USA
The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, UK

Notices

Knowledge and best practice in this field are constantly changing. As new research and experience broaden our understanding, changes in research methods, professional practices, or medical treatment may become necessary.

Practitioners and researchers must always rely on their own experience and knowledge in evaluating and using any information, methods, compounds, or experiments described herein. In using such information or methods they should be mindful of their own safety and the safety of others, including parties for whom they have a professional responsibility.

To the fullest extent of the law, neither the Publisher nor the authors, contributors, or editors, assume any liability for any injury and/or damage to persons or property as a matter of products liability, negligence or otherwise, or from any use or operation of any methods, products, instructions, or ideas contained in the material herein.

British Library Cataloguing-in-Publication Data
A catalogue record for this book is available from the British Library

Library of Congress Cataloging-in-Publication Data
A catalog record for this book is available from the Library of Congress

ISBN: 978-0-12-800028-1

Class 1 Devices

Case Studies in Medical Devices Design

DEDICATION

This book is dedicated to anyone who has never
had a book dedicated to them before.
(If you are reading this, does this mean you?)

ACKNOWLEDGEMENTS

I would like to acknowledge the contributions of the FDA, the MHRA, and the EU to this text. In addition, I would like to thank those who agreed to contribute to the case studies, in particular, Intelligent Orthopaedics Ltd and Onbone Oy. Of course, I am grateful to my editor, Fiona, at Elsevier who kept me on track. Lastly, but not least, I also thank my family for keeping me on track.

CONTENTS

CHAPTER 1

Introduction

This book complements the original text in *Medical Devices Design: Innovation from Concept to Market*[1] (from now on I am going to call this the *reference text*). The intention of this book, and its sister books in the series, is to support the concepts presented in the reference text through case studies. In the context of this book, the case studies consider Class I (EU) and 510(k) exempt (FDA).[2]

1.1 REMINDER CONCERNING CLASSIFICATION

Before we go any further with our discussions, we should remind ourselves about classification systems. In the European Union, there are four levels of classification, classes I, IIa, IIb and III. We are only considering those in Class I.[3] In the USA, the FDA system is different but similar; the classification we are considering is 510(k) exempt. We will be examining the classification of a device within one of the case studies in this text. We will be looking at making a classification in the next chapter.

What does a Class I or 510(k) exempt classification mean for a medical devices company? It *does not mean* that the design rigour is any less; it simply means the application process for clearance to market in the EU or in the USA is easier than for the others.

Note: This textbook, nor any textbook, is a classification bible. One should *always* refer to the current information to perform classification

[1]You should have a copy of this text, a copy of the Medical Devices Directive, and a copy of CFR 21 with you at all times – the last two being mandatory. A copy of ISO 14971 is also mandatory and ISO 13487 would be of great benefit.

[2]**Note:** The USA have class I 510(k) exempt AND class II 510(k) exempt. In the EU, the equivalent is Class I only.

[3]**Note:** Class I Sterile packed and Class I with Measuring Function *do not* fall into this category.

Class I Devices: Case Studies in Medical Devices Design. http://dx.doi.org/10.1016/B978-0-12-800028-1.00001-2

of a medical device. The only sources one should ever use are the EU and FDA website. Never use an out-of-date guideline, book or pamphlet; that way, madness lies!

1.2 A REMINDER CONCERNING THE IMPORTANCE OF DESIGN RIGOUR (OR DESIGN CONTROL)

Quite often, I have to talk to students concerning design rigour and the question comes back – why? It is very simple. One day, and I hope never, you may be in a criminal court because your device has hurt someone, potentially seriously. If you have not followed a rigorous design process, you should be prepared for a long holiday in a not-so-nice government funded resort. If you want to avoid a stay in prison, then why not simply do things properly from the start? As we say in England, this is a no brainer!

This text represents neither design theory nor design analysis. This subject matter is covered in the main text that this book refers to (the reference text). You should read the main book before attempting to go any further. Do not rely on this text alone.

1.3 A REMINDER CONCERNING UNDERSTANDING THE PROBLEM

One of the biggest frustrations I have when talking to some 'medical devices designers' is their lack of any clinical experience. Indeed, I have heard it said that they do not want to understand clinical practice as it 'limits their ability to design'. That is complete and utter rubbish. To design anything, one must understand, fully, the issues: the environment, the political, the social and the economic. If you do not appreciate what the problem is, and where the boundaries are, then you cannot design a commercially viable device. You may well have a device, but it will not be one you can ever be proud of; it will become a millstone around your neck[4] and you *will* live to regret it.

[4]An old saying that comes from the Bible, Luke 17:2, 'It were better for him that a millstone were hanged about his neck, and he cast into the sea, than that he should offend one of these little ones'. It now means a burden one has to bear, forever.

1.4 A REMINDER CONCERNING A TEAM/HOLISTIC APPROACH

When you start your design process, you have to define the *design* team. As stated in the reference text, include as many of your subcontractors as possible, at the earliest stage possible. This includes manufacturers, packaging suppliers and shippers. Include end users and their support staff. Get as much input into your designs as possible, as soon as possible. Do not sit yourself in an ivory tower pretending to be the 'design guru' that all bow down to. No man is an island, no matter what Simon and Garfunkel say.[5]

Teamwork is an essential part of design. A good designer needs to be able to bounce ideas off others and accept their critical feedback when it is given. No one is the sole expert on anything: opinions differ, attitudes differ and skills differ. You need to be able to *Design for All*, and not just design for one. You will only succeed in achieving this outcome if you operate with a team philosophy.

Remember to look at your project with a 'wide-angled lens'. Focusing on minutiae will not help you in the end. Be holistic in your approach; adopting a team philosophy is a start. However, you need to consider the project as a whole. If you do not, something will come back and 'bite you' at the very end, and design changes late in a project drive up costs astronomically.

1.5 A REMINDER CONCERNING COSTS

Research and development can be a very expensive business. Not only can you be stripped of cash by overuse of consultants but also the very cost of essentials can be daunting. Prototypes can be very costly, simply because they are prototypes. You will, undoubtedly, underestimate the time you will spend on the project, but you must try to avoid to. Design projects can get a life of their own and can act as a cash '*black hole*', sucking in funds for little or no return. Work out a project budget and stick to it: do not be tempted to say to yourself 'only need to spend a little more'; 'just a little further'; 'not quite right yet...a little more'.

---

[5]'I am a rock, I am an island' lyrics from a Simon and Garfunkel song.

One of the biggest issues is to know when to stop. Design teams can go on *ad infinitum* making ever more small changes, but only for changes sake. Determine the value of design modifications before going ahead. If a small change increases the value by 100%, so be it. But, if the change costs more than the potential benefit, why do it? Be strict with yourself, and that is one of the hardest things to do.

1.6 INTRODUCTION TO THE CASE STUDIES

As described previously, a number of case studies are to be used to provide the backbone of worked examples to enhance the content of the reference text. The bases of the case studies for this book are those considered to be either Class I (EU) or 510(k) exempt (FDA).

The case studies are drawn from a variety of disciplines. However, one should not assume that because a pertinent discipline to one's own area is missing that the content is, somehow, of no interest. The case studies are there as vehicles for application only. One can apply the principles to any discipline. Therefore, it is important that you look at each case study as a whole and do not skip examples because they are not in your discipline. If you do this, you may miss an important point that could be applicable across the board. Equally, skipping concepts that appear to be of no interest is not a good design practice. A good designer looks across disciplines with a 'designer's eye': in this way, the designer's skills can only be enhanced; in this way, the designer can pick up examples of good practice; and, finally, in this way, their own products may just become that little bit better.

Case Study: The OTC Joint Support

If you have ever sprained a wrist, twisted your knee or strained the ligaments of your ankle, you will be well aware of the over-the-counter (OTC) elasticated support. In the past, these were simple elasticated hose; however, nowadays, there are a plethora of items from simple elasticated hose through to velcro-attached mechanical structures. However, they all have one thing in common; in the EU, they are Class I devices, and in the USA, they are, generally, Class I/510(k) exempt.[6]

[6]An addendum to this are those supplied in a sterile condition that are not in this category.

This case study brings the concept of OTC products to medical devices. I am amazed how many times I have heard the comment 'oh it's not a medical device as it is only for sale to the general public and not to a hospital' – wrong! Any simple analysis of the medical devices regulations, across the World, shows the most Hogarthian[7] of designers that they are indeed *medical devices* designers.

Figures 1.1–1.3 illustrate the range of devices that fall into this category. All three figures are, effectively, for the same thing. They all

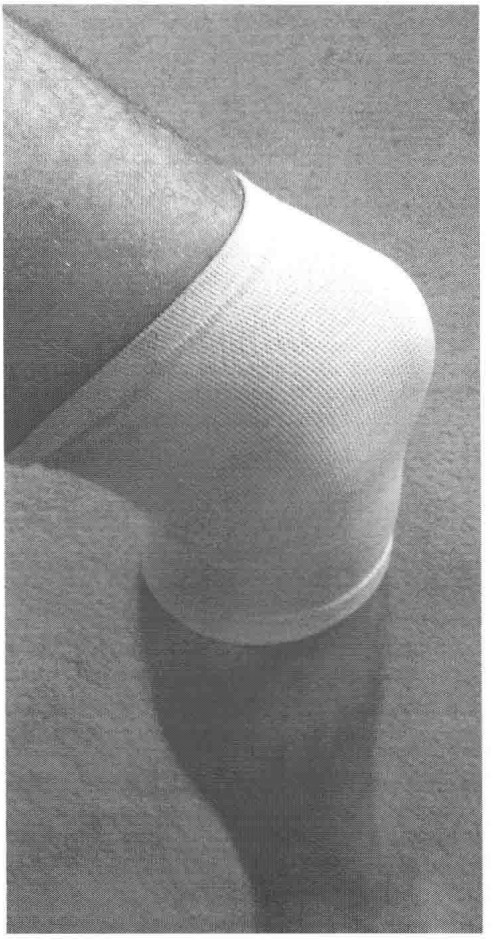

Fig. 1.1. Simple elasticated support.

[7]Hogarth was an artist of the early eighteenth century (1697–1764). He was particularly famous, amongst other things, for cartoon characters known as Hogarthian Grotesques whose visualisations hyper-extended their personal traits.

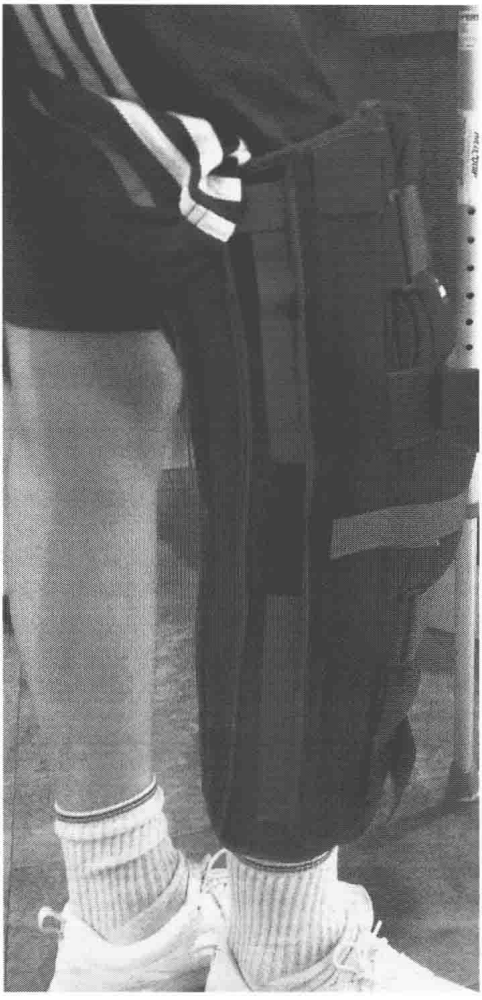

Fig. 1.2. Neoprene knee support using 'hook and loop tape' strapping.

provide some form of support for areas about the knee. However, their complexity increases from Figures 1.1–1.3.

Figure 1.1 illustrates a simple elasticated bandage. This is normally in some form of tubular fashion and is a mix of textiles and elastic material. The object of the hose is to provide compression, and it is an elasticated textile; this is all it can provide. It has no structural stability and can provide no axial or bending support at all.