Capita Selecta:
Guide on introducing medical devices into the OR

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Summary

This guide is written as a support for the design and introduction of new medical devices. It starts with an introduction which explains why this guide was written, and continues with some important subjects. These subjects are: The first section covers the new MDR, its general safety and performance requirements and how the conformity assessment is arranged. This is followed by a section which helps with identifying the classification of the new medical device. A flowchart was created for this to make things easier. Furthermore, a section is dedicated to explain the biocompatibility tests which may be necessary with the new device and is followed by some tips concerning electrotechnical aspects. The last part of the guide covers the various technical documentation which needs to be included with the device, some info about the post-market analysis and how hospitals process new medical device applications. In the end two examples are given to show how which design aspects would need extra attention, in which class the device falls and which biocompatibility tests would be needed.
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Chapter 1

Introduction

Within the MST in Enschede lies the Thorax Centre Twente. It belongs to the top 5 Thorax Centres in the Netherlands regarding annual patient volume. It focuses, as the name states, on the treatment of any heart related interventions and assists with lung surgeries as well. The Centre has their own operating rooms in the operating room complex of the MST. These operating rooms are filled with medical devices. Since the 14th of June 1993, the world of medical devices in the European union is governed by the Medical Device Directive. This directive was introduced to coordinate all laws within the European Union related to medical devices. As from the 26th of May 2021, this old directive will be replaced by the MDR [1]. Medical devices should be designed and tested according to this MDR in order to be accepted to the market. To create a new device which can be used in a Thorax OR, the guidelines of the new MDR have to be followed. These guidelines are being introduced in order to reduce the risk that medical devices can pose. What these guidelines consist of, will be explained in the guide. It features biocompatibility, design choices and classifications. Besides that, it also explained how medical centers introduce new medical devices into their standard equipment. This guide is written to find how medical devices are safely introduced into the Thorax OR. It consists of the red line from design to acceptance by the hospital.
Chapter 2

Developing a medical device

2.1 MDR

When designing a product, it is wise to consider the requirements found in the MDR. The MDR has a list of design and performance requirements which a device need to adhere to in order to successfully pass conformity assessment.

2.1.1 General Safety and Performance Requirements

Safety and Performance requirements as found in the documentation of the MDR are divided over three chapters. These chapters describe the general requirements, design and manufacturing requirements and information requirements supplied with the device. For this report a focus is laid on the general, design and manufacturing requirements.

General Requirements

Chapter 1 of the general safety and performance requirements contains several general bulletins which manufactures should incorporate in their design process in order to reduce risks concerning their device as much as possible. As such, devices should be designed in a way that it does not compromise the clinical condition or the safety for anyone involved. Any risks while using the device should be weighed against the benefits and should be compatible with a high level of protection of the health and safety of the patient. During manufacturing a risk management system should be implemented. This risk management includes a risk management plan and should ensure identification of foreseeable hazards linked to the device. Likewise, the risk of misuse of the device should be incorporated as well. Risks can be minimized by creating a safe design, with adequate protection measures, using ergonomic features and keeping the knowledge, experience, education and
use environment of the intended users in mind. During the lifetime of the device, change in performance and characteristics should not affect the health of patients or users negatively. This also holds for the packaging of medical devices. It should be adequate enough to protect the device from transport and storage such that its performance and characteristics are unchanged.

**Requirements regarding design and manufacturing**

Chapter 2 of the general safety and performance requirements is focused on manufacturing and design of medical devices. It covers choice of materials and material properties, mechanical properties, bio-compatibility and compatibility between devices. The rest of the chapter is divided in several subsections each concerning their own subjects. This ranges from the use of substances to the use by laypersons.

**Substances**

Devices should be designed such that the risks imposed by (foreign) substances or wear particles have as less as possible influence on the working of the device. Materials and fluids used with the device which are administered to the body can not contain more than 0.1% weight by weight substances that are carcinogenic, mutagenic or toxic to reproduction. Endocrine-disrupting substances should be justified when no other alternative substances are available. If any of the previously mentioned substances are used, it should be present on a label and the patient should be prepared for use with such substances when possible. When using materials or substances as found in directives 2004/23/EC and 2002/98/EC, pay attention to traceability and procurement.

**Infection and microbial contamination**

Concerning infection, devices should be designed to remove or reduce the risk of this to patients and users. This covers risk of unintended cuts or pricks, allowing safe handling and prevents microbial contamination. When needed, the design should incorporate easy and safe cleaning, disinfection or sterilization. Packaging should keep the device in such a microbial state as designed or should keep the device sterile when needed.

**Construction of devices and interaction with their environment**

When intended to use with other devices or equipment, the device should not be able to impair the performance of the other devices. Any connections, which could be between systems, gas/liquids or electromechanical should be designed such that any risk is reduced as much as possible.

Devices should be designed such that to remove as much as possible:

- Any risk or injury caused by physical features. This includes volume/pressure
• Risk concerning external influence. This can be environmental conditions like electromagnetic fields, electrostatic discharges, radiation from other devices (X-ray for example) variations in pressure and acceleration (moving device) or radio signal interference.

• Risks of contact with materials, liquids and other substances during normal use

• Risks of software / IT connection problems

• Risks of substance ingress into the device

• Risks during interaction with other devices

• Risks concerning calibration not being possible during loss of accuracy

Besides this, devices should not be able to explode and have the ability to be calibrated, adjusted and maintained safely and effectively. Intended use of the device with other instruments during use should be reflected onto the design such that interoperability and compatibility is guaranteed. Devices with a diagnostic or measuring function These devices should be designed to provide sufficient accuracy and stability for the purpose that they are made for. Measurements of these devices should be displayed in legal unit as per directive 80/181/EEC. Any limits regarding measurements should be clearly specified by the manufacturer.

**Protection against radiation**

Devices should be designed such that any exposure of radiation from the device to patients and users is reduced as much as possible. However, this should not limit the intended use of radiation with therapeutic and diagnostic purposes. When devices use (potentially) hazardous radiation, the operating instruction must reflect this and how the patient and users can be protected. With intended radiation, the device should be designed such that the reproducibility of relevant parameters, like radiation intensity, is in acceptable tolerances. Any device with intended radiation must have stickers and visual displays or audio warnings when emitting dangerous or ionizing radiation. When using ionising radiation, the design should follow directive 2013/59/Euratom. This radiation should not exceed the amount needed for sufficient image- or output quality. Aiming, the quantity and geometry of radiation should be able to be varied and controlled.

**Electronic programmable systems**

Software should be reliable and ensure repeatability and performance in line of intended use. It should be written such that the usability is optimal, especially for
mobile devices. A good example is screen ratio. It should be safe and protected against unauthorised access or tampering and come with set minimum hardware requirements.

**Active Devices and devices connected to them**

Active devices which are non-implantable should reduce risks from single fault events. When the safety of the patients depends on the power supply of the device, the status of the power supply should be clearly visible and have an alarm system for when problems arise. Monitoring devices should raise alarm when the patient could have a situation which would lead to death or severe deterioration of the patient's state of health. Devices should be immune to electromagnetic interference such as adequate to remain functioning as intended. It should also be designed such that the risk of injury to the patient or users by electric shock is avoided or reduced as much as possible. Next to that, devices should also be protected against tampering.

**Active implantable devices**

Active implantable devices must minimize electricity risks such as leakage currents, overheating and insulation. Also minimize risks concerning connection with medical equipment such as defibrillators, or during maintenance and calibration which could cause excessive increase of leakage current, aging materials, excessive heat and decreased accuracy of measuring or control. Implants need to be identifiable, like type of device and manufacturing date. Possibly without surgery.

**Protection against mechanical and thermal risk**

Patients and users should be protected against mechanical risk such as (resistance to) movement and instability. Vibrations and noise must be reduced as much as possible such that any risk attached is as low as possible. An exception is made for devices which use sound or vibration as treatment. Connectors and terminals for power, gas or liquid energy supplies which must be handled by users should be designed such that the risk while handling is minimized. Risks during this handling should be minimized by design such that placing certain components in the wrong way is impossible. When it is impossible to reduce this risk, warnings should be visible on the to be placed components.

**Protection against risk posed to the patients or user by devices supplying energy or substances.**

When any variable supplied amount of energy or substances is possible, these should be set and delivered accurately. Measures should be taken such that inadequate amounts are indicated, and dangerous levels are impossible to be administered. Control functions should be clearly specified in a visual and understandable way.

**Use by lay persons**

A Lay person, as explained in the Collins English Dictionary [2] and adapted to this
situation, is a person which is not part of the group of people that normally operate medical devices. They do not know the underlying effect of the device. These devices should be designed such that lay persons can use them safely and accurately during all stages of a procedure. Risk of bodily harm, such as pricks and cuts, must be reduced as much as possible. Wrong interpretation should not lead to errors. When possible, a procedure should be included such that the user can verify the intended working of the device and that the user is warned when the device is failing.

Requirements regarding the information supplied with the device

This would be chapter 3 of the MDR general safety and performance requirements. However, this guide focuses on the design aspects of a medical device. As chapter 3 is outside the scope of this capita selecta, this will not be explained here. For more information, please see Annex I ch3, Annex II and Annex VI of the MDR [3].

2.1.2 Conformity Assessment

Each medical device should be evaluated through a conformity assessment. These conformity assessments show that a device meets the expected requirements as found in the MDR (2017/645). The classification of the device can affect whether a Notified Body should be included in the process. Class I devices generally do not need a Notified Body to approve the conformity assessment. In this case the manufacturer can self-assess the device. Only when Class I devices are meant to be sterile, are re-usable surgical instrument or have a measuring function, a Notified Body should approve the conformity assessment. When a device meets the necessary conformity, it can receive a CE mark, and be introduced to the market. These notified bodies are appointed by the national authorities. They are independent and perform the conformity assessment inspection. For the Netherlands these notified bodies are ‘BSI Group’, ‘DEKRA Certification’ and ‘DARE!! Services’ [4]. For each type of medical device, there steps to be followed. These steps can be found in the Annexes of the MDR. Depending on what device, these steps can include Production Verification, Production Quality Assurance, Quality Management Systems, Technical documentation, Clinical Evaluation and so on. A smart overview of important steps can be found in the Conformity Assessment Router booklet of BSI [5].
2.2 Classification guide

Classification of a medical device is based on risks. The higher the risk affiliated with the device, the higher the classification. The MDR has 22 rules which need to be followed to determine which class a medical device belongs to. These rules are distributed over ‘non-invasive’, ‘invasive’ and ‘active’ -devices. In the coming part, these rules will be explained. For a clear overview of device classifications in flowchart form, see figure 2.1 which continues in Appendix A. The colors within the flowchart indicate in which classification the device falls. A bluish green rectangle indicates class I, a yellow rectangle indicates class IIa, an orange one indicates class IIb and a reddish purple one indicates class III. Any number in brackets in front of text, means that this is the rule number as found in the MDR classification annex. The flowchart is a modified flowchart from the "Medical Devices: Guidance document - Classification of medical devices" [6]. An updated document is expected of this classification of medical devices, as explained in the MDR, and should be finished within this year.

2.2.1 Non-invasive devices

Non-invasive devices are listed primarily as class I medical devices. (See figure 2.1) These are devices which do not touch the patient or only contact intact skin. Some examples of these devices are hospital beds or medical gloves (not surgical gloves). However, under the non-invasive category, 4 rules contain several exceptions which could lead to a different classification. Medical devices also remain classified as class I when they are intended to be used on wounds as a mechanical barrier, a compression device or to absorb ‘exudates’. Exudates are fluids that are excreted from lesions or inflammations. Second intent means that the wound heals from bottom upwards.

2.2.2 Invasive devices

Invasive medical devices are also defined by 4 rules. These rules are focused on the invasiveness, body orifice or surgically invasive, and the duration of use. Duration is divided over transient, short-term and long term. Transient means a duration of less than 60 minutes, short-term has a duration of 60 minutes to 30 days and the duration of long-term is defined as longer than 30 days.
Figure 2.1: First part of the classification flowchart, continues in Appendix A. Adapted from [6]. Higher class means higher risk. Numbers in brackets refer to the number of the rule as found in the MDR [3].

2.2.3 Active devices

An active device is defined by the MDR as a device which operates on a source of energy which is anything other than that of the human body or gravity. The flowchart also includes software in this case. Most active devices fall under class IIa or higher. There are some exceptions which would classify a device as class I.

2.2.4 Special exceptions

Besides the rules that are divided under the type of invasiveness, there are some extra rules that allow for exceptions. Devices which incorporate human tissue or derivatives from this are considered class III. When the device is meant for contra-
ception or the prevention of sexually transmitted diseases, it would fall under class IIb. However, when it is implanted or long-term invasive, it is considered class III. If the device is designed to disinfect or sterilize medical devices, it is a class IIa device. However, when the sterilized devices is a contact lens or meant for use invasively, it should be considered class IIb. Recording diagnostic images via X-ray gives a device a class IIa rating. Incorporating nanomaterials could place a device in class III, IIb or IIa considering a high-medium, low or negligible potential of internal exposure respectively. A device is considered class IIa if it is meant for administering medication by inhalation through a body orifice. But when the device can have an impact on the administered medication for life-threatening condition, it is a class IIb device. A device which is intended to dissolve and absorbed into the human body is class III when it’s intended to have an intended purpose in the stomach or gastrointestinal tract and is systematically absorbed by the human body. When applied to the skin or nasal/oral cavities and absorbed by the body the device is classified as class IIa. Other cases of absorbed devices are listed under class IIb. Active devices which have diagnostic functions which have a large impact on patient management are classified as class III. An example of such a device is an external defibrillator.

2.3 Biocompatibility

Biocompatibility is an important aspect of a medical device. It is the ability of a material to perform its function without triggering any adverse response from the host. The evaluation of biocompatibility is described in ISO 10993. Every material of a device which comes in contact with a user or patient should have been assessed with respect to their biocompatibility. Luckily the 2009 revision of ISO 10993 takes into account existing information of materials to determine if testing is necessary. The biocompatibility assessment subdivides the required tests under the device category, contact location and contact duration. The device categories consist of ‘surface devices’, ‘external communicating devices’ and ‘Implant devices’. Each of these categories has their own contact location subcategories. The possible contact locations for surface devices are ‘skin’, ‘mucosal membrane’ and ‘breached or compromised surface’. Contact locations for external communicating devices are ‘blood path, indirect’, ‘tissue/bone/dentin’ and ‘circulating blood’. Finally, the contact locations for implant devices are ‘tissue/bone’ and ‘blood’. Each of these subcategories are then again divided over three types of contact duration. Namely ‘limited’ (less than 24 hours), ‘prolonged’ (24 hours to 30 days) and ‘permanent’ (more than 30 days). The type of device, contact location and duration determines the types of tests needed to be performed to approve the material. A higher risk devices from the device categories combined with a higher risk contact location and the longest
contact duration requires the most amount of tests. The assessment contains a total of 12 biological effect tests. These are:

- Cytotoxicity
- Allergization
- Irritation or intracutaneous reactivity
- Systemic Toxicity
- Subcutaneous and subchronical toxicity
- Genotoxicity
- Implantation
- Hemocompatibility
- Chronical toxicity
- Carcinogenicity
- Reproduction/development toxicity
- Bio-degradation

Depending on what type of device the materials are incorporated with, such effects should be evaluated. An article written by the U.S. FDA, or the United States Food & Drug Administration gives a good overview on how such tests should be performed [7]. This document also gives a flowchart which can be used to decide if tests are needed or not, especially looking at already existing materials. An overview of which tests are needed for which type of device can be found in appendix B, along with the flowchart used to define the appropriate steps.

### 2.4 Electrotechnical aspects

Powered Medical Devices, especially in the Thoracic OR, have to be designed with safe electrotechnical aspects in mind. The electrotechnical standardization within the EU is governed by CENELEC, the European Committee for Electrotechnical Standardization. It is not mainly focused on medical devices, but there is an Electrical standard which is developed for medical electrical equipment. This standard is called IEC 60601. In this guide, there will be some remarks on grounding problems and solutions. However, for more information about all the electrical standards, please refer to IEC 60601 [8].
2.4.1 Grounding

Grounding is a common problem and can have severe consequences when ignored. In the thorax OR, there is quite some equipment which involves the heart. These devices can be connected to the heart via liquid filled catheters, epicardial and endocardial electrodes, and electrodes for intercardiac electrogram (EGM) measurements. There are two main ways that grounding can have an adverse effect on a device and its functions. These are broken grounds, and ground faults. A broken ground causes a device to not be connected to ground, and can cause a leakage current from the broken device through the patient into a well grounded secondary device (or table). When both devices are connected to the heart, this could lead to a leakage current high enough to cause ventricular fibrillation (VF). This is called a micro-shock. It is different from macro-shock, which for example could result from grabbing two power leads with both hands. The conductivity of the body plays a big role in this difference. Deadly currents for macro- and micro-shocks are 100 mA and 50 µA respectively. [9]

A ground fault happens when a device shorts to ground. Depending on how the grounds are managed in a setup, this could raise the ground potential locally. Devices which are connected near this faulty device, will have a higher ground level compared to devices connected elsewhere. When both such devices are connected to the heart, and one has an elevated ground potential, this can again cause a leakage current to go from the elevated ground potential device, through the heart and into the ground of the second device. Common solutions for this problem, is the addition of ground-fault circuit interrupters. However, as a manufacturer has no influence on how secondary devices in the OR behave, it is wise to incorporate extra failsafes into the design of a medical device. With heart connected equipment, the best way to protect the patient from micro-shock is to isolate or eliminate electrical connections to the heart. Modern blood pressure sensors already incorporate triple insulation, and conductive catheters can be used to distribute any current along the whole wall or the catheter connected to the patient. It is best to search for the most reliable solution with these problems in mind, in order to be prepared for a worst case scenario.

2.5 Technical documentation and Post-Market Analysis

The technical documentation, required for each medical device consists of multiple parts. [3] [10] These are:
1. Device description and specification

2. Information to be supplied by the manufacturer

3. Design and manufacturing information

4. General safety and performance requirements

5. Benefit-risk analysis and risk management

6. Product verification and validation

7. Post-market analysis documentation

2.5.1 Device description and specifications

The MDR forces manufacturers to include a Unique Device Identification (UDI) for each of their medical devices. It consists of the Device Identifier (UDI-DI) and the Production Identifier (UDI-PI). The UDI-DI is the primary identifier of a device and provides a link to the UDI database. The UDI-PI identifies the expiration date, the lot number and a serial number of a medical device. This UDI data is registered in the new EUDAMED database. EUDAMED stands for European Databank on Medical Devices and is introduced with the new MDR. It is a database which holds health and safety information of medical devices and provides access to specific data like identification, certifications and adverse events.

2.5.2 Information to be supplied by the manufacturer

The information supplied by the manufacturer consists of the user instructions and a complete set of labels. These labels consists of data regarding manufacturer data, indications of medicinal substances used and lots of other information. A complete set of instructions is to be found in the 2017/745 regulation under Annex I, chapter III.

2.5.3 Design and manufacturing information

Design and manufacturing information concerns the key design stages of the medical device. It should make clear how a medical device was designed, and show that the design aspects have been followed. The information also shows the manufacturing description, validation and final testing of the medical device.
2.5.4 General safety and performance requirements

General safety and performance requirements refer back to the design aspects, in the performance area of Annex I. It should show that the design incorporates the requirements found in Annex I. Methods and documents stating the conformity with these standards should be added as well.

2.5.5 Benefit-Risk analysis and risk management

During the pre-market phase, the risk management of the device and company should be described in this part of the technical documentation. It includes the risk management of the device, the known risks, benefit-risk evaluations but also the management of the post-market analysis. More on this can be found in Annex I, Chapter 1.4 and ISO 14791.

2.5.6 Product verification and validation

Product verification and validation is crucial for especially class III devices. The MDR states that low risk devices should have clinical evaluation reports, and high risk devices need thorough clinical investigations and clinical data. It also holds information on pre-clinical testing and special validations. These special validations are for devices which incorporate medical substances, human or animal cells and tissue, absorbable-, sterile- and measuring devices. The clinical evaluation for low risk devices can consist of scientific literature studies, clinical investigations and alternative treatment options. Class III devices which need clinical data, can request advice from an expert panel appointed by the commission of a notified body.

2.5.7 Post-Market Analysis

The final part of the technical documentation comes after introduction into the market, when a device has received the CE mark. This post market analysis collects information about incidents, corrective actions, undesired side-effects, feedback and complaints and tracking similar medical devices. The data gathered by this post-market surveillance is used to feed back into the technical documentation, and used for the device risk management. [11]
2.6 Acceptation by a hospital

Once a device has entered the market, it can be acquired by customers. One of these customers are hospitals. Within a hospital there are several groups which involve themselves with the acquisition, testing and accepting the devices into the clinical environment of the hospital.

2.6.1 Steps for acquisition

Within the MST, the policy of acquiring devices consists of 5 steps. These steps are depicted in figure 2.2.

![Diagram of 5 basic steps to device acceptation](image)

**Figure 2.2:** The 5 basic steps to device acceptation for the Medisch Spectrum Twente. MMC = Medical Materials Committee, PRIA = Prospective Risk Assessment and Analysis

It starts with an application to request a certain device with the Medical Materials Committee (MMC). This committee will have to approve the device before an acquisition is started. Every device being introduced in the hospital, regardless of having a CE certification or being the subject of research has to be approved by the MMC. The application covers what kind of device or material is is. If the device is new within the MST, it will need to undergo another procedure covering risk analysis and training. This procedure also covers software, and if it is used for a study or not. In the case that it is used for a study, the METC or Medical Ethical Review Committee will need to approve the study as well. The required training is also covered in the document. When needed, it should state how the training will be arranged. When the MMC approves the request, it will start to acquire the necessary data from the manufacturer. This consists of the Conformity Assessment and data regarding a set of requirements. An example of a requirement are service intervals. Afterwards, the MCC will inform the requesting department by a written decision. When a device is found to be in risk class IIb or III, the requesting department will have to do a risk analysis and add this to the user protocol. Which risk classification the device falls into, can be found from the conformity assessment. This additional risk analysis is referred to as a ‘Prospective Risk Assessment and Analysis’ or PRIA in Dutch and will be discussed later. In the case that an existing protocol already exists, it is allowed to adapt and use this. When the device is acquired and received,
it will be subjected to inspection and tests. During transport, the device might have been damaged.

If training is needed for the device, this will be arranged so that the users can handle the device as well as possible. These trainings are repeated and adjusted when needed after evaluation. High risk devices have a refresher course every three years.

Finally, the device will be evaluated during use. When the evaluation is positive, the device will be added to the standard material assortment. Devices which do not have a CE certification will be treated differently. This also holds for devices which will be used outside of their intended use. Generally such devices are not allowed to be used within the operating room, but there is a possible exception when used for research. Such devices are subjected to a strong risk analysis and boundary conditions. For each situation, these boundary conditions can differ. Only when the risks are acceptable, the device will be used.

2.6.2 PRIA

The PRIA, Prospective Risk Assessment and Analysis is carried out in order to determine and adjust any risk that might come from a change in treatment, procedure or technology. In order to perform the assessment, a group of experts is formed. This group of experts consists of any needed input concerning the device or change in procedure. It is even possible to involve patients during this assessment when needed. During the assessment the multidisciplinary group of experts come together to discuss the progress. A standard PRIA has 3 meetings of about 1,5 hours, spread over about 4 weeks. It also consists of one meeting which spans half a day. During the meeting the various tasks within a PRIA are discussed. Such tasks consist of creating flowcharts of risky processes, risk inventory and measures. From the assessment, the main necessary actions are communicated to the relevant departments. The feasibility of such actions are discussed prior to communication. Concluding, the PRIA-report is sent to the PRIA coordinator for inclusion in hospital-wide safety topics and the annual review.
Chapter 3

Examples

To conclude this guide, two examples are given to show how this can be used. These examples are a cardiac ablation catheter, and the commonly used scalpel.

3.1 Cardiac ablation catheter

A cardiac ablation catheter is a device used to scar heart tissue by using heat or cold. This is done to block abnormal electric signals within the heart. The procedure is commonly performed on patients suffering from arrythmias. Image 3.2 gives an example of how this catheter is used.

![Figure 3.1: Location and working of an ablation catheter](image)

3.1.1 Design aspects

Looking at the device from the design aspects, four aspects stand out. These aspects are infection, active implantable devices, active devices and protection against risk of supplying energy. Infection should be avoided by using well sterilised devices. This means that this device should be easy to clean and sterilize. For active implantable and active devices, extra attention should be given to single fault risks.
As the device can do quite some damage, it should have a fail-safe. This also holds for leakage current, overheating and insulation as the heat is produced by electrical current. Finally, the device should have a good and clear way to set the desired amount of energy for the ablation. The amount of energy may never be set too levels that could do too much damage. In this case there should be a reasonable indication of the useful damage as part of the procedure.

### 3.1.2 Classification

When going through the classification flowchart the following route is taken. It is an invasive medical device, which continues in Appendix A, figure A.2. A cardiac ablation surgery takes about 2 to 4 hours [13], which puts the device as short-term. As the device corrects the working of the heart, its classification will be class III.

### 3.1.3 Biocompatibility

Looking at the biocompatibility checklist, there are two options. If the material has already been used and tested for this particular intervention, there would be no need to test the materials. However, if this was the first device used in this way, the checklist from Appendix B figure B.3 shows which tests to apply. The device falls into the category describing ‘contacting from the outside with the inside of the body’. Its usage is short term and contacts the vascular circulatory system. This means that the used materials should be tested for their cytotoxicity, allergization, irritation or intracutaneous reactivity, systemic toxicity (acute) and hemocompatibility.

### 3.2 Scalpel holder (reusable)

The reusable scalpel holder is a broadly used device, and in this example will be used as a device in the thoracic OR. During the morrow procedure, a procedure which removes hypertrophic tissue from the inter-ventricular septum of the heart, a scalpel is used to cut away the hypertrophic tissue. The following aspects will be covered while looking at this device from this perspective. Image 3.2 shows a scalpel with its replaceable no. 36 blade.

#### 3.2.1 Design aspects

From a design aspect, this reusable scalpel is quite simple. The most important aspects will be found in the general requirement and from an infection and microbial contamination standpoint. The device should be designed such that the ergonomic
3.2.2 Classification

When looking at the classification from a thoracic OR point of view, it is possible to almost re-use the classification done as on the cardiac ablation catheter. The device is used surgically invasive, and transient or short-term. It also is used to correct the heart, which would give the device a classification of III. However, one of the exceptions in the classification shows that when the device is a reusable surgical instrument, its classification changes to class I. The blade holder will be class I, and the scalpel blade will be class III as it is not reusable.

3.2.3 Biocompatibility

For the scalpel, which is used for many applications, it is wise to check for all short-term biological effects. Coincidentally these are the same biocompatibility tests as found for the cardiac ablation catheter. Namely cytotoxicity, allergization, irritation or intracutaneous reactivity, systemic toxicity (acute) and hemocompatibility. As such scalpel blades are made from surgical steel, these would be suitable for use in this situation \[14\].
Bibliography


Appendix A

Classification Flowchart

Figure A.1: Risk classification flowchart, continues in next pages. Adapted from [6]. Higher class means higher risk. Numbers in brackets refer to the number of the rule as found in the MDR [3].
**Figure A.2**: Flowchart for Invasive Devices. Adapted from [6]. Higher class means higher risk. Numbers in brackets refer to the number of the rule as found in the MDR [3].
Figure A.3: Flowchart for Active Devices. Adapted from [6]. Higher class means higher risk. Numbers in brackets refer to the number of the rule as found in the MDR [3]
Figure A.4: Flowchart for Special rules. Adapted from [6]. Higher class means higher risk. Numbers in brackets refer to the number of the rule as found in the MDR [3].
Appendix B

Biocompatibility

B.1 Biocompatibility Flowchart

Figure B.1: Biocompatibility flowchart: Main [7]
Figure B.2: Biocompatibility Flowchart: Chart A [7]
## B.2 Biocompatibility Checklist

<table>
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<tr>
<th>Category</th>
<th>Contact</th>
<th>Biological effect</th>
<th>Evaluation of the biological evaluation</th>
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<td>Type of body contact</td>
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<td></td>
</tr>
<tr>
<td>Skin</td>
<td>Contact period</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Short term (&lt; 24 h)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Longer (&gt; 24 h bis 30 Tage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Permanent (&gt; 30 Tage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body surface</td>
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<td></td>
<td></td>
</tr>
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<td>O</td>
</tr>
<tr>
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<td>O</td>
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<td>O</td>
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<td></td>
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<td>B</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td></td>
<td>C</td>
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<td>O</td>
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<td>O</td>
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<tr>
<td></td>
<td>B</td>
<td>O</td>
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*Figure B.3: Biocompatibility checklist [15]*