MINISTRY of EDUCATION
National University of Science and Technology
POLITEHNICA Bucharest

Doctoral School of Industrial Engineering and Robotics

Marina Roxana IORDĂCHESCU (ȘOLEA)

Summary of the Phd Thesis

IDENTIFYING OPTIMAL SOLUTIONS FOR THE MAINTENANCE AND UPKEEP OF MEDICAL INSTRUMENTS

Research supervisor,

Prof. univ.dr.ing.mat. Augustin SEMENESCU (POLITEHNICA București)

2025

National University of Science and Technology POLITEHNICA Bucharest

CSUD Decision POLITEHNICA Bucharst nr. ……. from ……………………

Marina Roxana IORDĂCHESCU (ȘOLEA)

PhD Thesis

Doctoral Committee

President	Prof.Univ.Dr.Ing.Ec.Mat Augustin SEMENESCU	National University Of Science And Technology POLITEHNICA Bucharest
PhD Supervisor	Prof.Univ.Dr.Ing.Ec.Mat Augustin SEMENESCU	
Referent		
Referent		
Referent		

2025

Table of Contents

Introduction

The maintenance and upkeep of medical instruments are vital to ensuring their functionality, safety, and reliability in healthcare settings. As medical devices become more complex, proper maintenance is increasingly important to avoid procedural complications, ensure patient safety, and maintain high standards of care. However, challenges such as material degradation, wear, corrosion, and harsh sterilization can affect instrument performance and lifespan.

This research focuses on identifying the factors influencing the durability and performance of medical instruments, including materials, coatings, and sterilization processes. It also explores strategies to improve maintenance practices. A key issue is the lack of standardized, comprehensive approaches to instrument care, which can lead to safety risks and higher healthcare costs. Additionally, the study emphasizes the need for cost-effective and environmentally sustainable maintenance solutions, addressing the growing concern over medical waste and the financial burden of frequent instrument replacement.

Maintaining medical instruments is crucial for ensuring their safety, functionality, and reliability in healthcare. With the increasing complexity of medical technology, proper upkeep helps prevent complications, protects patients, and improves care quality. However, instruments face challenges like wear, corrosion, and damage from sterilization, which can shorten their lifespan.

This research explores how materials, coatings, and sterilization methods impact instrument durability. It highlights the lack of a standardized maintenance approach and the need for cost-effective, environmentally friendly practices. The goal is to develop better strategies that enhance instrument performance, reduce healthcare costs, and support sustainability.

This research emphasizes the critical role of medical instrument maintenance in ensuring patient safety and healthcare quality. Surgical tools must remain functional and durable, especially as healthcare systems face cost and environmental pressures. The study offers evidence-based strategies to improve maintenance practices, aiming for both cost-efficiency and sustainability. It also contributes scientifically by exploring how materials, coatings, and sterilization methods affect instrument longevity.

The thesis is organized into seven chapters:

- **Chapter I**: Reviews types and functions of surgical instruments, materials used, and their required properties.
- **Chapter II**: Examines damage types in steel instruments, including wear and corrosion.
- **Chapter III**: Discusses decontamination methods and their effects on instrument integrity.
- **Chapter IV**: Presents experimental results comparing coatings and steel grades to assess durability and performance.
- **Chapter V**: Proposes a business plan for implementing improved maintenance practices in healthcare settings.
- **Chapter VI**: Analyzes the costs of different maintenance strategies, highlighting economic benefits of optimized care.
- **Chapter VII**: Concludes the study, summarizes findings, and outlines the author's personal contributions to research and practice.

Overall, the thesis provides a comprehensive framework for enhancing surgical instrument care through scientific, practical, and economic insights.

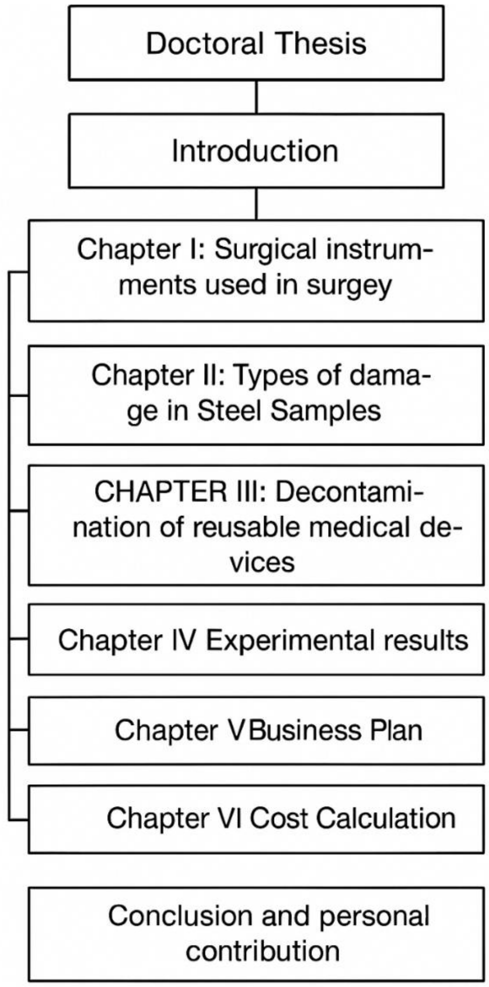


Fig I Schematic representation of the structure of the Phd Thesis

Part I.

Current stage of the research of OPTIMAL SOLUTIONS FOR THE MAINTENANCE AND UPKEEP OF MEDICAL INSTRUMENTS

Chapter I. Surgical instruments used in surgery

I.1 General considerations regarding surgical instruments

Medical instruments are essential tools used by healthcare professionals for diagnosis, treatment, and disease prevention. They range from simple diagnostic tools to complex surgical and life-support devices. Proper cleaning, storage, and sterilization of these instruments are vital to maintaining hygiene, ensuring patient safety, and preventing infections or complications.

The COVID-19 pandemic highlighted the critical role of medical instruments such as testing kits and ventilators. Advances in technology have also improved instrument precision and safety, introducing innovations like robotic surgery, portable health monitors, and virtual reality tools for training and education. However, high costs and limited access in low-resource areas remain significant challenges.

Medical instruments can be classified by:

1. **Infection risk**:
   - *Critical instruments* (e.g., scalpels, needles) penetrate the body and require strict sterilization.
   - *Semi-critical instruments* (e.g., endoscopes) contact mucous membranes and need high-level disinfection.
   - *Non-critical instruments* (e.g., stethoscopes) contact intact skin and require basic disinfection.
2. **Purpose**:
   - *Diagnostic tools* include stethoscopes, thermometers, reflex hammers, and tuning forks.
   - *Injection and puncture tools* like syringes and needles are used for administering or extracting fluids.
   - *Routine treatment tools* such as forceps, scissors, scalpels, and clamps aid in general procedures.
   - *Patient care devices* include catheters, irrigation systems, resuscitation kits, and sterile containers.
3. **Material composition**:
   - *Rubber and plastic instruments* include gloves, catheters, drainage tubes, infusion sets, and collection bags.
   - *Metal instruments* consist of surgical tools, bone instruments, and specialized kits made from stainless steel.
4. **Application**:
   - *General-purpose instruments* are used in standard procedures.
   - *Specialized instruments* are tailored for specific fields like orthopedics, ophthalmology, and neurosurgery.

Overall, this chapter highlights the critical role of medical instruments in modern healthcare, their classification, the need for proper handling, and the importance of technological advancements and equitable access.

I.2 Classification of Surgical Medical Instruments

Surgery is a critical medical specialty that addresses a wide range of health conditions through operative interventions. Successful surgical procedures depend not only on medical expertise but also on the use of specialized surgical instruments designed for precision, safety, and efficiency. These instruments are categorized based on their function within the surgical process.

The first category includes **cutting instruments**, such as scalpels and surgical scissors, which are essential for incising soft and hard tissues. Their shapes and handling techniques vary depending on the tissue type and procedure. **Scalpels** come in various designs—straight, curved, or sickle-shaped—and are held differently based on the incision's requirements. **Scissors** differ in blade and tip shapes, with specific uses ranging from cutting tissue to removing bandages.

Trocars, used for puncturing body cavities, consist of a stylet and cannula and are particularly useful in procedures involving fluid or gas evacuation.

The second category includes **instruments for tissue fixation and protection**, such as **forceps** and **retractors**. Forceps are adapted for either soft or firm tissues and may have anatomical or surgical designs. Retractors are used to hold back tissues and improve surgical field visibility, with some being self-retaining.

Exploration instruments, like **metal probes**, form the third category. These tools are used to investigate ducts, fistulas, or internal cavities, often serving as guides to protect surrounding tissues during incisions.

The fourth category encompasses **hemostatic instruments**, including **hemostatic forceps**, which help control bleeding by clamping vessels. These vary in design and are adapted to different tissue resistances.

Fifth, **tissue restoration instruments** such as **needles, needle holders, staples, and forceps** are used in suturing and tissue repair. Needles may be straight or curved, traumatic or atraumatic, with designs suited to different tissue types. Staples and specialized needles like Reverdin or Deschamp have unique applications in surgical closures.

The sixth category includes **bone surgery instruments**, designed for procedures involving cutting, shaping, and fixing bones. Tools such as **surgical hammers, saws, chisels, drills**, and **external fixators** ensure safe manipulation and stabilization of bone fragments or implants during orthopedic surgery.

The seventh category focuses on **ophthalmic instruments** used in eye surgeries. These include both diagnostic tools (e.g., **slit lamps, ophthalmoscopes, tonometers**) and surgical instruments (e.g., **microscopes, forceps, lasers, scissors, hooks**), which support delicate procedures like cataract removal or glaucoma treatment.

Finally, **surgical probes** serve multiple purposes across specialties—from diagnosis and drainage to aspiration and suturing. These instruments vary greatly, including specialized probes like the **Foley catheter, Sengstaken-Blakemore tube**, and **Kehr drainage probe**, tailored for specific anatomical functions.

In conclusion, surgical instruments are diverse and highly specialized, tailored to the demands of modern surgical techniques. Their proper use, maintenance, and sterilization are critical for ensuring patient safety, minimizing complications, and improving surgical outcomes.

I.3. Biomaterials Used in the Manufacturing of Surgical Instruments

This chapter examines the critical role of biomaterials in the manufacturing of surgical instruments, focusing on their properties such as biocompatibility, mechanical strength, corrosion resistance, and ability to withstand sterilization. Biomaterials are materials specifically engineered for medical use, designed to interact safely with biological tissues without causing adverse reactions.

The chapter begins by distinguishing biomaterials from natural biological materials. Biomaterials are developed for applications that involve direct or indirect contact with the human body and are essential in supporting, repairing, or replacing body functions during surgical interventions.

Several classification systems for biomaterials are presented. Based on their interaction with biological tissues, biomaterials can be classified as bioinert, bioactive, biotolerant, bioresorbable, or hybrid materials. According to their medical application, they can be intra-corporeal, para-corporeal, or extra-corporeal. Another classification considers their use in hard or soft tissue applications and whether they are temporary or permanent solutions.

Biomaterials are also categorized by chemical composition: metals and alloys, polymers, ceramics, and composites. Furthermore, they can be of natural or synthetic origin. Each class of biomaterials presents specific advantages and limitations, and the choice depends on the intended use and environment.

In the manufacturing of surgical instruments, stainless steel is the most commonly used material. It is preferred due to its excellent corrosion resistance, mechanical durability, and biocompatibility. Stainless steel contains chromium, which forms a passive oxide layer that protects against rust and degradation. It also offers good machinability and ease of sterilization.

Different grades of stainless steel are used for specific surgical applications. Martensitic stainless steel is chosen for its hardness and wear resistance. Molybdenum-alloyed stainless steels offer improved corrosion resistance. Precipitation-hardened stainless steels provide high strength and resistance to fatigue. Austenitic stainless steels, known for their ductility and non-magnetic properties, are often used for precision instruments such as needles and cannulas.

The chapter concludes by emphasizing that the selection of appropriate biomaterials is crucial for the performance, durability, and safety of surgical instruments. These materials must withstand repeated sterilization, resist chemical and biological degradation, and be suitable for use in clinical environments where precision and hygiene are vital.

I.4. Examples of Medical Instruments and the Materials They Are Made From

1. Biopsy Needle Materials:

- Austenitic stainless steel offers excellent corrosion resistance in most environments but can suffer from pitting and stress corrosion cracking in hot chloride conditions. It is resistant to potable water with limited chloride levels.
- Austenitic stainless steel alloyed with molybdenum (Mo) provides improved corrosion resistance, especially in chloride environments, tolerating higher chloride concentrations in potable water.
- High-resistance Mo-alloyed, vacuum-melted austenitic stainless steel features high purity and structural uniformity, resulting in excellent general, intergranular, pitting, and crevice corrosion resistance. It is widely used in medical implants and devices.
- Martensitic stainless steel is known for its hardening capability and cold plasticity; after heat treatment, it offers very good corrosion resistance and is used in surgical tools like suturing needles and drills.
- Mo-alloyed stainless steel combines excellent machinability, wear resistance, and corrosion resistance, making it suitable for precision instruments such as dental tools and watch components.

2. Staples Materials:

- Martensitic stainless steel (X35Cr14) is commonly used for its strength and corrosion resistance.
- Mo-alloyed stainless steel (X22CrMoNiSi13-1) provides enhanced corrosion resistance and machinability.
- Precipitation-hardening stainless steel offers high strength, good ductility, corrosion resistance comparable to austenitic steels, and good weldability. It combines features of both austenitic and ferritic steels.

3. Scalpel Blades Materials:

- Mo-alloyed stainless steel (X22CrMoNiSi13-1) delivers good corrosion resistance and machinability.
- Spring stainless steel provides high mechanical strength, a non-magnetic microstructure, excellent energy storage, corrosion resistance similar to ASTM 301-304 grades, and some vulnerability to stress corrosion cracking in chloride-rich environments.
- Martensitic stainless steel, after heat treatment, attains high hardness with excellent corrosion and wear resistance. It is also used in razor blades and various knives.

4. Suture Needles Materials:

- Martensitic stainless steel (X35Cr14) offers durability and corrosion resistance.
- Mo-alloyed stainless steel (X22CrMoNiSi13-1) features good corrosion resistance and mechanical properties.
- Precipitation-hardening stainless steel (S46910) provides high strength and corrosion resistance.

- Vacuum-melted Mo-alloyed austenitic stainless steel shows superior tensile and fatigue resistance, excellent corrosion resistance, and operates across a wide temperature range; it is also used in dental and acupuncture needles.

I.5 Conclusion

This chapter provides a comprehensive overview of surgical instruments and their critical role in modern medical procedures. It highlights the classification of these tools by function—cutting, grasping, retracting, and suturing—and stresses the importance of understanding their specialized uses to enhance surgical precision, patient safety, and outcomes. Proper selection, handling, and sterilization of instruments are vital to surgical success, with material properties and ergonomic design playing key roles.

Technological advances, including robotic-assisted surgery and AI integration, have revolutionized surgical practice by improving accuracy and minimizing invasiveness, though challenges like cost and training remain. The chapter also explores the impact of material choices, such as stainless steel, titanium, and composites, on instrument durability and functionality. Sterilization methods are examined as essential for maintaining patient safety.

The evolution of surgical tools from basic instruments to sophisticated devices underscores the continuous progress in surgical science. Emphasis is placed on the necessity of ongoing education and training through simulation and hands-on practice to keep pace with emerging technologies and ensure optimal surgical performance. Future innovations may include smart, biodegradable, and AI-enhanced instruments aimed at improving precision, accessibility, and affordability in healthcare.

Chapter II-Types of damage in Steel Samples

Steel is vulnerable to different forms of degradation that can impact its structure, performance, and longevity. These types of degradation can be categorized as chemical, mechanical, thermal, or electrochemical. Below are the primary ways steel samples can be affected:

II.1. Chemical Degradation

This occurs when steel interacts directly with chemicals in its environment, without involving an electrochemical reaction.

II.1.1 Direct chemical corrosion

Direct chemical corrosion occurs when metals react with aggressive chemicals in dry or high-temperature environments without involving moisture or electrochemical processes. Typical examples include the oxidation of steel forming iron oxides (FeO, Fe_2O_3, Fe_3O_4) in the presence of oxygen, and corrosion caused by sulfur compounds like sulfur dioxide and hydrogen sulfide, common in petrochemical industries. This corrosion also takes place in acidic conditions with substances such as hydrochloric or sulfuric acid, leading to rapid metal degradation.

Key causes include:

- High-temperature oxidation: Steel exposed to oxygen at elevated temperatures develops oxide scales that weaken the metal, common in furnaces and boilers.
- Sulfur-induced corrosion (sulfidation): Reaction with sulfur gases forms iron sulfides, compromising strength, especially in refineries and power plants.
- Nitrogen-related degradation (nitridation): Formation of iron nitrides at high temperatures leads to embrittlement, seen in aerospace and furnace components.
- Halogen-induced corrosion: Contact with chlorine or fluorine produces volatile metal halides, damaging surfaces in chemical and incineration industries.
- Acid corrosion: Exposure to strong acids accelerates material breakdown in chemical plants and industrial settings.

The effects of direct chemical corrosion include surface scaling, material weakening, brittleness, and increased risk of fractures and failure. To prevent this, industries use protective coatings (such as aluminum or chromium oxide layers), corrosion-resistant materials (stainless steel, advanced alloys like Inconel), and control environmental factors by reducing exposure to corrosive gases and neutralizing harmful chemicals. Heat treatments and passivation are also employed to improve resistance.

In conclusion, managing direct chemical corrosion through material selection, protective measures, and environmental control is essential for maintaining the integrity and extending the lifespan of metal components in harsh industrial environments.

II.1.2 Solubilization-Induced Degradation

The chapter II.1.2 focuses on solubilization-induced degradation, a corrosion mechanism where the dissolution of material components occurs due to interaction with solvents or aggressive chemical agents. This process leads to the gradual breakdown of metals and alloys as soluble compounds form and are carried away from the surface, weakening the structural integrity of the material. Factors influencing solubilization include the chemical composition of the environment, pH levels, temperature, and the presence of complexing agents that enhance solubility.

The chapter explores how different materials, especially metals used in industrial applications, respond to solubilization in various chemical environments. It discusses the role of surface films and protective oxide layers that can be compromised, accelerating degradation. Additionally, the impact of solubilization on mechanical properties, such as strength and fatigue resistance, is analyzed.

Preventive measures covered include material selection with improved corrosion resistance, surface treatments to enhance barrier properties, and environmental control to limit exposure to aggressive solvents. The chapter also highlights the importance of monitoring and maintenance to detect early signs of solubilization-induced damage, ensuring long-term durability of critical components.

Chapter II.1.3 examines solubilization-induced degradation specifically in steel, focusing on how exposure to aggressive chemical environments leads to the gradual dissolution of alloying elements from the steel matrix. This degradation mechanism weakens the material by altering its chemical composition and microstructure, making it more vulnerable to mechanical failure and corrosion.

The chapter outlines how factors such as low pH, high temperatures, and the presence of complexing agents (e.g., chlorides, acids, or chelating compounds) accelerate the solubilization process. In particular, it discusses the leaching of critical elements like chromium, nickel, and molybdenum from stainless and alloy steels, which compromises their corrosion resistance and structural performance.

Several industrial environments are identified as high-risk for this type of degradation, including chemical processing plants, petrochemical facilities, and wastewater systems. The chapter also highlights the consequences of solubilization, such as reduced tensile strength, intergranular attack, and premature failure of steel components.

To mitigate these effects, strategies such as using high-alloy steels, applying protective coatings, and maintaining controlled environmental conditions are recommended. The chapter concludes by emphasizing the importance of regular inspection, predictive maintenance, and material selection tailored to specific service conditions to ensure the long-term integrity of steel structures exposed to solubilizing environments.

II.3 Conclusions

This chapter provides a comprehensive overview of the key damage mechanisms affecting steel, including mechanical, thermal, and chemical degradation. By categorizing these forms of damage and examining their causes, the chapter offers a structured understanding of how steel deteriorates in various environments. Such insights are vital for improving the performance and durability of steel through informed material selection, processing, and maintenance.

The discussion emphasizes the practical significance of understanding steel damage in industrial sectors such as construction, automotive, aerospace, and energy. Preventive strategies—like applying protective coatings, choosing suitable alloys, and optimizing loading conditions—are essential for minimizing failures and enhancing safety and cost-effectiveness.

The chapter also explores the complex interactions between different damage types, which often act simultaneously in real-world applications. It underscores the value of advanced characterization techniques, such as electron microscopy and mechanical testing, in analyzing degradation and predicting failure.

Despite progress, challenges remain in accurately forecasting long-term degradation under complex service conditions. Future efforts should focus on developing predictive models using computational tools and AI, as well as on innovating materials with enhanced resistance to damage.

Finally, the chapter highlights the role of damage analysis in promoting sustainability. Extending the lifespan of steel components through improved design and repair strategies contributes to reduced waste, more efficient resource use, and a lower environmental impact in steel-intensive industries.

CHAPTER III: Decontamination of reusable medical devices

III.1 Introduction

This chapter highlights the critical importance of sterilizing reusable surgical instruments to maintain aseptic conditions during medical procedures. Steam sterilization remains the most reliable and widely used method, capable of achieving a sterility assurance level (SAL) of 10^{-6}, meaning the likelihood of one surviving microorganism is no more than one in a million. Sterilization must also eliminate biological residues, particularly proteins, to reduce the risk of transmitting diseases such as variant Creutzfeldt-Jakob disease (vCJD), with cleanliness standards limiting residual protein to under 5 mg of BSA per surface.

Despite well-established sterilization protocols, failures still occur, posing risks to patient safety. The Emergency Care Research Institute (ECRI) identified improperly sterilized instruments as a major health hazard in 2017. Large hospitals may reprocess tens of thousands of surgical tools daily, with instruments often reused many times before being discarded due to visible wear or damage. However, no universal guidelines exist to define safe reuse limits.

Decontamination encompasses cleaning, disinfection, and sterilization, aiming to ensure instruments are safe for both patients and healthcare workers. Reusable medical devices span a wide range, including surgical tools, prostheses, hospital equipment, and mobility aids—making effective decontamination essential for overall healthcare safety.

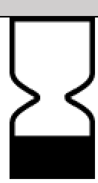
Table III.1 Classification Based on Infection Risk and Decontamination Recommendations for Reusable Medical Devices

Risk level	Use of device	Recommendation
High	• In close contact with areas where the continuity of the skin or mucous membranes is interrupte • Penetration of tissues or sterile cavities	Sterilization
Intermediate	• In contact with mucous membrane contaminated with highly virulent or easily transmissible microorganisms • Before use on immunocompromised patients	High-level sterilization or disinfection
Low	In contact with healthy skin	Cleaning

III.3 Decontamination Stages

The following table presents the meaning of graphical symbols found on the packaging of medical devices. These symbols must be recognized by medical personnel, who should consider the appropriate decontamination method for each medical device.

Table III.2 The meaning of graphic symbols found on medical device packaging

Graphic symbol for marking	Meaning of the symbol	Graphic symbol for marking	Meaning of the symbol
	Expiration date		Manufacturing date

CE	European Community Mark	LOT	ot Number
SN	Series Number	STERILE	Sterile product
STERILE	Thermally sterilized	STERILE EO	Sterilized with Ethylene Oxide
STERILE R	Sterilized with Gamma Radiation	2	Single Use, Do not use a second time!

Reusable medical devices must be processed according to a decontamination cycle. The stages of the cycle are highlighted in the figure below (Fig. III.1) and will be analyzed in detail.

Fig.III.1 Decontamination cycle

The decontamination cycle is a systematic and essential process in healthcare settings designed to ensure that reusable medical and surgical instruments are safe for use on patients. It begins with the preparation phase, during which instruments are carefully inspected, sorted, and documented. This step ensures that damaged tools are removed from circulation and that each item is properly categorized based on its intended use and required level of decontamination. Proper preparation also facilitates traceability and helps prevent cross-contamination between instruments used in different procedures.

Once instruments are prepared, the cycle moves into the cleaning phase. This involves the removal of all visible soil, organic matter such as blood or tissue, and other contaminants from the surfaces of the instruments. Cleaning can be performed manually or with automated systems such as ultrasonic cleaners or washer-disinfectors. The effectiveness of this step is crucial, as the presence of even microscopic organic material can protect microorganisms from subsequent disinfection and sterilization. Detergents and enzymatic solutions are commonly used to break down complex biological residues and ensure that instruments are thoroughly cleaned.

Following cleaning, the instruments undergo disinfection, a process that involves the use of chemical agents to destroy most pathogenic microorganisms. While disinfection does not guarantee the elimination of all bacterial spores, it significantly reduces the number of viable microbes and lowers the risk of infection. Disinfection is especially important for semi-critical instruments that contact mucous membranes or non-intact skin but do not penetrate sterile body areas. In some settings, high-level disinfection is applied to instruments that cannot withstand the high temperatures of sterilization.

The final and most critical stage of the decontamination cycle is sterilization. This step is designed to eliminate all forms of microbial life, including bacteria, viruses, fungi, and highly resistant bacterial spores. Steam sterilization, also known as autoclaving, is the most common method used due to its proven reliability, efficiency, and ability to penetrate complex instrument surfaces. Other sterilization techniques include ethylene oxide gas, hydrogen peroxide plasma, and dry heat, which are used for heat-sensitive devices. Achieving a sterility assurance level (SAL) of 10^{-6} is the goal of this step, meaning there is only a one-in-a-million chance that a single viable microorganism remains after sterilization.

Once sterilized, the instruments are allowed to cool and are then packaged or stored in sterile environments until they are needed. The integrity of the sterile barrier system must be maintained throughout handling and storage to prevent recontamination. Additionally, healthcare professionals must monitor and validate every phase of the decontamination process using indicators, routine maintenance, and adherence to protocols.

Altogether, the decontamination cycle forms a critical foundation of infection control and patient safety. Failure at any stage can compromise the effectiveness of the entire process and increase the risk of healthcare-associated infections. By following this cycle rigorously and maintaining high standards, medical facilities can ensure that reusable instruments remain safe, functional, and compliant with health regulations.

III.3 Conclusions

The conclusions presented in this chapter emphasize the critical importance of proper decontamination procedures for medical devices in ensuring patient safety and preventing healthcare-associated infections. A comprehensive and structured decontamination process, which includes cleaning, disinfection, and sterilization, is essential to eliminate all contaminants and maintain the sterility of instruments used in medical settings. Each stage of this process plays a specific role, and neglecting any of them may compromise the effectiveness of infection control.

Cleaning is identified as the foundational step, as it removes biological material that could hinder subsequent sterilization. The use of appropriate cleaning agents and methods, such as enzymatic detergents and automated washing systems, enhances this step’s effectiveness and prevents the development of biofilms. The required level of decontamination depends on how the instrument is used. Non-critical devices require basic disinfection, semi-critical devices demand high-level disinfection or sterilization, and critical instruments must be fully sterilized to eliminate all forms of microbial life.

After sterilization, proper storage using protective packaging ensures that sterility is maintained until the instruments are used. Monitoring tools such as chemical and biological indicators, along with routine audits and documentation, are necessary to verify the effectiveness of the process. The adoption of advanced sterilization technologies, such as hydrogen peroxide vapor, plasma sterilization, and UV-C light, contributes to more efficient and reliable decontamination practices.

Staff training plays a vital role in maintaining high standards, as well-informed healthcare workers are better equipped to follow infection control procedures correctly. Adhering to international guidelines and protocols established by health authorities like WHO, CDC, and AAMI ensures compliance and enhances patient safety.

In conclusion, an effective decontamination strategy—supported by strict procedures, quality control, modern technologies, and skilled personnel—significantly reduces the risk of infection and contributes to better healthcare outcomes.

Part II

Personal contribution for OPTIMAL SOLUTIONS FOR THE MAINTENANCE AND UPKEEP OF MEDICAL INSTRUMENTS

Chapter IV Experimental results

IV.1 Study of TiN and TiCN coatings for stainless steel surgical instruments

IV.1.1 Introduction

This chapter emphasizes the importance of strict regulations in hospitals and medical clinics concerning the use of surgical instruments to ensure the safety of both patients and healthcare personnel. Given that most surgical instruments are reused, they must undergo repeated cleaning and sterilization. These instruments are typically made from durable materials like austenitic stainless steel, which can withstand harsh sterilization conditions involving high temperatures, humidity, and pressure. However, such conditions can lead to corrosion, surface defects, and reduced mechanical performance, increasing the risk of microbial contamination due to trapped residues.

Austenitic stainless steel is widely used across various industries because of its corrosion resistance, mechanical strength, and ductility. Nonetheless, its surface can deteriorate when exposed to aggressive environments, compromising its protective properties. To address these issues, surface modification techniques have become increasingly important for enhancing the material's physical, mechanical, and tribological properties. One of the most promising approaches involves the use of thin film coatings to create a protective barrier against corrosion and wear.

Thin film deposition, especially with titanium-based compounds, offers significant benefits for medical applications. Coatings such as TiN (titanium nitride), TiC (titanium carbide), TiCN (a composite of TiN and TiC), and other titanium-based layers improve the corrosion resistance, durability, and overall mechanical performance of medical instruments. These coatings provide superior strength, thermal stability, biocompatibility, and wear resistance, making them ideal for surgical tools and implants.

The research presented focuses on a comparative analysis of using TiN and TiCN coatings to enhance the surface of austenitic stainless steel. TiCN, as a hybrid material, is anticipated to combine the benefits of both TiN and TiC, offering improved protection and performance. These advancements in surface engineering not only extend the service life of surgical instruments but also contribute to safer medical practices through better contamination control.

IV.1.2 Materials and methods

Stainless steels are widely used in the production of surgical instruments primarily due to their excellent corrosion resistance and diverse mechanical properties, which make them appropriate for a broad range of applications. Guidelines such as ASTM F899 and ISO 7153 provide comprehensive recommendations for selecting and applying stainless steels in the manufacturing of both cutting and non-cutting surgical tools, as well as in components like fittings and assemblies.

Austenitic stainless steels—specifically grades 302, 303, 304, and 316—are among the most commonly used materials in the production of both cutting instruments (such as knives, chisels, gouges, and curettes) and non-cutting tools or components (including cannulas, forceps, retractors, specula, tunnelers, and probes). These alloys offer the highest corrosion resistance among all stainless steel classes; however, their mechanical strength is relatively low. Therefore, enhancing their surface properties could lead to improved wear resistance.

Table IV.1 The deposition parameters

Parameters	TiN	TiCN
Cathode	Ti 99.99% purity	Ti 99.99% purity
Work pressure	$3x10^{-4}$mbar	$3x10^{-4}$mbar
Argon flow	10cc/min	10cc/min
Nitrogen flow	110cc/min	80cc/min
Methane flow	-	30cc/min
Current intensity	90A	90A
Substrate polarization potential	-150V	-150V
Deposition duration	30min	30min

To create two different types of coatings—titanium nitride (TiN) and titanium carbonitride (TiCN)—a 304 stainless steel substrate was coated using the cathodic arc evaporation technique, following parameters established in prior research. The main objective of this investigation was to assess and compare the surface topography and mechanical characteristics of the coatings in order to identify the more suitable option for commercial use. The deposition was carried out using a conventional cathodic arc system, with a 304 stainless steel strip serving as the substrate (refer to Table IV.1 for the specific processing parameters).

Before the coating process, the substrate was degreased and cleaned ultrasonically in trichloroethylene, then dried using carbon dioxide snow. Surface preparation was completed through argon ion bombardment for five minutes at an accelerating voltage of 950 V. To analyze the coatings, surface morphology and topography were investigated using a HITACHI TM3030Plus scanning electron microscope (SEM). Surface roughness and coating thickness were measured with a Dektak 150 Veeco-Brucker profilometer. Furthermore, Vickers microhardness tests were conducted with a TriboLab UMT system from Brucker, applying a load of 100 grams.

IV.1.3Results and discussion

The experiment employed three high-precision instruments to analyze surface modifications and material characteristics: the scanning electron microscope (SEM), Dektak 150 Veeco-Bruker profilometer, and TriboLab UMT by Bruker.

1. Scanning electron microscope (SEM)

   SEM provides high-resolution imaging of material surfaces using a focused electron beam. It enables detailed analysis through signals such as secondary electrons (for surface morphology), backscattered electrons (for atomic contrast), and X-rays (for elemental composition via EDS). Widely used in materials science, medicine, nanotechnology, and forensics, SEM offers magnifications up to 10 million times and is crucial for analyzing microstructures. However, it requires vacuum conditions and conductive coatings for non-metallic samples.

2. Dektak 150 Veeco-Bruker profilometer

   This stylus profilometer measures surface topography with nanometer precision. Using a diamond-tipped stylus, it evaluates step heights, film thickness, surface roughness (Ra, Rq, Rz), and stress in thin films. It accommodates various sample sizes and scanning lengths (50 µm to 55 mm), operating under Vision 64 software for 2D/3D mapping and statistical analysis. It is essential in semiconductor, materials science, optics, and MEMS applications.

3. TriboLab UMT by Bruker

   The TriboLab UMT is a modular mechanical tester for evaluating friction, wear, hardness, adhesion, and other tribological properties under customizable environmental conditions. It supports multiple motion types and test modes with high-resolution force and displacement sensors. Applications include automotive, aerospace, biomedical, electronics, and materials engineering, where it helps optimize coatings, lubricants, and surface treatments. Its versatile software enables real-time data acquisition and advanced multi-step testing

Summary of Methods: Cathodic Arc Evaporation

Cathodic arc evaporation is a widely used physical vapor deposition technique for producing high-quality thin films with tailored properties. The process begins by selecting an appropriate cathode material—commonly metals such as titanium, chromium, aluminum, or their alloys—depending on the desired coating characteristics like hardness, wear resistance, and chemical stability.

An electric arc is initiated on the cathode surface, generating a highly energetic plasma composed of ions, electrons, and neutral particles. This plasma vaporizes cathode material atoms, which then travel toward the substrate. The deposition occurs as these vaporized particles condense onto the substrate, forming a thin, dense film. Ionized particles in the plasma are accelerated by electric fields, resulting in coatings with enhanced density and adhesion.

Critical parameters such as arc current, bias voltage, gas composition and pressure, substrate temperature, and cathode-to-substrate distance are carefully controlled to optimize film quality, thickness, and microstructure. Substrate preparation—including cleaning and surface finishing—is also essential to ensure strong coating adhesion.

Advanced modifications, like filtered cathodic arc deposition (FCAD) and pulsed arc evaporation (PAE), help reduce macroparticle contamination and improve coating uniformity. Characterization methods such as scanning electron microscopy (SEM), X-ray diffraction (XRD), and energy-dispersive spectroscopy (EDS) are employed to assess coating morphology, composition, and structural properties.

Overall, cathodic arc evaporation enables the deposition of various nitride-based coatings (e.g., TiN, CrN, AlTiN, AlCrN) with excellent mechanical, thermal, and chemical properties, making it highly suitable for industrial applications in cutting tools, automotive parts, aerospace components, and more.

IV.1.4. Properties of the coatings used in the experiment

Titanium Nitride (TiN) is a durable ceramic coating that is well known for its characteristic golden color and is frequently used to enhance the wear resistance, corrosion protection, and surface hardness of various materials. TiN has a hardness of approximately 2400 HV (Vickers Hardness), which is significantly harder than steel. It improves tool life by reducing friction and abrasion and protects against oxidation and chemical degradation. The coating maintains thermal stability up to around 600 degrees Celsius and is electrically conductive, making it useful in microelectronics. Additionally, TiN is biocompatible and safe for use in medical implants such as hip joints and dental tools. It also reduces sticking and galling in metal-forming applications and provides an attractive gold-like finish, making it popular for decorative coatings.

TiN coatings are typically applied using deposition methods such as Physical Vapor Deposition (PVD) and Chemical Vapor Deposition (CVD). The PVD process involves vaporizing titanium metal within a vacuum environment, followed by the introduction of reactive nitrogen gas, which reacts with the titanium vapor to form TiN on the substrate surface. PVD coatings tend to be thin, dense, and uniform, generally between 1 and 5 micrometers thick. This method produces coatings that adhere strongly to metal substrates and operates at relatively low temperatures ranging from 400 to 500 degrees Celsius. PVD TiN is commonly used on cutting tools such as drills and end mills, medical implants including hip replacements and scalpels, and decorative items like watch casings and jewelry.

On the other hand, CVD involves a chemical reaction between titanium tetrachloride ($TiCl_4$) and nitrogen gas at elevated temperatures of about 900 degrees Celsius. This reaction produces a thicker TiN coating, typically between 5 and 10 micrometers, with superior adhesion due to deeper diffusion into the substrate. However, the higher temperature limits its use on heat-sensitive materials. CVD TiN coatings are often found in aerospace applications and high-performance wear-resistant parts where thickness and strong adhesion are essential. Another deposition method, Cathodic Arc Deposition (Arc-PVD), uses an electric arc to vaporize titanium, producing highly hard coatings at a fast deposition rate. Although Arc-PVD TiN coatings are extremely hard, they may cause surface roughness due to droplet formation during the process, and are best suited for applications requiring very hard surfaces.

Titanium Nitride coatings have a wide range of applications across multiple industries. In machining and cutting tools, including drill bits, milling cutters, and punches, TiN significantly increases tool lifespan—often by a factor of two to ten—and reduces friction and heat buildup during operation. In the medical field, TiN coatings are used for hip implants, surgical instruments, and dental implants because of their biocompatibility, corrosion resistance, and non-toxic, FDA-approved status. The automotive and aerospace sectors apply TiN coatings to engine components and aircraft bearings to reduce wear and improve performance at elevated temperatures. In microelectronics and semiconductor manufacturing, TiN serves as a conductive diffusion barrier in integrated circuits and MEMS devices. TiN is also widely used in decorative and consumer goods, providing a durable and attractive gold-like finish on items such as watches, luxury pens, and firearms.

The advantages of TiN coatings include a significant enhancement of wear resistance and tool life through friction reduction, excellent corrosion resistance suitable for medical and industrial environments, biocompatibility, non-toxicity, and an appealing gold-like aesthetic for decorative purposes. However, TiN coatings are not ideal for applications involving high-temperature oxidation above 600 degrees Celsius, where coatings like Titanium Aluminum Nitride (TiAlN) or Titanium Carbonitride (TiCN) may perform better. Additionally, TiN coatings involve higher costs compared to uncoated tools and require specialized deposition equipment.

In summary, TiN coatings provide a versatile and effective solution for improving surface durability, performance, and appearance across many fields, with deposition methods tailored to meet specific application requirements.

When compared to TiN, Titanium Carbonitride (TiCN) coatings offer several advantages. TiCN has higher hardness, typically ranging between 3000 and 4500 HV, which translates to greater wear resistance. It also exhibits better toughness than TiN, reducing the likelihood of chipping or coating failure during use. TiCN has a lower friction coefficient of about 0.4, helping to reduce tool wear and improve overall performance. The coating provides good corrosion resistance and is compatible with common tool materials such as high-speed steel and carbide. However, TiCN has lower thermal stability than TiAlN, making it less suitable for very high-temperature applications.

TiCN coatings are widely used on cutting and forming tools like end mills, drills, taps, punches, and dies, where their wear resistance and toughness improve performance, especially when machining challenging materials such as stainless steel, hardened steel, and cast iron. They are also applied on molds and wear-resistant parts, including injection molding tools and mechanical bearings, to reduce friction and extend service life. In the medical field, TiCN coatings are used on surgical instruments and implants due to their biocompatibility and corrosion resistance. The aerospace and automotive sectors use TiCN to reduce wear and friction on engine components and bearings, enhancing efficiency and reliability.

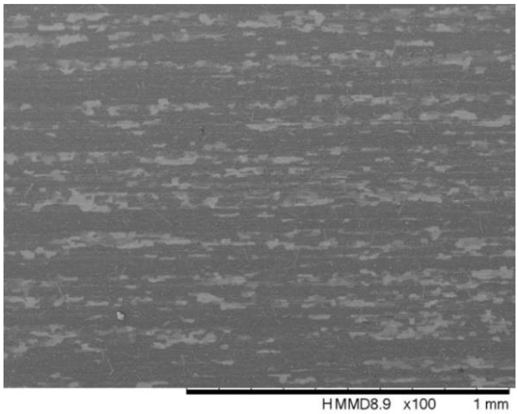
TiCN coatings are deposited using Physical Vapor Deposition (PVD) or Chemical Vapor Deposition (CVD). The PVD method uses sputtering or arc evaporation to vaporize titanium in a carbon-nitrogen plasma, creating thin, smooth coatings of about 1 to 5 micrometers thickness. PVD operates at lower temperatures of 400 to 500 degrees Celsius and is ideal for precision tools and heat-sensitive materials. The CVD process involves a chemical reaction between titanium tetrachloride, carbon-containing gases, and nitrogen at temperatures between 800 and 1000 degrees Celsius, producing thicker coatings (3 to 10 micrometers) with excellent wear resistance and toughness. CVD TiCN is used for heavy-duty cutting tools and demanding industrial applications.

In conclusion, TiCN coatings offer a balanced combination of hardness, toughness, wear resistance, and low friction, making them suitable for diverse industrial, biomedical, and mechanical applications. Although TiCN provides better wear resistance than TiN, its thermal stability is lower than TiAlN, which limits its use in very high-temperature environments. The choice between PVD and CVD deposition methods depends on the application's requirements, with PVD preferred for precision and medical tools and CVD favored for heavy-duty industrial

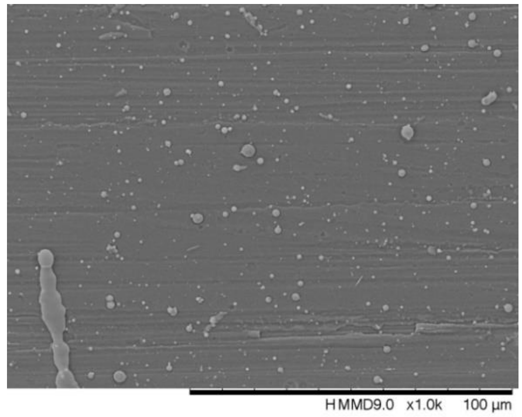
parts. Overall, both TiN and TiCN coatings remain essential in advanced manufacturing and engineering for improving tool performance and longevity.

IV.1.5 Experimental results

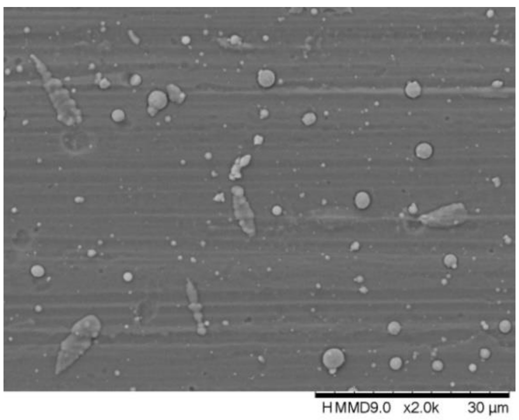
The SEM micrographs presented in fig. IV.1 show the topography of the TiN.



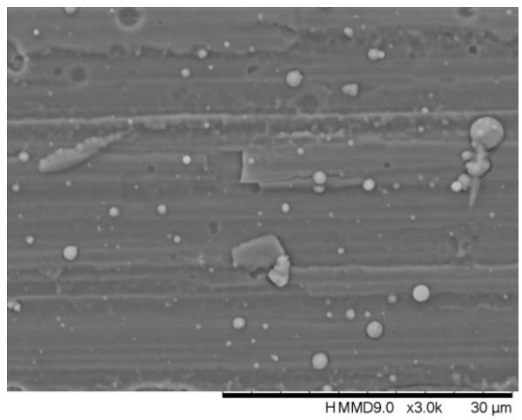
a.



b.



c.



d.

Fig. IV.1 The topography of the TiN coating

In fig. IV.1.a the coating appears to have a texture caused by the substrate finish. The coating appears to be homogenous, continuous, without voids and exfoliations. In fig. IV.1b and at higher magnifications, fig. IV.1c and d circular features appear that are normal for the method used. The splatter features have an average Feret diameter of 0.93±0.56µm and a frequency distribution depicted in fig. IV.2.

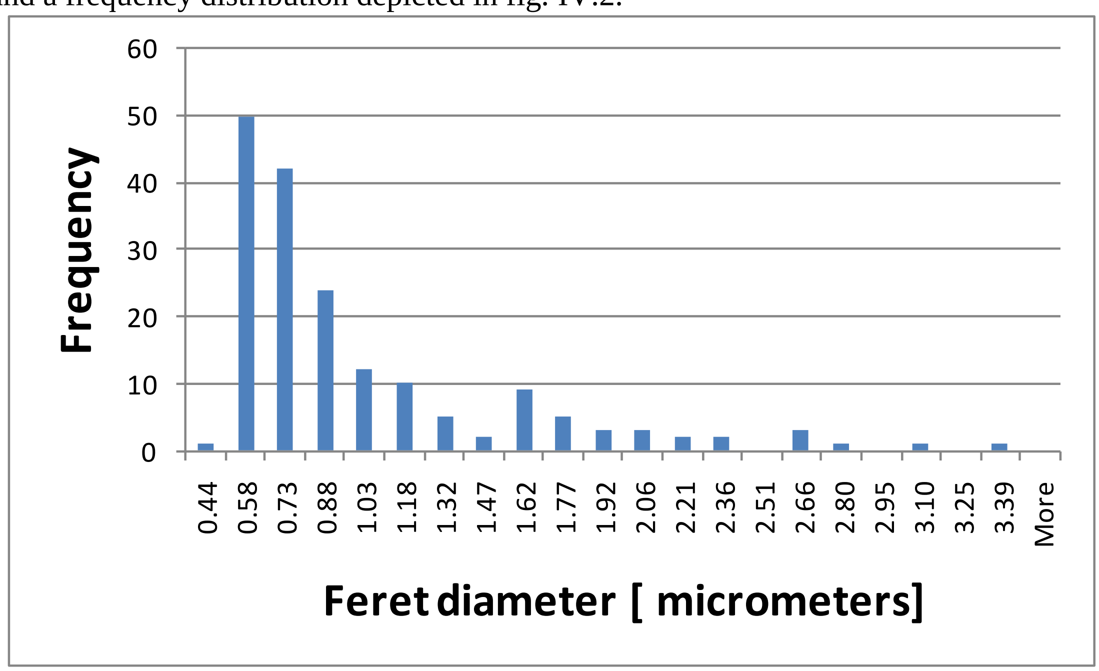


Fig. IV.2 Frequency distribution of the Feret diameter

The distribution reflects a large number of features with low Feret diameter, 94.32% of the counted particles have a Feret diameter up to 2.06µm.

The elemental mapping performed by energy dispersive spectrometry (EDS) depicted in fig. IV.3 reflect a uniform distribution of N and Ti on the surface, confirming the uniform coating.

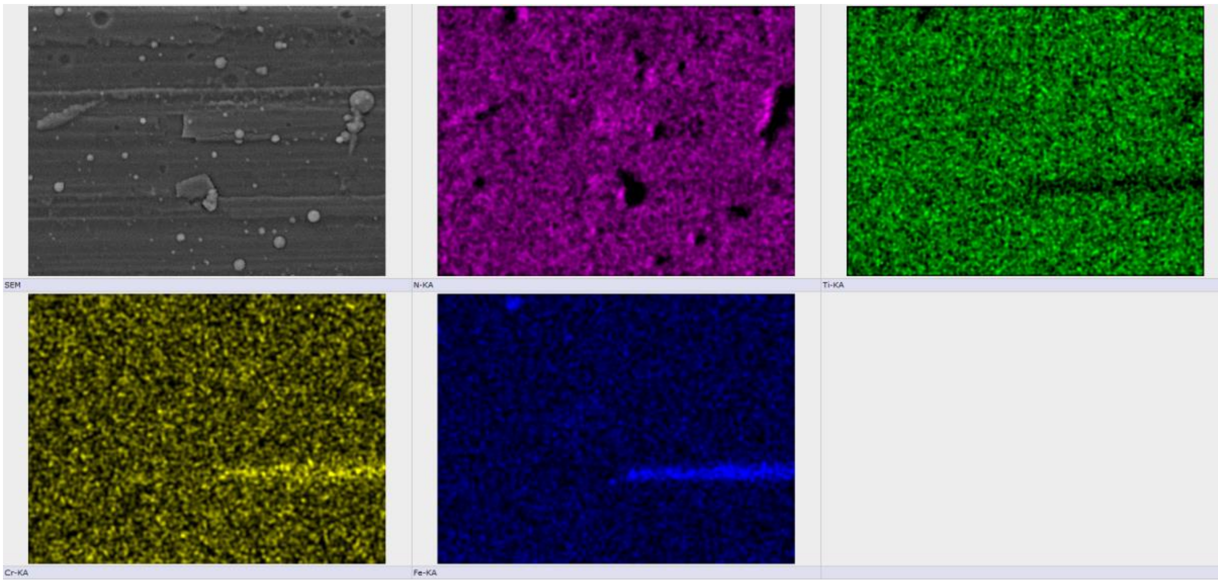


Fig. IV.3 Elemental mapping on the TiN coating

Circulars splatters of pure titanium are observed along elements from the substrate (Fe, Cr), more concentrated in a region where the substrate roughness alters the coating thickness.

The topography of the TiCN coating is presented in fig.IV.4.

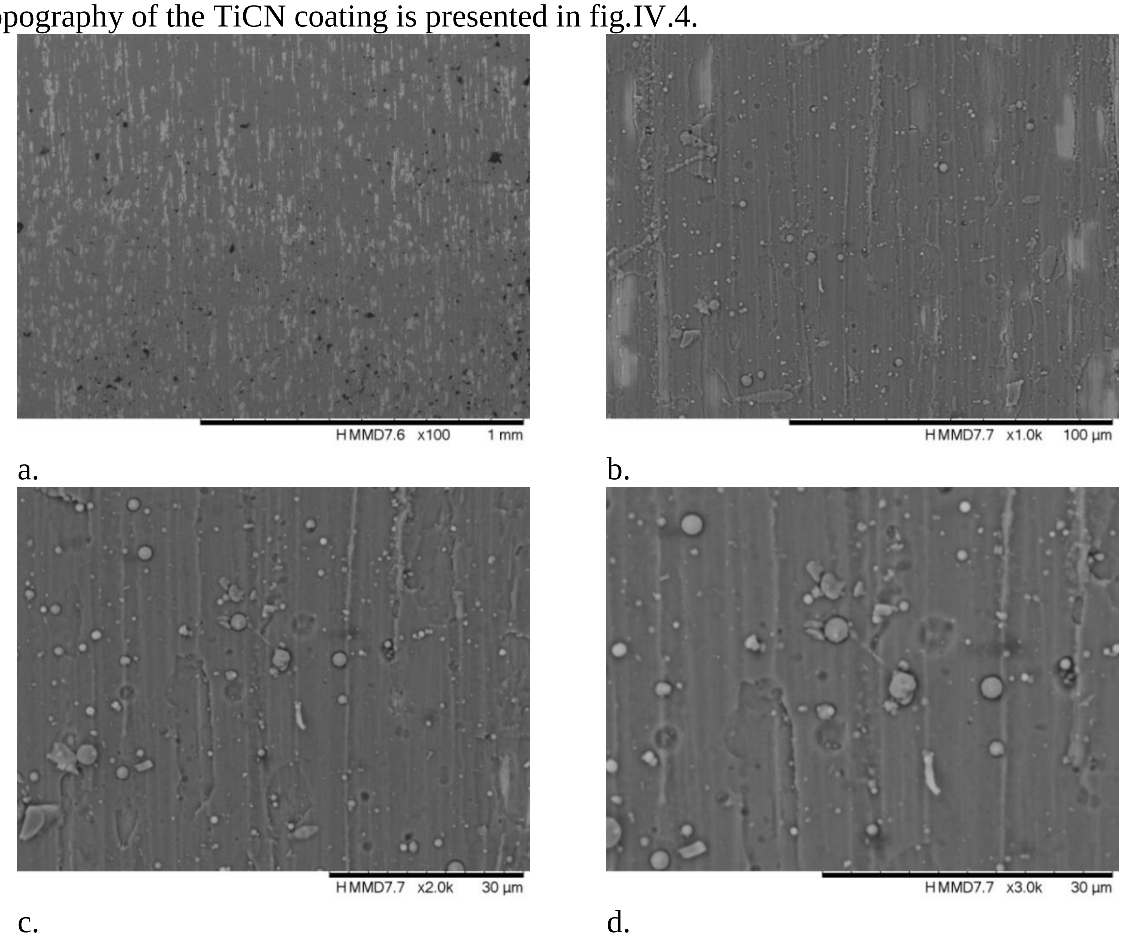


Fig.IV.4 The topography of the TiCN coating

Similar to TiN coating a texture can be observed in fig. IV.4.a induced by the substrate roughness and same circular features caused by cathode splatter are seen in fig. IV.4.b, c and d. The mean Feret diameter of these features is 0.85±0.35µm, slightly smaller than those on the TiN coating.

The frequency distribution according to Feret diameter is presented in fig. IV.5.

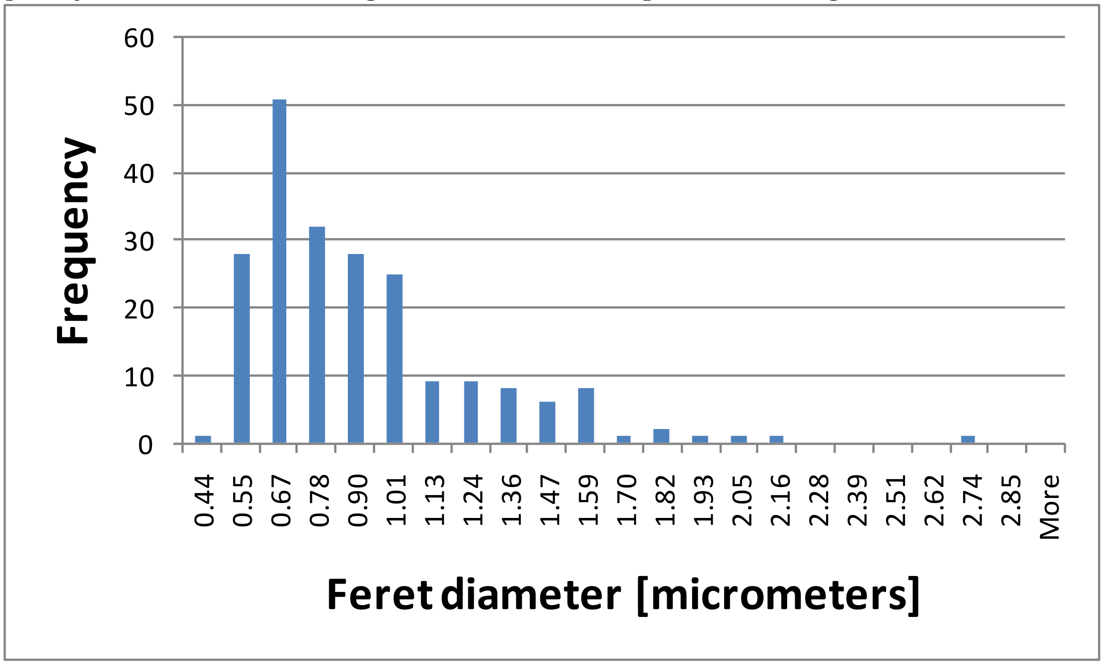


Fig. IV.5 Frequency distribution of the Feret diameter

The frequency distribution on the TiCN coating strongly resembles the one on the TiN coating, with a larger number of smaller particles, yet in this case 99.06% of the counted particles have a Feret diameter up to 2.05 µm.

The elemental mapping presented in fig. 6 show a roughly uniform distribution of Ti, C and N on the surface, except a region where, given the undercut nature of the groove in the substrate, the coating is not present.

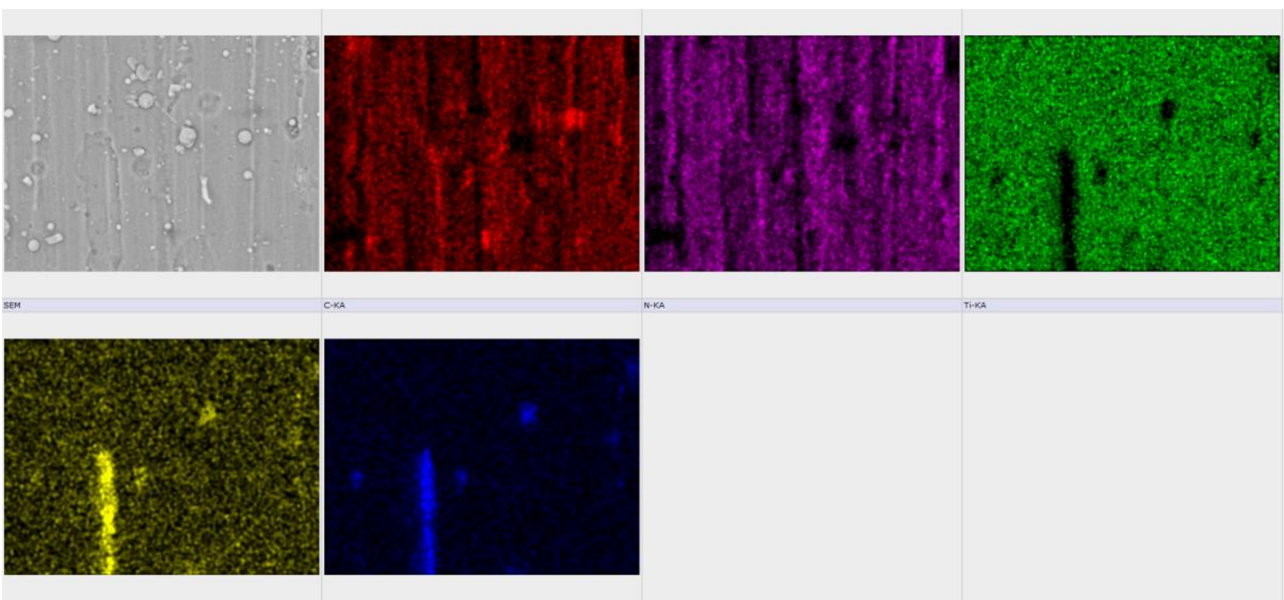
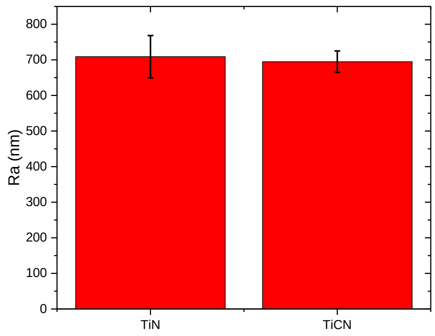
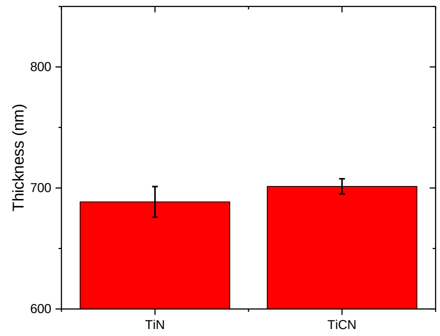


Fig. IV.6 Elemental mapping on the TiCN coating

Elements from the substrate, Fe and Cr are identified and appear in higher concentrations in the region without coating.

Surface roughness was determined in three regions, a comparison of the average roughness (Ra) determined for the two samples is presented in fig. IV.7.a.





a. b.

Fig. IV.7 Comparison on a. average roughness and b. coating thickness

The average roughness samples are 708,78±59.42nm for TiN and 694.77±30.17nm for TiCN which can be considered equal from a statistical point o view, the t-test performed on the results suggests that the means are equal.

Regarding the coating thickness it can be stated that the mean values, 688±12.67nm for TiN and 701,34±6.25nm for TiCN, can be assumed to be equal from a statistical point of view. The t test result suggests an equality of the means.

A comparison regarding the Vickers microhardness results is presented in fig. 4.8.

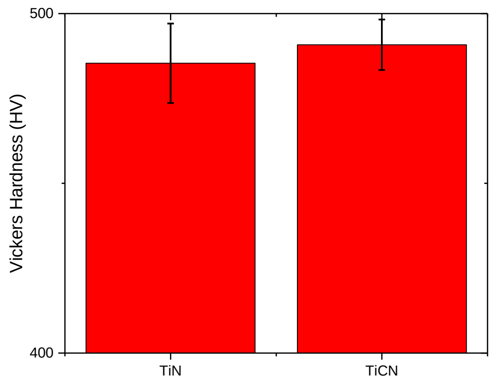


Fig. IV.8 Comparison of Vickers hardness values

The hardness of the TiCN coating (490.8±7.44 HV) appears slightly higher than that of the TiN coating (485.67±11.69 HV), but due to the variability in values, a t-test suggests the mean hardness values are statistically equal. Typically, TiN has an average hardness of about 2300 HV, while TiCN is expected to reach around 3000 HV. However, in this study, the measured hardness is lower because the composite hardness reflects the combined influence of the substrate properties and coating thickness. Despite this, there is a significant increase in surface hardness; annealed 304 stainless steel has an average hardness of 129 HV, and after coating, the hardness nearly quadruples.

IV.2 The surface free energy of STAINLESS STEEL

IV.2.1 Introduction

IV.2.2. Materials and methods

For this study, a collection of used surgical instruments was selected, labeled as S1 (chisel), S2 (forceps), S3 (chisel), S4 (retractor), and S5 (scissors).

Fig. IV.9. Macro images of the investigated surgical instruments: S1 - chisel, S2 - forceps, S3 - chisel, S4 - retractor and S5 – scissors

Samples were first analyzed for chemical composition using Energy Dispersive Spectroscopy (EDS) with a JEOL JED-2300. Contact angle measurements were then done with a KRÜSS DSA30 Drop Shape Analyzer using water, diiodomethane, and ethylene glycol to determine surface free energy (SFE) via Fowkes, Wu, and Owens–Wendt–Rabel–Kaelble (OWKR) models.

Initial tests were on untreated samples. Another set was mirror-polished, passivated in nitric acid (marked “P”), and measured again. These were then corroded in 3.5% NaCl at 400 mV for 8 hours before final contact angle tests.

Fowkes, Wu, and OWKR models estimate SFE based on different treatments of polar and dispersive interactions. Using all three provides a thorough assessment, important for corrosion resistance.

The JEOL JED-2300 is an advanced EDS system integrated with electron microscopes, featuring a dry silicon drift detector (no liquid nitrogen), automated mapping, and particle analysis software.

The KRÜSS DSA30 measures contact angles precisely with controlled liquid dosing, automated functions, and optional temperature and humidity control, useful for evaluating surface treatments and adhesion.

The Buehler Phoenix Beta is a manual grinder-polisher with adjustable speed and durable construction, suitable for preparing metallurgical samples and can be upgraded to semi-automatic operation.

Surface free energy cannot be measured directly, so it is estimated from contact angles using models:

- Fowkes separates dispersion and polar forces using a geometric mean, suitable for non-polar materials.
- Wu improves on Fowkes using a harmonic mean, increasing accuracy for mixed surfaces.
- OWKR further refines the calculation, requiring multiple liquids and covering a wider range of materials.

IV.2.3. Results

Chemical composition and steel grades. As mentioned, the samples were initially analyzed in their as-received state using EDS to identify their chemical composition. Table 1 displays the chemical composition alongside the corresponding steel grade.

Table IV.9 shows the chemical composition of the tested samples in weight percent, with the balance being iron.

Sample ID	Carbon (C) %	Manganese (Mn) %	Silicon (Si) %	Chromium (Cr) %	Nickel (Ni) %	Additional Elements	Steel Grade

S1	0.11 ± 0.02	1.52 ± 0.14	0.56 ± 0.10	18.50 ± 0.70	9.23 ± 0.63	0.52 ± 0.12 Mo	303
S2	0.05 ± 0.002	1.73 ± 0.22	0.76 ± 0.13	17.95 ± 0.63	8.63 ± 0.68	None	304
S3	0.065 ± 0.004	1.68 ± 0.27	0.66 ± 0.18	18.23 ± 0.33	7.95 ± 0.48	0.43 ± 0.06 Mo	304
S4	0.18 ± 0.026	0.92 ± 0.08	0.49 ± 0.05	13.65 ± 0.68	0.96 ± 0.05	None	420A
S5	0.32 ± 0.063	0.92 ± 0.06	0.63 ± 0.086	12.96 ± 0.35	0.68 ± 0.08	None	420B

The chemical compositions of the steels comply with ASTM F899 standards for wrought stainless steels used in surgical instruments and align with the intended applications outlined in ISO 7153. Using the average values from Table 1, the chromium and nickel equivalents were calculated and the corresponding points were plotted on the Schaeffler diagram, shown in Figure IV.10.

Samples S1, S2, and S3 are predicted to have a microstructure consisting of both ferrite (F) and austenite (A), whereas a fully austenitic structure was anticipated. The Schaeffler diagram predicts a mixture of martensite (M) and ferrite (F) for sample S4, while for sample S5 a mixture of martensite (M) and austenite (A). The expected structure for both would be a martensitic one.

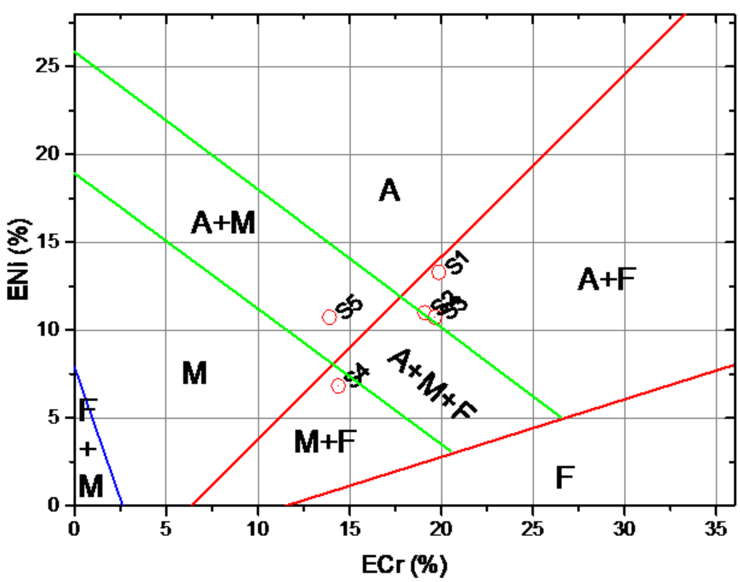


Fig. IV.10Schaeffler diagram showing with chromium and nickel equivalents plotted for the experimental samples

The Schaffler diagram effectively estimates the structure of austenitic stainless steels with good accuracy. Contact angle measurements were used to qualitatively assess surface wetting on untreated (U), passivated (P), and corroded (C) samples. Water contact angles were lowest on untreated surfaces, indicating strong wetting, which is undesirable for surgical instruments. Passivation increased the contact angle, making surfaces more hydrophobic, while corrosion slightly reduced the angle, increasing hydrophilicity. This trend was consistent across samples, showing that corrosion and wear during normal use reduce surface hydrophobicity and must be considered.

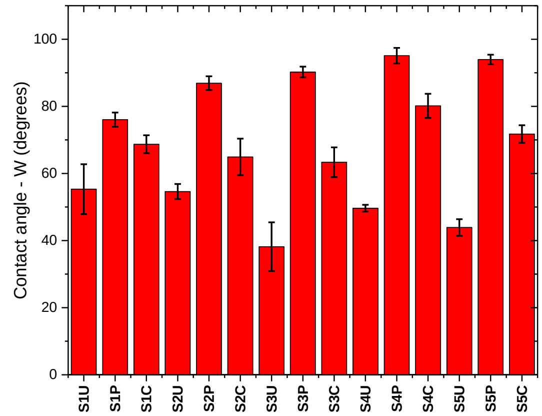


Fig. IV.11. Comparison of the contact angles for water

Surface roughness affects wetting behavior, thus the as received samples show the most hydrophilic surface, caused by a cumulated effect surface corrosion - roughness change.

The combined influence of corrosion and surface roughness can be deduced from the wide range of contact angle values observed on the as-received surface. Five measurements taken at random spots—specifically on the area deemed most active during use—showed significant variability in contact angle results.

As an example, for sample S1U, the measured contact angles ranged from 42.36° to 63.89°, the box-plot and water drop presented in fig. IV a. and b. reflect the situation.

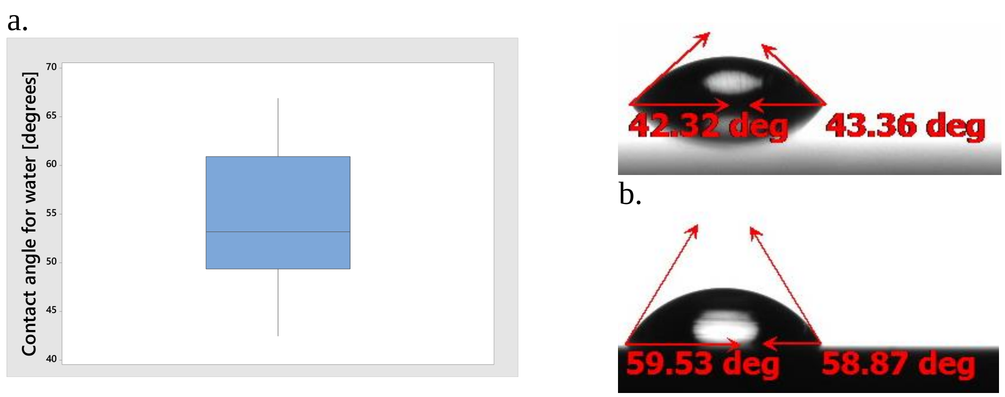


Fig.IV.12 Spread of contact angle values for water, sample S1U showing: a. the boxplot; b. water drops showing large and small angles

Analyzing the surface behavior against diiodomethane (D), as presented in fig. IV.12, it can be stated that a similar trend as for water appears, yet the change in contact angle values shows a lesser variability.

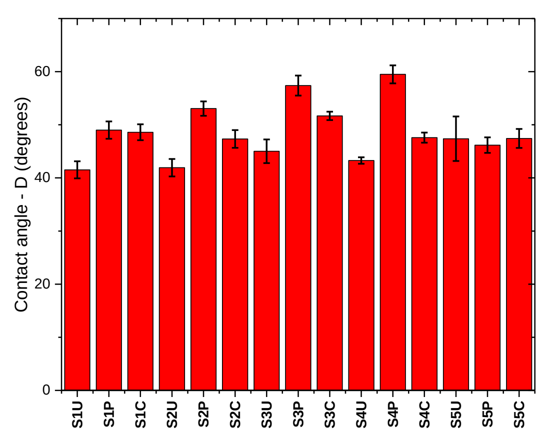


Fig. IV.12 Comparison of the contact angles for diiodomethane

The passivated samples generally exhibit reduced wetting by diiodomethane, similar to the behavior observed with water, except for sample S5, which showed no statistically significant change. A comparative analysis of the contact angles for ethylene glycol (E) is shown in Figure IV.13.

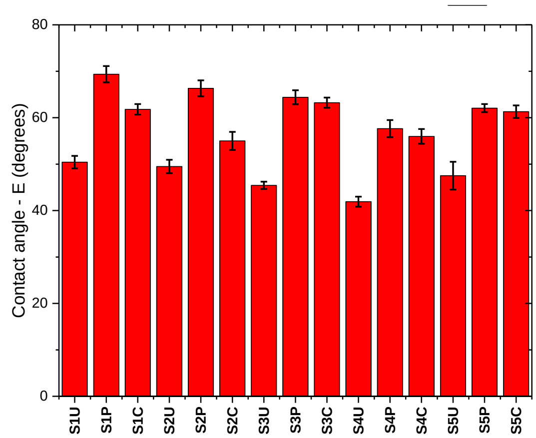


Fig. IV.13 Comparison of the contact angles for ethylene glycol

The behavior of ethylene glycol strongly resembles the one of water, the passivated samples are less wetted than the corroded samples, the lowest contact angles are observed on the as received surfaces, indicating an enhanced wetting.

Regarding surface wetting based upon contact angle values it can be observed that freshly passivated samples reveal lesser wetting, and, as the surface becomes more affected by corrosion and roughness changes, the contact angle values decrease enhancing wetting, an undesirable aspect.

Surface free energy

Surface free energy is directly related to contact angle measurements since it is derived from them. To assess the surface free energy of the samples, three widely used methods—Fowkes, Wu, and OWKR—were applied. Each method is based on different theoretical principles, which may result in differences in the calculated surface energy values. The surface free energy results obtained through the Fowkes method are shown in Figure IV.14.

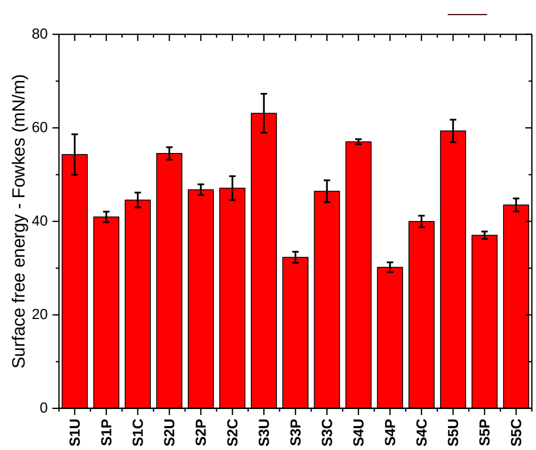


Fig.IV.14 Surface free energy values obtained using the method proposed by Fowkes

The highest surface energies are observed for the samples in as received condition, while the lowest appear on the fresh passivated ones. The corroded ones show intermediate values. Large discrepancies appear for the samples S3, S4 and S5, the chisel, retractor and scissors. It would be expected to observe a significant variation on S4 and S5, given the martensitic grades of steels, given the lower Cr content and higher C content, yet S3, given that it is a 304 steel, a behavior similar to S1 and S2 would be expected. Currently our inference relates the stresses and strains at the surface resulting from intensive use. The results obtained for the surface free energy determined according to Wu method are presented in fig. IV.15.

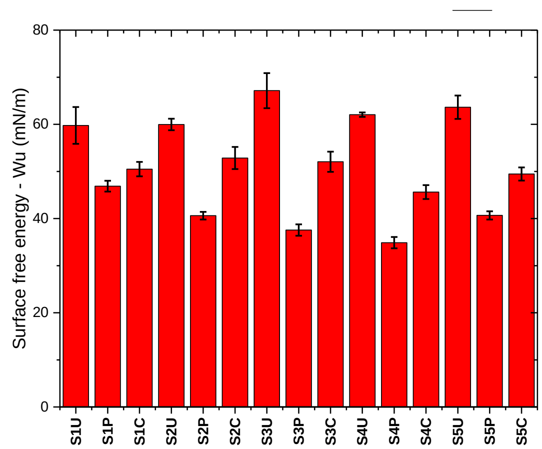


Fig. IV.15 Surface free energy values obtained using the method proposed by Wu

The surface free energies determined by the Wu method shows a similar trend as the ones determined by Fowkes method. The passivated surfaces show lowest surface free energies, the corroded surface intermediate ones, while as received highest ones.

According to this method, the surface free energies are higher when compared to the ones predicted by Fowkes method, except sample S2, where the surface free energy on the passivated sample is less. Generally, the trend is unchanged, the differences in energies are of maximum 5mN/mm.

The results regarding the surface free energy obtained by applying the OWKR method are presented in fig. IV.16.

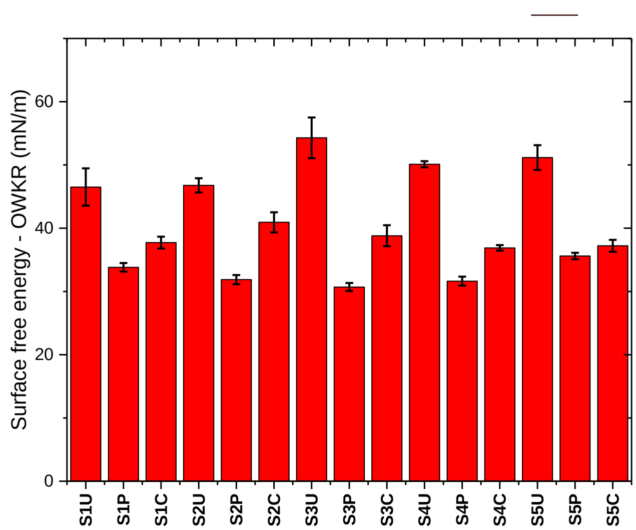


Fig. IV.16 Surface free energy values obtained using the OWKR method

The same trend for the surface free energy is obtained using the OWKR method. The passivated samples show lowest surface free energies and begin to increase as the surface becomes more and more degraded. As values, the OWKR method predicts lower values than previous methods, a global comparison is presented in fig. IV.17

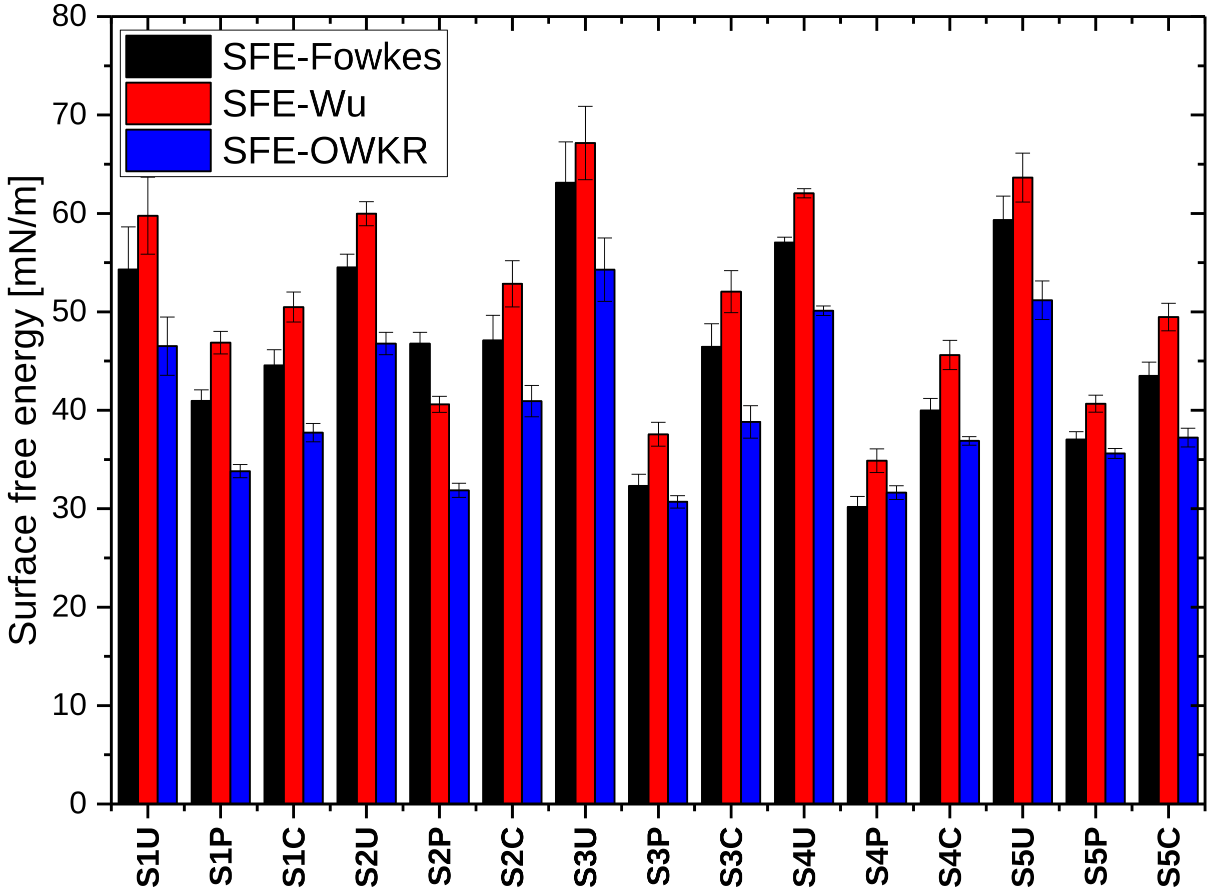


Fig. IV.17 Comparison of surface free energies determine by the three methods

Regardless of the method used, a similar trend was observed in the variation: as the surface becomes more and more degraded, its surface free energy tends to increase.

IV.3 Conclusion

Surface free energy is a key factor in corrosion resistance, as higher energy surfaces tend to interact more with the environment. The study examined surgical instruments made of austenitic and martensitic stainless steels, finding that freshly passivated surfaces have the lowest surface free energy. As surfaces degrade through corrosion and wear (like scratches), surface free energy increases significantly. This trend was consistent across different calculation methods (Fowkes, Wu, OWKR), indicating that changes in chemical composition have little effect on the estimates. The main factor raising surface free energy is the combined effect of corrosion and increased surface roughness, rather than corrosion alone.

CHAPTER V Business Plan "INSTRUMENTS OF THE FUTURE"

Instruments of the Future, based in Bucharest, Romania, specializes in high-quality medical instruments enhanced with advanced TiN and TiCN coatings. Their mission is to improve surgical tools' durability, performance, and biocompatibility, addressing the common problems of instrument wear and failure that affect patient outcomes. They offer a wide range of coated medical and dental instruments, along with customized solutions, selling directly to healthcare providers and through industry partnerships while focusing on ongoing innovation.

SWOT Analysis

Strength

1. **Innovative TiN and TiCN coating technologies**
2. **enhancing instrument durability.**
3. **Strong focus on biocompatibility ensuring safety for diverse medical applications.**
4. **High-quality manufacturing standards meeting rigorous healthcare regulations.**
5. **Unique market position with a specialization in advanced coating techniques.**
6. **Commitment to research and development fostering continuous**

Weaknesses

1. **1Relatively high production costs associated with**
2. **advanced coating technologies.**
3. **Limited brand recognition in a competitive medical instrument market.**
4. **Dependence on a niche market which may limit customer base.**
5. **Potential challenges in scaling production to meet increasing demand.**

Opportunitie

1. **Growing demand for advanced medical**
2. **instruments in healthcare settings.**
3. **Expanding market for biocompatible medical devices due to regulatory changes.**
4. **Potential partnerships with healthcare institutions for product development.**
5. **Opportunities to enter emerging markets with rising healthcare needs.**
6. **Increasing focus on surgical precision and**

Threat

1. **Intense competition from established medical**
2. **instrument manufacturers.**
3. **Rapid technological advancements could outpace company innovations.**
4. **Economic downturns affecting healthcare budgets and spending.**
5. **Regulatory changes impacting the production and sale of medical devices.**
6. **Potential supply chain disruptions affecting**

Company Overview:

Instruments of the Future is a Romanian medical company specializing in manufacturing surgical and diagnostic instruments coated with advanced Titanium Nitride (TiN) and Titanium Carbonitride (TiCN) technologies. These coatings significantly enhance the durability, strength, and biocompatibility of medical tools, improving surgical performance and patient outcomes.

Mission:

To revolutionize medical instruments by providing healthcare professionals with innovative, reliable, and long-lasting tools that prioritize patient safety and clinician satisfaction.

Products & Services:

- High-quality coated surgical instruments (scalpels, scissors, forceps, etc.)
- Diagnostic and dental tools with enhanced wear resistance
- Custom instrument design and coating services tailored to client needs

Market Opportunity:

Growing demand for durable, high-performance medical instruments due to increasing surgical procedures worldwide and the rising costs related to instrument failure and replacement. Focus on both local Romanian healthcare institutions and international markets.

Marketing Strategy:

- Direct sales to hospitals, clinics, and medical professionals to build trust and establish relationships.
- Strategic partnerships with medical device distributors to expand reach globally.
- Participation in medical trade shows, conferences, and exhibitions to showcase product benefits.
- Digital marketing through a professional website, social media, and targeted campaigns to raise brand awareness.
- Collaborations with key opinion leaders and healthcare influencers for endorsements and product validation.

Operations Plan:

- Production facility located in București with state-of-the-art coating equipment ensuring high-quality outputs.
- Dedicated R&D team focused on developing new coating technologies and customized solutions.
- Quality assurance protocols aligned with international medical standards (ISO 13485).
- Efficient supply chain management to ensure timely delivery and cost control.

Financial Projections:

- Initial investment allocated to equipment purchase, product development, and marketing launch.
- Revenue growth expected from local sales in year one, expanding internationally by year three.
- Break-even point anticipated within 2-3 years, with increasing profitability as market penetration grows.
- Reinvestment in R&D and facility upgrades to sustain competitive advantage and product innovation.

Conclusion:

Instruments of the Future is poised to become a leader in the medical instrument market by leveraging cutting-edge coating technologies, strong customer focus, and innovative solutions to address the critical needs of healthcare providers and improve patient care globally.

CHAPTER VI-COST CALCULATION

The cost of manufacturing medical instruments depends largely on the choice of materials and coatings. Common base materials like titanium alloys (e.g., Ti-6Al-4V) cost between $50 and $150 per kilogram, valued for their strength and biocompatibility. Coating materials, such as Titanium Nitride (TiN), add $2 to $10 per part for simple shapes, but can rise to $100–$500 for complex geometries. Titanium Carbonitride (TiCN) coatings are more expensive, typically $5 to $15 per part due to enhanced hardness. The coating process, usually Physical Vapor Deposition (PVD), costs $50 to $200 per batch (covering 50–100 parts) and is preferred for medical use. Chemical Vapor Deposition (CVD) is less common due to high temperatures and costs ranging from $30 to $150 per batch.

Table VI.1 Cost Comparison of TiN vs. TiCN Coatings

Coating Type	Cost per Part	Hardness (HV)	Key Applications
TiN	$2–$10	2,400	Surgical blades, orthopedic implants
TiCN	$5–$15	3,500	Dental drills, bone saws

TiCN coatings significantly extend tool life by improving wear resistance by 50-70% and increasing lifespan by 3 to 10 times. TiN coatings reduce friction, improving precision and performance, especially in surgical instruments. TiCN also offers strong thermal stability, suitable for high-speed applications like dental drills. Although coating adds 5-10% to costs, it can yield up to 100 times savings by reducing replacements.

Medically, TiN and TiCN coatings must meet certifications such as ISO 13485, CE Marking, and FDA 510(k), ensuring biocompatibility and sterilization resistance. TiN is FDA-approved and non-toxic, while TiCN is similarly inert, suitable for surgical tools.

Both coatings enhance hardness and reduce friction, helping maintain sharpness and minimize tissue damage during procedures. Strategic partnerships with coating experts and investment in R&D for advanced coatings and sustainable processes are recommended. Overall, these coatings improve surgical precision, durability, and safety in medical instruments.

Table VI.2 Tribological performance in biological environments

Coating Type	Key Tribological Property	Clinical Impact
TiN	Moderate COF, high hydrophilicity	Reduced tissue sticking
TiCN	Ultra-low COF, high hardness	Smoother tool operation
TiNbN	Optimal albumin interaction	Minimized wear in implants

TiN and TiCN coatings significantly increase the durability and lifespan of medical instruments and implants, reducing the need for frequent replacements. TiCN-coated cutting tools can last 2 to 8 times longer than uncoated tools and outperform TiN coatings by 2 to 4 times. Both coatings can be stripped and reapplied cost-effectively, extending tool usability. In implants, these coatings reduce wear and complications, lowering revision surgery risks. They are FDA-approved, corrosion-resistant, and non-toxic. Additionally, the coatings improve surgical tool performance, maintain sharpness, and enhance device appearance, leading to cost savings and better patient outcomes.

TiCN-coated molds used in injection molding processes last two to ten times longer than uncoated molds, significantly reducing downtime and production costs for manufacturing medical device components. Additionally, coatings on high-friction wear components in medical machinery help extend their operational life, thereby lowering maintenance expenses and improving equipment reliability.

By minimizing tool replacement needs, enabling cost-effective recoating, and enhancing the durability of implants and equipment, TiN and TiCN coatings contribute to substantial cost savings across both healthcare manufacturing and surgical practices.

Conclusions

Coating and Stripping Costs

TiN coatings are relatively inexpensive, with coating costs starting as low as $2.00 per tool for smaller instruments. Stripping TiN coatings typically costs around 40% of the original coating price. TiCN coatings, while more expensive, range from $8 to $16 per tool depending on size and complexity. Stripping costs for TiCN coatings are also approximately 40% of the initial coating cost.

Tool Life Extension

TiN coatings can extend tool life by 2 to 7 times compared to uncoated tools. TiCN coatings offer even greater durability, outperforming TiN by a factor of 2 to 4, and delivering an overall improvement of 2 to 8 times over uncoated tools. For example, a TiCN-coated brazed carbide dovetail tool achieved 8 hours of runtime versus just 15 minutes for an uncoated equivalent and could be resharpened and recoated up to 8 times without performance loss.

Recoating vs. Replacement

Both TiN and TiCN coatings can be chemically stripped and reapplied on steel alloy substrates such as stainless and tool steels. This allows manufacturers to avoid costly tool replacement and instead maintain the same tool through multiple resharpening and recoating cycles. Since stripping costs are significantly lower than the cost of manufacturing new tools, this strategy offers a path to "infinite" tool life with proper maintenance protocols.

Strategic Recommendations

TiCN is recommended for high-wear medical instruments that require maximum hardness and low friction, as its higher upfront cost is offset by significantly longer service intervals and durability. TiN remains a cost-effective option for smaller tools or applications with moderate wear demands, particularly where biocompatibility is critical. Regardless of the coating choice, incorporating regular stripping and recoating cycles can dramatically reduce lifetime tooling costs, especially for high-value surgical instruments.

Limitations

Stripping is generally not feasible for carbide substrates, as the process can chemically attack the cobalt binder in the tool, leading to structural degradation. Additionally, the high process temperatures required for TiCN deposition (up to 840°F or 450°C) may necessitate compatibility checks to ensure that the substrate material does not deform or degrade during coating.

Chapter VII Conclusion, personal contributions and future research

This research addresses a vital challenge in healthcare: optimizing the maintenance and reliability of medical instruments through a strategic, data-driven framework. By combining risk assessment, condition monitoring, and lifecycle cost modeling, the study promotes a shift from reactive to predictive maintenance, improving safety and operational efficiency in healthcare settings. Validation in real-world environments demonstrated that condition-based maintenance and advanced monitoring, aligned with standards like ISO 13485, significantly enhance performance.

The research also includes a comparative study of TiN and TiCN coatings applied to stainless steel surgical instruments via cathodic arc evaporation. Both coatings substantially improve hardness, wear resistance, and biocompatibility, enhancing instrument durability and functionality. However, TiCN did not outperform TiN in hardness, indicating a need for further process optimization.

Additionally, the study investigates the role of surface free energy, corrosion, and roughness on surgical instrument longevity. It finds that increased surface roughness combined with corrosion accelerates degradation and raises surface energy, which can negatively impact corrosion resistance. Various measurement methods confirmed these effects, emphasizing the importance of surface condition management.

Future research should explore different steel grades, surface treatments, and long-term clinical use to better understand and improve corrosion resistance and durability of surgical tools. Overall, the study contributes valuable insights into enhancing medical instrument performance, safety, and lifespan through coatings, maintenance strategies, and surface science.