selenium
MEDICAL

Your strategic one-stop-shop partner

Tailored support to accelerate time-to-market

www.selenium-medical.com

YOUR DEVICE, OUR CARE.

TOGETHER, WE MAKE IT HAPPEN!

ABOUTS US

Driven by innovation and committed to patient well-being, we partner with medical device manufacturers at every stage of their projects.

As a true one-stop-shop partner, we provide tailored support across the entire value chain, from concept to market access.

Our technical and regulatory expertise, combined with recognized agility, enables us to address highly complex projects in orthopedics, dental, soft tissues, in vitro diagnostics, robotics and endoscopic surgeries.

With operations worldwide, we ensure that every device complies with the regulatory and performance requirements of international markets.

ISO 9001 ISO 13485 FDA ANVISA

Consulting & laboratory testing

From product development to market introduction of medical devices.

Partners in your success

In a complex and fast-evolving environment, our dedicated teams support you on both technical and regulatory aspects, helping you design and implement the most effective development strategies to accelerate your time-to-market.

Comprehensive expertise

We support you from development to the time-to-market of your medical device.

Customized support

Because every project is unique, we offer either turnkey or tailored support to fit your specific needs.

Diverse projects

Supporting both start-ups and major companies.

Worldwide outlook

Expertise in European and International regulatory compliance.

Multidisciplinary approach

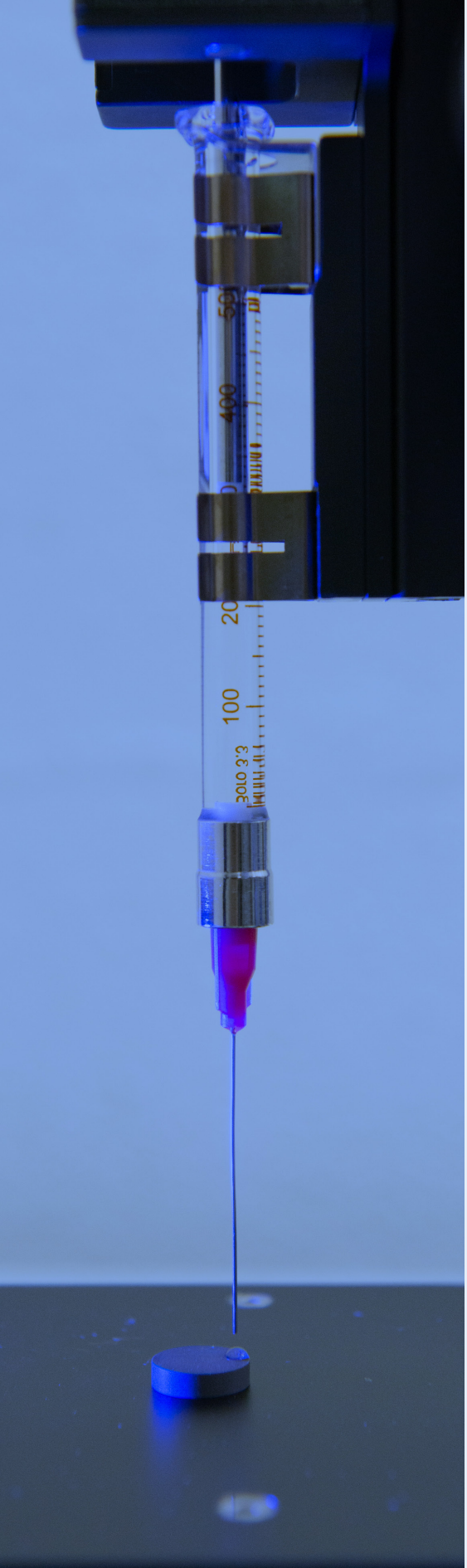
Our teams combine diverse skills to guide you throughout your project.

Integrated laboratories

Equipped with multiple laboratories, we perform a wide range of tests internally.

Strong capabilities

With over 15 years of experience and several patented innovations in packaging and processes, our teams have developed a deep understanding of medical device requirements.



From development to market introduction

» Quality & regulatory affairs

- Customized support for CE / 510(k) technical files.
- Audit and compliance of QMS and manufacturing processes.
- Implementation of control methods and action plans.
- Support for audits and inspections, management of NCs.
- Analysis of standards and their impact on products and processes.
- Support in change management.

» Verification & Validation

- Development of validation strategies and preparation of files, protocols, and reports.
- Support in qualification of critical areas (clean rooms), monitoring plans, and risk management.
- Update of client validation files.
- Qualification of equipment or production tools (IQ, OQ, PQ).
- Process validation (OQ, PQ) and sterile finished product validation (PPQ).

» Research & Development

- Development of special processes.
- Design of medical devices, accessories, and packagings.
- Feasibility studies and technical advice.

» Manufacturing engineering

- Technical support and feasibility studies.
- Creation of manufacturing workflows and process sheets.
- Development of specific tools and components.
- Definition of packaging and labeling.
- Monitoring and planning of development.

» Laboratory testing

Mechanical and sterile barrier testing:

- Dye penetration
- Visual inspection
- Seal strength
- Compression
- Bubble test
- Tensile testing
- Ageing
- Transport simulation

Dimensional measurements & surface analysis:

- Wettability
- 3D measurement
- Roughness
- Tensiometer
- SEM/EDS microscopy

Microbiological & residual analyses

- Biocompatibility
- Endotoxins
- Sterility
- Dose audit
- Bioburden
- TOC
- THC
- Particulate residues
- Inorganic residues

All tests are performed in compliance with international standards. For the full list of applied standards, scan the QR code.

Plastic injection molding

Manufacturing, assembling and packaging of medical devices in a controlled environment.

Proven mastery in plastic injection molding for medical devices

We apply our technical know-how to your most demanding projects, designing and manufacturing reliable, high-performance solutions under strict microbiological control.

Comprehensive support

From design to production.

ISO7

Controlled environment

Facilities and production in an ISO 7 controlled environment.

Scalable manufacturing

Small or large batch production to meet your needs.

Multidisciplinary team

Combining diverse expertise to guide you through every stage of your project.

Single point of contact

A dedicated project manager for smooth coordination and follow-up.

Industrial flexibility

Ability to integrate new processes and equipment based on specific requirements.

Our product expertise

Medical device accessories, implantable devices, custom packaging, and single-use instruments.

Tailored solutions, from design to production

» Design

- Co-design and prototyping.
- Use of thermoplastics, thermoplastic elastomers, and technical polymers.

» Tooling & qualification

- Molding and mold design expertise.
- Adjustment definition.
- Process optimization.
- Qualification file FAT SAT IQ OQ PQ.

» Production

- Manufacturing in a controlled environment.
- Assembling in clean rooms.
- Packaging in clean rooms.

» Metrology

- Functional and visual inspection.
- Dimensional control.

Surface Treatment

Surface treatment and laser marking of medical devices.

Optimizing protection and performance of your medical devices

Our expertise in surface treatment enables us to sustainably improve the surface quality of implants and surgical instruments in full compliance with regulatory requirements and device functional performance.

Qualified processes
Chemical, electrochemical, mechanical, and marking.

Material expertise
Mastery of stainless steel, nitinol, titanium and its alloys.

Property optimization
Identification, protection, performance, and traceability of your medical devices.

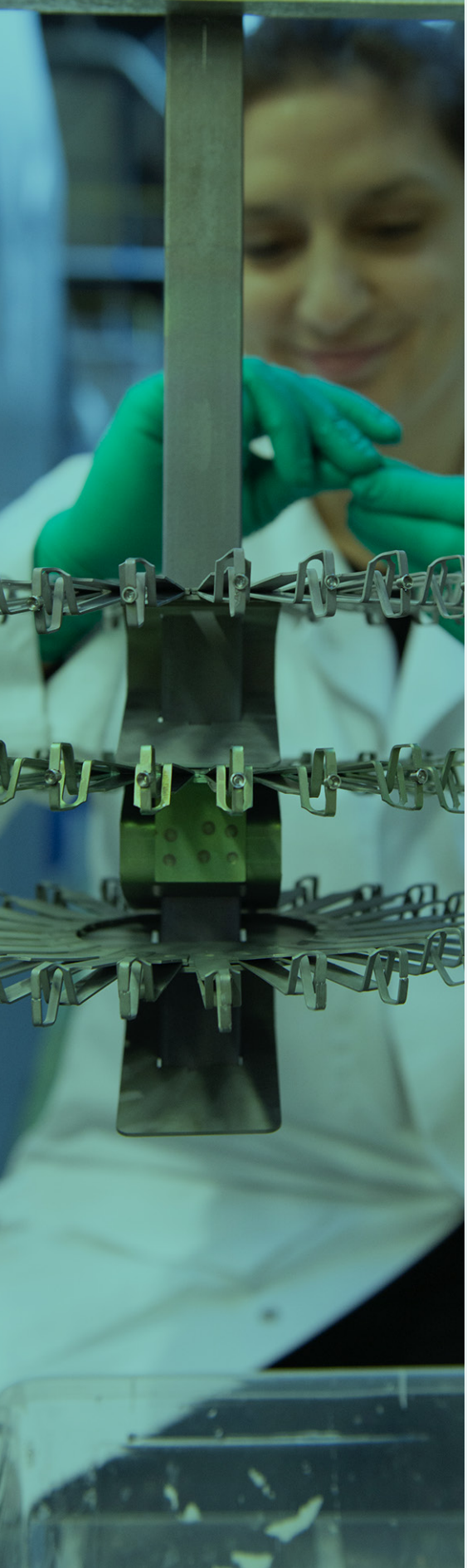
Environmental managed
Addressing issues related to corrosion, wear, and biocompatibility.

Single point of contact
A dedicated project manager for smooth coordination and follow-up.

Patented innovation
An innovative process developed for implant durability and anchoring.

A tailored, collaborative approach

Our R&D team works closely with you to develop and integrate new, innovative surface treatment processes perfectly adapted to the technical and regulatory requirements of your medical devices.



Our surface treatment processes

» Passivation

- Corrosion resistance.
- Stabilization of laser marking.
- Preservation of surface properties.

» Electropolishing

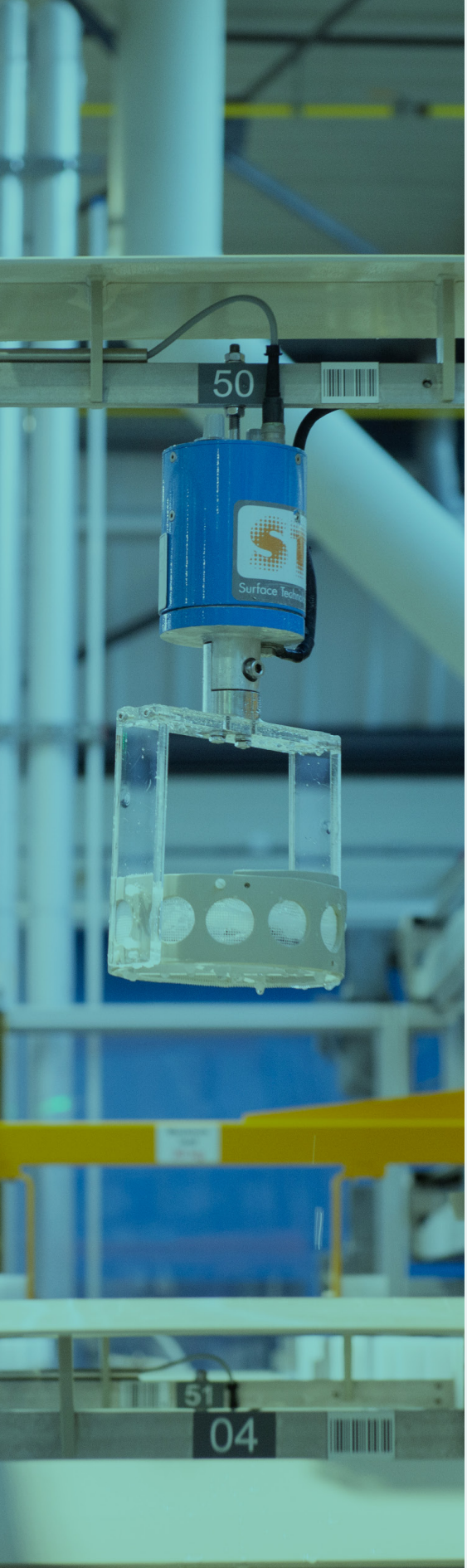
- Shiny finish.
- Removal of imperfections.
- Corrosion resistance.
- Preservation of functional and dimensional areas.

» Automated sandblasting

- Controlled roughness modification.
- Surface preparation for subsequent treatments.
- Option to integrate our StarSurf® process as a complementary step.

» Laser marking

- Identification & traceability.
- Graduation & positioning.
- Superficial marking that preserves mechanical properties.



» Masking

- Selective surface protection: two-tone anodization or heterogeneous treatment.

» Anodization

Type I

- Identification of ranges and sizes.
- Matte or satin finish.
- 52-color palette available.

Type III

- Identification and preservation of the original appearance.
- Shiny finish.
- 52-color palette available.

Type II

- Anthracite gray finish.
- Wear resistance.
- Enhanced protection.

» ColorBox®

- Automated equipment for titanium anodization.
- Controlled autonomy and quality within your facilities.
- Easy integration into your production flow.
- Proprietary electrolytes provided with the equipment.

We can also provide additional equipment with suitable electrolytes to integrate surface treatment processes directly into your facility.

STARSURF®

Osteopromotive surface treatment

A patented, specific etching process dedicated to titanium surfaces.

StarSurf®

- 3 porosity levels
- Hydrophilic surface
- Residue-free process
- Increased contact surface
- Adaptable process

Optimizing implant integration and performance

Enhanced biocompatibility
Improves compatibility between the implant and bone tissue for a natural and safe integration.

Accelerated osseointegration
Promotes rapid and homogeneous bone growth, ensuring stable and durable implant fixation.

Faster healing
Shortens healing time thanks to a textured surface which wettability accelerates cells development.

High mechanical strength
The process enhances the implant's mechanical properties, extending its lifetime.

Discover our White Paper

Sterile Packaging

Cleaning, assembling, and packaging of medical devices in an ISO 7 environment.

Comprehensive expertise to ensure the safety of your medical devices

With full control over every key stage of cleaning and packaging, we guarantee quality, cleanliness, and traceability in strict compliance with applicable standards.

End-to-End Support

From cleaning to full traceability of your medical devices.

ISO7

Controlled environment

Operations performed in ISO 7 clean rooms.

Optimized supply chain

Management of component sourcing and storage.

Single point of contact

A dedicated project manager for smooth coordination and follow-up.

Industrial flexibility

Ability to integrate new processes and equipment based on specific requirements.

Patented innovation

Packaging and handling solutions designed to protect your medical devices.

Validation optimization

As owner of cleaning, packaging and sterilization dose mapping validations, we provide rationales based on the scoring of your medical device to reduce the costs of the tests and accelerate the time-to-market.

Tailored solutions: from cleaning to labelling and sterilization

Cleaning & disinfection

- Spray washing in disinfecting washers.
- Supercritical CO_2 technology.
- Custom processes: plasma, ethanol cleaning, etc.

Assembling and kitting

- Complex manual operations: mechanical assembling, gluing, cutting, draping, etc.
- Semi-automated or robotized operations: press assembling, ultrasonic welding, mechanical testing, etc.

Packaging

- Standard or customized pouches and blisters.
- SoBliss®: the re-invented blister.
- Holders: SoTab®, SoEasy®, SoKlean® or tailor-made clamshells, foams and other packaging accessories .

Traceability

- Printing of standard or specific labels.
- QR codes and data matrix.
- Provision of full traceability certificates.
- Management of GAMMA or ETO sterilization.

Supercritical CO_2 cleaning for medical devices

An innovative technology using supercritical CO_2 for ultra-clean medical device cleaning.

- Water-free
- Non-toxic
- Chemical-free
- Non-corrosive
- Non-polluting
- No residues on DM
- Significative reduction of TOC, THC, bioburden...

- Implantable textile devices
- Electronic components
- Coated & bioresorbable implants
- Catheters - connectors
- Additive manufacturing implants

Process validated according to ISO 19 227

A clean and high-performance process

High-performance cleaning
Efficiency for medical devices with complex geometries and heat-sensitive materials.

Preserved materials
Non-corrosive process that maintains the integrity and properties of sensitive devices.

Optimal safety
Minimizes contamination risks through a safe, non-toxic, and residue-free cleaning method.

Sustainable cleaning
Solvent-free and water-free process in a closed-loop system, offering an environmentally friendly solution.

SOBLISS®

The next-generation blister

SoBliss® offers a new vision of blister packaging.

SoBliss®

- Robust
- No-touch
- Transparent
- Intuitive
- Customizable

Single or double barrier

Compact design

Fully transparent

Peelable Tyvek® strip

A safe holder

With SoBliss®, implants are perfectly stabilized thanks to a custom-fit holding solution or our SoTab®, SoEasy® and SoKlean® holders.

ISO 11607 & 868-5 | 5-year validation | Gamma or ETO sterilization

Innovation at the heart of packaging

Enhanced protection
a rigid, durable blister for superior implant protection.

Implant security
Perfect grip for a safer implant handling.

Easy identification
Quick implant recognition with 360° transparent design.

Operating room efficiency
Optimized for a fast, controlled opening via its peelable Tyvek® strip.

Risk reduction
Contact-free design minimizes contamination during aseptic transfer.

Optimized packaging
Reduces excess materials with a self-contained, no-overpack solution.

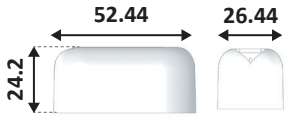
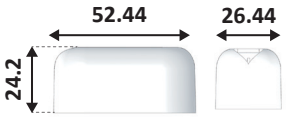
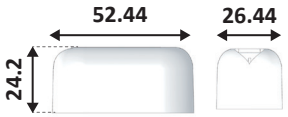
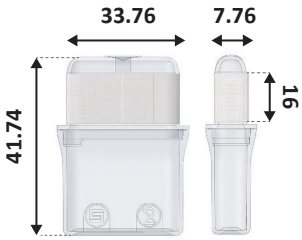
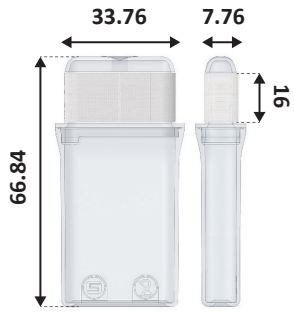
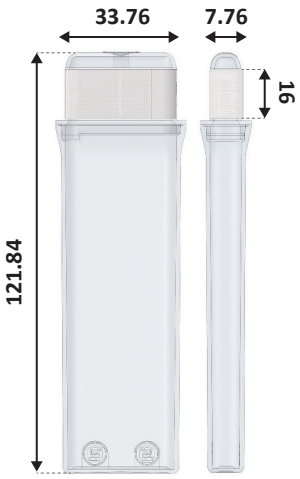
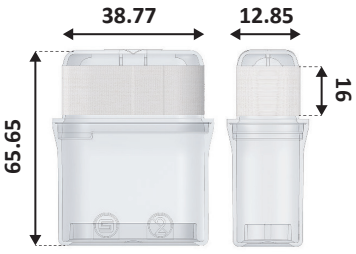
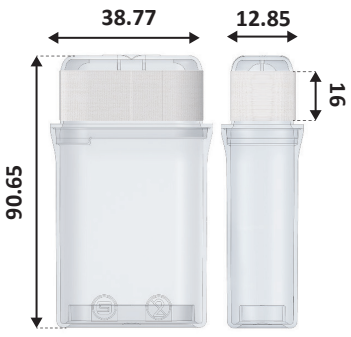
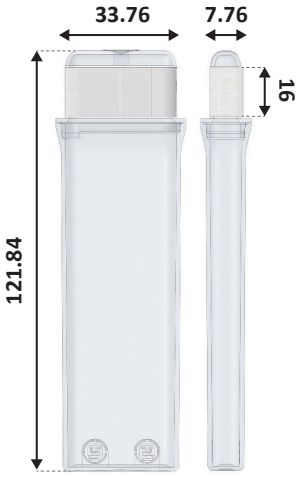
2018 AmeriStar

WPO WORLD PACKAGING ORGANISATION
WORLDSTAR WINNER 2015

MEDICAL DESIGN EXCELLENCE AWARDS® 1998–2014

Watch the SoBliss® video

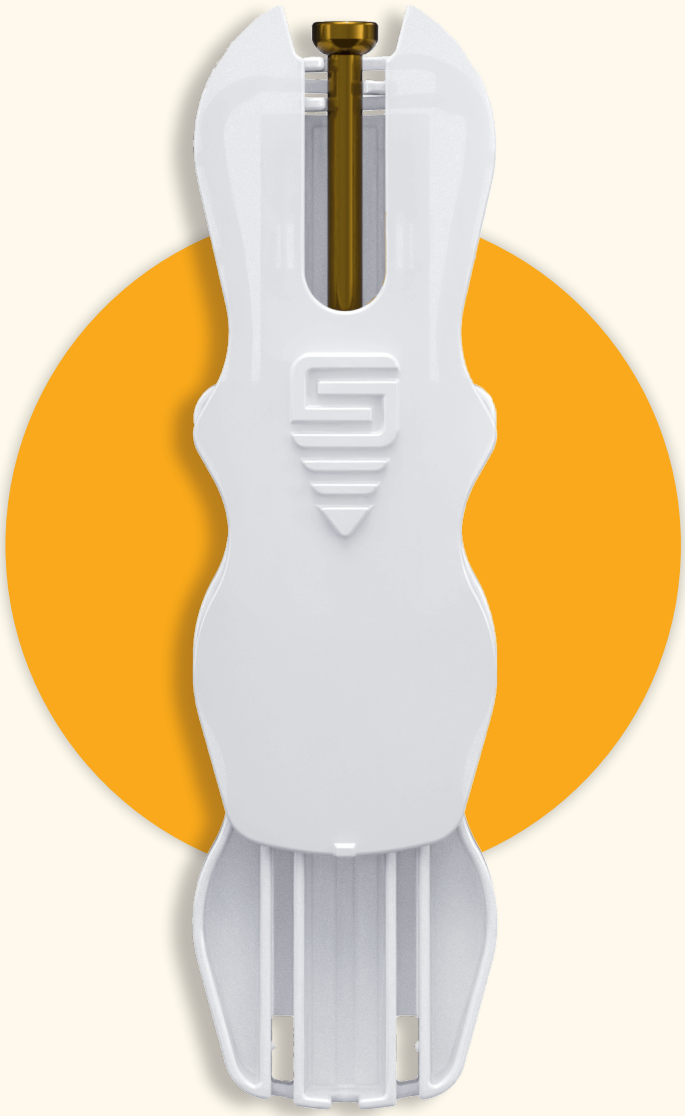
Available in single or double barrier versions

	SIZE S	SIZE M	SIZE L
EXTERNAL CAP			
INTERNAL BLISTER			
EXTERNAL BLISTER			

SOEASY®

The orthopedic no-touch holder

SoEasy® optimizes the handling and protection of orthopedic implants.



SoEasy®

- No-touch
- Protective
- Ergonomic
- Intuitive
- Customizable

Protective slider

Secure gripping zone

Retention hook

Customized sterile packaging

SoEasy® has the option of being sterilely packaged in pouches, blisters or with our SoBliss® solution!

Enhanced safety
Contact-free design minimizes contamination during aseptic transfer.

Ergonomic grip
Ambidextrous, suitable for both right- and left-handed users, ensuring a comfortable grip.

Secure holding
Ensures implant stability, allowing precise extraction without the risk of dropping.

SIZE M	SIZE L
Dmax: 4,2 Dmin: 1,6	Dmax: 8,5 Dmin: 4,5
Lmax: 60 Lmin: 10	Lmax: 110 Lmin: 10

**All dimensions are in millimeters (mm)*

SOKLEAN®

The dental holder for a Klean surgery

SoKlean® optimizes the handling and protection of dental implants.

SoKlean®

- No-touch
- Protective
- Ergonomic
- Intuitive
- Customizable

Slider with integrated cover screw

Titanium ring

Rotating hood

Customized sterile packaging

SoKlean® has the option of being sterilely packaged in pouches, blisters or with our SoBliss® solution!

SoKlean® is available in multiple colors!

SIZE M

Dmax: 5,5 Lmax : 18
Dmin: 3 Lmin : 6

SIZE L

Dmax: 7 Lmax : 24
Dmin: 3 Lmin : 11

**All dimensions are in millimeters (mm)*

An innovative design for controlled handling

Enhanced protection
The titanium ring isolates the implant and preserves its integrity in a perfectly clean state.

Safe handling
The rotating hood and sliding tray simplify manipulation for fast, fluid operation.

Secure holding
Ensures implant stability, allowing precise extraction without the risk of dropping.

Ergonomic design
Ambidextrous, suitable for both right- and left-handed users, ensuring a comfortable grip.

Risk reduction
Contact-free design minimizes contamination during aseptic transfer.

Optimized procedure
All essential elements combined in a single package for greater efficiency in the operating room.

Compatible with the Clean Implant label.

Selenium Medical

9049 rue de Québec, 17000 La Rochelle, FRANCE

contact@selenium-medical.com | +33 (0)5 46 44 40 82

Selenium America

6201 Fairview Road- Suite 200, Charlotte, NC 28210, USA

sea@selenium-medical.com | +1 704 808 0970