Terragene®

# Solutions to guarantee safety in **Dental Clinics**

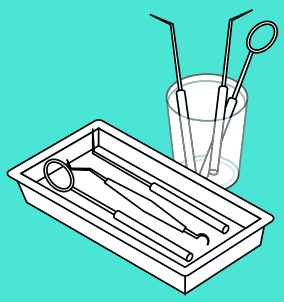
For dental services

Rev. 8 | March 2025

# What do we do?

At Terragene we offer a range of effective, simple-to-handle products to accurately control every step of instrument reprocessing in dental clinics. Available in a variety of formats, these high-performance control devices provide fast and consistent results in order to protect what matters most to you, your patient.

Wanna know more?



# Washing, Disinfection & Hygiene

It is vital to control the cleaning processes of instruments and devices since the result influences the success of the subsequent processes for sterilization. This control is crucial, particularly in automatic washing machines like washer-disinfectors and ultrasonic washing machines. The process parameters in the washing procedure may deviate from the acceptable limits. This can directly impact on the cleaning performance and affect negatively the final reprocessed materials. Moreover, the international Standards ISO 15883-1:2006, ISO 15883-5:2021, HTM01-01:2016, HTM01-05:2013 and ANSI/AAMI ST79:2017 require the monitoring of this process with a specific regime, through weekly or even daily check-ups.

# Washing, Disinfection & Hygiene

Controlling cleaning and washing processes of dental instruments and materials is highly important since its outcome affects the success of subsequent disinfection and/or sterilization processes.

## Cleaning Indicator

### Chemdye® Splat

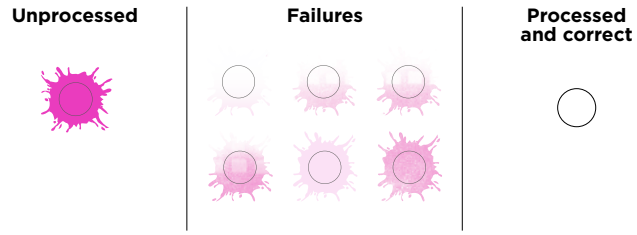
Chemdye® Splat indicators consist of a synthetic support, which is stable at disinfection temperatures. Each indicator contains a mixture of specially combined colored organic components. Splat indicators formulation allows monitoring of all factors that affect the cleaning/washing process outcome. Splat indicators can be used for routine monitoring of cleaning/washing processes in washer-disinfectors and ultrasonic washing machines.

•2 challenge levels.
•High level of accuracy and reproducibility to reveal deficiencies in the washing process.
•Non-toxic organic formulation that guarantees a long shelf-life.

CDWA4
Very high challenge level.
Compatible with CDWAH and CDWAH-U Holders.

CDWAH-U
*For Ultrasonic washing*

CDWAH
*For Thermodisinfection washing*




## Thermodisinfection Indicator

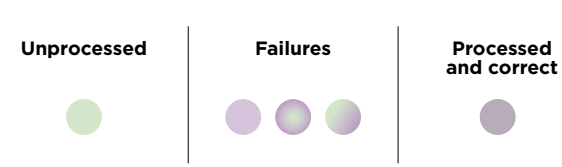
### Integron® IT27W

After cleaning, surgical instruments must be disinfected to ensure safe subsequent handling and processing. Thermal disinfection with moist heat, is the most common method for disinfection of medical devices in the hospital setting.

•Designed to react to moist heat disinfection processes in washer-disinfectors.
•Accurate and convenient method of routine control.
•Assurance of disinfection efficiency.
•Green indicating ink turns to purple when temperature and time conditions are met.

| Code | Time | Temp. |
|---|---|---|
| IT27W-1 | 1 minute | 90 °C |
| IT27W-5 | 5 minutes | 90 °C |
| IT27W-10 | 10 minutes | 93 °C |

IT27W
Compatible with CDWA-H Holder for Thermodisinfection washing



# Washing, Disinfection & Hygiene

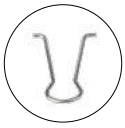
## Indicators for cavitation capacity test for ultrasonic washers

### Chemdye® CDWU-Z

Control of cleaning and washing of instruments and dental materials is highly important since its outcome affects the success of subsequent disinfection and/or sterilization processes.

•Reliable results in routine control of ultrasonic washers.
•High confidence and reliability to reveal deficiencies in the cavitation capacity of ultrasonic washing machines.

CDWU-Z
Compatible with CDWU-H Holder for Ultrasonic Cavitation indicator



#### Holder for ultrasonic cavitation test

Accessory for keeping the indicator in a fixed position without affecting its performance. This guarantees the correct performance evaluation of the nearest transducer.

**Unprocessed**

**Low cavitation capacity**

**High cavitation capacity**

# Washing, Disinfection & Hygiene

## Protein-based quantitative hygiene monitoring system

### Chemdye® PRO1 MICRO

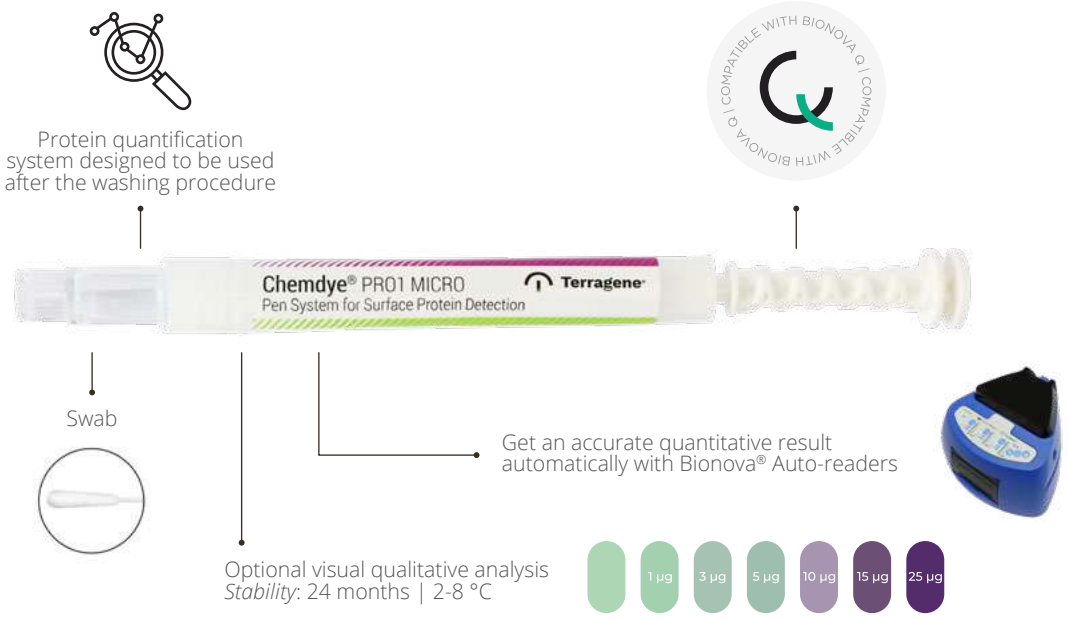
Terragene has developed the Chemdye® PRO1 MICRO hygiene monitoring system which not only detects but also quantifies proteins and reducing agents on the surfaces of instruments, after the cleaning and disinfection process.

The system consists of a pen that has a high absorption swab and two separate reactive solutions contained within the same device. After taking the sample from the selected surface, the swab is returned to the pen, activated and the result is then obtained at 7 minutes of incubation at 60 °C (using Bionova® IC10/20FR and IC10/20FRLCD) or 4 minutes at 60 °C (in Bionova® MiniPro Auto-reader). By its given final quantitative result, it is possible to determine whether reprocessing and/or retesting of the tested surface is necessary.

Chemdye® PRO1 MICRO system can obtain a quantitative result with a sensitivity of 0.3 µg.

### Advantages

- Unique absolute total protein quantification system.
- High sensitivity.
- Rapid test results in 4 minutes with Bionova® MiniPro.
- Alternatively provides qualitative data. Comparison of the final color against a color pattern included within the device allows estimation of cleanliness.
- It does not require handling dangerous chemical substances in specialized laboratories.
- Quick results that allow taking immediate remedial action and avoiding healthcare-acquired infections.
- Manufactured under ISO 15883-1:2006 standard and follow recommendations set in the HTM 01-05:2013 and HTM 01-01:2016 guidelines.
- Traceability with Bionova® Q Software.



# Washing, Disinfection & Hygiene

## Auto-reader for PRO1 MICRO hygiene monitoring system

### Bionova® MiniPro

**Quantitative analysis**
Bionova® MiniPro is an advantageous and very sensitive tool for incubation and reading of PRO1 MICRO hygiene monitoring systems since it offers the user the unique benefit of performing a quantitative analysis of small quantities of protein, thus providing an exclusive and convenient way to keep results recording and traceability of every surface checked for contaminants. This exclusive feature makes Bionova® MiniPro an innovative device to keep objective track of surface cleaning process monitoring unparalleled on the current market.

**Compact design**
Bionova® MiniPro is a compact table-top incubator that can be placed anywhere in your facility thanks to its small size.

**Time optimization**
Bionova® MiniPro has 3 incubation positions, thus allowing the incubation of 3 independent Protein System Pens at the same time.

**Built-in thermal printer**
A thermal printer delivers a ticket showing the final result of each active readout position. This allows to register each result in a record logbook.

4'
**Ultra Rapid**
Readout


**Reading & traceability system**
USB connection for PC, record keeping through Bionova® Q Reading and Traceability software.

**No maintenance required**
The device does not need any kind of routine maintenance.

**Temperature monitoring**
The device has an opening on its side to insert a thermometer, which allows temperature monitoring control.

# Sterilization monitoring

Sterilization procedures should be monitored using biological and chemical indicators. Biological Indicators, or spore tests, are the most accepted means of monitoring sterilization because they assess the sterilization process directly by killing known highly resistant microorganisms. Chemical Indicators do not guarantee sterilization; however, they help detect procedural errors (e.g., overloaded sterilizer, incorrect packaging) and equipment malfunctions. On the other hand, some Chemical Indicators should be used inside a package to verify that the sterilizing agent has penetrated it and reached the instruments inside.


PHOTON®

## THE FIRST **7-SECOND** BIOLOGICAL MONITORING SYSTEM

Fully compatible with Bionova® Wireless Assistant

Fully compatible with Bionova® Q

**7″**

HIGH SENSITIVITY

Self-Contained Biological Indicators (SCBI) for steam sterilization processes

STEAM BT225


Identification label with process indicator

Not exposed

Exposed

Spore carrier with *Geobacillus stearothermophilus*

PASS FAIL

Configuration & alarm cancellation button

Temperature progress & stability indicator

Fully compatible with Bionova® Q.

Two incubation positions

Easy & immediate

PC or mobile connectivity via USB, Bluetooth or Wi-Fi

**Bionova® Wireless Assistant**

### Urgent procedures, require immediate decisions

Monitor the results of your Photon (steam 7-second readout) auto-readers with one click and convert the information into correct decision making.

# **Sterilization** | Biological Indicators

## Ultra Rapid, Super Rapid & Rapid Biological Indicators

The demand for sterile instruments in less time can now be met by the Bionova® Rapid Readout Fluorescence System. Bionova® Rapid, Super Rapid and Ultra Rapid Self-Contained Biological Indicators allow the release of steam-sterilized loads between 20 minutes to a few hours.

Rapid, Super Rapid and Ultra Rapid BIs for sterilization in autoclaves should be incubated in the Bionova® Automatic Fluorescence Auto-readers IC10/20FR, IC10/20FRLCD or MiniBio at 60 ± 2 °C. These devices provide accurate, rapid, reliable and easy detection of positive and negative indicators, offering final results in short times. All this information can be recorded and stored in the Bionova® Q Traceability Software, available on our website.

| **Ultra Rapid** | **Super Rapid** | **Rapid** |
|---|---|---|
| 20′ | 1h | 3h |
|  |  |  |
| **BT224** | **BT222** | **BT220** |
| STEAM | STEAM | STEAM |
| 132-135 °C | 121-135 °C | 121-135 °C |



## Auto-reader incubator

Bionova® MiniBio is a compact Fluorescence Auto-reader for Rapid, Super Rapid & Ultra Rapid Biological Indicators.

- Compact design
- Time optimization
- Easy to use
- Automatic readout
- Temperature monitoring
- Built-in thermal printer
- No maintenance required

# **Sterilization** | Biological & Chemical Indicators

## Conventional Biological Indicators

### Bionova® BT20 | BT30 & Dual Incubator IC10/20

Biological Indicators are the only internationally accepted indicators that provide a direct measure of a sterilization cycle lethality.
By using Bionova® IC10/20 Dual Incubator, Bionova® Conventional SCBIs produce visible results within 24 and 48h.


## Fluorescence-based Process Challenge Devices (PCD)

### Steam PCDs

Process Challenge Devices are designed to simulate a Biological Indicator (BI) placed in a large hospital pack and emulate the 16 towel pack PCD described in ANSI/AAMI ST79:2017.

Bionova® PCD pre-assembled disposable test packs consists of a SCBI, a Type 5 Integrator Indicator and a self-adhesive Record Card, held within a stack of porous cards that poses resistance to steam penetration. The whole ensemble is contained within a cardboard box with a Type 1 Process Indicator that changes color when exposed to steam.

| Code | Readout | SCBI |
|---|---|---|
| KPCD220-C | 3 hs at 60 °C | BT220 |
| KPCD222-C | 1 hour at 60 °C | BT222 |
| KPCD224-C | 20 min. at 60 °C | BT224 |
| KPCD225-C | 7 sec. at 60 °C | BT225 |


**KPCD224-C**

# Sterilization | Chemical Indicators

## Bowie-Dick Test Pack

### Chemdye® BD125X/1 | BD125X/2

Chemdye® Bowie-Dick Test Packs are single-use devices that consist of a lead free Chemical Indicator, a BD Test Sheet, placed between porous sheets of paper, wrapped with crepe paper, with a steam indicator label on the top of the package.

**BD125X/1**
Developed for testing air removal efficiency. Simulates the 4 kg handmade pack described in ANSI/AAMI ST79. It contains a Warning Sheet, thus allowing an early detection of air removal failures.

**BD125X/2**
Developed for detecting inadequate air removal and Steam penetration. Simulates the 7 kg handmade pack described in EN 285.

## Bowie-Dick Test Card

### Chemdye® KBD8948X | KBD8948X/1

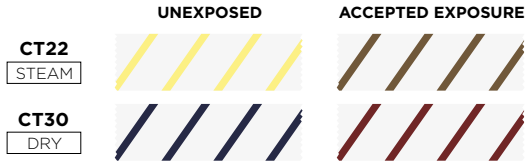
Chemdye® Bowie-Dick Test Cards (ISO 11140-1:2014 and ISO 11140-5:2007) are designed to monitor the effectiveness of air removal in vacuum-assisted steam sterilizers at 132 °C, 4 min and at 134 °C, 3.5 minutes. Chemdye® Bowie-Dick Test Card consists of a Type 2 metal free Chemical Indicator printed on one side of the card. Chemical Indicator changes from purple to green when processed. Non-uniform color change indicates presence of an air pocket during the sterilization cycle thus indicating sterilizer malfunction. BD8948H is a blue anodized aluminum re-usable Holder for keeping Test Cards in place for proper assessment of sterilization cycle.


**BD8948H**
Blue anodized aluminum re-usable Holder

## Tapes | Type 1

### Cintape® CT22 | CT30

Cintape® CT22 and CT30 Self-adhesive tapes have been designed to wrap and seal sterilization packages as well as to distinguish between items that have been exposed to sterilization processes from those that have not.



# **Sterilization** | Chemical Indicators

## Single and double strips | Type 4

### **Chemdye® CD29 | CD30**

Chemdye® Type 4 internal control strips are multivariable indicators that rapidly show if critical parameters of the sterilization process have been reached, ensuring appropriate penetration of the sterilizing agent inside the packages. These Chemical Indicators offer a distinct color change when exposed to the stated values (SVs) of the critical process variables.

| | Unprocessed | Failures | Processed and correct |
|---|---|---|---|
| **CD29** STEAM | | | |
| **CD30** DRY | | | |

## Unique point Integrator | Type 5

### **Integron® IT26-1YS**

Integron® IT26-1YS was developed for verification of steam sterilization cycles between 121 °C and 135 °C. These products ensure an adequate control of the effectiveness of sterilization processes (temperature, time, steam quality).
The accepted final color is achieved when a theoretical spore population reaches its kill time, indicating integration condition has been reached.

| Unprocessed | Failures | Processed and correct |
|---|---|---|
| | | |

## Moving front Integrator | Type 5

### **Integron® IT26-C**

Integron® IT26-C was developed for monitoring steam sterilization processes between 118 °C and 138 °C and to ensure an adequate control of the effectiveness of sterilization processes by monitoring all critical parameters of steam sterilization (temperature, time, steam quality). Chemical pellet melts and migrates as a dark bar along the paper wick. Migration occurs through a zone marked as accept or reject, thus indicating whether sterilization conditions were met or not. The accept result is reached when a theoretical spore population reaches its kill time, indicating integration condition has been reached.


| Unprocessed | Processed | |
|---|---|---|
| | *Accept* | *Reject* |
| | | |


# Digital workflow solutions for the Sterile Processing department

At Terragene we have developed a complete traceability system for monitoring processes in sterilization departments.

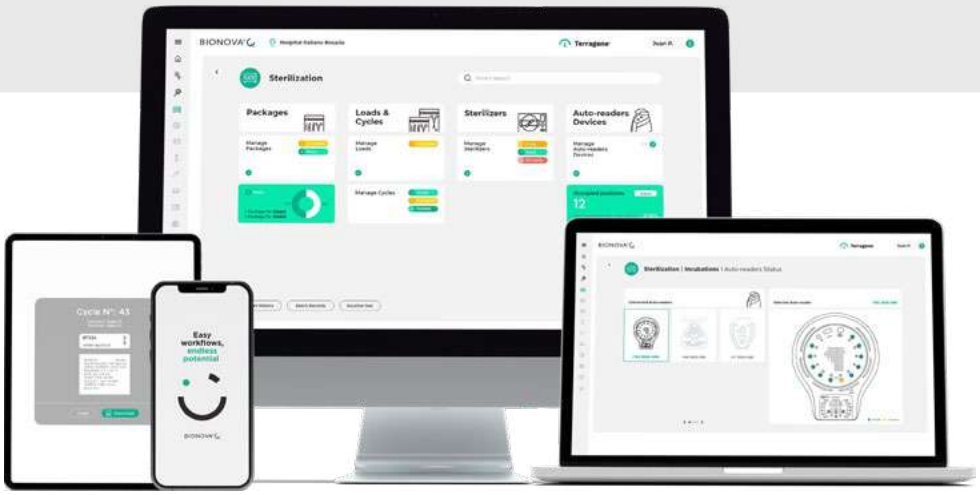
You can now have access to a complete solution associated with Terragene´s disposables. Streamline and automate the traceability associated with washing tests, Chemical Indicators (including the Bowie-Dick test), quantitative protein-based hygiene monitoring tests, and for any Bionova® fluorescence readout Biological Indicator.

## Easy workflows, endless potential

# BIONOVA®Q

**Your ally in CSSD**

*Terragene solution for streamlining process monitoring in the CSSD*




Discover Bionova's new digital tool, designed to transform sterilization center management. With a comprehensive approach, this solution goes beyond basic record-keeping: it optimizes every stage of the process, ensures complete traceability, and enhances safety for both patients and user's staff.

High security · High availability · No infrastructure costs · Scalability · Quick implementation · Anytime, anywhere · Auto-maintenance

## Why choose Bionova Q?

Boost operational efficiency and reduce errors.

Guarantee full traceability of every device and supply.

Integrate with your existing systems to maximize control and safety.

BIONOVA® Q App

# Artificial intelligence for infection prevention

A quick scan of chemical indicators ensures efficiency and safety, revolutionizing the way sterile surgical instruments are cleared right before every procedure.

**1**

Scan the chemical indicator

**2**

Automatically AI reads and interprets the chemical indicator

**3**


Done! The report is available on Bionova Q


## COMPATIBLE PRODUCTS

IT26-1YS
*Unique point integrator indicator*

IT26-C
*Moving front integrator indicator*

BD125X/1
BD125X/2
*Bowie-Dick Test Pack*



CD29
*Multivariable indicators*



CD40
*Multivariable indicators*



CD42
*Process indicators*

PCD-A-3.5Y
*Test strips for use in Helix-PCD System*

CDWA3
*Cleaning Indicator for cleaning performance tests*

CDWA4
*Cleaning Indicator for cleaning performance tests*

| PRODUCT | | DESCRIPTION | UNITS/PACKAGING |
|---|---|---|---|
| **CLEANING AND HYGIENE CONTROL** | | | |
| CDWA4 | | Cleaning Indicator for cleaning performance tests | 200 units per bag |
| CDWAH | | Holder for CDWA and IT27W cleaning indicators | 1 unit per box |
| CDWAH-U | | Holder for CDWA cleaning indicators | 1 unit per box |
| IT27W-1 | | Thermodisinfection Indicator for Moist Heat Disinfection | 200 units per bag |
| IT27W-5 | | Thermodisinfection Indicator for Moist Heat Disinfection | 200 units per bag |
| IT27W-10 | | Thermodisinfection Indicator for Moist Heat Disinfection | 200 units per bag |
| PRO1 MICRO | | Pen system for Surface Proteins Detection | 20 or 100 units per box |
| MiniPro | | Auto-reader Incubator for Hygiene Monitoring System | 1 unit per box |
| **BIOLOGICAL INDICATORS FOR STERILIZATION CONTROL** | | | |
| BT20 | STEAM | SCBIs for Steam sterilization. Final readout: 24 hours | 25/30/100 units per box |
| BT30 | DRY | SCBIs for Dry Heat sterilization. Final readout: 48 hours | 50 units per box: 25A+25B |
| BT220 | STEAM | SCBIs for Steam sterilization. Final readout: 3 hours | 50 units per box |
| BT222 | STEAM | SCBIs for Steam sterilization. Final readout: 1 hour | 50 units per box |
| BT224 | STEAM | SCBIs for Steam sterilization. Final readout: 20 minutes | 50 units per box |
| BT225 | STEAM | SCBIs for Steam sterilization. Final readout: 7 seconds | 50 units per box |
| IC10/20 | | Dual incubator for Biological Indicators | 1 unit per box |
| MiniBio | | Auto-reader Incubator for Fluorescence Biological Indicators | 1 unit per box |
| BPH-Photon | | Auto-reader Incubator for Fluorescence Biological Indicators | 1 unit per box |
| KPCD220-C<br>KPCD222-C<br>KPCD224-C<br>KPCD225-C | STEAM | Test pack for Steam sterilization processes. Contains: porous cards system holding a SCBI, a moving-front Type 5 integrator indicator and a self-adhesive record card.<br>KPCD220-C: Final readout: 3 hours<br>KPCD222-C: Final readout: 1 hour<br>KPCD224-C: Final readout: 20 minutes<br>KPCD225-C: Final readout: 7 seconds | 1 kit x 25 PCDs +<br>1 box x 25 SCBIs |
| **CHEMICAL INDICATORS FOR STERILIZATION CONTROL** | | | |
| BD125X/1 | TYPE 2 | Bowie-Dick Test Pack with Warning Sheet | 20 units per box |
| BD125X/2 | TYPE 2 | Bowie-Dick Test Pack | 20 units per box |
| KBD8948X | TYPE 2 | Bowie-Dick Test Card + Holder | 120 units + 1 holder per box |
| KBD8948X/1 | TYPE 2 | Bowie-Dick Test Card + Holder | 120 units + 1 holder per box |
| CT22 | TYPE 1 | Self-adhesive indicator tape for Steam | 1 roll of 50 m x 19 mm |
| CT30 | TYPE 1 | Self-adhesive indicator tape for Dry Heat | 1 roll of 50 m x 19 mm |
| CD29 | TYPE 4 | Multivariable indicators for Steam sterilization | 250 strips per bag |
| CD30 | TYPE 4 | Multivariable indicators for Dry Heat sterilization | 250 or 500 strips per bag |
| IT26-1YS | TYPE 5 | Unique point integrator indicator for Steam sterilization | 200 or 500 units per bag |
| IT26-C | TYPE 5 | Moving front integrator indicator for Steam sterilization | 100 or 250 units per bag |

**OEM**
DEVELOPMENT DIVISION

# YOUR BRAND, OUR INNOVATION

At Terragene, we understand that every brand has a unique vision. Our **OEM (Original Equipment Manufacturer)** and **Private Label** services provide tailored solutions to elevate your brand with high-quality products. Whether you're looking to develop products under your own brand or need a reliable manufacturing partner, we're here to turn your vision into reality.

**HEALTHCARE, DENTAL, INDUSTRIES, PHARMA.**

**Efficiency, quality, and advanced technology at your fingertips.**

CONTACT US

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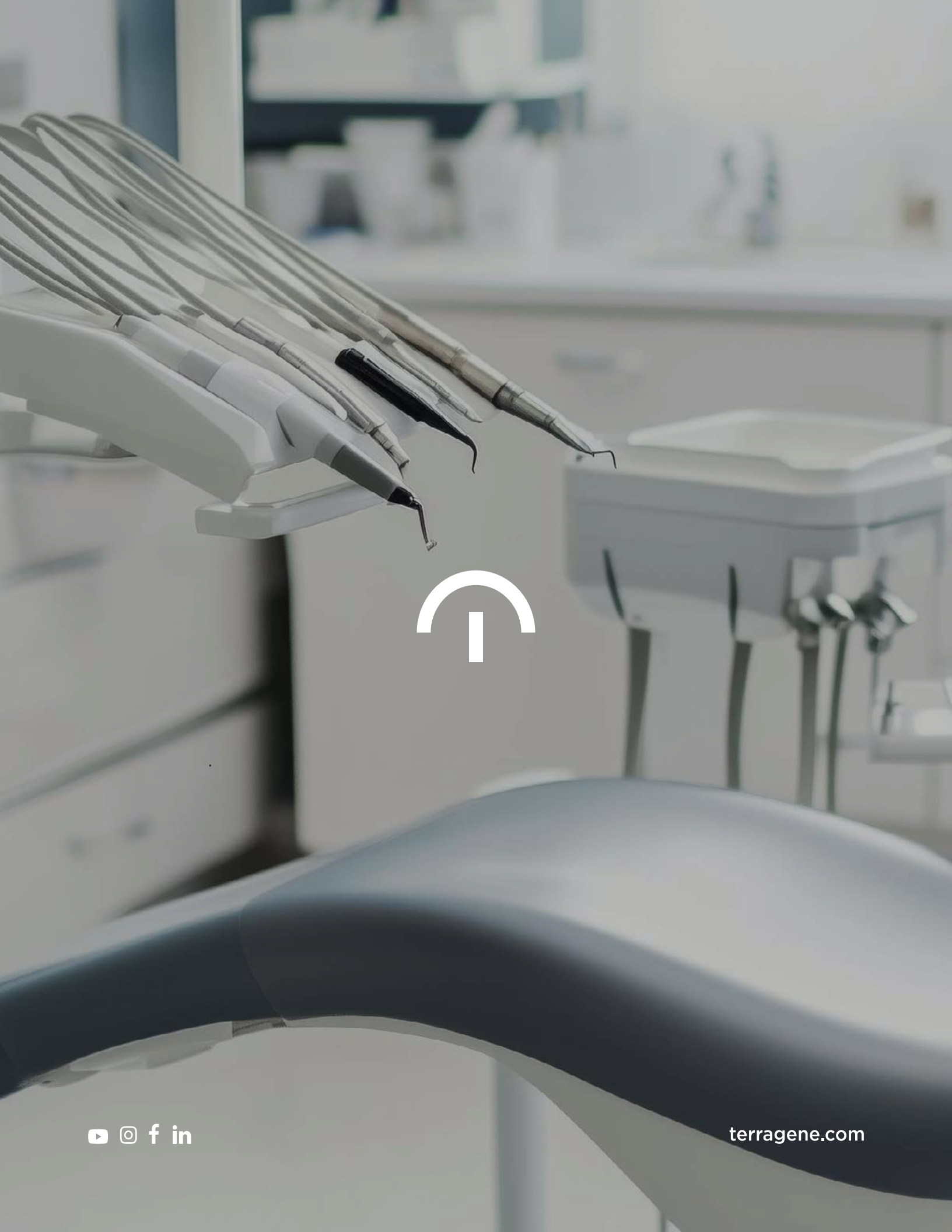

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