USER MANUAL FOR STRAUMANN® FALCON ACCESSORIES

VERSION 1.0

mininavident
FOR INNOVATORS IN IMPLANTOLOGY

CONTACT INFORMATION

Manufacturer's address

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EC representative

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Authorized service partners

mininavident's authorized service partners cover all service needs for the entire system life cycle.

To find your local authorized service partner visit our website:

www.mininavident.com/servicepartner

Replacing components

Only use original Straumann® Falcon Accessories and spare parts.

INTENDED USE FOR STRAUMANN® FALCON ACCESSORIES

The medical devices manufactured by Mininavident AG are intended to be used with the Straumann® Falcon with the following intended uses:

DENAREG

The DENAREG registration tool is used to calibrate the motor with handpiece and to register the drill and the round bur. It has an additional marker on the surface for straight handpiece.

DENAMARK single use

The marker serves as a reference point for the navigation system in the lower or upper jaw of the patient.

DENADAPT Bien-Air ventilated with cable

The adapter with cable connects the camera to the handpiece motor with a magnetic quick-release fastener. The cable supplies the motor with electricity.

DENACART

The system cart is an accessory that can be ordered optionally. It is intended to be used as storage space for Straumann® Falcon components (computer, screen, camera) and accessories.

Patient population

Partially edentulous patients who require dental implants as part of their treatment plan.

Intended user

Oral surgeons, cranio maxillofacial surgeons, and general practitioners with knowledge of dental implant surgery.

Anatomical location

Complete upper and lower jaw, depending on the individual mouth opening and the placement and line of sight of the marker.

Intended medical contraindication

All contraindications for Straumann® Falcon apply as well to the Straumann® Falcon Accessories.

↗ Refer to Straumann® Falcon User Manual

NOTES ON THE USER MANUAL FOR STRAUMANN® FALCON ACCESSORIES

General information on the User Manual for Straumann® Falcon Accessories

Table 1 Revision history

Publication version	Revision date	Change description
1.0	December 2023	First version

Edition notice

This User Manual is intended for operators of the Straumann® Falcon.

Every effort has been made to ensure that all the information contained in this User Manual for Straumann® Falcon Accessories is correct at the time of publishing. However, mininavident may need to update the User Manual for Straumann® Falcon Accessories information as a result of product surveillance.

Online portal for technical documents

mininavident has set up an online portal for the technical documents at http://www.mininavident.com/manuals.

From there, you can download this User Manual for Straumann® Falcon Accessories.

Names, symbols, and abbreviations

Component names

Component name	Descriptor
DENADAPT Bien-Air ventilated with cable	Adapter with cable
DENAREG®	Registration tool
DENACART®	System cart
DENAMARK® single-use	Marker, single-use

Symbols used on components

Symbol	Explanation
	CE mark
	Consult instructions for use
	Data matrix code for product information including UDI
	EC representative
	Date of manufacture
	Do not dispose of with domestic waste
	UK Representative
	Federal law restricts this system to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the system.

Symbol	Explanation
	Keep dry
	Manufacturer
	Non sterile
	Not for re-use
	Reference number
	Serial number
	Thermo washer disinfectable
	Sterilizable in a steam sterilizer (autoclave) at the specified temperature
	Electrical security. Applied part type B
	Batch code or Lot number

Abbreviations

Abbreviation	Definition
ANSI	American National Standards Institute
CBCT	Cone beam computed tomography
DIN	Deutsches Institut für Normung
EN	European standard
IEC	International Electrotechnical Commission
IFU	Instructions for use
ISO	International Organization for Standardization
UDI	Unique device identification

WARRANTY AND LIABILITY

Care and cleaning

The owner is responsible for making sure that all care and cleaning activities are performed.

Repair

As manufacturer of the Straumann® Falcon Accessories mininavident can assume the responsibility for the safety properties only if repairs or maintenance is done by mininavident or authorized service partners. And if the parts are replaced by original spare parts.

Exclusion of liability

Any customer modification of the Straumann® Falcon Accessories renders the warranty or service agreement null and void.

In the event that the accessories owner fails to fulfill its obligation to perform care and cleaning activities, mininavident and its authorized dealers cannot assume liability for any damage thus incurred.

Duration

Mininavident grants a product warranty of 24 months for DENAREG and 12 months for DENADAPT ventilated with cable.

SAFETY INFORMATION

GENERAL

General attention

To avoid serious or fatal injury, read this User Manual thoroughly before you use the Straumann® Falcon Accessories.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this User Manual for Straumann® Falcon Accessories.
- Keep this User Manual for Straumann® Falcon Accessories in a safe place to ensure that it is not damaged and remains available for use.
- This User Manual for Straumann® Falcon Accessories must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:

Safety alert

The safety alert symbol is used to alert you to potential physical injury hazards. Comply with all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

Warning

Warning...
...indicates a hazardous situation which, if not avoided, could result in death or serious injury.

Caution

Caution...
...indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

Notice

Notice...
...indicates a hazardous situation that, if not avoided, may result in damage to the system or components.

Important information that is not safety relevant is indicated with the following icon:

Note
Indicates additional information on correct use or useful tips.

SAFETY MESSAGES

Safety precautions

⚠ To avoid serious or fatal injury, read and comply with the following safety precautions.

ON-SITE INSTALLATION

- Only an authorized mininavident service partner shall install the adapter with cable.
- The installation must have been performed according to the requirements of mininavident.

↗ For more information about the installation, see "Installation, setup and use of Straumann® Falcon Accessories" on page 17

EXCHANGE OR REMOVAL OF PARTS

Unauthorized exchange or removal of components can damage the system or stop it from functioning correctly.

- Do not exchange or remove any part of the accessories not specified in the user documentation.
- The replacement of components can only be done by mininavident or authorized services partners.

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before using the accessories, read the warning messages carefully.

OPERATOR QUALIFICATION - INSUFFICIENT KNOWLEDGE AND SKILLS

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual for Straumann® Falcon Accessories.

- Do not carry out operation and maintenance unless you have read and understood the information provided in the user documentation.
- Leave installation, repair, and preventive maintenance to an authorized mininavident service partner.
- Carefully follow the procedures specified in the instructions for operation and maintenance.

Caution messages

⚠ List of caution messages

Failure to observe them may result in minor or moderate injury.

- Before operating, read the caution messages carefully.

INJURY TO THE PATIENT DUE TO WRONG INSTALLATION

Incorrect installation and setup of the adapter with cable may lead to injury to the patient and/or inaccurate navigation procedure.

- Leave installation, repair, and preventive maintenance to an authorized mininavident service partner.

↗ For more information about the installation, see "Installation, setup and use of Straumann® Falcon Accessories" on page 17

INJURY TO THE PATIENT DUE TO USE OF NON-FUNCTIONAL OR NON-CONFORM COMPONENTS

Use of damaged, contaminated, or not correctly working components may lead to inaccurate navigation procedure.

- Replace damaged components prior to surgery.
- Do not use components that are contaminated.
- Do not use components that may not work correctly (e.g. after falling down).
- Do not use components that are not intended for use with the Straumann® Falcon.
- Do not use components that passed their service interval.

↗ For a list of supported materials, see "Overview of the system components" on page 14

Notices

⚠ List of notices

Failure to observe the notices may result in damage to the system.

- Before operating, read the notices contained in this summary carefully.

DAMAGE TO THE COMPONENTS DUE TO MECHANICAL STRESS

Shock, vibration, or pressure can damage the components of the system.

- Keep sources of vibration away from the components.
- Do not place objects on the components.

INFECTION BY BIOHAZARDOUS WASTE

- Treat the Straumann® Falcon Accessories as biohazardous waste. Decontamination (cleaning, disinfection, and sterilization) is required before reuse, recycling, or disposal of the system.
- Dispose of the accessories according to the local regulations. For more information, contact your Service representative.

SAFETY LABELS ON THE COMPONENTS

The Straumann® Falcon Accessories have warning labels to draw your attention to areas of potential hazard.

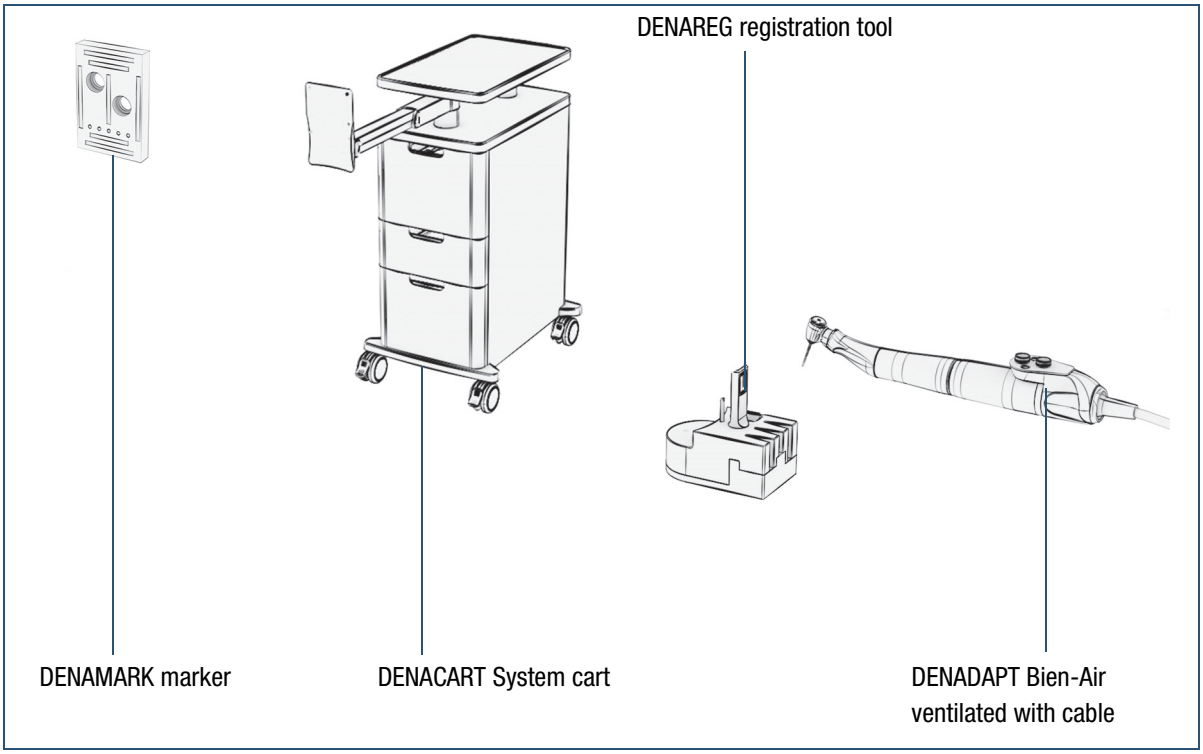
The following list explains the meanings of the labels at the locations where you find the labels.

Table 2 Safety labels on the components

Label	Where to find	Meaning
	Adapter with cable	Do not dispose with domestic waste
	Marker	The component has not been sterilized or treated with a process during manufacturing to eliminate potential microorganisms
	Marker	Do not re-use. Indicates a medical device that is intended for one single use only.
	Adapter with cable	Electrical security. Applied part type B.

SYSTEM OVERVIEW

OVERVIEW OF THE SYSTEM COMPONENTS



Picture 1 Straumann® Falcon Accessories

↗ For more information about unpacking Straumann® Falcon Accessories and setting up the components, see "Installation, setup and use of Straumann® Falcon Accessories" on page 17

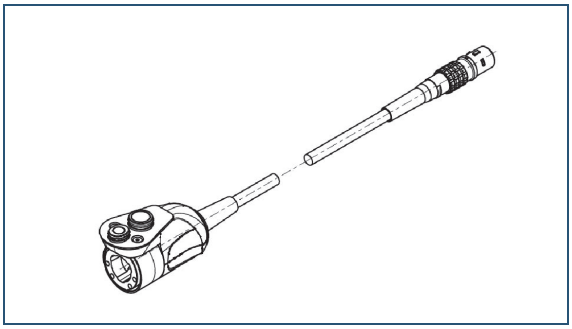
↗ For reference numbers, see "Reference numbers" on page 35

The DENADAPT Bien-Air ventilated with cable

The adapter connects the camera to the handpiece motor with a magnetic quick-release fastener. The cable supplies the motor with electricity.

↗ Refer to Straumann® Falcon User Manual

By means of a spring mechanism, the plate can be rotated around the handpiece motor, allowing the camera to be fixed in the most suitable position for surgery.



The adapter is mainly made of stainless steel and fiber-reinforced plastic.

The adapter is cleaned and sterilized together with the handpiece motor.

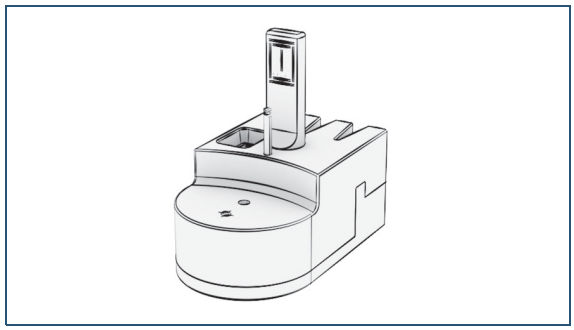
↗ For information about cleaning, see "Individual cleaning instructions" on page 25

The DENAREG registration tool

The registration tool is used to calibrate the motor with handpiece and to register the drill and the round bur. It consists of the following:

- An upper plate with embedded second marker (registration tool M1801)
- A base plate, attached by a magnet
- A pin for calibrating the motor with handpiece
- Three tapered slots for different drill lengths
- A conical cavity for different round bur diameters
- A deepening with cross marking for locator drills, taps, other shape drills and implant adapters
- A centrally positioned marker

REGISTRATION TOOL M1801 WITH EMBEDDED SECOND MARKER



The registration tool is made of stainless steel and zirconia.

The marker on the registration tool has a pattern that is captured by the camera. The pattern may lose the contrast after several reprocessings. Therefore, mininavident recommends to reprocess the registration tool no more than 50 times.

↗ For information about cleaning and inspecting, see "Individual cleaning instructions" on page 25

The DENAMARK marker

Mounted on a tray, the marker serves as a reference point for the navigation system in the lower or upper jaw of the patient.

- Single-use marker M1501

It has a pattern that is captured by the camera.

The marker M1501 is made of aluminum oxide.

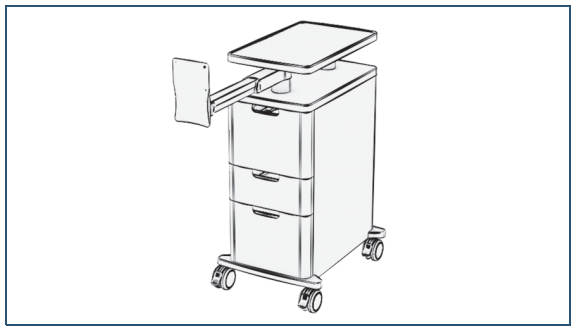
↗ For information about cleaning and inspecting, see "Individual cleaning instructions" on page 25

The DENACART system cart

The system cart is an accessory that can be ordered optionally.

It offers the following possibilities for working with the Straumann® Falcon:

- A swivel arm for holding the touchscreen
- Storage space for the computer
- Three drawers for extra storage space
- Equipment for cable management (pre-installed cables, holder for a magnetic multiple socket)



The surfaces of the system cart are made of plastic, steel, and aluminum.

⚠ Only wipe disinfection is allowed. The system cart must not be sterilized.

↗ For information about cleaning, see "Individual cleaning instructions" on page 25

INSTALLATION, SETUP AND USE OF STRAUMANN® FALCON ACCESSORIES

UNPACKING AND SETTING UP THE ACCESSORIES

As manufacturers of the Straumann® Falcon Accessories, mininavident can assume responsibility for the safety properties only if repairs of the accessories are performed by authorized service partners,

The main tasks for unpacking and setting up the system are:

1. Unpacking all components
2. Installing the system cart (optional)

PREREQUISITES

Correct transport and storage of the components.

↗ For more information about the transport and storage conditions, see "Transport and Storage Conditions for Straumann® Falcon Accessories" on page 36

↗ For more information about safety, see "Safety information" on page 8

Unpacking all components

Carefully unpack all components and check the containers to make sure that all the parts are in the package and in good condition.

Contents of the packages

↗ For reference numbers, see "Reference numbers" on page 35

DENACART SYSTEM CART (OPTIONAL)

- 1 System cart
- 1 Swivel arm inclusive screw for mounting the touchscreen

DENADAPT BIEN-AIR VENTILATED WITH CABLE

- 1 Adapter with cable

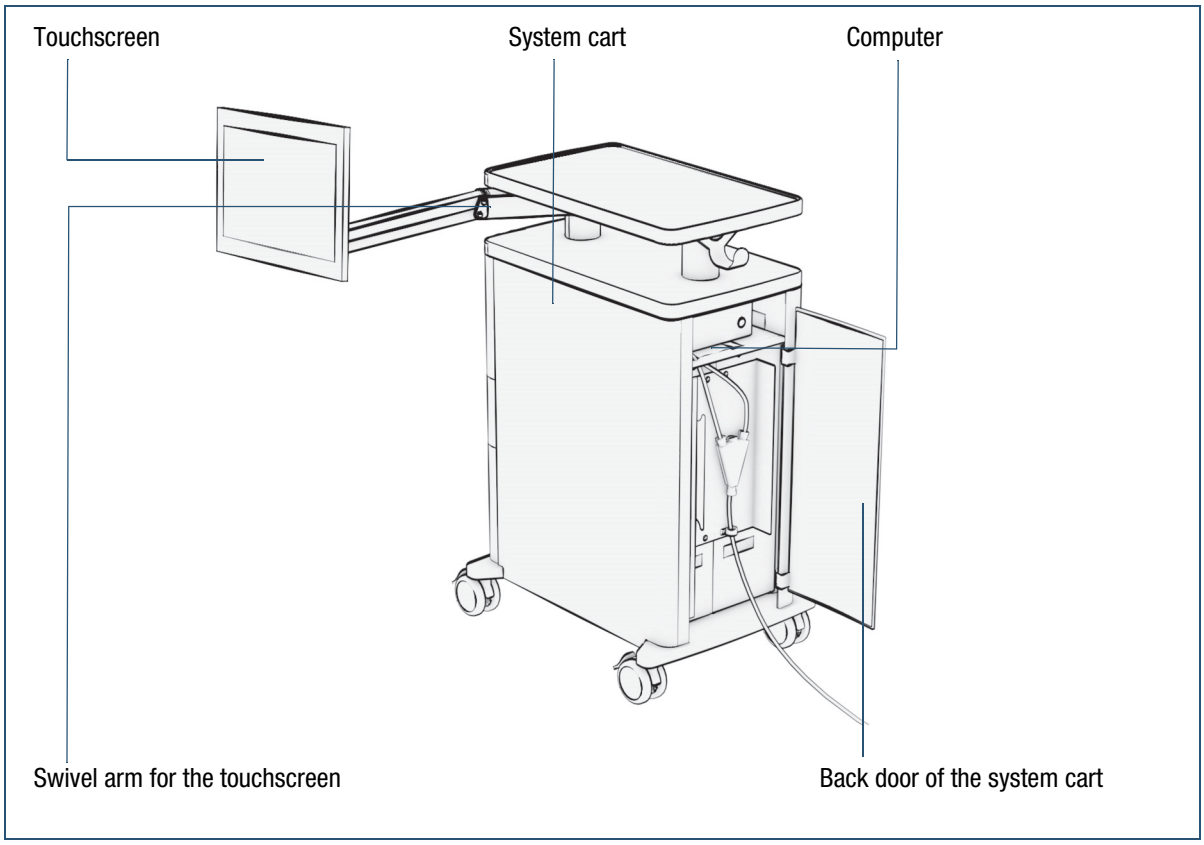
DENAREG REGISTRATION TOOL

- 1 Registration tool

DENAMARK MARKER

- 4 Markers (single-use M1501)

Installing the system cart (optional)



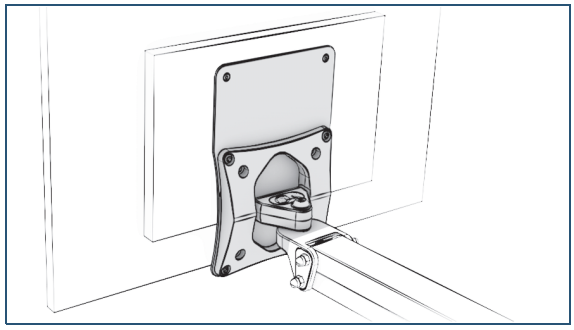
Picture 2 Installing the system cart

To install the system cart

1 Mount the swivel arm on the system cart.

2 Attach the touchscreen to the swivel arm. Use following tools:

- 5.5 mm Socket (Swivel joint with fixing plate/ Mounting plate)
- T20 Torx screwdriver (Mounting plate/ Touchscreen)
- 5 mm Allen key (Swivel joint with fixing plate/ Swivel arm)
- 13 mm Socket (Swivel joint with fixing plate/ Swivel arm)



3 Open the back door of the system cart.

4 Identify the pre-installed cables and connect the system.

5 Slide the computer into the intended compartment inside the system cart.

6 Close the back door of the system cart.

Installing the DENADAPT Bien-Air ventilated with Cable


Caution

The adapter DENADAPT Bien-Air ventilated with cable is fixed to the handpiece motor by Mininavident technical support. Before, first use, the motor with handpiece must be calibrated with the adapter.

Use of Straumann® Falcon Accessories

Please refer to Straumann® Falcon User Manual regarding the use of the Straumann® Falcon together with the accessories during surgery.

SAFETY


Warning

Serious injury to the patient due to incorrect handling

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual for Straumann® Falcon Accessories.

- Do not carry out operation, care and cleaning unless you have read and understood the information provided in the user documentation.
- Follow best practices, especially when you work with biohazardous material.


Caution

Injury to the patient due to incorrect marker handling

Incorrect marker handling may lead to inaccurate or shifted navigation procedure.

- Do not use a defect marker.

↗ For more information about safety, see "Safety information" on page 8

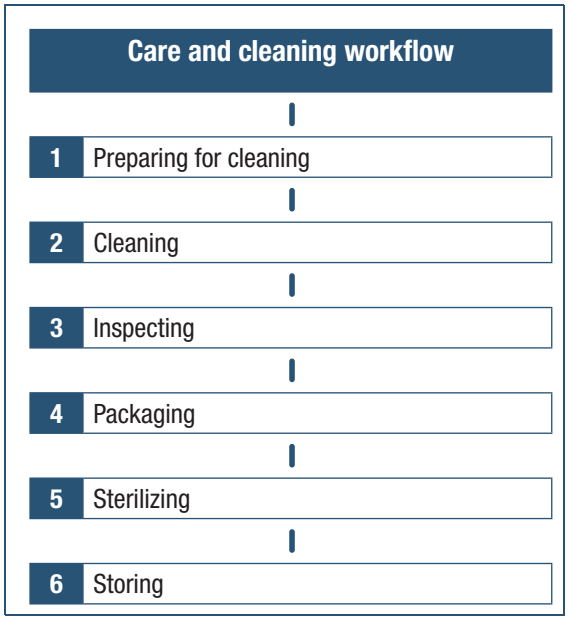
CARE AND CLEANING

BASIC PRINCIPLES

The basic principles, which are described in this section, have to be followed for all reprocessing steps.

Inappropriate care and cleaning of the components can result in failure or damage. Technical personnel must be trained in the handling of medical devices.

Care and cleaning involves the following basic steps:



About the reuse of components

Single use components

Components that are intended for single use (for example the marker) are labeled with the following symbol: ②.

Single use components that came into contact with blood or other bodily fluids of a patient are not allowed to be reused or used for another patient.

The manufacturer excludes any liability when single use components are reused.

Reusable components

Components that are not labeled for single use may be reused. These reusable components have to be reprocessed before each use. Frequent reprocessing has minor effects on the components. The end of the product life is normally determined by wear and damage during use. Therefore, components can be reused with appropriate care, provided that they are undamaged and not contaminated.

The reprocessing of the components described in this document was tested and validated by mininavident.

Components with limited life cycles

mininavident defines a maximum number of reuses for certain reusable components (for example the registration tool). Inspect these components carefully before and after each use.

About appropriate cleaning solutions and cleaning equipment

Notice

Damage to the components due to wrong cleaning, inspection, and sterilization

Inappropriate cleaning solutions, cleaning processes, or sterilization may lead to damage of the component.

- Do not use strongly alkaline or acidic cleaning solutions.
- Do not use excessive concentrations of cleaning solutions.
- Do not use aggressive cleaning equipment like metal brushes, steel wool, etc.
- Do not clean or rinse with a high pressure water jet.
- Do not sterilize components that are not suitable for sterilization.

Always follow these points when selecting cleaning solutions and cleaning equipment:

- They must be suitable for their intended use, for example for cleaning.
- The cleaning solution used must have a proven effectiveness. It must be approved by VAH / DGHM or FDA, or marked with a CE mark.
- The cleaning solutions must be suitable and compatible for use with the components.
- The manufacturer's instructions, such as those regarding concentration, exposure time, or temperature, must be followed.

mininavident recommends the use of freshly produced solutions.

ADDITIONAL INFORMATION:

The cleaning and sterilization information is provided in accordance with ISO 17664, AAMI TIR 12 and ISO 17665-1.

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing non-sterile mininavident medical devices. It remains the responsibility of the user to ensure that the processing is actually performed using appropriate equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the user from the recommendations provided should be properly evaluated for effectiveness and potential consequences.

Drying equipment

For drying, mininavident recommends lint-free single-use paper wipes or medical compressed air (according to the European Pharmacopoeia).

Water quality

Use only cold (20 °C ±2 °C / 68 °F ±3.6 °F) tap water of at least drinking water quality or deionized water for cleaning, sterilization, and rinsing steps.

Personal protective equipment

Wear personal protective equipment:

- Gloves
- Water repellent protective clothing
- Face protection mask or protective glasses

↗ See also the instructions of the manufacturer for the detergent and the disinfectant.

About preparing for cleaning

It is recommended to clean and disinfect the components as soon as possible, but within 2 hours after each use.

It is recommended to transport contaminated components in a closed box or container.

Preliminary cleaning should be done with lint-free disposable paper wipes.

To ensure that components undergoing cleaning can be properly assembled / re-assembled, pay attention to the individual assembly / re-assembly instructions.

INDIVIDUAL CLEANING INSTRUCTIONS

Ensure that the Straumann® Falcon Accessories are cleaned, and disinfected or sterilized prior to use. Always observe the following points:

- Wear personal protective equipment
- Use only device and component specific procedures for cleaning and sterilization. The procedures must be sufficiently validated.
- Make sure that the equipment used (washer-disinfector, sterilizer) is serviced and inspected on a regular basis.
- Respect for each cleaning cycle the validated parameters that are recommended by the equipment manufacturer.
- Consider the statutory regulations applicable in your country as well as the hygiene requirements of the practice or clinic. This applies in particular to the various instructions for effectively deactivating prions.

Table 3 Individual cleaning instructions - Overview

Component	Preparing for cleaning	Cleaning	Sterilizing
System cart	Shut down computer	Wipe disinfection of the surfaces	Not allowed
Adapter with cable	Separate camera from adapter	Automated cleaning and disinfection	Steam sterilization
Registration tool	Disassemble tool	Automated cleaning and disinfection	Steam sterilization
Marker	-	Manual cleaning and disinfection	-

Cleaning the system cart

Notice

Damage to the system cart due to sterilization

Sterilizing may damage the components.

- Do not sterilize the system cart

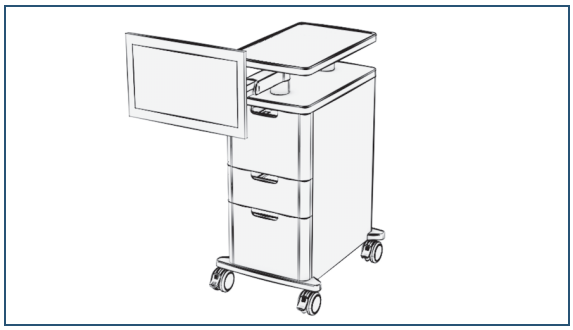
It is recommended to clean the components as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 22

To clean the system cart

1 Spray the surfaces of the system cart with a surface disinfectant.



2 Clean the surfaces using lint-free, disposable paper wipes.

3 Visually inspect the system cart for:

- Damaged surfaces
- Contamination

4 If the components are still contaminated, repeat the steps. In case of damage, replace the components.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 22

REQUIRED EQUIPMENT

- Surface disinfectant, for example:
  - MinutenSpray-Classic (ALPRO MEDICAL GMBH)
  - PlastiSept-eco (ALPRO MEDICAL GMBH)
  - FD 333 quick disinfectant (DÜRR DENTAL)
  - Isopropanol 70%
  - CaviWipes™ (Metrex)
- Lint-free, disposable paper wipes

Cleaning, disinfecting, and sterilizing the DENADAPT Bien-Air ventilated with cable

Note
The adapter can be cleaned, disinfected, and sterilized together with the Bien-Air motor.

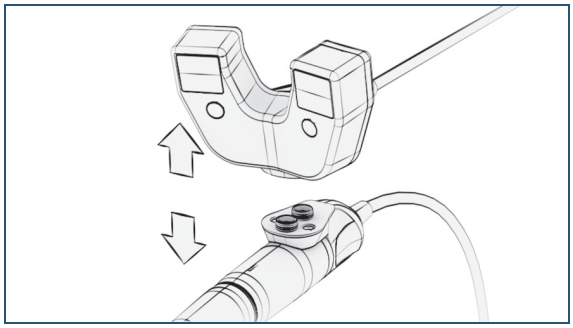
It is recommended to clean and disinfect the adapter as soon as possible, i.e., within 2 hours after each use.

1 To prepare and pre-clean the adapter with cable connected to the Bien-Air motor remove large debris using lint-free, disposable paper wipes.

2 Separate the camera from the adapter by pulling the two components apart. They are held together by magnets.

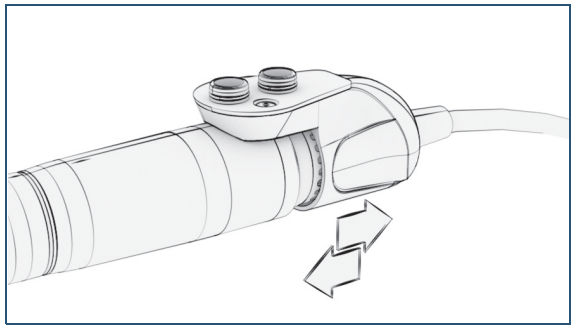
The camera does not need to be disconnected from the computer.

The adapter remains on the handpiece motor for cleaning and disinfection and sterilization.



3 Rinse the adapter with cable for at least 1 minute under running cold tap water and remove dirt with a soft brush.

4 Shift the movable part of the adapter under running cold tap water back and forth several times.



5 Rinse the adapter with cable with deionized water again and check the result visually.

6 Automated Cleaning and Disinfection

Required Equipment:

Approved Washer-disinfector which complies with ISO standard 15883-1

Place the DENADAPT Bien-Air ventilated with cable connected to the motor into the washer-disinfector.

Carry out automatic cleaning- disinfection using an approved washer-disinfector which complies with ISO standard 15883-1 according to the automated cleaning program outlined in Table 4.

Detergent and washing cycle:

Use a mildly alkaline cleaner or detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).

Table 4 Recommended automated cleaning and disinfection parameters using washer disinfector

Phase	Water Temp / Temp	Time	Cleaning Agent
Pre-cleaning / pre-rinsing	tap water, <45°C (113°F)	5 minutes	N/A
Cleaning	55 °C ±2 °C (131 °F ±3.6 °F)	10 minutes	mildly alkaline cleaner or detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11)
Neutralization	Cold deionized water	≥ 2 minutes	N/A
Rinsing	deionized water, ≤30°C (86°F)	≥ 2 minutes	N/A
Thermal disinfection	deionized water, 90°C - 95°C (194°F - 203°F)	5 -10 minutes	N/A
Drying	-	18 - 22 minutes	N/A

7 Check for damages and functionality of the adapter with cable.

8 Packaging

Place the DENADAPT Bien-Air ventilated with cable connected to the motor in a double-pouched packaging approved for sterilization compliant with EN ISO 11607, EN 868-3 to 10, or 58953.

9 Sterilization

Required Equipment:

Steam sterilizer according to DIN 13060 and/or EN 285

Sterilize the DENADAPT Bien-Air ventilated with cable connected to the motor packed in double pouch according to the parameters in Table 5.

Sterilization is according to EN ISO 17665-1 and EN ISO/TS 17665-2

Table 5 Recommended steam sterilization conditions for EU countries

Variable	Fractionated and dynamic pre-vacuum process
Exposure time	4 minutes
Temperature	132°C (269.6°F)

10 Storage

Store in sterilization pouch in dry, clean and humidity-free environment without direct solar irradiations. The temperature must not exceed 55°C (131°F).

Cleaning, disinfecting, and sterilizing the registration tool

Note

- The registration tool is delivered non-sterile and must be appropriately cleaned and sterilized before the first use after delivery.
- The registration tool can be exposed to temperatures up to a maximum of 135 °C (275 °F).
- The marker inside of the registration tool may lose the contrast after several reprocessings. Therefore, mininavident recommends to reprocess the registration tool maximally 50 times.
- Validated thermal disinfection program of 90 °C for 1 minute reaches A_0 = 600, 90 °C for 5 minutes reaches A_0 = 3000

It is recommended to clean and disinfect the registration tool as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 22

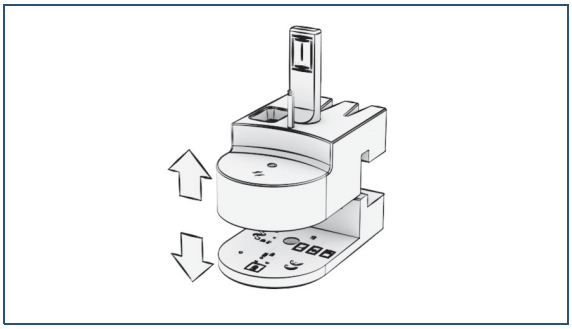
REQUIRED EQUIPMENT:

- Cleaning agent: neutral pH enzymatic detergent. Neodisher® Medizym, Dr. Weigert
- Washer-disinfector compliant with BS/EN/ ISO 15883 part 1 and 2, ISO 15883-5 (e.g. DGHM/ VAH). Belimed WD290IQ
- Steam sterilizer compliant with EN 16060 or EN 285. CISA 6464 LS
- Water bath or sink
- 20 mL syringe
- Autoclavable packaging in accordance with ISO 11607-1 and ANSI/AAMI ST79
- Autoclavable packaging with 510(k) clearance

AUTOMATED CLEANING (EN ISO 15883-1)

To prepare and pre-clean the registration tool

1 Disassemble the base plate from the upper part of the registration tool by pulling the two parts apart from each other. They are held together by a magnet.



2 Place the components in water bath at room temperature for 10 minutes.

3 Remove visible dirt by brushing with a soft bristled brushing under running tap water.

4 Rinse cavities five times (5x) using a 20 mL syringe filled with tap water.

To clean and disinfect the registration tool automatically

1 Place the disassembled registration tool in the washer-disinfector so that water could flow out of cannulas and blind holes.
   - Place the largest part of the registration tool on edge in the washer-disinfector to allow for maximum drainage of all cannulas and blind holes.
   - Place the smaller part of the registration tool flat with the smooth side facing upwards.

2 Ensure that devices do not touch each other.

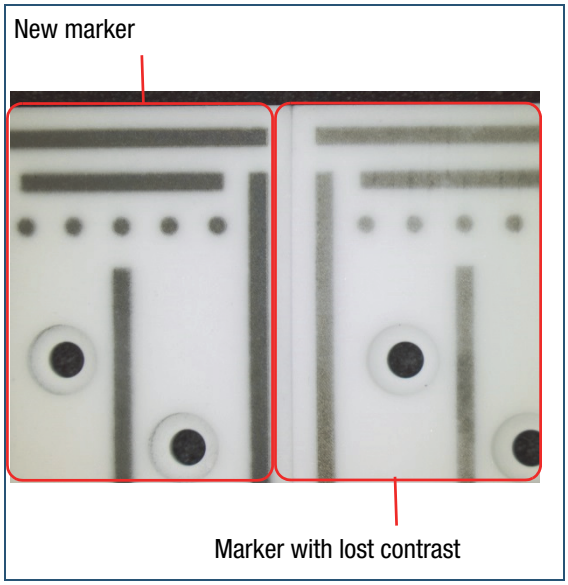
3 Run the automatic cleaning program based on the parameters in table 4.

4 Visually inspect the parts of the registration tool using a magnifying glass for:
   - Damaged surfaces
   - Fissures
   - Chipping

- Other abrasion
- Contamination
- Functionality

5 Inspect the marker of the registration tool for loss of marker contrast.

Perform a marker visibility check.



6 Re-assemble the registration tool to check correct matching.

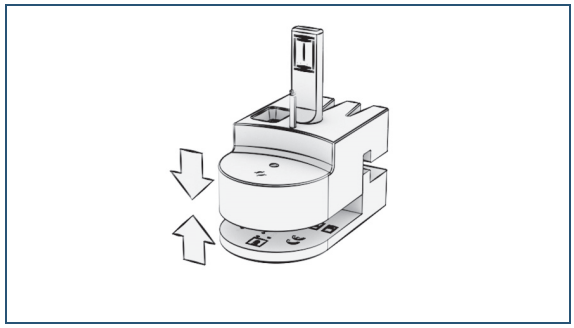


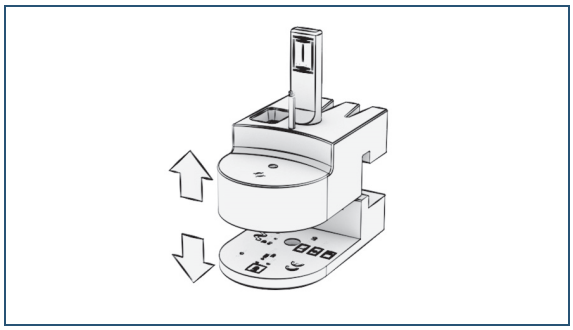
Table 6 Automated cleaning parameter using a washer-disinfector

Phase	Water temperature	Time	Cleaning agent
Pre-rinsing	Cold tap water	2 minutes	N/A
Wash	Hot tap water, set point 55 °C (131 °F)	5 minutes	Neutral pH enzymatic detergent, e.g. Neodisher® Medizym 0.2% (2 ml/L)
Rinse	Cold deionized water	3 minutes	N/A
Rinse	Cold deionized water	2 minutes	N/A
Thermal disinfection	90 °C (194 °F)	5 minutes	N/A

To sterilize and store the registration tool

Steam Sterilization method is validated according to EN ISO 17665

1 Disassemble the base plate from the upper part of the registration tool by pulling the two parts apart from each other. They are held together by a magnet.



2 Ensure the parts of the registration tool are air-dried before packaging them for steam sterilization.

3 Place the registration tool into autoclavable packaging compliant with ISO 11607-1 and ANSI/AAMI ST79.

4 Sterilize the disassembled registration tool based on the parameters in Table 7.

5 Store the registration tool in a dry, dust-, and humidity free environment without direct solar irradiation.

Table 7 Conditions for Steam Sterilization - Moist Heat (Autoclave), Fractionated vacuum

Variable	Europe	USA
Preconditioning Pulses	4	4
Temperature	134 °C (273 °F)	132 °C (270 °F)
Full cycle exposure time	3-18 minutes	4 minutes
Drying time	30 minutes	30 minutes

Cleaning and disinfecting the single-use marker M1501

Notice

Damage to the marker due to wrong cleaning
Inappropriate cleaning process damages the component.
- Do not clean the marker in a washer-disinfector.
- Do not clean the marker in a ultrasonic bath.

Note
- The marker can be exposed to temperatures of up to 135 °C (275 °F).

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 22

REQUIRED EQUIPMENT:

- Cleaning agent: pH neutral enzymatic detergent. Cidezyme Enzymatic Detergent
- Deionized water
- Cidex® OPA
- Disposable syringe, 20 ml
- Basin, stainless steel

To clean and disinfect the marker manually

CLEANING MANUALLY

1. A Cidezyme™ solution is prepared by adding 8 mL of Cidezyme™ to 1 L of deionized water at room temperature (20 °C ± 2 / 68 °F ± 3.6). The volume needed of the solution is 150 ml per marker.
2. Soak the marker into the Cidezyme™ solution for 10 minutes. During soaking mechanically clean the marker with a soft bristled brush for 15 seconds.
3. Remove the marker from the detergent solution.
4. Rinse the marker under running deionized water at room temperature for 10 seconds 3 times.
5. Air dry the marker for 30 minutes.

DISINFECTION MANUALLY

6. Immerse the marker in a disinfection bath of Cidex® OPA for 12 minutes at room temperature (20 °C ± 2/ 68 °F ± 3.6). Bath volume per marker is 1 L.

   Ensure that the marker is covered by the disinfection solution and that air is not trapped within features of the device. Ensure that the devices do not touch each other.
7. Rinse out all cavities of the marker 3 times with the disinfection solution at the beginning and at the end of the action time using disposable syringe (minimum syringe volume 20 ml).
8. Remove the marker from the bath.
9. Immerse the marker completely in purified water (5 L of water per device) for 1 minute at room temperature.
10. Rinse the marker thoroughly with water 5 times using a disposable syringe (minimum syringe volume 20 ml).
11. Remove the marker from the bath of water and discard the rinse water. Always use fresh volumes of water for each rinse.
12. Repeat steps 9 to 11, for a total of 3 rinses, in order to remove Cidex® OPA solution residues. Residues may cause serious side effects.

SERVICING

Regular servicing is necessary for safe operation and should be carried out once a year.

mininavident recommends that only an authorized service partner should undertake servicing and checking.

↗ For information about maintenance and repair protocol, see "Maintenance and repair protocol" on page 39

↗ For information about your local authorized service partner, see "Authorized service partners" on page 2

APPENDIX

REFERENCE NUMBERS

Product Description	Product name REF number
Adapter Bien-Air ventilated with cable	DENADAPT Bien-Air ventilated with cable M1204
Marker single-use	DENAMARK® M1501
Registration tool with embedded second marker	DENAREG® M1801

Accessory	Product name REF number
System cart	DENACART® M2001

TRANSPORT AND STORAGE CONDITIONS FOR STRAUMANN® FALCON ACCESSORIES

The components can be moved and stored without damage in the associated transport packaging under the following conditions.

Table 8 Transport and storage conditions

Topic	Specification
Temperature range	-10°C to 50°C (14°F to 122°F)
Relative humidity	10%-80%

STANDARDS AND APPROVALS

The Straumann® Falcon Accessories bears the CE symbol in accordance with the provisions of Regulation EU 2017/745 concerning medical devices. It complies with the following standards, among others:

Standard	Definition
EN ISO 13485	Medical devices - Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
IEC 62366-1 2016	Medical devices - Application of usability engineering to medical devices (IEC 62366:2016)
DIN EN ISO 13402	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:1995); German version EN ISO 13402:2000
ASTM F 1089	Standard Test Method for Corrosion of Surgical Instruments
ASTM F 1744	Standard Guide for Care and Handling of Stainless Steel Surgical Instruments
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/ AMD2:2020)
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020)
AAMI TIR12:2020	Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for the Devices Manufacturer
ANSI/AAMI ST98:2022	Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices
AAMI TIR34:2014/ (R)2021	Water for the reprocessing of medical devices
FDA:2015	Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi- critical medical devices
BS/EN/ISO 15883-1:2009	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (international standard)
ISO 14457:2017	Dentistry — Handpieces and motors
ISO 15883-5:2021	Washer-disinfectors – Performance requirements and test method criteria for demonstrating cleaning efficacy
	Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices :2017.
ANSI/AAMI ST15883-1:2009/(R)2014	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (international standard
FDA: 2002	Medical Washers and Medical Washer-Disinfectors - Class II Special Controls

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY DENADAPT BIEN-AIR VENTILATED WITH CABLE

Electrical Safety in conformance with IEC 60601-1 and Electromagnetic Compatibility in conformance with IEC 60601-1-2 of the DENADAPT Bien-Air ventilated with cable has been tested within the scope of the Straumann® Falcon, please refer to Straumann® Falcon User Manual.

MAINTENANCE AND REPAIR PROTOCOL

This protocol is used to document maintenance, safety inspection and repair tasks.

1 Check the system cart for visible damage and wear.

Instruct the user to replace them if a damage or wear is visible.

2 Check the adapter with cable for visible damage and wear.

In addition, check the adapter with cable according to the following points:

- The adapter with cable must be firmly attached to the motor and meet the following requirements:
  - The adapter with cable must engage in each possible position.
  - It must be free of a noticeable clearance
  - The adapter with cable is firmly connected and no gap is visible between the adapter and the motor.
- Attach the adapter with cable to the camera by the force of the magnets.
  - The magnetic force must be strong enough to lift the camera.
- Attach the camera to the adapter with cable.
  - The adapter with cable and the camera must engage tangibly.
  - The adapter with cable and the camera must not be twisted against each other.
  - The camera is firmly connected and no gap is visible between the adapter with cable and the camera.

Check the registration tool and marker under good light for visible damage and wear.

- Instruct the user to replace them if a damage or wear is visible.

3 New calibration of the system and compare the new calibrating data with the old and export the LOG data.

Table 9 Maintenance and repair protocol

Date:	**Signature:**	**Step 1:** System cart	**Step 2:** Check adapter, registration tool, marker	**Step 3:** New calibration	**Repair:**	**Remarks and observations:**
		☐	☐	☐	☐	
		☐	☐	☐	☐	
		☐	☐	☐	☐	
		☐	☐	☐	☐	
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