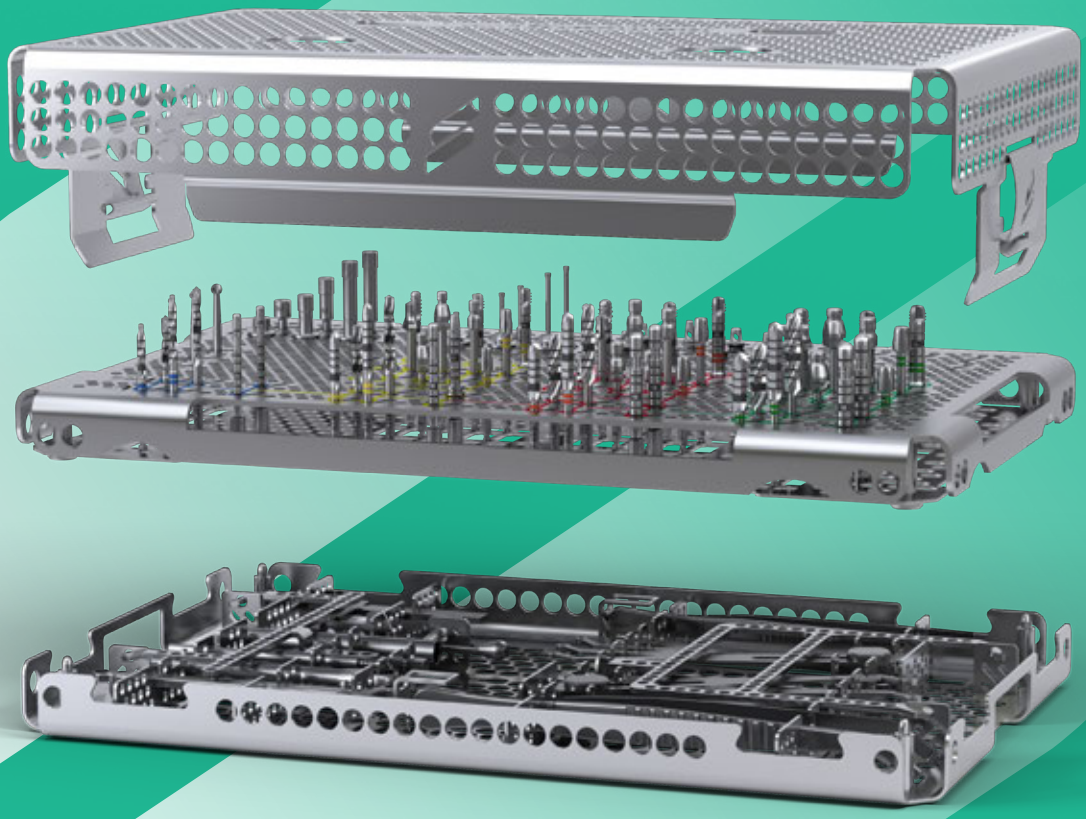
straumann

BASIC INFORMATION

Straumann® ProClean Cassette



Technical handling information

CONTENTS

1. STRAUMANN® PROCLEAN CASSETTE – UNCOMPROMISED HYGIENE

- outstanding cleaning results and uncompromised hygiene with a fully stainless steel cassette: no aluminum, plastic or silicone parts
- simple workflow due to validated, machine-based reprocessing
- increased productivity as more time becomes available for clinical activities
- enhanced staff safety since handling of sharp contaminated instruments is significantly reduced
- excellent efficiency and ease of use thanks to the fully integrated Straumann surgical workflow navigation

The Straumann® ProClean Cassette meets the highest requirements of dental practices and hospitals that demand uncompromised hygiene.

Designed specifically for automated reprocessing, the Straumann® ProClean Cassette is fully compatible with dental washer-disinfectors to simplify reprocessing workflow and deliver exceptional cleaning results.

The Straumann® ProClean is a fully stainless steel cassette containing no aluminum, plastic, silicone or other materials that may easily degrade following numerous reprocessing cycles. All parts of the Straumann® ProClean Cassette are solely made of high grade stainless steel to ensure uncompromised hygiene and performance during rigorous machine-based reprocessing.

2. STRAUMANN® PROCLEAN CASSETTE – PRODUCT AT A GLANCE

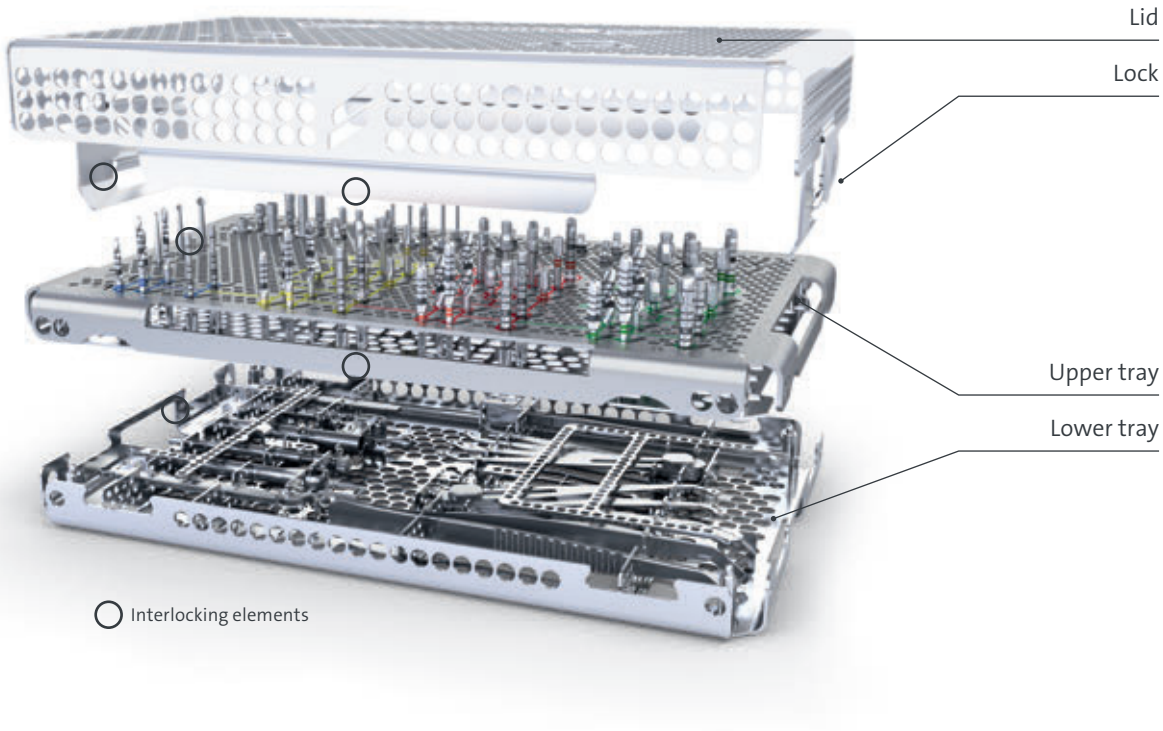
The Straumann® ProClean Cassette (Art. No. 040.561) is a container used for secure storage and reprocessing of surgical and auxiliary instruments of the Straumann® Dental Implant System.

The Straumann® ProClean Cassette has been designed for automated cleaning and disinfection – a machine-based process delivered by washer-disinfectors (e.g. Miele Thermodisinfector). During the process, the instruments remain in the cassette.

Similar to the Straumann® Surgical Cassette (040.165), the Straumann® ProClean Cassette consists of three components:

- Lower tray
- Upper tray
- Lid

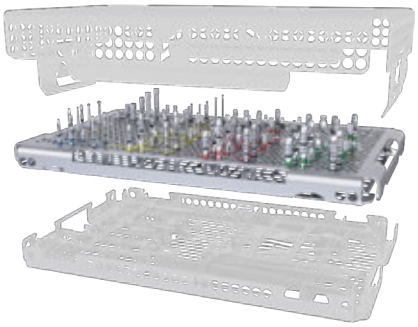
Thanks to the interlocking elements, the trays and the lid can be easily assembled and securely locked with the two integral latch locks.

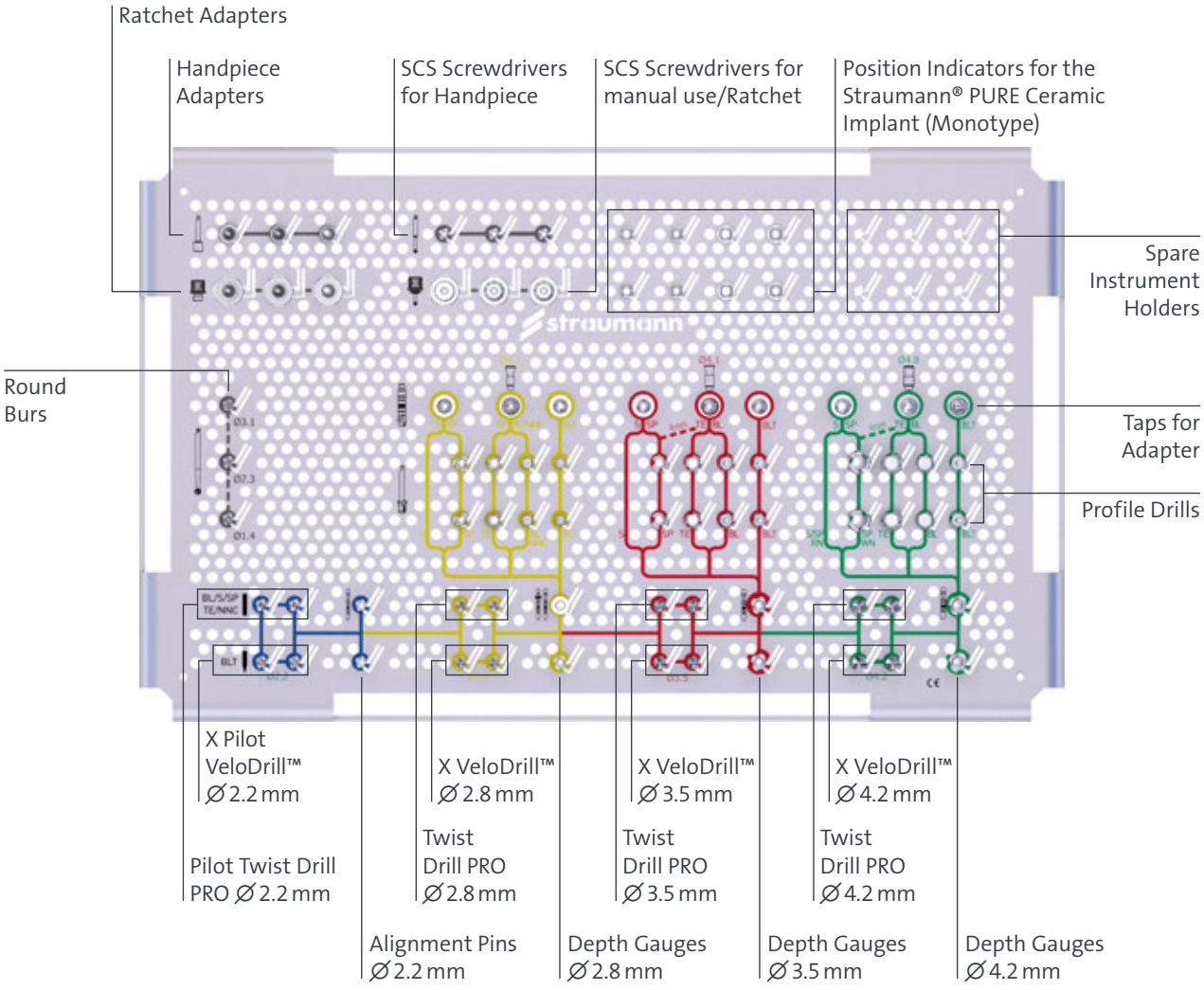


2.1 UPPER TRAY

To facilitate the surgical procedure and the correct use of the instruments, the Straumann® ProClean Cassette has instrument pictograms and color-coded workflows printed on the surface of the upper tray. The tray can hold all the instruments needed to place any Straumann implant line.

All the instruments in the upper tray are placed in their designated slots according to the surgical workflow and are securely fixed by the cleaning-friendly instrument holders.

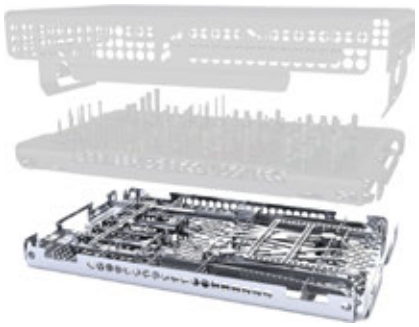




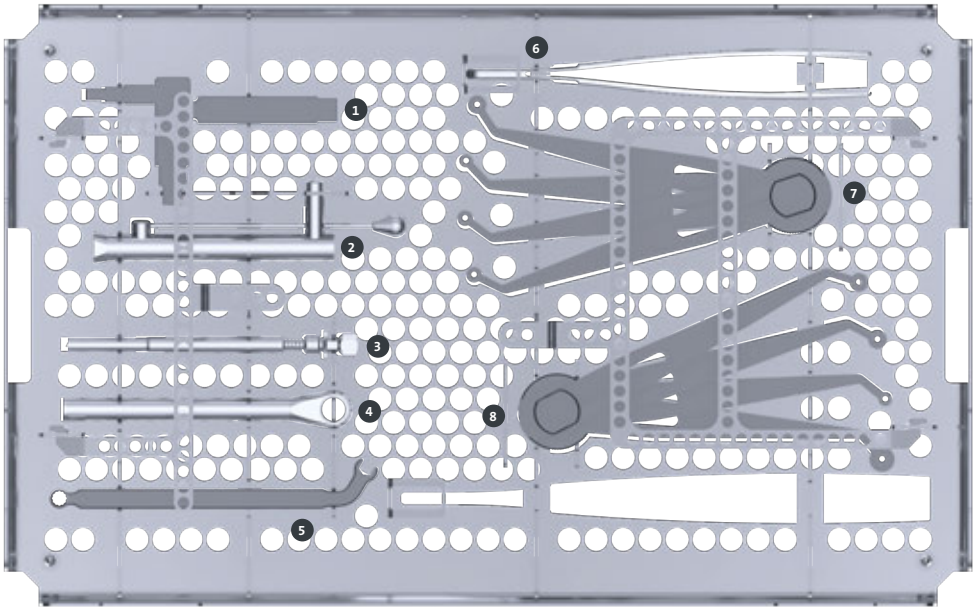
- Endosteal implant diameter 3.3 mm
- Endosteal implant diameter 4.1 mm
- Endosteal implant diameter 4.8 mm

2.2 LOWER TRAY

The lower tray contains the auxiliary instruments as well as the planning aids. For ease of use, the position of each instrument is clearly indicated by a cut-out silhouette. Two easy-to-use locks hold all the instruments in cleaning-friendly positions.



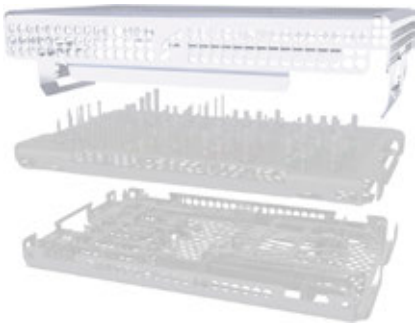
1. Diagnostic T
2. Torque Control Device for Ratchet
3. Ratchet
4. Ratchet
5. Holding Key
6. Tweezers
7. Distance Indicator for Tissue Level or Bone Level
8. Distance Indicator for Tissue Level or Bone Level



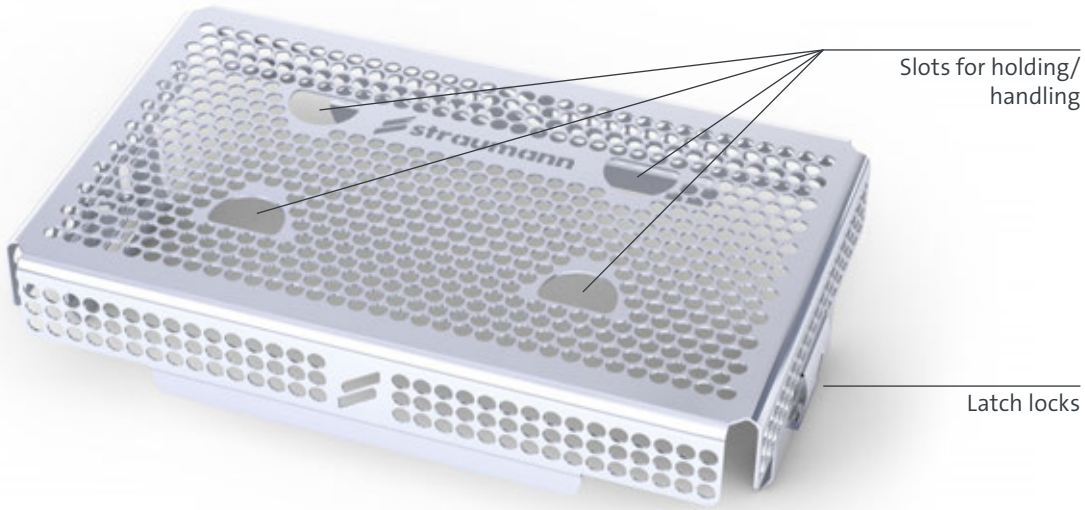
2.3 LID

The lid facilitates a safe and secure handling of the cassette.
It protects

- personnel from sharps exposure
- sterile pouches from drill puncture during sterilization, further handling and storage
- drills from damage during repossessing (e.g. drill damage due to their direct contact with the sterilization container)

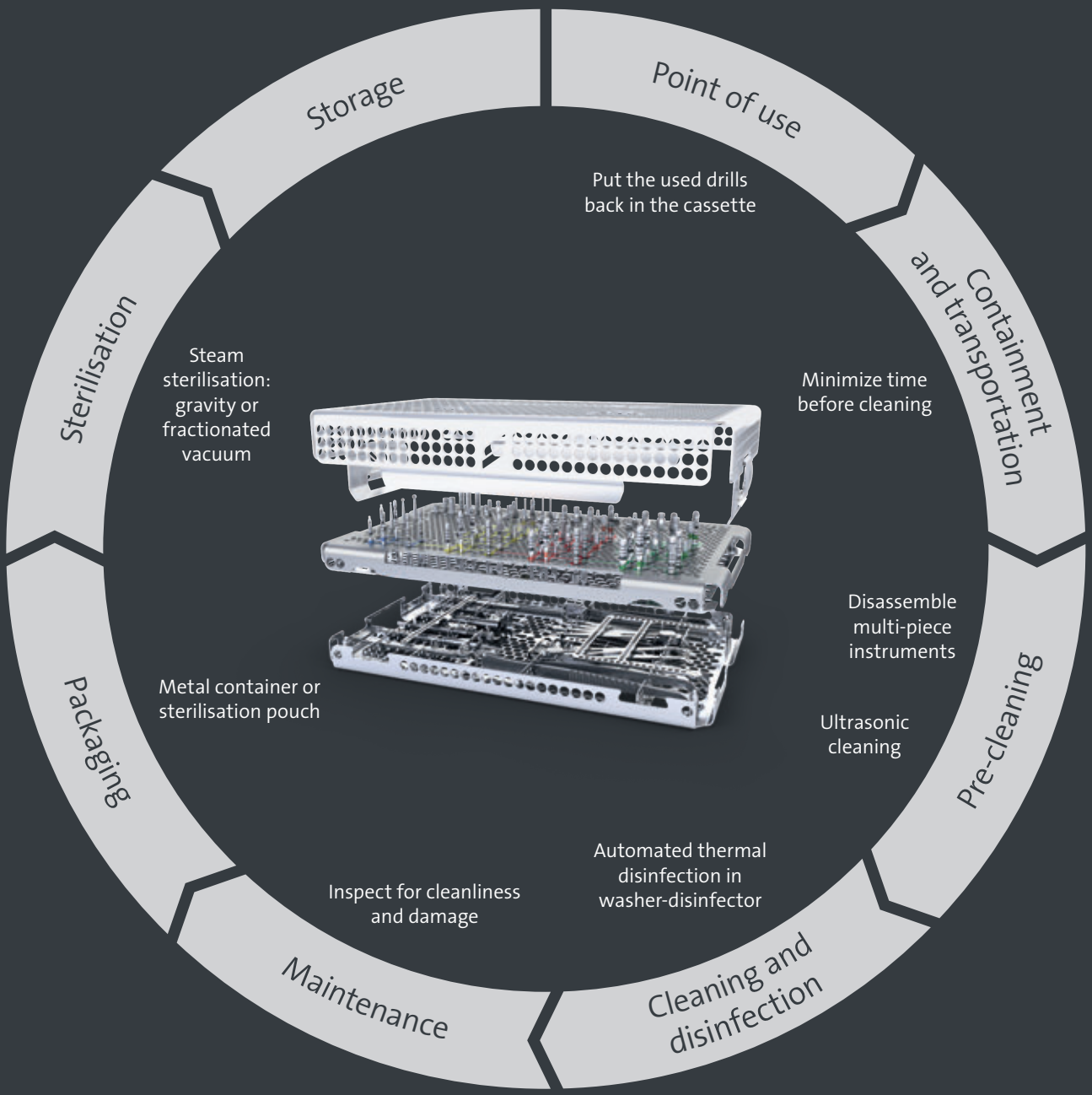


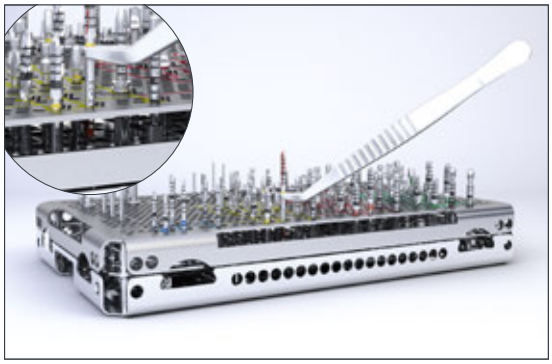
The two integral latch locks on the lid ensure that the assembled cassette is securely locked in one piece.



3. STEP-BY-STEP REPROCESSING

3.1 SIMPLE AND EFFICIENT WORKFLOW

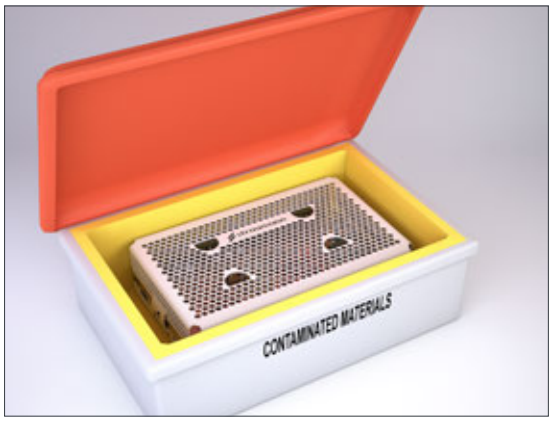




3.2 POINT OF USE

During surgery, the used instruments should be put back directly into the Straumann® ProClean Cassette. The instruments must be put back into their designated slots after each use. This ensures that each instrument remains in its intended place in the cassette. To avoid injury the cutting instruments should be handled with the instrument tweezers 046.110.

Blunt or otherwise damaged instruments must be disposed of at this stage.

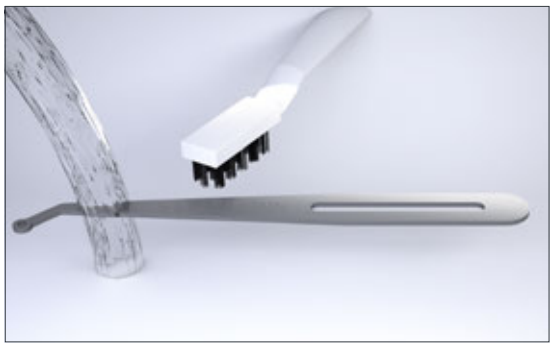


3.3 CONTAINMENT AND TRANSPORTATION

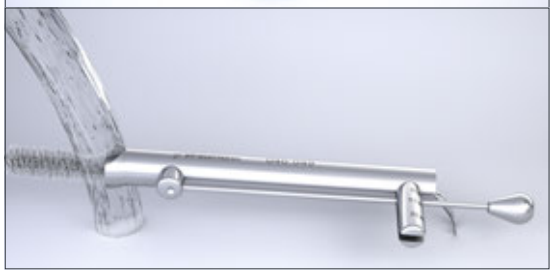
The instruments must be reprocessed as soon as possible and, in any case, no later than one hour after their usage. Safely store and transport the cassette with instruments in a closed container to the reprocessing area to avoid any damage and contamination to the environment.

3.4 PRE-CLEANING

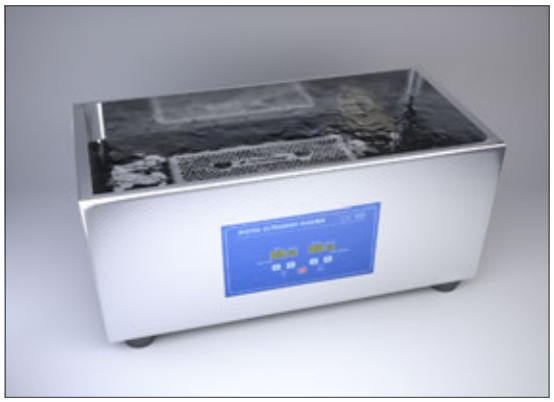
Automated (i.e. machine-based) pre-cleaning is recommended as a more effective and reproducible method compared to the manual procedure.



Automated procedure: All multi-piece instruments (i.e. Distance Indicators, Ratchet and Torque Control Device) must be disassembled into their single parts and pre-cleaned with a soft nylon brush under de-ionized water until no contamination is seen (use magnifying glasses 3x).



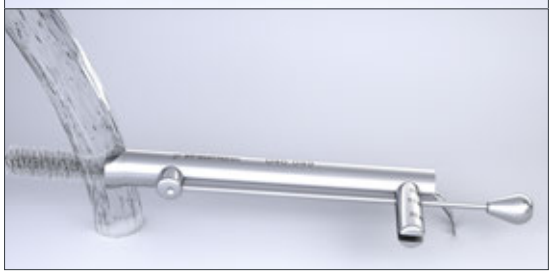
Use the Cleaning Brush for Ratchet (045.111V4) or an appropriate soft nylon bottlebrush to clean the lumens of the Ratchet and the Torque Control Device.



Assemble the Distance Indicators (screw not tightened). Place all instruments and the disassembled Ratchet into the designated slots in the cassette.

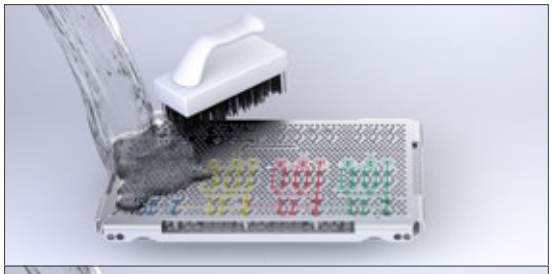
Place the fully assembled cassette (i.e. the lower tray, the upper tray and the lid assembled and securely locked) in an ultrasonic bath in de-ionized water with a detergent solution at room temperature. Run an ultrasonic cleaning cycle for 15 minutes.

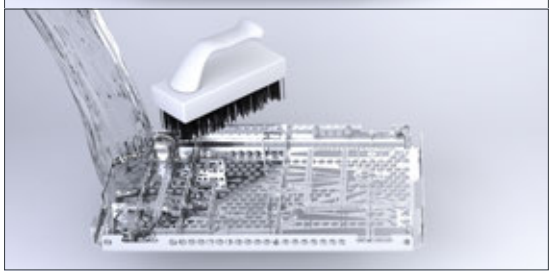
The manufacturer's instructions for use for the ultrasonic bath and detergent must be strictly followed.



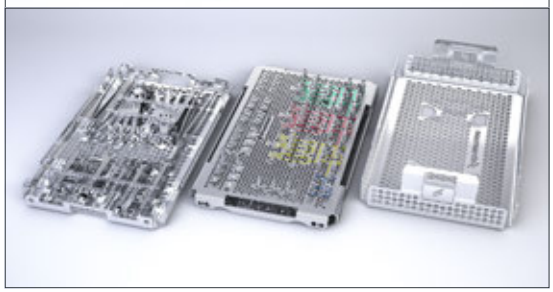
Manual procedure: All multi-piece instruments (i.e. Distance Indicators, Ratchet and Torque Control) must be disassembled into their single parts. All instruments must be taken out of the cassette and pre-cleaned with a soft nylon brush under de-ionized water until no contamination is seen (use magnifying glasses 3×).

Use the Cleaning Brush for Ratchet (045.111V4) or an appropriate soft nylon bottlebrush to clean the lumens of the Ratchet and the Torque Control Device.





Pre-clean all layers of the cassette with a soft nylon brush under de-ionized water until no contamination is seen (use magnifying glasses 3×).



Assemble the Distance Indicators (screw not tightened). Place all instruments and the disassembled Ratchet into the designated slots in the cassette. Ensure that the instrument holding locks in the lower tray are securely locked.

Note: The position of the instruments in the cassette is shown in the section 6. Product reference list.

3.5 CLEANING AND DISINFECTION

Automated Procedure: Place the cassette – disassembled into three parts (the lid, the upper and the lower tray) – separately in the washer-disinfector (in a flat or 45°-tilted position) and start the Vario TD cycle (Miele washer-disinfector) or a similar program.

Automated Thermal Disinfection and Drying in washer-disinfector under consideration of national requirements in regards to A0-Value (see EN 15883).

The manufacturer's instructions for use of the washer-disinfector must be strictly followed.

Manual Procedure: Not applicable. The Straumann® ProClean Cassette is intended to be used with an automated cleaning process only.

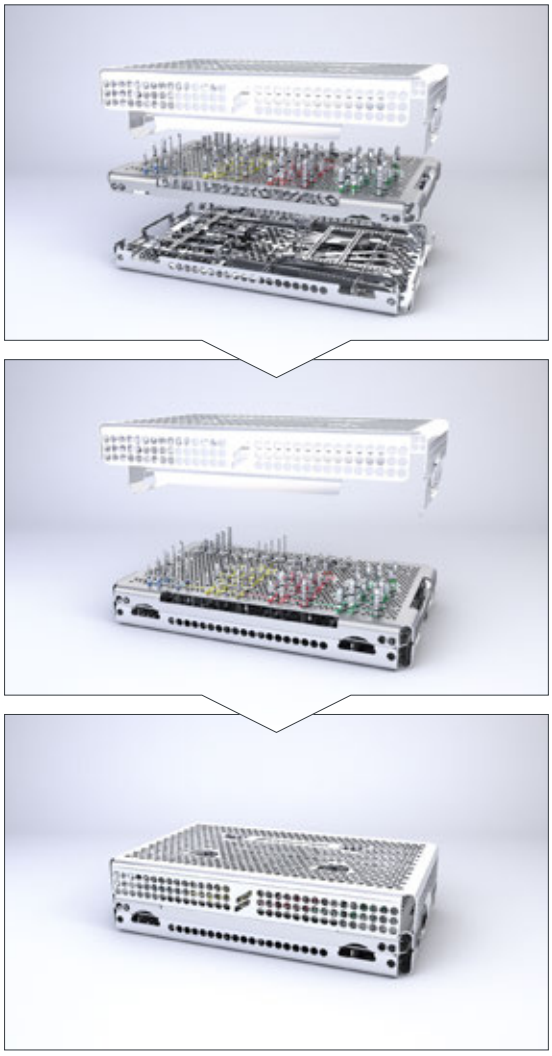
3.6 MAINTENANCE (INSPECTION AND FUNCTION TESTING)

Visual inspection (use magnifying glasses 3x) for cleanliness and function of the instruments and the cassette.

Check all parts of the devices for visual soil, corrosion and damage. If some discoloration marks are still visible on the Straumann® ProClean Cassette after cleaning, remove them by using a cleaning agent (e.g. Hu-Friedy IMS® Shine reNEW™Instrument Wipes). During this step, strictly follow the manufacturer's instructions for use.

If necessary, perform the reprocessing process again until the instruments are visibly clean.

All devices with signs of corrosion and/or damage must be disposed of.



3.7 PACKAGING

Assemble the cassette by putting together the upper tray, the lower tray and the lid. The locks must be securely locked.

Make sure that the cassette and instruments are completely dry before packing for sterilization.

Place the cassette in a metal sterilization container or in a double pouch packaging corresponding to the following requirements:

- suitable for steam sterilization including fractioned vacuum and gravity methods (sufficient steam permeability)
- sufficient protection of the instruments or sterilization packaging against mechanical damage
- EN ISO/ANSI AAMI ISO 11607 – Packaging for terminally sterilized medical devices

3.8 STERILIZATION

Only steam sterilization methods listed below may be used for sterilization. Other sterilization methods are not allowed.

The sterilizer must:

- offer either a fractionated vacuum method or a gravitation program (with sufficient device drying time)
- be compliant with EN 13060 or EN 285
- be validated according to EN ISO 17665 (valid IQ/OQ and product-specific performance assessment (PQ))
- provide a maximum sterilization temperature of 134 °C (273 °F; plus tolerance corresponding to DIN EN ISO 17665, i.e. 137 °C (278 °F). Do not exceed 138 °C (280 °F)

Steam-sterilization parameters

Method	Conditions	Drying time
For Europe:		
Moist Heat (Autoclave) Fractionated vacuum	134 °C (273 °F) for 3 min	Local practice

The manufacturer's instructions for use of the sterilizer must be strictly followed.

3.9 STORAGE

Store sterilized instruments in a dry, clean and dust-free environment at a temperature range of 5 °C to 40 °C (41 °F to 104 °F).

4. REPROCESSING VALIDATION STUDY INFORMATION

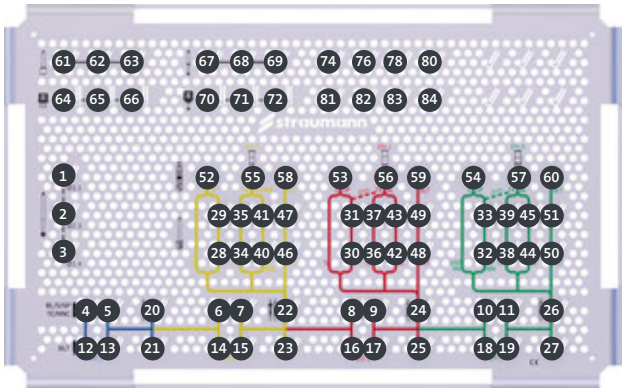
The following devices, materials and machines have been used in the Straumann® ProClean Cassette validation study:

Detergent:	ASP CIDEZYME®
Ultrasonic bath:	Bandelin Sonorex, RK 1028 (f=35kHz, HF power=300Weff.)
Cleaning agent:	neodisher® Mediclean; Dr. Weigert; Hamburg
Washer/Disinfector:	Miele 7735 CD
Instrument Rack:	Miele E 327-06

5. FURTHER INFORMATION

For further information (e.g. warnings, cautions, pre-cautions, compatibility), please consult the instruction for use *Straumann® ProClean Cassette* (701624) and the brochure *Straumann® Surgical and Prosthetic Instruments – Care and Maintenance* (702000/en).

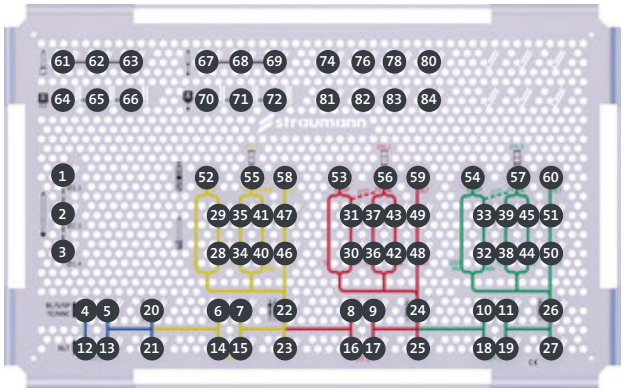
6. PRODUCT REFERENCE LIST



No.	Picture	Article	Art. no.
1		Round Bur	044.004
2		Round Bur	044.003
3		Round Bur	044.022
4		Pilot Twist Drill PRO*, short	044.783
		Pilot Drill 1**, short	044.210
5		Pilot Twist Drill PRO*, long	044.785
		Pilot Drill 1**, long	044.211
6		Twist Drill PRO*, short	044.787
		Pilot Drill 2**, short	044.214
7		Twist Drill PRO*, long	044.789
		Pilot Drill 2**, long	044.215
8		Twist Drill PRO*, short	044.791
		Twist Drill PRO**, short	044.250
9		Twist Drill PRO*, long	044.793
		Twist Drill PRO**, long	044.251
10		Twist Drill PRO*, short	044.795
		Twist Drill PRO, guided**, short	044.254
11		Twist Drill PRO*, long	044.797
		Twist Drill PRO**, long	044.255
12		X Pilot VeloDrill™, short	066.1301
13		X Pilot VeloDrill™, long	066.1701
14		X VeloDrill™, short	066.1302
15		X VeloDrill™, long	066.1702
16		X VeloDrill™, short	066.1304
17		X VeloDrill™, long	066.1704
18		X VeloDrill™, short	066.1306
19		X VeloDrill™, long	066.1706
20, 21		Alignment Pin	046.799
22, 23		Depth Gauge or Depth Gauge with Distance Indicator	046.800 or 046.704
24, 25		Depth Gauge	046.802
26, 27		Depth Gauge	046.804
28		SP Profile Drill, RN, short	034.332

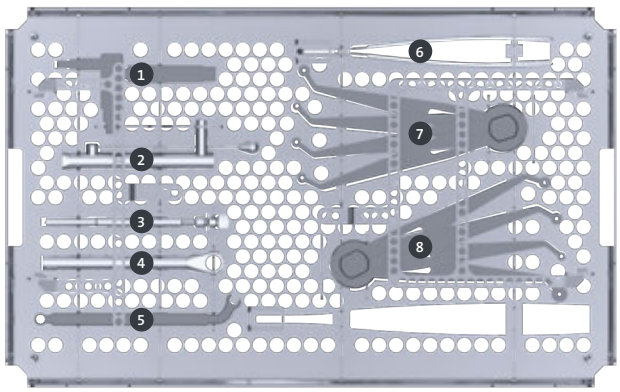
No.	Picture	Article	Art. no.
29		SP Profile Drill, RN, long	044.087
30		SP Profile Drill, RN, short	034.333
31		SP Profile Drill, RN, long	044.089
32		SP Profile Drill, WN, short	044.084
33		SP Profile Drill, WN, long	044.085
34		TE Profile Drill, RN, short	044.701
35		TE Profile Drill, RN, long	044.708
36		TE Profile Drill, RN, short	044.705
37		TE Profile Drill, RN, long	044.712
38		TE Profile Drill, WN, short	044.703
39		TE Profile Drill, WN, long	044.710
40		BL/NNC Profile Drill, short	034.327
41		BL/NNC Profile Drill, long	026.2306
42		BL Profile Drill, short	034.328
43		BL Profile Drill, long	026.4306
44		BL Profile Drill, short	034.329
45		BL Profile Drill, long	026.6306
46		BLT Profile Drill, short	034.324
47		BLT Profile Drill, long	026.0004
48		BLT Profile Drill, short	034.325
49		BLT Profile Drill, long	026.0006
50		BLT Profile Drill, short	034.326
51		BLT Profile Drill, long	026.0008
52		S/SP Tap	034.351
53		S/SP Tap	034.352
54		S/SP Tap	034.353
55		BL/NNC Tap	034.348
56		BL Tap	034.349
57		BL Tap	034.350
58		BLT Tap	034.345
59		BLT Tap	034.346
60		BLT Tap	034.347
61		Adapter for Handpiece, extra short	046.470
62		Adapter for Handpiece, short	046.471
63		Adapter for Handpiece, long	046.472

* Not all products are available in all countries.
** This article will be replaced with above article. For further information, please refer to *Straumann® Dental Implant System, Basic information* (702084/en).



No.	Picture	Article	Art. No.
64		Adapter for Ratchet, extra short	046.460
65		Adapter for Ratchet, short	046.461
66		Adapter for Ratchet, long	046.462
67		SCS Screwdriver for Handpiece, extra short	046.410
68		SCS Screwdriver for Handpiece, short	046.411
69		SCS Screwdriver for Handpiece, long	046.412
70		SCS Screwdriver for Ratchet, extra short	046.400
71		SCS Screwdriver for Ratchet, short	046.401
72		SCS Scr ewdriver for Ratchet, long	046.402

No.	Picture	Article	Art. No.
73		ND Position Indicator	031.102
74		ND Position Indicator	031.103
75		ND Position Indicator	031.112
76		ND Position Indicator	031.113
77		RD Position Indicator	031.123
78		RD Position Indicator	031.125
79		RD Position Indicator	031.143
80		RD Position Indicator	031.145



No.	Picture	Article	Art. No.
1		Diagnostic T	046.147
2		Torque Control Device for Ratchet	046.049
3, 4		Ratchet	046.119
5		Holding Key	046.064
6		Tweezers	046.095 or 046.057
7, 8		Distance Indicator for Tissue Level or Bone Level	026.0901

NOTES

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neodisher® Mediclean is a registered trademark of Chemische Fabrik Dr. Weigert GmbH & Co. KG,Germany.
CIDEZYME®, is a registered trademark of Johnson & Johnson Corporation, USA.
Sonorex® is a registered trademark of Bandelin electronic GmbH & Co. KG, Germany.

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