Straumann® Modular Cassette

Basic Information
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1. Straumann® Modular Cassette – System overview

The Straumann® Modular Cassette is used for the secure storage and reprocessing of surgical and auxiliary instruments of the Straumann® Dental Implant System. The Straumann® Modular Cassette works with any Straumann® implant line (e.g. SP, BLT, BLX), including with the Straumann® Guided Surgery workflow. The system consists of three modules named A, B and C.

- The A Module stores tools that can be shared among different implant lines. Removable trays provide dedicated spaces to store instruments.
- The B Module stores tools for a specific implant line. Removable trays are dedicated to an implant line workflow.
- The C Modules have embedded inserts to store additional instruments without removable trays.

As the modules are not intended to maintain sterility on their own, they should be enclosed in a steam sterilization packaging system and sterilized according to the Instructions for Use.

Each module comes with a writable blank label plate to help differentiate each set. These label plates can be pushed out from the hole in the back for cleaning or replacement. Laser-marked label plates are also offered as spare label plates (Art. No. 041.775).
**Straumann® Modular Cassette, B Module (041.776)**

B Module trays

![Image of B Module trays](image)

**Straumann® Modular Cassette C Module, Guided surgery (041.772)**

![Image of C Module, Guided surgery](image)

**Straumann® Modular Cassette C Module, Spare Tools (041.773)**

![Image of C Module, Spare Tools](image)
1.1 Straumann® Modular Cassette, A Module

The A Module (Art. No. 041.761) mainly stores surgical tools that can be shared among different implant lines. Users can set up the A Module according to their needs by changing the removable trays inside the A Module. Refer to the Straumann® Modular Cassette Selection Guide (USLIT 1291) to select the correct cassette set-up for your clinic.

The A Module box is a container for the trays. The grid allows the box to be set up as needed. There are four different tray sizes. Maximum loading capacity per box side is 2 by 3 of the 1x1 trays.

To insert a tray, simply click the tray into the interior holes of the A Module. Physical feedback and an audible click will confirm secure placement of the tray. To remove, use a blunt instrument (e.g. the ratchet bolt from the disassembled ratchet, Art No. 046.119) to push the trays out from the back.
There are six different trays for long surgical instruments, each with silhouettes for easy identification of the different instruments held.

- 041.766 Ratchet Tray
- 041.767 Release Aid Tray
- 041.768 Stop Key Tray
- 041.769 Planning Aid Tray
- 041.770 Tweezer Tray
- 041.771 Implant Depth Gauge Tray
There are four different grommet trays. The grommet tray can store shorter tools such as:
- SCS screwdriver
- Angulated screwdriver
- Implant adapter
- Bone profiler
- 48-hour explantation device

Users are free to assemble the A Module with any desired arrangement of tray combinations inside the module. Do not connect trays and label plates outside the A Module other than on the dedicated space for the label plate.

Verify that instruments do not touch each other when closing the A Module.
Example of A Module setup

041.761
A Module

041.764
Grommet trays
(3 small, 3 large)

041.769
Planning Aid Tray

041.767
Release Aid Tray

041.766
Ratchet Tray
1.2 Straumann® Modular Cassette, B Module

The B Module features different workflow trays that store cutting tools for specific implant lines. The B Module complements an A Module to complete the tools needed for an implant surgery.

External slots on the side of the module help align each module on the surgical table. Refer to the Straumann® Modular Cassette Selection Guide (USLIT 1291) to select the correct cassette set-up for your clinic.

To click the B Module trays in place, align the internal slots and gently push the tray into the base by hand. Push down on the connection point for trays. Physical feedback and an audible click will confirm secure placement of the tray. To remove the tray, gently pull the tray out by hand, holding the alignment tabs.

Straumann® Modular Cassette, B Module (041.776)
1.2.1 Fully Tapered Tray and Guided Fully Tapered Tray

The Fully Tapered Tray is intended for BLX implants using freehand surgery. For complete information on the surgical and prosthetic procedures for the Straumann® BLX Implant System, please refer to *Straumann® BLX Implant System, Basic Information* (USLIT 1205).

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041.777 B Module, Fully Tapered Tray

- Implant driver
- Round bur
- Needle drill
- Drill protocol table
- Bone class
- Final drill recommended for each implant diameter and bone class
- Illustration for drill depth mark
- Drill diameter
- Drill number
- Implant diameter
- In brackets: recommended drill for coronal bone widening

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041.780 B Module, Guided Fully Tapered Tray

- Guided implant driver
- Long drill
- Medium drill
- Short drill
- Mucosa punch
- Milling cutter
### 1.2.2 Basic Tray and Guided Basic Tray

The Basic Tray is intended for one implant line (e.g. SP, BL, BLT, CI, CIM) using freehand surgery. For complete information on the surgical and prosthetic procedures, refer to *Basic information on the surgical and prosthetic procedures - Straumann® PURE Ceramic Implant* (USLIT 1099), *Straumann® Dental Implant System, Basic information* (NAMLIT 1017).

The Guided Basic Tray is intended for one implant line using guided surgery. For complete information on the guided surgery procedure, please refer to *Straumann® VeloDrill™ Guided Surgery, Basic Information* (USLIT 1275).
1.2.3 Parallel Walled Tray and Guided Parallel Walled Tray

The Parallel Walled Tray is intended for Standard Plus, Bone Level and Standard Plus Short implants using freehand surgery. Refer to Straumann® Dental Implant System, Basic information (NAMLIT 1017) for surgical information.

The Guided Parallel Walled Tray is intended for Standard Plus, Bone Level and Standard Plus Short implants using guided surgery. For complete information on the guided surgery procedure, please refer to Straumann® VeloDrill™ Guided Surgery, Basic Information (USLIT 1275).

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### 041.779 B Module, Parallel Walled Tray

- **Tap**
- **Profile drill**
- **Implant adapter**
- **Round bur**
- **Needle drill**

**For 4 mm SP implants,** use the BL tap

**For Ø 4.8 RN implants,** no profile drilling

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### 041.782 B Module, Guided Parallel Walled Tray

- **Fine implant bed adapter, sleeve height**
- **Implant diameter**
- **Long drill**
- **Medium drill**
- **Short drill**
- **Mucosa punch**
- **Milling cutter**

**Alignment pin**

**Drill diameter**
1.3 Straumann® Modular Cassette, C Module

C Modules have silicone strips that allow horizontal storage of instruments. External slots on the side of the module help align each module on the surgical table.

Refer to the Straumann® Modular Cassette Selection Guide (USLIT 1291) to select the correct cassette set-up for your clinic.

The C Module can be used on its own, stacked with other C Modules or connected under a B Module base for sterilization and storage. The maximum permissible stacking height is one B Module on top of two C Module bases, without the C Module lids.
Gently push the different bases by hand to engage. Physical feedback and an audible click will confirm secure placement. To remove the base, gently pull on one side by hand to break the connection. Note that the modules are easiest to separate when the force is evenly distributed over the long side of the modules, as shown in the picture.

1.3.1 C Module Guided Surgery (041.772)
The guided surgery module stores guided handles and instrumentation for template fixation pins. All tools are stored horizontally on the holder.
1.3.2 C Module Spare Tools (041.773)
The spare tools module can be used to store other auxiliaries for implant surgery. For example:
• PURE position indicator for the PURE Ceramic Implant
• Profile drills and taps for a specific implant line
• Additional alignment pins for ProArch cases.

1.4 Lids
The B Module lid can be used in combination with an Ultrasonic Mat (Art. No. 041.774) for ultrasonic bath cleaning of contaminated instruments. After surgery, contaminated instruments should be pretreated and then placed on the Ultrasonic Mat that is placed in the B Module lid for ultrasonic bath cleaning.

The C Module lid can be used to enclose the B Module lid to protect the contaminated instruments from dropping out during transportation between uses and reprocessing.

For more information on the handling and reprocessing of Straumann® Instruments, please refer to chapter 2 - Step-by-step reprocessing, and Straumann® Surgical and Prosthetic instruments, Care and maintenance (NAMLIT 1055).
2. Step-by-step reprocessing

Always wear protective clothes for your own safety. Use only properly maintained equipment and materials approved according to national laws and regulations.

2.1 Point of use

To avoid injury during surgery, the cutting instruments should be handled with tweezers.

Make sure that all contaminated instruments are collected separately. The instruments can be damaged by incorrect handling, such as throwing them on a hard surface. Do not reinsert the contaminated instruments back into the trays and grommets.

Damaged and/or blunt instruments must be sorted out and disinfected, cleaned and disposed of separately. Process contaminated instruments as soon as possible for cleaning (within one (1) hour at the most). Immerse instruments in disinfection solution after usage to avoid drying of debris.

2.2 Containment and transportation

Safely store and transport the cassette with instruments in a closed container to the reprocessing area to avoid any damage to, or contamination of, the environment.
2.3 Pretreatment

Sort the instruments according to their material groups to clean these groups separately.

Disassemble all trays, modules and multi-piece instruments into their individual parts (e.g. ratchet, distance indicator, 48h Explantation Device). To disassemble the ratchet, loosen the cover screw with the service instrument for ratchet (Art. No. 046.108) and unscrew the ratchet bolt.

The modular cassette should be disassembled into each individual component (lid / base / tray). To remove trays from the A Module, use a blunt instrument (e.g. the ratchet bolt from the disassembled ratchet, Art No. 046.119) to push the trays out from the back. For the B Module trays, gently pull the tray out by hand. See Chapter 1 Straumann® Modular Cassette – System overview for more information on assembling and disassembling.
Immerse the disassembled trays, modules and multi-piece instruments in a water bath for 10 minutes.

All visible debris should be removed by brushing with a suitable soft bristled brush under running tap water. Never use metal brushes or steel wool.

All movable components should be actuated 3 times under running water.

Use the cleaning brush for ratchet (045.111V4) or an appropriate soft nylon bottle brush to clean the lumina of the ratchet and the torque control device.
2.4 Cleaning

When selecting the cleaning agents, ensure the following:

- Always follow the instructions for use of the manufacturers of cleaning agents.
- Cleaning agents are suitable for cleaning metal and non-metallic instruments.
- The cleaning agent (if used) is suitable for ultrasonic cleaning (no development of foam).
- The chemicals used are compatible with the instruments and cassette components.
- Do not combine different cleaning agents.
- The concentrations and action times stated by the manufacturer of the cleaning agent must be strictly adhered to. Use only freshly made solutions.

Pollutants/minerals from water can reduce the lifetime of instruments and impair the performance of cleaning solutions. Always use the highest permissible water quality for cleaning (e.g. distilled or deionized). At least potable water quality should be used. For the final rinse Straumann® strongly recommends the use of fully demineralized, endotoxin-free water.

Use only filtered air for drying.
Cleaning Procedure:

Place the disassembled cassette parts (lid, trays, base) in an ultrasonic bath.

Place the disassembled instruments on an Ultrasonic Mat (041.774) that is secured in a B Module Lid. The C Module lid can be used to enclose the B Module lid to protect the contaminated instruments during transportation.

Make sure that the instruments do not touch each other. Instruments made of different materials may not be placed in the same bath.

Run an ultrasonic cleaning cycle (frequency 35 kHz) for 10 minutes in a bath of deionized water with a 0.8% Cidezyme detergent solution (Johnson & Johnson).

Rinse out all cavities of the instruments and cassette parts with deionized water for 10 seconds or until no debris residues are visible.

Dry the instruments and cassette parts inside and outside with filtered compressed air.

Pack the instruments and cassette parts as quickly as possible after removal. If additional drying is necessary, dry in a clean location.
2.5 Inspection

Check all instruments after cleaning for corrosion, damaged surfaces, chipping and contamination and sort out damaged instruments. Critical areas such as handle structures, joints or blind holes, in particular, must be inspected carefully. You can use a magnifying glass and direct lighting for better visibility. Instruments with illegible markings/labeling must also be replaced.

Instruments which are still contaminated must be cleaned again. Damaged, corroded or worn instruments should not come into contact with intact instruments to avoid contact corrosion.

Check the modular cassette for functionality:
• Inspect the condition of all modules. Replace modules if there is damage, markings, deformation or wear.
• Visually inspect that all labeling printed on the lid, tray and modules is clear and legible.
• Ensure that all trays are correctly assembled with the cassette before loading with instruments. The trays are connected correctly when they do not fall out of the cassette when the cassette is turned upside down.
• Ensure a secure connection between lid and module base.
• For stacked storage, ensure a secure connection between modules.
  • B Module base on C Module base
  • C Module base on C Module base
2.6 Packaging

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

Place all instruments and the disassembled ratchet in the designated slots in the cassette. Assemble the cassette by putting together the tray, module and lid. Refer to the Straumann® Modular Cassette Selection Guide (USLIT 1291) for guidance on loading the cassette.

When connecting different modules, the maximum permissible stacking limit is one B Module on top of two C Module bases without C lids. The A Module should be sterilized alone.

An indicator strip with the date of the sterilization should be affixed to every sterilization packaging. This will help to indicate whether and, if so, when the material was sterilized.

Place the cassette in a metal sterilization container or in double-pouch packaging satisfying the following requirements:

• Suitable for steam sterilization
• EN ISO/ANSI AAMI ISO 11607 – Packaging for terminally sterilized medical devices
• Use FDA-cleared sterilization accessories

The Ultrasonic Mat should be packaged and sterilized individually in a double pouch. Sterilizing instruments on the Ultrasonic Mat is not allowed.
2.7 Sterilization

As the cassette is not intended to maintain sterility on its own, place the instruments in the appropriate module and seal the module in a sterilization double pouch or metal sterilization container.

When loading the sterilizer, always place the cassette on the shelf in such a way that it does not come in contact with the walls of the sterilizer. Do not put the cassette on its side or upside down on top of the lid.

Do not place corroded, rusty instruments in the cassette for sterilization. These contaminate the water circulation system of the sterilizer with rust particles. During every subsequent sterilization cycle, these rust particles cause rust on instruments that were originally intact.

Only steam sterilization methods listed below may be used for sterilization. Other sterilization methods are not allowed. The sterilizer manufacturer’s instructions for use must be strictly followed.

The sterilizer must:
- Offer a fractionated vacuum method with sufficient device drying time and 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).

Recommended sterilization time (exposure time at the sterilization temperature) and drying time:

<table>
<thead>
<tr>
<th>Sterilization parameter for USA</th>
<th>Sterilization method</th>
<th>Procedure</th>
<th>Drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fractionated vacuum</td>
<td>4 min, 132 °C (270 °F)</td>
<td>30 min</td>
</tr>
</tbody>
</table>

If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time.

Note: Users in the United States should ensure that the sterilizer and all sterilization accessories (sterilization wraps, pouches, sterilization trays, biological indicators and chemical indicators) are cleared by the FDA for the intended sterilization cycle.
3. Further information

For further information (e.g. warnings, cautions, precautions, compatibility), Straumann® Modular Cassette Selection Guide (USLIT 1291) and Straumann® Surgical and Prosthetic instruments, Care and maintenance (NAMLIT 1055).
### 4. Product Reference list

#### A Module overview

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<th>Picture</th>
<th>Description</th>
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<td>041.761</td>
<td><img src="image1.png" alt="Image" /></td>
<td>Straumann® Modular Cassette, A Module</td>
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<tr>
<td>041.762</td>
<td><img src="image2.png" alt="Image" /></td>
<td>A Module, Grommet Tray, 6 small</td>
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<td>041.763</td>
<td><img src="image3.png" alt="Image" /></td>
<td>A Module, Grommet Tray, 6 large</td>
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<td>041.764</td>
<td><img src="image4.png" alt="Image" /></td>
<td>A Module, Grommet Tray, 3 small 3 large</td>
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<td>041.765</td>
<td><img src="image5.png" alt="Image" /></td>
<td>A Module, Grommet Tray, 3 medium 3 large</td>
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<td>A Module, Ratchet Tray</td>
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<td>A Module, Release Aid Tray</td>
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<td>A Module, Stop Key Tray</td>
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<td>A Module, Implant Depth Gauge Tray</td>
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## B Module overview

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<td>B Module, Guided Fully Tapered Tray</td>
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### C Module overview

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<td>Straumann® Modular Cassette, C Module Guided surgery</td>
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<td><img src="image2.png" alt="Image" /></td>
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### Auxiliaries

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<td>Spare Label Plate: Blank, BLX, BLX Guided, BLT, BL, SP, TE, SP/BL, Short Implant, BLX Auxiliary, BLX Guided, BLT Guided, BL Guided, TE Guided, SP/BL Guided, Short Implant Guided, Guided Surgery</td>
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