Transpalatal Distractor. A bone-borne modular distraction device for surgically assisted, rapid, palatal expansion.
Introduction

Transpalatal Distractor Technique Guide

Transpalatal Distractor

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Warning
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing
Transpalatal Distractor. A bone-borne modular distraction device for surgically assisted, rapid, palatal expansion.

Transpalatal Distractor

The Transpalatal Distractor is a modular, intraoral distraction system available in three widths.

Right, blue footplate

Distractor body = right, blue threaded pin + central body + left, gold threaded pin

Left, gold footplate
Features and Benefits

Transpalatal distractor body
- Central body with two telescopic threaded pins
- Available in three widths
- Titanium alloy

<table>
<thead>
<tr>
<th>Transpalatal Distractor Body</th>
<th>Length in Closed Position (mm)</th>
<th>Length in Open Position (mm)</th>
<th>Total Distractor Expansion (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.509.005</td>
<td>16</td>
<td>24</td>
<td>8</td>
</tr>
<tr>
<td>04.509.006</td>
<td>20</td>
<td>36</td>
<td>16</td>
</tr>
<tr>
<td>04.509.007</td>
<td>24</td>
<td>48</td>
<td>24</td>
</tr>
</tbody>
</table>

Closed position

Three "L" markings indicate the left side of the patient.

Three threaded holes for blocking screw. The blocking screw prevents distractor rotation and turns the distractor from an expander into a retainer during latency and consolidation periods.

Open position

Central ring for central placement and retention of activation instrument.

The numbers 1, 2, 3 control/monitor the distractor expansion. Arrows indicate the direction of rotation for distractor expansion (cranial to caudal direction).
Threaded pins
- Left, gold
- Right, blue
- Contains Ø 0.6 mm hole for the Ø 0.4 mm titanium safety wire

Footplates
- Left, gold footplate to be assembled with the gold threaded pin
- Right, blue footplate to be assembled with the blue threaded pin
- Allows horizontal placement of the distractor body:
  - angled socket
- Easy-entry opening facilitates engagement with the threaded pin
- Tapered edges minimize soft tissue damage and facilitate footplate slippage under the palatal mucosa
- Large external contact surface facilitates handling with instruments
- 2 bone screw holes Ø 2.1 mm, 8 mm apart
- 4 spikes located underneath footplate improve bone grip
- Etched “L” on the left, gold footplate and “R” on the right, blue footplate for correct placement in the patient’s mouth
- Pure titanium
**Blocking screw**
- Blocks the left, gold threaded pin
- Prevents unintentional distractor rotation
- Titanium alloy

**Titanium safety wires**
- Ø 0.4 mm safety wires anchor the distractor to the teeth during the treatment period
- Length 140 mm
- Pure titanium
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.1

**Anatomic reduction**
Fracture reduction and fixation to restore anatomical relationships.

**Stable fixation**
Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

**Preservation of blood supply**
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

**Early, active mobilization**
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

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Intended Use, Indications and Contraindications

**Intended use**
The Synthes Transpalatal Distractor is intended for use as a bone-borne maxillary expander and retainer for surgically assisted, rapid, palatal expansion.

The Synthes Transpalatal Distractor is intended for single use only.

**Indications**
The Synthes Transpalatal Distractor is indicated in surgically assisted, rapid, palatal expansion (SARPE) for correction of maxillary transverse deficiencies in skeletally mature patients.

**Contraindications**
The Synthes Transpalatal Distractor is not indicated for patients with flat and/or scarred cleft palates.

**Precaution:** The hard palate cleft or alveolar cleft is likely to open if the scar is disrupted by the distractor when used in cleft maxillae with steep slopes.
Preoperative Planning

Instruments

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>03.509.005</td>
<td>Plate Holder, curved</td>
</tr>
<tr>
<td>03.509.015</td>
<td>Transpalatal Distractor Sizer, L 16 mm</td>
</tr>
<tr>
<td>03.509.016</td>
<td>Transpalatal Distractor Sizer, L 20 mm</td>
</tr>
<tr>
<td>03.509.017</td>
<td>Transpalatal Distractor Sizer, L 24 mm</td>
</tr>
</tbody>
</table>

Determine the post-distraction anatomical goal by conducting an evaluation of the craniofacial pathology through clinical exams, CT scan, frontal cephalogram and/or x-ray. Dental models are beneficial for selecting the appropriate distractor size, determining the location of the corticotomies and placement of the distractor footplates.

A and B: Two possible placement options for the transpalatal distractor.
Transpalatal distractor sizers are available for preoperative planning in each distractor's closed position size: 16, 20 and 24 mm.

**Sizers can be used to:**
- Select the appropriate distractor size for the patient’s anatomy
- Determine the location of the footplate incisions
- Determine the available distractor expansion measurement

**Evaluate:**
- Desired vector of movement and the magnitude of the desired skeletal correction
- Palatal mucosa thickness
- Anatomic abnormalities of the distraction site (e.g. low maxillary sinuses) and bone quality; especially in young patients, cleft patients and patient’s with edentulous maxillae
- Necessary space for distractor placement and movement of the activation instrument during the entire course of treatment
- Surgical access for osteotomy (e.g. proximity of the incisors)
- Patient cooperation with device activation process and oral hygiene

Explain the treatment process to the patient before surgery, including the corticotomies, the application and functionality of the transpalatal distractor and the time needed for the distraction and consolidation periods.
1

Perform corticotomies

Perform the planned corticotomies for surgically assisted, rapid, palatal expansion. 1, 2, 3, 4, 5

Precautions
– The distractor is not designed or intended to break bone and/or complete an osteotomy.
– Avoid causing damage to the palatal blood vessels and critical structures during progressive expansion.
2

Assemble transpalatal distractor

**Instrument**

| 03.509.005 | Plate Holder, curved |

Manually adjust the length of the threaded pins to span the palate where the distractor placement is planned. Allow 3 mm on each side for the footplate thickness.

Assemble the distractor body with both footplates. Assemble the blue threaded pin with the blue footplate and gold threaded pin with the gold footplate. Alternatively, match the left side of the main distractor body with the left footplate.

**Precaution:** Do not touch the spikes underneath the footplates. Handle the footplates with the plate holder included in the set.

**Note:** There is a light press fit between the footplate hexagonal hole and the distractor threaded pins to keep the parts together as one construct.
3
Fit transpalatal distractor

Instrument

| 03.509.005 | Plate Holder, curved |

Hold the central body with the plate holder.

Place the expanded distractor in the planned location.

Note: Expand the distractor symmetrically until the footplate spikes contact the palatal mucosa.

Place the footplates with the easy-entry openings facing anteriorly. Place the left, gold footplate (marked “L”) on the left side of the palate and the blue footplate (marked “R”) on the right side of the palate.

Note: Actual placement may vary depending on the patient’s clinical situation. Be sure to consider areas where more expansion is required, i.e., parallel or V-shape expansion.
Mark the locations of the footplate holes or of the inferior footplate edge on the palatal mucosa. These markings are used later as reference points for the incision lines.

Remove the distractor from the patient's mouth.

**Precautions**

- When possible, use the tooth roots behind the footplates as additional reinforcement of palatal bone.
- Be sure to evaluate bone quality and any anatomic abnormalities of the distraction site; especially in young patients, cleft patients, and patients with overdeveloped maxillary sinuses or edentulous maxillae.
- Confirm that plate positioning allows for adequate clearance of the tooth roots and critical structures while drilling or inserting the screws.
- Do not touch the spikes underneath the footplates. Handle the footplates with the plate holder included in the set.
- Do not place the distractor in a location where it interferes with the lower teeth in occlusion.
- Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
- Make sure that there is sufficient space for placement of footplates and for movement of the activation instrument during the activation period.
4

Make incisions for footplate placement

Mark the incision lines on the palatal mucosa using the previous marks as reference points.

Make the mucoperiosteal incisions. For a cross-shaped incision, use the hole marking; for a T incision, use the footplate edge marking.
Place footplates

**Instruments**

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<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
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<tr>
<td>03.503.203</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>03.509.240</td>
<td>Drill Bit Ø 1.1 mm, length 110/16 mm, 2-flute, for J-Latch Coupling</td>
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Disengage the distractor body from the footplate.
- Use the plate holder to grab the footplate.
- Slip the footplate under the mucoperiosteal flap with the easy-entry opening facing the incisors.
- Place the blue footplate marked R on the right side of the palate.
- Press the footplates into the palatal bone using finger pressure to partially insert the spikes into the bone.
Keep the footplate in place with the plate holder and drill through the anterior hole in the footplate hole.

Insert the screw on the footplate without fully tightening to avoid possible screw extrusion caused by the insertion forces of the second screw.
Drill the posterior hole. The plate holder can be removed to improve visibility.

Tighten the screws in an alternating fashion until they are fully inserted into the bone.
Repeat the above steps to place the gold footplate marked "L+ on the left side of the palate.

**Precautions**
- Do not touch the spikes on the underside of the footplates. Handle the footplates with the plate holder included in the set.
- Do not bend the footplates.
- Confirm that plate positioning allows for adequate clearance of the tooth roots and other critical structures while drilling or inserting the screws.
- Irrigate adequately to prevent overheating of the drill bit or the bone.
- Always use two screws with each footplate to ensure adequate distractor stability.

**Notes**
- The distractor can be used alternatively as an all-in-one device.
- If the distractor is used as an all-in-one device and the posterior screw is difficult to insert, remove the distractor body from the footplates.
- Use the distractor as a three-piece device (footplates separate from the distractor body) if you need more room to handle the instruments in the patient's mouth.
- Self-drilling and self-tapping screws are available in the set.
- Ø 1.85 mm MatrixORTHOGNATHIC screws could be used as optional screws. See the optional screws and their Ø 1.4 mm drill bits on page 40.
6
Place distractor body

**Instrument**

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</table>

Manually adjust the length of the threaded pins by rotating the threaded pins so that the distractor body bridges the span between the footplate’s easy-entry openings.

Hold the central body with the plate holder and place the threaded pins in the footplates. Assemble the blue threaded pin with the blue footplate and the gold threaded pin with the gold footplate (or match the “L” side of the main distractor body with the “L” footplate).

**Note:** If the palatal mucosa is very thick and covers the safety wire holes of the distractor, place the safety wires in the distractor before the distractor body is placed into the footplates.

**Precautions**

- Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa.
- Place the distractor body so that the hole for the safety wire is in a horizontally accessible position.
- Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
7

Confirm activation of transpalatal distractor

<table>
<thead>
<tr>
<th>Instruments</th>
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</thead>
<tbody>
<tr>
<td>03.509.002</td>
<td>Activation Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>03.509.003</td>
<td>Patient Instrument for Transpalatal Distractor</td>
</tr>
</tbody>
</table>

Confirm stability of the device by verifying the pins’ insertion in the footplates.

Check that expansion takes place when the distractor central body is rotated from the cranial to the caudal position, as the arrows on the central body indicate.

Confirm symmetrical movement of both palatal halves.
Secure transpalatal distractor with safety wires

**Instrument**

| 03.509.005 | Plate Holder, curved |

Using the plate holder, insert a Ø 0.4 mm titanium safety wire in each hole of the threaded pin necks. Anchor each side of the distractor to the teeth with the titanium safety wires.

**Warning:** At any time while the distractor is in the patient’s mouth, both sides of the distractor must be secured to the teeth with the safety wires in order to avoid hazard of swallowing or choking.

**Precaution:** If the palatal mucosa is very thick and covers the safety wire holes of the distractor, place the safety wires into the holes before the distractor body is placed into the footplates.
9

Lock transpalatal distractor

**Instruments**

<table>
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<tr>
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<tbody>
<tr>
<td>03.503.203</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, self-holding, length 96 mm, with Hexagonal Coupling</td>
</tr>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
</tbody>
</table>

Remove the green blocking screw from the case with the screwdriver blade or the blade with sleeve.

Ensure proper blade engagement with the screw recess.
Tighten the blocking screw in one of the three holes of the central body until it contacts the threaded pin to prevent central body rotation during the latency period.

**Precautions**
- When inserting the screw, rotate the screwdriver shaft using your fingertips. **Note:** The screwdriver handle is not attached to the shaft. Once the blocking screw is properly engaged, the screwdriver handle may be mounted to the shaft to further tighten the blocking screw.
- Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.

**Notes**
- Maintain a clear view of the hole.
- Place the blocking screw perpendicular to the distractor.
Blocking screw removal

Instruments

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>03.503.206</td>
<td>Screwdriver Shaft MatrixMIDFACE, long, with Holding Sleeve, length 95 mm, with Hexagonal Coupling</td>
</tr>
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<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
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</tbody>
</table>

Following the latency period, remove the green blocking screw from the central body of the distractor with the screwdriver.

**Precaution:** Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.
2

Suggested distraction protocol

<table>
<thead>
<tr>
<th>Instrument</th>
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</thead>
<tbody>
<tr>
<td>03.509.002</td>
<td>Activation Instrument for Transpalatal Distractor</td>
</tr>
<tr>
<td>Optional instrument</td>
<td></td>
</tr>
<tr>
<td>03.509.003</td>
<td>Patient Instrument for Transpalatal Distractor</td>
</tr>
</tbody>
</table>

Activate the device 0.33 mm per day (2 activation instrument strokes), after a 7 day latency period.

To open the distractor 0.33 mm, the central body must be rotated in the direction of the arrows (from the cranial to the caudal position); from one number to the next (e.g. from 1 to 2, from 2 to 3 or from 3 to 1).

Follow the steps below to accomplish 0.33 mm distractor expansion.
Two instrument activations, as described below, are necessary to expand the distractor by 0.33 mm.

A number is visible on the front surface of the distractor central body.

Hold the activation instrument by its handle and push its pivot head forward.

Center and fully engage the tip on top of the distractor central body. The instrument head has a slot that must mate with the central body ring ①.

Push the activation instrument handle forward along a horizontal plan ② ① until its head comes to a stop ④. The instrument head together with the distractor central body will rotate 60° exposing the next distractor surface ⑤.

Carefully slide the activation instrument downward off the distractor central body and remove it from the mouth.

After this first activation sequence, a new distractor front surface is visible. This surface is not marked with a number.

Repeat the above steps to rotate the distractor central body and to expose the surface marked with the next number (e.g. from 1 to 2, from 2 to 3 or from 3 to 1).

The next number must be visible on the distractor front surface.
Precautions
– Carefully plan the rate and frequency of the distraction in order to avoid injuries to important neurovascular structures that may result from forces associated with the maxillary expansion.
– Do not force the instrument after it comes to a stop. Its head may slip off the distractor central body causing damage to the soft tissue of the mouth.
– Do not activate the distractor central body in reverse during palatal distraction.

Notes
– A full (360°) rotation of the central body will expand the distractor 1 mm (e.g. the central body is rotated from 1 to 1, from 2 to 2 or from 3 to 3).
– The patient activation instrument (wrench design) could also be used in case of unrestricted mouth opening. The head of the wrench is turned upside down after every rotation.
3

Document patient progress

Distraction progress must be observed by documenting the changes in the intended diastema. The Patient Care Guide is included in the system to help the patient record and monitor distraction activation. This Patient Care Guide must be provided to the patient.
4

Patient care

Accept the transpalatal distractor as a foreign body in your mouth:

- Do not tamper with, remove or activate the distractor with the tongue, finger, toothbrush or other foreign objects.
- Comply fully with your doctor’s instructions. Regular follow-up visits are essential for long term clinical success.
- Observe arrow direction when operating the distractor.
- Follow a soft diet during the entire distraction period.
- Careful oral hygiene is indicated during the entire treatment.
5

Optional: Exchange distractor body during distraction period

**Instruments**

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<tr>
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</table>

It is possible to exchange the distractor body with the next available size when further expansion of the maxilla is desired.

Rotate the distractor central body with the plate holder or patient instrument from the caudal to the cranial position until the threaded pins disengage from the footplates.

Cut the safety wires from around the teeth.

Remove the distractor body from the patient’s mouth.

Select the next size distractor body.

Repeat steps 6–8 to place and secure the distractor in the patient’s mouth.

Follow the distraction steps according to the distraction protocol.

**Warning:** At any time while the distractor is in the patient’s mouth, both sides of the distractor must be secured to the teeth with the safety wires.
Precautions

- Press plate holder against the footplate while removing the threaded pin from the footplate socket to prevent extrusion of the bone screws.
- Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa during rotation of the central body.
- Place the new distractor body so that the holes for the titanium safety wires are in a horizontally accessible position.
- Symmetrically expand both threaded pins so that the central body is kept in the center/midline.
- If the palatal mucosa is very thick and it covers the safety holes of the distractor, place the safety wires into the holes before the distractor body is placed into the footplates.
Surgical Technique

Consolidation Period

**Instruments**

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</table>

Once the planned expansion is accomplished, the new bone must be given time to consolidate.

Insert the green blocking screw using the screwdriver blade with holding sleeve and handle. The blocking screw must contact the threaded pin to prevent rotation during the consolidation time.

**Precaution:** Place gauze in the mouth to prevent ingestion in the event the blocking screw drops from the screwdriver blade.

**Notes**

- Allow the bone to consolidate for 12 weeks. This time period may vary in relation to patient age and to accomplished palatal expansion.
- Active orthodontic treatment may possibly start after six weeks.
## Instruments

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</table>

Remove the green blocking screw from the distractor central body using the screwdriver shaft with holding sleeve and handle.

Cut the titanium safety wires.

Remove the distractor body. Rotate the central body counterclockwise using the plate holder or the patient instrument until the threaded pins disengage from both footplates.
Remove both footplates by incising the palatal mucosa, exposing the footplates and removing the four bone screws with the long screwdriver shaft with handle.

**Precautions**
- Hold the central body with the front tip of the plate holder to avoid harm to the palatal mucosa during rotation of the central body.
- Place gauze in the mouth to prevent ingestion in the event the blocking screw and/or the bone screws drop from the screwdriver blade.

**Note:** The timing for distractor removal should be determined by clinical evaluation and radiographic or CT evidence of bone healing (minimum 4 months).
## Distractor Implants

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>04.509.008</td>
<td>Blocking Screw for Implant, for Transpalatal Distractor</td>
</tr>
<tr>
<td>04.509.001</td>
<td>Foot Plate, right, for Transpalatal Distractor</td>
</tr>
<tr>
<td>04.509.002</td>
<td>Foot Plate, left, for Transpalatal Distractor</td>
</tr>
<tr>
<td>04.509.010.02</td>
<td>Titanium Wire, Ø 0.4 mm, L 140 mm, pack of 2 units</td>
</tr>
<tr>
<td>04.509.005</td>
<td>Transpalatal Distractor Body, 16–24 mm</td>
</tr>
<tr>
<td>04.509.006</td>
<td>Transpalatal Distractor Body, 20–36 mm</td>
</tr>
<tr>
<td>04.509.007</td>
<td>Transpalatal Distractor Body, 24–48 mm</td>
</tr>
</tbody>
</table>
Screws

1.5 mm MatrixMIDFACE Self-Drilling Screw, 4 in clip*

- 04.503.225.04C  length 5 mm
- 04.503.226.04C  length 6 mm
- 04.503.228.04C  length 8 mm

1.5 mm MatrixMIDFACE Self-Tapping Screw, 4 in clip*

- 04.503.205.04C  length 5 mm
- 04.503.206.04C  length 6 mm
- 04.503.208.04C  length 8 mm

1.8 mm MatrixMIDFACE Emergency Screw, 1 in clip

- 04.503.235.01C  length 5 mm
- 04.503.236.01C  length 6 mm
- 04.503.238.01C  length 8 mm

*Screws are also available in packs of 1 screw in clip. Substitute 04C with 01C in the part number to order.
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</tr>
<tr>
<td>03.509.280</td>
<td>Drill Bit Ø 1.1 mm, length 110/16 mm, 2-flute, for Quick Coupling</td>
</tr>
<tr>
<td>03.503.248</td>
<td>Drill Bit Ø 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling</td>
</tr>
<tr>
<td>03.503.288</td>
<td>Drill Bit Ø 1.1 mm with Stop, length 44.5/8 mm, for Mini Quick Coupling</td>
</tr>
<tr>
<td>03.509.015</td>
<td>Transpalatal Distractor Sizer, L 16 mm</td>
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<td>03.509.005</td>
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## Cases

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<tr>
<td>68.509.001</td>
<td>Module for Transpalatal Distractor System, 2/3, with Lid, without Contents</td>
</tr>
<tr>
<td>01.509.001</td>
<td>Transpalatal Distractor Set</td>
</tr>
</tbody>
</table>
## Screws

### MatrixORTHOGNATHIC Screws, Titanium Alloy (TAN)

**Self-tapping screws Ø 1.85 mm***

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.511.205.04C</td>
<td>5 mm</td>
</tr>
<tr>
<td>04.511.206.04C</td>
<td>6 mm</td>
</tr>
<tr>
<td>04.511.208.04C</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

**Self-drilling screws Ø 1.85 mm***

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.511.225.04C</td>
<td>5 mm</td>
</tr>
<tr>
<td>04.511.226.04C</td>
<td>6 mm</td>
</tr>
<tr>
<td>04.511.228.04C</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

**Matrix screws Ø 2.1 mm, self-tapping**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.511.235.01C</td>
<td>5 mm</td>
</tr>
<tr>
<td>04.511.236.01C</td>
<td>6 mm</td>
</tr>
<tr>
<td>04.511.238.01C</td>
<td>8 mm</td>
</tr>
</tbody>
</table>

*Screws are also available in packs of 1 screw in clip. Substitute 04C with 01C in the part number to order.
Drill bits

**Matrix Drill Bits Ø 1.4 mm, for J-Latch Coupling**

- 03.511.244 Drill Bit with Stop, length 44.5/4 mm
- 03.511.246 Drill Bit with Stop, length 44.5/6 mm
- 03.511.248 Drill Bit with Stop, length 44.5/8 mm

**Matrix Drill Bits Ø 1.4 mm, for Mini Quick Coupling**

- 03.511.284 Drill Bit with Stop, length 44.5/4 mm
- 03.511.286 Drill Bit with Stop, length 44.5/6 mm
- 03.511.288 Drill Bit with Stop, length 44.5/8 mm
Bibliography


