



Guidance for implant removal
Basic Information

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1. About this guide

Straumann implants have been extensively researched, clinically tested and successfully used. The optimized design follows a philosophy called Bone Control Design™, which is based on the five biological key principles in implant dentistry:

- Osteoconductivity of the implant surface
- Control of the microgap
- Biomechanical implant design
- Biological distance
- Position of the surface interface

With the Bone Control Design™, Straumann implants are designed to achieve preservation of crestal bone and soft tissue stability.

However, there might be circumstances that require a removal of an implant. In the event a removal of a Straumann implant is needed, this guide provides rules and instructions. It is valid for the whole Straumann® Dental Implant System.

This guide contains two major sections: Removal of non-osseointegrated implants and removal of osseointegrated implants.

Note:

It is the clinicians' responsibility to assess the extent of osseointegration at the time of the planned removal.

Warning:

The descriptions given are insufficient to allow immediate use of the Straumann® Dental Implant System. Guidance in the handling of the Straumann® Dental Implant System by an operator experienced in its use is strongly recommended. Straumann implants must only be used by dentists, doctors, and operators trained in the use of the system.

Straumann products must be secured against aspiration and swallowing when used intraorally. Do not use damaged or blunt instruments. Always inspect instruments before use. The Straumann® 48h Explantation Device for the Straumann® Dental Implant System may only be used for the explantation of non-osseointegrated Straumann implants.

Warning:

U.S. federal law restricts this device to sale by or on the order of a dental professional.

2. Guidance for implant removal

2.1 Removal of non-osseointegrated implants

In principle, tools for the removal of non-osseointegrated implants must only be used within 48 hours after implant insertion. It is the clinicians' responsibility to assess the extent of osseointegration at the time of the planned removal.

Using the 48h Explantation Device beyond the 48 hour time frame may result in damage to the device due to excessive forces applied to it. If you notice any damage to the device, please discard the tool immediately.

2.1.1 Potential situations that might require the removal of non-osseointegrated implants

- Surgical complications
- Sub-optimal position with or without broken Transfer Piece
- Infection of the surrounding tissue
- Patient's wish

2.1.2 Devices required for the removal of non-osseointegrated implants



Note:

For Straumann implants with the Loxim™ Transfer Piece, the Transfer Piece can be used to remove the implants. As with 48h Explantation Devices, the explantation with the Transfer Piece must only be done within 48h of implant placement. If the Transfer Piece (Loxim® or PURE Ceramic Implant Transfer Piece) is not available at the time of explantation, please use the 48h Explantation described below.







Warning:

In case the implant has to be removed after implant placement, the retention of the Transfer Piece (Loxim™ / PURE Ceramic Implant Transfer Piece) in the implant may be reduced. Always secure the implant against aspiration when removing the implant.

Explantation Devices for Straumann® Bone Level Implants

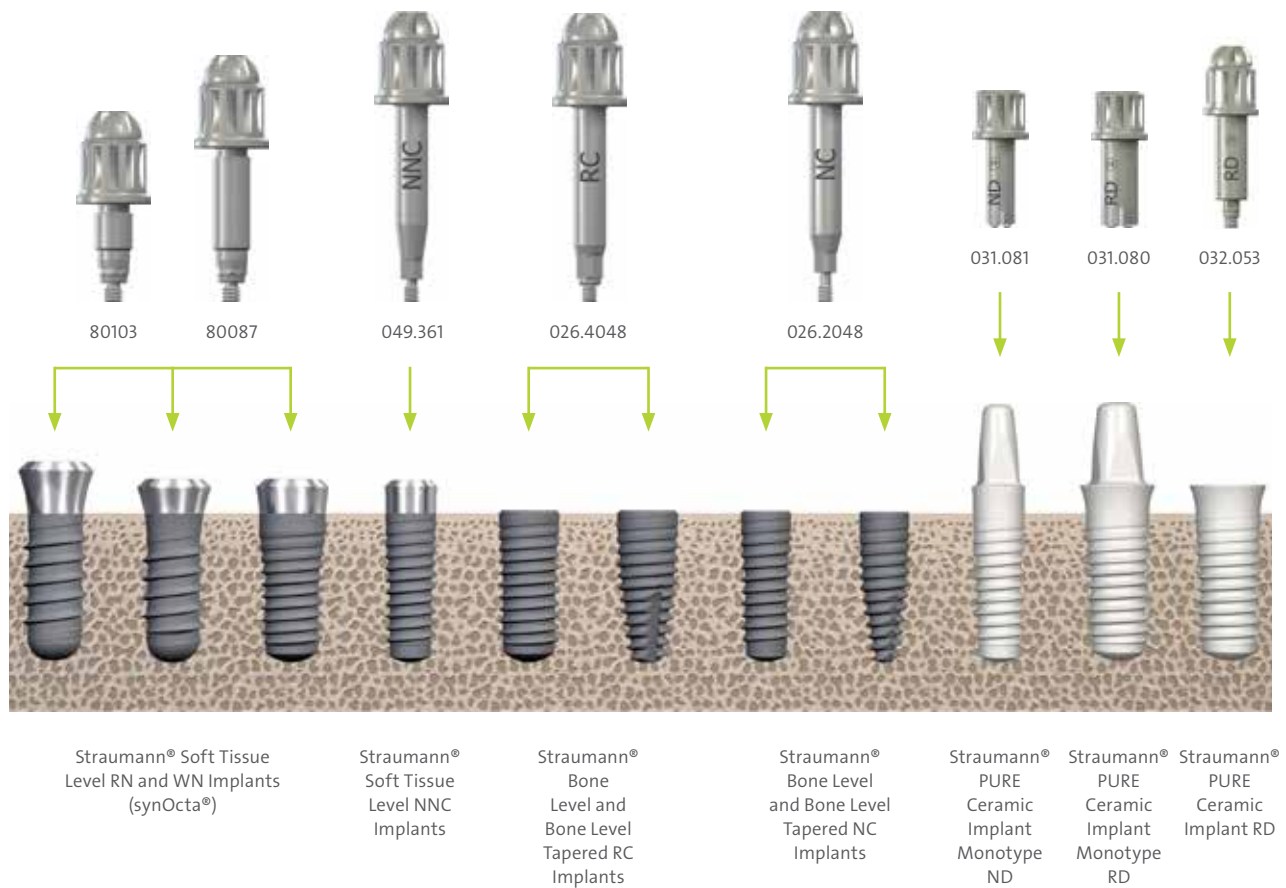
Art. No.		Article	Dimensions
026.2048		48h Explantation Device for Bone Level NC Implants	∅ 8.0mm Length 31.4mm
026.4048		48h Explantation Device for Bone Level RC Implants	∅ 8.0mm Length 31.2mm

Explantation Devices for Straumann® Soft Tissue Level Implants

Art. No.		Article	Dimensions
049.361		48h Explantation Device for NNC Implants	∅ 8.0mm Length 31.4mm
80103		48h Explantation Device for Soft Tissue Level synOcta® Implants, short	∅ 8.0mm Length 20.6mm
80087		48h Explantation Device for Soft Tissue Level synOcta® Implants, long	∅ 8.0mm Length 26.6mm
031.081		48h Explantation Device for ND Straumann® PURE Ceramic Implant (Monotype)	Length 19.8mm
031.080		48h Explantation Device for RD Straumann® PURE Ceramic Implant (Monotype)	Length 19.7mm
032.053		48h Explantation Device for RD Straumann® PURE Ceramic Implant	Length 26.2mm


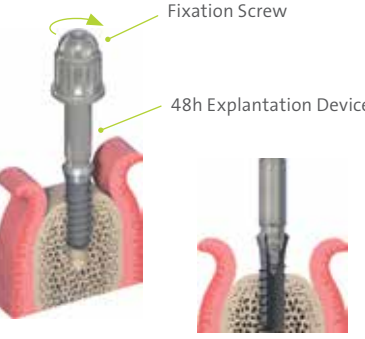
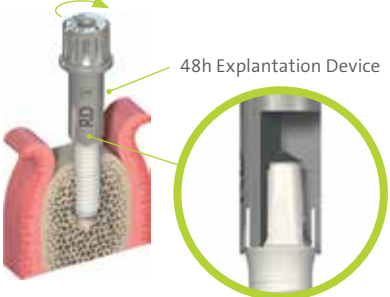
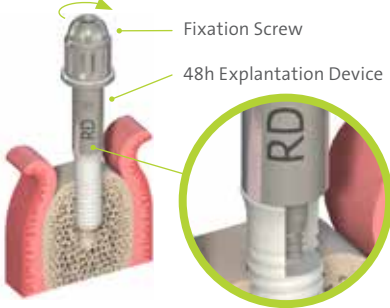
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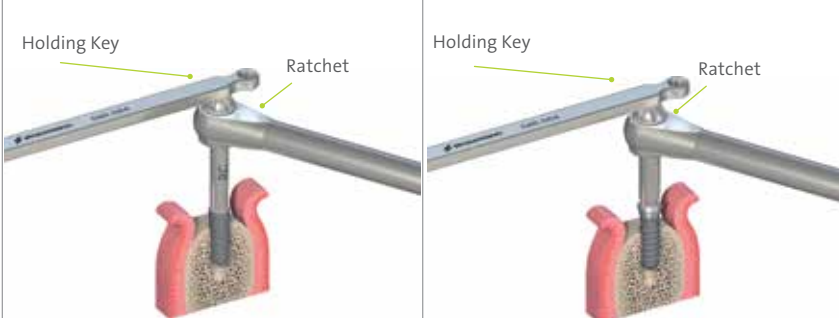
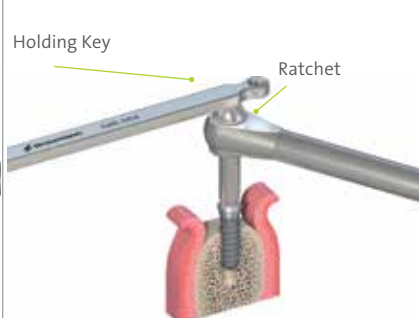
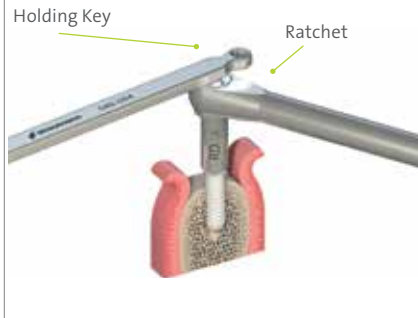
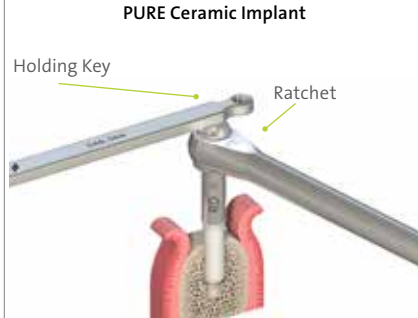

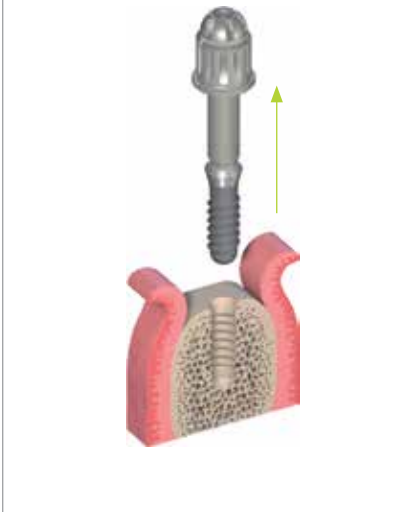


- The Straumann® 48h Explantation Devices must be used neither for adjusting the rotational position of the implant nor for adjusting its height. Otherwise the internal connection could be damaged.
- The Straumann® 48h Explantation Devices must only be used for the explantation of non-osseointegrated implants.



2.1.3 Step-by-step instructions for removal of non-osseointegrated implants

There are several surgical techniques for the removal of non-osseointegrated implants. The procedure shown below is recommended by Straumann.

Bone Level	Soft Tissue Level	Straumann® PURE Ceramic Implant System
<p data-bbox="332 541 386 569">Step 1</p> <p data-bbox="164 579 553 632">Position the Explantation Device into the internal connection of the implant.</p> <p data-bbox="164 659 553 737">Hand-tighten it to the implant with the Fixation Screw which secures the implant against aspiration.</p> 	<p data-bbox="751 541 805 569">Step 1</p> <p data-bbox="586 579 976 632">Position the Explantation Device into the internal connection of the implant.</p> <p data-bbox="586 659 976 737">Hand-tighten it to the implant with the Fixation Screw which secures the implant against aspiration.</p> 	<p data-bbox="1166 541 1219 569">Step 1</p> <p data-bbox="1008 579 1382 606">Straumann PURE Ceramic Implant Monotype</p> <p data-bbox="1000 611 1390 684">Snap the 48h Explantation Device onto the implant abutment. A click is heard when the 48h Explantation Device is attached correctly.</p>  <p data-bbox="1166 1056 1219 1083">Step 1</p> <p data-bbox="1057 1094 1333 1121">Straumann PURE Ceramic Implant</p> <p data-bbox="1000 1125 1390 1220">Position the Explantation Device into the internal connection of the implant. Hand-tighten it to the implant with the Fixation Screw which secures the implant against aspiration.</p> 

Step 2	Step 2	Step 2
<p>Use the Ratchet (Art. No. 046.119) and Holding Key (Art. No. 046.064) to slowly unscrew the implant by applying force counterclockwise to the 48h Explanation Device. The Holding Key is used for stabilization.</p> 	<p>Use the Ratchet (Art. No. 046.119) and Holding Key (Art. No. 046.064) to slowly unscrew the implant by applying force counterclockwise to the 48h Explanation Device. The Holding Key is used for stabilization.</p> 	<p>Use the Ratchet (Art. No. 046.119) and Holding Key (Art. No. 046.064) to slowly unscrew the implant by applying force counterclockwise to the 48 h Explanation Device. The Holding Key is used for stabilization.</p> <p>PURE Ceramic Implant Monotype</p>  <p>PURE Ceramic Implant</p> 
Step 3	Step 3	Step 3
<p>Remove the implant and disposed of it.</p> 	<p>Remove the implant and dispose of it.</p> 	<p>Remove and dispose the tool with the implant.</p> <p>PURE Ceramic Implant Monotype</p>  <p>PURE Ceramic Implant</p> 

Warning:

Removed implants must not be reused! The connection configuration of the implant might be damaged after usage of the 48h Explanation Device which may impact the prosthetic restoration.

2.1.4 Removal of a fractured Loxim™ or PURE Ceramic Implant Transfer Piece

The Loxim™ and PURE Ceramic Implant Transfer Piece are provided. (Step 1) If the Loxim™/PURE Ceramic Implant Transfer Piece breaks during implant insertion, one part remains in the Adapter and the other part in the implant. Both parts can be removed with tweezers.

To extract the implant, simply take out the broken part from the Adapter and re-insert the Adapter on the Loxim™/PURE Ceramic Implant Transfer Piece part remaining in the implant (Step 2). Counterclockwise turns will remove the implant.

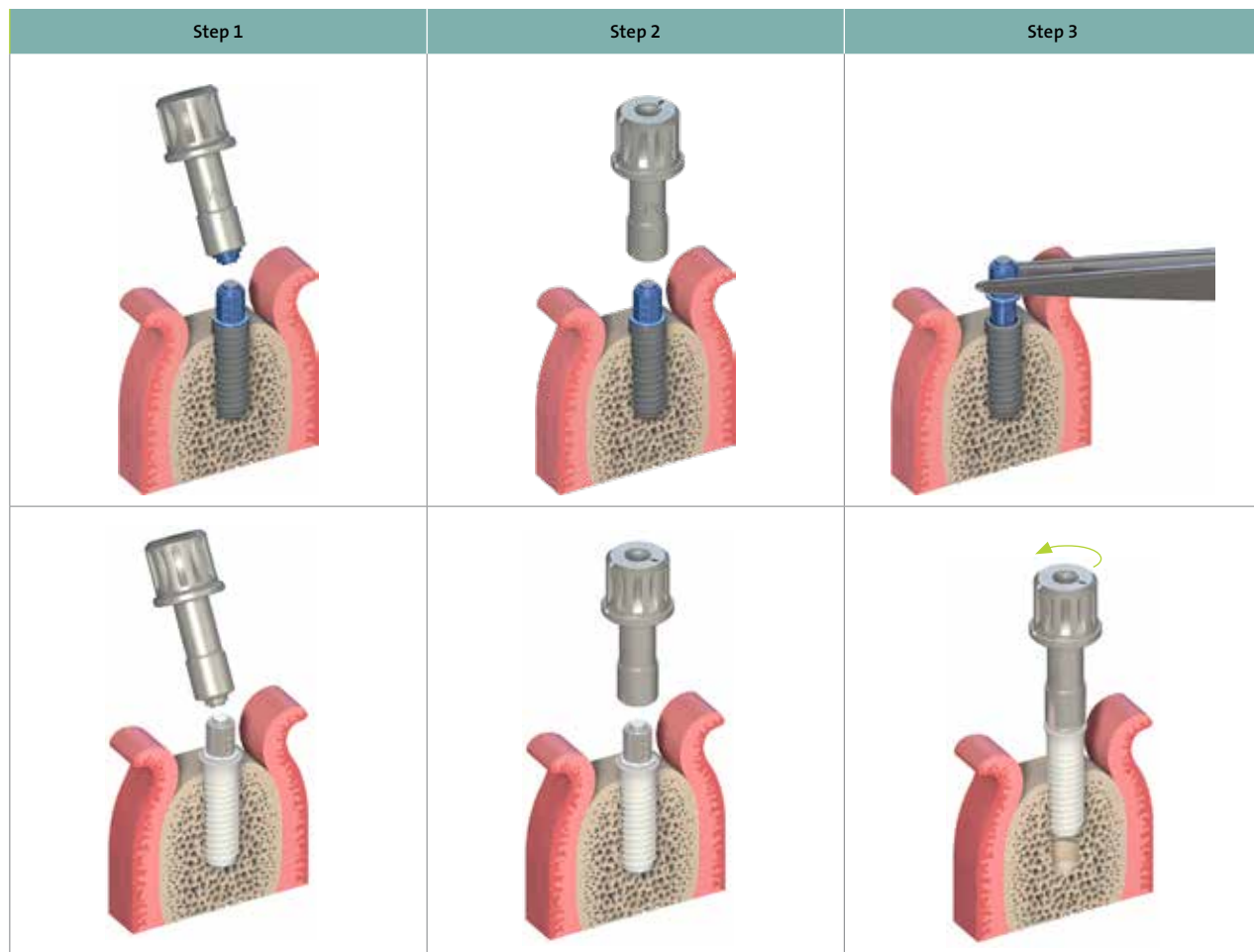
The part of the Loxim™/PURE Ceramic Implant Transfer Piece below the cap are not secured in the Adapter and, additionally, need to be secured against aspiration when taking out the implant.

Warning:

In case the implant has to be removed after implant placement, the retention of the Loxim™/the PURE Ceramic Implant Transfer Piece in the implant may be reduced. Always secure the implant against aspiration when removing the implant.

Caution:

The broken parts of the Loxim™/PURE Ceramic Implant Transfer no longer protect against high torque. Therefore, it is not to be used to advance the placement of the implant.



2.1.5 Removal of a fractured Transfer Piece

A broken Transfer Piece is a result of a too high torque.

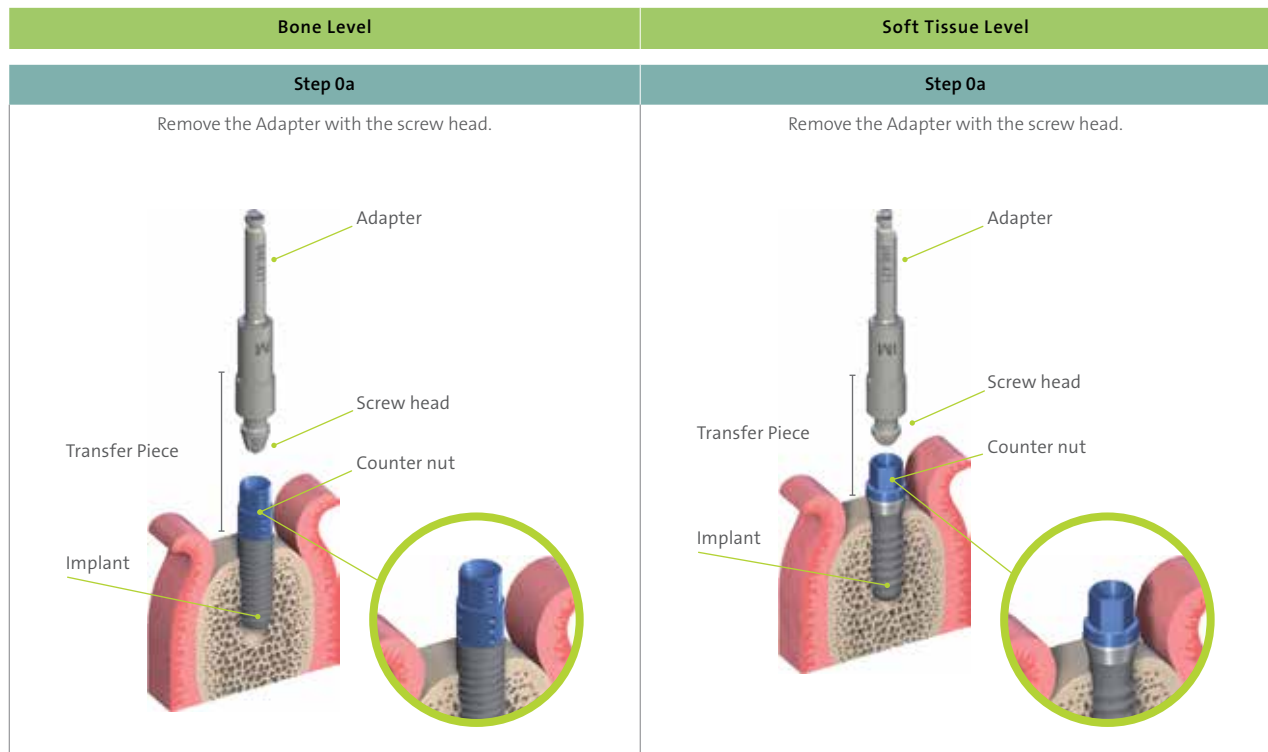
In case of fracture of the Transfer Piece, the following additional steps (steps 0a, 0b and 0c) are required first, followed by the general procedure shown in Step 1, Step 2 and Step 3 (see pages 16–19).




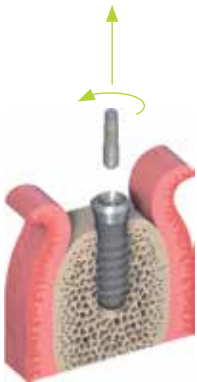
Note:

If the implant is positioned correctly, only the broken Transfer Piece has to be removed. The implant can be kept.

Caution:

Small parts can be swallowed or aspirated. Make sure the counter nut is not aspirated or swallowed! As a protection, the use of rubber dam or a fixation with dental floss is recommended.



Bone Level	Soft Tissue Level
<p data-bbox="435 401 496 422">Step 0b</p> <p data-bbox="293 438 634 489">Remove the counter nut from the implant. Unscrewing is not needed.</p> <p data-bbox="193 518 737 569">In case of jamming, turn the counter nut counterclockwise with the Holding Key until it loosens. Then remove the counter nut.</p> 	<p data-bbox="1060 401 1122 422">Step 0b</p> <p data-bbox="919 438 1260 489">Remove the counter nut from the implant. Unscrewing is not needed.</p> <p data-bbox="818 518 1362 569">In case of jamming, turn the counter nut counterclockwise with the Holding Key until it loosens. Then remove the counter nut.</p> 
<p data-bbox="435 1003 496 1024">Step 0c</p> <p data-bbox="193 1041 737 1092">Remove the remaining screw, which is still fixed with the implant by Tweezers, artery forceps or by hand with counterclockwise rotations.</p> 	<p data-bbox="1060 1003 1122 1024">Step 0c</p> <p data-bbox="818 1041 1362 1092">Remove the remaining screw, which is still fixed with the implant by Tweezers, artery forceps or by hand with counterclockwise rotations.</p> 

Then follow steps 1–3 as described on pages 6 and 7.

2.2 Removal of osseointegrated implants

It is the clinicians' responsibility to assess the extent of osseointegration at the time of the planned implant removal.

2.2.1 Potential situations that might require the removal of osseointegrated implants

- Unsatisfactory osseointegration
- Peri-implantitis
- Infection of the surrounding tissue
- Sub-optimal position of the implant
- Patient's wish

2.2.2 Devices required for the removal of osseointegrated implants

For the removal of an osseointegrated Straumann dental implant an Explantation Drill as well as the corresponding explantation aid must be used.

Explantation Drills

Make sure that the length of the inner bore of the Explantation Drill is longer than the overall length of implant and explantation aid. Otherwise a full immersion of the Explantation Drill into the bone is not possible.




Explantation Drill length	Maximum implant length		
	BL Implants	S Implants	SP Implants/Straumann® PURE Ceramic Implants (except Monotype)
Short drill	10mm	6mm	8mm
Medium drill	all lengths	12mm	14mm
Long drill	for all implant lengths		

Choose diameter of the Explantation Drill according to endosteal implant diameter. For TE Implants choose Explantation Drills for Straumann dental implants \varnothing 4.8mm. Note, there is no drill for the TE WN Implant (with shoulder \varnothing 6.5mm).




Note:

Osseointegrated Straumann® PURE Ceramic Implants (Monotype): Bone preservation is considered to be a core competence required by the clinician in the case of implant removal. The clinician should use a technique suitable to the implant and patient situation.




Explantation Drills for Straumann dental implants Ø 3.3mm

Art. No.		Article	Dimensions	Speed
044.330		Explantation Drill, short	Inner Ø 3.6mm Outer Ø 4.2mm Overall length 32mm	max. 400rpm
044.331		Explantation Drill, medium	Inner Ø 3.6mm Outer Ø 4.2mm Overall length 37.5mm	max. 400rpm
044.332		Explantation Drill, long	Inner Ø 3.6mm Outer Ø 4.2mm Overall length 40.5mm	max. 400rpm

Explantation Drills for Straumann dental implants Ø 4.1mm




Art. No.		Article	Dimensions	Speed
044.340		Explantation Drill, short	Inner Ø 4.2mm Outer Ø 4.8mm Overall length 32mm	max. 300rpm
044.341		Explantation Drill, medium	Inner Ø 4.2mm Outer Ø 4.8mm Overall length 37.5mm	max. 300rpm
044.342		Explantation Drill, long	Inner Ø 4.2mm Outer Ø 4.8mm Overall length 40.5mm	max. 300rpm

Explantation Drills for Straumann dental implants Ø 4.8mm

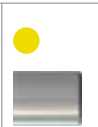




Art. No.		Article	Dimensions	Speed
044.344		Explantation Drill, short	Inner Ø 4.9mm Outer Ø 5.5mm Overall length 32mm	max. 200rpm
044.345		Explantation Drill, medium	Inner Ø 4.9mm Outer Ø 5.5mm Overall length 37.5mm	max. 200rpm
044.346		Explantation Drill, long	Inner Ø 4.9mm Outer Ø 5.5mm Overall length 40.5mm	max. 200rpm

Explantation aids

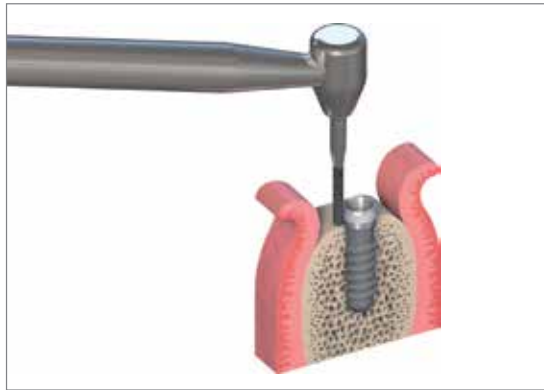
Explantation of Soft Tissue Level Implants without Abutment			
Art. No.		Article	Dimensions
049.182		SCS Guiding Cylinder, for Straumann dental implants Ø 3.3mm Narrow Neck (NN)	Ø 3.6mm Length over implant shoulder 5mm
049.360		SCS Guiding Cylinder, for Straumann dental implants Ø 3.3mm Narrow Neck CrossFit® (NNC)	Ø 3.6mm Length over implant shoulder 4.5mm
049.082		SCS Guiding Cylinder, for Straumann dental implants Ø 3.3mm Regular Neck (RN)	Ø 3.6mm Length over implant shoulder 5.5mm
049.083		SCS Guiding Cylinder, for Straumann dental implants Ø 4.1mm Regular Neck (RN)	Ø 4.2mm Length over implant shoulder 5.5mm
032.054		SCS Guiding Cylinder for Straumann® PURE Ceramic Implant 4.1 mm Regular Diameter (RD)	Ø 4.2mm Length over implant shoulder 5.5mm
049.167		SCS Guiding Cylinder, for Straumann dental implants Ø 4.8mm Regular and Wide Neck (RN and WN)	Ø 4.9mm Length over implant shoulder 5.5mm

Explantation of Bone Level Implants without abutment			
Art. No.		Article	Dimensions
026.2801		NC Guiding Cylinder, for explantation of Ø 3.3mm Bone Level Implants	Ø 3.6mm Length over implant shoulder 4.5mm
026.4801		RC Guiding Cylinder, for explantation of Ø 4.1mm Bone Level Implants	Ø 4.2mm Length over implant shoulder 4.5mm
026.6801		RC Guiding Cylinder, for explantation of Ø 4.8mm Bone Level Implants	Ø 4.9mm Length over implant shoulder 4.5mm

In case the abutment cannot be removed, use the following Guiding Sleeves
(only available for RN and WN Implants):

Explantation of Soft Tissue Level Implants with abutment (only RN and WN)			
Art. No.		Article	Dimensions
049.850		Guiding Sleeve, for Straumann dental implants, Ø 3.3mm Regular Neck (RN)	Ø 3.6mm Length 4.5mm
049.071		Guiding Sleeve, for Straumann dental implants, Ø 4.1mm Regular Neck (RN) and monotype implants	Ø 4.2mm Length 5.6mm
049.851		Guiding Sleeve, for Straumann dental implants, Ø 4.8mm Regular and Wide Neck (RN and WN)	Ø 4.9mm Length 6.4mm
048.350		SCS Occlusal Screw, short for screw-retaining of guiding sleeves on a cone abutment 6° or 8° and on monotype implants	Length 4.4mm
049.181		SCS Occlusal Screw, long for screw-retaining of guiding sleeves on an Octa, synOcta® or cone abutment 15°	Length 7.6mm

No explantation aids for implants with abutment available for NN, NNC, NC and RC Implants.



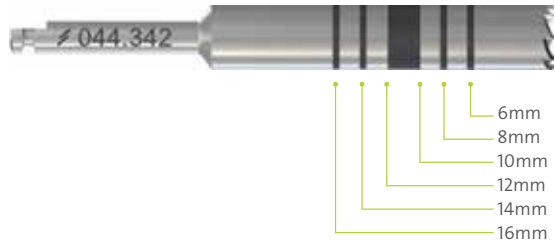
Note:

For Straumann® Soft Tissue Level Implants, the overlapping implant shoulder needs to be ground with an appropriate grinding device (e.g. diamond bur) before explantation. The Explantation Drill can be used for controlling the fit. The grinding is not necessary for NN Implants.



Alternatively, the Guiding Cylinder may be used for guiding the grinding device.

- Always try to remove the Abutment and use the Guiding Cylinders instead of the Guiding Sleeves.
- SCS Screwdriver (see Straumann Product Catalog) is needed to hand-tighten the appropriate explantation aid.
- The Guiding Sleeves can be cemented onto Solid Abutments.
- The Guiding Sleeves cannot be used in combination with Angled Abutments.
- The Explantation Drills and explantation aids are intended for single use only.


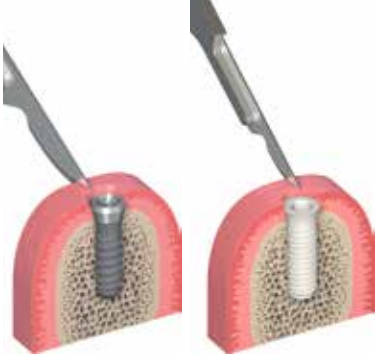





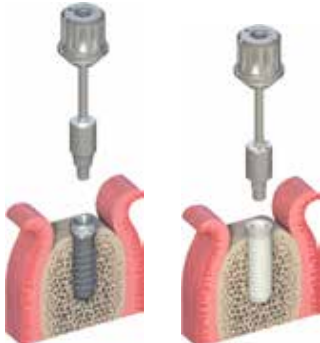


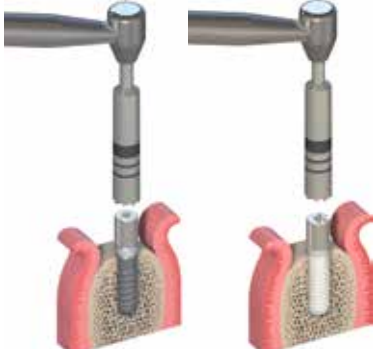

Depth coding/marking on the Explantation Drills


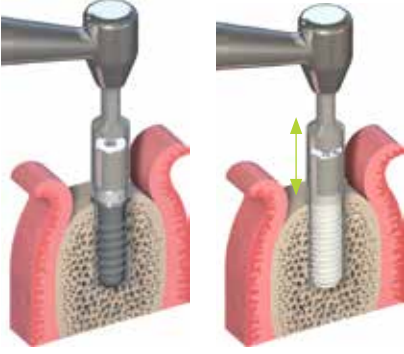

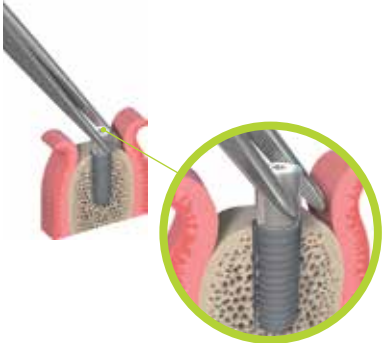
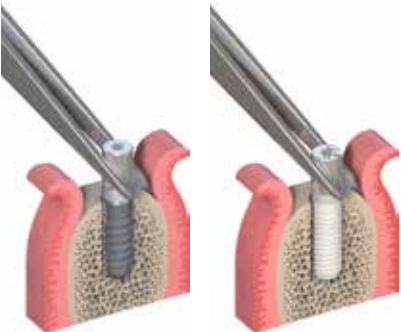

The Explantation Drills feature a depth coding that allows evaluating the endosteal drilling depth. The first marking on the Explantation Drill starts at 6mm. The other markings follow in 2mm distances. The space between 10mm and 12mm is filled.

2.2.3 Step-by-step instructions for removal of osseointegrated implants

Bone Level	Soft Tissue Level
Step1	Step1
<p>Remove the Healing Cap or the Abutment.</p>	<p>Remove the Healing Cap or the Abutment.</p> <p>In case the Abutment cannot be removed, go to Step 2b, otherwise go to Step 2a.</p>

Bone Level	Soft Tissue Level	
<p data-bbox="354 401 407 422">Step 2</p>	<p data-bbox="768 401 829 422">Step 2a</p>	<p data-bbox="1190 401 1252 422">Step 2b</p>
<p data-bbox="228 436 532 485">Incise the mucosa to gain good access for the procedure.</p> 	<p data-bbox="613 436 992 512">Incise the mucosa to gain good access for the procedure. If possible, this step should be done after grinding.</p> 	<p data-bbox="1032 436 1411 512">Incise the mucosa to gain good access for the procedure. If possible, this step should be done after grinding.</p> 
<p data-bbox="602 921 1000 1077">Grind the overlapping part of the implant (not necessary for NN Implants) with an appropriate grinding device (e.g. diamond bur) in order to prepare the implant for the removal. Ensure ample cooling of the grinding device. Remove the debris with a surgical aspirator.</p> 		<p data-bbox="1024 921 1422 1052">Grind the overlapping part of the implant with an appropriate grinding device (e.g. diamond bur) in order to prepare the implant for the removal. Ensure ample cooling of the grinding device. Remove the debris with a surgical aspirator.</p> 

Step 3	Step 3a	Step 3b
<p data-bbox="170 384 545 432">Hand-tighten the appropriate Guiding Cylinder using the SCS Screwdriver.</p> 	<p data-bbox="591 384 966 432">Hand-tighten the appropriate Guiding Cylinder using the SCS Screwdriver.</p> 	<p data-bbox="1011 384 1386 457">Hand-tighten or cement (for Solid Abutments) the appropriate Guiding Sleeve on the top of the Abutment.</p> 
Step 4	Step 4a	Step 4b
<p data-bbox="162 949 553 997">Choose the Explantation Drill and position it over the Guiding Cylinder.</p> 	<p data-bbox="581 949 972 997">Choose the Explantation Drill and position it over the Guiding Cylinder.</p> 	<p data-bbox="1002 949 1393 997">Choose the Explantation Drill and position it over the Guiding Sleeve.</p> 

Step 5	Step 5a	Step 5b
<p>Mill out the implant with the aid of the Explantation Drill. Use irrigation to avoid overheating of the bone.</p> 	<p>Carefully and with slow up and down movements, mill out the implant with the aid of the Explantation Drill. Regularly check mill depth according to marking on the Explantation Drill. Use irrigation to avoid overheating of the bone.</p> 	<p>Mill out the implant with the aid of the Explantation Drill. Use irrigation to avoid overheating of the bone.</p> 
Step 6	Step 6a	Step 6b
<p>Remove the implant using Tweezers or dental forceps by gentle rotation.</p> 	<p>Remove the implant using Tweezers or dental forceps by gentle rotation.</p> 	<p>Remove the implant using Tweezers or dental forceps by gentle rotation.</p> 

Warning:

Removed implants and devices must not be reused! In case Explantation Drill has to be de-attached from the Guiding Cylinder during procedure, verify tight fit of the Guiding Cylinder in the implant before re-attaching the Explantation Drill.

3. Further information

3.1 Care and maintenance

Some of the instruments mentioned in this guide are delivered sterile, some of them are delivered non-sterile. Please take notice of the product label.

Detailed information regarding sterilization methods can be found in the brochure *Straumann® surgical and prosthetic instruments, Care and maintenance* (152.008/en).

4. Important guidelines

Please note

Practitioners must have appropriate knowledge and instruction in the handling of the Straumann CAD/CAM products or other Straumann products ("Straumann Products") for using the Straumann Products safely and properly in accordance with the instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Products are part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Straumann, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in this document or in the instructions for use for the respective Straumann Product. If use of products made by third parties is not recommended by Straumann in this document or in the respective instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

Availability

Some of the Straumann Products listed in this document may not be available in all countries.

Caution

In addition to the caution notes in this document, our products must be secured against aspiration when used intraorally.

Validity

Upon publication of this document, all previous versions are superseded.

Documentation

For detailed instructions on the Straumann Products contact your Straumann representative.


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Explanation of the symbols on labels and instruction leaflets


 Batch code


 Catalogue number


 Sterilized using irradiation

 Lower limit of temperature


 Upper limit of temperature

 Temperature limitation


 Caution: Federal law restricts this device to sale by or on the order of a dental professional.


 Do not re-use


 Non-sterile

 Caution, consult accompanying documents

 Use by

 Keep away from sunlight

 Straumann Products with the CE mark fulfill the requirements of the Medical Devices Directive 93/42 EEC

 Consult instructions for use
Please follow the link to the e-IFU www.ifu.straumann.com

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