More than Primary Stability
The New Tapered Standard
Bone Level Tapered Implant

Introduction
Why Bone Level Tapered Implants?

Patients

- Need immediate restoration of their esthetics, function and self-confidence.
- Want simpler, more cost-effective and less time-consuming dental treatment.

Clinicians

- Need to offer immediate implant and restorative solutions for patients using more efficient procedures and products.
- Want less invasive procedures for patients:
  - One stage procedures
  - Improved primary stability in soft bone or extraction sockets
Current Trend

Global implant market by implant design (in units)\(^1\)

Anticipated growth of the tapered implant segment until 2020 by region

\(^1\) Source: Millennium Report Dental Implants & Final Abutments 2014 and 2015 (actual 2013 or part of 2014).
After 2014, more tapered implants are expected to be sold in Europe, when compared to parallel-walled implants.
Current Trend

- By 2020, the tapered design implant will dominate the global markets.
### Straumann® Dental Implant System

<table>
<thead>
<tr>
<th>Tissue Level Implants</th>
<th>Bone Level Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>BLT</td>
</tr>
<tr>
<td>SP</td>
<td>BL</td>
</tr>
<tr>
<td>TE</td>
<td></td>
</tr>
</tbody>
</table>

- **S**: Straumann® Standard Implant (S)
- **SP**: Straumann® Standard Plus Implant (SP)
- **TE**: Straumann® Tapered Effect Implant (TE)
- **BL**: Straumann® Bone Level Implant (BL)
- **BLT**: Straumann® Bone Level Tapered Implant (BLT)
Straumann® Bone Level Tapered Implant

Mechanics (primary stability) + Material (stability & strength) + Biology (secondary stability)

Tapered Design + Roxolid® + SLActive®
BLT is designed with clinically proven features

**Bone Control Design™**
- Allows optimized crestal bone preservation and soft tissue stability

**CrossFit® connection**
- Simplified handling, legacy of Bone Level system
- Same prosthetic portfolio for BL and BLT

**Roxolid®**
- Reducing invasiveness with smaller implants

**SLActive®**
- Designed to maximize treatment success and predictability
Bone Level Tapered Implant

Product Information
The Bone Level Portfolio

Parallel implant body

Full corono-apical position flexibility

Apically tapered

Simplifies placement in underprepared sites
Features and Benefits

Proven Bone Level Implant features

- Bone Control Design™
- CrossFit® connection

Proven material and surface

- Roxolid®
- SLActive®

NEW!

- Consistent Emergence Profiles™
- Pleasing esthetic results
- Broader surgical treatment options
- Apically tapered implant body
Bone Control Design™

- Allows optimized crestal bone preservation and soft tissue stability
CrossFit® connection

- Easier handling and confidence in component positioning
Roxolid® shows a 20% higher tensile strength than Straumann cold worked titanium and a 80% higher strength than standard titanium Grade 4.

1Norm ASTM F67 (states min. tensile strength of annealed titanium).
2Data on file for Straumann cold-worked titanium and Roxolid® Implants

SLActive®

- Allows fast and predictable osseointegration

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The SLActive® surface shows a faster integration into new bone after 4 weeks (50 %) compared to the SLA® surface (30 %).

[Graph showing osseointegration comparison between SLActive® and SLA® surfaces]

Consistent Emergence Profiles™

- Optimizes and simplifies the soft tissue management process
Apically tapered implant body

- Designed for excellent primary stability in challenging clinical situations such as:
  - soft bone
  - extraction sockets
  - anatomical limitations

Full-depth threads and 3 cutting notches
Soft Bone

- Tapered implants offer improved primary stability in an underprepared osteotomy by adequate compression of the soft bone.
Extraction Sockets

- Mimic shape of root facilitating placement in extraction sockets
- Immediate engaging of bone in apical part
Anatomical Limitations

- Limited anatomy
  - Facial undercuts
  - Narrow interdental spaces

- Protects anatomical structures
  - Nerves
  - Sinus
  - Convergent root tips

Radiograph shown courtesy of Dr Bob Miller, USA
Bone Level Tapered Implant

Technical Specifications
## Overview

<table>
<thead>
<tr>
<th>Straumann® Bone Level Implants</th>
<th>Straumann® Bone Level Tapered Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parallel design</strong></td>
<td><strong>Body Design</strong></td>
</tr>
<tr>
<td>Roxolid®, Ti Grade IV</td>
<td>Material</td>
</tr>
<tr>
<td>SLActive®, SLA®</td>
<td>Surface</td>
</tr>
<tr>
<td>Ø 3.3, 4.1, 4.8 mm</td>
<td>Diameter</td>
</tr>
<tr>
<td>8, 10, 12, 14 mm</td>
<td>Length</td>
</tr>
<tr>
<td>twisted, parallel</td>
<td>Drills</td>
</tr>
<tr>
<td>Optional tap</td>
<td>Drill protocol flexibility</td>
</tr>
<tr>
<td>yes</td>
<td>Guided Surgery</td>
</tr>
<tr>
<td>yes</td>
<td>Osteotome</td>
</tr>
</tbody>
</table>
Surgical flexibility

- Corono-apical position flexibility due to parallel wall design in upper part
- Fully-threaded and self-cutting apex for immediate engagement in osteotomy
- Round tip to protect anatomical structures
- Lean instrument set due to only one apex shape for all implant lengths
Parallel body and tapered apex

- Tapered apex: 5mm
- Thread pitch: 0.8 mm
- Flank lead: 20°
- Apical taper: 9°

- Due to the tapered apex, the surface area is reduced by 6-9% (depending on diameter and length) compared to full parallel walled implant (BL).

* On the 8mm implant the apex is 4mm to maintain minimal wall thickness around the cross-fit connection
Implant and drill diameters

Ø 1.4 mm
Ø 2.2 mm
Ø 2.0 mm
Ø 2.1 mm
Ø 2.8 mm
Ø 2.7 mm
Ø 3.5 mm
Ø 3.2 mm
Ø 4.1 mm
Ø 4.8 mm
BLT instruments

- SHORT DRILLS: 33 mm
- LONG DRILLS: 41 mm
- LONG PROFILE DRILLS: 33 mm
- TAPS: 25 mm
- SHORT PROFILE DRILLS: 25 mm
BL instruments are not compatible with BLT implants, please use dedicated drill set only.
The Straumann® Surgical Cassette has been updated to integrate the BLT instruments.

This allows flexibility, simple-to-follow surgical workflows and ease of use.
# Straumann® Surgical Cassette – BLT instruments

<table>
<thead>
<tr>
<th>Color coding</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>yellow</td>
<td>Endosteal implant diameter 3.3 mm</td>
</tr>
<tr>
<td>red</td>
<td>Endosteal implant diameter 4.1 mm</td>
</tr>
<tr>
<td>green</td>
<td>Endosteal implant diameter 4.8 mm</td>
</tr>
</tbody>
</table>

![Diagram of Straumann Surgical Cassette](image)

- **BLT Implant Diameter:** Ø 3.3 mm
- **BLT Implant Diameter:** Ø 4.1 mm
- **BLT Implant Diameter:** Ø 4.8 mm

- **BLT Tap**
- **BLT Profile Drill**
- **BLT Pilot Drill** Ø 2.2 mm
- **BLT Drill** Ø 2.8 mm
- **BLT Drill** Ø 3.5 mm
- **BLT Drill** Ø 4.2 mm
Drills

- 2 lengths: Short 33mm, Long 41mm
- 4 diameters: Ø2.2, 2.8, 3.5, 4.2mm
- Depth markings from 4 - 16mm
- Color coding – 2 ring
- Straight flanks
- Tapered tip
Profile Drills

- 2 lengths: Short 25mm, Long 33mm
- 3 diameters: Ø 3.5, 4.1, 4.8mm
- Color coding – 2 ring
Taps

- Length: 25mm
- 3 diameters: Ø 3.5, 4.1, 4.8 mm
- Color coding – 2 ring
- Tapered apex
Alignment Pins and Depth Gauges

- 5 diameters: Ø 2.2, 2.8, 2.2/2.8, 3.5, 4.2 mm
- Additional Ø 2.8 mm gauge
- Depth markings 4 - 16mm
- Tapered tip
Prosthetic components

- Single- and multi-unit replacements: screw- or cemented-retained
- Edentulous treatment: fixed or removable options
- Cost-effective and premium: conventional or digital workflow

Refer to brochure 490.038 Basic information for Surgical procedures for Straumann Bone Level Tapered Implant for more information.
Bone Level Tapered Implant
Surgical Procedure
Surgical Planning

Rule 1

≥1.5 mm

Rule 2

≥3 mm
Surgical Planning

- In multiple tooth gaps
Drilling Protocols

Example shown for Bone Level Tapered implant Ø 4.1 mm, length 12 mm

<table>
<thead>
<tr>
<th>Type</th>
<th>Bone Type</th>
<th>Pilot</th>
<th>BLT Drill 2.8 mm</th>
<th>BLT Drill 3.5 mm</th>
<th>Profile Drill 4.1 mm</th>
<th>BLT Tap 4.1 mm</th>
<th>rpm max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Very hard bone</td>
<td>2.2 mm</td>
<td>600</td>
<td>500</td>
<td>300</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Type 2</td>
<td>Hard bone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 3</td>
<td>Soft bone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 4</td>
<td>Very soft bone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Flexible protocol depending on bone class

- **Type I** Very hard bone: e.g. “Healed posterior mandibular site”

- Full preparation of osteotomy
- Same procedure as for parallel-walled Bone Level Implant
Flexible protocol depending on bone class

- **Type IV** Very Soft Bone: e.g. “Full edentulous immediacy case”

  - Under preparation of osteotomy
  - Condense bone along full length of implant
Flexible protocol depending on bone class

- **Soft Bone** with dense cortex: e.g. “Anterior extraction sockets”
  - Full preparation of osteotomy in cortical part
  - Under preparation of osteotomy in apical part only
  - Condense bone in apical part only
Flexible protocol depending on bone class

- **Soft Bone** with dense cortex: e.g. Anterior extraction sockets

- Full preparation of osteotomy in cortical part.
- Under preparation of osteotomy in apical part only
- Condense bone in apical part only
Implant bed preparation

**Round bur**

800 rpm

**Twist drills, Depth gauge and alignment pins**

800 rpm

600 rpm

500 rpm

**Profile Drill**

15 rpm

**Tap**

Example of Bone Level Tapered implant Ø 4.1 mm / length 12 mm
Ideally, in the esthetic region, the implant shoulder should be positioned about 3 – 4 mm subgingival of the prospective gingival margin. The round markings in the Loxim™ Transfer Piece indicate the distance to the implant shoulder in 1mm steps.
Implant Placement

- Use the Ratchet Adaptor, Ratchet and holding key (shown here) in clockwise direction no faster than 15rpm.

- Orientation of prosthetic connection for angled abutments.
Insertion Torque

- NO specific insertion torque for all situations
  - Range is determined by technical factors
- 80 Ncm is the pre-defined breaking-point of the Loxim™ transfer piece
  - Prevent damage of the implant’s inner configuration

**Recommended tightening torques**

<table>
<thead>
<tr>
<th>Hand-tight</th>
<th>15 Ncm</th>
<th>15–35 Ncm</th>
<th>35 Ncm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure screws</td>
<td>Temporary copings</td>
<td>Temporary abutments</td>
<td>Final abutments</td>
</tr>
<tr>
<td>Healing abutments</td>
<td>Copings</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Insertion Torque

- Flexible surgical procedure to achieve preferred torque range
  - If 35 Ncm is used before the implant has reached its final position, check if the implant bed preparation is correct to avoid over-compression of bone.
Bone Level Tapered Implant

Scientific Evidence
Scientific Reviews

- Bone Level SLActive® Implants
- Clinical studies show excellent performance in different clinical indications and patient conditions

Youth replacement with implants biologically demands excellent esthetics. Straumann® Bone Level implants can be effectively used for restorations with high aesthetics, thus satisfying the high expectations of the dentist and the patient.

Over the last years, the Straumann Bone Level Implant has been extensively researched in preclinical and clinical studies.

The preclinical studies assessed the effectiveness of the tissue level of the implant abutment interface, with inflammatory reactions and biologic stability. The marginal bone level compared to bioactive connections could be seen, also assessed was the optimal distance of adjacent implants.

A number of 7 clinical studies have been performed. In general, the clinical studies have demonstrated an excellent performance of Straumann Bone Level implants in different clinical indications and in different patient conditions. The implants have been used also in cases with very demanding indications, such as only placement in the anterior area or implant placement in augmented sites. All of these studies the implant survival rates after 1 year have always reached between 95% and 100%. In a recent review of the published literature by van Herwaarden et al. (2010), an overall implant survival rate of 96% implants in composite indications has been documented with 95% marginal bone loss in the first year ranged between 0.0 mm and 0.3 mm, and more importantly, more stable marginal bone levels were achieved over the years in function. As a consequence, the aesthetic outcomes was very pleasing, and the satisfaction of the patient and dentist was always at a very high level.

The following statements for Straumann Bone Level SLActive® Implants are proven by scientific evidence:
- No harmful effects of the implant to the surrounding bone tissue are observed. Inflammation, bone loss, and bone stability is supported by the design of the implant abutment connection. (Zey et al., 2004; Casillas 2009; Herlo-Kalafat et al., 2011; Casillas 2011)
- Excellent clinical performance, outstanding esthetics and high patient satisfaction in daily dental practice (Lindau et al., 2014; Kusuda et al., 2012)
- Flexibility during placement of adjacent implants (Buser et al., 2011)
- Long-term proven clinical performance and pleasing esthetics outcomes in the anterior area (Buser et al., 2008; Buser et al., 2013; Buser et al., 2016, not published)
- Proven evidence for one-stage surgical procedure in the aesthetic area. A second surgery is not needed after implant placement, allowing in reduced treatment time, lower costs and higher comfort for the patient (Dehne et al., 2007; Casillas et al., 2012; Sara et al., 2016).
- High predictability of implant placement in augmented sites (Sung et al., 2013; Chirmossé et al., 2017; Chiapasco et al., 2012).

In conclusion, based on the available evidence, Straumann® Bone Level implants can be recommended in all kinds of clinical indications, but especially in esthetically challenging indications like the anterior maxilla.

See scientific summary “Bone Level SLActive® Implants” – 490.009
Roxolid® SLActive® Implants

Material and surface of these implants are scientifically proven and widely documented.

Scientific Reviews

Scientific Review for Straumann® SLActive Implants

Higher Security in All Indications

Roxolid® is a unique implant material combining both excellent biocompatibility and high mechanical strength. Roxolid® is a metal alloy composed of 15% chromium and 65% titanium which leads to an increased mechanical resistance compared to pure titanium. A higher mechanical strength of titanium-chromium alloy compared to pure titanium has been reported by Kakogianni et al. (1999). Roxolid® implants have up to 40% higher fatigue strength than comparable titanium implants (Brombacher et al. 2015). In addition, it has been shown that titanium-chromium alloys have a better biocompatibility than titanium (Kakogianni et al. 2000).

Today, clinicians and their patients expect not only a successful dental implant treatment but also a predictable healing time. Straumann® SLActive® is a clinically modified hydrophilic surface. In previous studies, it has shown that the osseointegration process of the SLActive® surface is accelerated compared to the SL2 surface (Kielhorn et al. 2004, Scharer et al. 2005). A shorter healing time does not only allow early implant loading but also improves the security by shortening the critical healing phase. Beyond that, Roxolid® implants with the SLActive® surface show significant properties which are at least as good or even superior to those of titanium implants within the SLActive® surface (Catheline et al. 2012, Liu-Wong et al. 2016).

Also in human studies, it was proven that the osseointegration process is accelerated for implants with the SLActive® surface (Datawai et al. 2009) and (Lietz et al. 2009). Furthermore, it was demonstrated that implants with the SLActive® surface can successfully be used in immediate and early treatment protocols without compromising on performance or predictability of the implant therapy (Catheline et al. 2011, Brombacher et al. 2012, Bayr et al. 2013). These conclusions are supported by the predictable findings of a shortened healing phase which indicates an increased security during this critical phase of implant therapy.

Further clinical studies showed that Roxolid® SLActive® Implants are equally effective as titanium implants (Bathé et al. 2011, Manna et al. 2011, Freidinger et al. 2015). In these studies Roxolid® SLActive® Implants reached success and survival rates of 97% or higher after ten years—and as reported for titanium implants. Also clinical bone-level changes of less than 0.5 mm per year following the first year after implant placement have been documented for Roxolid® SLActive® Implants.

Predictable Treatment Success Even in Challenging Cases

Many patients have a difficult health condition which could compromise the treatment outcome of implant therapy. Especially in challenging indications like as an implant system needs to be clinically tested and whether the performance decreases into situations it is necessary to minimize the risk of Treatment Failure. Straumann® Roxolid® SLActive® Implants have been tested in very challenging indications and successful treatment outcomes were documented. Clinical studies have been performed in the following challenging clinical situations:

- Implant placement in a horizontally augmented ridge with 97% survival rate after one year (Bergen et al. 2010)
- Deficient defects after implant placement; 97% survival rate after one year (Van den Berg et al. 2010)
- Early placement from healthy patients results; 100% survival rate after one year (Boekestra & Wittera 2008)
- Treatment of irradiated patients in the head and neck area; 100% survival rate after 14 months (Kleber et al. 2011)
- Treatment of irradiated patients with poorly controlled type II diabetes; 96% survival rate after 11 years (Ehlers et al. 2011)
- Immediate loading of overdentures supported by two implants; 96% survival rate after up to 40 months (Helm et al. 2011)
Pre-clinical Studies

Pre-clinical Study I: A comparative study in a minipig model

- **Status**: Completed
- **Hypothesis**: BLT implant and the BL implant systems show similar bone response concerning alveolar ridge bone remodelling and osseointegration.
- **PI**: David Cochran (USA) & Andreas Stavropoulos (SE)
- **Test System**: 12x Göttingen Minipig, adult female
- **24 BL Implants / 24 BLT Implants**
- **Model**:
  - Intra-oral mandible model – hard bone
  - partly edentulous (P2-M1)
  - group 1: immediate loaded (8 weeks)
  - group 2: submerged healing (4 weeks)

Note: internal and preliminary data, final evaluation still ongoing, publication expected Q2 2015
Pre-clinical Studies

Pre-clinical Study I: A comparative study in a minipig model

- Preliminary conclusion:
  - Initial placement stability, marginal bone maintenance and osseointegration of the new Bone Level Tapered Implant (BLT) implants are consistent with current Bone Level implant standards (BL).
  - No significant difference in mean values was found between the 2 groups under immediate loaded and unloaded conditions.
  - Publication expected for Q2 2015

Standardized radiograph after 8 weeks of loading. BL (left) and BLT (right)
### Non-interventional study

- **“PI/Country**
  - 6 sites, USA
- **Indication**
  - Open (in agreement with IfU)
- **Implant**
  - Roxolid BLT SLActive
- **Study Design**
  - Non-Interventional
- **Study population**
  - 90 patients
- **Primary Endpoint**
  - Implant success & survival
- **Secondary Endpoints**
  - ISQ, bone level changes, AEs
- **Follow Ups**
  - 1 Year
- **Status**
  - started
- **Publication**
  - expected by mid 2016
# Key Clinical Studies

## Multi-Center Study USA

<table>
<thead>
<tr>
<th>Item</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI/Country</td>
<td>Cochran/Martin, USA</td>
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<tr>
<td>Indication</td>
<td>Single tooth</td>
</tr>
<tr>
<td>Implant</td>
<td>Roxolid BLT SLActive</td>
</tr>
<tr>
<td>Study Design</td>
<td>Immediate placement/early loading</td>
</tr>
<tr>
<td>Study population</td>
<td>50 patients</td>
</tr>
<tr>
<td>Primary Endpoint</td>
<td>Crestal bone level changes 1Y post loading</td>
</tr>
<tr>
<td>Secondary Endpoints</td>
<td>Implant success &amp; survival, 1Year</td>
</tr>
<tr>
<td>Follow Ups</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>initiated, start in Q1 2015</td>
</tr>
</tbody>
</table>
Key Clinical Studies

Multi-Center Study CH

- PI/Country: Sailer, CH
- Indication: Single tooth
- Implant: Roxolid BLT SLActive
- Study Design: Immediate vs. conv. placement
- Study population: 2 x 25
- Primary Endpoint: TBD
- Secondary Endpoints: Implant success & survival,
- Follow Ups: 1 Year
- Status: initiated, start in Q1 2015
Testimonials from controlled case series

- “With the BLT system I appreciate the precise Instruments, the great retention even in defect situations and the very good primary stability”  Dr. Bruno Schmid, CH

- “As a primary stability implant, it offers advantages in cases of immediate loading, both single and multiple implants, immediate and early surgical protocols and type 4 bone where primary stability may be compromised”  Dr. David Furze, UK

- “With BLT I feel a real benefit in terms of achievable primary stability and insertion in narrow ridges”  Dr. Paulo Casentini, IT

- “Straumann® Bone Level Tapered Implant is a revolutionary product like no others”  Dr. Jean-Louis Zadikian, FR