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

⚠️ Combination with other products:
The products are intended for exclusive use within the SDS system; combination with other implant systems is not indicated unless explicitly approved by SDS.
1. Product Description

SDS implants are provided in sterile packaging and are intended for single use; they must not be reused!

For hygienic, technical and quality reasons, SDS implants must not be sterilized or disinfected either.

SDS1.2 dental implants are an implant system to fit a synthetic root replacement into the human jaw; they consist of the implant that is inserted into the jaw.

The implants are made of TZP-A (tetragonal zirconia poly-crystal) zirconium dioxide ceramics in accordance with ISO 13356. The SDS1.2 dental implants are used to fix the prosthetic restoration and are suitable for patients with an intolerance to metal.

The outer surface of the SDS1.2 implants is abrasive blasted for good osseointegration.
The implants have a self-tapping Dynamic Thread® in the lower section of the implant for good primary stability. Its bone-condensing section has a 2.5x thread depth. The upper section of the implant has a micro-thread.

The implant shoulder is machined.

Drill holes are prepared by using accessory *SDS Instrument set implantology* following SDS drilling sequences (see chapter 5).

An internal thread has been integrated into the SDS1.2 abutment to allow screw-retained fixation of insertion tools and healing- or temporary caps.

SDS1.2 implants are delivered sterile and are mounted with the disposable *SDS1.2_ITscrewST_single-use* insertion tool which allows to remove the SDS1.2 dental implant from the sterile packaging without touching it and then insert it into the prepared drill hole.

The abutment itself has been designed with reduced dimensions to enable osseointegration without using protective measures.

Healing caps (*SDS1.2_HC-disc-xxx*) can be used during osseointegration to protect the implant during the healing phase up to 180 days. They can be fixed by screw retaining with SDS1.2 standard screw (*SDS1.2_SS-T*). SDS1.2 healing caps may not be used in combination with temporary caps.

SDS1.2 implants can heal without any temporary restoration or can be restored with a temporary restoration immediately, if achieved primary stability is adequate for appropriate functional loading.

Temporary restorations can be produced either individually or by using a prefabricated temporary cap (*SDS1.2_PC_x.x-P*) as basis.

The temporary cap may only be used for screw-retaining temporary restorations with SDS1.2 standard screw (*SDS1.2_SS-T*) and must not be cemented.

Temporary caps are allowed to stay for a maximum period of 180 days in situ.

The implant shoulder can be prepared (see chapter 8) to adapt the preparation margin to gingival level (warning: preparation of SDS1.2 Ø 3.3 mm implant is not permitted).

The SDS1.2 implant abutment can be directly fitted with cemented crowns or bridges.

The healing phase should be 3 months in good and 6 months in cancellous bone quality.
2. Product Variants

SDS1.2 implants are available in different diameter/length combinations and with 2 different implant shoulder designs. Please note that the Ø3.3 implant body measures at Ø3.25.
The different shoulder designs allow for insertion in interdental gaps of different dimensions. The same surgical technique is used for the 2 different implant shoulder designs.

### SDS1.2 Dental implants

<table>
<thead>
<tr>
<th>Article number</th>
<th>Device name</th>
<th>Dimensions</th>
<th>Shoulder design and dimension</th>
<th>Material: TZP-A zirconium dioxide ceramics</th>
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<tr>
<td>SDS1.2_3311</td>
<td>SDS 1.2 Dental Implant</td>
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<td>Standard: Ø 4.2 mm</td>
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</tr>
<tr>
<td>SDS1.2_3314</td>
<td>SDS 1.2 Dental Implant</td>
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<td>Standard: Ø 4.2 mm</td>
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<td>SDS1.2_3808</td>
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<tr>
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<td>SDS 1.2 Dental Implant</td>
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<tr>
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<td>Ø 5.4 mm / length 11 mm</td>
<td>Oval: 6x8 mm</td>
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<tr>
<td>SDS1.2_5414-ov</td>
<td>SDS 1.2 Dental Implant</td>
<td>Ø 5.4 mm / length 14 mm</td>
<td>Oval: 6x8 mm</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: SDS1.2 implants, product variations
3. SDS1.2 Indications for Use

SDS1.2 dental implants are intended as artificial replacements to be placed in the human upper or lower jaw to provide anchor points for the prosthetic restoration. They are indicated for transgingival healing. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. SDS1.2_33xx implants are recommended as single-tooth implant for upper lateral and lower incisors for fixed prosthetic restorations only.

SDS1.2 healing caps-disc, SDS1.2 temporary caps and SDS1.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS1.2 dental implant and enable the production/fixation of long-term temporary restorations or protect the implant during the healing phase for up to 180 days.

4. Additional information for the use of SDS1.2 dental implants

Please note that the Ø3.3 implant body measures at Ø3.25.

SDS1.2 dental implants are particularly suitable for patients with an intolerance to metal and associated chronic diseases.

- Indicated for situations where implants are connected by interlocking or bridge restoration
- SDS1.2_33xx is permitted exclusively as single-tooth implant for upper lateral- and lower incisors for fixed prosthetic restorations
- SDS1.2_38xx is permitted as single-tooth implant for upper lateral- and lower incisors, as well as for premolars and interlocked implants
- SDS1.2_46xx / SDS1.2_54xx are permitted as single-tooth implant for incisors, cuspids, premolars and molars and as bridge post

Contraindications SDS1.2

Existing medical conditions or poor general health can limit the possibility to insert dental implants surgically. Bruxism and insufficient bone quality/quantity requires specific measures to ensure treatment success.

SDS implants are not suitable for applications in which the risk of excessive bending moments exists (e.g. extended crowns, extension bridges, bridges with more than one pontic unit).

- SDS1.2_33xx may not be used for upper central incisors, cuspids, premolars, molars
- SDS1.2_33xx and SDS1.2_38xx may not be used in bridge restorations
- SDS1.2_38xx may not be used for upper central incisors, cuspids and molars
- Implant diameter smaller than 4.6 mm for upper central incisors, cuspids, molar region and/or bridge restoration
- Bone not completely healed (residual osteitis/NICO)
- Serious and systemic health problems in patient
- Bruxism
- Untreated periodontitis, poor oral hygiene, untreated abscess or bone infection
- Crown-length greater than the osseointegrated threaded segment
- Cantilever bridges/extension crowns (mesial or distal)
- Pontic width between two bridge abutments bigger than one pre-molar width
- Connection of tooth with implant
- No reliable precautionary measures possible or patient fails to comply

The patient must be informed of risks, side-effects and complications, as well as of necessary precautions in connection with SDS1.2 dental implants (see instructions for the use of SDS 1.2 dental implants).

Anatomical and general health conditions can have a negative impact on dental implants.
5. Surgery and Drilling Sequences

SDS1.2 dental implants must be placed at tissue-level.

A tulip height (prosthetic platform) of 3 mm corresponds to the median gingival margin (biological width), placing the edge of the implant at the gingival margin.

The edge of the cement-retained crown added later would then be at the gingival margin (equigingival).

Angulation or divergence up to 20° possible without modification of the abutment post.

- All SDS drills include laser designations by type and diameter, as well as color-coding so that you can easily follow the drilling sequences.
- Apply low pressure during the preparation up to the required depth. Work at a speed of 300 – 600 rpm. Do not exceed the recommended speed to prevent fracture of the instrument.
- All below described drilling sequences relate to the standard insertion depth at “tissue-level” meaning the 3 mm high tulip is situated above bone level.
- All drilling sequences are adapted to different bone classes.

Drilling sequences are adapted to different bone classes.

All images on next pages show each of the drilling sequences – from round bur to final drill – projected onto the implant, thus illustrating the remaining thread depth for stabilisation and use SDS1.2 implants with an endosseous thread length of 11 mm as example, inserted at tissue-level.

The red bar at the bottom of the image indicates the implant type and its application with respect to different bone densities.
**SDS1.2 Implant with Ø 3.25 mm**

- SDS1.2_33xx is permitted exclusively as single-tooth implant for upper lateral- and lower incisors for fixed prosthetic restorations
- SDS1.2_33xx may not be used for upper central incisors, cuspids, premolars and molars
SDS1.2 Implant with Ø 3.8 mm

- SDS1.2 3.8 mm Ø implant is permitted as single-tooth implant for upper lateral- and lower incisors, as well as for premolars and interlocked implants.
- SDS1.2 3.8 mm Ø implant may not be used for upper central incisors, cuspids and molars or bridge restorations.

SDS1.2 (Dynamic Thread®) Ø 3.8 mm: Knochen Klasse IV / Bone Class IV

SDS1.2 (Dynamic Thread®) Ø 3.8 mm: Knochen Klasse III / Bone Class III
SDS1.2 (Dynamic Thread®) Ø 3.8 mm: Knochen Klasse II / Bone Class II

SDS1.2 (Dynamic Thread®) Ø 3.8 mm: Knochen Klasse I / Bone Class I
SDS1.2 Implant with \( \varnothing 4.6 \text{ mm} / \varnothing 5.4 \text{ mm} \)

- SDS1.2 4.6 / 5.4 mm \( \varnothing \) implants are permitted as single-tooth implant for incisors, cuspids, premolars and molars and as bridge abutment.
SDS1.2 (Dynamic Thread®) Ø 4.6 mm: Knochen Klasse II / Bone Class II

SDS1.2 (Dynamic Thread®) Ø 4.6 mm: Knochen Klasse I / Bone Class I
SDS1.2 (Dynamic Thread®) Ø 5.4 mm: Knochen Klasse IV / Bone Class IV

SDS1.2 (Dynamic Thread®) Ø 5.4 mm: Knochen Klasse III / Bone Class III
SDS1.2 (Dynamic Thread®) Ø 5.4 mm: Knochen Klasse II / Bone Class II

SDS1.2 (Dynamic Thread®) Ø 5.4 mm: Knochen Klasse I / Bone Class I
6. SDS1.2 sterile packaging and sterile implant removal

Components of SDS1.2 sterile packaging

Attention: SDS1.2 sterile implant shall be removed immediately prior to implant placement. The sterile implant must be placed immediately after opening the blister and must not be placed or stored in the sterile field / surgical tray or elsewhere before implantation. Do not touch the implant. If the implant is touched it is non-sterile and must be discarded.

Fig. 11: SDS1.2 cardboard packaging includes the sealed blister and IFU.

Fig. 12: There is neither a second sterile barrier nor container in which the implant is held; the insertion tool SDS1.2 single use with mounted SDS1.2 implant is clicked directly into attachment clip of blister inlay.

Fig. 13: Components: sealed blister includes the blister inlay, insertion tool SDS1.2 single use and SDS1.2 implant.

Fig. 14: Blister inlay, insertion tool SDS1.2 single use with mounted SDS1.2 implant fixed in the attachment clip of blister inlay.

Fig. 15: Blister inlay, insertion tool SDS1.2 single use with mounted SDS1.2 implant after removal from blister inlay.
Sterile removal of SDS1.2 implant from SDS1.2 sterile blister

Attention: SDS1.2 sterile implant shall be removed immediately prior to implant placement. The sterile implant must be placed immediately after opening the blister and must not be placed or stored in the sterile field / surgical tray or elsewhere before implantation. Do not touch the implant. If the implant is touched it is non-sterile and must be discarded.

Fig. 16: non-sterile dental assistant opens SDS1.2 implant packaging in non-sterile area and removes the sealed blister, clinician double-checks label to identify implant type.

Fig. 17: non-sterile dental assistant opens the sealed blister-lid without touching the sterile inner surface of blister or the sealing edge.

Fig. 18: non-sterile dental assistant presents opened blister to the clinician without touching the sterile inner surface of blister or the sealing edge.

Fig. 19: clinician (sterile) grips the sterile blister inlay (with the mounted implant) with thumb and index finger without touching the outer surface of the blister.

Fig. 20: clinician removes the blister inlay from the blister by first lifting the front part with the insertion tool and implant.

Fig. 21: clinician turns the side with the implant up.
Sterile removal of SDS1.2 implant from SDS1.2 sterile blister

**Attention:** SDS1.2 sterile implant shall be removed immediately prior to implant placement. The sterile implant must be placed immediately after opening the blister and must not be placed or stored in the sterile field / surgical tray or elsewhere before implantation. Do not touch the implant. If the implant is touched it is non-sterile and must be discarded.

![Image 1](image1.jpg)

![Image 2](image2.jpg)

![Image 3](image3.jpg)

![Image 4](image4.jpg)

- SDS1.2 implants are inserted manually into the jaw bones using the accessory torque ratchet (SDStw) or mechanically, using the accessory insertion adapter tool, ISO attachment (SDS_ITISO-ST).
- SDS1.2 implants reach their target depth always by using the accessory torque ratchet. Maximum insertion torque is 35 Ncm. After insertion, loosen the fixing screw of the insertion tool, remove and dispose.
- SDS1.2 implants osseointegrate transgingivally into the jaw bone.
Features of the SDS1.2 implant packaging:

- Surgical trays may be contaminated by surgical residues (e.g. extracted teeth, suture material that has touched the patient's cheek, etc.) or by uncontrolled air in the dental practice. With the SDS1.2 implant system, neither the inner blister nor the sterile implant is ever stored temporarily on a potentially contaminated surgical tray, since the sterile barrier may only be opened directly before implant placement.

- The blister inlay is designed so that the implant can be removed directly from the inlay with the contra-angle handpiece. The contra-angle handpiece adapter (SDS.ITISO-ST) simply grips around the insertion tool SDS1.2 single use (SDS1.2.ITscrew-ST_single-use). No adapter or transfer-tool must be changed for mechanical implant insertion.

- The SDS1.2 blister inlay is held securely by the clinician after removal from the blister reducing the chances of the inner sterile blister falling down when dumping it from the outer blister onto the tray.

- The clinician checks the label for the correct article-number directly before the assistant opens the blister lid, thus avoiding unpacking the wrong implants as the blister is only opened after final preparation of the drill hole and directly prior to implant placement.
7. SDS1.2 Healing- / Temporary Caps and SDS1.2 Standard Screw

SDS1.2 healing caps-disc, SDS1.2 temporary caps and SDS1.2 Titanium standard screws are provided non-sterile. They are intended for single use and must not be reused!

Before use they must be cleaned, disinfected and sterilized according to the instructions provided in respective IFU or user manual.

Healing caps (SDS1.2_HC-disc-xxx) can be used to protect the implant during the healing phase up to 180 days. They are fixed after try-in and cleaning/drying of the abutment and internal thread by screw retaining (use accessory SDS screw driver (SDS-SD-ST/SDS-SD_short-ST) + torque ratchet (SDStw)).

Apply max. 10 Ncm to SDS1.2 standard screw (SDS1.2_SS-T).

SDS1.2 healing caps may not be used in combination with temporary caps.

SDS1.2 implants can heal without any temporary restoration or can be restored with a temporary restoration immediately if achieved primary stability is adequate for appropriate functional loading.

The healing phase should be 3 months in good and 6 months in cancellous bone quality.

Temporary restorations can be produced either individually or by using a prefabricated temporary cap (SDS1.2_PC_x.x-P) as basis.

The temporary cap may only be used for screw-retaining temporary restorations with SDS1.2 standard screw (SDS1.2_SS-T) (use accessory SDS2.2 screw driver (SDS-SD-ST/SDS-SD_short-ST) + torque ratchet (SDStw)).

Apply max. 10 Ncm to SDS1.2 standard screw (SDS1.2_SS-T).

Temporary caps are allowed to stay for a maximum period of 180 days in situ.

Temporary restorations can be produced either individually or by using a prefabricated temporary cap (SDS1.2_PC_x.x-P) as basis.
The direct chairside production of a cemented temporary restoration without using the SDS1.2 temporary cap (is considered the standard procedure).

Implant shoulder may be prepared!

Fig.29: SDS1.2 implant placed in molar region; implant shoulder may be prepared individually (observe SDS preparation rules)

Fig.30: closure of the internal thread with composite

Fig.31: application of resin (SDS recommends the use of Luxatemp®)

Fig.32: application of resin (SDS recommends the use of Luxatemp®). Undercut of adjacent tooth blocked out with wax

Fig.33: adaptation of vacuum formed template

Fig.34: vacuum formed template before removal
Fig. 35: temporary crown before refining

Fig. 36: temporary crown after final refining

Fig. 37: try-in of finished temporary crown, occlusal check

Fig. 38: cementing with temporary cement (SDS recommends the use of Durelon™), removal of cement residues, final occlusal check
Direct chairside production of a screw retained long-term temporary restoration using an SDS1.2 temporary cap.

Implant shoulder may not be prepared!

Fig. 39: SDS1.2 implant placed in molar region; **implant shoulder may not be prepared** to ensure fit of SDS1.2 temporary cap

Fig. 40: SDS1.2 temporary cap, try-in

Fig. 41: SDS1.2 temporary cap after individual preparation for adjusting the height to occlusal distance; graphic on the right highlights (red) the area that may be shortened individually

Fig. 42: try-in of SDS1.2 temporary cap (after shortening) with vacuum-formed template (prefabricated in the dental lab)

Fig. 43: application of resin (SDS recommends the use of Luxatemp®)

Fig. 44: application of resin (SDS recommends the use of Luxatemp®). Undercut of adjacent tooth blocked out with wax
SDS does not recommend cementing of temporary restorations based on an SDS1.2 temporary cap.
8. Grinding of SDS1.2 Implants

The SDS1.2 abutment must not be prepared before insertion of the implant.

SDS recommends preparation of the SDS1.2 abutment if necessary, after final osseointegration of the implant before the impression taking procedure or after the implant has been inserted and the wound has been closed.

Additional information for grinding SDS1.2 implants:

- Do not grind SDS1.2_33xx implants
- Only prepare SDS1.2_38xx / SDS1.2_46xx / SDS1.2_54xx in the visible/aesthetic area of the implant shoulder to adjust them to the contours of the gingiva.

  The outer diameter of the implant shoulder may be reduced by a maximum of 0.5 mm.
  The reduced circle segment must not exceed 5 mm.
  The reduction of the implant shoulder must not exceed 3 mm.

Adhere to the following preparation rules:

- Use single-use, sterile fine-grain diamond bur, granulation 46 µm (red-ring) (standard dental instrument, not included in blister package).
- Spray-jet cooling not less than 50 ml/min
- Observe the operation instructions of the diamond bur manufacturer for maximum speed (warning: pay attention to the transmission of your angle piece)
- Application pressure on the rotating instrument must not exceed 20 N.
9. Taking Impression

In general, conventional direct impression is taken analogously to the prepared natural tooth (no retraction cord, Impregum™) by using irreversible elastic impression materials. Finally, the impression is casted with plaster to produce the master model.

Fig.52: SDS1.2 – view into the direct impression

Fig.53: SDS1.2 – master model produced without laboratory analogs

10. Prosthetic Options

General Considerations

- SDS1.2 implants are suitable for fixed crown- and bridge restorations as well as for removable restorations.
- Indications/contraindications (see chapter 3 + 4) for one-piece SDS1.2 implants must be followed.
- Always use the SDS1.2_46xx / SDS1.2_54xx for upper central incisors, canini, molars and bridge restorations.
- Zirconia should be used as standard material for fixed prosthetic restorations.
- Prosthetic restoration must fit passively/without any tension and may not show any friction on the abutment.
- Cementation with glass ionomer cement (Ketac™ Cem) combines long-term stability with good biocompatibility.
- Prosthetic restoration of patients who show bruxism or parafunctional habits is recommended with high-performance plastics like e.g. PEEK (polyetheretherketone).
- In general, equigingival (“tissue-level”) implant positioning is recommended for SDS1.2 implants. This is considered being the best biological approach (soft tissue support and - formation, meeting the principles of biological width, etc.) and it allows optimal distribution of chewing forces.

- Crown must always be cemented on implant shoulder/preparation margin.

Fig.54: SDS1.2 implant with final crown cemented on implant shoulder
Fixed Restorations with Cemented Crown/Bridge

- Intraoral preparation of SDS1.2 abutments can be performed easily (see chapter 8) if appropriate to create scalloped preparation margins.

- Either, the non-modified, or by preparation modified SDS1.2 abutment is the choice for standard restorations with cemented crown or bridge.

- Cementation with glass ionomer cement (Ketac™Cem) combines long-term stability with good biocompatibility.

- The groove which is milled into the abutment allows the design of a “cement-lock”, respectively “cement-ring”, securing long term cementation.

- For this, the dental technician creates a circular groove in the corresponding crown area.
11. MRI safety information:

The SDS1.2 dental implant system has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SDS1.2 dental implant system in the MR environment is unknown. Scanning a patient who has this device may result in injury.