INSTRUCTIONS FOR USE AND SAFETY

For the prosthetic elements of Denti® Implant Systems

1. Instructions for use and safety, important information

All products of Denti® Implant Systems are recommended exclusively for Dentists and oral surgeons who are well proficient in dental implantology and oral surgery. In every case, it is the responsibility of the user to decide about the proper utilization of Denti® Implant Systems in accordance with proper medical examinations. It is also the responsibility of the user of Denti® Implant Systems to decide whether the products are appropriate for a certain patient in a given case. Denti System Ltd. disclaims any obligations or responsibility for any direct or indirect damages caused by the implantation or utilization of Denti® products among conditions that resulted from decisions which were not appropriately made or which were the results of inexperience of the user.

All elements of this surgical and prosthetic set are part of an integrated system, therefore this set can only be utilized safely and successfully – in accordance with instructions and guides included by the supplier – with its original components and devices. In case any parts of these sets are utilized along with any foreign devices or tools, this may negatively influence the results, which exempts Denti® System Ltd. from any guarantee or other events involving legal procedures. Every device and tool within Denti® Implant Systems has been developed for special applications, any incorrect utilization may cause these devices to wear off sooner than usual, thus endanger the success of application.

Drills, devices and all other components of Denti® Implant Systems have been developed for certain conditions and diameters. Utilization among inappropriate conditions or with inappropriate diameters may cause mechanical damage to the components of the system or even tissue damage to the patient. There is an appropriate surgery set for each implant type. Color marks help with the selection of necessary tools and components.

Studying the details of the utilization of Denti® Implant Systems is the responsibility of the user. In case of any doubt or dubious situations, the user is obliged to contact Denti System Ltd.

Denti® Implant System implants can be utilized to provide implant based prosthesis for the functional or esthetic rehabilitation of both the lower and the upper jaws. Implants can be used in case of single and multiple restorations as well. Abutments can be used to make cemented, screwed or removable prostheses. All indications of various types of Denti® implants and prosthetic elements as well as instructions for special use can be found in guides supplied with Denti® Implant Systems.

2. Materials used in Denti® abutments, prosthetic accessories and screws.

Denti® abutments and prosthetic accessories are made of titanium and titanium alloys, zirconium oxide ceramics, while screws are made of titanium alloys.

Denti® abutments:	Diameter 4.0 - 4.5 - 5.5: titanium Grade 2
	Diameter 3.4: titanium Grade 4
Denti® Ball Head:	Titanium alloy (Ti6A14V)
Denti® screws:	Titanium alloy (Ti6A14V)
Zirconium head pieces:	Zirconium-dioxide
Dental impression caps:	POM
Burnout plastic cylinder:	PMMA

3. Packaging

Abutments are packed and delivered in a physically decontaminated, but not sterile condition, therefore they need to be sterilized before use.

Head pieces cannot be used more than once.

Plastic, so-called temporary head pieces cannot carry any assemblies built upon them. After trying them on, discard these. These can only be sterilized in an autoclave.

Plastic components can only be sterilized once.

Each Denti® abutment is shipped and packaged along with the appropriate screw.

4. Sterilization

Head pieces are packed and delivered in a physically decontaminated, but not sterile condition, therefore they need to be sterilized before use. The abutments can only be used once and in a single patient only. They must be cleansed, decontaminated and sterilized before application. Head pieces and accessories can be sterilized in an autoclave or by means of heat sterilization. Autoclave sterilization should be carried out at a temperature of 121 C°/250 F° and a pressure of 108 kPa for a minimum of 40 minutes. Each autoclave sterilization cycle must be followed by 30 minutes of drying.

Heat sterilization must be carried out at a temperature of 160 C°/320 F° for 45 minutes. Before any sterilization, remove the outer and the inner package.

5. Instruments to be utilized with Denti® abutments

Screwdrivers marked 8000-076 (power-driven) or 8000-077 (manual) are appropriate for use to fix Denti® head pieces of all types.

Ratchet adapters can be used to fix Denti® ball heads (Ref. No.: 8000-002).

6. Prosthetic procedures

Fixed or removable prostheses are made in a prosthetic laboratory in accordance with Denti® prosthetic requirements. All instructions for prosthetic procedures are detailed in Denti® System Ltd. product catalogues and guides supplied with Denti® Implant Systems.

During prosthetic procedures, one should pay special attention to weight distribution, the stress-free location of the assembly and the proper occlusion.

Final prosthetic care for the implant is only possible once all surrounding soft tissue structures are without inflammation and fully healed. X-ray control examination is required before prosthetic care.

7. Selecting abutments of appropriate size

Both two stage Denti® implant systems – Denti® Screw (further referred to as DS) and Denti® Root form (further referred to as DR) – can be used with the same prosthetic elements. DS Ø3.4 mm implants have the exact same external dimensions as DR Ø3.8 mm implants, thus, they can be used with the same accessories. DS Ø4.0 mm implants have the exact same external dimensions as DR Ø4.3 mm implants, while DS Ø4.5 mm implants have the same internal dimensions as DR Ø4.8 mm implants; also, DS Ø5.5 mm ones have the same internal dimensions as DR Ø5.3 mm implants.

8. Selecting the appropriate abutment

Selecting the abutment depends on two factors:

1. How the vertical axis of the implant is related to the vertical axis of the other pillar teeth (or in case of several implants how the axes of the implants are related to each other) and whether or not the longitudinal axis of the implants is perpendicular to the occlusion surface.
2. Whether the Denti®st wishes to make a fix or a removable prosthesis.

When selecting the abutment, the diameter and angular position of the implant and the height of the gingiva must be taken into consideration. A maximum angle correction of 25° is allowable to prevent bone tissue damage around the implant.

DENTI® CEMENTABLE ABUTMENT TYPES

Uni abutment

Recommendations for use:

The conical, universal abutments can be used for the preparation of both individual crowns and bridgework. They can also be reshaped by means of milling when necessary.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-521, 2034-522	3.3, 3.4, 3.8	7.5 and 9.5	yellow
2040-521, 2040-522	4.0, 4.3	7.5 and 9.5	red
2045-521, 2045-522	4.5, 4.8	7.5 and 9.5	blue
2055-521, 2055-522	5.5, 5.3	7.5 and 9.5	green

Contraindications:

- Any deviation from the axis of the implant that is larger than 9 degrees.
- Any prosthesis which is larger than 1:1.25 when compared with the length of the implant

Tapered abutment with inner thread

Recommendations for use:

Tapered abutment with inner thread can be used with prostheses including both crowns and bridges (for cementation and screwing). The bridge screw fixing the crown to the interior screw-thread of the abutment can be used when preparing a prosthesis fixed by screws. Packaged along with the head piece there is also a closing screw (Ref. No.: 2455-573), which can be used to close the head-part when cementing. The horizontal notches on the outer surface of the abutment are designed to increase the retention surface.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2040-501, 2040-502	4.0, 4.3	5 and 7.5 mm	red
2045-501, 2045-502	4.5, 4.8	5 and 7.5 mm	blue
2055-501, 2055-502	5.5, 5.3	5 and 7.5 mm	green

Contraindications:

- Any deviation from the axis of the implant that is larger than 9 degrees.
- Any prosthesis which is larger than 1:1.25 when compared with the length of the implant

Cylindrical abutment for angled correction

Recommendations for use:

The cylindrical abutment is recommended whenever there is a need to correct axial deviations in case any implants are not adequately parallel with each other. It can be used for the preparation of both individual crowns and bridge and can be corrected by means of milling whenever necessary.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-661, 2034-662	3.3, 3.4, 3.8	7.5 and 9.5	yellow
2040-661, 2040-662	4.0, 4.3	7.5 and 9.5	red
2045-661, 2045-662	4.5, 4.8	7.5 and 9.5	blue
2055-661, 2055-662	5.5, 5.3	7.5 and 9.5	green

Contraindications:

- Any deviation from the axis of the implant that is larger than 23 degrees.
- Any prosthesis which is larger than 1:1.25 when compared with the length of the implant

Reverse conical abutment for angled correction

Recommendations for use:

Denti® reverse conical abutments are recommended whenever there is a need for the correction of considerable axial deviations in case implants could not be prepared in an adequately parallel position. It can be used for the preparation of both individual crowns and bridge and can be reshaped by means of milling whenever necessary.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-671	3.3, 3.4, 3.8	7.5	yellow
2040-671	4.0, 4.3	7.5	red
2045-671	4.5, 4.8	7.5	blue
2055-671	5.5, 5.3	7.5	green

Contraindications:

- Any deviation from the axis of the implant that is larger than 35 degrees.
- Any prosthesis which is larger than 1:1.25 when compared with the length of the implant

Zirconium abutments (conical and cylindrical)

Recommendations for use:

Advantages of using Denti® Zirconium-oxide abutments: The screw tightening the abutment is positioned deep into the head piece, thus, it does not turn the transparent crown grey; these abutments can be processed by means of traditional dental techniques; they are not fragile even despite their small size, and can resist chewing tension in a flexible manner; zirconium-oxide crowns and bridges are not break.

Zirconium abutments are available in two types – cylindrical and conical. They can be corrected by means of milling whenever necessary (conical zirconium head pieces can be reshaped up to a deviation of 9 degrees, cylindrical ones up to a deviation of 23 degrees). They are recommended for use under zirconium-oxide crowns.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-691, 2034-695	3.3, 3.4, 3.8	8	yellow
2455-691, 2455-695	4.0, 4.5, 5.5, 4.3, 4.8, 5.3	8	red

Milling Denti® zirconium abutments

Zirconium is an extremely rigid material, when exposed to sudden thermal effects it can easily crack. Sandblasting can be carried out by means of a liquid-cooled turbine or with special silicone-carbide grindstones. Silicon-carbide grindstones are soft stones that rub off easily, thus, they are able to carry the particles of air along thereby cooling their environment. To reshape the collar parts, sinter diamonds can be used as well, however, these can only be used at a small revolution per minute speed and with gentle accentuation to avoid sudden thermal exposure. Confectioned head pieces can be utilized without sandblasting, especially in posterior areas, even by means of taking direct impressions from those.

TYPES OF DENTI® SCREWED (REMOVABLE) ABUTMENTS

Both tapered abutment with inner thread and tapered abutment with shoulder and inner thread are designed for use with screwed prostheses. They are produced with an inner screw-thread and a hygienic screw cap. There is a screw-thread inside the abutment for fixation with screws. It is also possible to use these head pieces for fixation with cementing, in these cases, the hygienic cap-screws (Ref. no.: 2455-573) should be tightened into these threads.

See the **Tapered abutment with inner thread** at the section describing abutments fixed by cementing.

Tapered abutment with shoulder and inner thread

Recommendations for use:

Denti® tapered abutment with shoulder and inner thread are recommended mainly for the implantation of bridge prostheses in the posterior region. Packaged along with the head part there is also a closing screw (Ref. No.: 2455-573), which can be used to close the head-part when cementing.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-601, 2034-602	3.3, 3.4, 3.8	5 and 7.5	yellow
2040-601, 2040-602	4.0, 4.3	5 and 7.5	red
2045-601, 2045-602	4.5, 4.8	5 and 7.5	blue
2055-601, 2055-602	5.5, 5.3	5 and 7.5	green

Contraindications:

- Any prosthesis which is larger than 1:1.25 when compared with the length of the implant

Intermediary head pieces

Recommendations for use:

Denti® intermediary head pieces are especially useful when treating tight edentulous gaps. Reshaping of the crowns and bridgework can be carried out by prefabricated burnout plastic cylinder.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-637, 2034-632	3.3, 3.4, 3.8	2.3 and 4.5	yellow
2040-637, 2040-632	4.0, 4.3	2.3 and 4.5	red
2045-637, 2045-632	4.5, 4.8	2.3 and 4.5	blue
2055-637, 2055-632	5.5, 5.3	2.3 and 4.5	green

Contraindications:

- Any prosthesis which is larger than 1:1.25 when compared with the length of the implant

Ball abutment

Recommendations for use:

The ball head can be tightened into abutments with ratchet insert (Ref: 8000-143 and 8000-002).

Reference number	Implant Ø (mm)	Height (mm)	Color code	Színkód
2034-551, 2034-552	3.3, 3.4, 3.8	5 and 6.5 mm	2.5	yellow
2040-551, 2040-552	4.0, 4.3	5 and 6.5 mm	2.5	red
2045-551, 2045-552	4.5, 4.8	5 and 6.5 mm	2.5	blue
2055-551, 2055-552	5.5, 5.3	5 and 6.5 mm	2.5	green

Contraindications:

- An uneven number of implants in the jaw bone.
- Prostheses fixed by different means
- Any deviation from the axis of the implant that is larger than 9 degrees.

GINGIVA FORMERS

Denti® gingival formers are designed with heights, the appropriate one to choose is the one which is approx. 1 mm longer than the mucoperiosteum, thus, when tightened, it will protrude into the oral cavity.

In case of implants assembled by a two stage surgery method, we recommend the use of Denti® gingival formers for the healing period after the second operation. The so-called transgingival healing screws allow for the esthetic shaping of the gingiva around the implant. These can be used when implants are assembled by a half-open, half-closed operation method.

Reference number	Implant Ø (mm)	Height (mm)	Color code
2034-641,-642, 2034-651,-652	3.3, 3.4, 3.8	3.5 and 5 mm	yellow
2040-641,-642, 2040-651, -652	4.0, 4.3	3.5 and 5 mm	red
2045-641,-642, 2045-651, -652	4.5, 4.8	3.5 and 5 mm	blue
2055-641,-642, 2055-651, -652	5.5, 5.3	3.5 and 5 mm	green

LABORATORY COMPONENTS

A precise copy of the intraoral conditions can be made by the means of impression copings and laboratory implants.

Impression copings and laboratory implants

Reference number	Implant Ø (mm)	Height (mm)	Color code
3034-721, -722, 3034-840, 3034-870	3.3, 3.4, 3.8	8, 11, 7.5, -	yellow
3040-721, -722, 3040-840, 3040-870	4.0, 4.3	8, 11, 7.5, -	red
3045-721, -722, 3045-840, 3045-870	4.5, 4.8	8, 11, 7.5, -	blue
3055-721, -722, 3055-840, 3055-870	5.5, 5.3	8, 11, 7.5, -	green

Burnout plastic cylinders

Denti® burnout plastic cylinders are recommended for the precise copying of the intermediary abutments (Ref. No.: 2034, 2040-, 2045-, 2055-637). Burnout plastic cylinders are available in two types. Cylindrical types (-009) are recommended for several interposed abutments for bar prostheses. Flat sided types are recommended for solo or telescopic prostheses. Shipped in units containing 5 pieces per package.

Reference number	Implant Ø (mm)
3034-009, -010	3.3, 3.4, 3.8
3455-009, -010	4.0-4.3, 4.5-4.8, 5.5-5.3

9. Implanting and fixing the assembly

After removing the gingival formers, the cavity of the implants should be cleaned and abutments are to be fitted into the implant.

When the hexagonal positioning part of the head part fits into the hexagonal inside of the implant, there is a small click and the abutment becomes stable. After that, the fixing screw is screwed in and tightened with the torque wrench through the abutment. The torque recommended for tightening of the abutment should be 25 Ncm and 30 Ncm for ball heads and floating grapnels.

10. Methods of taking impressions

Transmitting the structure of implants to the specimen must be extremely precise. By using Denti® Implant Systems, taking a dental impression can be done with open or closed tray. There are appropriate impression copings for both impression methods. Each element is color coded according to the diameter of the implant.

Impressions taken during prosthetic procedures can be direct or indirect.

Direct impression methods are iDenti®cal to usual Denti®stry impressions taken from prepared teeth.

Taking impressions from Denti® OP and Denti® C implants

Denti® OP and conical C implants are taken in exact impressions by means of impression caps. Impressions taken from impression caps can be taken by means of a closed-tray method (see below). The colors of impression caps inform about the diameter of the implants.

In case it is necessary to align the head part of OP or DC implants in order to achieve correct angle positions, a direct impression method should be taken. Impression caps are used to take impressions of spherical retention Denti® C implants similarly to ball head parts.

It is important to use the proper materials to make the impressions.

Reference number	DOP, DC Implant Ø (mm)
OP 33887, OP 33887, C 33887, C 33887,	3,8
OP 34378, OP 34384 C 34378, C 34384	4,3
OP 34887, OP 34884, C 34887, C 34884	4,8

Head piece heightening abutments for OP implants

When necessary, the height of the head pieces can be increased by 2 mm in the frontal region by height increasing abutments. These abutments are available in three different diameters in accordance with OP implant diameters.

Indirect impression taking techniques

This technique is based on using impression/transmission abutments to copy the position of implants and to align the implants within the plaster model.

Indirect impressions can be taken via two techniques: by means of open or closed tray impression methods.

Closed tray impression technique:

- Before taking the impression, the healing screw (or gingival former) must be removed temporarily, the impression coping is put in instead and fixed with a screw. Pay attention to precisely position the impression coping into the implant. The impression coping is in position when the surface of the screw used for fixation is in line with the flattened surface of the abutment.
- After the plaster has hardened, it is removed from the mouth and off the impression copings, then the impression copings are removed from the implants.
- Implants are once again sealed with healing abutments.
- Impression copings are put back into the plaster along with laboratory implants.
- The whole impression is then checked again after the plaster hardens. Please check if the area, which the impression was taken from (prepared teeth, alveolar ridge, etc.), is properly represented on the plaster and whether the imprints of the abutments properly represent the negative of the abutments and implants. This guarantees that abutments can be put back into the impression correctly.

Open tray impression method:

- A situation impression is taken from the implants along with the gingival formers inside them. A dental technician prepares a special tray for the specimen. Individual trays made of hard materials are, on the one hand, able to house the impression copings to be fixed into the implants. The occlusion surface of these trays should be punctured in accordance with the screws fixing the impression abutments.
- Fixing screws (or gingival formers) removed from the implants are replaced with direct impression copings (3034-840, 3455-840) and then fixed again with screws.
- The holed tray is tried in the mouth and then corrected if necessary. This specific tray must be positioned on the impression abutment so that the fixing screws protrude from the bore holes of the tray by at least 1-2 mm.
- The tray is then filled with plaster and placed in the mouth. In case the tray is positioned correctly, fixing screws protrude from the occlusion surface of the tray. Make sure the position of the tray is iDenti®cal to that during the try of tray.
- After the plaster hardens, fixing screws should be removed through the bore holes of the tray (after removing the tray one can see whether retention impression head parts are fixed within the impression).
- Laboratory implants are then inserted into the impression copings in the impression, then laboratory implants are tightly fixed (by pushing them back through the implant) to the part of impression abutment protruding from the impression.
- In order to proceed, a wax bite is also necessary (with the fixing screw fixed into the implant),
- Taking the impression of the antagonist denture,
- Facial arch registration,
- Taking a sectional plaster impression (avoid the plaster expansion) and positioning it inside the articulator,
- Inside the articulator, the properly chosen abutment is fixed into the laboratory implants according to the design previously discussed with the Dentist, and then the prosthesis is made. Then the prosthetic assembly can be completed.

11. Exchange

In case the original package is damaged, Denti System Ltd. cannot exchange any implants.

12. Packing units

In case there are no other specifications involved, implants are packed one by one.

Failure to take any of the instructions detailed above excludes any and all liability of the company.

13. Documentations and guarantee

Denti System Ltd recommends its customers to preserve the entire documentation of single cases. The inner package of products contains the reference number and lot number. Inner packing also contains a label with the reference number, LOT (individual registry) number and a bar code of the product which is recommended to be documented along with patient medical data, so that implants can be iDentified when necessary. The guarantee of any product is only valid when LOT numbers and bar codes are both available.

For technical details or further information please refer to your local representative.

14. Notation

	Date of Expiry (year, month)
Ø	Size: Diameter (mm)
LOT	Registry number – individual product iDenti®fication
CE 1011	CE markings
	Date of manufacture (year, month)
2	Do not use more than once
REF	Product code
STERILE R	This product was sterilized with gamma rays
NON STERILE	Not sterile
	Attention, see instruction for use
Rx only	Caution: Federal law (USA) restricts this product to sale by or on the order of a Denti®st or phisician

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