

## Warnings

These instructions for use must be read **before** using DENTIX MILLENNIUM prosthetic and auxiliary components. DENTIX MILLENNIUM® prosthetic and auxiliary components must only be used in accordance with the indication under the generally accepted rules for dental and surgical treatment and as specified by workplace safety and accident prevention regulations. DENTIX MILLENNIUM prosthetic and auxiliary components are intended for medical or dental use in combination with the DENTIX MILLENNIUM implant system only. If the indication or the nature of use is not clear, do not use them until all points have been clarified.

The following descriptions are not sufficient to ensure that dentists and surgeons who are not experienced with implant-prosthetic treatment can use the components correctly. We therefore recommend instruction in use by an experienced user. The user must be familiar with dental surgery and prosthetics, including diagnostics and preoperative planning and/or laboratory procedures. Dentix Millennium SRL is not liable for damage resulting from use outside the intended use of the product.

When using prosthetic and auxiliary components, general complications related to prosthetic restoration could arise, such as:

- Aspiration or swallowing of components used in the mouth of the patient
- Fracture of the screw in the abutment as a result of excessive torque
- Rotation of abutments if the specified torque is not reached

## Legend

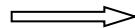
All Dentix Millennium Implant System components codes are capital letters of the names in English, i.e.:

- SSAC-3810 stands for "Slim straight abutment conical connection" 3,8 mm diameter and 10 mm length
- RSMAH-4510 stands for "Regular straight medium abutment internal hex" 4.5 mm diameter and 10 mm length

## How to open the prosthetic's bag

In order to open the Dentix superstructure bag, please follow the instruction:

Please cut here:



## Dentix Millennium Implant System has four (4) platforms:

Slim or Regular Abutment System platforms, Conical Connection or Internal Hex platforms, for both Soft Bone (SB) and Hard Bone (HB) implants.

Consequently, there are four types of Healing Caps, Abutments, Transfer Components, etc.



**Contraindications** None known

**Indications for Use**

- All Abutments: for temporary and final restorations.
- All platforms Implant Analog: simulation of implant position on master cast
- All Healing Caps: use for transgingival healing, forming the gingiva around the implant.
- All Transfer Components: transfer of implant position to the laboratory by impression taking
- All Screw Retained Superstructures: for screw retained superstructures

**Reactions** None known

**Storage.**

The DENTIX MILLENNIUM prosthetic and auxiliary components are supplied non-sterile and are intended for single use only. Do not use the components after the expiration date or if the blister/bag is damaged. Store them at room temperature in the original packaging under conditions normal for dental practices. Do not expose to direct sunlight. For type, platform, size and, if applicable, angulation, see product label.

**IMPORTANT:** Prior to clinical use, all components and instruments delivered non-sterile must be cleaned, disinfected and sterilized according to a validated method (autoclave, etc). Instruments that can be disassembled must be disassembled for cleaning and may be assembled again for sterilization only in a dry condition. Products that are not heat-resistant must not be sterilized. They must be disinfected in a cold disinfectant solution (e.g., CIDEX OPA, ID 213, Metricide OPA, Rapicide OPA, Sporox II) in accordance with the disinfectant manufacturer's instructions.

Item	Procedure	Re-use	Material	Torque
Healing cap	Sterilization	no	Ti CP4	<10Ncm
Abutments	Sterilization	no	Ti CP4	<20Ncm
Transfers	Sterilization	no	Ti CP4	<10Ncm
Screws	Sterilization	no	Ti CP4	<10Ncm

**Manual pre-cleaning**

Coarse soiling must be removed immediately after use (soft brush until visibly clean).

Ultrasonic cleaning (optional for very heavy soiling) The action times and concentrations specified by the manufacturer of the cleaning agent must be observed.

**Mechanical processing**

Manual pre-cleaning is necessary to ensure efficient mechanical cleaning.

For mechanical cleaning have to be used suitable washer disinfectors, cleaning and neutralization agents. The instructions from the manufacturer of the washer disinfectant must be followed. Cleaning and neutralization agents are to be dosed and used in accordance with their manufacturer's instructions. A cleaning program with thermal disinfection (disinfection values of not less than  $A_0=3000$ ) is recommended.

Either demineralized water or water which satisfies this level of purity is recommended for cleaning.

Dentix Millennium proper cleaning protocol:

- Pre-rinsing with cold water 4 min
- Cleaning 10 min from 45-55°C
- Neutralization 6 min
- Intermediate rinsing with cold water 3 min
- Thermal disinfection 5 min at 90°C ( $A_0=.3000$ )
- Drying 30 min at 105°C

Sterilization is to be performed corresponding to the following scheme:



1. Preparation for sterilization: Place components in a sterilization pouch which is legally marketed (for the US market: FDA-cleared) for use with the recommended sterilization parameters. Every sterilization package must have a sterilization indicator and sterilization date.

2. Sterilization:

Method	Cycle	Temperature	Cycle Time	Dry Time
Steam	Pre-vacuum (air removal)	134°C (273F)	7 min	20 min
Steam	Normal machine cycle	122°C (252F)	30 min	20 min

Minimum exposure times, the operating times are longer and may vary depending on the device.

3. Storage: Store the all components in original packing dry and particle-free at room temperature.

### Compatibility of DENTIX MILLENNIUM CC and IH implants, Slim and Regular !

"CC" stands for the conical connection platform (Slim or Regular). "IH" stands for the internal hex platform (Slim or Regular). The correct use of the platforms guarantees the fit, rotation lock and stability. DENTIX MILLENNIUM "CC" implants (i.e. SBC, HBC) must only be used with components that have **last letter C** in their codes (i.e. RSSAC-4508).. DENTIX MILLENNIUM "IH" implants (i.e. SBH, HBH) must only be used with components that have **last letter H** in their codes (i.e. RSSAH-4508). The use of incompatible components may cause fitting problems, reduction of fatigue strength, or damage to the implant.

Do never cross use Slim and Regular components: Slim abutments must be only used on Slim implants. Regular abutments must be only used on Regular implants.

The size of anti-rotational hex for each DENTIX MILLENNIUM® platform is presented in bellow table:

	<b>Slim platform</b>	<b>Regular Platform</b>
<b>Conical Connection platform</b>	Anti-rotational 2,1 mm hex	Anti-rotational 2,5 mm hex
<b>Internal Hex platform</b>	Anti-rotational 2,1 mm hex	Anti-rotational 2,4 mm hex

### ATTENTION: Compatibility with implants and implant analogs

DENTIX MILLENNIUM® Slim analog *conical connection* must be used with slim transfer *conical connection* and *conical connection* slim implants only.

DENTIX MILLENNIUM® Slim analog *internal hex* must be used with slim transfer *internal hex* and *internal hex* slim implants only.

DENTIX MILLENNIUM® Regular analog *conical connection* must be used with regular transfer *conical connection* and conical connection implants only.

DENTIX MILLENNIUM® Regular analog *internal hex* must be used with regular transfer *conical connection* and slim implants conical connection only.

**CAUTION:** The geometry of the platforms must not be altered in any matter!

**CAUTION:** The system has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment.

### Precautions

The following precautions are to be met prior to or during treatment:

- Always wear protective clothing for your own safety.
- Prior to each procedure it must be ensured that all necessary components, instruments and materials are available in the required quantities and are fully operational.
- Position the patient to minimize the danger of components aspiration.
- All components that are used intraorally must be secured with a DIGA to prevent aspiration or swallowing.
- No product intended for single use may be reused. Reusing, generally leads to the risk of infection and complications due to a loss of fit accuracy and the component's precision. This may lead even to implant loss.
- Provide adequate suction during grinding.

- Always apply specified torques.
- If, due to unfavorable anatomical conditions, instruments do not fit or cannot be used for other reasons, the course of treatment planned with them must not be continued and alternatives must be taken.

### **Application**

See the Dentix Millennium all other materials for more detailed instructions.

Insertion of Gingiva Former

Screw in gingiva former in the internal thread of the implant hand tight with the 1.25 mm hex screwdriver, not exceeding 10 Ncm torque. Healing Caps remain in place for approx. 14 days after the uncover procedure; in transgingival healing, over the healing phase.

**NOTE:** The same Healing Caps are used for straight and angled abutments. Where the gingiva is stiff, gradually stretch it to the desired diameter. Switch to larger diameters after 5-7 days.

**NOTE:** Suitable Healing Caps corresponding to the abutments provided subsequently should be used. If smaller Healing Caps than the abutments subsequently provided are used, then an incongruity will develop between the Healing Caps and the

abutment in the region of the sulcus. This may lead to index positioning problems and or soft tissue pinching.

### **Impression Taking**

#### **Open tray technique/PickUp technique**

Remove gingiva formers, spray tapered connection with air/water spray and dry them. Select the appropriate transfer coping, position in one of six possible index positions, check correct seating, and fix manually with transfer screw, not exceeding 5-10 Ncm torque. The inner hexagon of the screw is only for loosening the screw. If applicable, ensure access to screw with screw extension. Do the impression taking with open tray. After hardening, loosen transfer screw and remove the impression with the abutment.

#### **Transfer of the Implant Position**

**Closed tray technique/Reposition technique CAUTION:** Reposition technique is contraindicated where the implants have visible axial divergences. Remove gingiva formers, spray tapered connection with air/water spray and dry them. Position the closed tray transfer abutment in one of six possible index positions, check correct seating, and screw in manually. Block the hex of the transfer screw with wax. The impression is made with soft silicone, hydrocolloid, or polyethylene compounds. After hardening remove the impression, remove wax blocking, and remove transfer abutment from the mouth. Mount reposition transfer abutment on an DENTIX MILLENNIUM® implant analog and then reposition the abutment in the impression. Make sure that impression material is not pinched.

**NOTE** If the index is not to be used prosthetically, transfer components can also be used without the index.

### **Inserting the Regular Abutment**

Remove gingiva formers, spray tapered connection with air/water spray and dry them. Position abutment the correct index position and then tighten to a torque of 15 Ncm. The prosthetic key with the 1.25 mm hexagonal is used for retention.

### **Inserting the Superstructure**

Test the fit of the superstructure on the abutment. Then clean and disinfect the superstructure. Screw-retain laterally or cement in the superstructure.

**Screw retention:** Screw in crown to a torque of **10** Ncm with the retaining screw supplied by the laboratory.

**Cementing in:** Completely remove excess cement from edge of the crown. Provisional or phosphate cement may be used.

**NOTE:** Ceramic crowns or crowns with a ceramic shoulder must be cemented to titanium abutments. Then check static and dynamic occlusion.

### **Customizing the Abutments**

- The wall must not be ground to less than 0.5 mm thick
- The abutment must not be ground to less than 5 mm length.



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- Grinding must be carried out outside the mouth. Otherwise, in the case of intraoral grinding, cover the pharynx and ensure adequate suction during grinding.
- The abutment must **not** be ground when using prefabricated caps.

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The present Instruction of Use is revised in July 2018.