ATTENTION

The use **of Riellens implants** can only be performed by specialized dentists with experience in Implant Dentistry Techniques, Anatomy and Anesthetic Techniques. The product **is single-use,** sterilized by gamma rays, re-sterilization is prohibited, failure to comply with this recommendation can seriously harm the patient's health. Possible risks include transmission of infectious diseases and loss of the implant.

We recommend the use **of Riellens Prosthetic Components** with adaptation to the platform of the selected implant system and, depending on the protocol, the use **of compatible Surgical Instruments**. If the surgical protocol is not followed at implant placement, implant loss and/or partial bone loss may occur.

Respect the instructions for use recommended by the manufacturer, otherwise **Riellen's Industry and Commerce** is not responsible for the final result of the application.

1 - INTENDED USE

Riellens implants are intended to restore masticatory function by anchoring to the jawbone or maxilla.

2 - INSTRUCTIONS FOR USE

The **Riellens Implant System** is indicated for surgical procedures on the maxillary or mandibular bones that provide support for prosthetic components intended to restore masticatory function.

The Riellens implants of the **Remis, Reaction, Reactive, Retech, Revel A, Revel B, Reneo** and **Remark** lines are applied in intraoral surgeries, and are indicated for the support of fixed or removable prostheses, whether multiple or single. They can be installed **in bone density types I, II and III,** even in regions reconstructed with bone grafts, as long as there is quantity and quality of bone in the area to be implanted. The Remark line of implants is designed to be applied in conventional or immediate loading protocols when there is acceptable primary stability (maximum 45N.cm) and adequate occlusal loading.

The **Remis, Reaction, Reactive, Retech, Revel A, Revel B, Reneo and Remark** implant lines They are designed to be applied in conventional or immediate loading protocols when there is acceptable primary stability (maximum 45N.cm) and adequate occlusal loading.

3- SPECIFICATIONS AND TECHNICAL CHARACTERISTICS

The **Riellens Implants Recovered, Reaction, Reactive**, **Retech**, **Revel A**, **Revel B, Reneo** and **Remark** They are screw-shaped composite implants made of pure titanium (Grade 4) according to ASTM F67-13 and ISO 5832-2 (Implants for surgery - Metallic materials - Unalloyed titanium).

PRODUCT DESCRIPTION	IMPLANT CODE & DESCRIPTION	IMAGE
Riellens Remark implants have cylindrical geometry and are superficially treated with acid etching **(SLA).** With External Hexagon **(HE) Prosthetic Interface and** internal tightening torque for installation. **Remark implants** are available in the following systems: **NP:** with **1.8 mm** internal thread and **Ø 3.3 mm platform** for prosthetic components. **RP:** with **2 mm** internal thread and **Ø 4.1 mm** platform for prosthetic components. **WP:** with **2.5 mm** internal thread and **Ø 5 mm** platform **for prosthetic components.** **Remark Implant -** Compatible with the prosthetic components of the **HE B Riellens system**.	**RMK 3.3x8 - Riellens Remark RMK NP 3.3 x 8** **RMK 3.3x10 - Riellens Remark RMK NP 3.3 x 10** **RMK 3.3x11,5 - Riellens Remark RMK NP 3.3 x 11,5** **RMK 3.3x13 - Riellens Remark RMK NP 3.3 x 13** **RMK 3.3x16 - Riellens Remark RMK NP 3.3 x 16** **RMK 3.3x18 - Riellens Remark RMK NP 3.3 x 18** **RMK 3.75x8 - Riellens Remark RMK RP 3.75 x 8** **RMK 3.75x10 - Riellens Remark RMK RP 3.75 x 10** **RMK 3.75x11,5 - Riellens Remark RMK RP 3.75 x 11,5** **RMK 3.75x13 - Riellens Remark RMK RP 3.75 x 13** **RMK 3.75x16 - Riellens Remark RMK RP 3.75 x 16** **RMK 3.75x18 - Riellens Remark RMK RP 3.75 x 18** **RMK 4.3x6 - Riellens Remark RMK RP 4.3 x 6** **RMK 4.3x8 - Riellens Remark RMK RP 4.3 x 8** **RMK 4.3x10 - Riellens Remark RMK RP 4.3 x 10** **RMK 4.3x11,5 - Riellens Remark RMK RP 4.3 x 11,5** **RMK 4.3x13 - Riellens Remark RMK RP 4.3 x 13** **RMK 4.3x16 - Riellens Remark RMK RP 4.3 x 16** **RMK 4.3x18 - Riellens Remark RMK RP 4.3 x 18** **RMK 4.3x20 - Riellens Remark RMK RP 4.3 x 20** **RMK 4.3x22 - Riellens Remark RMK RP 4.3 x 22** **RMK 4.3x24 - Riellens Remark RMK RP 4.3 x 24**	

PRODUCT DESCRIPTION	IMPLANT CODE & DESCRIPTION	IMAGE
For descriptions of these items, see the previous page.	**RMK 5x6 - Riellens Remark RMK WP 5 x 6** **RMK 5x8 - Riellens Remark RMK WP 5 x 8** **RMK 5x10 - Riellens Remark RMK WP 5 x 10** **RMK 5x11,5 - Riellens Remark RMK WP 5 x 11,5** **RMK 5x13 - Riellens Remark RMK WP 5 x 13** **RMK 5x16 - Riellens Remark RMK WP 5 x 16** **RMK 5x18 - Riellens Remark RMK WP 5 x 18**	See the illustrative image of the product on the previous page.
The **Riellens Remis implants** They have a cylindrical geometry and are superficially treated with acid etching **(SLA).** With Internal Hexagon **(HI)** Prosthetic Interface and Internal Tightening Torque for installation. The implants of the **Remis** line are available in the system **(RP)** with 1.8 mm internal thread and **Ø 3.75 mm** platform for prosthetic components. **Remis Implant -** Compatible with components of the **MS Riellens prosthetic system.**	**RMS3.75x8 - Riellens Remis RP 3.75 x 8** **RMS3.75x10 - Riellens Remis RP 3.75 x 10** **RMS3.75x11.5 - Riellens Remis RP 3.75 x 11.5** **RMS3.75x13 - Riellens Remis RP 3.75 x 13** **RMS3.75x16 - Riellens Remis RP 3.75 x 16** **RMS3.75x18 - Riellens Remis RP 3.75 x 18** **RMS4.3x8 - Riellens Remis RP 4.3 x 8** **RMS4.3x10 - Riellens Remis RP 4.3 x 10** **RMS4.3x11.5 - Riellens Remis RP 4.3 x 11.5** **RMS4.3x13 - Riellens Remis RP 4.3 x 13** **RMS4.3x16 - Riellens Remis RP 4.3 x 16** **RMS4.3x18 - Riellens Remis RP 4.3 x 18** **RMS5.0x8 - Riellens Remis RP 5.0 x 8** **RMS5.0x10 - Riellens Remis RP 5.0 x 10** **RMS5.0x11.5 - Riellens Remis RP 5.0 x 11.5** **RMS5.0x13 - Riellens Remis RP 5.0 x 13** **RMS5.0x16 - Riellens Remis RP 5.0 x 16** **RMS5.0x18 - Riellens Remis RP 5.0 x 18**	
The **Riellens Reaction Implants and** the **Riellens Reactive Implants** They have a cylindrical geometry and are superficially treated with acid etching **(SLA).** With Morse Taper **(CM)** prosthetic interface and internal torque for installation. **Reaction** and **Reactive** implant lines are available in the following systems: **3.0:** with **1.4 mm** internal thread and **Ø 3 mm** platform for prosthetic components. **NP:** with **1.8 mm** internal thread and **Ø 3.5 mm** platform for prosthetic components. **RP:** with **2 mm** internal thread and **Ø 3.9 mm** platform for prosthetic components. **Reaction Implant -** Compatible with components of the **NA Riellens prosthetic system**.	**NCR 3.0x6 - Riellens Reaction RCN 3.0 x 6** **RCN 3.0x8 - Riellens Reaction RCN 3.0 x 8** **RCN 3.0x10 - Riellens Reaction RCN 3.0 x 10** **RCN 3.0x11.5 - Riellens Reaction RCN 3.0 x 11.5** **RCN 3.0x13 - Riellens Reaction RCN 3.0 x 13** **RCN 3.0x16 - Riellens Reaction RCN 3.0 x 16** **RCN 3.0x18 - Riellens Reaction RCN 3.0 x 18** **RCN 3.5x8 - Riellens Reaction RCN NP 3.5 x 8** **RCN 3.5x10 - Riellens Reaction RCN NP 3.5 x 10** **RCN 3.5x11,5 - Riellens Reaction RCN NP 3.5 x 11,5** **RCN 3.5x13 - Riellens Reaction RCN NP 3.5 x 13** **RCN 3.5x16 - Riellens Reaction RCN NP 3.5 x 16** **RCN 3.5x18 - Riellens Reaction RCN NP 3.5 x 18** **RCN 4.3x8 - Riellens Reaction RCN RP 4.3 x 8** **RCN 4.3x10 - Riellens Reaction RCN RP 4.3 x 10** **RCN 4.3x11,5 - Riellens Reaction RCN RP 4.3 x 11,5** **RCN 4.3x13 - Riellens Reaction RCN RP 4.3 x 13** **RCN 4.3x16 - Riellens Reaction RCN RP 4.3 x 16** **RCN 4.3x18 - Riellens Reaction RCN RP 4.3 x 18** **RCN 4.3x20 - Riellens Reaction RCN RP 4.3 x 20** **RCN 4.3x22 - Riellens Reaction RCN RP 4.3 x 22** **RCN 4.3x24 - Riellens Reaction RCN RP 4.3 x 24** **RCN 5.0x8 - Riellens Reaction RCN RP 5.0 x 8** **RCN 5.0x10 - Riellens Reaction RCN RP 5.0 x 10** **RCN 5.0x11,5 - Riellens Reaction RCN RP 5.0 x 11,5** **RCN 5.0x13 - Riellens Reaction RCN RP 5.0 x 13** **RCN 5.0x16 - Riellens Reaction RCN RP 5.0 x 16** **RCN 5.0x18 - Riellens Reaction RCN RP 5.0 x 18**	

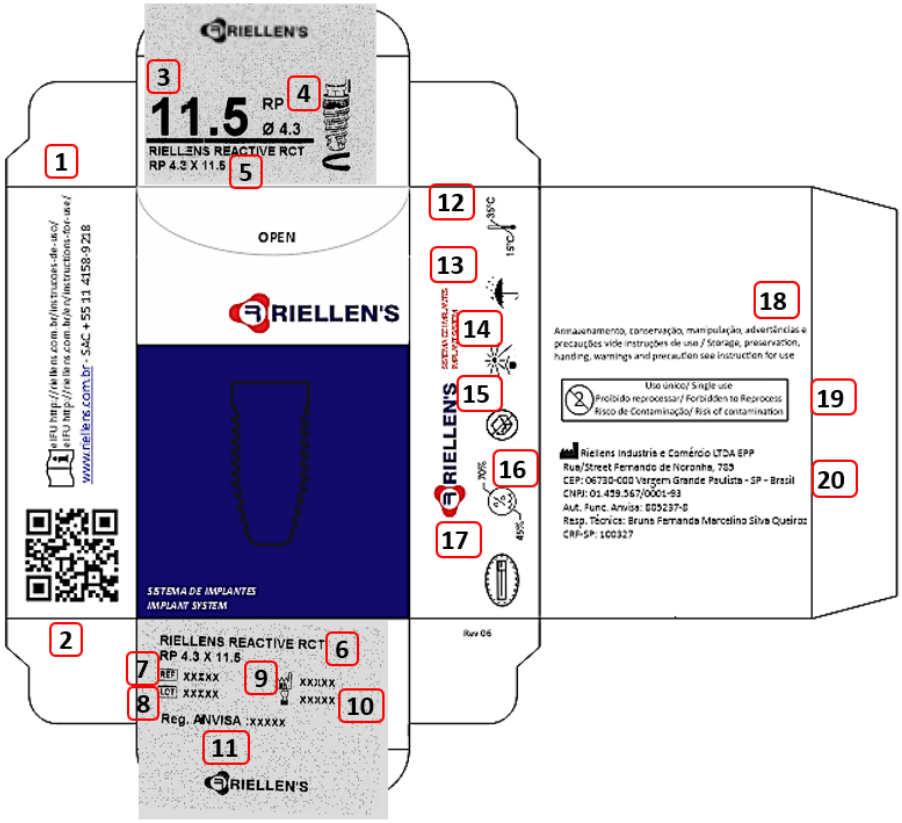
PRODUCT DESCRIPTION	IMPLANT CODE & DESCRIPTION	IMAGE
For descriptions of these items, see the previous page. **Reactive Implant -** Compatible with components of the **NA Riellens prosthetic system**.	**RCT 3.0x8 - Riellens Reactive RCT 3.0 x 8** **RCT 3.0x10 - Riellens Reactive RCT 3.0 x 10** **RCT 3.0x11,5 - Riellens Reactive RCT 3.0 x 11,5** **RCT 3.0x13 - Riellens Reactive RCT 3.0 x 13** **RCT 3.0x16 - Riellens Reactive RCT 3.0 x 16** **RCT 3.0x18 - Riellens Reactive RCT 3.0 x 18** **RCT 3.5x8 - Riellens Reactive RCT NP 3.5 x 8** **RCT 3.5x10 - Riellens Reactive RCT NP 3.5 x 10** **RCT 3.5x11,5 - Riellens Reactive RCT NP 3.5 x 11,5** **RCT 3.5x13 - Riellens Reactive RCT NP 3.5 x 13** **RCT 3.5x16 - Riellens Reactive RCT NP 3.5 x 16** **RCT 3.5x18 - Riellens Reactive RCT NP 3.5 x 18** **RCT 4.3x8 - Riellens Reactive RCT RP 4.3 x 8** **RCT 4.3x10 - Riellens Reactive RCT RP 4.3 x 10** **RCT 4.3x11,5 - Riellens Reactive RCT RP 4.3 x 11,5** **RCT 4.3x13 - Riellens Reactive RCT RP 4.3 x 13** **RCT 4.3x16 - Riellens Reactive RCT RP 4.3 x 16** **RCT 4.3x18 - Riellens Reactive RCT RP 4.3 x 18** **RCT 4.3x20 - Riellens Reactive RCT RP 4.3 x 20** **RCT 4.3x22 - Riellens Reactive RCT RP 4.3 x 22** **RCT 4.3x24 - Riellens Reactive RCT RP 4.3 x 24** **RCT 5.0x8 - Riellens Reactive RCT RP 5.0 x 8** **RCT 5.0x10 - Riellens Reactive RCT RP 5.0 x 10** **RCT 5.0x11,5 - Riellens Reactive RCT RP 5.0 x 11,5** **RCT 5.0x13 - Riellens Reactive RCT RP 5.0 x 13** **RCT 5.0x16 - Riellens Reactive RCT RP 5.0 x 16** **RCT 5.0x18 - Riellens Reactive RCT RP 5.0 x 18**	
Riellens Retech implants they have a cylindrical geometry and are superficially treated with acid etching **(SLA).** With Morse Taper **(CM) prosthetic interface and** internal torque for installation. The implants of the **Retech** line are available in the following systems: **NP:** with **1.4 mm** internal thread and **Ø 3 mm** platform for prosthetic components. **RP:** with **1.6 mm** internal thread and **Ø 3.5 mm** platform for prosthetic components. **WP:** with **2 mm** internal thread and **Ø 4.5 mm** platform for prosthetic components. **Retech Implant** - Compatible with components of the **AT Riellens prosthetic system.**	**BTI 3.0x8 - Riellens Retech RTC NP 3.0 x 8** **RTC 3.0x11.5 - Riellens Retech RTC NP 3.0 x 11.5** **RTC 3.0x13 - Riellens Retech RTC NP 3.0 x 13** **RTC 3.0x16 - Riellens Retech RTC NP 3.0 x 16** **RTC 3.5x8 - Riellens Retech RTC RP 3.5 x 8** **RTC 3.5x11.5 - Riellens Retech RTC RP 3.5 x 11.5** **RTC 3.5x13 - Riellens Retech RTC RP 3.5 x 13** **RTC 3.5x16 - Riellens Retech RTC RP 3.5 x 16** **RTC 3.5x18 - Riellens Retech RTC RP 3.5 x 18** **RTC 4.0x8 - Riellens Retech RTC RP 4.0 x 8** **RTC 4.0x11.5 - Riellens Retech RTC RP 4.0 x 11.5** **RTC 4.0x13 - Riellens Retech RTC RP 4.0 x 13** **RTC 4.0x16 - Riellens Retech RTC RP 4.0 x 16** **RTC 4.0x18 - Riellens Retech RTC RP 4.0 x 18** **RTC 4.5x8 - Riellens Retech RTC WP 4.5 x 8** **RTC 4.5x11,5 - Riellens Retech RTC WP 4.5 x 11,5** **RTC 4.5x13 - Riellens Retech RTC WP 4.5 x 13** **RTC 4.5x16 - Riellens Retech RTC WP 4.5 x 16** **RTC 4.5x18 - Riellens Retech RTC WP 4.5 x 18** **BTI 5.0x8 - Riellens Retech RTC WP 5.0 x 8** **RTC 5.0x11.5 - Riellens Retech RTC WP 5.0 x 11.5** **BTI 5.0x13 - Riellens Retech RTC WP 5.0 x 13** **BTI 5.0x16 - Riellens Retech RTC WP 5.0 x 16** **BTI 5.0x18 - Riellens Retech RTC WP 5.0 x 18**	

PRODUCT DESCRIPTION	IMPLANT CODE & DESCRIPTION	IMAGE
The **Riellens Revel A Implants** and the Riellens Revel B Implants they have a cylindrical geometry and are superficially treated with acid etching **(SLA).** With prosthetic interface, Morse Taper **(CM) and** internal tightening torque for installation. Revel implants are available in the following systems: **SC:** with **1.4mm** internal thread and **Ø 3mm** platform for prosthetic components. **NC:** with **1.6mm** internal thread and **Ø 3.3mm** platform for prosthetic components. **RC:** with **1.6mm** internal thread and platform models **Ø 4.1mm** and **Ø4.8mm** for prosthetic components. **Revel A** and **Revel B** Implants **-** These are compatible with the prosthetic components of the **BL Riellens system**.	**RBA3.3x8 - Riellens Revel A RBA NC 3.3 x 8** **RBA3.3x10 - Riellens Revel A RBA NC 3.3 x 10** **RBA3.3x11,5 - Riellens Revel A RBA NC 3.3 x 11,5** **RBA3.3x13 - Riellens Revel A RBA NC 3.3 x 13** **RBA3.3x16 - Riellens Revel A RBA NC 3.3 x 16** **RBA3.3x18 - Riellens Revel A RBA NC 3.3 x 18** **RBA4.1x8 - Riellens Revel A RBA RC 4.1 x 8** **RBA4.1x10 - Riellens Revel A RBA RC 4.1 x 10** **RBA4.1x11,5 - Riellens Revel A RBA RC 4.1 x 11,5** **RBA4.1x13 - Riellens Revel A RBA RC 4.1 x 13** **RBA4.1x16 - Riellens Revel A RBA RC 4.1 x 16** **RBA4.1x18 - Riellens Revel A RBA RC 4.1 x 18** **RBA4.8x8 - Riellens Revel A RBA RC 4.8 x 8** **RBA4.8x10 - Riellens Revel A RBA RC 4.8 x 10** **RBA4.8x11,5 - Riellens Revel A RBA RC 4.8 x 11,5** **RBA4.8x13 - Riellens Revel A RBA RC 4.8 x 13** **RBA4.8x16 - Riellens Revel A RBA RC 4.8 x 16** **RBA4.8x18 - Riellens Revel A RBA RC 4.8 x 18** **RBL3.0x10 - Riellens Revel B RBL SC 3.0 x 10** **RBL3.0x11,5 - Riellens Revel B RBL SC 3.0 x 11,5** **RBL3.0x13 - Riellens Revel B RBL SC 3.0 x 13** **RBL3.3x8 - Riellens Revel B RBL NC 3.3 x 8** **RBL3.3x10 - Riellens Revel B RBL NC 3.3 x 10** **RBL3.3x11,5 - Riellens Revel B RBL NC 3.3 x 11,5** **RBL3.3x13 - Riellens Revel B RBL NC 3.3 x 13** **RBL3.3x16 - Riellens Revel B RBL NC 3.3 x 16** **RBL3.3x18 - Riellens Revel B RBL NC 3.3 x 18** **RBL4.1x8 - Riellens Revel B RBL RC 4.1 x 8** **RBL4.1x10 - Riellens Revel B RBL RC 4.1 x 10** **RBL4.1x11,5 - Riellens Revel B RBL RC 4.1 x 11,5** **RBL4.1x13 - Riellens Revel B RBL RC 4.1 x 13** **RBL4.1x16 - Riellens Revel B RBL RC 4.1 x 16** **RBL4.1x 18 - Riellens Revel B RBL RC 4.1 x 18** **RBL4.8x8 - Riellens Revel B RBL RC 4.8 x 8** **RBL4.8x10 - Riellens Revel B RBL RC 4.8 x 10** **RBL4.8x11,5 - Riellens Revel B RBL RC 4.8 x 11,5** **RBL4.8x13 - Riellens Revel B RBL RC 4.8 x 13** **RBL4.8x16 - Riellens Revel B RBL RC 4.8 x 16** **RBL4.8x18 - Riellens Revel B RBL RC 4.8 x 18**	
The **Riellens Reneo Implants** they have a cylindrical geometry and are superficially treated with acid etching **(SLA).** With Morse Taper **(CM)** prosthetic interface and internal torque for installation. The **Reneo** implants They have an internal thread of **1.8** mm and a platform of **Ø 3.75 mm** and **Ø 4.3 mm** for prosthetic components. **Reneo Implant** - Compatible with components of the **CMN Riellens prosthetic system**.	**RCMN3.75x8 - Riellens Reneo 3.75 x 8** **RCMN3.75x10 - Riellens Reneo 3.75 x 10** **RCMN3.75x11,5 - Riellens Reneo 3.75 x 11,5** **RCMN3.75x13 - Riellens Reneo 3.75 x 13** **RCMN3.75x16 - Riellens Reneo 3.75 x 16** **RCMN3.75x18 - Riellens Reneo 3.75 x 18** **RCMN4.3x8 - Riellens Reneo 4.3 x 8** **RCMN4.3x10 - Riellens Reneo 4.3 x 10** **RCMN4.3x11.5 - Riellens Reneo 4.3 x 11.5** **RCMN4.3x13 - Riellens Reneo 4.3 x 13** **RCMN4.3x16 - Riellens Reneo 4.3 x 16** **RCMN4.3x18 - Riellens Reneo 4.3 x 18**	

4- FORMS OF PRESENTATION

The **Riellens implants** They are individually packaged in blister packs and boxes, which guarantees the integrity and sterility of the product until its professional use. Information such as description, batch, and expiration date is available on the product label.

BE CAREFUL WHEN OPENING THE PACKAGE, AVOIDING FALLS AND DIRECT CONTACT OF THE PRODUCT WITH CONTAMINATED PLACES.



Description Packing Views

Left Side View:

1	Referral to the website, Consultation on the Instruction for Use, Customer Service System.
2	QR Code that directs the customer to the product's Instruction for Use.

Top View:

3	Implant Height.
4	Diameter of the implant platform.
5	Standard Implant Description.

Bottom View:

6	Product Description.
7	Code.
8	Lot.
9	Date of Manufacture.
10	Expiration Date.
11	Anvisa Registration Number.

Right Side View:

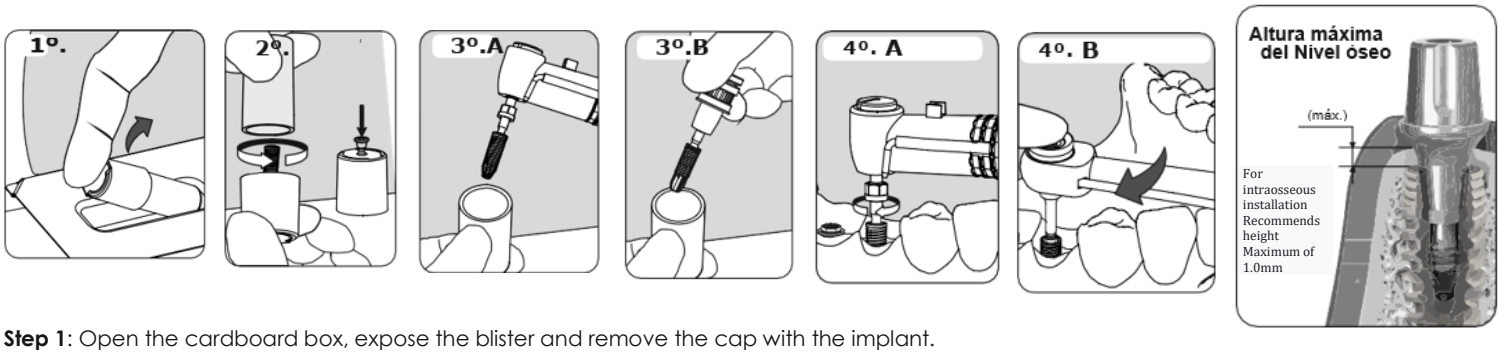
12	Minimum and maximum temperature limit.
13	Store in a dry environment.
14	Keep away from sunlight.
15	Do not use if open.
16	Minimum and maximum humidity limit.
17	Sterilized product.

Reverse View:

18	Minimum and maximum temperature limit.
19	Store in a dry environment.
20	Keep away from sunlight.

5 - MANIPULATION

Before applying the product, carefully read the entire contents of these instructions for use.



Step 1: Open the cardboard box, expose the blister and remove the cap with the implant.
Step 2: Keep the plug pointing down, twisting and pulling the tube slightly upwards. The implant protection screw is screwed into the top of the cap.
Step 3 A: For contra-angle motor and handpiece installation – Use the wrench to capture the implant from the cover bracket and make sure it fits the implant. Use a maximum torque of **30N.cm and** a maximum rpm of **30 rpm** on the engine. **Step 3 B**: For digital installation- Place the key on the hex adapter and capture the implant in the shell (make sure it is fully seated in the implant).
Step 4: Transport the implant into the bone cavity and tighten clockwise. Bone-level installation is recommended. Position one of the faces of the hexagon towards the buccal side to promote prosthetic orientation. Insertion instruments are marked to facilitate positioning.
Attention: The maximum recommended torque for the final installation of the implants is **45 N.cm.** Never exceed the recommended torque during implant placement. Over-tightening of the implant can damage the product and cause fracture or necrosis of the bone cavity.
If the implant becomes stuck during installation or if the **45 N.cm** Before finishing, rotate the implant counterclockwise. Use the contra-angle handpiece or torque wrench in reverse mode and remove the implant. Place the implant back into the cap holder, packing it properly until the bone workshop rework has been completed. Use the wider rear cutter, respecting the

Protocol indicated for higher bone density. Finalize implant placement using the maximum insertion torque of **45 N.cm.**
For immediate function, the implant must withstand a final tightening torque between **35 N.cm and 45 N.cm**.

6 - SURGICAL PROTOCOL

Step-by-step protocol for universal implant insertion of the following lines: **Remark, Remis, Reaction, Reactive, Retech, Revel** y **Reneo**.

Drilling Protocol

1. Rotate the flap and view the alveolar ridge.

2. To prepare the socket, start the drilling protocol with the drill bit

Drilling Protocol	Drill Bit Sequence									
	PD 2.0	FSD 2.50	NTD 2.80	STD 3.20	GTD 3.65	WTD 4.30	NTD ZS	NTD Z	STD ZS	STD Z
Remark 3.3	x	x	-	-	-	-	-	-	-	-
Remark 3.75	x	x	x	(x)	-	-	-	-	-	-
Remark 4.3	x	x	x	x	(x)	-	-	-	-	-
Remark 5	x	x	x	x	x	(x)	-	-	-	-
Remis 3.75	x	x	x	(x)	-	-	-	-	-	-
Remis 4.3	x	x	x	x	(x)	-	-	-	-	-
Remis 5.0	x	x	x	x	x	(x)	-	-	-	-
Reaction 3.0	x	x	-	-	-	-	-	-	-	-
Reaction 3.5	x	x	x	(x)	-	-	-	-	-	-
Reaction 4.3	x	x	x	x	(x)	-	-	-	-	-
Reaction 5.0	x	x	x	x	x	(x)	-	-	-	-
Reactive 3.0	x	x	-	-	-	-	-	-	-	-
Reactive 3.5	x	x	x	(x)	-	-	-	-	-	-
Reactive 4.3	x	x	x	x	(x)	-	-	-	-	-
Reactive 5.0	x	x	x	x	x	(x)	-	-	-	-

Drilling Protocol	Drill Bit Sequence									
	PD 2.0	FSD 2.50	NTD 2.80	STD 3.20	GTD 3.65	WTD 4.30	NTD ZS	NTD Z	STD ZS	STD Z
Retech 3.0	x	x	-	-	-	-	-	-	-	-
Retech 3.5	x	x	x	(x)	-	-	-	-	-	-
Retech 4.0	x	x	x	x	(x)	-	-	-	-	-
Retech 4.5	x	x	x	x	(x)	-	-	-	-	-
Retech 5.0	x	x	x	x	x	(x)	-	-	-	-
Revel A 3.3	x	x	x	(x)	-	-	-	-	-	-
Revel A 4.1	x	x	x	x	(x)	-	-	-	-	-
Revel A 4.8	x	x	x	x	x	(x)	-	-	-	-
Revel B 3.0	x	x	-	-	-	-	-	-	-	-
Revel B 3.3	x	x	x	(x)	-	-	-	-	-	-
Revel B 4.1	x	x	x	x	(x)	-	-	-	-	-
Revel B 4.8	x	x	x	x	x	(x)	-	-	-	-
Reneo 3.75	x	x	x	(x)	-	-	-	-	-	-
Reneo 4.3	x	x	x	x	(x)	-	-	-	-	-

2 mm diameter pilot, install a parallelism pin (PT) in place
Perform a control x-ray to assess the length and direction of the hole.

3. Use the step drill bit according to the drill sequence table indicated for the system to be used. To achieve successful implant stability and properly prepare the surgical site, the drilling protocol relies on bone quality to ensure primary stability when the immediate loading function is applied. Conventional protocols suggest that the surgical socket should be approximately 0.7 mm smaller than the diameter of the implant of choice. The milling process is geared to extend 1 mm beyond the length of the implant when seated, a high speed of no more than 2000 rpm is indicated for spiral, spiral/step drills under constant and abundant irrigation through a sterile saline solution (at room temperature).
Due to the small size of the implants and components, precautions must be taken so that they are not aspirated or ingested by the patient.

Surgical protocol

1.Detach as conservatively as possible (use a circular scalpel).
2.If necessary, use a torque wrench (FC) or manual implant guide (HSD) to install the implant.
3.If necessary, use a long implant guide if adjacent teeth do not allow the implant to be installed at the desired level.
4.Install a protective cover or healer with a hex wrench.
5.Suture

Attach the identification/traceability labels to the medical record, in the tax billing documentation and in the document to be delivered to the patient.

7 -CONTRAINDICATIONS

The use of **Riellens implants** is contraindicated in the following cases:
Vascular disorders, uncontrolled diabetes, anticoagulant therapy, metabolic disease, hypersensitivity to titanium, and habits for inadequate functional conditions. The use of implants before the end of the final growth phase is contraindicated. In cases of bruxism, insufficient bone height and/or width, insufficient spacing between arches, and cigarette and alcohol abuse also represent scenarios that are not indicated for its use.
Temporary contraindications are: chemotherapy and radiotherapy

8 - ADVERSE EFFECTS

If the technique used is not adequate and the patient is not submitted to the indicated tests, the final result of the application of the product may not be successful, generating risks and complications, in addition to subjecting the patient to infection, injury, bleeding and unnecessary resorption of the bone structure.
The surgical process can have effects on the area where it was applied, such as chronic pain, edema, hematoma, inflammatory reaction, slurred speech, temporary numbness, and, in very rare cases, permanent numbness. Perforation of the maxillary sinus can lead to infections due to implant migration.

9 -STERILIZATION

Riellens Implants are sterilized by gamma rays and in this way we guarantee the sterility of the product, except in cases where the package has been opened or tampered with, in which case the product must be discarded. **Riellen's Industry and Commerce** is not responsible for the re-sterilization performed by the professional.

10 PRICES / WARNINGS

High precision in the preparation of the bone cavity, verification of the quality and quantity of the bone, implant geometry and surgical preparation technique are indispensable. Always use compatible calibrated surgical instruments, always taking care to use the entire sequence of drills corresponding to the diameter and length of the implant. We recommend changing the initial cutters every 20 holes, always taking great care with the thermal trauma caused in the drilling by the lack of irrigation and the wear of the cutters in the cutting area, a fundamental factor for the success of the product application. The professional should sterilize all surgical instruments before use, prepare an environment with sterile surgical gowns and drapes, subdue the patient

for good oral asepsis and, at the time of handling and installation of the implant, avoid contact with any non-sterile object to minimize the risk of contamination. The professional should check the identification and integrity of the product's packaging, pay attention to the expiration date of the product and never use it if the expiration date has passed or if the packaging has been tampered with. **Riellens implants** are single-use, the reuse of the product involves risks for the patient: total loss of function and risk of infection. The professional must pay attention to the force exerted when applying the product, never exceeding the installation load recommended by the manufacturer **(45N.cm**) so as not to damage it. When fixing the prosthetic component under the cortical screw seat platform for a period longer than 60 minutes, we do not recommend that the professional use stainless steel material. The practitioner should attach to the patient's medical record the identification label found inside the product container. The professional should inform the patient of the proper form of hygiene, the need for periodic postoperative follow-up, that the patient avoids physical and mechanical efforts after surgery, and that the product is not subjected to undue stress, even after osseointegration.

11 - NOTICE / CARE

For perfect bone integration, the entire procedure must be performed under controlled surgical conditions. It is necessary for the professional to perform a pre-surgical preparation through radiographic examinations and panoramic and periapical tomography, elaborating a surgical execution plan to choose the appropriate implant with the patient's bone conditions and a prosthetic execution plan to choose the type of restoration to be performed depending on the implant platform used. The professional should submit the patient to a thorough visual inspection to diagnose the cases mentioned above in the contraindications. The use of implants before the end of the growth phase is discouraged. The product should be handled in a sterile environment with a sterile drape. Occlusal guards are recommended for all patients who have functional habits (bruxism, excessive compression of the teeth).

If the implant has more than 50% mobility or bone loss, the practitioner should evaluate the clinical condition and remove the implant if necessary.

If the practitioner opts for short implants, they should use longer periods to allow osseointegration and avoid the use of the immediate loading protocol. Riellens dental implants have not been evaluated for safety and compatibility in the context of MRI. No tests related to the possibility of heating, migration or imaging artifacts in the MRI (Magnetic Resonance Imaging) environment were performed.

12- STORAGE CONDITIONS

The **Riellens Implant** should be kept in its original packaging and stored in a dry place at room temperature up to 35°C.

13- PRODUCT DISPOSAL

In the event that the product needs to be disposed of, legal procedures must be followed for the disposal of the product, and the product must be cut, folded, or filed.

14- VALIDADE/LOTE

Date of manufacture, expiration date and batch, see packaging.

15- INSTRUCTIONS FOR USE NOTICE

These **Instructions for Use** are available in non-printed (electronic) format through the manufacturer's website www.riellens.com.br.

The **Instructions for Use** are indexed on the website through the respective PRODUCT NAME, informed on the label of the purchased product.

If it is of interest to the practitioner, the Instructions for Use can be provided in printed format at no additional cost. The request must be made to the manufacturer's Customer Service (SAC).

16–SYMBOLS

REF Number in the Catalogue number Catalog Number	Date of Date of manufacture Date of manufacture	Keep dry Keep dry Keep Dry	Sterilized by irradiation Sterilized by Irradiation Sterilized by irradiation
LOT Lot Code Batch code Lot Code	Valid until Use by Expiry date	Keep out of the sun Keep out of the sun Keep out of the sun	Do not re- Not resterilize Do not re-
Manufactured Manufacturer Maker	Do not use if packaging is damaged Do not use if package is damaged Do not use if the container is	Single-use product Single-use Product Single-use product	Limite superior de temperatura Upper limit of temperature Limite superior de temperatura

RIELLEN'S

RIELLEN´S INDUSTRIA E COMÉRCIO LTDA EPP.
Rua Fernando de Noronha 785 - Jardim Margarida Código postal: 06730-000 Vargem Grande Paulista/SP – Brasil CNPJ. 01. 459. 567/ 0001-93 AUTORIZ/MS: 8.05237.8
SAC / Consumer Attendance Service: 55 11 4158 - 9218 Correo electrónico: sac@riellens.com.br ***www.riellens.com.br***

Resp. Técnica / Technical Responsible / Resp. Tecnica:
Bruna Fernanda Marcelino Silva Queiroz
CRFSP n° / Professional ID.: *100327*
ANVISA Registration No. /ANVISA Registration n°.: *80523780009*