

## Implant Mount

The Implant Mount are intended to specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.



### PRODUCT DESCRIPTION

The Implant Mount and Adapters are manufactured in Grade V Titanium and are surgical instruments with the function of being an intermediary base between the implant and the several existing components for the fixation of the implant in the surgical alveolus. They have varying diameters and snap for keys and connections, according to chosen plan.

#### **Revolution Implant Mount (applicable to models: MI 2703/MI 2715)**

- Product sterilized with gamma ray;
- It has a 3,12mm external hexagonal connection;
- It has a 2,7mm internal hexagonal connection;
- Screwing torque: 10Ncm (ratchet wrench);
- Product with through bolt (with screw);
- Compatible with Revolution Implants.

#### **Revolution Implant Mount Micro Mini (applicable to models: MI 3403/MI 3415)**

- Product sterilized with gamma ray;
- It has ionization (magenta color);
- It has a 3,12mm external hexagonal connection and
- It has a 2,55mm internal hexagonal connection;
- Screwing torque on the implant: 10Ncm (ratchet wrench);
- Product with through bolt (with screw);
- Compatible with Revolution Micro Mini implants.

#### **Revolution Implant Mount (applicable to the MIG 2710 model)**

- Product sterilized with gamma ray;
- It has a 3,12mm external hexagonal connection;
- It has a 2,7mm internal hexagonal connection;
- Screwing torque on the implant: 10N.cm (ratchet wrench);
- Product with through bolt (with screw);
- Compatible with Revolution Implants.

#### **Adapter Implant Mount for Angled Mini Abutment (applicable to the model: MMAAH)**

- Product sterilized with gamma ray;
- It has a 3,12mm external hexagonal connection;
- It has a 2,7mm internal hexagonal connection;
- Screwing torque on the implant: 10N.cm (ratchet wrench);
- Product with through bolt (with screw);

- Used to facilitate assembly of Angled Mini Abutment for internal hexagon.

#### **Zygomatic Implant Mount (applicable to the model: MIZ 41)**

- Product sterilized with gamma ray;
- It has a connection 3.9mm external square;
- It has a 2,7mm internal hexagonal connection;
- Screwing torque on the implant: 30N.cm (ratchet wrench);
- Product with through bolt (with screw);

Compatible with Zygomatic implants.

### INDICATIONS OF USE

Used during the process of transporting and installing the implant in the surgical alveolus.

### PURPOSE AND OPERATION PRINCIPLE

The Implant Mount are used as intermediaries, and the torque given on them is necessary for fixing the implants that have this system. They work based on mechanical principles of force transmission, for the activation of secondary elements.

### HOW TO USE THE INSTRUMENT

The surgeon dentist must use Implant Mount according to aseptic surgical techniques that are appropriate to each case. Below, follows the description and handling according to the model of the assembler:

#### **Revolution Implant Mount (MI 2703/MI 2715)**

The Implant Mount Tryon is cylindrical with hexagon head, contains internal hexagon with corresponding locking the implant external hexagon. It has already through bolt to the torque applied between the assembler and the implant, leaving the assembly ready for installation of the implant.

**Handling:** After removal of the packaging assembly with the corresponding key, the torque is given in the upper end of the assembler, required for fixation of the implant. After placement of the implant in approximately two minutes, the implant Mount is removed by releasing the assembler internal screw using the 1.2. Digital Wrench

#### **Revolution Implant Mount Micro Mini (MI 3403/MI 3415)**

The Revolution Implant Mount Micro Mini is cylindrical with a hexagonal head and contains an internal hexagon with a socket corresponding to the external hexagon of the implant. It has a mounting screw with a pre-applied torque between the assembler and the implant, leaving the assembly ready for installation of the implant.

**Handling:** After removal of the packaging assembly with the corresponding key, the torque is given in the upper end of the assembler, required for fixation of the implant. After placement of the implant in approximately two minutes, the implant Mount is removed by releasing the assembler internal screw using the 1.2. Digital Wrench.

#### **Revolution Implant Mount (MIG 2710)**

The Revolution Implant Mount is cylindrical with hexagon head, contains internal hexagon with corresponding locking the implant external hexagon. It has already bolt through to the

torque applied between the assembler and the implant, leaving the assembly ready for installation of the implant.

**Handling:** After removal of the packaging assembly with the corresponding key, the torque is given in the upper end of the assembler, required for fixation of the implant. After placement of the implant in approximately two minutes, the implant Mount is removed by releasing the assembler internal screw using the 1.2. Digital Wrench

#### **Adapter Mount for Angled Mini Abutment (MMAAH)**

The Adapter Mount for Angled Mini Abutment has a cylindrical shape with a hexagon head, contains an internal hexagon socket with a corresponding external hexagon on the adapter. It has a mounting screw.

**Handling:** After removal of the package assembly with the corresponding keys, torque is given at the upper end of the fitter, which is required for attachment of the adapter. After attaching the adapter to the installed implant, within two minutes, the trimmer is removed by loosening the internal screw using the 1.2. Digital Wrench

#### **Zygomatic Implant Mount (MIZ 41)**

The Zygomatic Implant Mount is cylindrical in shape with a square head, it contains an inclined adaptation face with an internal socket hexagon corresponding to the external hexagon of the implant. It has a through bolt with a torque applied between the assembler and the implant, leaving the assembly ready for installation of the implant.

**Handling:** After removing of package assembly with the corresponding wrenches, torque is applied at the upper end of the assembler, which is required for implant fixation. After placing the implant, approximately two minutes later, the implant fitting is removed by loosening the internal screw using the 1.2. Digital Wrench.

### **ATTENTION**

The Implant Mount are intended for specialized procedures, which must be performed by qualified professionals in implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

### **PRECAUTIONS**

Use of excessive force or disengagement between parts can damage the product. Before each procedure, make sure the perfect fit between the parts, and the conditions of the instruments, always respecting their useful life. It is necessary to replace the instruments in case of damage, erased markings, compromised sharpening, deformations and wear.

### **RECOMMENDATIONS**

The product should be used only by qualified dental professionals who already have all the scientific information necessary for the correct use of the product. Always perform cleaning and sterilization as recommended before the surgical procedure. It is necessary to check the functionality, fitting capacity or accuracy of these products after each procedure and if there is natural wear and tear generated by use, they must be replaced and discarded.

## CONTRAINDICATION

Use for purposes other than the installation or removal of implants and prosthetic components.

## SIDE EFFECTS

Failure may occur due to factors intrinsic to the surgical procedure, such as the local and health conditions of the implanted individual and the skill and knowledge of the professional who practices it.

## WARNING

Do not use the instrument if you notice cracks, wear or spots of oxidation/corrosion. This may cause problems in the operation of the instruments. All items may exhibit natural wear and tear and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the end result of the work.

## TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, thus promoting greater safety for professionals skilled for the procedure. Through this lot number it is possible to know all product history from the manufacturing process to the time of distribution.

## STORAGE

The Implant Mount should be stored in a cool dry place at a temperature of 15°C to 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

## HANDLING

Once sterilized, the instruments should be handled in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants. Scratches or notches of the instruments should be avoided as such factors can increase the possibility of corrosion of the products.

## DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

## TRANSPORTATION

The Implant Mount must be transported adequately to avoid falling and stored at a maximum temperature of 35°C, protected from heat and moisture. Transport must be carried out in its original packaging.

## COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing not allowed. Refer to the cleaning and sterilization conditions contained in this instruction for use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use, without any cost, please request by e-mail to [sin@sinimplantsystem.com](mailto:sin@sinimplantsystem.com) or call to 0800 770 8290 will receive until 7 days calendar.

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## FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) unitarily packed in a package that offers double protection.

## EXPIRATION DATE

Information regarding the expiration date can be found on the product labeling. After installation in the patient, the product must be monitored by a professional.

	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUCTO ESTERILIZADO POR RADIACIÓN GAMA
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO LEJOS DE LA LUZ SOLAR
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	LÍMITE DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE DE TEMPERATURA
<b>Rx only</b>	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO.	CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.	PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO.
	FABRICANTE	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA DUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	SISTEMA DE DOBLE BARRERA ESTÉRIL
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTRIUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN

LOT	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE



**MANUFACTURER****S.I.N. Implant System LTDA.**

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**PRODUCT**

Implant Mount