Unitite

From the synergy between exclusive macrogeometry and the most advanced surface nanoactivation, Unitite® emerged. A line of implants that has revolutionized the global market due to its originality, innovation and extremely high performance.

PRODUCT DESCRIPTION

Unitite implants are produced from commercially pure titanium (Grade 4). Cylindrical macrogeometry (Unitite Compact) and hybrid (Unitite Slim and Prime), with cervical microthreads and Morse taper prosthetic coupling. The implant surface is composed of an ultra-thin layer of hydroxyapatite and has moderate roughness obtained by a double acid etching process. Comes with the implant cover as an accessory. The Unitite line has three models: Prime, Slim and Compact.

Implant line	Implant diameter (mm)	Implant length (mm)
Prime	3.5; 3.8; 4.3; 5.0	8.5; 10; 11.5; 13; 15
Slim	2.9	10; 11.5; 13
Compact	4.0; 5.0; 6.0	5; 6; 7

Implant Chemical Composition according F67:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.015
Iron	≤ 0.50
Oxygen	≤ 0.40
Titanium	Balance
Hydroxyapatite Coating	< 1.0

The coating is Hydroxyapatite (HAnano), composed of $Ca_5(PO_4)_3OH$, also known as Calcium Phosphate. It has a Ca/P ratio of 1.67.

The cover screw is according ASTM F136:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05

Carbon	≤ 0.08
Hydrogen	≤ 0.012
Iron	≤ 0.25
Oxygen	≤ 0.13
Aluminum	5.5 - 6.5
Vanadium	3.5 - 4.5
Titanium	Balance

INDICATIONS FOR USE

The Unitite is indicated for adults and elderly people with good general health, surgical procedures in maxilla or mandible bones, generating a support platform for the installation of prosthetic components that will receive the artificial teeth, restoring the masticatory function of the edentulous patient. They can be used in conventional processes (1 and 2 surgical stages) and immediate loading (activation within 48 hours) when there is acceptable primary stability (above 45N.cm) and adequate occlusal loading. They can be used in single or multiple prostheses. The Unitite implant line was developed to suit bone availability in the surgical socket and has 3 (three) models, namely:

Prime: Suitable for all regions of the mandible and maxilla.
Slim: Indicated for rehabilitation in narrow areas and limited interdental spaces, as well as regions of upper lateral incisors and lower incisors.
Compact: Indicated for situations of reduced bone height availability in the maxilla and mandible.

PURPOSE AND OPERATING PRINCIPLE

The purpose is to replace missing teeth, condemned teeth or conventional prostheses, with the aim of recovering aesthetics and chewing function, curbing bone resorption and reducing the overload on remaining teeth. They are based on the mechanical principles of load transmission system assembly.

HOW TO USE UNITITE MORSE TAPER IMPLANTS

Unitite implants are indicated for surgical installation in all bone densities, in maxilla or mandible, as long as the maximum insertion torque (60N.cm for Prime and Compact implants and 45N.cm for Slim implants) is respected. If the installation reaches torque that exceeds the limit, it is recommended to use a specific thread tap for each model before the end of the installation. The Thread Taps can be used in the surgical socket with ratchet or counter angle depending on the fit of the purchased product. For Prime and S implants, 1.5mm intraosseous installation must be performed, while for Compact implants, installation must be performed at bone level.

- Remove the blister from the outer cartridge;
- Reserve the traceability labels that accompany the product;
- In a sterile surgical field and after breaking the sterility seal of the blister, hold the primary packaging (tube) with the non-dominant hand and open the lid;
- The implant will be exposed inside the tube to capture the key;
- For installation with motor, use the contra angle wrench;
- Capture the Unitite implant by keeping the key still and slightly rotating the internal support, seeking the perfect fit between the connection and the implant. Press the key on the implant for better fixation;

- Transport the implant to the bone bed;
- In the surgical motor, use a maximum torque of 35 N.cm and rotation between 20-40 RPM;
- Preferably, complete the implant installation with the surgical torque wrench or a ratchet wrench;
- The maximum recommended installation torque is 60N.cm for Prime and Compact implants, and 45N.cm for Slim implants;
- The choice between the installation of the implant cover, healer or prosthetic component is at the discretion of the professional;
- Select the intermediaries between the implant and the prosthesis, observing their indications and limitations, according to the applicable literature.

HOW TO USE UNITITE MORSE TAPER IMPLANTS WITH GUIDED SURGERY KIT

- Remove the blister from the outer cartridge;
- Reserve the traceability labels that accompany the product;
- In a sterile surgical field and after breaking the sterility seal of the blister, hold the primary packaging (tube) with the non-dominant hand and open the lid;
- The implant will be exposed inside the tube to capture the key;
- For installation with a motor, use the contra-angle wrench observing the diameter of the chosen implant;
- Capture the implant by keeping the key still and slightly rotating the internal support, seeking the perfect fit between the connection and the implant. Press the key on the implant for better fixation;
- Fit one of the implantation guides according to the selected implant diameter inside the washer of the prototyped surgical guide;
- Transport the implant to the implantation guide already fitted;
- In the surgical motor, use a maximum torque of 35 N.cm and rotation between 20-40 RPM;
- Preferably, complete the implant installation with a surgical torque wrench or a ratchet wrench adjusting the length of the wrench (short or long) according to the adjacent dental crown and available mouth opening.

*Remembering that the connection of this switch must be the same as the pre-used contra angle switch;

- The maximum recommended installation torque is 60N.cm for Prime and Compact implants, and 45N.cm for Slim implants;
- The choice between the installation of the implant cover, healer or prosthetic component is at the discretion of the professional;
- Select the intermediaries between the implant and the prosthesis, observing their indications and limitations, according to the applicable literature;
- The patient should be informed of all possible surgical complications, contraindications, warnings, precautions, and adverse reactions. All documentation that accompanies the product must also be made available to the customer;
- The form of use is inherent to the training of the professional who will use the material. It can only be used and/or applied by dentists who specialize in surgery/implant dentistry.

⚠ ATTENTION

Unitite implants are intended for specialized procedures, which must be performed by professionals qualified in Implantology. The use of the product must be carried out in a surgical environment and in conditions appropriate for the health and safety of the patient.

PRECAUTIONS

Observe the conditions of the intraoral tissues, the bone quality and quantity of the implant recipient bed, by means of radiographic and/or tomographic examinations. Failure to perform the pre-surgical evaluation may result in the impossibility of verifying pre-existing diseases. Consider the patient's general health condition, he must be submitted to a thorough clinical and radiological analysis before surgery, evaluating his physical and psychological state. Patients who have local or systemic factors that may interfere with the healing processes of bone or soft tissues, or in the process of integration, should receive special attention. Perform material handling only in sterile field. All material used in the procedure must be sterile. Sterilization is only guaranteed if the secondary packaging (blister) is not damaged. Do not use the product if the packaging is tampered with. Open the package only at the time of surgery and use the product immediately. Implants not used after opening the package should be discarded. Products with expired expiration dates should not be used. In one-stage surgical rehabilitations (immediate loading), primary stability should reach at least 45N.cm. The maximum angle allowed for S.I.N. implants is up to 30° degrees. Insertion torque higher than the recommended maximum may damage the product, losing its primary function. Observe the conditions of use of surgical instruments. Milling cutters and others instruments with low cutting power can generate overheating during their use, hindering the osseointegration process. Replace instruments in case of damage, erased markings, compromised sharpening, deformations and wear. The surgical motor used in the procedure must be adjusted according to the specification of the implant to be used (torque and RPrime). Check the condition of your motor and contra angle before surgery. If necessary, perform preventive/corrective maintenance with the manufacturer. Unregulated equipment can directly interfere with the product's performance. During the surgical and prosthetic procedure, use only components and instruments specified by S.I.N., they have specific dimensions and tolerances for each implant system, ensuring the longevity of the product. Components from other brands or adapted to implant models can reduce the useful life of the system, causing irreversible damage. The professional must ensure that the patient does not aspirate the product. It is the responsibility of the practitioner to use the S.I.N. products in accordance with the instructions for use, as well as to determine if it is suitable for the individual situation of each patient. The patient should be informed of all possible surgical complications, contraindications, warnings, precautions, and adverse reactions. All documentation that accompanies the product must also be made available to the customer. The form of use is inherent to the training of the professional who will use the material. It can only be used and/or applied by dentists specialized in surgery/implantology.

RECOMMENDATIONS

S.I.N recommends prior planning of the installation surgery for Unitite implants. Inadequate planning and/or lack of occlusal adjustment may compromise the performance of the implant/prosthesis combination resulting in system failure, such as implant loss or fracture, loosening or fracture of the prosthetic screws. S.I.N does not recommend the installation of the implant in patients with inadequate oral hygiene, uncooperative and unmotivated patients, with drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, bruxism, other parafunctional habits, tobacco abuse. Diseases that can compromise the immune system, diseases that require the use of steroids regularly, endocrine disorders, drug allergy, diabetes mellitus, anticoagulation/ bleeding diathesis medications, should be evaluated with the primary medical for a combination of the treatment plan.

CONTRAINDICATIONS

S.I.N. does not recommend the installation of implants in patients with: acute inflammatory or infectious processes of living tissues, inadequate bone volume or quality (as assessed by the clinician), root remains in the surgical site, serious medical issues, including bone metabolism disorders, blood coagulation disorders, poor healing capacity, incomplete maxillary growth, allergy or hypersensitivity to titanium, patients with a history of head and neck irradiation, bone condition anatomically unfavorable for implant stability, acute periodontitis, treatable pathological maxillary diseases and alterations of the oral mucosa. S.I.N. does not recommend the installation of dental implants in children, and pregnant or lactating women.

SIDE EFFECTS

As it is a surgical procedure, the installation of implants can cause side effects such as irritation at the implantation site, slight bleeding, slight inflammation, localized pain, tenderness, edema, and ecchymosis. In case of failure in the planning or execution of the surgical procedure, adverse effects such as chronic pain, paresthesia, paralysis, infection, hemorrhage, oro-antral or oro-nasal fistula, affected adjacent teeth, bone necrosis, fractures of the implant or prosthesis, bone loss around the implant or loss of the implant (non-osseointegration) may occur.

WARNINGS

Implants should receive components with compatible geometry and installation indication. S.I.N. suggests an application table of implants and components according to the region to be applied, but it is up to the dentist, trained in the specialty, the choice and arbitration with regards the diameter and length of the implant installation in relation to the region and anatomy. S.I.N. Implants are designed to withstand the maximum torque of 80N.cm. Torques above this value can cause irreversible damage, as well as surgical complications. This product is for single use and cannot be reused nor reesterelized. The reuse or re sterilization of this product may cause loss of the implant (non Osseointegration), contagious infectious disease, deformation and wear of the product. The torque for fixation of the intermediates on the implant is 20N.cm. The torque for fixation of components above intermediates is 10 N.cm. Do not install the protective screw (implant cap) with ratchet driver or torque driver in order to not damage the implant; the tightening must be performed manually through digital driver. During prosthesis maintenance, the recommended torque value for each component must be respected. Higher values can damage/fracture the implant, reducing its useful life.

TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, thus promoting greater safety for the professional qualified for the procedure. Through this batch number, it is possible to know the entire history of the product from the manufacturing process to the moment of distribution. The implants are available with 3 (three) copies of traceability labels.

STORAGE

The S.I.N. medical device 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

S.I.N implants are sent to professionals properly packaged, sealed and sterilized. Therefore, its packaging (blister) must be opened in a sterile surgical field, and the implant must be handled only with the specific instruments available in the Unitite Surgical Kit and Unitite Guided Surgery Kit.

DISPOSAL OF MATERIALS

The disposal of materials must be carried out in accordance with hospital standards and current local legislation.

TRANSPORTATION

Unitite implants must be transported appropriately to prevent falling and stored at a maximum temperature of 35ºC, away from heat and humidity. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATION

Magnetic Resonance Imaging (MRI): Non-clinical tests and simulations in an MRI environment performed in vitro have demonstrated that S.I.N. devices are MRI conditional.

CAUTION: The patient image can only be obtained by delimiting at least 30cm from the implant or by ensuring that the implant is located outside the radiofrequency coil.

A patient with this device can be safely scanned in an MRI system under the following conditions:

Device Name	S.I.N. Implant System
Static Magnetic Field Strength (B0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5.00 gauss/cm).
RF Excitation	Circular Polarization (CP)
RF Transmission Coil Type	Head coil and body coil allowed. T/R end coils allowed.
Mode of Operation	Normal operating mode in the allowed image zone.
Specific Absorption (SAR) Maximum Rate Body Type Coil	2.0 W/kg (15 minutes scanning, normal operation mode)
Specific Absorption (SAR) Rate Maximum Coil Type Head	15 minutes
Scanning Time.	15 minutes
Temperature Rise	Maximum temperature rise of 0.45°C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field and 3 T with head-type or body-type coils.

Artifacts	When scanned using a gradient-echo sequence and a 3 T MR system, the image artifact can extend to approximately 12 mm with a body-type coil, and up to approximately 32 mm with a head-type coil.

Exclusive Product for Dental use. Reprocessing not allowed. 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 or a copy of the safety and clinical performance summary (SSCP), at no cost, please request it by email to sin@sinimplantsystem.com or call 0800 770 8290 and you will receive it within 7 calendar days.

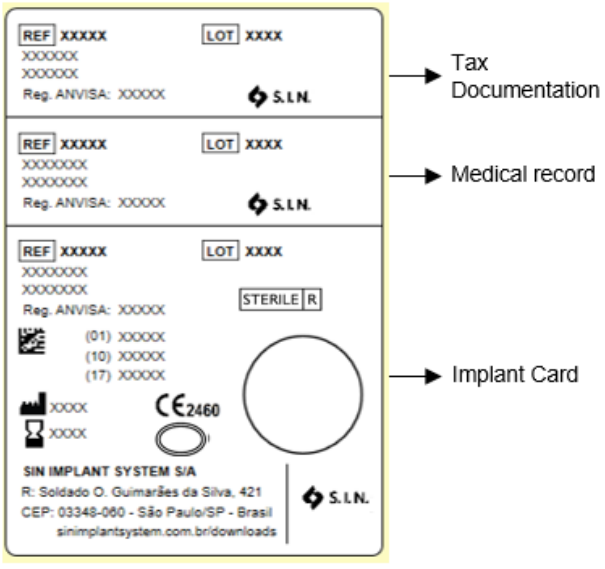
TRACEABILITY LABELS

The implants of the Unitite line are available by S.I.N. com 3 (three) labels containing the product information. Labels should be used as follows:

Tax label: The dental surgeon must reserve a label to stick on the implant's tax documentation.

Label of the medical record: The dental surgeon must stick a label on the patient's record in order to maintain the traceability of the products used

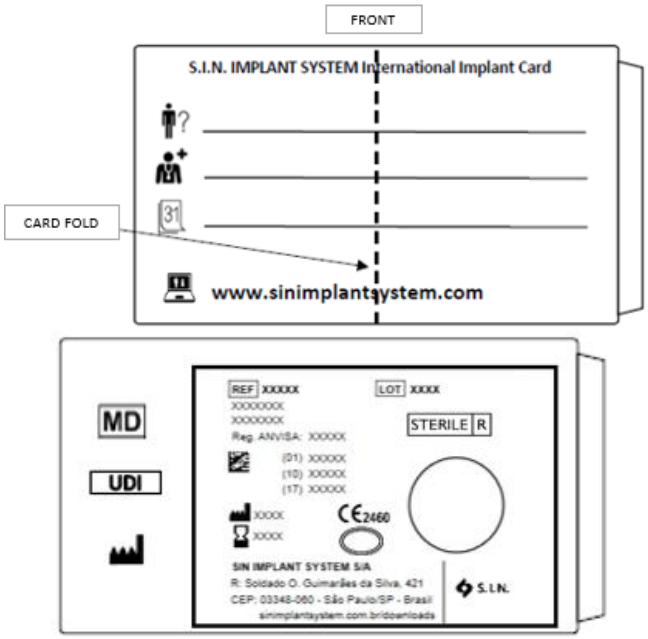
Implant card label: The dentist should stick a label on the implant card in order to inform about which products were used.



*Merially illustrative image

IMPLANT CARD

The Unitite line implants are provided by S.I.N. com an implant card. This card must be given to the patient, who must be instructed on the safekeeping and conservation of this information.



*Merially illustrative image

STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) packaged individually in packaging that offers triple protection: tertiary packaging (cardboard), secondary blister-type packaging (pet film and surgical grade paper) and primary packaging (transparent tube).

EXPIRATION LIFE

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

INDICATION OF IMPLANT APPLICATION BY REGION

				Cone Morse	
Arch	Position		Tooth	Implant Diameter	Component Diameter
MAXILAR	11	21	CENTRAL INCISOR	Ø3.5 / Ø3.8	Ø3.3 / Ø3.5
	12	22	LATERAL INCISOR	Ø2.9 / Ø3.5 / Ø3.8	Ø3.3 / Ø3.5
	13	23	CANINE	Ø3.8	Ø3.5
	14	24	1st PREMOLAR	Ø3.8 / Ø4.0 / Ø4.3	Ø3.5 / Ø4.5
	15	25	2nd PREMOLAR	Ø3.8 / Ø4.0 / Ø4.3	Ø3.5 / Ø4.5
	16	26	1st MOLAR	Ø4.0 / Ø4.3 / Ø5.0 / Ø6.0	Ø4.5
	17	27	2nd MOLAR	Ø4.0 / Ø4.3 / Ø5.0 / Ø6.0	Ø4.5
	18	28	3rd MOLAR	Ø4.0 / Ø4.3 / Ø5.0 / Ø6.0	Ø4.5
MANDIBLE	41	31	CENTRAL INCISOR	Ø2.9 / Ø3.5	Ø3.3 / Ø3.5
	42	32	LATERAL INCISOR	Ø2.9 / Ø3.5	Ø3.3 / Ø3.5
	43	33	CANINE	Ø3.8	Ø3.5
	44	34	1st PREMOLAR	Ø3.8 / Ø4.0 / Ø4.3	Ø3.5 / Ø4.5
	45	35	2nd PREMOLAR	Ø3.8 / Ø4.0 / Ø4.3	Ø3.5 / Ø4.5
	46	36	1st MOLAR	Ø4.0 / Ø4.3 / Ø5.0 / Ø6.0	Ø4.5
	47	37	2nd MOLAR	Ø4.0 / Ø4.3 / Ø5.0 / Ø6.0	Ø4.5
	48	38	3rd MOLAR	Ø4.0 / Ø4.3 / Ø5.0 / Ø6.0	Ø4.5

DRILLING SEQUENCE OF UNITITE PRIME IMPLANTS

	Instrument codes	1.200 RPM		800 RPM					20 RPM			
		FRLD 2005	FHCD 2015	FUM 2915	FUM 3515	FUM 3815	FUM 4315	FUM 5015	CMRU 35	CMRU 38	CMRU 43	CMRU 50
 Unitite® Prime	Ø 3.5	•	•	•	•				•			
	Ø 3.8	•	•	•	•	•				•		
	Ø 4.3	•	•	•	•	•	•				•	
	Ø 5.0	•	•	•	•	•	•	•				•

• In type I and II bones it is necessary to use the Male drill to ensure the healing process.

☐ Male drill: Tightening should not exceed 60N.cm.

DRILLING SEQUENCE OF UNITITE SLIM IMPLANT

	Instrument codes	1.200 RPM		800 RPM	20 RPM
		FRLD 2005	FHCD 2015	FUM 2915	CMRU 29
 Unitite® Slim	Ø 2.9	•	•	•	•

• In type I and II bones it is necessary to use the Male drill to ensure the healing process

☐ Male drill: Tightening should not exceed 60N.cm.

DRILLING SEQUENCE OF UNITITE COMPACT IMPLANT

	Instrument codes	1.200 RPM	800 RPM								20 RPM		
		FRLD 2005	FHCD 2015	FUM 2915	FUM 3515	FPUC 3338	FHCD 3215	FPUC 3848	FHCD 4215	FPUC 4858	FHCD 5215	CMRUC 40	CMRUC 50	CMRUC 60
 Unitite® Compact	Ø 4.0	•	•	•	•	•	•					•		
	Ø 5.0	•	•	•	•	•	•	•	•				•	
	Ø 6.0	•	•	•	•	•	•	•	•	•	•			•

• In type I and II bones it is necessary to use the Male drill to ensure the healing process

☐ Male drill: Tightening should not exceed 60N.cm.

DRILLING SEQUENCE WITH GUIDED SURGERY KIT UNITITE IMPLANT

	20 RPM			400 RPM			1.500 RPM	800 RPM				25 RPM				
Instrument codes	EM 29	EM 35U	EM 45	FPG 29	FPG 35U	FPG 43	FHCDG 20	FUMG 29	FUMG 35	FUMG 43	FHCDG 40	CMRUG 29	CMRUG 35	CMRUG 35E	CMRUG 40	CMRUG 43
Ø 2.9 *Slim*	●			●*			●	●				●				
Ø 3.5 *Prime*		●			●*		●	●	●				●	●**		
Ø 4.0 *Compact*			●			●*	●	●	●		●				●	
Ø 4.3 *Prime*			●			●*	●	●	●	●						●

●** The use of the male drill will only be in surgical planning with narrow washers.

● The use of a male drill is optional in type I and II bone because it is a compressive implant, but the maximum torque must always be respected

●* The use of the flat drill is optional, this instrument is used for planning the alveolar ridge, creating a stable face for drilling with the other drills of the system.

☐ Male drill: Tightening should not exceed 60N.cm.

	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
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE DE TEMPERATURA
Rx only	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	DESTRIBUTOR	DISTRIBUIDOR

	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE
	MR CONDICIONAL	MR CONDITIONAL	MR CONDICIONAL
	DATA DA IMPLANTAÇÃO	DATE OF IMPLANTATION	FECHA DE APLICACIÓN
	NOME E ENDEREÇO DA INSTITUIÇÃO	NAME AND ADDRESS OF THE IMPLANTING HEALTHCARE INSTITUTION	NOMBRE Y DIRECCIÓN DE LA INSTITUCIÓN
	NOME DO PACIENTE OU IDENTIFICAÇÃO DO PACIENTE	PATIENT NAME OR PATIENT ID	NOMBRE DEL PACIENTE O IDENTIFICACIÓN DEL PACIENTE
	SITE DE INFORMAÇÕES PARA OS PACIENTES	INFORMATION WEBSITE FOR PATIENTS	PÁGINA WEB DE INFORMACIÓN AL PACIENTE

MANUFACTURER
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ANVISA REGISTRATION
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