

### **1. Description and Presentation:**

Systhex dental implants are machined in grade 4 titanium (ASTM F67) in biocompatible and osseointegratable material. Porous surface. For prosthetic fixture, products include optional internal hex, external hex and cone morse in different models and sizes. See table 01.

Dental implants and cover screws are sterile for single use only. They are sold together or separately.

They are conditioned in triple protection packaging.

Primary packaging:

The implant and cover screw are inserted in a tube with a lid made of crystal OS and EVA.

The lid has a special adhesive to protect and isolate the cover screw.

Secondary packaging: Products are placed in a blister of virgin APET, which is sealed with surgical grade paper.

Tertiary packaging: Cartridge.

### **2. Indications:**

Indicated for oral, functional and aesthetic rehabilitation as a structure in the replacement of teeth with prostheses.

Systhex dental implants can be used in the maxilla or mandible. For successful surgery, the bone site must be correctly prepared according to bone type of the patient.

### **3. Contraindications:**



Evaluate the patient prior to surgery to determine factors that may pose a risk to the patient during the procedure and after surgery.



Systhex dental implants are not indicated for patients with uncontrolled diabetes, malign neoplasia, bruxism, locations with bone or infectious pathologies and other contraindications described in dental literature. They are also contraindicated for individuals with unsatisfactory oral hygiene and addiction to tobacco, alcohol or chemicals and drugs.

The implants should not be inserted when alveolar bone height and width is insufficient to accommodate and encircle the implants.

### **4. Precautions and Warnings:**



This product can only be implanted by qualified dental surgeons. The use of implants without knowledge of the correct techniques and/or procedures or under inadequate conditions may cause harm to the patient and result in implant failure and substantial loss of surrounding bone. Specific radiological testing is required for placement of dental implants to evaluate bone quantity, quality and height. These tests include panoramic x-ray (DPR), computerized tomography and periapical radiography. The dental surgeon will evaluate which tests should be requested to the patient after clinical evaluation. Dental implants can interfere in magnetic resonance (image distortion). The dental surgeon must notify the patient of this risk.

#### **WARNING:**



- Do not use the product if the packaging is damaged. Sterilization is only guaranteed if packaging is complete and undamaged.

- Surgical instruments must be correctly sterilized to prevent infection.

- Implants are single-use only and must not be re-sterilized.



Excessive bone loss and implant breakage may occur when the implant load exceeds its functional capacity. To force an implant into the osteotomy beyond the depth determined by the drill may result in alteration to the hex interface of the driver inside the implant, driver alteration, fusion of the assembler/driver interface of the implant or alterations to the osteotomy walls, which may prevent initial effective fixation of the implant.

**5. Traceability Items:**

Inside the tertiary packaging of the implants (cartridge) there are three stickers containing the following information: name and size of product, product lot or batch number and expiration date of the product. Sticker size: 50 mm x 15 mm.

The traceability procedure is responsibility of the dental surgeon, who should adhere one of these stickers to the “Patient File”, another on the patient x-ray and the third must be handed to the patient. The aim of these measures is to allow consultation of full product information when necessary.

**6. Instructions for Use:****6.1 Preparation of Receiver Site:**

To prevent surgical trauma, drills should present perfect cutting conditions and constant irrigation should be maintained during placement of the implants. Maximum torque of 65 N.cm must be maintained in implants to prevent prosthetic adaptation problems (excessive torque causes distortions at the hex of the implant) and osseointegration problems. **Preparo do**

**6.2 Drill Sequence:**

Drill sequence is selected according to planning and implant model, namely cylindrical or conical. Drill insertion depth during perforation should be equal to length of the implant that will be placed. For this reason, burs have laser markings that show implant depths. For cylindrical implants, the marking is from 5 mm to 15 mm and for conical implants the marking is from 8.5 mm to 15 mm.

Drill models: Helical, Conical, Countersink and Pilot.

**6.3 Dental Implant Placement:**

The choice of length and width of the implant depends on bone availability and expected occlusal load on the bone.



- 1) Complete the receiver site preparation procedure (osteotomy).
- 2) Open the secondary packaging (blister) by breaking the seal (surgical grade paper).
- 3) Hold the cartridge with the non-dominant hand and remove the lid.
- 4) Use the dominant hand to remove the lid and fix the corresponding connection to the implant model (see table 01).
- 5) Insert the implant in the bone site according to surgical planning for each implant model.
- 6) Insert the cover screw using a 0.9 driver or healing abutment of choice.

*NOTE: For a single surgical procedure or immediate loading, the selected intermediate pillar/abutment must be installed. This choice is a dentist's discretion.*

The success of all dental implants is quite susceptible to use of the correct surgical technique. The choice of single or multiple implants of the appropriate size and configuration for the existing anatomy is essential for implant success.

**7. Side-effects:**

The implant placement procedure may cause slight discomfort and localized oedema. Loss of implant (osseointegration fault) and loss of prosthesis may occur during treatment. Some of the causes are insufficient reminiscent bone quality and quantity, infection, defective oral hygiene and systematic diseases or disorders. Fracturing of the implant or restoration components may occur in time.

**8. Postoperative Care and Maintenance:**

Advise the patient on the importance and requirement of professional postoperative follow-up and provide guidelines on oral care, nutrition and drug prescriptions. During the first 10 days after surgery, hygiene may be complemented with oral antiseptics.

Oral hygiene of the patient and treatment adhesion requires special attention.

**9. Permanence:**

Systhex Dental Implants have an undetermined permanence period if correctly installed and osseointegrated.

**10. Storage Conditions:**

Store in a clean, dry place away from sunlight and umidity.

**11. Expiration Date:**

Systhex dental implants are valid for 5 years from date of sterilization, insofar as packaging is not damaged. This information is included on product labelling.

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**12. Sterilization Method**

Gama Radiation.

**13. Disposal:**

All disposable material used during surgical dental implant placement should be discarded in accordance with local waste disposal standards.

**14. Presentations****Systhex Implants are sold in two presentations:**

01 titanium implant and 01 cover screw or 01 titanium implant without cover screw. See table 01.

Model, specifications and sizes are included in product labelling.

**Manufactured by:**

SYSTHEX SISTEMAS DE IMPLANTES ÓSSEO INTEGRADO LTDA

Rua Procópio Ferreira Martins, 586 – Cajuru – CEP 82.940-190 – Curitiba – PR - Brazil

CNPJ 05.644.129/0001-56 – State Inscription 9034995408 – Aut. Func. K225Y402LYXY.

Chief Technician: Flávia Ventura Nicolau Melhem – CRO-PR 15749.

Customer Assistance: 0800 600 6905 – [www.systhex.com.br](http://www.systhex.com.br) – Made in Brazil.

ANVISA Registration #80290080001

EC

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**European Representative:**

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**Corporate Offices: Obelis S.A**

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Flávia Ventura Nicolau Melhem

Legal responsible

Technical Responsible CRO-PR 15749

This Instructions for Use is applicable to the Systhex Dental Implant line:

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
Implante Classic-CI	3.75	4.1	7	817.001 8.170.018
			8.5	817.002 8.170.028
			10	817.003 8.170.038
			11.5	817.004 8.170.048
			13	817.005 8.170.058
			15	817.006 8.170.068
	4.0	4.1	7	817.007 8.170.078
			8.5	817.008 8.170.088
			10	817.009 8.170.098
			11.5	817.010 8.170.108
			13	817.011 8.170.118
			15	817.012 8.170.128
4.5	5.0	7	817.013 8.117.013	
		8.5	817.014 8.117.014	
		10	817.015 8.117.015	
		11.5	817.016 8.117.016	
		13	817.017 8.117.017	
		15	817.018 8.117.018	
Implante Classic-CI	5.0	5.0	7	817.019 8.117.019
			8.5	817.020 8.117.020
			10	817.021 8.117.021
			11.5	817.022 8.117.022
	5.0	5.0	13	817.023 8.117.023

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
			15	817.024 8.117.024
Implante Fit-Hex	3.3	3.3	8.5	821.001 8.121.001
			10	821.002 8.121.002
			11.5	821.003 8.121.003
			13	821.004 8.121.004
			15	821.005 8.121.005
Implante Fit-Hex CI	3.3	3.3	8.5	821.010 8.121.010
			10	821.011 8.121.011
			11.5	821.012 8.121.012
			13	821.013 8.121.013
			15	821.014 8.121.014
Implante Classic-IN CR	3.5	3.6	8.5	818.701 8.118.701
			10	818.702 8.118.702
			11.5	818.703 8.118.703
			13	818.704 8.118.704
			15	818.705 8.118.705
	3.75	4.3	7	818.706 8.118.706
			8.5	818.707 8.118.707
			10	818.708 8.118.708
			11.5	818.709 8.118.709
			13	818.710 8.118.710
	4.0	4.3	15	818.711 8.118.711
			7	818.712 8.118.712

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
Implante Classic-IN CR			8.5	818.713 8.118.713
			10	818.714 8.118.714
			11.5	818.715 8.118.715
			13	818.716 8.118.716
			15	818.717 8.118.717
	5.0	5.0	7	818.718 8.118.718
			8.5	818.719 8.118.719
			10	818.720 8.118.720
			11.5	818.721 8.118.721
			13	818.722 8.118.722
			15	818.723 8.118.723
	Implante Estetic-CI	3.5	4.1	8.5
10				819.012 8.119.012
11.5				819.013 8.119.013
13				819.014 8.119.014
15				819.015 8.119.015
4.0		4.1	8.5	819.001 8.119.001
			10	819.002 8.119.002
			11.5	819.003 8.119.003
			13	819.004 8.119.004
			15	819.005 8.119.005
Implante Estetic-CI	5.0	5.0	8.5	819.006 8.119.006

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
			10	819.007 8.119.007
			11.5	819.008 8.119.008
			13	819.009 8.119.009
			15	819.010 8.119.010
Implante Estetic-IN CR	3.5	3.6	8.5	820.095 8.120.095
			10	820.096 8.120.096
			11.5	820.097 8.120.097
			13	820.098 8.120.098
			15	820.099 8.120.099
	4.0	4.3	8.5	820.101 8.120.101
			10	820.102 8.120.102
			11.5	820.103 8.120.103
			13	820.104 8.120.104
			15	820.105 8.120.105
	5.0	5.0	8.5	820.106 8.120.106
			10	820.107 8.120.107
			11.5	820.108 8.120.108
			13	820.109 8.120.109
			15	820.110 8.120.110
	Implante Unik Implante Unik	3.75	4.3	8.5
10				816.002
11.5				816.003
13				816.004
15				816.005
4.0		4.3	8.5	816.006
			10	816.007
			11.5	816.008
			13	816.009
			15	816.010

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
	5.0	5.0	8.5	816.011
			10	816.012
			11.5	816.013
			13	816.014
			15	816.015
Implante Attract	3.5	-	8.5	821.901 8.121.901
			10	821.902 8.121.902
			11.5	821.903 8.121.903
			13	821.904 8.121.904
			15	821.905 8.121.905
	4.3	-	8.5	821.906 8.121.906
			10	821.907 8.121.907
			11.5	821.908 8.121.908
			13	821.909 8.121.909
			15	821.910 8.121.910
	5.0	-	8.5	821.911 8.121.911
			10	821.912 8.121.912
			11.5	821.913 8.121.913
			13	821.914 8.121.914
			15	821.915 8.121.915
Implante Ortodôntico	1.4	-	6 cinta de 1	822.001
			8 cinta de 1	822.002
			10 cinta de 1	822.003
	1.6	-	6 cinta de 1	822.004
			8 cinta de 1	822.005
			10 cinta de 1	822.006
Implante Ortodôntico	1.4	-	6 cinta de 2	822.007
			8 cinta de 2	822.008
			10 cinta de 2	822.009



Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
	1.6	-	6 cinta de 2	822.010
			8 cinta de 2	822.011
			10 cinta de 2	822.012
Implante Classic Tradicional	3.3	4.1	8.5	817.201 8.117.201
			10	817.202 8.117.202
			11.5	817.203 8.117.203
			13	817.204 8.117.204
			15	817.205 8.117.205
	3.75	4.1	7.0	817.295 8.117.295
			8.5	817.296 8.117.296
			10	817.297 8.117.297
			11.5	817.298 8.117.298
			13	817.299 8.117.299
			15	817.300 8.117.300
	4.0	4.1	7.0	817.301 8.117.301
			8.5	817.302 8.117.302
			10	817.303 8.117.303
			11.5	817.304 8.117.304
			13	817.305 8.117.305
			15	817.306 8.117.306
	Implante Classic Tradicional	5.0	5.0	7.0
8.5				817.318 8.117.318
10				817.319 8.117.319
11.5				817.310 8.117.310
13				817.311 8.117.311

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
			15	817.312 8.117.312
Implante Classic Curto	4.0	3.3	5.0	817.701 8.117.701
			6.0	817.702 8.117.702
	5.0	4.1	5.0	817.703 8.117.703
			6.0	817.704 8.117.704
Implante Classic-CI TS	3.75	4.1	8.5	817.500 8.117.500
			10	817.501 8.117.501
			11.5	817.502 8.117.502
			13	817.503 8.117.503
			15	817.504 8.117.504
	4.0	4.1	8.5	817.505 8.117.505
			10	817.506 8.117.506
			11.5	817.507 8.117.507
			13	817.508 8.117.508
			15	817.509 8.117.509
	5.0	4.1	8.5	817.510 8.117.510
			10	817.511 8.117.511
11.5			817.512 8.117.512	
13			817.513 8.117.513	
15			817.514 8.117.514	
Implante Cone Fix	2.8	2.8	9	888.776 8.188.776
			11	888.777 8.188.777
			13	888.778 8.188.778
			15	888.779 8.188.779

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code	
Implante Zigomático	4.4	4.1	30	870.000	
			35	870.001	
			40	870.002	
			45	870.003	
			47.5	870.004	
			50	870.005	
			52.5	870.006	
Implante Attract TS	3.75	-	8.5	821.930 8.121.930	
			10	821.931 8.121.931	
			11.5	821.932 8.121.932	
			13	821.933 8.121.933	
			15	821.934 8.121.934	
	4.3	-	8.5	821.935 8.121.935	
			10	821.936 8.121.936	
			11.5	821.937 8.121.937	
			13	821.938 8.121.938	
			15	821.939 8.121.939	
	Implante Attract TS	5.0	-	8.5	821.940 8.121.940
				10	821.941 8.121.941
11.5				821.942 8.121.942	
13				821.943 8.121.943	
15				821.944 8.121.944	
Implante Allure	3,75	-	5	821.950 8.121.950	
			6	821.951 8.121.951	
			7	821.952 8.121.952	
				5	821.953 8.121.953

Dental Implant Model	Diameter (mm)	Platform (mm)	Length (mm)	Code
	4.5	-	6	821.954 8.121.954
			7	821.955 8.121.955
Classic-in CR TS	3.75	4.3	8.5	818.500 8.118.500
			10	818.501 8.118.501
			11.5	818.502 8.118.502
			13	818.503 8.118.503
			15	818.504 8.118.504
	4.0	4.3	8.5	818.505 8.118.505
			10	818.506 8.118.506
			11.5	818.507 8.118.507
			13	818.508 8.118.508
			15	818.509 8.118.509
	5.0	5.0	8.5	818.510 8.118.510
			10	818.511 8.118.511
			11.5	818.512 8.118.512
			13	818.513 8.118.513
			15	818.514 8.118.514

**Table 01:** Models, sizes and codes of the Systhex Dental Implant line