BIONNOVATION CLASSIC DENTAL IMPLANTS
BIONNOVATION PRODUTOS BIOMÉDICOS LTDA

VALID FOR ALL COUNTRIES, EXCEPT BRAZIL

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Technical Responsible: Gustavo Telli Athaide **CREA-SP** 5069918500
Technical Product Name: Dental Implants (Osseointegrable) (2701125)
Trade name: Dental Implants Bionnovation Classic

Keep out of the sun

Keep dry

Do not use if the packaging is damaged

See instructions for use

Temperature Limit

Do not reuse

Do not resterilize

Product sterilized by gamma radiation

Expiration date

Manufacturing date

Lot

Reference / code

1. DETAILED DESCRIPTION OF THE MEDICAL PRODUCT, INCLUDING THE FUNDAMENTALS OF ITS OPERATION AND ITS ACTION, ITS CONTENTS OR COMPOSITION, IF APPLICABLE, AS WELL AS LIST OF ACCESSORIES INTENDED TO INTEGRATE THE PRODUCT.

Osseointegrated dental implants are devices inserted into the bone tissue of mandibles and / or maxillary of partially or totally edentulous patients in order to replace the roots of the missing teeth and even support single or multiple dentures.

The titanium, raw material of the implants, is a biocompatible and non-cytotoxic material that naturally produces a layer of oxides capable of attracting bone cells from adjacent tissue and then induced by this physicochemical process, tend to deposit in the external layer of the metal, securing the implant to the bone tissue. Titanium also allows the installation of implant-supported dental prostheses.

Bionnovation Classic Dental Implants are subjected to a surface corrosion treatment, Supex. The Supex treatment provides a rough texture to the metal, which facilitates the migration of bone cells and increases the area of contact between implant and tissue, accelerating the osseointegration process and the dynamic interaction process between the metal surface of the implants and the tissue Bone.

The Bionnovation Classic Dental Implant family has implants with Conical and Cylindrical formats. In the case of dental implants with external hexagon (EH) the torque is applied on the assembler and in the dental implants with internal hexagon (IH) and Medullar implants the torque is performed directly on the internal hexagon. On the other hand, in EH Biodirect implants the application of the torque is directly in the fitting of the implant, and in implants CM Biomorse the torque is applied directly on the implant, dispensing the use of assemblers.

List of accessories that should integrate the Bionnovation Dental Implants

 	**Cover cap -** It avoids waste deposit and even gum invagination in the implant's internal thread. <u>Models</u>: MP, SP, RP, WP, T.D RP/WP, T.D 4,0/5,0, CM BIOMORSE	**Cover cap Models:** Cover cap EH MP Cover cap EH SP Cover cap EH RP Cover cap EH WP Cover cap IHSP Cover cap IH RP Cover cap IH WP Cover cap RP/WP

		Cover cap TD 4,0/5,0 Cover cap CM Biomorse
	**Bushing** –Implant Fixation in the package (plastic tube), support, it avoids damaging the product.	
 	**Assembler and Screw Assembly –** Transporting the implant into the cavity and assisting in placement.	**Assembler Models:** Assembler EH MP 8,0 mm Assembler EH SP 8,0 mm Assembler EH RP 8,0 mm Assembler EH WP 8,0 mm Assembler IH.MP 8,0 mm Assembler IH SP 8,0 mm Assembler IH RP 8,0 mm Assembler IH WP 8,0 mm Assembler EH MP 15,0 mm Assembler EH SP 15,0 mm Assembler EH RP 15,0 mm

1.1 DENTAL IMPLANTS WITH EXTERNAL HEXAGON - EH

The implants with an external hexagon provide a large quantity of components to solve esthetic and mechanical limitations, in addition to providing greater predictability and facilitating to surgeon's work.

The wrenches used to installation (do not come with the product and are sold separately) can be easily adapted and provide torque on the assemblers. Check recommended maximum torques according to **table 14.**

IMPLANT EH CLASSIC CYLÍNDRICAL	IMPLANTEH CONICAL
	

WARNING: The images above are merely illustrative. They do not represent the actual surface dimensions and characteristics of the product

Table 1 - Bionnovation Classic Dental implants EH with and without assembler.

	Micro Platform - MP	Small Platform - SP	Regular Platform - RP	Wide Platform - WP
	Ø 2,90 mm	Ø 3,30 mm	Ø 3,75 / Ø 4,00 mm	Ø 5,00 mm
Length			7,0 mm	7,0 mm
			8,5 mm	8,5 mm
	10,0 mm	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm	13,0 mm
	15,0 mm	15,0 mm	15,0 mm	
			18,0 mm	

Table 2 - Bionnovation Dental implants EH Conical with and without assembler

	Small Platform-SP	Regular Platform-RP	Wide Platform-WP
	Ø 3,30 mm	Ø 3,75 mm	Ø 5,00 mm
Lengths		7,0 mm	7,0 mm
		8,5 mm	8,5 mm
	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm
	15,0 mm	15,0 mm	
		18,0 mm	
		20,0 mm	

Table 3 - Indication of use of Bionnovation E.H. Dental Implants

Implants	Indications
MP	- Used for single rehabilitations. - Installation in regions where the bone tissue has reduced thickness. - Indication for reduced mesiodistal spaces and with less mechanical demands. - Implants of Ø2.9 mm are indicated for lower incisors (lateral incisors), contraindicated for upper central incisors, canines, premolars and molars.
SP	- Used for single rehabilitations. - Installation in regions where the bone tissue has reduced thickness. - Indication for small mesiodistal spaces, where it does not require large mechanical requests, that is, for lower incisors (lateral incisors) contraindicated for centralincisors, superiorincisors, canine, pre molar and molar incisors.
RP	- Used for single or multiple rehabilitations. - Indicated for use after exodontia and for healed regions of central incisors, canines and premolars, contraindicated for reduced spaces.
WP	- Used for single or multiple rehabilitations. - Indicated for use after exodontia and cicatrized regions of molar teeth, contraindicated for reduced spaces.

1.2 DENTAL IMPLANTS WITH INTERNAL HEXAGON – IH

The implants with internal hexagon have greater prosthetic stability and the helix-shaped cutting chambers that accompany the entire implant body from the apex to the microscrews favor the drainage of the blood clot as well as aid in the wettability of the implant surface during its installation.

The IH implants do not require an assembler, since the torque is applied directly on the implant's internal hexagon. The torque applied during the implant installation procedure is transferred to the implant's body ensuring there is not alteration in the connection between the implant and the prosthetic component, which may lead to complications during the prosthetic phase. Check recommended maximum torques according to **table 14.**

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Table 4 - Bionnovation Classic Dental implants IH

	Small Platform-SP	Regular Platform-RP	Wide Platform-WP
	Ø 3,50 mm	**Ø 4,00 mm**	**Ø 5,00 mm**
Lengths	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm
	15,0 mm	15,0 mm	

Table 5 - Bionnovation Dental implants IH Conical and Conical Medullar.

	Small Platform-SP	Regular Platform-RP	Wide Platform-WP
	Ø 3,50 mm	**Ø 4,00 mm**	**Ø 5,00 mm**
Lengths	8,5 mm	8,5 mm	8,5 mm
	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm
	15,0 mm	15,0 mm	
		18,0 mm	

Accessories integrating and exclusive of the Classic and Conical Implants:

Bush;

Cover cap;

Assembler;

Screw of Assembler.

Accessories integrating and exclusive of the Classic and Conical Implants without assembler:

Bush;

Cover cap.

Table 6 - Intended Use of Dental Implants Bionnovation IH Conical

Implants	Indications
SP	- Used for single or multiple rehabilitations. - Indicated for use after extraction and for healed regions of central incisors, lateral incisors, canines and premolars. - Type of bone classification for installation (recommendation): Medullar Implant: Type III and IV Bone
RP	- Used for single or multiple rehabilitations. - Indicated for use after extraction and for healed regions of premolars and e molars. - Type of bone classification for installation (recommendation): Medullar Implant: Type III and IV Bone.
WP	- Used for single or multiple rehabilitations. - Indicated for use after extraction and for healed regions of molars. - Type of bone classification for installation (recommendation): Medullar Implant: Type III and IV Bone.

1.3 IMPLANTES BIODIRECT

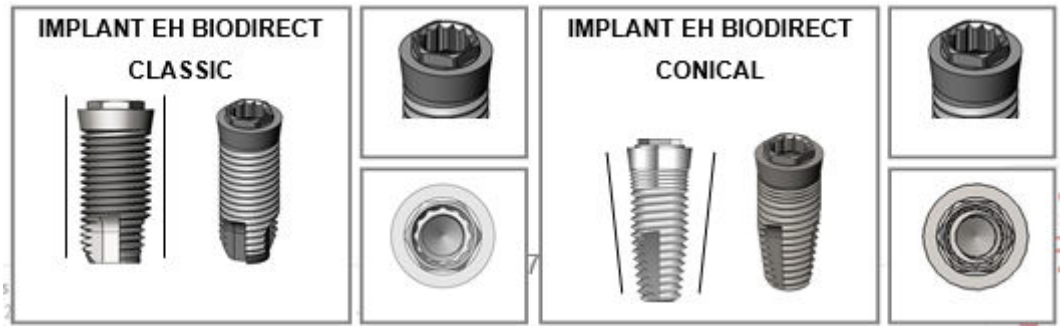
The dental implants with EH Biodirect are devices that dispense the use of assemblers, whose main advantage is a decrease in surgical times and in the probability of contamination. In addition to that, these implants have an external hexagon that allows for a universal prosthetic adaptation and have internal geometry for installation (direct torque). The direct torque is applied internally in the implant, in whose cervical third there is an adaptation for the direct torque wrench (for torque wrench or contra-angle). Check recommended maximum torques according to **table 14.**

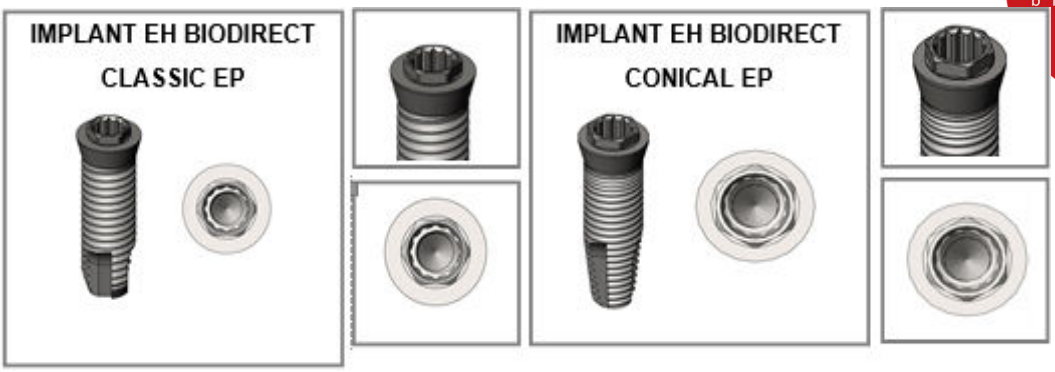
The direct torque wrenches for contra-angle or torque wrench (they do not come with the product and are sold separately), are used for direct torque application in the implant's internal part and there is no contact with the external part of the external hexagon. These wrenches are coupled into the implant's upper internal part, whose fitting must be perfect between both of them. In addition, they allow its transporting from the packaging to the surgical bed for installation. The wrenches must undergo a process of decontamination and sterilization before use, being the responsibility of the professional.

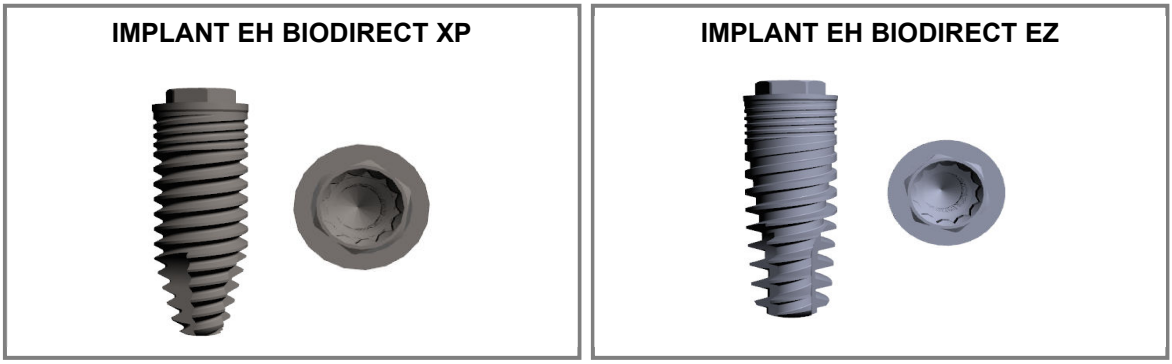
*It is recommended for wrenches with contra-angle connection not to exceed torque of 32NCM, above recommended torque use ratchet with connection wrench to ratchet.

The implants with EH Biodirect also are available in the Expanded Platform (EP) models. In these models, the diameter of the platform is greater than the implant's external diameter. The possibility of using the prosthetic components model related to the size of the platform (components for larger prosthetic spaces) is one of its advantages, as well as installation of implants in an area with smaller osseous space, due to the presence of anatomical repairs and/or divergent tooth roots from the adjacent teeth, and greater prosthetic space, which favors both esthetics and bone tissue preservation.

The implants with **Biodirect XP** come with cut chambers at 120°, micro threads with a round profile, double thread, direct torque fitting for installation, 2.7-mm hexagon, active conical apex to facilitate installation and reduced height collar. As regards the **Biodirect EZ** implants, they have cut chambers at 120°, direct torque fitting for installation, 2.7-mm hexagon, micro threads with round profile, double threads with variable levels, spirals with a high cutting power, and conicity in the internal part of the thread (conical core). **Biodirect SWE** implants feature cutting chambers with through holes, direct torque fitting for installation, 2.7mm hex and double threads with varying levels







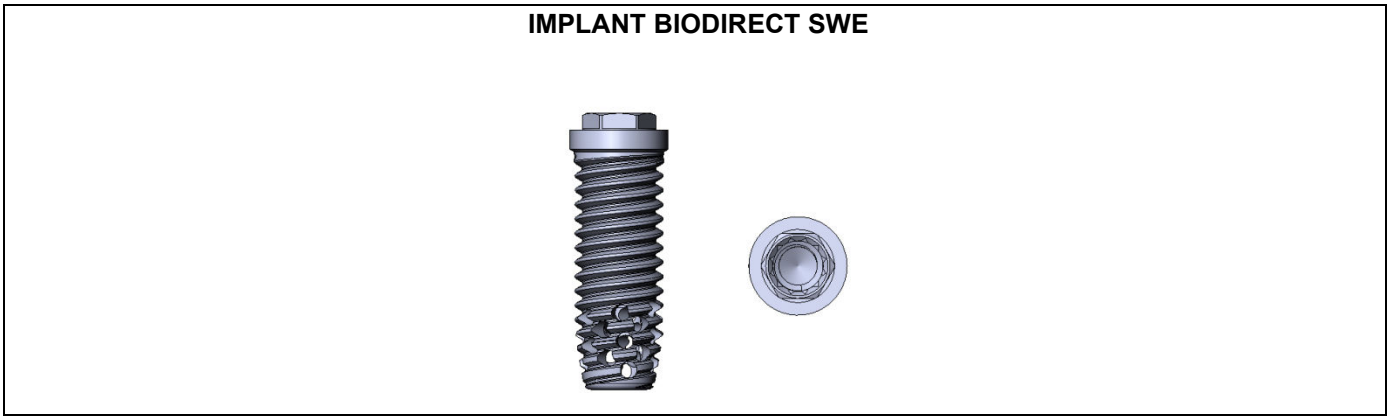


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Table 7 - Bionnovation Classic, Conical and SWE Dental Implants EH Biodirect. Available in such platforms, diameters and lengths

	Micro Platform-MP	Small Platform-SP	Regular Platform-RP	Regular Platform-RP	Wide Platform-WP
	Ø 2,90/3,30	Ø 3,30/3,30	Ø 3,75 / 4,10	Ø 4,00/4,10	Ø 5,00/5,00
Lengths	7,0 mm	7,0 mm	7,0 mm	7,0 mm	7,0 mm
	8,5 mm	8,5 mm	8,5 mm	8,5 mm	8,5 mm
	10,0 mm	10,0 mm	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm	13,0 mm	13,0 mm

	15,0 mm	15,0 mm	15,0 mm	15,0 mm	15,0 mm
	18,0 mm	18,0 mm	18,0 mm	18,0 mm	18,0 mm
	21,0 mm	21,0 mm	21,0 mm	21,0 mm	21,0 mm

Table 8 - Bionnovation Classic and Conical Dental implants EH Biodirect with Expanded Platform (EP). Available in such platforms, diameters and lengths

	Platform PE 3,3/4,1	**Platform PE 3,75/5**	**Platform PE 4/5**
	Ø 3,30 mm PL. 4,10 mm	**Ø 3,75 mm PL. 5,00 mm**	**Ø 4,00 mm PL. 5,00 mm**
Lengths	7,0 mm	7,0 mm	7,0 mm
	8,5 mm	8,5 mm	8,5 mm
	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm
	15,0 mm	15,0 mm	15,0 mm
	18,0 mm	18,0 mm	18,0 mm
	21,0 mm	21,0 mm	21,0 mm

Ø external diameter of the screw;

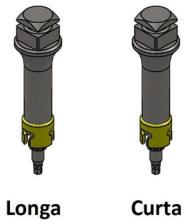
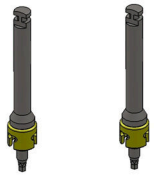
PL. Platform diameter;

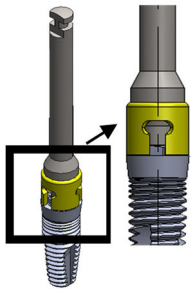
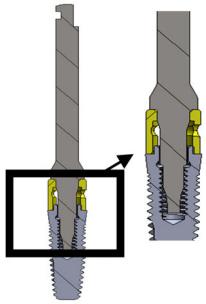
Accessories integrating and exclusive of the Biodirect Implants:

Bush;

Cover cap.

List of exclusive optional accessories for the Biodirect implant's installation (sold separately, do not accompany the product)

Wrenches for direct torque to Biodirect Implant	
 Longa Curta	**Torque wrenches for direct torque** – used for installation and apply torque to the implant. The Wrenches for Biodirect torque follow an internal design for adaptation in a Bionnovation torque wrench.
 Longa Curta	**Contra-angle wrenches direct torque** – used for installation and apply torque to the implant with surgical engine (contra-angle). The fittings of **Contra-angle wrenches direct torque** are in accordance with ISO 1797- Dentistry - Shanks for rotary and oscillating instrument, in which their manufacture is monitored.

Assembler of the Biodirect Implant and of the Direct Torque Wrench	
	**Assembly -** Direct torque wrench for contra-angle adapted to the Biodirect implant. Feature to the cervical region: the wrench does not has external contact with the external hexagon.
	**Assembly -** Direct torque wrench for contra-angle adapted to the Biodirect implant. Longitudinal cut, feature to fitting in the cervical region.

The Biodirect implant should be installed with the contra-angle only until obtaining a torque of 32Ncm, after the ratchet must be used.

Table 9 - Indication of use of Biodirect Implants

Implants	Indications
Biodirect XP	- Used for single or multiple rehabilitations - Type of bone classification for installation (recommendation): I, II, III and IV
Biodirect Cylindrical	- Used for single or multiple rehabilitations - Type of bone classification for installation (recommendation): I and II
Biodirect Conical	- Indicated for post-implant installations of single or multiple implants. - Type of bone classification for installation (recommendation): I, II, III and IV
Biodirect MP	- Used for single rehabilitations. - Installation in the bone tissue of lesser thickness; - Indication for small mesiodistal spaces, where it does not require great mechanical requests;
Biodirect SP	- Used for single rehabilitations. - Installation in the bone tissue of lesser thickness; - Indication for small mesiodistal spaces, where it does not require great mechanical requests
Biodirect Swe	- Used for single or multiple rehabilitations - Type of bone classification for installation (recommendation): I, II, III and IV

1.4 DENTAL IMPLANTS WITH BIOMORSE

Dental implants Biomorse have an accurate internal conic format, which during installation of the abutment into the implant promotes a close adaptation between the interposed surfaces, acquiring a mechanical resistance similar to a single piece.

It is considered the internal retention system of the prosthetic element on the implant, employing the mechanical friction between the prosthetic component's contact surface and the implant's internal wall.

Implants with Biomorse have been developed to improve the biomechanical properties of the implant/pillar prosthetic sets, and to reduce the incidence of the mechanical problems found in the internal and external hexagon systems.

The connections provide a better adaptation between the prosthetic component and the implant, reducing micro-gap between component and implant, reducing the peri-implant bone reabsorption levels, also providing a better mechanical stability for the pillar, minimizing the occurrence of micro-moves. The micro-moves cause an increase in the incidence of relaxation and screw fractures. The Biomorse implants have a better anti-rotational fixation with indexer and greater resistance through the implant/pillar set fixed with a screw because the close link between both of them practically provides a mechanical response similar to a single body one and the incidence of mechanical complications are low. The Biomorse has greater ability to support horizontal loads because it has a higher interposition surfaces between the implant and the abutment, also has better stability of bone and gum tissues (discreet absorption).

The internal geometry of implants is comprised of a hexagon whose function is to convey the insertion torque to the implant. This internal torque system avoids the use of an assembler, eliminating the need of making transversal grooves on the implant's platform, decreasing bacterial proliferation and facilitating prosthesis hygiene.

The **Biomorse XP** implants have cut chambers at 120°, micro threads with round profile, double thread (faster installation), internal hexagon fitting for installation and anti-rotational fitting for the prosthesis, active conic apex to facilitate installation and lack of smooth collar. As regards the **Biomorse EZ** implants, they have cut chambers in the shape of a helix, micro threads with round profile, double threads with variable levels, spirals with high cutting power, and conicity in the internal part of the thread (conic core), and lack of smooth collar. **Biomorse SWE** implants have cutting chambers with through holes, micro threads with rounded profile, double threads with varying levels, coils with high cutting power, taper in the inner part of the thread (conical core) and absence of smooth collar. Check recommended maximum torques according to **table 14.**

IMPLANTCM BIOMORSE CONICAL	IMPLANTCM BIOMORSE XP	IMPLANT CM BIOMORSE EZ
		

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IMPLANT BIOMORSE SWE

Table 10 - Biomorse Classic, Conical and SWE Dental Implants. Available in diameters and lengths

Ø	3,50	3,80	4,00	4,30	4,50	5,00	5,50
LENGTHS	7,0	7,0 mm	7,0 mm	7,0 mm	7,0 mm	7,0 mm	7,0 mm
	8,5	8,5 mm	8,5 mm	8,5 mm	8,5 mm	8,5 mm	8,5 mm
	10,0	10,0	10,0	10,0	10,0	10,0	10,0
	11,5	11,5 mm	11,5 mm	11,5 mm	11,5	11,5	11,5
	13,0	13,0 mm	13,0 mm	13,0	13,0	13,0	13,0
	15,0	15,0	15,0	15,0	15,0	15,0	15,0
	18,0	18,0	18,0	18,0	18,0	18,0	18,0
	21,0	21,0	21,0	21,0	21,0	21,0	21,0

Accessories integrating and exclusive of the Biomorse Implants:

Bush;

Cover cap.

List of optional accessories exclusive to the installation of the Biomorse implant (sold separately, do not accompany the product and have separate registration).

Wrenches for Implant with Cone Morse type connection	
 Long Short	**Wrenches for Biomorse Torque** – used for installation and application torque in the implant. The Wrenches for Biomorse torque follow an internal design for adaptation in a Bionnovation torque wrench.
 Long Short	**Biomorse contra-angle wrenches –** used for installation and application torque in the implant with surgical engine (counter - angle). The fittings of Contra-angle **Biomorse contra-angle wrenches** are in accordance with ISO 1797- Dentistry - Shanks for rotary and oscillating instrument, in which their manufacture is monitored.
Assembler of the Biomorse Implant with Morse Cone	
	**Assembly** - Morse Cone Wrench for contra-angle adapted to the Biomorse implant. Longitudinal cut, featuretofitting in the cervical region

The Biomorse implant must be installed with the contra-angle only until obtaining a torque of 32Ncm and then the ratchet must be used.

Table 11 - Indication of Use Biomorse Implants.

Implants	Indications
Biomorse XP	-Used for single or multiple rehabilitations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV - Indicated for all teeth except molars; Ø 4.0 mm: Bone typeI, II, III and IV – Indicated for all teeth except lateral incisors and lower incisors; Ø 5.0 mm: Bone typeIII and IV- Indicated for molars.
Biomorse EZ	-Used for single or multiple rehabilitations; - Indicated for post-extraction installations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 4.0 mm: Bone type I, II, III and IV- Indicated for all teeth except lateral incisors and lower incisors; Ø 5.0 mm: Bone type III and IV- Indicated for molars.
Biomorse	-Used for single or multiple rehabilitations; - Indicated for post-extraction installations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 4.0 mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 5.0 mm: Bone type III and IV- Indicated for molars.
Biomorse SWE	-Used for single or multiple rehabilitations; - Indicated for post-extraction installations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 4.0 mm: Bone type I, II, III and IV- Indicated for all teeth except lateral incisors and lower incisors; Ø 5.0 mm: Bone type III and IV- Indicated for molars.

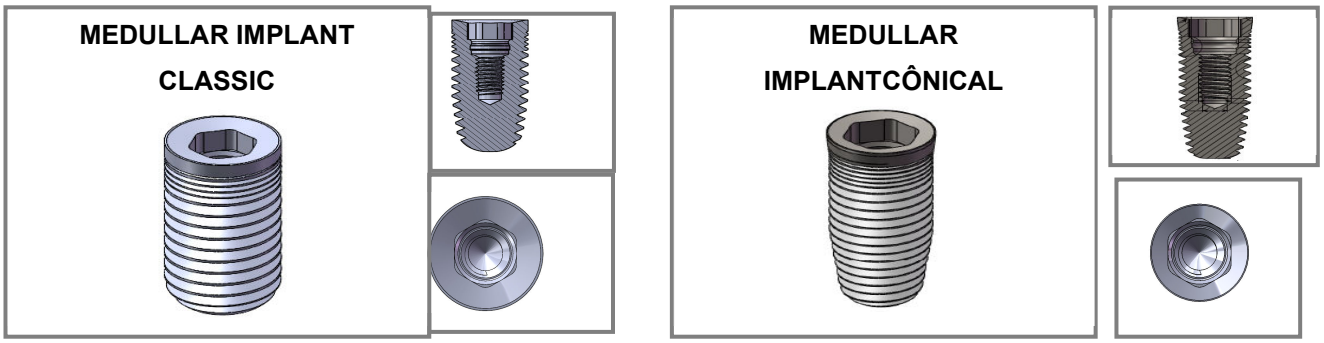
1.5 BIONNOVATION MEDULLAR IMPLANT

The Bionnovation Medullar Implants have an Internal Hexagon system with Conic and Cylindrical designs, with pyramidal thread profile, for faster installation and smaller traumas.

These implants are devices that dispense the use of assemblers, its torque is applied directly on the internal hexagon and the implants' transportation and installation are undertaken by the same wrench models used in the internal hexagon – IH.

They do not have an apex with cut chambers; however, they are indicated for bone densities of grade III and IV according to the bone classification of Lekhom and Zarb (1985).

The medullar implants' advantage is that they decrease surgical times and provide high mechanical resistance. However, due lack of chambers they can only be used in the upper maxilla, but not in the mandible. Check recommended maximum torques according to **table 14**.



WARNING: The images above are merely illustrative. They do not represent the actual surface dimensions and characteristics of the product..

Table 12 - Bionnovation Dental Implants IH Medullar conical. Available in such platform, diameter and lenghts

	Small Platform -SP	Regular Platform-RP	Wide Platform -WP
	Ø 3,50 mm	Ø 4,00 mm	Ø 5,00 mm
Lengths	8,5 mm	8,5 mm	8,5 mm
	10,0 mm	10,0 mm	10,0 mm
	11,5 mm	11,5 mm	11,5 mm
	13,0 mm	13,0 mm	13,0 mm
	15,0 mm	15,0 mm	
		18,0 mm	

According to Lekholm and Zarb (1985), below you'll find the bone quality classification in the maxilla and mandible: Grade I (Compact and homogeneous bone); Grade II (Compact bone surrounding the dense spongy bone); Grade III (Slim cortical bone surrounding a dense and spongy bone); and Grade IV (Fine cortical bone surrounding a little dense and spongy bone).

For bones type I and II it is indicated use of the countersink drill (biodirect and biomorse). Rotation indication for the torque wrenches during drill installation:

- Type bone I and II: 1000 to 1200 RPM approximately,
- Type bone III and IV: 500 to 800 RPM approximately.

Table 13 - Bone classification

	Bone type I	Bone type II	Bone type III	Bone type IV
				
Implants with EH and IH	•	•	•	•
Implants with EH Biodirect	•	•	•	•
Implants with CM Biomorse	•	•	•	•
Implants Medullar			•	•

1.6. Recommended Implant Installation Torques:

The Bionnovation Classic dental implant family has tapered and cylindrical shapes. In the case of External Hexagon (H.E) dental implants the torque is applied to the assembler and to the Internal Hexagon (H.I) and Medullary implants, directly over the internal hexagon. In Biodirect and Biodirect SWE implants, the torque is applied directly to the implant socket and in Biomorse and Biomorse SWE implants, the torque is applied directly over the implant, eliminating the use of fitters. The insertion torques of the implants vary between 45N.cm and 55 N.cm, according to the table below:

Table 14 - Maximum recommended torque according to implant type.

Implant Type	Platform / model	Recommended maximum torque (N/cm)
External Hexagon (E.H)	**Implant E.H MP**	55 N/cm
	Implant E.H SP	55 N/cm
	Implant E.H RP	55 N/cm
	Implant E.H WP	55 N/cm
Internal Hexagon (I.H)	**Implant I.H SP**	55 N/cm
	Implant I.H RP	55 N/cm
	Implant I.H WP	55 N/cm
Biodirect Implants	**Biodirect XP Implant**	45 N/cm
	Biodirect Cylindrical Implant	55 N/cm
	Biodirect MP Implant	55 N/cm
	Biodirect SP Implant	55 N/cm
	Biodirect SWE Implant	45 N/cm

Biomorse Implant	**Biomorse Implant**	45 N/cm
	Biomorse XP Implant	45 N/cm
	Biomorse EZ Implant	45 N/cm
	Biomorse SWE Implant	45 N/cm

1.7. Drill Protocol

It is a professional choice the sequence of installation drills according to the previous evaluation of the implant to be used, for choosing the sequence of drills Bionnovation recommends tables 1.7.1 Biodirect, H.E and H.I Implant and 1.7.2 Biomorse Implant, the choice of drill diameter influences stability and primary fixation of the implant, the drilling depth must be in accordance with the planned implant length.

1.7.1 Biodirect, H.E and H.I Implant

Drill Protocol	Biodirect XP		Biodirect Conic/ H.E / H.I				Biodirect	
	Ø3,75mm	Ø4,00mm	Ø3,30mm	Ø3,75mm	Ø4,00mm	Ø5,00mm	Ø3,75mm	Ø4,00mm
Lance Drill	X	X	X	X	X	X	X	X
Helicoidal Drill Ø2,2	X	X	X	X	X	X	X	X
Conic Drill Ø2,8	X	X	X					
Helicoidal Drill Ø3,2				X	X	X	X	X
Conic Drill Ø3,2	X	X		X	X			
Conic Drill Ø3,6		X		X	X	X		
Conic Drill Ø4,4						X		
Countersink SP/RP			X					
Countersink RP				X	X		X	X
Countersink WP						X		

1.7.2 Biomorse Implant

Drill Protocol	**Biomorse**			**Biomorse XP**			**Biomorse EZ**		
	Ø3,50mm	Ø4,00mm	Ø5,00mm	Ø3,50mm	Ø4,00mm	Ø5,00mm	Ø3,50mm	Ø4,00mm	Ø5,00mm
Lance Drill	X	X	X	X	X	X	X	X	X
Helicoidal Drill Ø2,2	X	X	X	X	X	X	X	X	X
Conic Drill Ø2,8	X	X	X	X	X	X	X	X	X
Conic Drill Ø3,2	X	X	X	X	X	X		X	X
Conic Drill Ø3,6		X	X		X	X			X
Conic Drill Ø4,4			X			X			X

2 COMPOSITION

Bionnovation Implants are produced with grade 4 titanium, according to the Standard ASTM F67 e ISO 5832-2.

3 FORMS OF PRESENTATION IN MARKET OF THE MEDICAL PRODUCT

Content:01 dental implant vv, ww, x,xx mm X yy,yy mm, machined with titanium G4 alloy, fixed to the protection and support bushing, packed in plastic tube with silicone cap containing a cover cap (ww) as primary package. As a secondary package, the product is packaged in rigid and transparent blister pack (PETG film) sealed with surgical grade paper Tyveck® (high density polyethylene fibers) and in tertiary package, a box made of cardboard triplex with attached adhesive label for Product Identification. There are three adhesive labels with information for traceability of the product that must be attached to the medical record, in the document to be delivered to the patient and in the tax documentation that generates the charge. **See annex:** Bionnovation Classic Dental Implant family table: Model (vv); Platform (ww), diameter (x, xx mm), length (yy, yy mm) and cover cap (ww).

4. INDICATION, PURPOSE OR USE INTENDED FOR THE PRODUCT, ACCORDING TO MANUFACTURER'S RECOMMENDATIONS

Treatment with implants is indicated for cases where there is a need for replacement of lost dental elements. The purpose of the treatment is the installation of dental prostheses to recover aesthetics and masticatory function.

The choice of implant diameter, length and platform should respect bone quantity and quality, prosthetic space, as well as anatomical repairs, through previous radiographic and clinical analyzes.

The indication is through the diameter of the prosthetic platform, ie the surface where the connection of the implant with the prosthetic component occurs. In the case of implants with external Hexagon, the Micro Platform (MP) and SmallPlatform (SP) have a diameter of 3.30 mm, the Regular Platform (RP) has a diameter of 4.10 mm and the Wide Platform (WP) has a diameter of 5.00 mm. In relation to implants with internal Hexagon, the SmallPlatform(SP) has a diameter of 3.8 mm, a Regular Platform (RP) 4.2 mm and a Large Platform (WP) have a diameter of 5.0 mm.

Dental implants with EH Biodirect with Expanded Platform (EP) present 03 different models, the 3.3 / 4.1 that corresponds to 3.30 mm of external diameter of the implant and 4.10 mm of platform for use of prosthetic components related to the RP model (platform also 4.10 mm), 3.75 / 5 that corresponds to 3.75 mm of external diameter of the implant and 5.00 mm of platform and the 4/5, with 4.00 mm of external diameter of the implant and platform of 5.00 mm. These last two models are adapted to the components whose platforms have 5.00 mm and are indicated for cases where there is more prosthetic

space and the local bone quantity is smaller due to the presence of anatomical repairs or divergent dental roots. It allows the installation of implants whose screw has smaller external diameter and larger platform, adapting to prosthetic components with larger platforms and favoring the installation and preservation of local tissue, as well as aesthetics and masticatory function.

The criteria for choosing implants and implant platforms that will be installed are the responsibility of the specialized professional.

5. INSTRUCTIONS FOR USE OF MEDICAL PRODUCT

1. The planning should also take into consideration the prosthetic options most appropriate to the masticatory forces balance, occlusal adjustment, esthetics and other factors related to the good performance of the prosthesis. The exchange of information between the dental surgeon, the prothesis specialist and the laboratory technician is important for the success of the treatment.
2. After implant installation, the surgeon should evaluate the initial stability to determine if the implants may or may not receive immediate function.
3. Surgeries should be performed with special care about refrigeration, which should be done continuously with saline solution, gradual increase of drill diameter and low speeds because the high heat can cause permanent damage to host tissue and the consequent loss of implant. The milling sequence indicated for each implant diameter is described in table 10 below.
4. Implants with External Hexagon (EH) and Internal Hexagon (IH) are in the public domain.

6. RESTRICTIONS, SPECIAL CARE AND CLARIFICATIONS ON THE USE OF MEDICAL PRODUCT, STORAGE, TRANSPORT AND PRODUCT DISPOSAL

1. STERILE - provided that an integrity of the package, shelf-life and storage conditions are maintained;
2. Implants should only be used for their intended purpose;
3. The implants are supplied in sterile double packaging (25 kGy Gamma Radiation). Since the integrity of the package is not compromised in any way, save the sterile product to 5 years from the date of sterilization;
4. In cases of Adverse Effects occurring in the patient, the responsible professional should contact the SAC Bionnovation immediately (Customer Service) by phone **0800 770 3824** or email sac@bionnovation.com.br. Bionnovation Biomedical Products Ltd and all others involved

(dentists, patients and physicians) are responsible for notifying ANVISA (Sanitary Surveillance Agency - Brazil) of the relevant occurrences according to internal technovigilance procedure, by the website www.anvisa.gov.br/notivisa;

5. Should any adverse effects occur with the patient on the use of our products in the European Community, countries should contact our authorized representative Bionnovation Europe SL by phone +34 931407240 and / or contact the factory and by email sac@bionnovation.com.br . Recalling that professionals are responsible for reporting adverse events to local authorities within the European Union, health monitoring contact points are listed on the European Commission website: http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm.
6. Bionnovation Dental System are Developed in order to avoid its use compromising patients' clinical status and safety;
7. The bone region to be implanted must be exposed and prepared (drilled) with appropriate drills to receive the implant. The milling sequence indicated for each implant diameter is described in table below:

Table 15 - Milling Sequence for Bionnovation Classic Dental Implants

Ø 2,90 mm	Ø 3,30 mm	Ø 3,75 / Ø 4,00 mm	Ø 5,00 mm
Drill bit	Lança	Lança	Lança
Helical Ø 2,20 mm	Helical Ø 2,20 mm	Helical Ø 2,20 mm	Helical Ø 2,20 mm
Pilot Ø 2,45 mm	Pilot Ø 2,80 mm	Pilot Ø 3,20 mm	Pilot Ø 3,20 mm
Helical Ø 2,45 mm	Helical Ø 2,80 mm	Helical Ø 3,20 mm	Helical Ø 3,20 mm
ThreadØ 2,80 mm	ThreadØ3,20 mm	Countersink	Pilot Ø 4,20 mm
		ThreadØ 3,60 mm	Helical Ø 4,20 mm
			Countersink
			ThreadØ 4,80 mm

OBS: The cutters should be replaced regularly to maintain cutting efficiency. They do not accompany the product, sold separately.

The sequence of drills may vary according to the bone quality presented in radiographic planning.

6.1. WARNINGS AND RESTRICTIONS

1. PROFESSIONAL USE ONLY – Bionnovation Classic Dental Implants should be implanted only by dentists and professionals with knowledge of implant techniques;
2. PROHIBITED TO REUSE, REPROCESSING OR RESTERILIZE: If reused, resterilized or reprocessed, oxidation may occur on the surface of the implant, with fibrointegration occurring instead of

osseointegration. Bionnovation does not recommend re-use, resterilization or reprocessing. Disposal should be in accordance with applicable environmental and biosafety laws. Do not dispose of contaminated products in normal household waste;

3. The use of the product with inadequate surgical techniques and biosafety conditions may harm the patient leading to unsatisfactory results;
4. Always sterilize surgical instruments before using them;
5. Careful clinical and radiographic evaluations are necessary for the correct planning of the treatment as well as for the verification of anatomical structures that must be observed before the perforation. An adequate margin of safety adjacent to other teeth and vital structures should be preserved;
6. In all operations involving dental implants observe the appropriate techniques of asepsis and antisepsis;
7. Abusive use of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of treatment;
8. It is supplied in the sterile state and after opened should be used under aseptic conditions. Always work with sterile fields, instruments appropriate to the procedure and in a good state of conservation in order to eliminate sources of infection;
9. If uncontrollable complications, tissue inflammation or evidence of infection arise, immediate removal of the implant is recommended;
10. Implants with Ø 2.9mm are indicated for lower incisors and unitary prosthesis. The use in areas not indicated can fractures the implant. Dental professional is responsible by use;
11. The installation of the CM Biomorse implant should always be parallel, without angles and installed 2mm below the crest;
12. The surgeon should evaluate the indication in patients who are carriers of diseases or who use medications that may alter the repair metabolism;
13. If there is an impact and it has scratches, fissures or dents of great intensity that may impair the proper functioning of the product, it must be discarded and a new one must be purchased. The impact can cause damage to the platform and dimensional characteristics.
14. MAGNETIC RESONANCE (MR) - SAFETY INFORMATION The Bionnovation Implants has not been evaluated for safety in the MR environment. It has not been tested for heating, migration, in the MR environment. The safety of products Bionnovation in the MR environment is unknown. Scanning a

patient with this device can result in injury to the patient with tissue damage due to radiofrequency-induced heating and metallic implants can result in image artifacts that cause misinterpretation of results.

15. There are no contraindications for implant placement in elderly patients, as long as the previous evaluation (anamnesis), quantity and sufficient bone quality are respected.

6.2. ADVERSE EFFECTS

All potential adverse effects should be informed in advance to the patient.

The following complications associated with surgery are listed as adverse effects:

1. Dehiscence, inflammation, bone loss, hemorrhage, allergic reaction, fracture and / or implant loss;
2. There may be no osseointegration or subsequent loss of the implant in cases where there is no quality or quantity of bone.
3. Incorrect surgical technique may cause discomfort such as painful sensation, hypoaesthesia and edema.
4. The implants can cause interference or distortion in the images, in magnetic resonance imaging.

6.3. CONTRAINDICATIONS

1. Implants should not be placed in existing active infection or any other degenerative disease that affects the placement of implants;
2. It should not be used in patients who are not clinically fit to undergo dental intervention. As for example, in patients with blood disorders such as Diabetes Mellitus and uncompensated periodontal disease;
3. Bionnovation implants is not intended for procedures where the patient does not have complete bone formation (patients pediatric);
4. Contraindicated for other procedures besides of recommended in "Intended Use"
5. Is safe for implants a waiting period of 6 to 8 weeks should be enough to allow the implant to be held securely in the tissue, which should be safe for MRI scan.

6.4. PRE– and POST-OPERATIVECARES

In the preoperative evaluation, the correct indication of the materials and the use of techniques and compatible procedures, as well as monitoring and postoperative controls are essential to the desirable results.

PREOPERATIVE CARE

The anamnesis must be made so that the dentist knows the patient's health history and condition, the surgeon must evaluate the indication in patients who have pre-existing diseases such as Diabetes Melitus and periodontal disease or who make use of medication that can alter reparational metabolism, preferably patients who will undergo implant placement will be accompanied by a person who can drive.

All patients who will be undergo the surgical procedure should be carefully examined and evaluated in order to determine the physical and radiographic condition, as well as bone deficit or adjacent soft tissue that may influence the outcome of the intervention.

Also, they need a prior evaluation in order to minimize situations that could compromise the success of the treatment or even the safety of the patient.

POSTOPERATIVE CARE

Observe postoperative care for surgical procedures. Painkillers, antibiotics and rest for 24-48 hours may be prescribe, varying according to the procedure and the professional technical conduct.

Immediately after surgery to install the implant the patient should avoid any activity that requires excessive physical effort, do not smoke, do not drink alcoholic drinks, use ice pack press, ingest cold or icy foods. Pain, swelling, discomfort, phonetic difficulties and inflamed gingiva may be reactions of the surgical procedure. If these reactions persist the surgeon should be consulted. Guide the patient about the need to follow-up after surgery, alerting the importance of strictly obeying all guidance on care, nutrition, prescription of medicines, and special care with the patient's oral hygiene. The period for removing the suture must be longer than 7 days depending on the type of suture used determined in the professional's surgical planning.

Depending on the lifetime of use of the implants, it is recommended that the professional assess the conditions of the implant and prosthesis, including accessories, abutments and crowns to check the need for adjustments or removal after a long period of use. The stability of the implants can be compromised due to loosening of fixation between implants and prostheses, so they must be evaluated by the professional after long periods, in case of any deviation, the professional should evaluate the best

procedure, which can be replaced if necessary.

Instruct the patient as to the need for a professional medical monitoring annual to assess osseointegration and prosthesis placement. The professional in charge is responsible for providing these guidelines.

7. CONDITIONS OF STORAGE, CONSERVATIONOR HANDLING OF MEDICAL PRODUCT.

7.1. STORAGE AND TRANSPORTATION

Transport and store the product away from direct sunlight, and from heat (maximum temperature: 15 -25° C and humidity .Keep the package sealed until the moment of use. Make sure of the integrity of it before use. Do not use if sterile package be opened or damaged or validity date expired to avoid possible contamination. Disposal the product mischaracterized according legislation for medical waste or return the damaged package and the included device to the Factory.

7.2. CONSERVATION AND MANIPULATION

In case of any change in the characteristics of the implants, discard it in a discharacterized way according to current legislation for hospital waste orreturn the damaged package and the included device to the Factory.

8. PRODUCT DISPOSAL CARE

The disposal of the product must comply with environmental laws and existing biosafety. Do not dispose of contaminated products in normal waste.

LEGAL GUARANTEE TERM

(According to the Protection and Defense of Consumer Code: Law 8.078 of September 11, 1990).

In compliance with Article 26 of Law 8.078, of September 11, 1990, the ***Bionnovation Biomedical Products LTD***

company establishes the right of the consumer to complain about apparent defects or about easy verification of all products manufactured and marketed by it for a period of 90 days from the effective date of delivery of the products.

In the case of hidden defects, the decadential period starts when the defect is evidenced,

as provided in Paragraph 3 of Article 26 of Law 8.078.

In order for this Legal Guarantee Term to take effect, the consumer must observe the conditions described below:

Do not allow unauthorized persons to handle the materials in question.

Do not allow the improper use as well as misuse of the materials in question.

Follow all the guidelines for use, as well as the care described in the User Manual or Instructions for Use.

We declare true the information presented in this Model of Instructions for Use