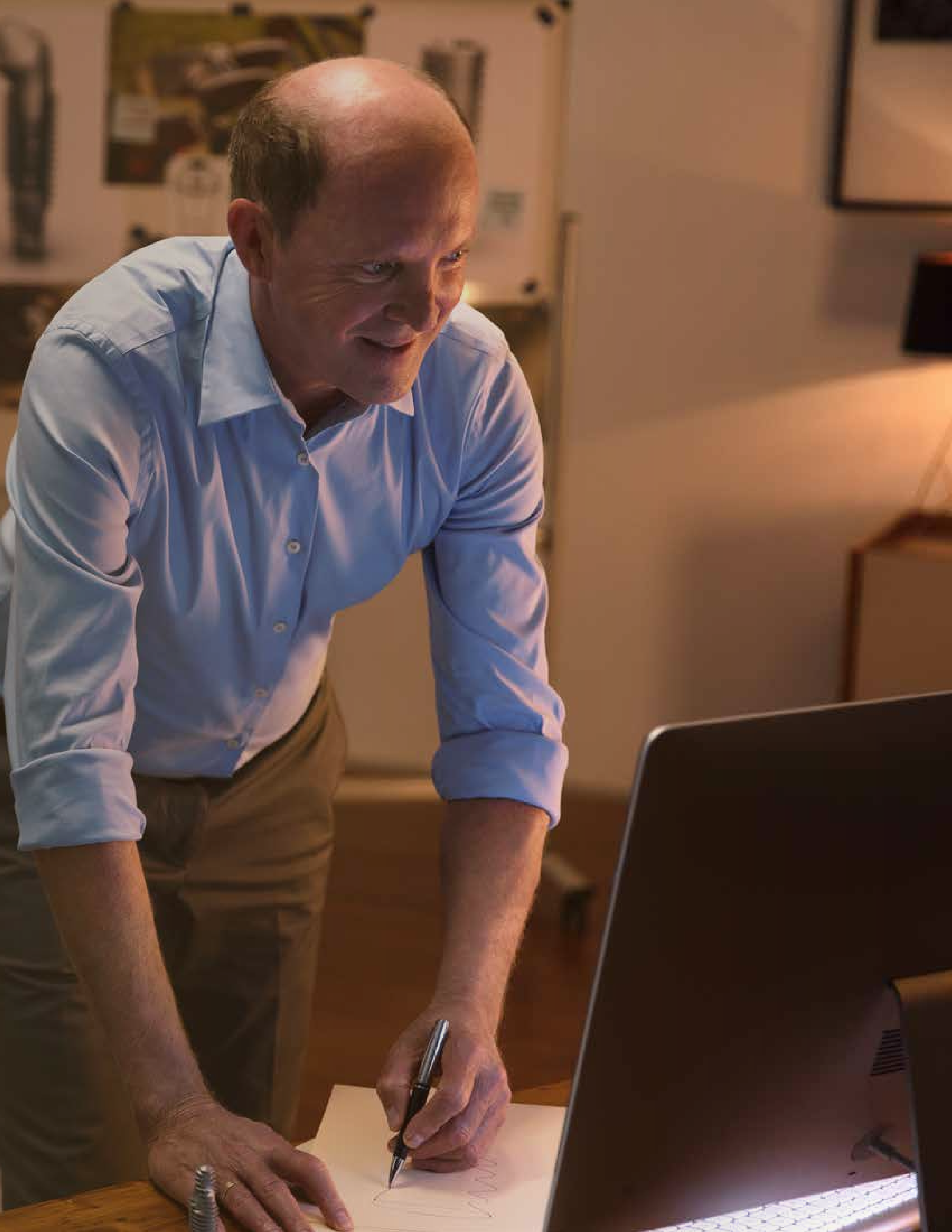
SURGICAL MANUAL

GRAND MORSE™

NEODENT®
A Straumann Group Brand

THE GRAND MORSE™ IMPLANT SYSTEM



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1.0 BASIC INFORMATION ON SURGICAL PROCEDURES

The modern era of implant dentistry is characterized as beginning in 1977 when the first clinical results of osseointegration were first published[1]. Since then, dentistry has undergone significant changes. The current treatment plan for patients usually offers implant-retained and/or implant-supported prostheses as an accessible and reliable solution. The number of dental implants being placed has increased rapidly in recent years,[2,3] and this form of treatment requires specific knowledge and skills, which are relevant to the results.[4] Based on these facts, the objective of these guidelines is to provide dental surgeons and specialists with basic information and guidelines on planning, surgical procedures and treatment options.

These guidelines do not substitute each product's instructions for use (IFU). These can be found at our website: www.ifu.neodent.com.br. It is the surgeon's sole responsibility to analyze the patients' general health, the viability of the surgical procedure and the most appropriate products for each clinical situation.

2.0 NEODENT® IMPLANT SYSTEM

2.1 Overview

Neodent®'s Grand Morse™ (GM) Implant System offers various design options for implants, screw threads, and apex, as well as two types of surface treatment. Neodent's philosophy is to offer an implant solution suited to each specific indication, including bone density and quantity and surgical technique. All implants can be placed with the Grand Morse Surgical Kit. The procedures are standardized and have sequential steps.

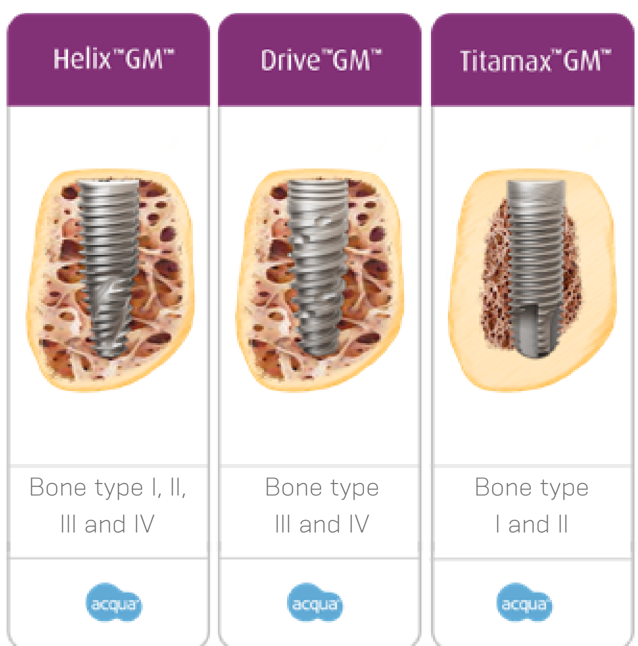


FIGURE 1 – Options for Neodent implants according to their indication.

All Grand Morse™ implants (Helix GM™, Drive GM™ and Titamax GM™) have the same size prosthetic connection, regardless of the implant's diameter (Figure 2), with a total internal angle of 16°. Thicker implant internal walls result in higher mechanical resistance when compared to implants with thinner internal walls. The relation among implant internal walls and its connection were strategically designed for the Grand Morse™ implants.

FIGURE 2. The connection of the Neodent Grand Morse implant has the same width, regardless of the implant's diameter.

FIGURE 3. Neodent's Grand Morse implant features a deep connection in its interior, designed to increase the contact area between the implant and the prosthetic abutment.

The Grand Morse™ conical connection features an internal hexagon index in the lower portion called the GM Exact. GM Exact is used to surgically position the implant and reposition prosthetic abutments when working at the implant level.

FIGURE 4. Internal hexagon index, created to surgically guide the implant and and position the implant during the prosthetic phase.

The system has a complete portfolio, adapted to the patient's bone density and quality.

	Diameter (mm)						
Implant	3.5	3.75	4.0	4.3	5.0	6.0	7.0
Helix™ GM	✓	✓	✓	✓	✓	✓	✓
Drive GM™	✓			✓	✓		
Titamax GM™	✓	✓	✓		✓		

TABLE 1. Available diameters according to implant design.

Implant	Length												
	7	8	9	10	11	11.5	12	13	14	15	16	17	18
Helix™ GM		✔		✔		✔		✔			✔*		✔*
Drive GM™		✔		✔		✔		✔			✔		✔
Titamax GM™	✔	✔	✔		✔			✔		✔**		✔**	

TABLE 2. Available lengths according to implant design.
*Helix™ Ø6.0 and Ø7.0 mm are not available in lengths 16 or 18 mm.
**Titamax GM Ø5.0 is not available in lengths 15 or 17mm

3.0 IMPLANT DESIGNS

Neodent®'s Grand Morse™ implants are classified according to their macrostructure, screw thread characteristics, apex and microroughness.

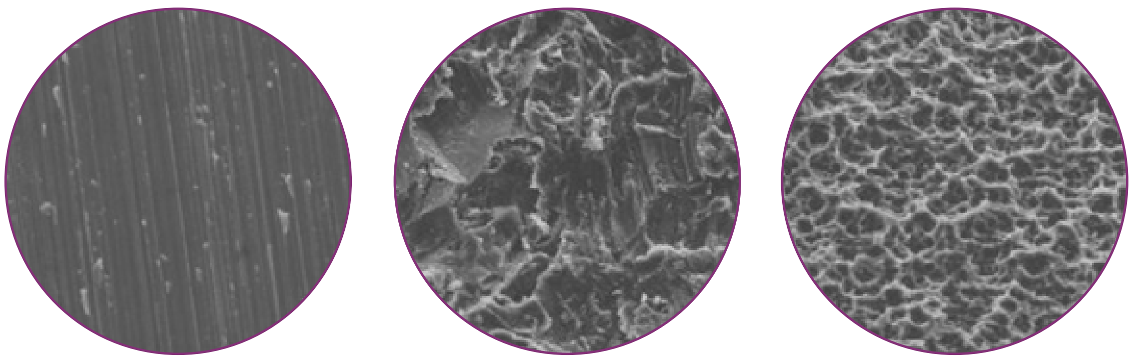
FIGURE 7. General features of Neodent® Grand Morse™ implants.

3.1 Surface

Neodent® implants are available in two types of surface treatment, as shown below. The decision regarding the use of each surface should be guided by the clinical indication.

3.1.1 NeoPoros

NeoPoros is a process specially created for the surface of Neodent implants. First, roughness is obtained by means of sandblasting, in which the particle size and pressure are adjusted to the implant design. After sandblasting, the implant undergoes an acid etching process under specific conditions. Figure 8 shows this procedure.



Machined
Sa= 0.26 µm

Sandblasting
Sa= 0.67 µm

Sandblasting + Acid etching
Sa= 0.93 µm

FIGURE 8. Physical manufacturing process for the Neodent® surface treatment.

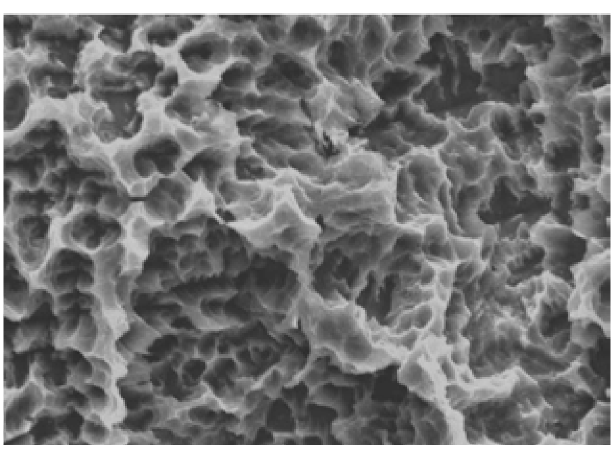


FIGURE 9. Micro (0.3 - 1.3 µm) and macro (15 - 30 µm) roughness for Acqua and NeoPoros.

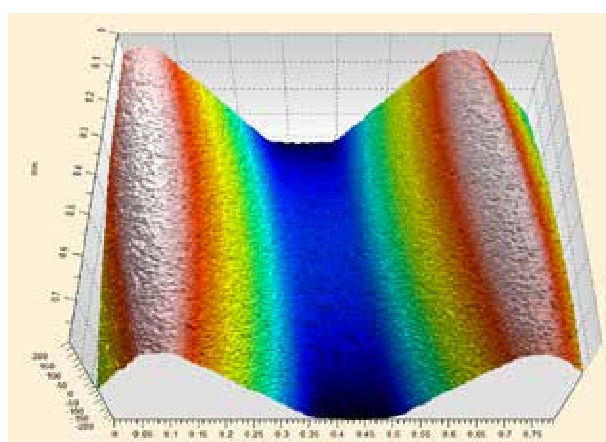


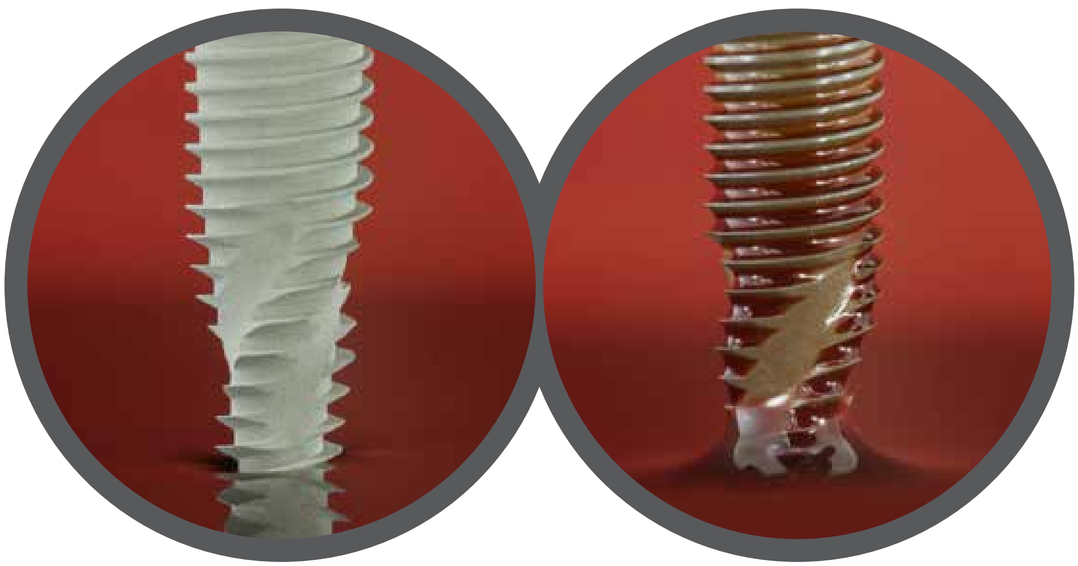
FIGURE 10. Confocal laser scanning microscopy in the screw thread region.[14]

3.1.2 Acqua®

Acqua is a hydrophilic implant with surface-modified titanium. The physical process of the NeoPoros surface is performed on the Acqua implants; however, the Acqua surface is obtained in a special area of the production center where all the implants are packaged and stocked in liquid thus preventing contact with the atmosphere. This isolation results in wettability (presenting a contact angle <5°) and a polarized surface with positive ions[14].

The hydrophilic surface (Figure 9) presents a smaller contact angle when in contact with organic fluids. This provides greater accessibility of blood to the implant surface[14]. A rabbit-femur model animal study demonstrates that Titamax CM implants with a Acqua surface achieves the same bone-implant-contact and bone area fraction occupied more quickly than a Titamax CM implant with a NeoPoros surface. This preclinical testing is not correlated to long term clinical outcomes.

Comparison between Surfaces



NeoPoros Surface

Acqua Hydrophilic Surface

FIGURE 11. Comparison between NeoPoros surface and the Acqua hydrophilic surface.

Note: Chemical composition analysis of the Acqua and NeoPoros surfaces using the XPS method

	NeoPoros (Atom %)	Acqua (Atom %)
Oxygen O	55.9 ± 0.9	59.3 ± 0.2
Titanium Ti	21.1 ± 0.7	22.7 ± 0.3
Nitrogen N	0.4 ± 0.6	0.6 ± 0.4
Carbon C	22.7 ± 2.0	15.3 ± 1.0

3.2 Implant Options

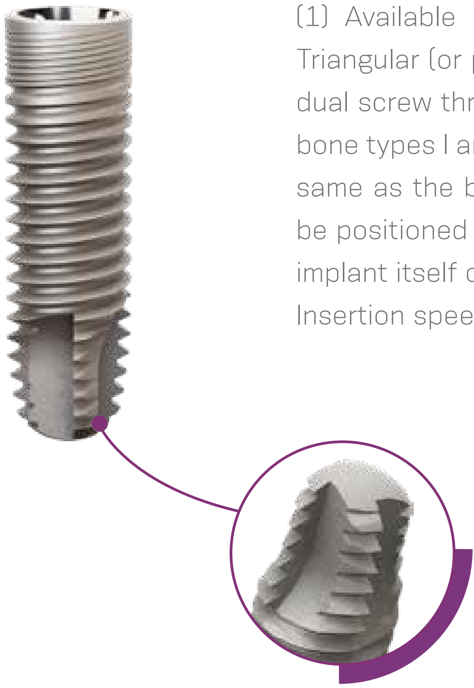
3.2.1 Helix GM™

(1) Available in the Acqua surface; (2) Tapered implant; (3) Compacting trapezoidal screw threads with a thread pitch from 1.2 to 1.5 mm (depending on the implant diameter); (4) Implant with dual screw threads (5) Conical apex with low-activity chambers and helicoidal chambers; (6) Indicated for all bone density types and post-extraction placement; (7) A tapered contour drill is required if used in bone types I and II; (8) Same prosthetic connection for all implant diameters; (9) Final pilot drills are highly recommended for bone types I and II; (10) The implant should be positioned 1-2 mm below bone level (11) Drilling speed: 800-1200 rpm for bone types I and II; (12) Drilling speed: 500-800 rpm for bone types III and IV; (13) Insertion speed: 30 rpm; (14) Maximum insertion torque: 60 Ncm.

3.2.2 Drive GM™

(1) Available in Acqua surface; (2) Implant with conical central core; (3) Main screw threads have a square format with a thread pitch of 2.2 mm; (4) Implant with dual thread (5) Counterclockwise cutting chambers distributed throughout the implant body; (6) Lower portion of the screw thread with cutting edge; (7) Round apex; (8) Indicated for bone types III and IV and immediate placement of a postextraction implant; (9) Same prosthetic connection for all implant diameters; (10) The implant should be positioned 1-2 mm below bone level (11) Drilling speed: 500 - 800 rpm; (12) Insertion speed: 30 rpm; (13) Maximum insertion torque: 60 Ncm.

3.2.3 Titamax GM™



(1) Available in the Acqua surface; (2) Implant with parallel walls (cylindrical); (3) Triangular (or pyramidal) screw threads with a thread pitch of 1.2 mm; (4) Implant with dual screw thread (5) Active cutting apex with self-tapping chambers; (6) Indicated for bone types I and II and block bone graft areas; (7) The implant's cervical diameter is the same as the body; (8) Final pilot drills are highly recommended as the implant should be positioned 1-2 mm below bone level (9) The use of tap drill is not necessary as the implant itself cuts the bone during placement; (10) Drilling speed: 800 - 1200 rpm; (11) Insertion speed: 30 rpm; (12) Maximum insertion torque: 60 Ncm.

	Bone Density			
Implant	Bone type I	Bone type II	Bone type III	Bone type IV
Helix GM™ Acqua / Neoporos	✔*	✔*	✔	✔
Drive GM™ Acqua / Neoporos	-	-	✔	✔
Titamax GM™ Acqua / Neoporos	✔	✔	-	-

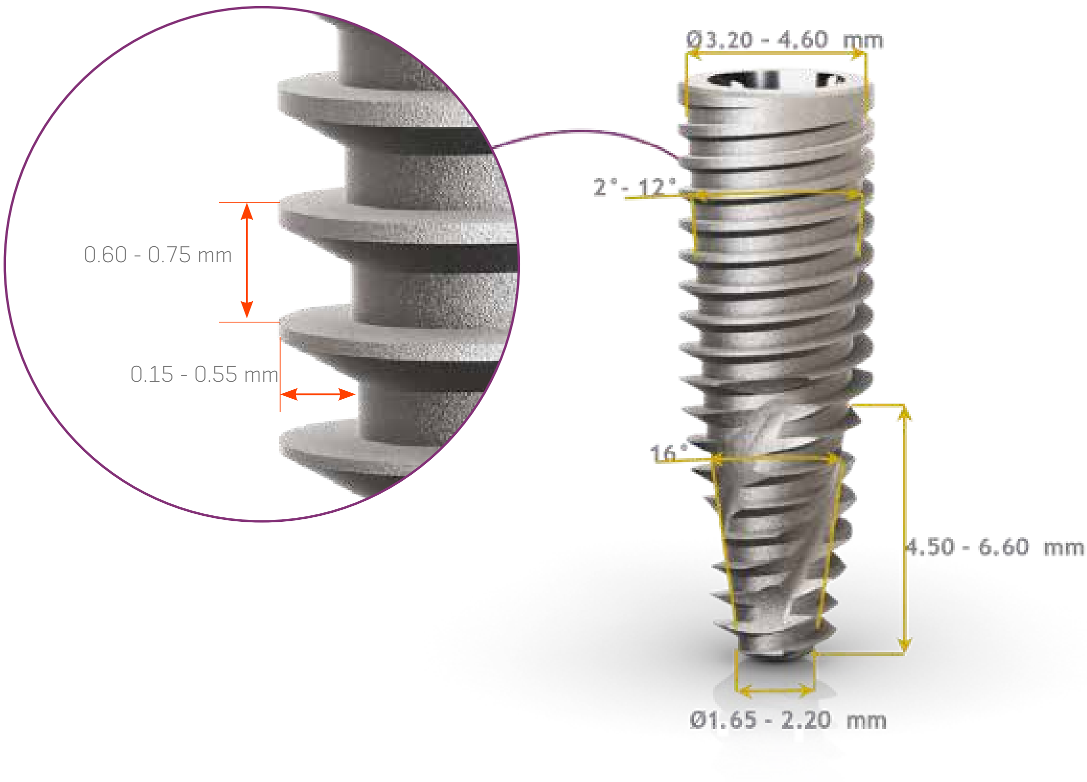
TABLE 3. Summary of the implant indication according to bone type (Lekholm and Zarb, 1985).

*Helix® Ø 6.0mm and Ø 7.0mm are contraindicated for healed bone bed with I/II quality. Conical contour drill is required

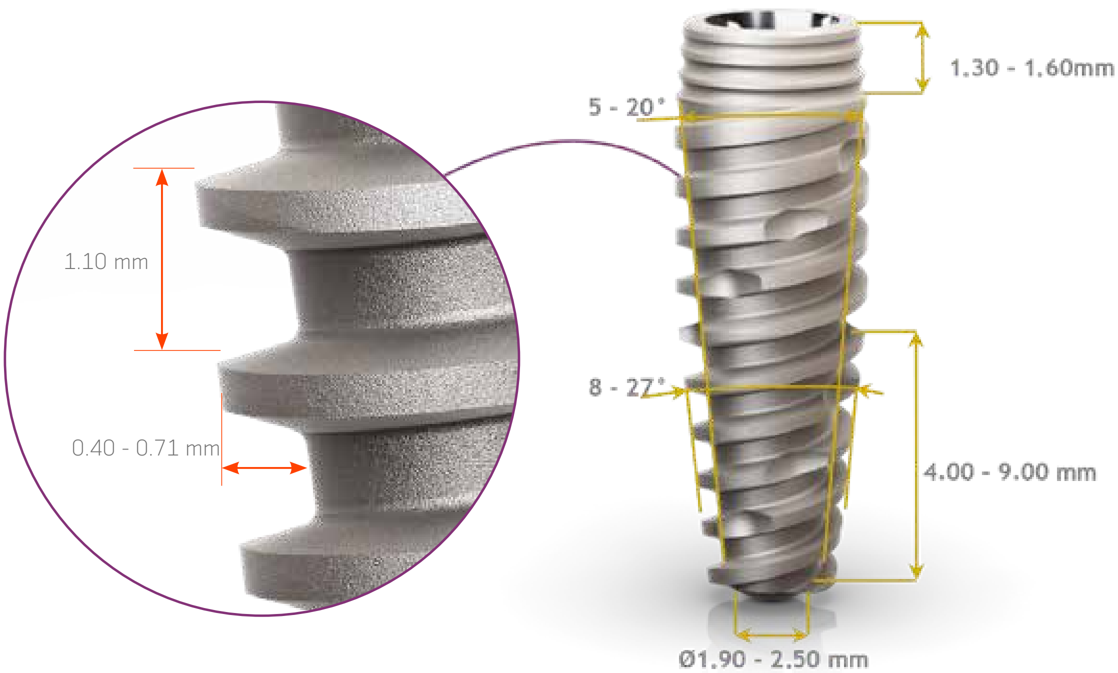
3.3 Options for Screw Threads and Overview of the Format According to Implant Design

*There are variations due to the length and diameter options for the implant.

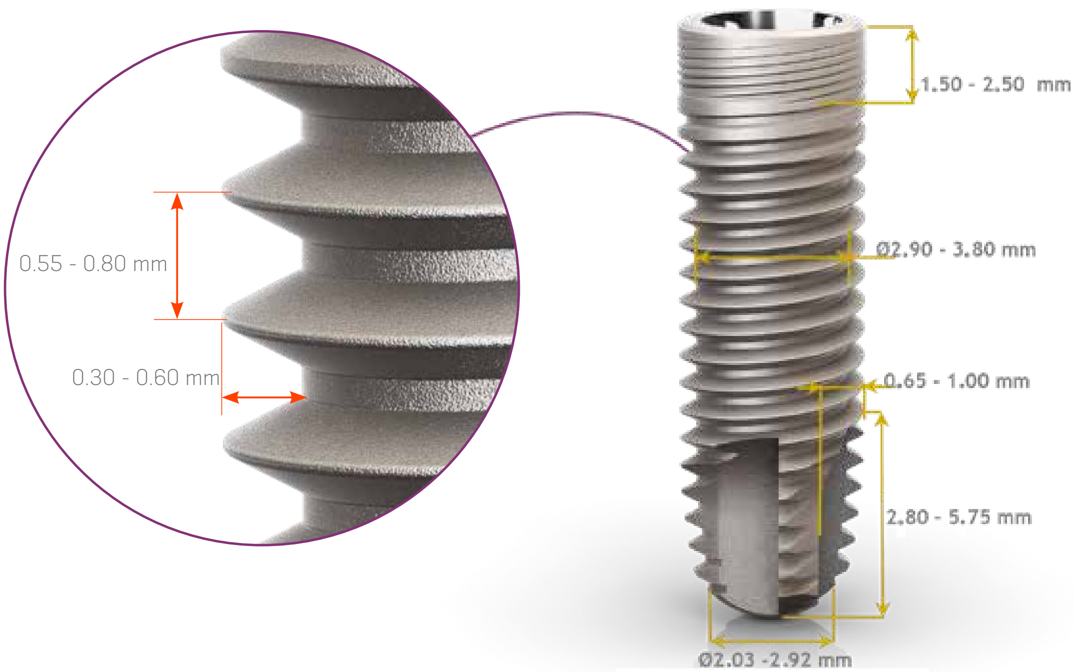
Helix™ GM™:



Drive GM™:



Titamax GM™:



4.0 APPLICATIONS

Neodent® implants are manufactured with cold-worked grade 4 titanium to support the product's mechanical resistance. All posts and abutments are made of titanium alloy (TAV). The following table lists the specific measurements for these items.

Implant	Application	Minimum width of alveolar ridge*	Minimum width of the gap**	Available lengths
 Helix GM™	Placement in bone types III and IV (with the possibility of sub-instrumentation), I and II with use of a tapered contour drill. The GM Helix Implant in diameters 6.0 and 7.0 is an exception, being indicated only for bone type III or IV.	5.5 mm	5.5 mm	8/10/11.5/13/ 16***/18*** mm
 Drive GM™	Bone tissue with density III or IV, postextraction placement and in regions grafted with biomaterial.	5.5 mm	5.5 mm	8/10/11.5/13/16/18 mm
 Titamax GM™	Bone tissue with density type I or II, placement in block graft area.	5.5 mm	5.5 mm	7/8/9/11/13/15/17 mm

Note: Bone types according to Lekholm & Zarb's jawbone quality classification (1985)

*Minimum width of the alveolar ridge: minimum buccal-lingual width of the alveolar ridge, rounded to 0.5 mm.
**Minimum width of the gap: minimum mesiodistal width of a single tooth gap restoration, between adjacent teeth, rounded to 0.5 mm.
***Helix® Ø6.0 and Ø7.0 mm are not available in lengths 16 or 18 mm are contraindicated for healed bone bed with I/II quality.

For more information on indications and contraindications for each implant, consult the corresponding instructions for use. The instructions can also be found at ifu.neodent.com.br.

5.0 PREOPERATIVE PLANNING

5.1 Implant positioning and peri-implant tissue

Positioning of the implant is the key for obtaining the correct positioning of the prosthetic restoration and is the basis for the surgical plan. Proper communication between the patient, surgeon, restorative doctor and dental tehnician is essential for achieving the desired prosthetic results.

To establish the correct plan, with proper spatial positioning and design choice (diameter and length) and the correct number and distribution of implants, the following steps are recommended:

- Perform the wax-up in the patient's study model.
- Define the edentulous gap to be restored.
- Define the type of superstructure.
- Perform computer-aided tomography and radiography.
- Perform intraoral or model scanning

The wax-up can be used to make the radiographic and/or surgical guide and the provisional restoration. Physiological occlusion is essential for the short- and long-term success of the implant. Immediate loading procedures should not be performed on patients with occlusion problems.

Notes: Prosthetic abutments should always receive axial loads, and the implant's long axis should be aligned with the cusps of the opposing teeth. The extreme anatomy of the cusps should be avoided, because it can lead to pathological overload.

The diameter, type, position and number of implants should be decided on an individual basis for each patient, taking into consideration the anatomy and prosthetic gap. Poorly positioned or angled teeth should be considered and analyzed. The recommendations in these guidelines should be considered a basic guide for proper biological healing, adequate restorations and for the patient to have efficient hygiene in that area. The design of the restoration has a strong effect on occlusion and hygiene and should be considered.

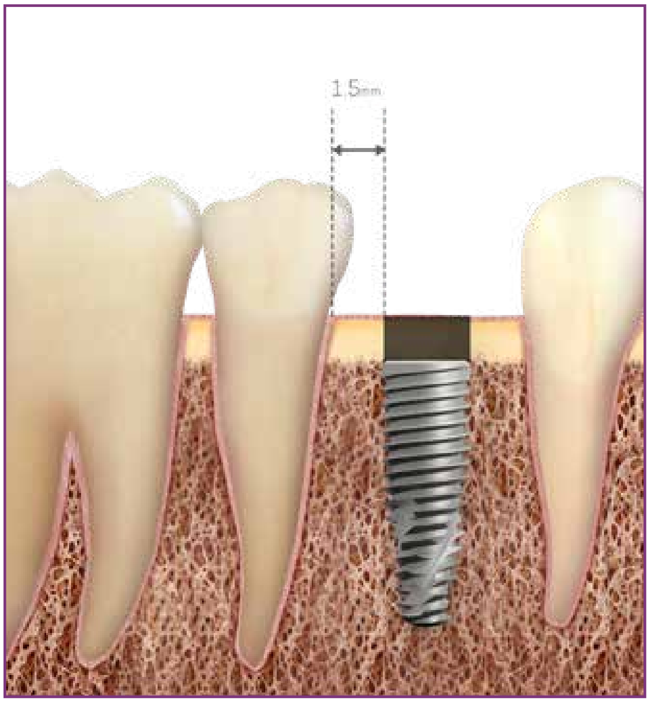
The final response of soft and hard tissue is highly influenced by the position of the abutment; therefore, three-dimensional positioning of the implant needs to be studied and consists of the following:

- Mesiodistal
- Vestibulolingual
- Cervicoapical

5.1.1 Mesiodistal positioning of the implant

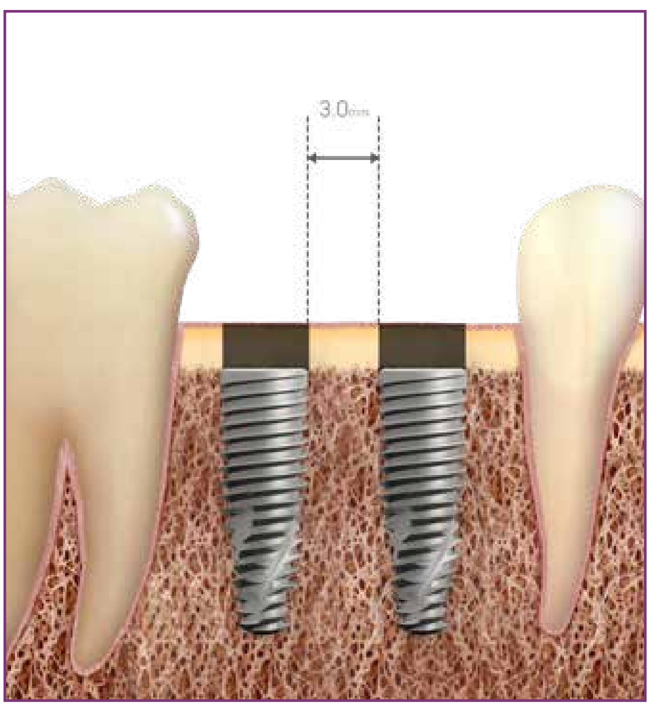
The mesiodistally available bone is an important factor in choosing the diameter and number of implants. The mesiodistal gap is the distance between the implant and the teeth or between implants, when multiple implants are necessary. The point of reference is the measurement of the largest mesiodistal width of the implant, usually in the cervical regions. Implants generally require a minimum of adjacent bone surrounding them of 1.5 mm. The distances listed here are rounded to a minimum of 0.5 mm of bone. However, in preclinical studies, Cone Morse implants placed below bone level present bone and soft tissue maintenance up to an interimplant distance of 2.0 mm.[9]

The basic rules are as follows:



Rule 1

Ideally, the distance from the implant to the adjacent teeth should be at least 1.5 mm between the largest portion of the implant and the teeth, in both the mesial and distal aspects.



Rule 2

Given that the implants require a minimum adjacent bone of 1.5 mm, the minimum distance to other implants is 3.0 mm.

5.1.1.1 Examples of single teeth gaps

For single tooth restorations, the implant should be placed in the center of the gap. The following example shows how to follow Rule 1.

For all Neodent® Grand Morse™ implants, the gap size needs to be considered when selecting the implant diameter. To position an implant within the gap according to Rule 1, the following aspects may be used as an approximation:

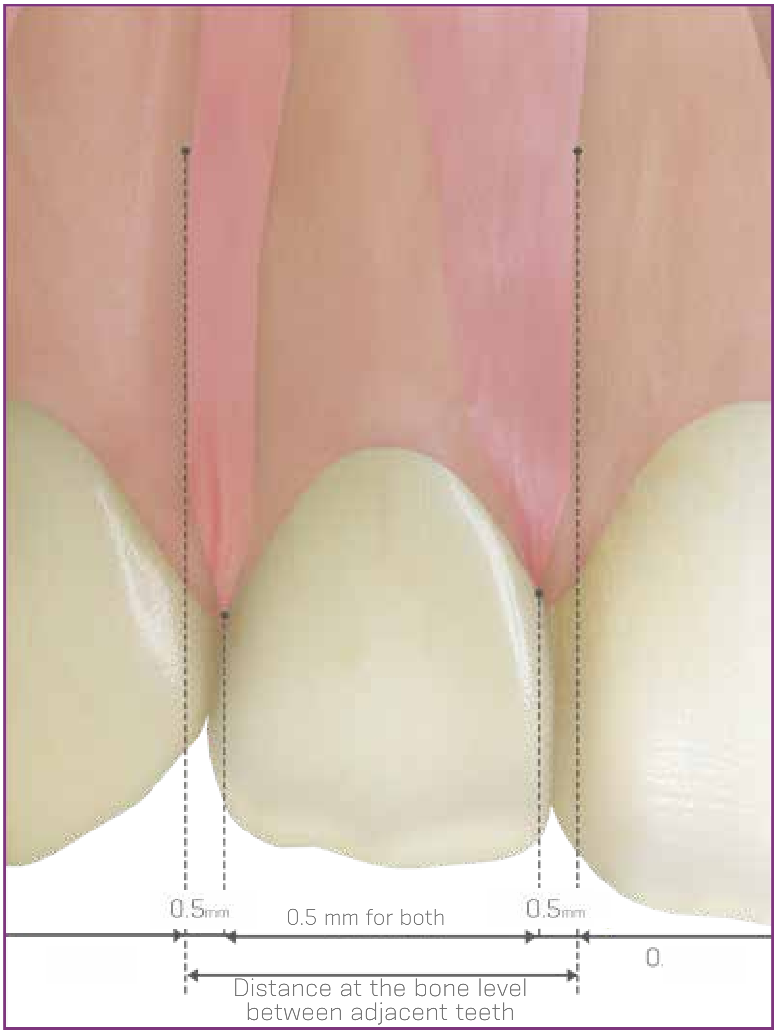
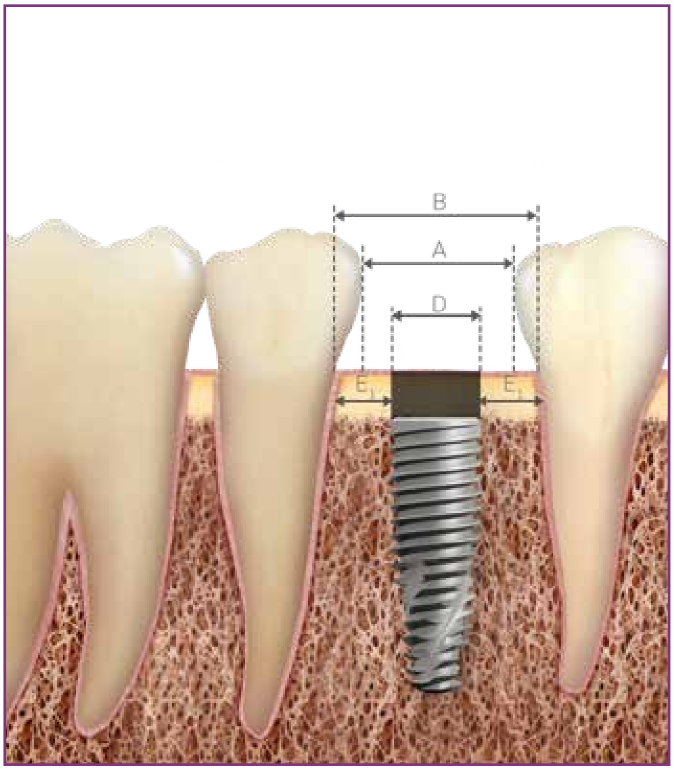


FIGURE 12. The distance between adjacent teeth is approximately 1.0 mm greater at the bone level due to the dental anatomy and the interproximal contact point, when compared with the actual bone width of the gap (2 x 0.5 mm). Therefore, applying Rule 1, the gap must be 2.0 mm wider than the width of the implant.

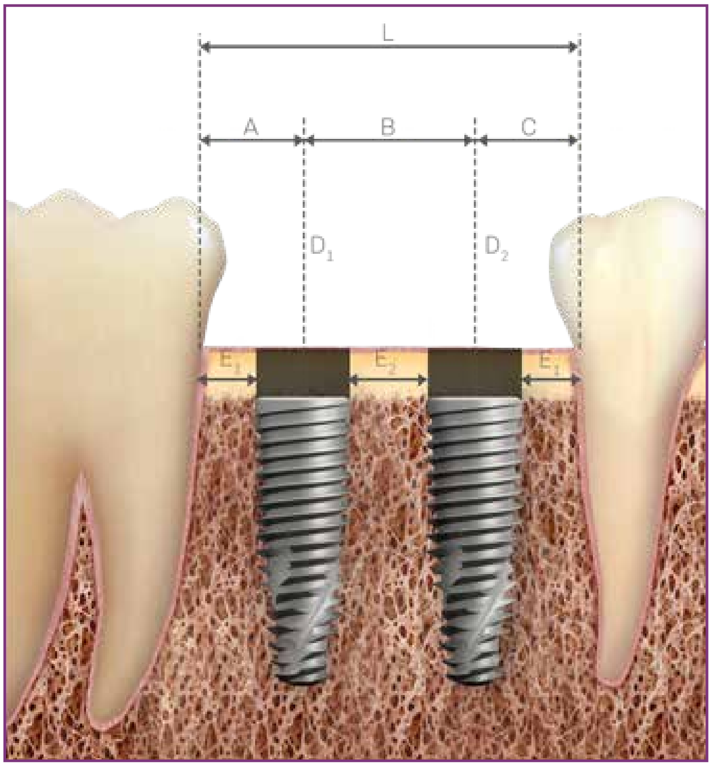


D - Diameter of the Implant (mm)	A - Width of the Gap (mm)	B - Distance between the adjacent teeth at the bone level (mm)	E_1 - Tooth-implant distance (mm)
3.5	5.5	6.5	1.5
3.75	5.75	6.75	
4.0	6.0	7.0	
4.3	6.3	7.3	
5.0	7.0	8.0	
6.0	8.0	9.0	
7.0	9.0	10.0	
Rule	D + 2 mm	D + 3 mm*	

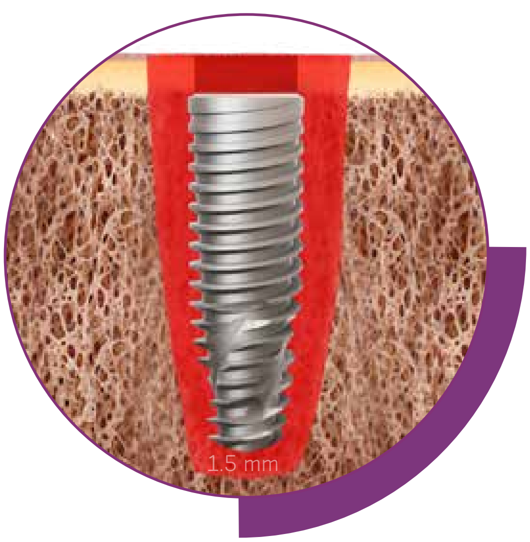
*Rule 1 applied on both sides of the implant.

5.1.1.2 Examples of multiple teeth gaps

The examples below show how Rules 1 and 2 are applied to multiple tooth gaps. The measurements are performed in the bone crest of the tooth adjacent to the center of the implant and between the centers of the implants. The center of the implant should be considered due to the initial drilling during the osteotomy. The minimum distance of 3 mm should be followed between the cervical regions of the implants (Rule 2), which is important for flap closure, to avoid proximity of the abutments and provide adequate space for maintenance, emergency restoration profile and oral hygiene.



D_1 - Diameter of the Implant (mm)	D_2 - Diameter of the Implant (mm)	A	B	C	L	E_1 - Tooth-implant distance (mm)	E_2 - Implant-implant Distance (mm)
3.5	3.5	3.3	6.5	3.3	13	1.5	3.0
3.75	3.75	3.4	6.8	3.4	13.5		
4.0	4.0	3.5	7.0	3.5	14		
4.3	4.3	3.7	7.3	3.7	14.6		
5.0	5.0	4.0	8.0	4.0	16		
6.0	6.0	4.5	9.0	4.5	18		
7.0	7.0	5.0	10.0	5.0	20		



Normally, clinical cases have different gaps and consequently D_1/D_2 can be different. The implants should therefore be adapted for each situation. In search of a simpler rule, the dentist should consider that each implant requires a minimum of 1.5 mm of adjacent bone, regardless of the implant's diameter. Therefore, during planning, we need to remember that regardless of the implant diameter, it is important to have a minimum of 1.5 mm of mesial and distal peri-implantation bone.

5.1.2 Buccal-lingual implant position

The buccal and palatal bone plate should be at least 1 mm thick to ensure the stability of the bone tissue and the condition of the soft tissue. The minimum vestibulolingual width for each implant diameter is listed in Table 4. Within this limitation, the vestibulolingual position and the long axis of the implant should be chosen to provide the best possible restorative results. The surgeon also needs to know whether the plan is to place a screw-retained or cement-retained prosthesis.

Warning: Bone graft techniques are highly advisable in the alveolar ridges in which the buccal bone plate is 1 mm thick or less or when bone is lacking on one of the sides. These procedures should be conducted only by surgeons with advanced experience in bone regeneration with grafts.

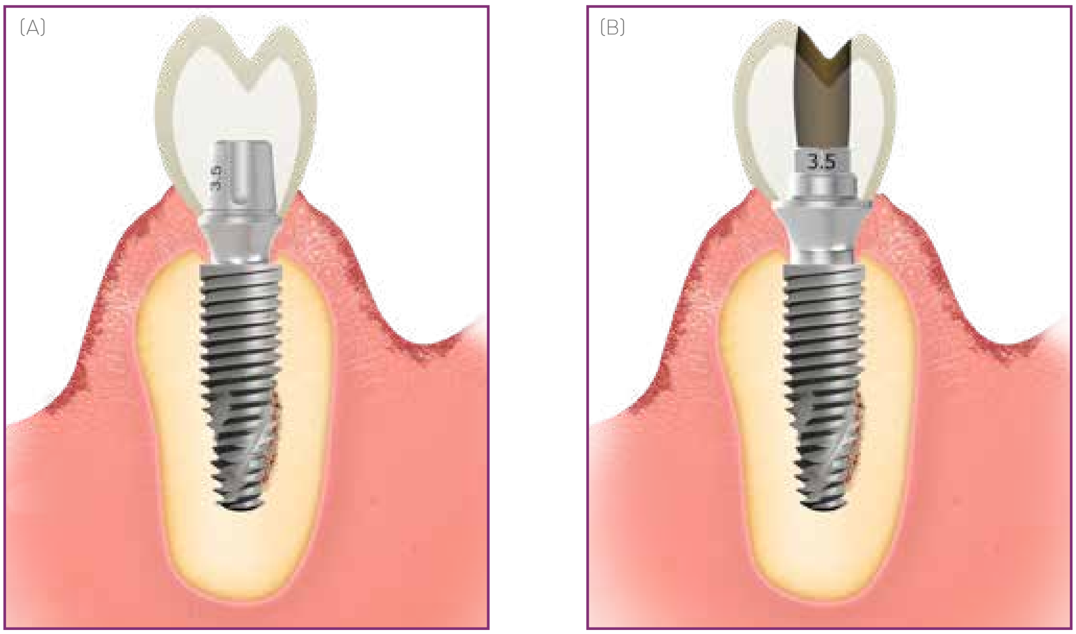
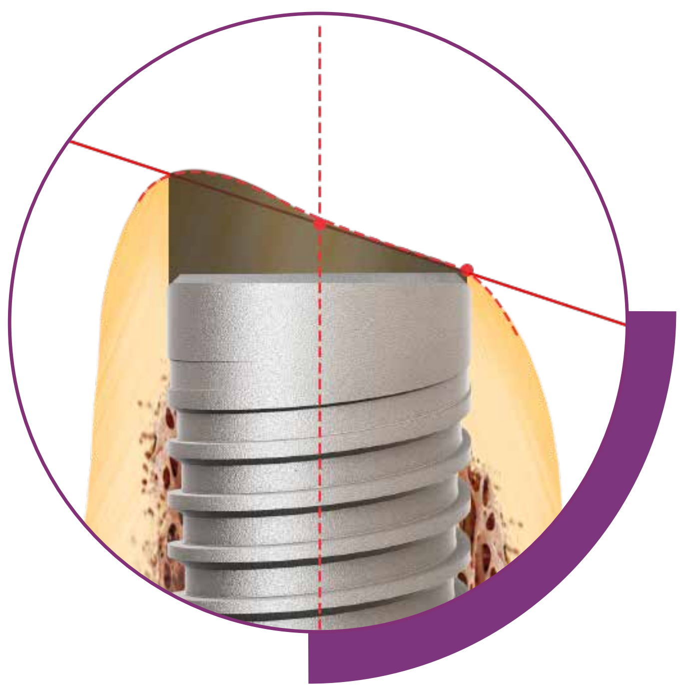


FIGURE 13. Example of implant positioned for cement-retained prosthesis (A) and screw-retained prosthesis (B), where there is access to the retaining screw.

5.1.3 Cervicoapical position of the implant

Neodent® Grand Morse™ implants were developed for 2 mm positioning below bone level to optimize the stability of hard and soft tissue and for better esthetic results of the restorations, especially in the anterior regions.[9,12]



For situations with uneven ridges, position the implant at the bone level corresponding to the most apical bone wall. Depending on the clinical case, some osteotomy might be required, given that the abutments have limitations in the transmucosal height. The implant should be completely covered with bone or graft with biomaterials to prevent titanium dehiscence.

5.2 Planning Aids

5.2.1 Space Planning Instrument for assisting in the diagnosis and positioning of implants

When using the 7/9 mm Space Planning Instrument in the patient's mouth or in the study model, an initial analysis of the spatial relationships can be performed, in order to select the implant diameter and the prosthetic reconstruction. The Space Planning Instrument has two ends measuring 7 and 9 mm in diameter, with a mark exactly in the middle of each end (3.5 and 4.5 mm); this serves as a reference for the surgeon to position the implant, respecting the rule of a 1.5 mm minimum adjacent peri-implant bone thickness.

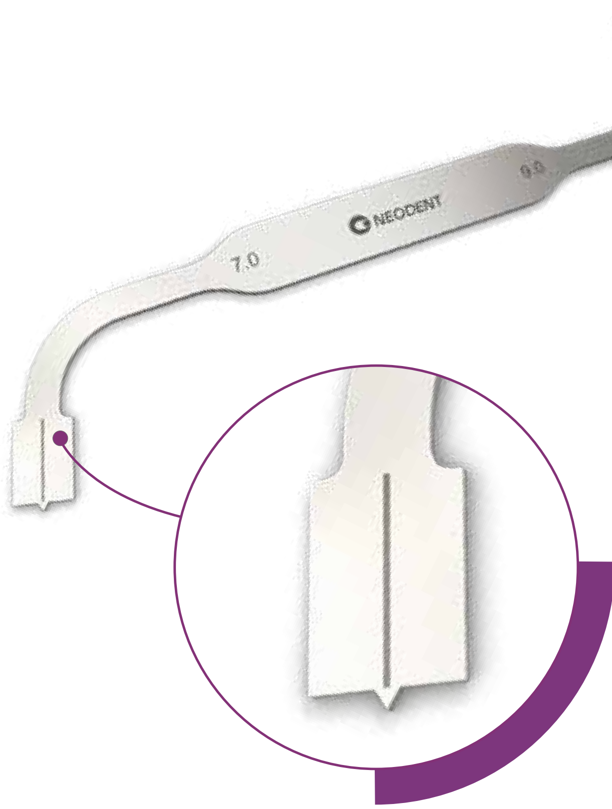


FIGURE 14. Diagnostic Space Planning Instrument for gaps and positioning of implants.

FIGURE 15. Close-up of the 7-mm end of the Space Planning Instrument for analyzing the gaps. The mark is 3.5 mm from the edge.

The 1.5-mm rule is important for placing the implant based on the position of the teeth, implants and anatomical structures, such as nerves. The Space Planning Instrument can help with the positioning of an implant close to the foramen.

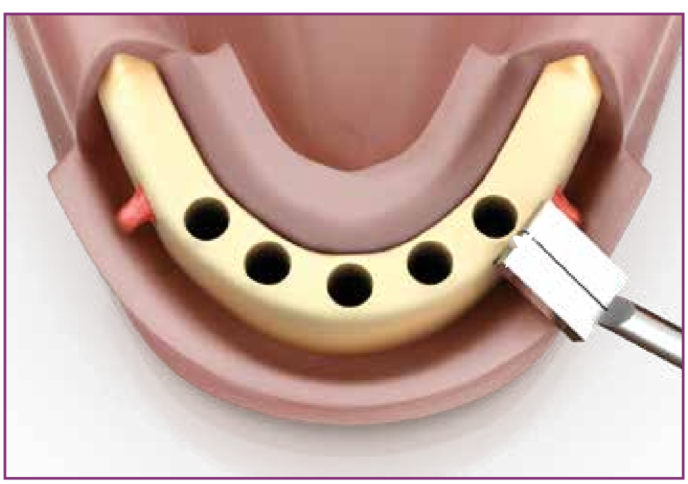


FIGURE 16. Using the Space Planning Instrument for the positioning of the osteotomy for implant placement.

5.2.2 Direction indicators for orientation of angulation and positioning

All Neodent® Direction Indicators have different dimensions for analyzing the amount of bone surrounding the osteotomy. All indicators have the following parts: (1) lower, (2) middle and (3) upper.

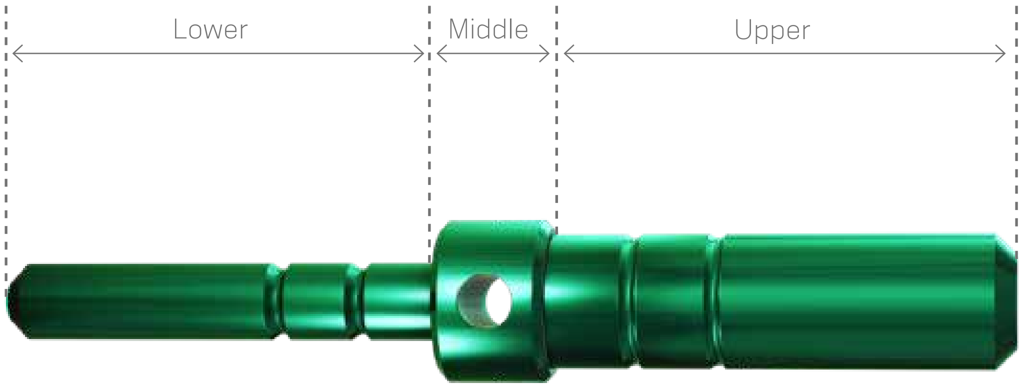


FIGURE 17. The lower (2 mm), middle (diameter of the implant) and upper (diameter of the last drill used in the basic osteotomy) parts of the Direction Indicator.

The lower part of all Direction Indicators are 2.0 mm in diameter, to be adjusted after the initial osteotomy. The middle part of the Direction Indicator has the diameter of the respective implant. All diameters are color coded and are listed in Table 4.

	Diameter	
Direction Indicators	Middle	Upper
	3.5	2.8
	3.75	3.0
	4.0	3.3
	4.3	3.6
	5.0	4.3

TABLE 4. Options for Colored Direction Indicators. The center part of the direction indicator has the same width as the implants, based on the measurements marked on the upper part.

The upper part of each direction indicator has the same diameter as the last drill used before the placement of the implant, according to the Neodent® osteotomy protocols. The positioned Direction Indicator allows the surgeon to check the adjacent bone, as illustrated below.

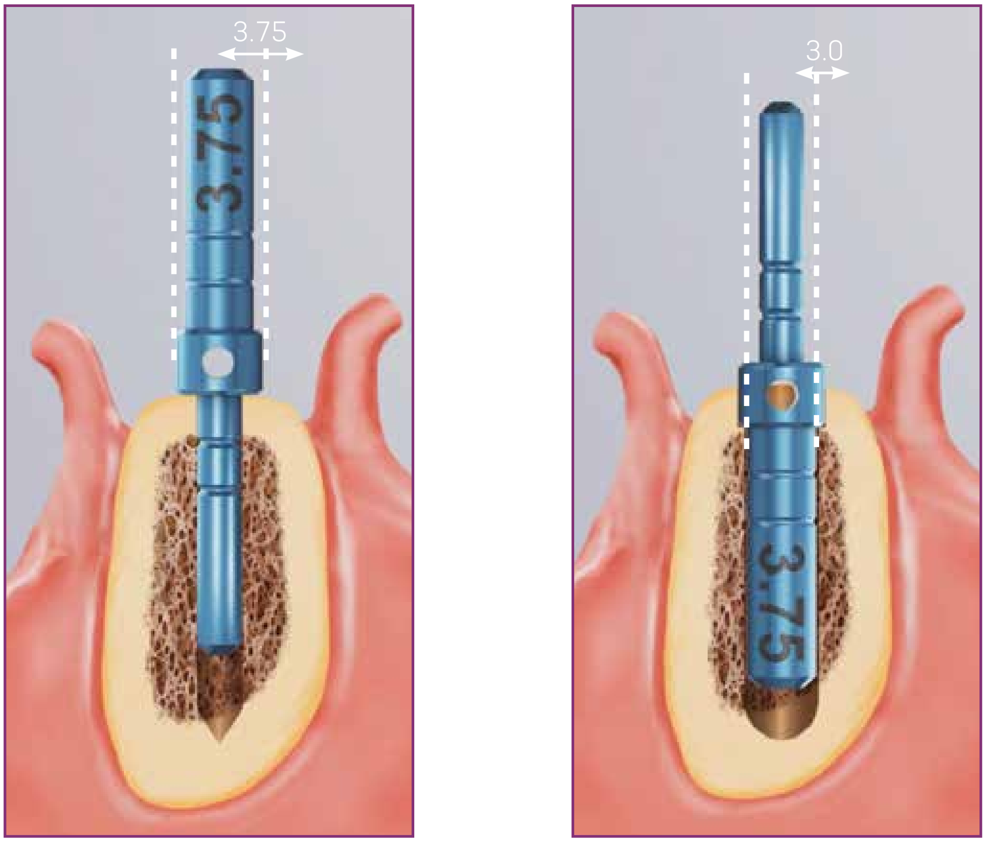


FIGURE 18. Direction Indicator inserted after the initial drilling and fitted inside the osteotomy according to the drill protocol. The indicator helps analyze the remaining adjacent bone when positioned.

There are also angle measurement guides that help the surgeon assess the angulation of abutments before the implant placement. These measurement guides are available in two angles (17° and 30°) and are inserted in the 2.0 mm osteotomy.

FIGURE 19. Angle measurement guides for selecting abutments.

Notes: The Titanium Tweezers have a ruler at the apex.

FIGURE 20. Titanium tweezers calibrated in millimeters.

5.2.3 Surgical drill guide

A customized surgical guide produced by the dental laboratory facilitates the preparation of the implant bed, enabling the precise use of cutting instruments. The basis for the manufacture of this guide should be the desired prosthetic results.

The study models can be drilled with 2.0 mm drills in the position of the implant, and guides for the 2.0 mm diameter pins are fitted on the perforations. Guides manufactured with wax or vacuum-formed are built with the pins positioned in their interior. Once the surgical guide has been made aseptic, it can be used during surgery, and its guides will direct the initial drilling of the surgical procedure.

FIGURE 21. 2.0 mm diameter guides and pins to be fitted in the patient’s study model.

6.0 SURGICAL PROCEDURES

6.1 Implant bed preparation

The diameter, position and number of implants should be selected based on the anatomy and spatial circumstances. The measurements should be performed according to the basic guidelines.

The basic preparation of the implant bed involves preparing the ridge and perforating it with a twist drill under irrigation, for which the diameter and design (if cylindrical or conical) of the selected implant will determine the instruments to be used.

The refined implant bed preparation involves the instruments that conform to the emergence profile and the bone. For this, the implant type and bone density determine the instruments to be used.

Steps	Instruments
1. Basic implant bed preparation	
Preparation of the ridge	Initial Drill
Twist drilling	2.0 mm twist drill; Direction Indicator; Depth Gauge with millimeter markings
2. Refined implant bed preparation	
Conical or cylindrical drills and bone profile drills	Drill format is defined according to the implant design, and the sequence and diameter defined by its width
Tapered Contour Drill	For Helix GM™ in bone types I and II

Note: The Titamax GM™, Helix GM™ and Drive GM™ implants can be placed using the same surgical kit (110.302).

6.1.1. Basic implant bed preparation

After opening the flap and exposing the bone tissue, the preparation of the alveolar ridge begins. Once the implant's position has been established with the aid of surgical guides, the cervical cortical layer is drilled with the Initial Drill (step 1), and the spatial positioning of the implant is checked visually with the direction indicator. The indicated number of rotations per minute (rpm) for drilling is based essentially on bone density, whereby 800-1200 rpm will be applied in bone types I and II, and 500-800 rpm in bone types III and IV. Subsequently, the 2.0 mm twist drill is used to establish the desired height for the selected implant, always keeping in mind that the placement of the Grand Morse™ implant is 1-2 mm below bone level. Consequently, a subsequent drill is employed to prepare the osteotomy, following the sequence based on the implant type and diameter, as chosen in the preoperative plan. All drills are fitted to the contra-angle handpiece according to ISO 1797-1 – Dentistry – Shanks for rotary instruments.

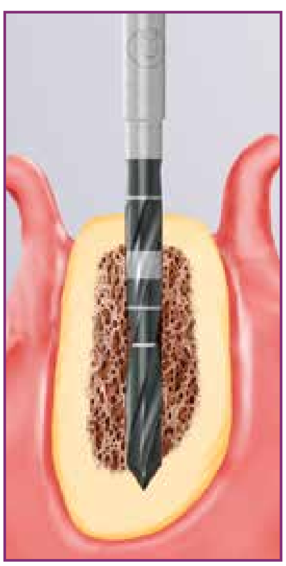
Step 1 – Preparing the site of the implant and initial drilling with the Initial Drill

Carefully reduce and regularize the bone surface before marking the position of the implant with the initial drill. Insert the initial drill to approximately 5-7 mm with a drill speed consistent with the bone density.

Note: Bone reduction/preparation should be considered in the preoperative plan, because it affects the choice of implant diameter and length.

Step 2 – Checking the long axis of the implant

After using the initial drill, check the long axis of the implant using the direction indicator. The implant diameters and measurements of adjacent bone can be checked as described in 3.2.2.



Step 3 – Twist Drill 2.0

Use the 2.0 mm twist drill to reach the planned drilling length. Use of the depth gauge is recommended for controlling the depth.

Note: 1 – Periapical radiography is recommended at this point to check for available vertical bone or to verify the long axis of the drilling in relation to the adjacent roots, for example. The Direction Indicator should be completely inserted into the instrumented area, allowing for visualization of the entry of the drilling in relation to the anatomical structures.

2 – The 2.0 mm Neodent® twist drill has an active apex that can be used as an initial drill. For flat bony ridges, this drill can replace the initial drill.

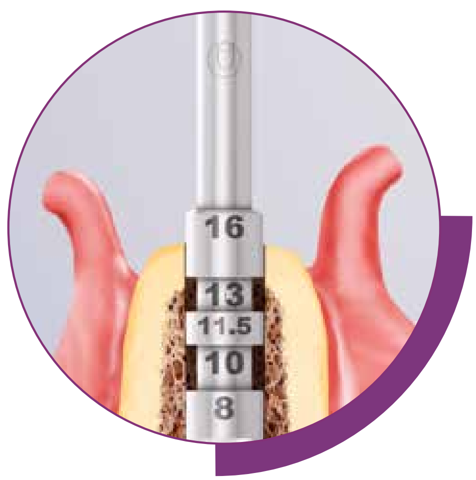
6.1.1.1 Implant bed preparation for Helix GM™ tapered implants

	Initial 103.170	Ø 2.0 103.425	Ø 3.5 103.561	Ø 3.5+ 103.578	Ø 3.5 103.513	Ø 3.75 103.564	Ø 3.75+ 103.579	Ø 3.75 103.514	Ø 4.0 103.567	Ø 4.0+ 103.580	Ø 4.0 103.515	Ø 4.3 103.570	Ø 4.3+ 103.581	Ø 4.3 103.516	Ø 5.0 103.573	Ø 5.0+ 103.582	Ø 5.0 103.517	Ø6.0 103.576	Ø 7.0 103.577
Ø 3.5	✓*	✓		✓	✓														
Ø 3.75	✓*	✓	✓				✓	✓											
Ø 4.0	✓*	✓	✓			✓				✓	✓								
Ø 4.3	✓*	✓	✓			✓			✓				✓	✓					
Ø 5.0	✓*	✓	✓			✓			✓*			✓				✓	✓		

*Optional / Bone types I and II

	Initial 103.170	Ø 2.0 103.425	Ø 3.5 103.561	Ø 3.5+ 103.578	Ø 3.5 103.513	Ø 3.75 103.564	Ø 3.75+ 103.579	Ø 3.75 103.514	Ø 4.0 103.567	Ø 4.0+ 103.580	Ø 4.0 103.515	Ø 4.3 103.570	Ø 4.3+ 103.581	Ø 4.3 103.516	Ø 5.0 103.573	Ø 5.0+ 103.582	Ø 5.0 103.517	Ø6.0 103.576	Ø 7.0 103.577
Ø 3.5	✓*	✓	✓																
Ø 3.75	✓*	✓	✓			✓*													
Ø 4.0	✓*	✓	✓						✓*										
Ø 4.3	✓*	✓	✓			✓						✓*							
Ø 5.0	✓*	✓	✓									✓			✓*				
Ø 6.0	✓*	✓	✓			✓						✓			✓			✓	
Ø 7.0	✓*	✓	✓									✓			✓			✓	✓*

*Optional / Bone types III and IV



Note: Periapical radiography is recommended after the use of tapered drills to check for available bone or to verify the long axis of the drilling in relation to the adjacent roots. A radiographic positioner should be inserted in the osteotomy.

Instruments for basic bone implant preparation					Diameters (mm)				
Step	Code	Product	Max. RPM	Image	Ø 3.5	Ø 3.75	Ø 4.0	Ø 4.3	Ø 5.0
1 – Prepare the implant bed and initial drilling	103.170	Initial Drill	1200		Optional	Optional	Optional	Optional	Optional
2 – Check the long axis of the implant	128.019	Direction indicator 2.8/3.5	–						
3 – Taperd Drill 2.0*	103.425	Tapered Drill 2.0	1200						
4 – Tapered 3.5	103.561	Tapered Drill 3.5	1200		–				
	103.578	Tapered Contour Drill 3.5	1200			–	–	–	–
	128.019	Direction indicator 2.8/3.5	–			Optional	Optional	Optional	Optional
	129.009	Tapered X-Ray Positioner 3.5	-			Optional	Optional	Optional	Optional
5 – Pilot Drill 2.8/3.5	103.513	Pilot Drill 2.8/3.5	1200			–	–	–	–
6 – Tapered 3.75	103.564	Tapered Drill 3.75	1200			–			
	103.579	Tapered Contour Drill 3.75	1200				–	–	–
	128.020	Direction indicator 3.0/3.75	-				Optional	Optional	Optional
7 – Pilot Drill 3.0/3.75	103.514	Pilot Drill 3.0/3.75	1200				–	–	–
8 – Tapered 4.0	103.567	Tapered Drill 4.0	1200				–		Optional
	103.580	Tapered Contour Drill 4.0	1200					–	–
	128.021	Direction indicator 3.3/4.0	-					Optional	Optional
9 – Pilot Drill 3.3/4.0	103.515	Pilot Drill 3.3/4.0	1200					–	–
10 – Tapered 4.3	103.570	Tapered Drill 4.3	1200					–	
	103.581	Tapered Contour Drill 4.3	1200						–
	128.022	Direction indicator 3.6/4.3	-						
	129.013	Tapered X-Ray Positioner 4.3	-						Optional
11 – Pilot Drill 3.6/4.3	103.516	Pilot Drill 3.6/4.3	1200						–
12 – Tapered 5.0	103.573	Tapered Drill 5.0	1200						–
	103.582	Tapered Contour Drill 5.0	1200						
	128.023	Direction indicator 4.3/5.0	-						
	129.014	Tapered X-Ray Positioner 5.0	-						
13 – Pilot Drill 4.3/5.0	103.517	Pilot Drill 4.3/5.0	1200						

*The sequence can be started directly with the 2.0 drill if the bone bed is flat.

Instruments for basic bone implant preparation					Diameters (mm)						
Step	Code	Product	Max. RPM	Image	Ø 3.5	Ø 3.75	Ø 4.0	Ø 4.3	Ø 5.0	Ø 6.0	Ø 7.0
1 – Prepare the implant bed and initial drilling	103.170	Initial Drill	800		Optional	Optional	Optional	Optional	Optional	Optional	Optional
2 – Check the long axis of the implant	128.019	Direction indicator 2.8/3.5	–								
3 – Taperd Drill 2.0*	103.425	Tapered Drill 2.0	800								
4 – Tapered 3.5	103.561	Tapered Drill 3.5	800								
	103.578	Tapered Contour Drill 3.5	800		–	–	–	–	–	–	–
	128.019	Direction indicator 2.8/3.5	–			Optional	Optional	Optional	Optional	Optional	Optional
	129.009	Tapered X-Ray Positioner 3.5	-			Optional	Optional	Optional	Optional	Optional	Optional
5 – Pilot Drill 2.8/3.5	103.513	Pilot Drill 2.8/3.5	800			–	–	–	–	–	–
6 – Tapered 3.75	103.564	Tapered Drill 3.75	800			Optional	–		–		–
	103.579	Tapered Contour Drill 3.75	800			–	–	–	–	–	–
	128.020	Direction indicator 3.0/3.75	-				–	Optional	Optional	Optional	Optional
7 – Pilot Drill 3.0/3.75	103.514	Pilot Drill 3.0/3.75	800				–	–	–	–	–
8 – Tapered 4.0	103.567	Tapered Drill 4.0	800				Optional	–	–	–	–
	103.580	Tapered Contour Drill 4.0	800				–	–	–	–	–
	128.021	Direction indicator 3.3/4.0	-					Optional	–	–	–
9 – Pilot Drill 3.3/4.0	103.515	Pilot Drill 3.3/4.0	800					–	–	–	–
10 – Tapered 4.3	103.570	Tapered Drill 4.3	800					Optional			
	103.581	Tapered Contour Drill 4.3	800					–	–	–	–
	128.022	Direction indicator 3.6/4.3	-						Optional	Optional	Optional
	129.013	Tapered X-Ray Positioner 4.3	-						Optional	Optional	Optional
11 – Pilot Drill 3.6/4.3	103.516	Pilot Drill 3.6/4.3	800						–	–	–
12 – Tapered 5.0	103.573	Tapered Drill 5.0	800						Optional		
	103.582	Tapered Contour Drill 5.0	800						–	–	–
	128.023	Direction indicator 4.3/5.0	-							Optional	Optional
	129.014	Tapered X-Ray Positioner 5.0	-							Optional	Optional
13 – Pilot Drill 4.3/5.0	103.517	Pilot Drill 4.3/5.0	800							–	–
14 – Tapered 6.0	103.576	Tapered Drill 6.0	800								
15 – Tapered 7.0	103.577	Tapered Drill 7.0	800								Optional

*The sequence can be started directly with the 2.0 drill if the bone bed is flat.

6.1.1.2 Implant bed preparation for Drive GM™ tapered implants

	Initial 103.170	Ø2.0 103.425	Ø3.5 103.399	Ø2.8/3.5 103.414	Ø4.3 103.408	Ø3.6/4.3 103.417	Ø5.0 103.411	Ø4.3/5.0 103.418
Ø3.5 mm	✓	✓	✓	Optional				
Ø4.3 mm	✓	✓	✓		✓	Optional		
Ø5.0 mm	✓	✓	✓		✓		✓	Optional

For bone types III and IV

Drive GM™

Instruments for basic bone implant preparation					Diameters (mm)		
Step	**Code**	**Product**	**Max. RPM**	**Image**	**Ø3.5**	**Ø4.3**	**Ø5.0**
1-Prepare the implant bed and initial drilling*	103.170	Initial Drill	800				
2-Check the long axis of the implant	128.019	Direction indicator 2.8/3.5	-				
3-Tapered Drill 2.0*	103.425	Tapered Drill 2.0	800				
4-Tapered Drill 3.5	103.399	Taperedl Drill 3.5	800				
	128.019	Direction indicator 2.8/3.5	-				
	129.009	Tapered X-Ray Positioner 3.5	-				
5-Pilot Drill 2.8/3.5	103.414	Pilot Drill 2.8/3.5	800		Optional	-	-
6-Tapered Drill 4.3	103.408	Tapered Drill 4.3	800				
	128.022	Direction indicator 3.6/4.3	-				
	129.013	Tapered X-Ray Positioner 4.3	-				
7-Pilot Drill 3.6/4.3	103.417	Pilot Drill 3.6/4.3	800			Optional	-
8-Tapered Drill 5.0	103.411	Tapered Drill 5.0	800				
	128.023	Direction indicator 4.3/5.0	-				
	129.014	Tapered X-Ray Positioner 5.0	-				
9-Pilot Drill 4.3/5.0	103.418	Pilot Drill 4.3/5.0	800				Optional

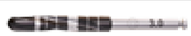
*The sequence can be started directly with the 2.0 drill if the bone bed is flat.

6.1.1.3 Implant bed preparation for Titamax GM™ cylindrical implants

	Initial	Ø2.0	Ø2/3	Ø2.8	Ø3.0	Ø2.8/3.5	Ø3.3	Ø3.0/3.75	Ø3.3/4.0	Ø3.8	Ø4.3	Ø4.3/5.0
	103.170	103.162	103.213	103.163	103.164	103.414	103.166	103.415	103.416	103.167	103.168	103.418
Ø3.5 mm	✓	✓		✓		✓						
Ø3.75 mm	✓	✓	✓		✓			✓				
Ø4.0 mm	✓	✓	✓		✓		✓		✓			
Ø5.0 mm	✓	✓	✓		✓			✓		✓	✓	✓

For bone types I and II 

Titamax GM™

Instruments for basic bone implant preparation					Diameters (mm)			
Step	Code	Product	Max. RPM	Image	Ø3.5	Ø3.75	Ø4.0	Ø5.0
1-Prepare the implant bed and initial drilling*	103.170	Initial Drill	1200					
2-Check the long axis of the implant	128.019	Direction indicator 2.8/3.5	-					
3-Twist Drill 2.0*	103.162	Twist Drill 2.0	1200					
4-Twist Drill 2.8	103.163	Twist Drill 2.8	1200			-	-	-
	128.019	Direction indicator 2.8/3.5	-			-	-	-
	103.414	Pilot Drill 3.5	-			-	-	-
5-Pilot Drill 2/3	103.213	Pilot Drill 2/3	1200					
6-Twist Drill 3.0	103.164	Twist Drill 3.0	1200					
	128.020	Direction indicator 3.0/3.75	-					
	103.415	Pilot Drill 3.0/3.75	1200				-	
7-Twist Drill 3.3	103.106	Twist Drill 3.3	1200					-
	128.021	Direction indicator 3.3/4.0	-					-
8-Pilot Drill 3.3/4.0	103.416	Pilot Drill 3.3/4.0	300					-
9-Twist Drill 3.8	103.167	Twist Drill 3.8	1200					
10-Twist Drill 4.3	103.168	Twist Drill 4.3	1200					
	128.023	Direction indicator 4.3/5.0	-					
11-Pilot Drill 4.3/5.0	103.418	Pilot Drill 4.3/5.0	300					

*The sequence can be started directly with the 2.0 drill if the bone bed is flat.

NOTE: Length comparison between drills and implants.

1: All twist drills have similar marks related to each length of GM Titamax implants, regardless of diameter.

2: The implant in the image is 13 mm long.

1: All tapered drills have similar marks related to each implant length, regardless of diameter.

2: All drills are available in the short version, and some are available in the long version.

3: The implants in the image are 13 mm long.

6.1.2 Details on special implant bed preparation

The special implant bed preparation considers the use (1) of the pilot drill and (2) the tapered contour drill when necessary. The instruments depend on the implant type and diameter and bone type. Osteotomies in bone types I and II need final pilot drills for the final positioning of the implant. Tapered contour drills are required only for the use of the Helix™ GM™ implant in regions of high bone density.

6.1.2.1 Tapered Contour Drill (+)

Tapered Contour Drills are specifically indicated as supplemental instruments for preparing the osteotomy when implanting Helix™ GM™ implants in bone types I and II. There are different tapered contour drills selected according to the implant diameter. The drills are used only on bone types I and II, connected to the contra-angle handpiece, with a rotation speed of approximately 800-1200 rpm. This step is intended to keep the insertion torque at a desirable level in bone types I and II.

Note: The Tapered Contour Drills have the "+" symbol to indicate that they are supplementary instruments.

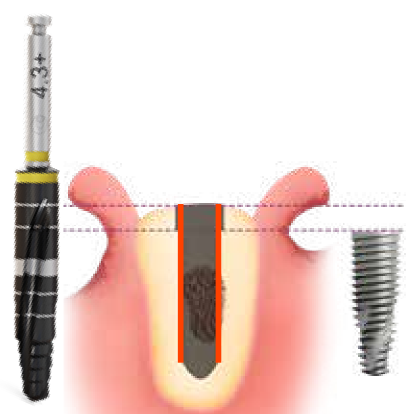
6.1.2.2 Pilot Drill

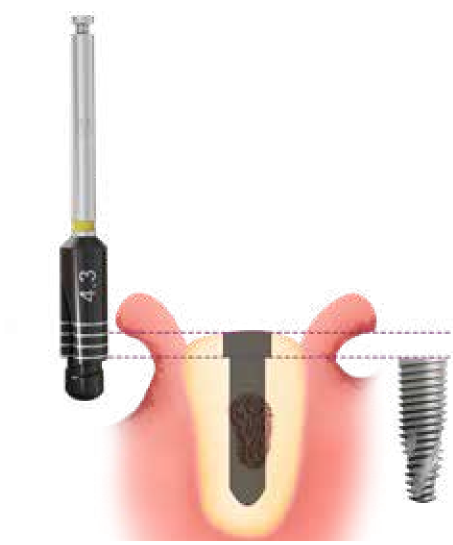
Pilot drills are employed to prepare the implant bed to widen the diameter of one twist drill to another, in the basic instrumentation procedure. For the special bone preparation, pilot drills help position the platform of the Grand Morse™ implants according to the bone bed, if there is a denser cortical bone bed of 1, 2 or 3 mm below bone level. Pilot drills are generally used in this manner in bone types I and II and are indicated as optional in bone types III and IV. For Drive GM™ implants, the use of this drill is optional. The maximum rotation speed used for these drills is 800 rpm for bone types III and IV and 1200 rpm for bone types I and II.

FIGURE 22: Pilot drill for the refined implant bed preparation for the implant. The drill helps in the cervical positioning of the implant in areas of greater bone density: if at bone level, 1, 2 or 3 mm below bone level. Pilot drills are optional for Drive GM™ implants.

6.1.2.3 Example of special implant bed preparation

The following is an example of the special preparation of the implant bed for a Helix GM™ implant (Ø4.3 mm and 13 mm long) in bone type I or II, making the use of contour and pilot drills necessary. The steps described follow the basic preparation of the implant bed (6.1.1.1).





Step 1 - Drilling in dense bone

Use the tapered contour drill across the entire length of the planned implant.

Step 2- GM Pilot Drill

Perform the osteotomy with the conical drills. Depending on the level of the final positioning of the implant (bone level, 1 or 2 mm below bone level), use the pilot drill for the final positioning of the implant.

6.1.2.4 Options for drills

Neodent® drills are available in short (31 mm), standard (35 mm) or long (43 mm) formats to cater for limitations in mouth opening or for use between two teeth. In case of necessity a Drill Extension can also be used.

FIGURE 23. Length options for Grand Morse™ drills (31 mm, 35 mm and 43 mm).

FIGURE 24. Drills fit inside the Neodent® Drill Extension.

6.1.2.5. Neodent® Control System

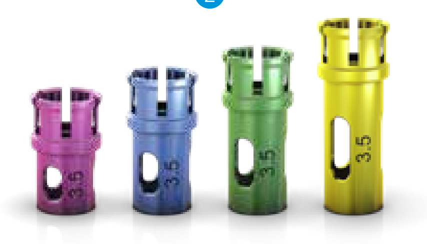
The surgical procedure for implant placement can be perceived as complex, especially when performed in the posterior regions with limited visibility, or in proximity with anatomical structures such as nerve canals. The Neodent® Control System brings confidence and efficiency building trust during the surgical procedure.

Neodent® Control System is composed by:

1

Neodent® Control Stop Drills.

2



Neodent® Control Drill Stops.

3

Neodent® Control System Kit and
Neodent® Helix GM® Compact Surgical Kit

Drill Sequence with Neodent® Control System

	Initial 103.170	Ø 2.0 103.492	Ø 3.5 103.493	Ø 3.5+ 103.500	Ø 3.5 103.513	Ø 3.75 103.494	Ø 3.75+ 103.501	Ø 3.75 103.514	Ø 4.0 103.495	Ø 4.0+ 103.502	Ø 4.0 103.515	Ø 4.3 103.496	Ø 4.3+ 103.503	Ø 4.3 103.516	Ø 5.0 103.497	Ø 5.0+ 103.504	Ø 5.0 103.517	Ø6.0 103.498	Ø 7.0 103.499
Ø 3.5	✓*	✓		✓	✓														
Ø 3.75	✓*	✓	✓				✓	✓											
Ø 4.0	✓*	✓	✓			✓				✓	✓								
Ø 4.3	✓*	✓	✓			✓			✓				✓	✓					
Ø 5.0	✓*	✓	✓			✓			✓*			✓				✓	✓		

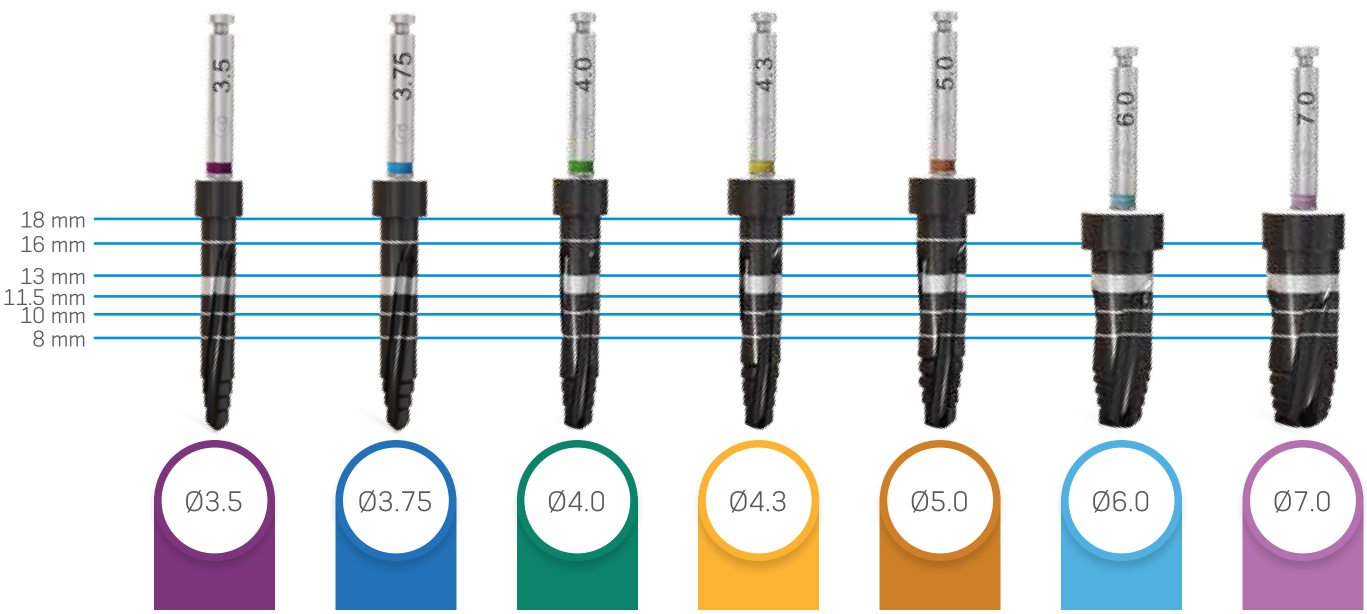
*Optional / Bone types I and II

	Initial	Ø 2.0	Ø 3.5	Ø 3.5+	Ø 3.5	Ø 3.75	Ø 3.75+	Ø 3.75	Ø 4.0	Ø 4.0+	Ø 4.0	Ø 4.3	Ø 4.3+	Ø 4.3	Ø 5.0	Ø 5.0+	Ø 5.0	Ø6.0	Ø 7.0
Ø 3.5	✓*	✓	✓																
Ø 3.75	✓*	✓	✓			✓*													
Ø 4.0	✓*	✓	✓						✓*										
Ø 4.3	✓*	✓	✓			✓						✓*							
Ø 5.0	✓*	✓	✓									✓			✓*				
Ø 6.0	✓*	✓	✓			✓						✓			✓			✓	
Ø 7.0	✓*	✓	✓									✓			✓			✓	✓*

*Optional / Bone types III and IV

Neodent® Control Stop Drills

Neodent® Tapered Control Stop Drills are available for bed preparation for Helix GM® implants in all bone types, from Ø 2.0 to Ø 7.0 mm. They were designed to be used with stops, but the laser marks on the drills also enable their use without them. The drills are connected to the contra-angle handpiece, with a rotation speed of approximately 500-800 rpm in bone types III and IV and 800-1200 rpm in bone types I and II. They have a color code according to the diameter, as shown below, and a total length of 35 mm. For diameters Ø 6.0 mm and Ø 7.0 mm, the drills are available with 32 mm in length.



Differentiation for Tapered + drills:

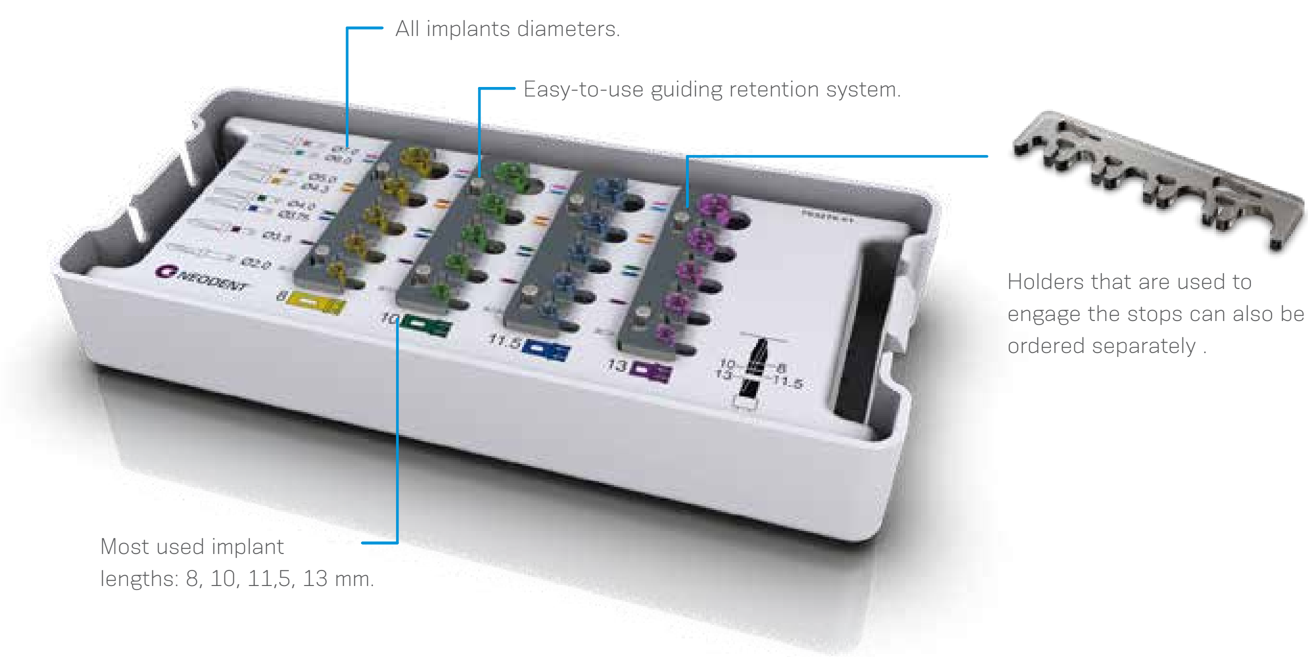
Neodent® Tapered + Control Stop Drills are especially indicated as supplementary instruments for osteotomy when implanting Helix GM® in bone types I and II. This step is intended to keep the insertion torque at a desirable level in harder bones. They follow the same color code as the Neodent® Tapered Control Stop Drills and have two stripes of color, and the "+" laser-marked.

Neodent® Control Stop Drills

Attached to the Stop Drills, Neodent® Control Drill Stops allow easy depth control during the osteotomy. They come in different diameters and lengths, to be selected according to the implant to be placed and related drilling sequence. Neodent® Control Drill Stops are reusable and made of titanium.

Neodent® Control Stop Drills

The kit is used for storage and sterilization procedure for Neodent® Control Drill Stops. During surgery, it allows easy engagement and disengagement of the stops on the stop drills. The holders can be purchased separately, in the case they need to be replaced.



To capture the stop in the Control Drill Stop Kit, follow the steps below:

1 Initially position the Tapered Control Stop Drill inside the Stop.

2 Slide it to the right.

3 Remove the set Tapered Control Stop Drill and Stop from the case.

To remove the stop in the Control Drill Stop Kit, follow the steps below:

1 Initially position the set Tapered Control Stop Drill and Stop on the right.

2 Slide to the left.

3 Pull the Drill so that it can be removed from the Stop.

6.2 Neodent® Implant Packaging

Neodent packaging has been specially updated for easy handling, providing practicality from implant stocking to the capture and transport and implant bed. The implant's features, such as type, diameter and length, are readily identifiable on the outside of the packaging.

Three self-adhesive labels are provided for recording in the patient's medical records and for reporting to the prosthesis team. They also allows traceability for all articles.

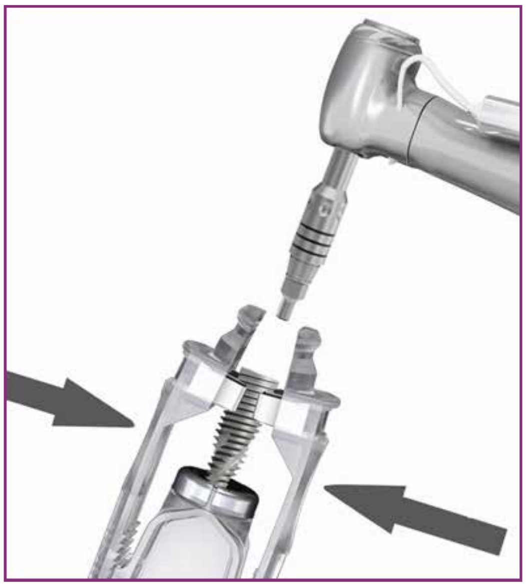
Instructions for opening the implant packaging		
Step 1	Open the blister and place the vial on a sterile surface.	
Step 2	After breaking the blister's sterile seal, hold the primary packaging (vial) in one hand and open the lid. **Note:** For Acqua implants, hold the bottle in the vertical position to avoid spilling the liquid.	
Step 3	Remove the holder containing the implant from the vial along with the lid. **Note:** For Acqua implants, hold the bottle in position.	
Step 4	Push down and remove the lid.	
Step 5	Capture the implant with the contra-angle driver, moving the support until the perfect fit is found between the driver and the implant. Check that the driver is completely fitted to the implant.	
Step 6	Carry the implant to the implant bed.	

6.3 Placing of the Grand Morse™ Implant

Neodent® Grand Morse™ implants were developed to begin placement with the contra-angle handpiece or manually, and completed with the Torque-indicating Wrench. The maximum recommended rotation speed for the surgical motors is 30 rpm, with a torque of 35 Ncm.

6.3.1 Placing of the implant with the contra-angle handpiece

The following instructions show the steps for handling the Neodent Grand Morse implant for placement with the contra-angle handpiece.



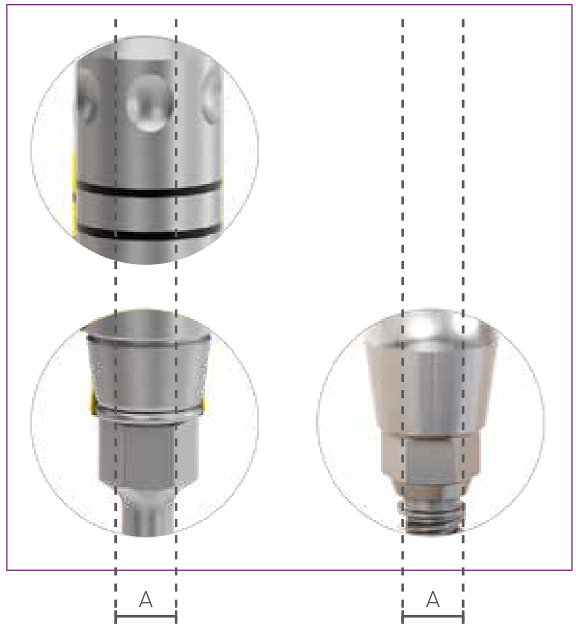
Step 1 - Adapt contra-angle implant driver

Hold the implant through the blister, and attach the contra-angle implant driver to the Grand Morse™ implant.

Step 2 – Place the implant with the contra-angle handpiece in the implant bed

Place the implant to its final position with a maximum torque of 35 Ncm and speed of 30 rpm, clockwise.

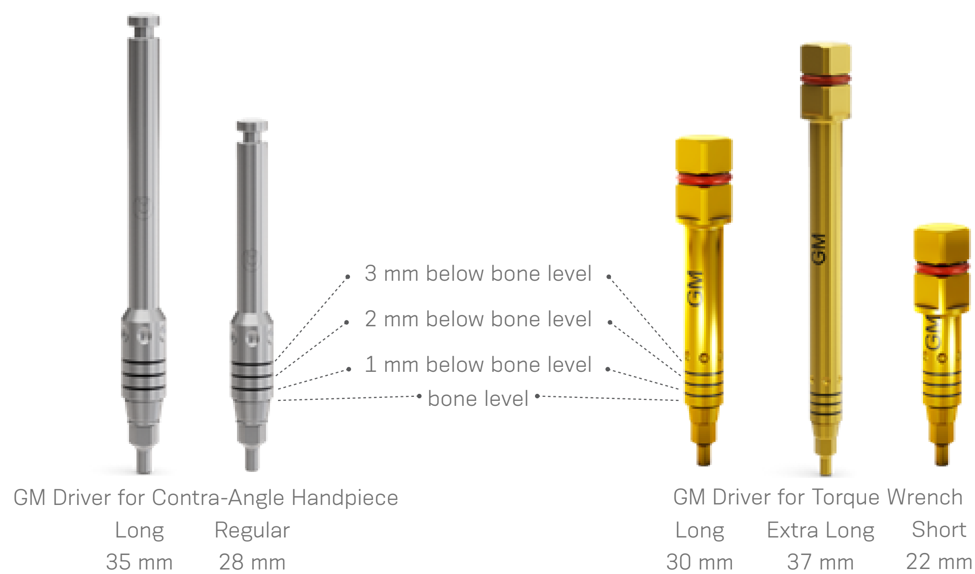
Warning: Corrections in the vertical position by means of reverse rotations during surgery can lead to reduced primary or mechanical stability.



Step 3 – Final positioning of the implant

Neodent® Grand Morse™ implants have an internal hexagon index known as Exact. Ensure that the final position of the implant shows one of the prosthetic orientation marks facing the buccal aspect.

The implant drivers have six marks that line up with the six sides of the GM Exact. Position one of the driver marks towards the buccal aspect to ensure the optimal positioning of the indexed abutments with GM Exact.



Note 1: There are 3 similar markings at 1 mm intervals in the Drivers for the Contra-angle handpiece and Torque Wrench. These markings guide the depth of the final positioning of the implant in the following way: first stripe for 1 mm below bone level, second for 2 mm and third for 3 mm. Each full turn of the implant results in: (a) 2.2 mm for the Drive implants; (b) 1.4 mm on average for the Helix™ implants; and (c) 1.2 mm for the Titamax implants.

Note 2: Torque Wrench drivers are not indicated for transporting the implant from the blister to the patient's mouth.

FIGURE 25. All instruments for contra-angle handpieces can be fitted to the Manual Implant Driver - Contra-angle.

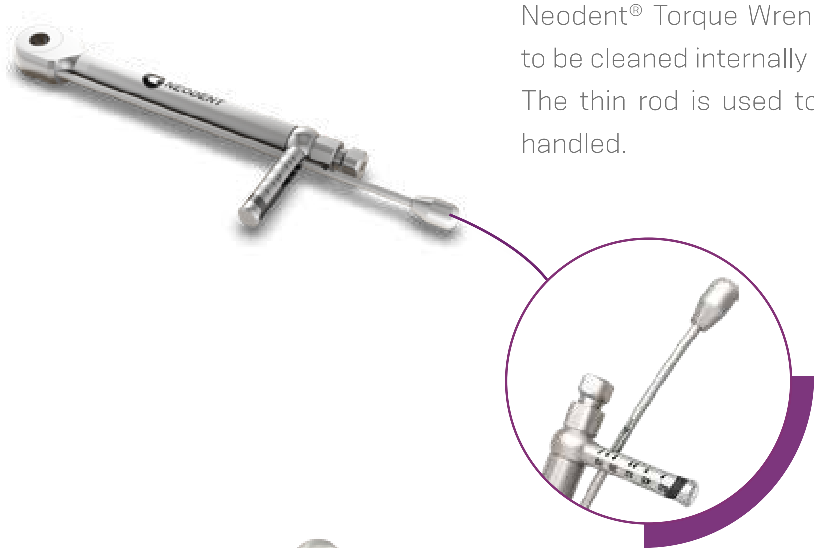
The implant placement sequence can also be achieved manually, using the Manual Implant Driver - Contra-angle instead of the contra-angle handpiece.

6.3.2 Completing the positioning of the implant with the Torque Wrench

Remove the Grand Morse™ contra-angle handpiece driver from the implant, and fit the torque wrench driver for the final positioning of the implant and torque measurement. There are two torque wrench driver options: short and long. First, use the fingers to fit the driver to the interior of the implants and then hitch the torque wrench onto the driver. The torque wrench drivers should not be used to transport the implant from one place to another because the product can fall out. Apply torque until the implant reaches its final position. All torque wrenches show torque levels. A value above 60 Ncm is contraindicated.

Warning: Corrections in the vertical position by means of reverse rotations during surgery can lead to reduced primary or mechanical stability.

6.3.3 Torque Wrench



Neodent® Torque Wrenches can be disassembled because they need to be cleaned internally before the sterilization process in the autoclave. The thin rod is used to measure and indicate the torque value when handled.

Note: *Implants can be placed with these drivers fitted to a GM Torque Wrench Driver. However, this does not allow the surgeon to apply the final torque for the implant and thus is only indicated for the initial positioning of the implant with the Handle Implant Driver.*

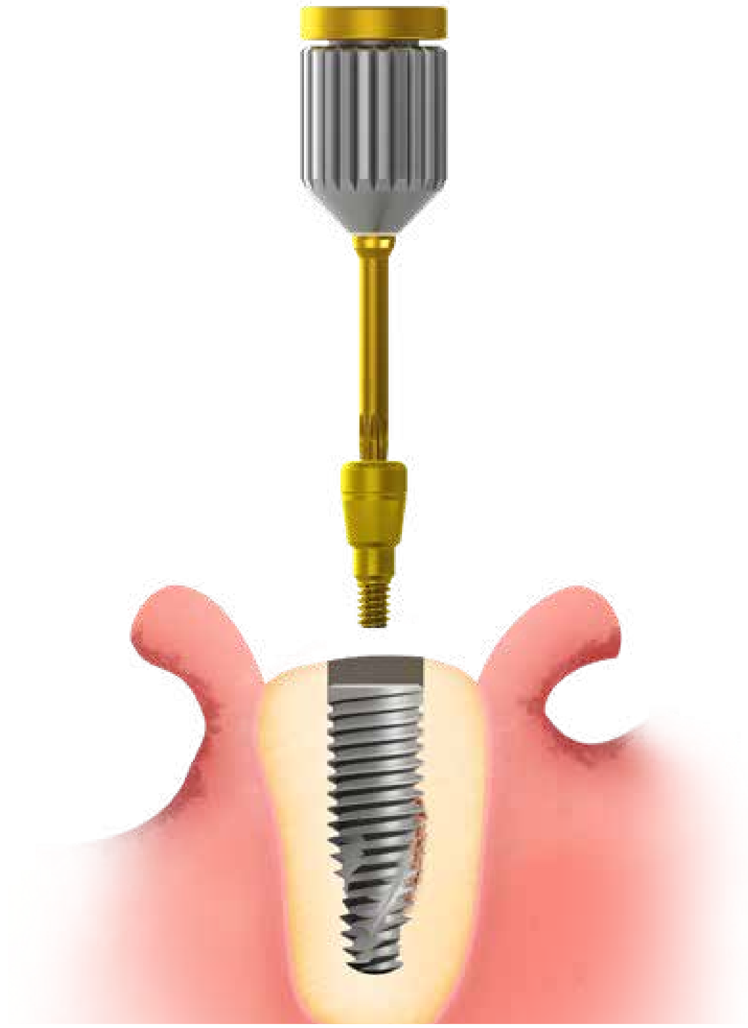
6.4 Handling soft tissue

After implant placement, the implant is covered with a cover screw or healing abutment to protect it. The surgeon may choose between submucosal or transmucosal healing and has all available options for handling soft tissue by means of a secondary healing component kit.

6.4.1 Two-step/submucosal healing

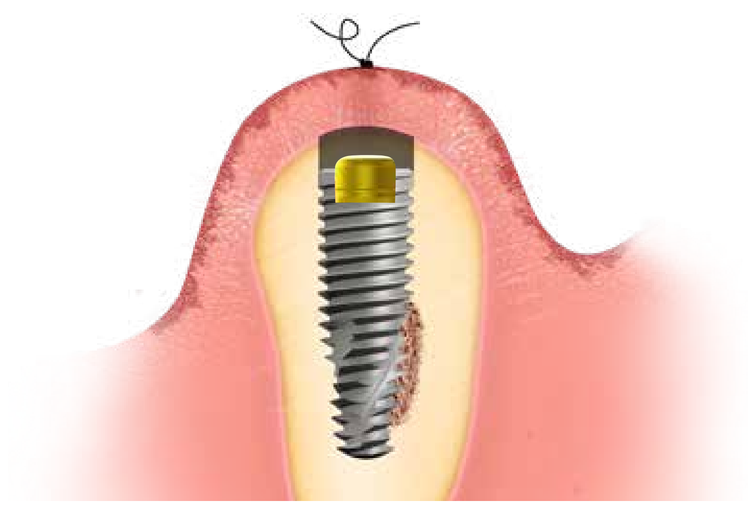
For submucosal healing (under a closed mucoperiosteal flap), the use of the GM Cover Screw is indicated. A second surgical procedure is necessary to reveal the implant and insert the desired abutment.

The Neodent® system has two cover screws, which are sold separately and sterile packed, at the implant level and 2 mm (above the implant shoulder) for positioning below bone level.



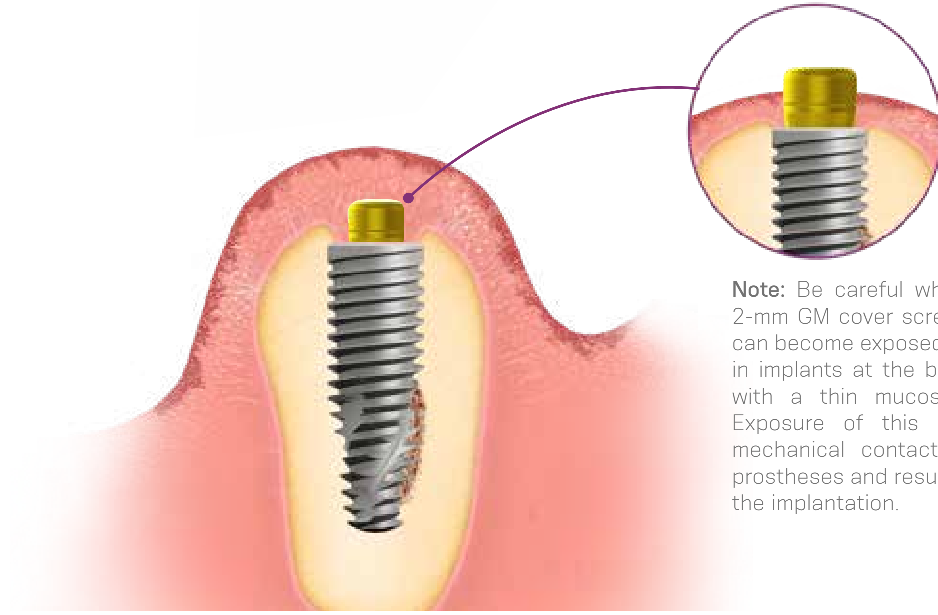
Step 1 – Inserting the cover screw

Ensure that the internal configuration is clean and free of blood residue. Capture the GM Cover Screw with the Neo Manual Screwdriver. A perfect fit ensures the transport for the implant, and manually tighten the screw.



Step 2 – Close the incision

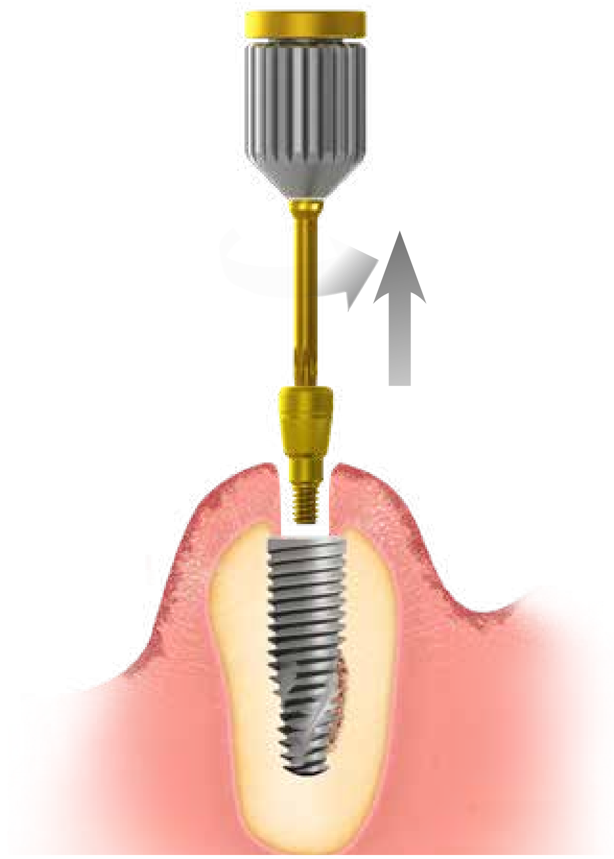
Adjust the edges of the flap and suture with tension-free stitches.



Note: Be careful when using the 2-mm GM cover screw because it can become exposed when placed in implants at the bone level and with a thin mucosal thickness. Exposure of this screw allows mechanical contact with mobile prostheses and results in failure in the implantation.

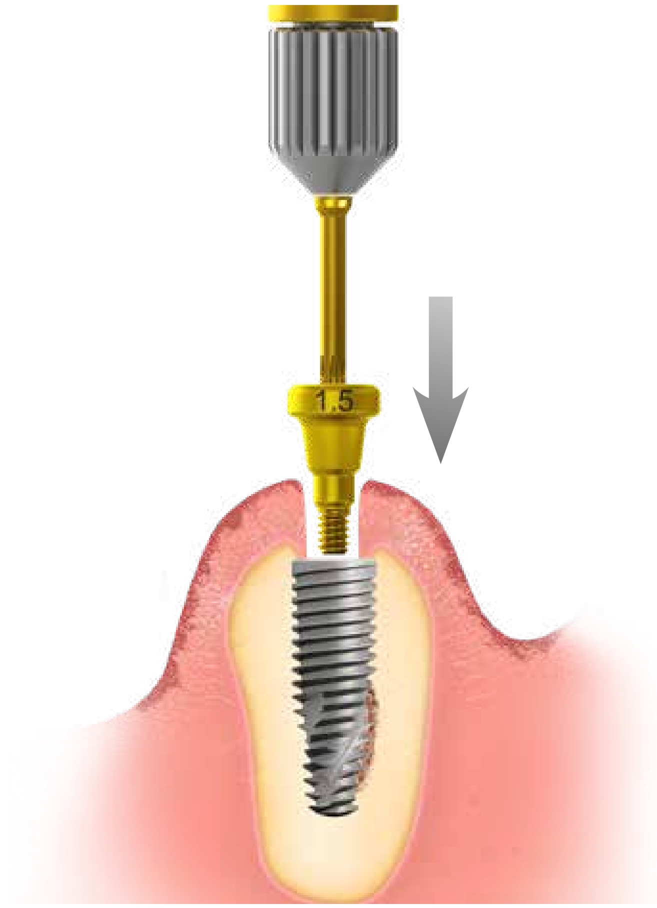
Step 3 – Regeneration period

Remove the suture after approximately 7 days or once it has lost its function and wait for the bone regeneration phase.



Step 4 – Reopening and removal of the GM Cover Screw

Second surgery – After the bone regeneration period for each type of implant and bone, locate the implant with the help of the surgical guide, X-rays or measurements, and, with the desired technique, make an incision to reach the implant, and remove the GM Cover Screw with the Neo Manual Screwdriver.



Step 5 – Insertion of healing abutment

Irrigate the implant's exposed internal connection with sterile saline solution, insert the healing abutment (or an abutment, if applicable). Adjust the soft tissue and suture around the healing abutment.

More information on healing abutments can be found in 6.5 (page 51).

Step 6 – Close the wound

Adjust the soft tissue and suture around the healing abutment.

6.4.2 Transmucosal healing: one-step or immediate loading

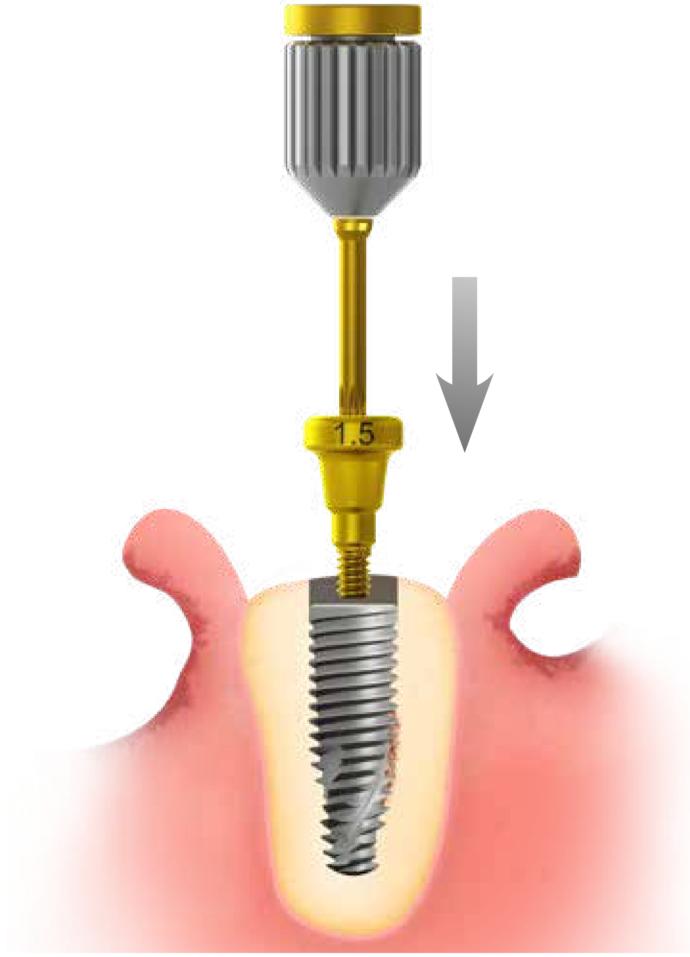
A variety of healing abutments and abutments are available for the Neodent® Grand Morse™ system, to shape the soft tissue during the transmucosal healing after placing the implant. The abutments can be used provisionally (to be replaced in the final restoration phase), or a final abutment can be used along with a provisional restoration. This phase can be defined as a one-step operation (if the healing abutment is chosen after the surgical procedure) or immediate loading (if a definitive abutment is selected).

The implant's final placement torque determines the protocol. Correct and physiological occlusion is also a determinant in the decision. Patients deprived of a balanced occlusion are not good candidates for the immediate loading protocol. Table 5 lists the criteria to be observed for the use of the immediate loading protocol.

Torque (Ncm)	Healing protocol	General characteristics
≥ 35 to ≤ 60 Ncm	Immediate loading or selection of abutment	- Lateral mechanical load on provisional crowns is contraindicated. - Patients should present a balanced or physiological occlusion. - Periodontally compromised patients should have their condition controlled prior to treatment, especially when a component is exposed to the oral environment.

TABLE 5: Immediate loading protocol according to torque level.

6.4.2.1 Transmucosal healing: one-step



Step 1 – Insertion of healing abutment after implant placement
Ensure that the internal configuration is clean and free of blood.
Insert the healing abutment manually with the Neo Manual Screwdriver.

Step 2 – Close the wound
Adjust the soft tissue to the component, and suture with tension-free sutures.

6.5 Overview of the healing abutments

The Neodent® system has a variety of healing abutments, with various diameters and transmucosal heights corresponding to the definitive abutment. Choosing the correct healing abutment is therefore extremely important to ensure proper healing of soft tissue, with controlled pressure and respect for biological distances.

Below are the various formats of Grand Morse™ healing abutments to be adapted to the surgeon's needs:

Healing Abutments

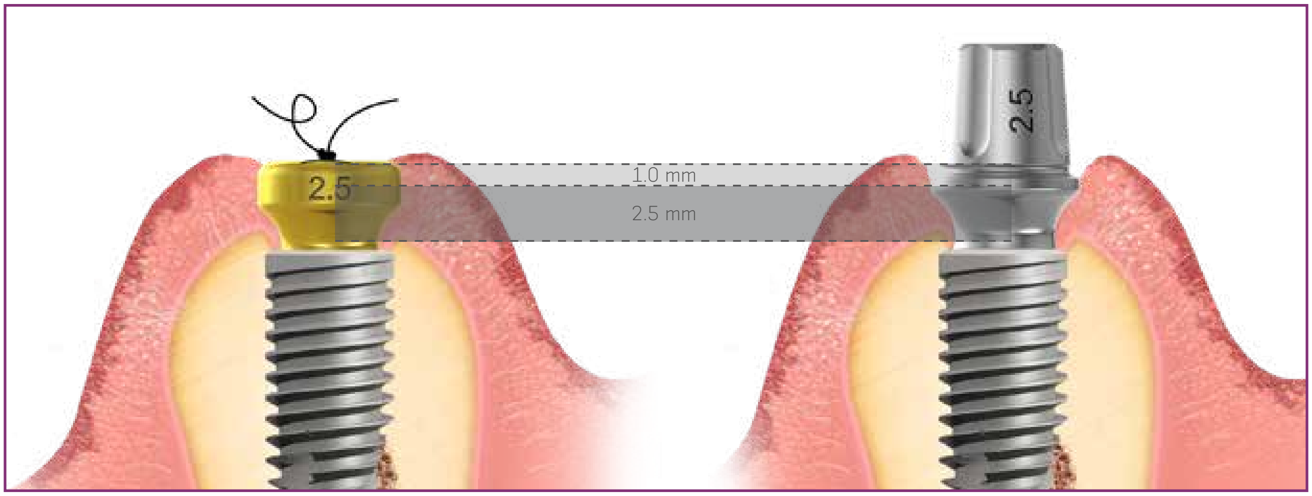
	Ø 3.3	Ø 4.5	Ø 5.5	Ø 6.5
Transmucosal height	0.8 mm	0.8 mm	-	-
	1.5 mm	1.5 mm	1.5 mm	1.5 mm
	2.5 mm	2.5 mm	2.5 mm	2.5 mm
	3.5 mm	3.5 mm	3.5 mm	3.5 mm
	4.5 mm	4.5 mm	4.5 mm	4.5 mm
	5.5 mm	5.5 mm	-	-

GM Height Measurer

To select the correct prosthetic abutment and check the thickness of the remaining mucosa, there is the Grand Morse™ Height Measurer, which can be fitted to the implants and serves as a reference for selecting the most suitable abutment.

The height of the abutments varies from 0.8 to 5.5 mm and should be chosen based on the gingival height. Given that the healing abutment's internal design is identical to that of the definitive abutment, if the height of the chosen healing abutment is very high, the soft tissue will heal this way as well. If the height of the chosen definitive abutment is not compatible (lower, for example), it will exert great pressure on the soft tissue, and the patient will complain of compression pain. It is therefore advisable to choose an abutment with the same transmucosal width and height as the healing abutment. If the definitive abutment needs to be replaced, the patient should be anesthetized, and the tissue should be given time to readapt.

All Neodent® healing abutments have been strategically designed to create a proper emergence profile, adjusted to the margin of all abutments in such a way that they remain 0.9 mm under the mucosa.



6.5.1 Overview of Grand Morse™ abutments and corresponding healing abutments

	Type	GM Mini Conical Abutment	GM Exact Angled Mini Conical Abutment	GM Micro Abutment	GM Exact Abutment
Abutment	Ø Available	4.8 mm	4.8 mm	3.5 mm	4.8 mm
	Gingival height	0.8 mm		0.8 mm	0.8 mm
		1.5 mm	1.5 mm	1.5 mm	1.5 mm
		2.5 mm	2.5 mm	2.5 mm	2.5 mm
		3.5 mm	3.5 mm	3.5 mm	3.5 mm
		4.5 mm		4.5 mm	4.5 mm
		5.5 mm		5.5 mm	5.5 mm
Corresponding healing abutment	Ø Available	4.5 mm	4.5 mm	3.3 mm	4.5 mm
	Gingival height	0.8 mm		0.8 mm	0.8 mm
		1.5 mm	1.5 mm	1.5 mm	1.5 mm
		2.5 mm	2.5 mm	2.5 mm	2.5 mm
		3.5 mm	3.5 mm	3.5 mm	3.5 mm
		4.5 mm		4.5 mm	4.5 mm
		5.5 mm		5.5 mm	5.5 mm

	Type	GM Titanium Base				GM Titanium Base AS			GM Titanium Base for Bridge		
Abutment	Ø Available	3.5 mm	4.5 mm	5.5 mm	6.5 mm	4.0 mm	4.5 mm	5.0 mm	3.5 mm	4.5 mm	5.5 mm
	Gingival height	0.8 mm	0.8 mm	0.8 mm					0.8 mm	0.8 mm	0.8 mm
		1.5 mm	1.5 mm	1.5 mm	1.5 mm	0.8 mm	0.8 mm	0.8 mm	1.5 mm	1.5 mm	1.5 mm
		2.5 mm	2.5 mm	2.5 mm	2.5 mm	1.5 mm	1.5 mm	1.5 mm	2.5 mm	2.5 mm	2.5 mm
		3.5 mm	3.5 mm	3.5 mm	3.5 mm	2.5 mm	2.5 mm	2.5 mm	3.5 mm	3.5 mm	3.5 mm
		4.5 mm	4.5 mm	4.5 mm	4.5 mm				4.5 mm	4.5 mm	4.5 mm
Corresponding healing abutment	Ø Available	3.3 mm	4.5 mm	5.5 mm	6.5 mm 7.0 mm	4.0 mm	4.5 mm	5.0 mm	4.0 mm	4.5 mm	5.0 mm
	Gingival height	0.8 mm	0.8 mm			0.8 mm	0.8 mm		0.8 mm	0.8 mm	
		1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm	1.5 mm
		2.5 mm	2.5 mm	2.5 mm	2.5 mm	2.5 mm	2.5 mm	2.5 mm	2.5 mm	2.5 mm	2.5 mm
		3.5 mm	3.5 mm	3.5 mm	3.5 mm				3.5 mm	3.5 mm	3.5 mm
		4.5 mm	4.5 mm	4.5 mm	4.5 mm				4.5 mm	4.5 mm	4.5 mm

Note: All digitally designed copings and/or crowns to be used with Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Grand Morse™ Cement-retained Options

	Type	GM Universal Abutment (straight)	
Abutment	Ø Available	3.3 mm	4.5 mm
	Transmucosal height	0.8 mm 1.5 mm 2.5 mm 3.5 mm 4.5 mm 5.5 mm	0.8 mm 1.5 mm 2.5 mm 3.5 mm 4.5 mm 5.5 mm
Corresponding healing abutment	Ø Available	3.3 mm	4.5 mm
	Gingival height	0.8 mm 1.5 mm 2.5 mm 3.5 mm 4.5 mm 5.5 mm	0.8 mm 1.5 mm 2.5 mm 3.5 mm 4.5 mm 5.5 mm

Note: GM angled Universal abutments are only available with transmucosal heights of 1.5, 2.5 and 3.5 mm.

6.5.2 Grand Morse™ Customizable Healing Abutments

The Grand Morse™ line also features customizable healing abutments. They are produced in titanium, with a customizable portion made of PEEK. The available diameters and transmucosal heights are presented below. It is also important to notice the height of the parallel portion, which is of 1.5 mm for all options, with the exception of the 7.0 X 5.5 mm (with a 2.5 mm high parallel portion) and the 7.0 X 6.5 mm (with a 3.5 mm high parallel portion). In all cases, there is the possibility of customizing the upper and lateral portions of the product. A minimum thickness of 0.5 mm is recommended to be maintained between the screw and the lateral and upper portions.

Customizable Healing Abutments

	Ø5.5	Ø7.0
Transmucosal height	1.5 mm	2.5 mm
	2.5 mm	3.5 mm
	3.5 mm	4.5 mm
	4.5 mm	5.5 mm*
	5.5 mm	6.5 mm**

*parallel portion of 2.5 mm

**parallel portion of 3.5 mm

7.0 HEALING PHASE

The healing protocol depends on:

(1) The implant's final placement torque or primary stability, as measured with the Torque-indicating Ratchet Wrench.

(2) The bone type.

More time is needed when low torque values are reached. Immediate loading procedures may also be applied in cases of minimum placement torque of 35 Ncm.

8.0 GENERAL PROSTHETIC GUIDELINES

Once this stage has been reached, the definitive prosthetic abutment should be chosen for the final restoration. This step can be conducted in the healed mucosa (submucosal healing, conventional protocol) or during surgery for protocols such as one-step/transmucosal healing or immediate loading.

To help with the selection of abutments, Neodent® offers the GM Height Measurer, which can also be sterilized and visualized in X-rays.

The following features should be considered:

a. Single tooth or multiple tooth restoration
b. Screw-retained or cement-retained restoration
c. Interocclusal gap, height and width
d. Gingival height (transmucosal height)
e. Biological distance (distance from abutment platform to bone crest)
f. Whether the implant angulation needs to be corrected for the abutment or whether adjacent abutments are parallel.

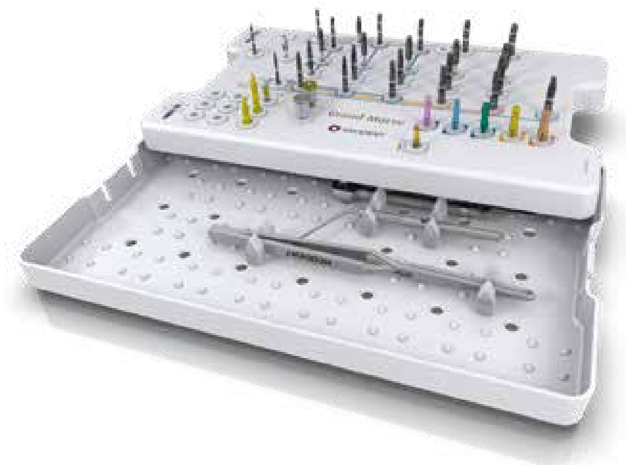
The GM Height Measurer helps determine the gingival height.

The positioning of implants below bone level results in a certain amount of bone over the cervical region. This tissue can interfere with abutments fitted on the implant. For these situations, Neodent provides a GM Bone Profile Drill.

9.0 NEODENT® KITS

Neodent Kits are available in cassettes to help keep the instruments organized and sterile. The cassette is manufactured with a heat-resistant polymer and is indicated for frequent sterilization in an autoclave.

The New Grand Morse™ Surgical Kit is intuitive and functional and features exclusive instruments for placing the new Helix GM™, Drive GM™ and Titamax GM™ implants.



Grand Morse™ Surgical Kit

Compact Kit

There is also a compact kit, for placing only tapered implants.
The Helix GM® Compact Surgical Kit can be used for Helix GM® and Drive GM® implants.

9.1 Cleaning, Sterilization and Care of the Cassette and Instruments

Please refer to the article specific instructions for use for instructions on cleaning, sterilization, storage conditions and lifecycle. The instructions for use are available at Ifu.neodent.com.br.

Complete GM Surgical Kit (Reference IFU 330.388)

Cleaning

Clean this product according to the following instructions after each use:

1. Remove the instruments from the Kit Case and clean separately (see specific instrument instructions).
2. Disassemble the three parts of the Kit Case. Soak the lid, tray and base for at least 1 min in the cleaning solution (Enzol® enzymatic detergent, prepared per manufacturer directions) so that the components are sufficiently covered. Pay attention that there is no contact between the components. Assist cleaning by careful brushing with a soft brush, paying particular attention to the interface between the silicone block inserts and the tray or base. Do not use metal brushes or steel wool.
3. Soak the lid, tray and base for 15 min in the cleaning solution (Enzol® enzymatic detergent, prepared per manufacturer directions) with ultrasonic treatment so that the components are sufficiently covered. Pay attention that there is no contact between the components.
4. Remove the Kit Case components from the cleaning solution and rinse them at least 3 times intensively (at least 1 min) under running water (local potable water is sufficient).
5. Repeat the cleaning steps of components that remain visibly contaminated.
6. Check all components after cleaning for signs of corrosion or damage. Do not continue to use corroded or damaged components.
7. Dry the components thoroughly before storage and sterilization; the accumulation of moisture on the components and instruments may cause corrosion that can detrimentally affect instrument performance.
8. Insert the cleaned, disinfected and dried instruments in the corresponding locations of the Case Kit tray and base. Assemble the Kit Case by inserting the tray into the base and attaching the lid.
9. Protect the assembled Kit Case from moisture and dust if it will not be used for an extended time.

Presentation And Sterilization

For traceability, each kit case presents on its tray the laser engraving of the UDI code (Unique Device Identification). The instruments are supplied along with Kit, according to configuration table.

This product is reusable and supplied non-sterile, being unitarily packaged. This product must be correctly cleaned and sterilized before each use. Sterilize the products on the previous day or on the day of the procedure. ATTENTION: This product cannot be autoclaved in its original packaging.
Please use for sterilization only the steam sterilization according to the following parameters:

	Fractionated Vacuum / Dynamic Air Removal[1]	Gravity Displacement
Sterilization Time	4 minutes	15 minutes
Sterilization Temp.	132° C	132° C
Drying Time	20 minutes[2]	20 minutes[2]

[1] At least three vacuum steps.
[2] The effectiveness required in drying time depends directly on the parameters of sole responsibility of the user (density and load configuration, sterilizing conditions, which must be determined by the user). Nevertheless, a drying time shorter than 20 minutes cannot be applied.

NOTE: After sterilization, pack the instruments at a dry and dust-free place.

Neodent® drills should be properly sanitized after each use. Proceed as follows:

Initial Drill (Reference IFU 330.035)

Sanitation

This product should be correctly cleaned after each use.

Proceed as follows:

Manual cleaning and disinfection

Cleaning

1. Disassemble the instruments as possible (see specific dismantling instructions).
2. Soak the disassembled instruments for at least 1 min in the cleaning solution (CIDEZYME®, 1.6 % v/v) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush. Sway movable parts several times during cleaning.

If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning of the soaking time by application of a single-use syringe (minimum volume 10 mL) and of a suitable rinsing adapter.

3. Soak the disassembled instruments for 15 min in the cleaning solution (CIDEZYME®, 1.6 % v/v) with ultrasonic treatment so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments.
4. Then, remove the instruments of the cleaning solution and post-rinse them at least 3 times intensively (at least 1 min) under running water.

If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times by application of a single-use syringe (minimum volume 10 mL) and of a suitable rinsing adapter.

Disinfection

1. Soak the disassembled instruments for 12 min in the disinfectant solution (CIDEX® OPA — OPA Solution -, undiluted) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Sway movable parts several times during disinfection.

If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 10 mL) and of a suitable rinsing adapter.

2. Remove the instruments of the disinfectant solution and post-rinse them according to the instructions of tha manufacturer of CIDEX® OPA — OPA Solution -:

Rinsing Instructions

- Following removal from CIDEX® OPA — OPA Solution — Solution, thoroughly rinse the medical device by immersing it completely in a large volume of water. Use sterile water unless potable water is acceptable. See item 2 or 3 below.

- Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.
- Manually flush all lumens with large volumes (not less than 100 mL) of rinse water unless otherwise noted by the device manufacturer.
- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure 2 additional times, for a total of 3 RINSES, with large volumes of fresh water to remove CIDEX® OPA — OPA Solution — Solution residues. Residues may cause serious side effects.

3. Check and pack the instruments immediately after the removal.

Automated cleaning/disinfection
(WD (Washer-Disinfector))

Use of neodisher® MediZym.

1. Disassemble the instruments as possible.
2. Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact).
3. Start the program.
4. Remove the instruments of the WD after end of the program.
5. Check and pack the instruments immediately after the removal.

NOTE:

1. Pay attention to following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration);
- possibility for an approved program for thermal disinfection (A0 value > 3000 or — in case of older devices — at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments);
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program;
- post-rinsing only with sterile or low contaminated water (max. 10 germs/mL, max. 0.25 endotoxin units/mL), for example purified/highly purified water;
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying;
- regularly maintenance and check/calibration of the WD.

2. Please do not clean any instruments by use of metal brushes or steel wool.
3. Check all instruments after cleaning or cleaning/disinfection, on corrosion, damaged surfaces, and impurities. Do not further use damaged instruments. Still dirty instruments are to be cleaned and disinfected again.
4. Packaging: Please insert the cleaned and disinfected instruments in the corresponding sterilization trays and pack them in single-use sterilization packagings (single or double packaging) and/or sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance);
- suitable for steam sterilization;
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage;
- regular maintenance according to the instructions of the manufacturer (sterilization container).

5. Remove coarse impurities of the instruments directly after application, performing the pre-treatment, before cleaning and disinfection (within a maximum of 2 h).

The pre-treatment step is to be performed in both cases of cleaning and disinfection, automated and manual.

a. Disassemble the instruments as possible;
b. Rinse the instruments at least 1 min under running water2 (temperature < 35 °C/95 °F);
c. If applicable: Rinse all lumens of the instruments five times by application of a single-use syringe (minimum volume 10 mL). Sway movable parts several times during pre-treatment;
d. Remove manually all visible impurities by use of a clean and soft brush (or a clean, soft, and lint-free cloth) only to be for this, in no case metal brushes or steel wool;
e. Rinse again at least 1 min under running water.

6. If the cleaning/disinfection products mentioned are not found, make sure to use products that are similar to those indicated. The replacement is of the owner's responsibility.
7. The drying of the parts is of utmost importance before storage and sterilization, because the accumulation of moisture on the products is harmful and may cause oxidation.

NOTE: During the sanitation try to avoid contact between the cutting tools and other tools so the cutting power is not harmed.

Presentation and sterilization

This product is reusable and supplied nonsterile, packed individually. This product must be correctly sanitized and sterilized before each use. Sterilize the products the day before or on the day of the procedure.

ATTENTION: It is not recommended to autoclave these products in their original packaging.

Please use for sterilization only the steam sterilization according to the following parameters:

	Fractionated Vacuum / Dynamic Air Removal[1]	Gravity Displacement
Sterilization Time	4 minutes	15 minutes
Sterilization Temp.	132° C	132° C
Drying Time	At least 20 minutes[4]	At least 20 minutes[4]

[1] At least three vacuum steps

[2] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure.

[3] Maximum sterilization temperature 134 °C (273°F)

[4] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

NOTE:

1. Please store the instruments after sterilization in the sterilization packagings at a dry and dust-free place.
2. The flash/immediate use sterilization procedure must not be used.
3. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

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