Surgical Manual D.B.E. System

sweden & martina

D.B.E. System

Introduction

Kit D.B.E. System is a kit of screw expanders that allow the surgical preparation of the implant sites and at the same time of the bone crest expansion. It was designed by Dr. Antonio Grosso.

The expansion techniques have gained more and more popularity among implantologists during the last years because they allow the expansion of the resorbed ridge and the placement of implants in the desired positions in one single surgical step. This is the main advantage compared to other augmentation techniques that require deferred surgical procedures and are a bigger discomfort for the patient. This is in contrast to the classical techniques of crestal expansion, that are characterized by a long learning process, during which the use of the mallet procedures can become very uncomfortable for the patient.

"It is important to notice that the patients do not stand, from the psychological point of view, the use of the surgical mallet to obtain an expansion. The research of alternative techniques to open bone flaps after their incision aims at minimizing a technical process considered traumatic. In all cases in which the expansion techniques are necessary for a correct implant insertion, we use a method based on a sequence of expansion screws with a growing diameter, designed by Dr. Antonio Grosso." (Ricucci D., Grosso A., Valutazione dell'elemento gravemente compromesso: conservazione o implantologia. Dental Cadmos 8:I-LIV; 2005)

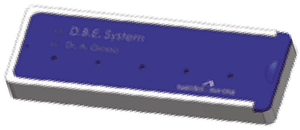
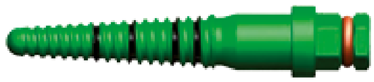
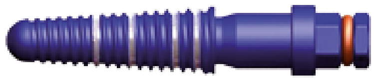
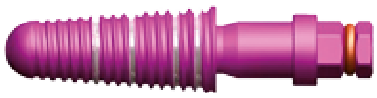
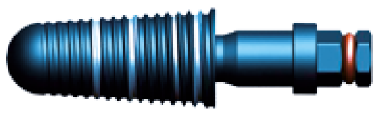
The **D.B.E. (Drill Bone Expander) System** represents a new approach to the implant site preparation, based on a **non-traumatic screw system** that connects with a dedicated handle, bypassing the use of standard surgical drills. This system permits to **control the bone expansion**. The long lever arm of the handle, with the screws inserted gradually, allows the bone wall to be easily moved while screwing, so that a wide implant site is created and the implant can be located in the desired position in a **four wall site**.

The shape of the threads allows the screws to proceed in a self-threading way in all maxillary bone conditions (of type 3 and 4), in order to create a site for the implant location without opening a flap, but using a simple circular scalpel. D.B.E. System can be easily used also in **flapless technique**, in post-extraction and in **transcrestal sinus elevation** exploiting the shape of its screws with round tip to create a repositioning (of **localized expansion**) of the sinus floor.

Surgical kit

The surgical kit is composed by an easy-to-use **autoclavable box** that contains five expanders in titanium Grade 5 and the dedicated handle in which the tips can be inserted thanks to a hexagon connection. The procedure of insertion/extraction of the expander is simple, fast and does not need the use of a particular additional instrument.

Accessory codes included in the D.B.E. kit

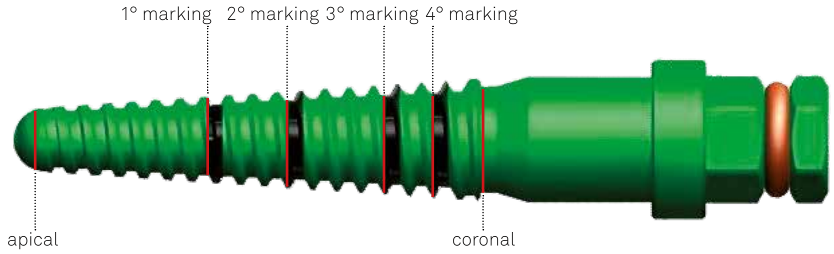
description	code
Surgical kit containing the expanders and the handle	**ESP-G-KIT** 
Bone expander diameter 2.70 mm	**ESP-G-270** 
Bone expander diameter 3.50 mm	**ESP-G-350** 
Bone expander diameter 4.50 mm	**ESP-G-450** 
Bone expander diameter 5.50 mm	**ESP-G-550** 
Bone expander diameter 6.50 mm	**ESP-G-650** 
Handle for expanders	**ESP-G-GRIP** 
Randel instrument tray for expanders	**ESP-G-TRAY** 

All measurements are given in mm, unless indicated otherwise.

Depth markings

The following table reports the expander diameters at the apical level, at the coronal level and in correspondence of the depth laser markings:

DIAMETER VALUES IN CORRESPONDENCE OF THE LASER MARKINGS						
device	apical	1° marking h 6.00 mm	2° marking h 8.50 mm	3° marking h 11.50 mm	4° marking h 13.00 mm	coronal h 14.50 mm
ESP-G-270	**1.50**	--	**2.28**	**2.64**	**2.82**	**3.00**
ESP-G-350	**2.00**	**2.67**	**3.00**	**3.40**	**3.63**	**3.80**
ESP-G-450	**3.00**	**3.62**	**3.97**	**4.39**	**4.59**	**4.80**
ESP-G-550	**4.00**	**4.65**	**5.05**	**5.52**	**5.73**	**6.00**
ESP-G-650	**5.00**	**5.58**	**5.98**	**6.47**	**6.71**	**6.95**



Surgical procedures

The D.B.E. System surgical protocol consists of preparing a partial thickness flap, using the piezosurgery or the sonosurgery to cut the crest for about 9 mm in depth and to perform some mesial and distal releases. The following step is to create an initial hole in the cortical area with a round drill, with diameter 1.80 for about 2-3 mm. The D.B.E. System (Drill Bone Expander) instruments in sequence will determine the **relocation of the cortical plate**. This will allow the insertion of the implant in the desired position in a **four wall site**. The D.B.E. System permits the use of its **round tip** screws to create a repositioning (or localized expansion) of the floor of the maxillary sinus with a **minimal sinus lift**. The shape of the threads allows the expanders to proceed in a self-threading way in those conditions of type 3-4 maxillary bone, in order to create a site without opening a flap, but using a simple circular lancet. Finally, the **tapered shape with self-threading spirals** is particularly indicated in all cases of post-extraction implants.
The D.B.E. System **can be easily used** with **flapless technique, in post-extraction and in sinus elevation with transcrestal approach**.
Some clinical cases are presented below as performance of the different protocols.

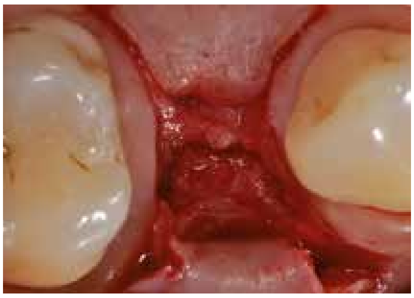
Premolar expansion with Kohno implant

Clinical case by courtesy of Dr. Antonio Grosso, Rome.

Clinical view. The socket profile in the site of the first missing premolar looks concave.

Occlusal view. The ideal insertion of the implant would be possible only in a palatal position.

Crest cut with mesial and distal releases using sonic tips.

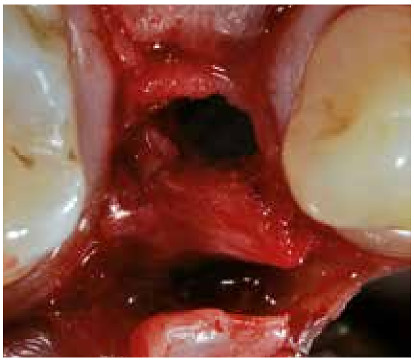


Occlusal view of the partial thickness flaps and of the cuts: horizontal in the crest area, and release mesial and distal cuts.

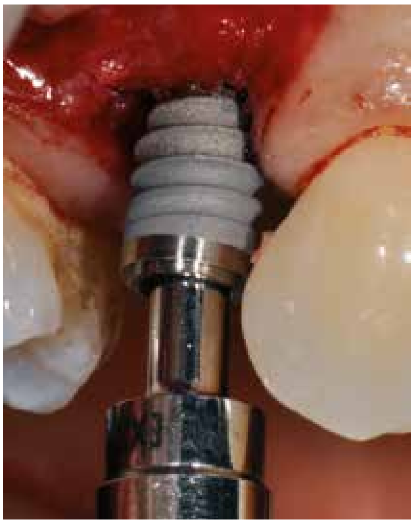
The second expander begins to be inserted.

The second expander has arrived to the planned depth. The combination of the expander and the handle has moved the palatal wall to the vestibular.

Insertion of the third expander.

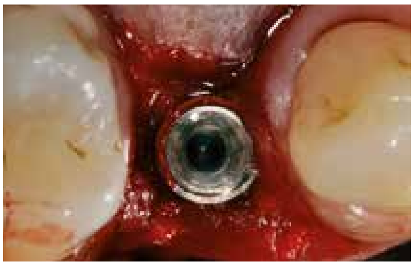


Preparation of the site with four walls.



Implant insertion: the ideal direction is verified and small relocation in the insertion axis are eventually performed.

Implant with the driver. You can now give the planned torque with the dynamometric key.



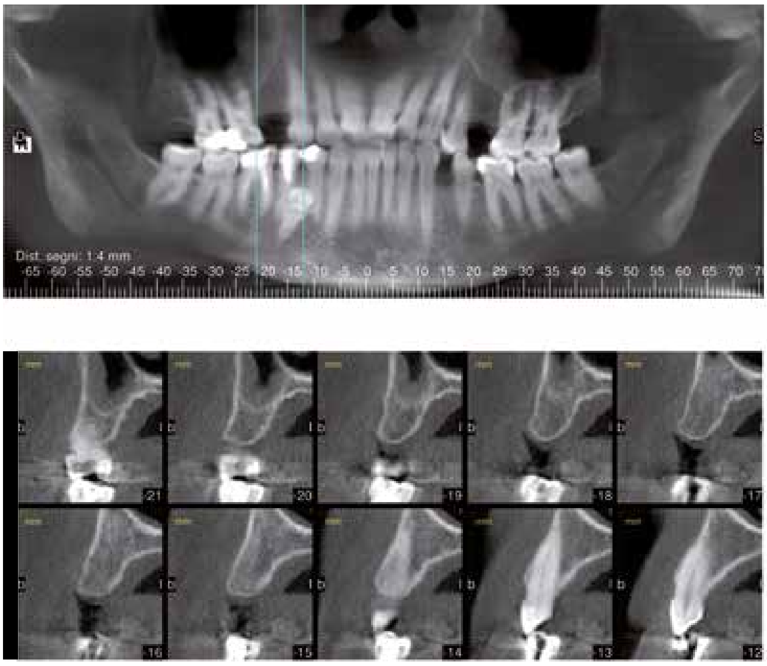
Occlusal view of the inserted implant. The bone relocation obtained is ideal

Frontal view of the inserted implant.

Aspect of the conditioned tissues after 4 months.

Cemented crown.

Control x-rays image after 3 years.



CBCT 1. The initial cone beam shows that if the implant site was prepared with the traditional procedure, using drills, the axis would result inclined and its position would be palatal.

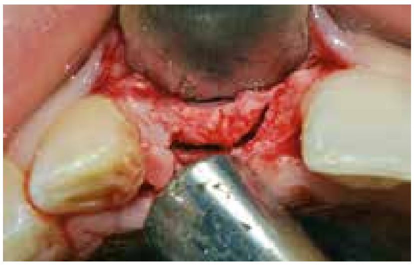
CBCT 2. Implant inserted with the D.B.E. System. The CBCT shows that the direction of the implant inserted is the ideal one, as is the morphology of the bone.

Expansion of the central incisor with Pilot implant

Clinical case by courtesy of Dr. Antonio Grosso, Rome.

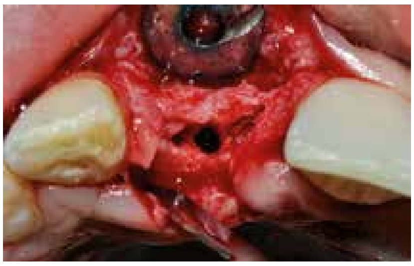
Original conditions.

The occlusal view of the cleft highlights the alteration in the socket profile, due to the bone loss.



Initial cut in the crest area, with mesial and distal releases. The flap is partial thickness.

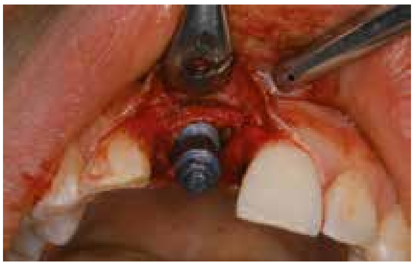
Insertion of the first expander.



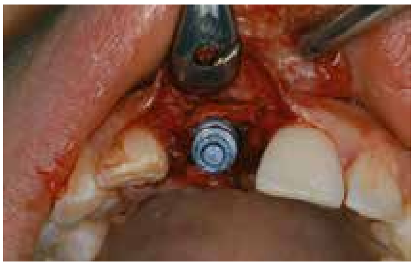
Initial relocation of the bone wall after the use of the first expander.

Insertion of the second expander.

Vestibular view of the second expander. The insertion axis looks ideal.

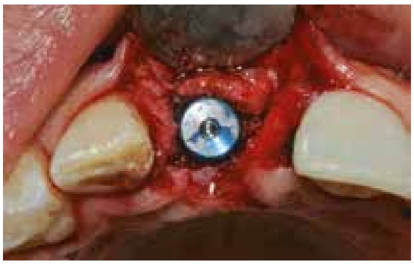


Insertion of the third expander.

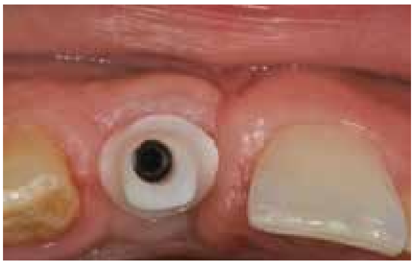


The occlusal view allows visualization of how the vestibular bone has been relocated.

The prepared site.



Pilot implant inserted in the site.



Zirconium abutment after 3 months. From the occlusal view, we can see that the tissue contours are natural looking and similar to the adjacent incisor.

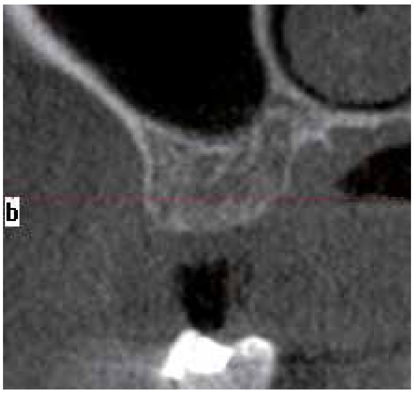
Ceramic crown.

Final x-rays image.

Expansion of the maxillary sinus with Pilot implant

Clinical case by courtesy of Dr. Antonio Grosso, Rome.

Endo oral x-ray image.



Frontal section in the CBCT. You can see the floor and the palatal wall of the maxillary sinus that need to be relocated to create the implant site.

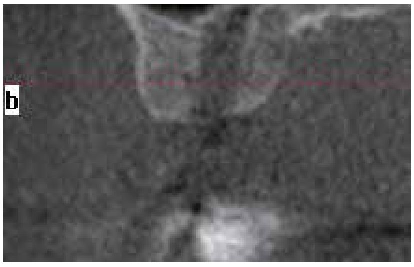
Original clinical conditions. Lateral view of the occlusion.

Occlusal view of the site.

After the preparation of an initial hole in the cortical area with a round drill for about 2 mm, the first expander is inserted from an angle of 45°. The expander proceeds only with a tailspin motion since it is provided with a tip. Since the surgical mallet is not used there is no risk of perforating the sinus floor. The expander tip would slide toward areas of less resistance made by the trabecular bone bone.

Second expander of the D.B.E. System with round tip. After an initial insertion with an axis of 45° towards the palatal wall, the axis can be relocated, moving the sinus floor.

Third expander of the D.B.E. System, it shows the axis is now right.



CBCT section obtained after the use of the third expander. It shows how the sinus floor has been relocated in a limited fashion.

The floor relocation is visible also in the lateral section of the CBCT. The possible perforation of the membrane is taken into consideration with the Valsala operation.

Fifth expander, 15 mm inserted into the gingival margin.

Insertion of the Pilot implant with diameter 5.5 mm and height 13 mm, with handle. During this phase it is still possible to continue with the relocation of the wall, if necessary.

Implant inserted. The insertion axis looks ideal.

Occlusal view of the implant.

Final x-rays image.

Post-extraction with Pilot implant

Clinical case by courtesy of Dr. Antonio Grosso, Rome.

Non-traumatic post-extraction site. The infra-root bone is visible. With a small round drill or using the diamond piezosurgery insert a hole in the infra root bone is made.

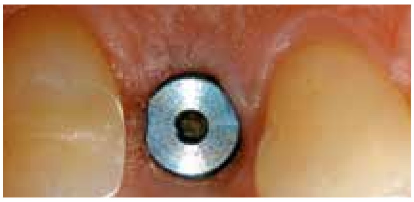
The first expander of the series is screwed-in in the septum.

After the use of the first expander the septum preparation that starts to expand is visible.

Second expander of the D.B.E. System.

Aspect of the septum after the passage of the second expander.

X-rays image after the implant insertion.



Clinical view after 2 months.

Crown cemented over the implant.

X-rays image after 3 months.

X-rays image after 5 years.

Identification of the manufacturer

The manufacturer of the instruments and the respective surgical kit is:

Sweden & Martina S.p.A.
Via Veneto 10 - 35020 Due Carrare (Padova) - Italy
Tel. +39 049.9124300 - Fax +39 049.9124290
e-mail: info@sweden-martina.com - www.sweden-martina.com

D.B.E. System instruments and the respective surgical kit are Medical Devices intended for transient use in the oral cavity (for less than 60 minutes at a time). The functions of these surgical instruments are to prepare sites for implants using the expansion technique.
In accordance with Directive 93/42/EEC implemented in Italy with L.D. 46/97 of 26/03/97, Annex IX, Sweden & Martina declares that it is the manufacturer of D.B.E. surgical kit and instruments and identifies the risk class of these products as shown in table:

device	risk class	rule annex IX	pack
Expanders	1	6	**NON sterile packages**
Handle for expanders			
Instrument tray, complete with bowl and cover		1	
D.B.E. surgical kit complete with all instruments for the execution of the expansion technique		6	

Sweden & Martina declares on its own responsibility that the products are in compliance with the directives mentioned.
The product must be used and handled only by medical and dental clinicians with the necessary accreditation and professional training.

Material composition

The materials used for manufacturing the surgical instruments and the D.B.E. surgical kit were selected based on the properties indicated for their intended use, according to directive 93/42, implemented in Italy with Law 46/97, Annex I - Essential Requirements, point 7.1.
These devices contain no animal origin material.
Patients must be asked if they are allergic to any of the materials used.
Surgical trays are made of:
- PPSU: Cover
- PP-HT: Tray

Expanders and handle for expanders are made of Gr. 5 titanium conform to the harmonised standards.

Warnings

D.B.E. System instruments and the respective surgical kit are sold **NON STERILE**. Before use, they must be cleaned, disinfected and sterilised according to the following procedure. Do not follow these warnings may expose the patient to infection.
It is recommended to collect and file all the clinical, radiological and radiographic records.
Each packaging indicates the code, description of the contents and batch number. These same details, which are also indicated on the labels inside the packs, must always be provided by the practitioner in any relevant correspondence. When handling the devices, both during use and during cleaning and sterilisation, it is recommended to use surgical gloves for personal protection from bacterial contaminations. The packaging is in compliance with the European law.

Contraindications
When assessing the patient, in addition to his/her eligibility as regards implant-prosthetic rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:
- Clotting disorders, anticoagulant therapy
- Healing or bone regeneration disorders, for instance:
    - Decompensated diabetes mellitus
    - Metabolic or systemic diseases that compromise tissue regeneration with a particular influence
    - Alcohol abuse, smoking and use of drugs
- Immunosuppressive therapies, such as: chemotherapy and radiotherapy
- Infections and inflammations, such as periodontitis and gingivitis
- Poor oral hygiene
- Inadequate motivation
- Occlusion and/or articulation disorders as well as an inadequate interocclusal space
- Inadequate alveolar process

The expanders must be used with caution in low-density bone cases, and the sites must be under-prepared.
It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover.
In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment and guided surgery is not recommended. Contraindications also include: allergy to titanium, acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia.

Secondary effects
Situations that may occur after surgical procedures include:
- Temporary local swelling, oedema, haematoma
- Temporary sensitivity alterations
- Temporary masticatory limitations
- Post-surgical micro-hemorrhages in the following 12-24 hours

Cleaning / disinfection / sterilisation / storage

Attention! D.B.E. System instruments and the respective surgical kit are sold **NON STERILE**. Before use, they must be cleaned, disinfected and sterilised according to the following procedure validated by Sweden & Martina S.p.A. These processes must be performed before use and before each subsequent reuse. Repetition of the processes described in this paragraph has minimal effect on the wear of these devices.

a. Cleaning and disinfection

Containers and transport to be used for washing: there are no special requirements. In case of automatic cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually. When cleaning manually: use a suitable neutral detergent and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes. For drills with internal irrigation, use the special pins provided with the handpieces to ensure that the irrigation holes are completely clean and free of bone fragments or biological tissues. After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags. Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilisation

In a vacuum autoclave, proceeding as follows:
- Autoclave (Gravity - Displacement Cycles), Temperature: 121 °C, with autoclave cycle of at least 30 minutes and drying cycle of 15 minutes.
- Autoclave (Dynamic - Air - Remove Cycles) Temperature: 132 ÷ 134 °C, with autoclave cycle of at least 5 minutes and drying cycle of 20 minutes.

c. Storage

After sterilisation, the product must remain in the sterilisation bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilisation bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilise in new bags before using them again. The storage time of products sterilised inside the bags should not exceed that recommended by the manufacturer of the bags.

Maintenance

In order to ensure maximum efficiency, instruments should not be used for more than 20 work cycles and should be replaced in case of damage of the working part. Before every single use it is necessary to verify the ritention of the o-rings located at the basis of each expander and, eventually, replace the damaged ones.

Disposal

The surgical instruments, once used, must be disposed of as biological waste. In general, the local regulations apply.

Responsibility for defective products and warranty terms

Instructions provided by Sweden & Martina and generally accepted by dental practice are available during the treatment and generally accepted by dental practice; it is compulsory to follow the instructions and apply them during all the surgical phases.
The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty. The warranty terms are available on the website www.sweden-martina.com.

Key to symbols used on the surgical instrument packs

description	symbol
Caution! See instruction for use	
Batch number	LOT
Code	REF
Manufacturer	
Consult instructions for use	
CE conformity mark for class I products	CE
American federal law restricts this device to sale by or by order of a professional pratictioner	Rx Only
Single use product, do not reuse	
NON-STERILE device	NON STERILE

Date and validity of the instructions to use

The latest revision date of this manual is **JUNE 2016**.

Customer service

Tailor made training
To be always informed on the most advanced techniques and technologies of the implantology worldwide market, Sweden & Martina organizes a wide range of education courses and events to illustrate the procedures required to complete the personal dental practice.
During the training, you will be accompanied by a staff of experts who will support you for every single demand to improve your professional performances. Our plan of courses involves national and international experts from all over the world, and also in the production of publications, educational material for implantology techniques, surgical manuals, etc.
On the website **www.sweden-martina.com** you can find regularly our updated full agenda of education courses and events organized or sponsored by Sweden & Martina; the agenda is also available and ready to be downloaded online.
nline registration to the courses is easy and fast. Otherwise it is possible to contact our Customer Service Office at: **customerservice@sweden-martina.com**

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The products in this manual are Medical Devices, manufactured by Sweden & Martina S.p.A. and produced in compliance with the UNI EN ISO 9001 and UNI EN 13485 standards and are certified with the CE (Class I) compliance with European Medical Device Directive No. 93/42 and European Directive No. 2007/47/CE.

We have met the good manufacturing standards (GMP) set forth by many countries worldwide, including the United States FDA.

The contents are up to date at the time of publication. Check with the company for any subsequent updates.