Brånemark System®

Zygoma
First from Nobel Biocare.

NobelPerfect®, (NP, RP, WP), NobelDirect® (NP, RP, WP), Brånemark System®, NobelReplace™ and NobelSpeedy™ Implants. A complete assortment with FDA clearance for Immediate Function™ in all single, partial and fully edentulous restorations in the mandible and maxilla.

Nobel Biocare AB and all production units are certified according to the Environmental Management System ISO 14001

Some products may not be available in all markets. Please contact your local Nobel Biocare office for current product assortment and availability.

Nobel Biocare is in compliance with
Canadian Medical Devices Regulation

For USA only: Federal law restricts this device to sale by or on the order of a licensed dentist or physician.
All products are subject to change without notice.
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Beautiful teeth now™

Congratulations! You have made an excellent choice. Welcome to the Nobel Biocare family. Nobel Biocare is providing dentists with more choices than ever before. But our goals remain the same:

• To ensure that your patients leave the treatment room satisfied, comfortable, with beautiful teeth and with a renewed quality of life.

• To help your practice run more smoothly, efficiently and profitably.

This manual is designed to provide quick access to important information regarding treatments, procedures and options for the solution based on the Bränemark System® Zygoma TiUnite™ implant system.

Nobel Biocare solutions are designed to facilitate:

• Short & long-term Easy esthetics
• Patient comfort

For abstracts, study references and for more information, please visit our website: www.nobelbiocare.com
Pre-Surgical treatment planning

Osseoconductive implant surfaces

The TiUnite surface on Nobel Biocare Implants has been shown to support the healing process and better maintenance of the initial implant stability than machined titanium implants. TiUnite is a highly Osseoconductive surface.

Indications

1. Where sufficient anterior bone remains for the installation of standard Brånemark System® implants and the posterior alveolar crest has resorbed to such an extent, that additional implants would otherwise require the support of onlay or inlay grafts.

2. Where an anterior onlay graft is required for implant placement and the need to extend the graft posteriorly can be eliminated by placing the Zygoma implant.

3. The partially edentulous maxilla with uni- or bilateral loss of premolars and molars, combined with severe bone resorption. In such situations, a Zygoma implant, in combination with at least two regular implants, will offer adequate support for a fixed restoration.
Pre-surgical Prosthetic Considerations

There are many factors which contribute to the long-term success of this technique. It is important to carefully evaluate as many of these factors as possible before the surgical procedure is started. In order to achieve proper treatment planning and secure long-term success, an effective team approach must be established.

The pre-surgical prosthetic examination and evaluation should include:

• the facial profile and contours
• any parafunctional habits
• the horizontal and vertical jaw relationships
• the occlusal plane orientation
• the occlusal relationships
• the status of the opposing dentition

Position and angulation of implants

The tooth positions for the planned restoration should be decided preoperatively. This will allow the most appropriate position and angulation to be selected for each implant. The existing removable prosthesis will often serve as a guide for these positions. In some instances a diagnostic wax-up will be necessary. It is up to the prosthetic team to ensure that the surgical team has a clear understanding of the tooth positions required for the final prosthesis. One of the most appropriate means of doing this is by providing a surgical guide. A simple and quick way of fabricating a surgical guide is to make a replica, in clear acrylic resin, either of the existing removable denture or of the waxed-up try-in. The palatal area of the replica, except for a supporting posterior connection, is then cut away leaving only the buccal contours of the teeth.
Biomechanical Considerations

Number of implants

When compared to a standard implant, the Zygoma implant has an increased tendency to bend under horizontal loads. This is related to two factors:

1. The greatly increased length of these implants (30-52.5 mm)
2. The fact that in some circumstances there is limited bone support in the maxillary alveolar crest.

Consequently, these implants should be rigidly connected to stable conventional fixtures in the anterior maxilla. Based on clinical experience and biomechanical theoretical calculations (ref. Zhao, Skalak), a full arch restoration in the maxilla, supported by two Zygoma implants (one on each side), should be assisted by at least two stable regular Brånemark System implants in the anterior maxilla.

Bending moments

Forces that cause bending moments are known to be the most unfavorable. These forces can potentially jeopardize the long-term stability of an implant-supported restoration. In order to decrease bending moments, the distribution of forces should be optimized by:

• cross arch stabilization
• decreased buccal lever arms
• decreased cantilevers
  – mesial/distal and anterior/posterior
• balanced occlusion
• decreased cuspal inclination
Prosthetic design

General guidelines for prosthetic design when utilizing the Zygoma implant should include efforts to:

- incorporate sufficient rigidity and precision in the restoration
- decrease bending moments
- balance functional, esthetic, phonetic, and hygiene requirements
- facilitate maintenance

If the prosthesis is insufficiently rigid, deformation and deflection of the zygoma implant can lead to implant loss or screw loosening.

Local anatomy

The Zygoma implants typically pierce the oral mucosa in the premolar region, and are in a slightly more palatal position compared to the implants in a standard maxillary restoration. It is important for the surgeon to carefully confirm the position of the implant head at the time of implant insertion. The direction and position of the screw attaching the implant mount to the implant represents the future position of the abutment screw.
General pre-surgical examination
The same pre-surgical routine is used as for any other intra-oral surgical procedure requiring local or general anesthesia.
Prior to surgery, the patient
• must have clinically symptom-free sinuses
• must have no pathology in associated bone and soft tissue
• must have completed any necessary dental treatment

Recommended Electronic Equipment & Machinery
For OsseoSet 100 users Article No
Handpiece Zygoma 20:1 32615

Note: Do not use with parts from any other sources. Any manipulation is impermissible and may result in damage or injury. Handpiece Zygoma is a medical product according to the applicable national provisions of law.

Recommendations for using surgical units other than OsseoSet™ 100
The possibility to adjust the gear mechanism of the contra-angle handpiece to 20:1 ratio.
Maximum drill speed limited to 2000 rpm.
Maximum speed for implant installation limited to 45 rpm.
Maximum torque for implant installation limited to 50 Ncm.
Pre-operative radiographic examination

The radiographic examination of the resorbed frontal alveolar bone of the upper jaw is performed, applying the same principles as for standard implant installation:

*Panoramic image* to identify anatomic structures and detect pathological changes within the jaw.

*Intraoral radiographs* in the frontal area as a supplement to panoramic image to exclude pathology.

*Lateral cephalogram* (profile radiograph) to evaluate jaw width in the midline to determine the sagittal relationship between jaws.

*Tomography*, conventional or computed tomography to determine available bone volume in the frontal area as well as in the posterior area.

The objectives of radiographic examination of the zygomatic bone are:

- to detect pathology in the maxillary sinus.
- to evaluate zygomatic bone volume. **Note** that the extension of the maxillary sinus into the zygomatic bone shows large individual variations. Even within the same individual, there may be a difference between right and left.
- to determine the topography of the anterior wall of the temporal fossa, the presence of concavities.
- to estimate the thickness of the alveolar process to the maxillary sinus in the premolar region for bone support of the Zygoma implant.
Techniques

For this kind of treatment, two optional radiographic techniques are highly recommended. The first is computed tomography and the second is conventional tomography. *Computed tomography* with axial or coronal (frontal) scans.

- Axial scans (scan plane parallel to hard palate) are preferable, as the scan plane is identical to the one used for frontal alveolar bone.

- Reformatted frontal images, produced in a plane perpendicular to the scan plane, show the extension of the maxillary sinus into the zygoma and the thickness (width) and height of the zygomatic body can thus be determined.

- Both axial scans and reformatted images show whether pathology of the maxillary sinus exists.

- 3D reconstructions of the zygomatic bone can be useful for the topographic evaluation of the temporal fossa (anterior wall).

It is essential that the CT scan images concern the maxilla, the total sinus height as well as the total zygoma height.

*Conventional tomography*

- Multidirectional motions (spiral, hypocycloidal) are preferred.

- Frontal tomograms (2–4 images some mm apart) perpendicular to the hard palate.

- These frontal tomograms demonstrate the extension of the maxillary sinus. Sinus disease can be diagnosed. The images do not visualize the anterior wall of the temporal fossa.

- The thickness of the alveolar bone between the maxillary sinus and palatal outer border of the crest can be determined.

- If the Scanora® technique is available, sinus tomographic programs, or preferably maxilodental tomographic programs with thinner layer thickness, can be used.
Precautions

- Avoid lateral pressure on drills during implant site preparation. Lateral pressure may cause drill fracture.
- Verify the locking of drills in the handpiece before starting any drilling. A loose drill may accidentally harm the patient or members of the surgical team.
- Verify the locking of any interconnecting instruments before use intraorally to prevent accidental swallowing or aspiration.
- Always use the drill guard in combination with drills to prevent contact between the rotating drill shaft and soft tissue.
Surgery

Standard Le Fort 1 Incision
The reason for using this incision technique is to obtain coverage of the implant by the periosteum and a wide wound area to minimize the risk of dehiscence during healing. It is recommended to make vertical incisions along the infrazygomatic crest region and to continue the incisions in a downward direction, thereby facilitating the exposure of the maxilla and the zygomatic bone and protecting the parotid gland duct.

Alternative:
Incision can be done on the crest or 10 mm palatally to the crest to reflect the soft tissue as well as the periosteum up to the level of the zygoma.

The lateral surface of the maxilla is exposed and the infraorbital foramen identified for the anatomic orientation of the area prior to installation.

To prevent the involvement of the orbital floor during the implant installation sequence, extend the exposure in the posterior-superior direction to the lateral surface of the zygomatic bone up to the point of the incisura between the zygomatic arch and the lateral and medial surface of the frontal process of the zygomatic bone.

Caution: It is imperative to be aware of neighboring arteries, veins and nerves in the surgical area. Injuries on these anatomical structures might lead to complications such as eye injury, extensive bleeding and nerve related dysfunction.
Expose the alveolar crest, including the palatal side of the alveolar crest.

Make a 10 by 5 mm window on the lateral wall of the sinus close to the infrazygomatic crest.

Ideally, the sinus mucosa should be kept intact during this process. Carefully lift the sinus mucosa away from the area where the implant will pass through the sinus, from the floor of the sinus to the roof, trying not to penetrate the mucosa.
Ideally, plan to place the implant as posteriorly as possible, with the implant head as close to the alveolar crest as possible. Simultaneously, the implant must pass through the sinus close to the crest of the zygomatic bone and perforate the cortical bone of the zygomatic bone close to the incisura described previously. Adjustment of this ideal placement may be necessary due to anatomical variations.

Determine the exact point on the alveolar crest to start the drilling sequence and the direction of the long axis of the implant based on the known anatomy of the sinus, the zygomatic bone and its processes.

Place a retractor at the previously described incisura to facilitate the correct 3-dimensional orientation of the implant bone site, with special emphasis on avoiding penetration of the orbital floor.

Due to the length of the drills used for preparing the Zygoma implant bone site, it is important to protect all the oral soft tissues along the drill shaft during drilling. Always use the drill guard to prevent contact between the rotating drill shaft and soft tissue.
Operating Instruments

Please refer to the depth measurement system on page 25.

**Note!** Do not exceed 2,000 rpm when drilling. **Sufficient irrigation is recommended throughout the drilling sequence.**

Make the palatal mark for the implant entrance with the round burr. Penetrate and pass the round burr through to the sinus while checking the direction of the burr through the sinus window. The burr must be directed towards the retractor which was previously placed at the incisura.

Make an entrance mark in the posterior-superior roof of the sinus and then continue with the twist drill, Ø 2.9 mm which is available in two lengths, until the drill penetrates the outer cortical layer of the zygomatic bone at the incisura.

*It is imperative to:*

- *have full control and to protect the soft tissue at the zygomatic bone penetration site*
- *have full control of the area where the drill is penetrating the zygoma and also with a view of the outer cortical layer at the level of the incisura*

Now use the straight depth indicator to determine the desired length of Zygoma implant to be used.

If the radiographs reveal that the zygomatic bone is thin, make sure the drill is directed towards the lateral surface of the incisura in order to minimize or avoid the medial perforation of the bone with the implant.
Widen the bone site successively using the following drills:

The pilot drill (diameter) 3.5 mm is available in two lengths. The pilot end is used to find the entrance of the penetration of the sinus roof previously made by the twist drill, Ø 2.9 mm. 2 different lengths of drill guards are available.

The twist drill, Ø 3.5 mm, which is available in two lengths, is the last instrument to be used in the drilling sequence.

Verify the depth of the prepared bone site with the angled depth indicator to ensure that the selected implant length can be fully seated without apical bone interference.

*If the sinus mucosa can not be kept intact, it is essential to prevent the mucosa from entering the bone site for the implant. Any mucosal remnants in the bone site may preclude osseointegration of the implant.*

*Take care to ensure the correct angulation and to avoid drill wobble, since this can widen the preparation site.*
Implant installation

There are four special areas of concern when installing the Zygoma implant, due to its length and design.

1. Ensure that the implant is guided along the right path of insertion through the sinus.

2. If the drilling unit stalls several turns before the final seating position of the implant when the drilling unit is set at 45 Ncm, this indicates that the bone site has not been prepared to its full depth with the twist drills.

In such an event, back out the implant and prepare the bone site again to match the chosen implant length. Applying excessive torque can distort the implant head or fracture the implant mount or implant mount screw.

3. Rotate the implant to such a position that the angulated hexagonal top is directed towards an ideal occlusal plane. This can easily be verified by observing the position of the implant mount screw which corresponds to the position of the abutment screw.
Installation Sequence

Attach the Connection to Handpiece to the handpiece Zygoma.

Please refer to page 23–24 for information about package opening.

Engage the implant assembly and carry it to the prepared implant site.

Use slow speed on the drilling unit while engaging the implant apex in the prepared bone site. Confirm the correct insertion angle of the implant while continuing through the sinus until the implant apex engages the zygomatic bone.
Disengage the Connection to Handpiece from the implant mount.

Connect the handle with its adapter end to the implant mount.

Rotate the implant clockwise, using the handle, until the desired depth and head position is obtained. The implant head can be positioned accurately by observing the screw which locks the implant mount to the implant. The screw position duplicates the future abutment screw position exactly.

**Caution:** Do not apply bending forces during this procedure. These forces may distort the implant head or cause the implant mount screw to fracture or loosen. If the hand-wrench has to be used excessively, check the implant mount screw for loosening and retighten it if necessary.
When the correct implant head position has been verified, secure the insertion tool with a surgical suture through the hole in the insertion tool.

Use a manual Unigrip Screwdriver or a screwdriver installed on the contra-angle to remove the insertion tool.

Back out the screw 1 to 2 turns and, if necessary, wiggle the insertion tool gently from side to side to ensure that it is not binding on the implant head.

Loosen the screw in the insertion tool completely and remove the screw before removing the insertion tool from the implant head.

**Caution:** The locking screw will always come lose completely which will increase the risk for inhalation.

Use a Cover Screwdriver Hexagon Brånemark System to connect the cover screw.

**Caution:** The cover screw must be completely seated to avoid ingrowth of bone in the internal threads of the implant head. Ingrowth of this kind may prevent the complete seating of the permanent abutment at the time of uncovering if a two-stage procedure is used.
Suturing
To minimize post-surgical bleeding and to ensure complete closure of the wound, the following steps should be followed:

- Start with submucosal sutures, using a resorbable suture material.
- Use non-resorbable vertical mattress sutures in the submucosa and mucosa. This technique minimizes the risk of post-surgical dehiscence formation.
- Place simple sutures between the mattress sutures. Do not suture them as deeply into the submucosa as the mattress sutures. These sutures assure the liquid tight closure of the wound.

Connection of Healing Abutment
Healing Abutments are attached to the implant to allow the formation of a surrounding soft-tissue collar. The abutments are available in two lengths. Use the depth gauge for soft tissue to measure the amount of tissue through which an opening must be maintained.

1. Open the package containing the abutment.
2. Empty the contents into a sterile bowl.
3. Press the UniGrip Screwdriver into the healing abutment and carry the assembly to the implant.
4. Screw the abutment into place.
5. Suture the mucosa between the abutments.
Implant removal

The patient must be informed pre-operatively about the consequences of losing a Zygoma implant and the treatment of such a loss.

Failure of a Zygoma implant to osseointegrate or the loss of an implant due to the loss of osseointegration or fracture renders the implant useless when it comes to supporting a prosthetic restoration. Such an event may lead to a delay in treatment, additional surgical procedures and/or a change in the treatment plan.

To remove the implant, a Zygoma implant mount is secured to the implant with the implant mount screw. The adapter part of the handle is connected to the implant mount and the implant is rotated in a counter-clockwise direction until it is fully disengaged from the bone. Any connective tissue in the bone site is carefully removed before a mucoperiosteal flap is positioned over the entrance and sutured. After a healing period of approximately one year, a new implant can be installed, if so desired.

If a fracture of a Zygoma implant has occurred, the coronal portion of the implant is removed and the apical portion is left to heal in the bone.
Packaging - plastic

1. Note: Loose cover screw

2.

3.

4.
Packaging - glass

1. 
2. 
3. 
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5. 
6. 
7. 
8.
Depth Measurement System

Brånemark System® Zygoma
Abutment connection

Uncovering and Abutment Connection

Uncovering of the implant and abutment connection is accomplished according to standard protocol for Brånemark System® implants when a two-stage procedure is used.

Prosthetic Procedure

Note: Only Brånemark System® Zygoma Abutment Multi-unit (RP) are to be used together with Brånemark System® Zygoma TiUnite implants. Likewise, only Zygoma abutment Multi-unit (RP) are to be used together with Zygoma implants.

Clinical procedure

The prosthetic clinical procedure follows the same sequence as a conventional Brånemark System Regular Platform (RP) case. See Nobel Esthetics Prosthetic Procedure, Multi-unit section.

The prosthetic procedure includes the following steps:

1. Impression

A rigid impression material and impression coping Multi-unit open tray is recommended. An impression of the lower jaw is also recorded, as well as a preliminary registration and jaw relation records.

Note: Before taking the impression it is important to verify proper seating of all abutments using intraoral radiographs. The rotational stability of all abutment screws should also be verified.

2. Adjustment and relining of removable prosthesis

It is imperative to carefully adjust the patient’s existing denture during the course of the prosthetic treatment. This entails an extensive relief of the palatal base. It is important to ensure that the healing caps do not interfere with the hard acrylic of the denture.
3. Master cast fabrication
The impression is delivered to the dental laboratory and a master cast is made. An acrylic record base with a wax occlusal rim is fabricated on this cast.

4. Registration of jaw relations
The record base is attached to the abutments and the occlusal rim is adjusted to the correct vertical height and occlusal plane orientation. Adequate lip support and facial contours are also evaluated and appropriate adjustments are made to the occlusal rim. Tooth shape and shade are selected.

5. Tooth set-up in wax
A preliminary tooth set-up is made according to conventional prosthetic principles.

6. Try-in of preliminary tooth set-up
The wax set-up is tried in the patient. Evaluation of vertical dimension, occlusal relationships, cantilevers, cuspal inclination, tooth shade and shape, hygiene access, lip support, facial contours, etc. is made.

7. Framework fabrication
A rigid framework with adequate volume and precision is made. Cast gold-alloy or precision-milled titanium frameworks (Pro-cera® Implant Bridge) are recommended. A passive fit of the frame-work on the master cast is imperative.

8. Try-in of framework
The passive fit of the framework is verified intra-orally. Use of magnification loops facilitates the procedure.
9. Processing and delivery of final restoration

The passive fit of the final restoration, once fabricated, is verified intra-orally and the retaining prosthetic screws are tightened to 15 Ncm. The occlusion is carefully checked and, if necessary, adjusted.

**Note:** Eliminate any primary occlusal contacts on distal cantilevers.

Screw access holes are temporarily sealed and the oral hygiene procedures are discussed with the patient and necessary instructions given. Intra-oral radiographs are recommended for verification of component fit and recording of baseline marginal bone levels.

10. Post-insertion visit

The patient should be seen one to two weeks after delivery for a check-up. The stability of the restoration is checked, and a general evaluation of function, phonetics and esthetics is made. The stability of the bridge retaining gold screws are also tested and, if necessary, the screws are re-tightened. The screw access holes can be permanently sealed. A soft, easily removed material is placed over the screw head and a hard filling material, e.g. composite resin, is placed on top to completely seal the holes.

11. Re-call schedule

A re-call schedule is established based on an individual evaluation of each patient’s needs and circumstances. Annual clinical check-ups are recommended, with intra-oral radiographic examinations after one, three and five years.
Rigid Bar splinting

In situations when the Zygoma implant has no, or very limited, support by marginal bone, it is recommended to splint the individual fixtures to each other. This should be done immediately after stage II surgery (abutment connection).

Ideally, an impression is made at the time of stage II surgery. Rubber dam can be used to cover the surgical incisions and sutures. The abutments and impression copings penetrate the dam. A laboratory working cast is poured and gold copings are attached to the abutment replicas.

A gold bar is then adjusted to fit and is soldered to the gold copings. The rigid bar is attached to the abutments intra-orally and secured in place with gold screws.

The patient’s removable prosthesis is carefully adjusted and relined, using a soft relining material, as previously described.

Cautions:

- The mechanical performance of implants, abutment screws and prosthetic components, as well as longterm osseointegration, may all be adversely effected by lack of passive fit of the restoration, inadequate prosthesis design, trauma to the oral region and various other aspects of biomechanical overload.

- The Zygoma implant can only withstand functional load if rigidly connected to a minimum of two or more osseointegrated implants.
Product Catalog

**Brånemark System Zygoma TiUnite™ Implants RP**

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<td>Implant 52.5 mm</td>
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All Brånemark System® Zygoma TiUnite™ Implants are delivered with the implant mount pre-mounted. Each package also includes a cover screw.

**Note:** Brånemark System® Zygoma TiUnite Implants are only to be used together with Brånemark System Zygoma Implant Cover Screws, Brånemark System Zygoma Healing Abutments and Brånemark System Zygoma Multi-unit Abutments.

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**Brånemark System® Zygoma Healing Abutments**

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**Brånemark System Zygoma Multi-unit Abutments RP**

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**Zygoma Implants RP Machined**

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All Zygoma Implants are delivered with the implant mount pre-mounted. Each package also includes a cover screw.

**Note:** Zygoma Implants are only to be used together with Zygoma Implant Cover Screws and Zygoma Abutments Multi-unit. Use Healing Abutments from standard assortment.

**Zygoma Abutments RP**

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Brånemark System® Zygoma Drills

DIA 578-0  Round Bur
32628  Twist Drill Ø 2.9 mm
32629  Twist Drill Ø 2.9 mm short
32630  Pilot Drill Ø 3.5 mm
32791  Pilot Drill Ø 3.5 mm short
32631  Twist Drill Ø 3.5 mm
32632  Twist Drill Ø 3.5 mm short

Zygoma Instruments

29162  Zygoma Surgical Kit
Includes: Z handle, Z drill guard,
Z drill guard short, Z depth indicator straight,
Z depth indicator angled.
DIB 097-0  Cover Screw Driver Bmk Syst Hexagon
29152  Screwdriver Machine UniGrip™ 25 mm
(to implant mount screw)
29149  Screwdriver Manual UniGrip™ 28 mm
(to implant mount screw)
32615  Zygoma Handpiece
(to be used with OsseoSet 100)
(semi straight ratio 20:1)
29081  Connection to Handpiece
Achievements

- Inheritors and developers of the work of Professor Brånemark – founder of modern implantology. World leaders in the field
- Providers of the most comprehensive and flexible crown, bridge and implant solutions in the world
- Creators of unique biocompatible material TiUnite® for optimal osseointegration, Immediate Function™ and Soft Tissue Integration™
- Creators of CAD/CAM dentistry
- Creators of unique Procera® System – one seamless procedure from 3D planning to fully guided surgery right through to customized ceramic restoration
- FDA cleared for Immediate Function™ (except 3.0 and Zygoma)
- FDA cleared for Teeth-In-An-Hour™ in 2004

Quality

- Zero non-conformities in 2004 FDA inspection of Nobel Biocare production units in Göteborg, Karlskoga and Stockholm

Research

- Formal collaboration with over 50 academic institutions and 600 independent scientists around the world
- More clinical studies on immediate or early loading than all other competitors combined (Medline Feb 2005)
- More prospective clinical studies with at least 5-year follow-up than all other competitors combined (Berglund et al 2002)

Support

- 165,000 customers trained by 1,985 dental professionals in 37 countries and in 19 languages, during 2004
- Own sales organizations with local Nobel Biocare staff in 29 countries
- Leading business website in 8 languages, with complete online service supplying all products and at least 500 courses available at all times

Nobel Biocare cares about the environment and all production units are certified according to the Environmental Management System ISO 14001.

www.nobelbiocare.com