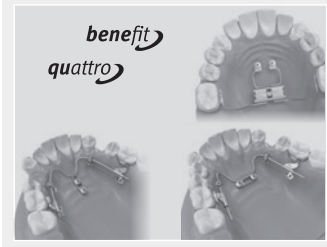

Instruction for Use
BENEfit® and *quattro®* systems

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1. GENERAL INFO

REF These instructions for use refer to any article labelled with: "IFU/Label Reference: KAT-PB-030 "

Warning: Non-compliance with these instructions for use might lead to user/patient injuries

Carefully read these instructions before using these products. Keep them in a safe place for future reference. Every patient must be informed about any contraindications, warnings, precautions and side effects.

2. SYSTEM DESCRIPTION

PSM MEDICAL SOLUTIONS has implemented several Mini-Anchor Systems or Temporary Anchorage Devices (TAD's). BENEfit® and Quattro® Systems represent some solutions. They are made out of different elements embracing implants (BENEfit/Quattro screws), delivered in sterile conditions and several components such as abutments, fixation screws and plates (BENEplates), lingual sheaths, mobilizers, springs and tubes (BENEtubes), delivered in non-sterile conditions.

Recommendation: Only use these systems for the purposes described in these instructions.

The temporary skeletal anchorage option for orthodontic treatment is created using BENEfit®/ Quattro® implantable screws in combination with BENEplates. The screws have a selfdrilling thread in different lengths and diameters of 1.5, 2.0 and 2.3 mm. The screwheads can be connected with different orthodontic appliances in order to achieve the required tooth movement. The BENEplates consist of a single plate (short or long) or a plate with one or two connected wires in different thicknesses and lengths and a fixation screw for each plate hole to connect the plate with the screws. Plates and wires can be bent according to the anatomical situation of the patient using orthodontic wire bending pliers to ensure a strain less (passive) and optimal fit on top of the screws and in the palate. BENEplates and wires are made from pure Titanium acc. ASTM F67 (REF 33-54409-TI and 33-54420 only) or from Stainless Steel acc. ISO 5832-1 (all other parts). Fixation screws are made from Titanium Alloy acc. ASTM F136/ ISO 5832-3. BENEplates without wire can be combined (welded/soldered) with commercially available stainless-steel orthodontic wires in a laboratory.

Recommendation: BENEplates must only be used in combination with original implantable screws and original BENEfit/Quattro accessories.

3. INTENDED USE

BENEfit® and ***QUATTRO®*** systems are intended for stable anchorage in orthodontic treatment.

4. INDICATIONS FOR USE

BENEfit® and ***Quattro®*** systems are indicated for:

- Distalization and Mesialization of teeth
- Mandibular/maxillary tooth anchorage
- Aligning teeth
- Molar uprighting
- Palatal expansion
- Temporary pontics
- Improving the tooth position as part of a preprosthetic treatment

5. INTENDED USER AND USE ENVIRONMENT

Only licensed orthodontists, dentists, and oral and maxillofacial surgeons may insert these products. Prior to the insertion, we recommend that dentists attend a specific mini-implant training course, as these instructions contain only a limited amount of information. Prior to the use of the product, each patient has to be thoroughly examined and informed. The system must be managed in aseptic conditions.

Warning: The attending dentist and all persons involved in handling of the products are responsible, within the scope of their function, to be skilled in product knowledge based on the present state of the technology. Sources of information may include product catalogues, manuals, videos, technical specifications, instructions by a dental consultant, study groups, seminars, publications etc. Product training, including the handling of the product, must occur prior to clinical use.

Precaution: We assume the doctor has experience and knowledge of standard protocols regarding dental practice and limit these instructions only to the use of these products. In case of questions or concerns, please contact us or your local PSM distributor.

℞only **US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner**

6. PATIENT POPULATION

There is no restriction concerning the patient population other than the ones provided in the sections "Contraindications" and/or "Surgical Procedures".

7. CONTRAINDICATIONS

Do not use our systems whether one or more below listed condition is detectable:

- Osteomyelitis
- Cranial radiotherapy
- Lack of vascularization and/or bone in the insertion area
- Infection
- Ulcerations
- Inadequate or lack of oral hygiene
- Manipulation with the tongue
- Fixation on loose teeth
- Fixation on loose implants
- Inaccurate adaptation of the accessories on the implants
- Mental, psychological or neurological conditions that could prevent adequate postoperative healing
- Bleeding disorder, healing problems and/or compromised immune system

8. SAFETY PRECAUTIONS

Precaution: When bending (see Figure 1) the BENEplates and the wires care must be taken that the welding point between plate and wire does not receive any load. Holding or bending within this area will lead to breakage of welding point. Adequate wire bending pliers are recommended. The BENEplate has to sit strain free (passively) on top of the benefit screw.

Precaution: It is strongly recommended that the orthodontic appliance be inserted as soon as possible after the placement of the implant to prevent screw manipulation with the tongue by the patient. The patient has to be instructed in postoperative hygiene and advised to report any change in the operation site or appliance to the doctor. (see also patient information KAT-007-EN)

9. UNDESIRABLE SIDE-EFFECTS AND COMPLICATIONS

Complications are, in most cases, not directly related to used devices, but caused by poor patient selection, manipulation of the implant with the tongue, delayed insertion of the appliance, inadequate training of the dentist or inappropriate implant placement. Placement of the orthodontic appliance in the palate may lead to a temporary speech disorder. In case of known patient nickel allergy, products without nickel should be used (Titanium). Surgical procedures may cause contact with adjacent roots, tooth damage and pain. Insertion of two mini implants in the alveolar process may cause: implant tipping, fracture and failure because of insufficient space on the buccal side to insert a mini-implant safely between the roots, especially in the region of the upper molars. When a mini-implant is inserted in the posterior area of the upper alveolar process, there is a risk of penetration of the maxillary sinus. Surgical procedures involving the application of rapid palatal expansion devices (RPE) may increase the risk of root lesions and infection. Miniscrew loosening or tipping can result from any of the following factors:

- insufficient bone quantity or quality at the insertion site
- overloading
- mobilization
- use of a screw of inadequate diameter or length
- root contact during insertion
- manipulation by the patient's fingers or tongue
- poor oral hygiene
- noncompliance with orthodontic treatment
- application of excessive forces or moments
- too long a lever arm, if the miniscrew is inserted in a region where the gingiva or mucosa is too thick
- peri-implantitis from insertion in the mucosal region
- insufficient primary stability
- orthodontist's inexperience regarding the treatment modality
- bone damage on insertion from stress or overheating
- bone density and cortical bone thickness

Furthermore, implant breakage could be caused by an excessive resistance during insertion or an inappropriate device selection.

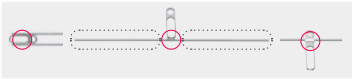

Fig. 1: Bending precaution

10. SURGICAL PROCEDURES

Prior to surgery, evaluate the preferred implant site carefully for bone quality and quantity, using the lateral and anteroposterior cephalometric films, panoramic or periapical x-rays or computed tomographic scans. Select the insertion area and the screw size. Use local anesthesia. Drill a pilot hole through the cortical bone if applicable. Use the appropriate screwholder (see accessories) to pick up the screw from the sterile holder and insert it directly through the gingiva. Screw insertion is done manually with steady rotational movements with the selected accessories until the screw heads touches the gingiva.

If a torque limited screwdriver is used, apply the following adjustment:

1.5 mm Screw max. 15 Ncm,

2.0 mm Screw max. 30 Ncm,

2.3 mm Screw max. 40 Ncm.

The screw can be loaded immediately. Connect the screw with the selected orthodontic appliance. Screw removal is done by turning the screw counter-clockwise without local anesthesia. Following the insertion of the screws the BENEplates are bent either directly chairside or by means of impression taking and a plaster model in a laboratory. After precise bending of the BENEplate to fit the implantable screw the wire is bent to the desired position (see safety precautions) according to the anatomical situation of the patient without touching the soft tissue. If the BENEplate is used for a BENEslider care has to be taken that the lead wire stays absolutely straight along the intended direction of move. Using the provided fixation screws the Beneplate is provisionally tightened on the implantable screws and the accessories are connected and activated. Now the fixation screw is finally tightened (max. 10 Ncm) on the implantable screws. When the tooth movement is occurring, the accessories have to be activated several times until the final tooth position is reached. The BENEfit® System used in tandem (2 screws connected with a BENEplate) is the most used in the palate. The anterior palate is the most suitable insertion area. The screws can be inserted median or paramedian. The adaptation and connection of BENEfit® accessories should be done as soon as possible after the screw insertion either directly on the patient or in a laboratory using the impression cap (REF 33-54410) and the laboratory analogs (REF 33-54425) using a PVS impression.

11. PILOT HOLE DRILLING

Self-drilling miniscrews normally do not need a pilot hole prior to screw insertion in the bone with the following (but not limited to) exceptions. Insertion of 1.5 mm screws in the mandible requires a predrilling through the outer cortex. Palatinally, a perforation of the outer cortical bone in adult patients is recommended. The diameter of the pilot hole depends on the screw diameter. The drills are colored and correspond to the color of the screw holders in the sterile blister. Green = 1.5 mm screw / 1.1 mm drill, red = 2.0 mm screw / 1.4 mm drill, grey = 2.3 mm / 1.8 mm drill. For each patient a new drill must be used. Ensure a maximum of 500 – 800 rpm and provide adequate cooling using a sterile, cooled physiological saline solution. We recommend a manual drilling using a normal contra-angled hand piece with the manual turning unit 10-63025.

12. ACCESSORIES

The Quattro® and Quattro® MINI screws can be combined with commercially available orthodontic appliances like elastics, springs, wires etc. The BENEplates can be bend using commercially available bending pliers. General accessories for the BENEfit System are shown in KAT-PB-032. Furthermore, refer to KAT-002 and KAT-003 for BENEfit® and Quattro® System pictures respectively.

13. DELIVERY CONDITIONS

STERILE R **Implantable screws are delivered in sterile state. Sterilization is achieved by irradiation.**

Re-sterilization of implantable screws is absolutely forbidden.

Do not use the sterile devices after expiration date.

Implantable screws must not be used if package has been opened or damaged. Device sterility may be jeopardized.

Abutments, fixation screw and plates, lingual sheath, mobilizers, springs and tubes are delivered in non-sterile state. They must be reprocessed before use.

Reuse of implantable screw and components, as well as the multiple reprocessing on components are absolutely forbidden.

14. REPROCESSING PROCEDURES

Recommendation: Components must be checked after reprocessing and before surgical procedure meticulously. Only cleaned components must be used.

Precaution: Pay attention to the manufacturer´s detergent instructions regarding concentration, temperature and soaking time as well as post-rinsing. We assume the doctor has experience and knowledge of standard protocols regarding dental practice and limit these instructions only to the use of this product.

Precaution: Use freshly prepared solutions and demineralized water only.

PSM MEDICAL SOLUTIONS components are made out of suitable materials. There are no concerns regarding material resistance and/or any known sensitivity to process parameters during reprocessing (heat, cleaning agents etc.) which may affect the safety of our devices.

15. AUTOMATED CLEANING AND DISINFECTION PROCEDURES

STEP	DESCRIPTION
Preparation	Whenever possible disassemble the instruments. Place the disassembled instruments in the washer disinfector (e.g.: Miele & Cie. KG Gütersloh, Type: G 7836 CD). Ensure that the instruments do not touch each other. If products with narrow lumen or cavities cannot be connected, they must be placed in a way that water and cleaners can drain of completely. Then start the program (e.g.: Shortened Vario TD Program)
Pre Cleaning	For 4 mins
Cleaning	For 10 mins at 55°C using an alkaline cleaner (e.g.: Neodisher MediClean forte [0.5%])
Neutralization	For 6 mins using a neutralizer (e.g: Neodisher Z [0.5%])
Final Rinsing	For 3 mins with deionized water
Thermal Disinfection	For 95 sec at 95°C
Remotion	After completion of the program, remove the instruments from the washer disinfector
Inspection	Control and wrap the instruments immediately after removal from the washer disinfector

16. PACKAGING

Sort the cleaned and disinfected instruments into the sterilization trays and package them in disposable sterilization packages (Single or double packaging) and / or sterilization containers meeting the following requirements:

- acc. to AAMI ISO 11607, suitable for steam sterilization (temperature resistance up to at least 137 ° C (279 ° F), sufficient vapor permeability), adequate protection of instruments or sterilization packaging from mechanical damage and regularly maintained according to the manufacturer's instructions (sterilization container).

17. STERILIZATION

Sterilize the components in accordance with parameters defined below:

Type	Steam sterilization performed in fractionated vacuum process / pre-vacuum process or gravity process (with sufficient product drying)
Temperature	132 ° C (270 ° F) or 134 ° C (273 ° F) (plus tolerance acc. to ISO 17665)
Time	min. 5 mins (132°C) or min. 18 mins (134°, for prion inactivation)

18. STORAGE

PSM devices must be stored in a suitable environment. The storage room has to be dust-free, with low microbiological contamination, dark and free of temperature fluctuations.

Keep the devices away from sunlight

Keep the devices in dry area

19. DISPOSAL

The products are to be disposed of according to the local laws and regulations.

20. QUALITY AND WARRANTY

PSM ensures to the user an immaculate, inspected quality of all products. The responsibility for proper use remains with the user. National regulations and their restrictions have to be observed. All our products are designed and manufactured to the highest quality standards. PSM, as manufacturer of the products, excludes all warranty claims and takes no responsibility for direct or subsequent damage resulting from:

- use for the wrong purpose
- improper use, application or handling
- lack of training
- improper or repeated reprocessing or use
- combination with foreign products (BENEfit)
- disregard of the instructions for use

21. USE OF PSM ORIGINAL PRODUCTS

BENEplates and its accessories are produced and designed to be used together with BENEfit® Screws and BENEfit® accessories. No part of the system should be replaced with a different manufacturer's product, even if the product appears to be visually and dimensionally comparable or identical to the PSM product. The use of other manufacturers' products along with PSM products can involve incalculable risks and/or contamination of the material and misalignment of the implant to the instrument, thereby endangering the patient, user or third parties. For an optimized traceability and patient file documentation each package contains adhesive and detachable product data labels.

22. USED SYMBOLS EXPLANATION

Manufacturer	Keep away from sunlight
Consult the Instruction for Use	Keep dry
E English Description	Do not Re-Sterilize
REF Symbol for "Article Number"	Do not Reuse
LOT Batch Code	Caution, consult accompanying documents
Qty Quantity	Barcode for Reference Number
STERILE R Sterilized by Irradiation	GTIN Global Trade Item Number
Do not use if packaging is open or damaged	℞only US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
Use by	CE 0044 European conformity to the essential requirements with notified body number
Non-Sterile	

Fig. 2

For further informations please contact:

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