



INDICATION FOR USE:

The Pasin-Pin is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only

FEATURES AND CHARACTERISTICS:

Pasin-Pins are self-drilling, self-taping screw composed of titan grade 5 (Ti Al6V4, material no. 3.7165) and are delivered sterile. The screws are available in different diameters and lengths. Length and diameter of the screw thread are always indicated. The Pasin-Pin's slot width is 1.2 mm. The height of the transgingival collar is min. 1.2 mm. The screw head height is 3.0 mm. The Pasin-Pin accessories consist of different materials (indicated on the respective product label) and are delivered non-sterile. The Pasin-Pin and its accessories are determined for single use only and are not suitable for repeated clinical use! By using the removable sticker on the Pasin-Pin's product label it has to be made sure that the lot number can be tracked. The Pasin-Pin's universal head design allows to connect an orthodontic round or square wire / plate with a screwable connection using the Pasin-Pin Fix Cap (article no.: M115).

INSERTION:

The insertion may only be performed by dentists or orthodontists. The dentist's appropriate dentistry-oral surgery expertise is required to perform the implantology treatments.

The treatment must be preceded by an extensive medical diagnosis and careful implantology planning. A careful examination must be performed to determine whether the patient's general anamnestic condition allows for an implantation, particularly with regard to possible allergies to the implant components as well as illnesses that prevent or complicate implantation (e.g.: Diabetes mellitus).

CONTRAINDICATION:

Do not use the devices whether one or more below listed condition is present:

Patients with poor or non-compliance to oral hygiene procedures history, Patients with oral infections, Patients with blood dyscrasias, Patients with uncontrolled diabetes, Patients with psychiatric disorders, Patients affected by malignancies, Patients affected by AIDS, Patients affected by hyperthyroidism, Patients affected by myocardial infarction within the last 12 months, Patients under medications that would compromise healing of an implant site, Patients sensible to titanium.

WARNINGS:

Implant failure / loss could be determined by:

Peri-Implantitis, Post Operative Infections, Systemic diseases, Osteoporosis, Smoking, Not appropriate oral hygiene procedures, Inflammations, Bacterial contamination at implant insertion, Periodontitis, Patients with poorly controlled diabetes suffer from elevated risk of peri-implantitis., Hot beverages after implant placement may affect the healing of tissues, Nerve Injury due to surgical procedures, Periapical lesions due to surgical procedures, Fractures of the atrophic edentulous mandible due to surgical procedures, Abutment fractures due to surgical procedures, TADs implants are associated with a risk of implant failure, Sufficient bone quality, with regards to bone width and height, must be present., The healing of the implant must be monitored regularly by means of x-rays, infected implants must be removed promptly.

TREATMENT PROCEDURE

PLANNING:

The specified length of the Pasin-Pin is the result of thread length and transgingival collar. Pasin-Pins with a diameter of 1.6 mm are provided for the lower jaw. The pin diameters 2.0 mm and 2.3 mm are provided for the upper jaw. Prior to insertion of the Pasin-Pin, place of insertion, relation to adjacent teeth, and position of the roots should be evaluated by means of clinical findings, model analysis and x-rays. The Pasin-Pin should be placed within the attached gingiva (gingiva alveolaris). The placement of the screw requires a location that has sufficient bone depth of minimum to accommodate the miniscrew and to protect the anatomic structures. Common locations for Pasin Pin are the midpalatal suture (only in adults), parasagittal midpalate and a interradicular insertion between the tooth roots. We do not recommend inserting Pasin-Pins close to dental follicles. For the insertion of a Pasin-Pin, hygienic measures have to be taken just like for an invasive surgery.

ANESTHESIA:

For anesthesia during insertion of a Pasin-Pin, surface or infiltration anesthesia is required.

MEASUREMENT OF GINGIVAL THICKNESS:

At the place of insertion the gingiva should be as thin as possible. The measurement of the gingiva is performed with a pointed dental probe with an elastic stopper attached. Information about the gingival thickness is needed to define the screw length. For sufficient stability, the pin should be anchored in the bone at least with a length of 7 mm.

METHODS OF PLACEMENT OF PASIN-PIN:

Self-drilling method:

The miniscrew is driven directly into bone without pre-drilling and without previously punching or incision of the gingiva or without forming a flap. Pasin-Pins have a self-drilling and self-taping thread; therefore they can be inserted without pre-drilling.

Self-tapping method:

In this method, the miniscrew is driven into the tunnel of bone formed by pre-drilling, making it tap during implant driving. This method is recommended in adults.

PRE-DRILLING:

If pre-drilling is required due to bone quality, it should be performed using NaCl-suspension for cooling and with approx. 800 rotations per minute. We recommend a direct pre-drilling resp. direct insertion of the screw through the gingiva without previously punching or incision of the gingiva or without forming a flap.

INSERTION:

The sterilized packaging (blister) must be removed only inside the treatment room directly before implantation takes place. The label with information about the Pasin-Pin-implant and the LOT-no. with the UDI barcode is transferred to the patient's file. The Screw Holder (article no.: SD25G) can be used for manual or mechanical insertion of Pasin-Pins. The implant can then be screwed into the right position without being touched. The turning moment recommended is maximal 25 Ncm and the screwing speed should not exceed 25 rotations per minute. After insertion of the Pasin-Pin, the screw holder is removed. For adjustment of the Pasin-Pin slot, the Screwdriver (article no.: SD25) is used. The Screwdriver does not cause any clamping force on the implant while removing.

CONNECTION OF THE PASIN-PIN TO AN ORTHODONTIC APPLIANCE OR ORTHODONTIC WIRE:

The Pasin-Pin system allows to directly attach round or square wires starting from dimensions of 0,5 mm up to 1.15 mm. The connecting element (round or square wire / plate) is secured with a screwable connection using the Pasin-Pin Fix Cap (article no.: M115). The Pasin-Pin Fix Cap is screwed on the Pasin-Pin with the Screwdriver (article no.: Q2114). Pasin-Pin connecting elements: The connecting elements supplied facilitate the construction of different orthodontic appliances.

STORAGE CONDITIONS:

The implant must be kept dry and stored in a dry place at room temperature in the original packaging, protected from direct sunlight. The implant is intended for single use only! If the blister is damaged the implant must be discarded because of the risk of bacterial contamination. There should be no unauthorised re-sterilisation. In case of intact sterile packaging and proper storage, sterility is only guaranteed until expiry date.

LIABILITY:

There is no liability for unsatisfying results. The appliance must only be used by a dentist or an orthodontist. The dentist or orthodontist is responsible for the use himself.

SAFETY INSTRUCTIONS:

The firmness of the screws must be checked by the doctor in regular intervals to recognize loosened screws and to prevent a loss of the appliance with the danger of swallowing or aspirating the appliance or parts of it. The patient must be instructed for self-control.

CLEANING AND DISINFECTING:

Suitable measures for cleaning, disinfection and if necessary sterilization must be carried out with a validated method before using the product. Detailed instructions on cleaning are provided separately and can be requested.

MRI SAFETY INFORMATION:

The Pasin-Pin System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Pasin-Pin System in the MR environment is unknown.

Scanning a patient who has this device may result in patient injury.

SIDE EFFECTS:

- Reversible or irreversible damage is possible when the implants are inserted close to specific structures (e.g. adjacent teeth, maxillary sinuses, nerve fibers).
- In rare cases, allergies to the implant components can prevent successful implantation.
- In cases of inflammation, periimplantitis the implant must be removed.
- Directly after insertion of the dental implants, activities where the body is subject to high physical stress should be avoided. Possible complications can be: temporary discomfort, pain, swelling, phonetic difficulties, gum inflammation.
- Other long-lasting disorders can be: permanent paraesthesia, dysaesthesia, anaesthesia, localised or systematic infections, orofacial or oronasal fistulas, compromised adjacent teeth, implant / jaw / bone or denture fractures, aesthetic problems, nerve damage, exfoliation, hyperplasia.





INSTRUMENTS:

The instruments needed to insert the implant are provided in an unsterilized state, shrink-wrapped in a foil pouch, and labeled with the corresponding article description. Instruments are made from titanium alloy in accordance with ISO 5832-3 or titanium in accordance with ISO 5832-2 and must be prepared by the user before each procedure. Please follow the specific reprocessing instruction for reusable instruments.

PASIN-PIN FIX CAP

Article No. M115
Screw nut for the Pasin-Pin

PASIN-PIN LABORATORY ANALOG

Article No. LA11
After the implant insertion an impression of the jaw can be performed by means of Alginate, respectively silicone to obtain a negative form of the clinical situation. There by the Pasin-Pin is positioned laboratory analog in the impression.

P-SCREWDRIVER

Article No. SD25, SD35, SD70
The screwdriver is available in different lengths. This instrument serves to align the implant, respectively the slot after the insertion. In contrast to the screw holder the screwdriver thereby does not cause any friction, respectively pulling forces during the removal of the implant screw.

P-SCREW HOLDER

Article No. SD25G, SD35G, SD70G
The screw holder is available in different lengths. This instrument ensures a secure, sterile removal from the packaging, as well as a secure hold during the implantation.

P-SCREW HOLDER GUIDE

Article No. SD30G
Special Pasin-Pin Screw Holder to use in combination with a surgical guide splint

P-DRILL GUIDE SLEEVE

Article No. DGS1
Guide Sleeve for „DR10“ Drill; to use in combination with a surgical guide splint

P-SCREW HOLDER GUIDE SLEEVE

Article No. HGS1
Guide Sleeve for „SD30G“ Screw Holder; to use in combination with a surgical guide splint

SCANBODY PASIN-PIN

Article No. SB018
To use in combination with intraoral scanner and 3D software

P-SCREW HANDLE

Article No. L3
Screwdriver handle for screwdriver SD70 and SD70G for a manual insertion of the implants

DRILL 1.0 X 15 MM

Article No. DR10
Pilot drill

P-PLATE T-TYPE

Article No. P1200
Prefabricated coupling element for two Pasin-Pin. Connects square wire to round wire.

P-PLATE H-TYPE

Article No. P1201
Prefabricated coupling element for two Pasin-Pin. Connects square wire to round wire.

ACTIVATION LOCK WITH SCREW

Article No. AL120
Screwable and sliding body for activation of the coil spring

TITANIUM FIXING SCREW

Article No. TIFS
Replacement screws for Activation Lock with Screw

NITI-SPRING 250 CN

Article No. NS045
Coil spring with 250 cN

SPRING 500 CN

Article No. SS500
Coil spring with 500 cN

Q SCREW HANDLE

Article No. Q2116
Screwdriver handle for all dental handpiece screwdriver

SCREWDRIVER FC

Article No. Q2114, Q2114L
The screwdriver is available in different lengths. Screwdriver handle for the Pasin-Pin Fixing Cap

SCREWDRIVER HEX

Article No. Q2115, Q2115L
The screwdriver is available in different lengths. Screwdriver for the Titanium Fixing Screw, respectively Activation Lock

BONDABLE CONNECTOR ROUND

Article No. BDC12
Prefabricated coupling element for direct bonding to the tooth

BAYONET CONNECTOR ROUND

Article No. BYC12
Adapter from round wire to orthodontic lingual Sheath

TORQUE-RATCHET

Article No. QX30
Torque ratchet, support instrument to insert the implant in the jaw with a certain maximum torque

P-STERILIZATION-BOX

Article No. PSB1
Sterilisable instrument tray

JET HOOK

Article No. JH16
Prefabricated coupling element for TPA or a closed coil spring

Sterilization Instruction:

Temperature: 132°C
Holding Time: 4 minutes
Drying Time: 20 minutes

Packaging: The products are delivered in non-sterile state. Transport packaging is not suitable for sterilization. Devices must be either packed in suitable steam sterilization packaging systems in accordance with to ISO 11607 and/or AAMI / ANSI ST77:2006 or FDA cleared wrap (e.g.: Steriking-foil: RB51-3P and RB52-3P).

Explanation of symbols used on the label		0297	European conformity to the essential requirements with notified body DQS Medizinprodukte GmbH / August-Schanz-Straße 21 / 60433 Frankfurt am Main, Germany NB Number: 0297		Double sterile barrier system
	Medical device		In accordance with US-American federal law, this product can only be sold directly to trained medical practitioners or on their behalf.		Sterilization using irradiation
	Unique Device Identification		GS1 Datamatrix - Unique Device Identification		Do not resterilize
	Order number		Caution, consult accompanying documents		Only sterile if the package is undamaged
	Lot number		Consult instructions for use eFU: bbc-orthotec.de		Non-sterile
	Manufacturer		Do not reuse		Keep dry
	Manufacturing Date		Use by		for "Keep away from sunlight"



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