



Abutments and healing caps Instructions for Use

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Device description and intended use:

All QRS' abutments, cover screws, healing caps, Straight ball attachment, smart attachment and straight multi-unit abutments are made of Ti6Al4V ELI titanium alloy.

Abutments (straight abutments, angulated abutments (15°, 25°), and anatomic angulated abutments (15°, 25°)) are intended to be used in conjunction with endosseous dental implants fixture to aid in prosthetic rehabilitation. The abutments are intended for long term use and are in contact with tissue.

The abutments are available straight or angulated, in different heights and diameters to accommodate the patient's specific needs. They are available in 0, 15 or 25 degrees angulation.

Straight Abutment SP Titanium Abutment is provided in height of 5, 7 and 9mm.

Standard shoulder abutment in heights of 1, 2, 3 and 4mm

Standard Wide Shoulder Abutment is provided in heights of 1, 2, 3 and 4mm

Standard 15° Abutment is provided in heights of 2, 3 and 4mm

Standard 25° Abutment is provided in heights of 2, 3 and 4mm

The healing caps are intended for use with the implant system to protect the inner configuration of the implant, maintain, stabilize and enable formation of the soft tissue during the healing process. Healing Caps are provided in 4.5 diameter in heights of 3, 4, 5, 6 and 7mm. Wide Healing Cap is provided in 6 diameter in heights 3, 4, 5 and 6mm.

Straight Ball attachment are designed to increase retention of (partial) overdentures, supported on implants. QRS titanium Ball Attachments (Straight) provide firm retention and stabilization of the overdenture when used with tissue-supported implant-retained overdentures and are compatible with QRS internal hexagon connection implants. Ball attachments are provided in heights of 2, 3, and 4mm. The device is intended as an intra-oral abutment secured to implants onto which a multiple unit prosthetic restoration is screw retained. Straight Ball Attachments allow a maximum 30° divergence between two implant



constructs, with each implant/ abutment construct having no more than 15° correction. They are available with internal hex connection.

Smart Attachment - Locator abutments are designed for use with overdentures or partial dentures retained in whole or in part by dental implants in the mandible or maxilla. They offer multiple levels of retention and low vertical profile. The self-aligning design enables patients to easily seat their dentures. Smart attachment are provided with heights of 1, 2, 3 and 4mm.

Straight Multi-unit abutment are indicated for multiple unit reconstructions when screw retained prosthetics is preferred. Multi-unit abutments allow either direct screw of the prosthesis into the multi-unit abutment or connection to a fixed overdenture bar. Multi-unit abutments are provided in heights of 2, 3, 4 and 5 mm.

Abutments, healing caps, smart attachments and straight multi-unit abutment are provided non-sterile to the user and have to be sterilized prior to use by moist heat.

All the Abutments, healing caps, smart attachments and straight multi-unit are intended for single use only.

QRS Abutments are compatible with QRS implant systems: Red Class, Blue Class and Gold Class

Implant System	Platform Connection	Compatible Abutment
Blue Class (Internal Hex)	Narrow Platform Standard Platform Wide Platform	NP prosthetic Abutment SP prosthetic Abutment WP prosthetic Abutment
Gold Class (Internal Hex)	Standard Platform	SP prosthetic Abutment
Red Class (Internal Hex)	Narrow Platform Standard Platform Wide Platform	NP prosthetic Abutment SP prosthetic Abutment WP prosthetic Abutment
One piece	NA	NA

Indications for use:

QRS Dental Implants Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.

The implants (Ø3.3 mm and one-piece) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary



lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

Contraindication:

General contraindications associated with elective surgery should be observed. Allergic or hypersensitive response to Ti-6Al-4V alloy (titanium, aluminum, vanadium).

Directions for Use**Recommended tightening torque:**

Prosthetic Device	Recommended Torque (Ncm)
Cover Screw	30
Healing Cap	15
Ball Attachment	20
Standard Multi-Unit	30
Straight Abutment	30
Angled Abutment	30
Smart Attachment	30

Warnings:

- Never exceed the recommended tightening torque for the abutment screw. Over tightening of the abutment may lead to a screw fracture
- All the abutments are provided cleaned and non-sterile and are intended to be sterilized prior to use.
- All the abutments are intended for single-use.
- Abutments are not intended to be further processed and used again.
- Re-use of abutments may cause cross-contamination and infection.
- Multi-Unit abutments are only intended for multi-unit restorations and are not intended for single-unit restorations.
- Small diameter implants and angled abutments are not recommended for the posterior region of the mouth.

CAUTIONS

- QRS abutments must only be used by certified dentists and technicians.
- The dentist is responsible for determining whether the product is suitable for the particular patient and case.
- Due to the small size of the devices, care must be taken that they are not swallowed or inhaled by the patient.
- Cleaning should not contain any of the following ingredients: Strong organic acids or mineral acids, strong base solvents, organic solvents (e.g. acetone, ether, hexane, Benzene), oxidizing agents (e.g. peroxide), halogens (chlorine, iodine, bromine) or aromatic,



MRI Environment: MRI conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	Dental implant system
Static Magnetic Field Strength (B ₀)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

based on published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically induced Displacement force and torque on Metal Alloys Used in Medical Devices." Journal of testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments and fixation screws).

Sterilization Instructions:

Important note: A sterilization pouch suitable for steam sterilization should be used. We recommend you to use of an FDA-cleared pouch for the intended sterilization cycle. (e.g.: WIPAK, self-sealing sterilization pouch that was used by QRS in the steam sterilization study).

Prior to use, abutments are to be sterilized, by steam sterilization as follows: For Pre-vacuum process:

1. Place the abutment in the sterilization pouch.
2. Heat up to a minimum sterilization temperature of 132°C/269.6°F
3. Minimum Holding time: 4 min
4. Drying time: 20 min

For gravity process:

1. Place the abutment in the pouch.
2. Heat up to a minimum sterilization temperature of 132°C/269.6°F
3. Minimum Holding time: 15 min
4. Drying time: 15 min



Explanation of symbols

Symbols on the product package and labels should be interpreted as follows:

	Medical device
	Manufacturer
	Consult instructions for use or consult electronic instructions for use
	Caution
	Batch code
	Catalogue number
	Date of manufacture
	Quantity
	Do not resterilize
	Do not reuse
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-sterile
	Keep dry
	Keep away from sunlight
	Unique device identifier
	Do not use if package is damaged and consult instructions for use

Registration number in the Israeli MOH registry 34960002



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