



Implants Instructions for Use

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

This document applies to **QRS** Dental Implants group (**Red Class, Blue Class, Gold Class & One-piece**)

All **QRS** products are intended to be used by appropriately trained and licensed professionals. A warned practitioner to implantable technics should always perform **QRS** Dental Implant system placement. The absence of practitioner's adequate training induces a major risk for the success rate of dental implants and can even compromise the state of the general health of the patient

Indication 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 (Ø3.3mm 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.

Description:

QRS Dental Implants are self-tapping, root-form, one piece or two piece screw (Red Class, Blue Class, Gold Class) type dental implants, indicated for use in surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. The **QRS'** dental implant is a two stage screw type device that can equally well be used as one stage, surgically placed in the upper or lower jaw to provide support for prosthetic devices in partially or completely edentulous patients. The **QRS'** two piece implant is to be used in combination with several different abutments and superstructures provided in order to aid in the prosthetic rehabilitation.

QRS dental implants (Red Class, Blue Class and Gold Class) are a standard internal hex implant system which provided in 3.3, 3.75, 4.2, 5.0 and 6.0mm diameter for lengths of 8, 10, 11.5, 13 and 16mm.

The **QRS** Dental Implants two piece are to be used in combination with cover screws, healing caps and abutments according to commonly used protocol in the dental implantation field.

QRS dental implant one-piece is provided in 3.3 and 3.5mm diameter for lengths of 10, 11.5, 13 and 16mm.

The **QRS** Dental Implants are made of Ti6AL4V ELI complying with standard ASTM F 136- 13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

The implants are grit blasted and acid etched surface. The system includes Straight abutments, ball attachments, healing caps, smart attachments, angulated abutments 15° and 25°, anatomic angulated abutments, multi-unit abutments are included in the system.

**Important:**

QRS implants are to be used in combination with cover screw, healing caps, standard abutments, including up to 25° angulated abutments and additional abutments for prosthetic reconstruction. It is highly recommended to use only QRS prosthetic parts with QRS implants.

Maximum compatibility and accuracy can be achieved when using compatible QRS tools, drills, accessories and prosthetic parts manufactured by QRS.

Contraindications:

The contraindications customary in oral surgery with other implant materials should be observed. These include patients on corticosteroids or anticonvulsant, and those receiving radiation of other immunosuppressive therapies are not candidates, nor are patients with diabetes, cardiovascular disease, hypertension. Osteoporotic crush fractures, respiratory disease, thyroid or parathyroid disease, should be excluded as well as patients with diagnosed malignancy in the past five years and those with nodular endangerments, tenderness or unexplained lump in the head or neck. Implanting procedure should not be performed on persons with active osteolytic, inflammatory or infectious process in the implanting site.

Additional Contraindications:

The following outline lists the contraindications:

- Pregnancy, Hemophilia, Granulocytopenia or other bleeding problems.
- The consumption of tobacco seems to be a factor associated with the increase in the loss of dental implants.
- Hypersensitivity of the patient in the specific components of the implant.
- Lack of adequate training of practitioner.
- Conditions, diseases or treatment that severely compromise healing.
- impossible prosthetic reconstruction
- Poor patient motivation.
- Psychiatric disorders that interfere with patient understanding and compliance with necessary procedures.
- Unrealistic or Inability patient expectations.
- Inability of patient to manage oral hygiene.

Secondary Effects

The risks associated to this surgical operation can be divided into four categories:

1. Immediate risks related to the anesthesia and the surgery procedure.
2. Psychological or psychiatric risks
3. Long-term medical complication
4. Long-term deleterious effects of implants on health

The following long-term problems can also appear: damaged nerve, local or systemic bacterial infection, infectious endocarditis in sensitive or post-transplantation individuals. The incorrect placement of an implant can damage the natural set of teeth.

Temporary phenomena resulting from the insertion of the implant such as: pain, swelling, speech disorders and inflammation of the gums.

Drilling and perforation of the nasal and maxillary sinus, local and systemic infections, perforation into soft tissue spaces, and nerve injury. Temporary conditions that may include pain and swelling, speech problems and gingivitis.

long-term problems may include nerve, local or systemic bacterial infection and infectious endocarditis in susceptible individuals, including those with body part



replacement. Existing natural dentition may be compromised by improper implant placement.

The following outline list of organ systems with corresponding pathophysiological problems may influence risks:

- Cardiovascular failure: Coronary artery disease, Arrhythmia's.
- Respiratory: chronic obstructive pulmonary disease.
- Gastrointestinal: Hepatitis, Malabsorption, Inflammatory bowel disease.
- Genitourinary: chronic renal failure.
- Endocrine: Diabetes, Thyroid disease, Pituitary/adrenal disorders.
- Hematological: Anemia, Leukemia, Bleeding clotting disorders.
- Musculoskeletal: Arthritis, Osteoporosis.
- Neurologic disorders: Stroke, Palsy, Mental retardation.

Limited warranty:

In case of implant failure, QRS undertakes to replace such implant unit, free of charge, subject to the following conditions: A written notice of such failure is submitted to QRS, not later than within 6 months of first sign indicating such failure. Accompanied by a follow-up report in the form issued by QRS, the relevant X-Ray and failed implant. This is complete warranty for the implant by QRS, setting forth your exclusive remedies respecting thereto.

Precautions

The surgical techniques required to place endosseous dental implants require specialized and complex procedures. Formal training for placement of implants recommended. Important: determine local anatomy and suitability at the available bone for implant placement. Adequate radiographs direct palpation and visual inspection of the implant site are necessary prior to treatment, planning and use of QRS implants.

Warnings:

- Use of implant may require preoperative antibiotic prophylaxis
- QRS Dental Implant system is used in association with specific related prosthetic parts manufactured by QRS. These prosthetic parts must not be substituted by references not manufactured by QRS.
- Any use of prosthetic material and/or ancillary not validated by QRS pull de facto the loss of the manufacturer's guarantee.
- Invasive and implantable parts of the QRS system are single-use devices and must not be reused. Any re-use of a single-use device induces a significant risk of infection for the user and the patient and a loss of the mechanical properties of the implants and the prosthetic parts. Re-use of implants may cause cross-contamination, infection and implant failure.
- QRS implants are provided sterile. Do not re-sterilize implants. Re-sterilization of implants may cause cross-contamination, infection and implant failure.
- QRS Implants are made of Titanium which is not ferromagnetic metal and doesn't react to magnetism. QRS implants can be safely used in the MR environment.
- Small diameter implants and angled abutments are not recommended for the posterior region of the mouth.



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 (Bo)	≤ 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).

Packaging:

QRS Dental Implants is provided sterile (gamma sterilization) in one unit package with a cover screw.

A witness label affixed on the packaging indicates the actual passage of implants in irradiation. The sterility is guaranteed 5 years (from the date of sterilization).

Only an intact packaging guarantees the sterility of the products. Do not use implants with damaged or prematurely opened package.

Every packaging, besides the product reference, contains self-stick labels resuming all the specifications of the implant (cat number, lot number, sterilization, use by date, etc.) which are to be affixed on the patient file.

QRS Implants must be stored in a clean, dry, fresh and appropriate place.

QRS dental implants are single-use devices. Never reuse an extracted and/or failed implant. The re-use and/or the re-sterilization of any implant might cause infectious disorders of the user and the patient.

Procedural Precautions:

All components must be checked before use.

The presence of the bone and its capacity to support the implant must be estimated from radiographies of the zone of implantation, according to the current techniques for the realization of false teeth.

Also, it is necessary to study very carefully the location of blood vessels, maxillary sine, nasal cavity, cavities in mild parts, as well as their relation in the zone of setting-up.

Surgical Procedure:

1. Open the implant and cover screw case onto a sterile surface.
2. Disinfect the implant site



3. Marking the bone according to the planning of the established intervention
 4. Preliminary drilling before the implant insertion: the insertion of the implant has to respect a surgical protocol including a sequence of drilling adapted to the clinical case and to the osseous criteria of the patient.
 5. Insertion of the implant: do not exceed strength of 60N during the insertion of the implant
 6. Screwing of the cover screw supplied with the implant or of a healing cap.
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Recommended Surgical Steps:

QRS/BLUE CLASS

RPM	Type for Bone	Implant Diameter			
		Ø3.3	Ø3.75	Ø4.2	Ø5
1200-1500	-	Marking Drill			
900-1200		Pilot Drill Ø2			
900-1200		Pilot Drill Ø2.5			
800-1000		-	Drill Ø2.8		
500-700		-	-	Drill Ø3.2	
400-600		-	-	-	Drill Ø3.65
300-500		-	-	-	Drill Ø4.5

QRS/RED CLASS

RPM	Type for Bone	Implant Diameter			
		Ø3.3	Ø3.75	Ø4.2	Ø5
1200-1500	-	Marking Drill			
900-1200		Pilot Drill Ø2			
900-1200		Pilot Drill Ø2.5			
800-1000		-	Drill Ø2.8		
500-700		-	-	Drill Ø3.2	
400-600		-	-	-	Drill Ø3.65
300-500		-	-	-	Drill Ø4.5

QRS/GOLD CLASS

RPM	Type for Bone	Implant Diameter			
		Ø3.3	Ø3.75	Ø4.2	Ø5
1200-1500	-	Marking Drill			
900-1200		Pilot Drill Ø2			
900-1200		Pilot Drill Ø2.5			
800-1000		-	Drill Ø2.8		
500-700		-	-	Drill Ø3.2 *	
400-600		-	-	-	Drill Ø3.65 *
300-500		-	-	-	Drill Ø4.5 *



QRS/One-Piece

RPM	Type for Bone	Implant Diameter	
		Ø3.3	Ø3.5
1200-1500	-	Marking Drill	
900-1200		Pilot Drill Ø2	
900-1200		Pilot Drill Ø2.5	
800-1000		Drill Ø2.8	
500-700		-	Drill Ø3.2

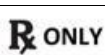
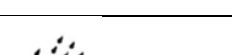
*** reach 2mm less and up to 2/3 of drill length**

Note

- All measurements are in mm
- The recommended drill protocol procedure should not replace the dentist's/surgeon's judgment.

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
	Use-by date
	Quantity
	Do not resterilize
	Do not reuse
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	Single sterile barrier system
	Sterilized using irradiation
	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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