

INSTRUCTIONS FOR USE REX TL 1.8

ENGLISH (USA) – INSTRUCTIONS FOR USE

⚠CAUTION: U.S. Federal law restricts this device to sale only by or on the order of a licensed dentist or physician.

Device Description

The Piezoplant System consists of endosseous dental implants, surgical instruments, and restorative components in a variety of dimensions to accommodate differing patient anatomy. The Piezoplant REX TL 1.8 endosseous implants are blade-form and include a retention screw and are pre-packaged with resorbable blast media (grit-blasted and acid passivated). These are provided with a buccolingual thickness of 1.8 mm, mesiodistal width of 5 mm, and lengths ranging from 10 mm to 15 mm. Cover screws provide protection to the threads of the abutment connection during the tissue healing process. Retention screws fasten the implant and abutment. A variety of Piezoplant® abutments are offered including Straight, Angled, UCLA, Healing, Cylinder, and Multi-unit. Restorations can be screw and/or cement-retained to the abutments. Laboratory aids, impression transfers, and pins facilitate creation and verification of the prosthetic restoration. A torque of 15 Nm is recommended for cover screws, coping screws, and healing abutments. A torque of 25 Nm is recommended for retention screws and all other abutments. Associated surgical instrumentation includes the alignment pin, fit gauges, hex drivers, thumb knob, removal carriers, expanders, and Piezoturgy® Handpiece inserts for site preparation, and the REX IPD removal/insertion tool.

The Piezoplant REX TL 1.8 implants are provided preassembled to an impression transfer; that may also function as a straight abutment, via a retention screw, to facilitate implantation. A cover screw is pre-packaged with each preassembled implant. These devices are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The assembled implant and included cover screw are provided sterile.

The Piezoplant System surgical instruments and restorative components are provided in a non-sterile condition and must be sterilized prior to use.

Indications for Use

The Piezoplant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. The prosthetic components are connected to the implants by the corresponding abutments. The Piezoplant System is intended for delayed loading.

Contraindications

Do not use the Rex Piezoplant System in patients who suffer from any medical conditions that make surgery inadvisable or may be otherwise deemed to be a contraindication by the treating dental practitioner. Such conditions may include and not be limited to: heart disease, diabetes, arthritis, HIV positivity, puberty, pregnancy or breastfeeding, radiotherapy, chemotherapy, immunosuppressant therapy, paraneoplastic therapy, and psychiatric disorder. Do not use the Rex Piezoplant System in the presence of following conditions: uncontrolled bleeding disorders, uncontrolled diabetes, inadequate wound healing capacity, uncompleted growth of the maxilla or mandible, drug or alcohol abuse, xerostomia, weakened immune system, uncontrollable endocrine disorders, steroid use, titanium allergy, an insufficient quantity of bone volume (height and width) at the implant site, untreated periodontal disease (loosening of the teeth), untreated severe grinding or clenching of the teeth, infection at the operative site or in the neighboring teeth (pockets, cysts, granulomas), including major sinusitis, or poor hygiene of the mouth and teeth and low compliance (uncooperative or unmotivated).

Relative Contraindications

Caution should be exercised in the presence of the following: exposure to long-term use of opioids or bisphosphonate drugs, previously irradiated bone, diabetes mellitus, anticoagulation drugs, hemorrhagic diatheses, unfavorable anatomic bone conditions, temporomandibular joint disorders, tobacco use including moderate to heavy smoking, or an unbalanced relationship between the upper and lower teeth.

Warnings and Precautions

• Techniques required to place and restore dental implants are highly complex, requiring specialized knowledge. Practitioners must be trained in implantology and piezoelectric bone cutting techniques as well as insertion techniques of press-fit implants before using the Piezoplant System.

ENGLISH (UK) – INSTRUCTIONS FOR USE

Device Description

The Piezoplant System consists of endosseous dental implants, surgical instruments, and restorative components in a variety of dimensions to accommodate differing patient anatomy. The Piezoplant REX TL 1.8 endosseous implants are blade-form and include a retention screw and are pre-packaged with resorbable blast media (grit-blasted and acid passivated). These are provided with a buccolingual thickness of 1.8 mm, mesiodistal width of 5 mm, and lengths ranging from 10 mm to 15 mm. Cover screws provide protection to the threads of the abutment connection during the tissue healing process. Retention screws fasten the implant and abutment. A variety of Piezoplant® abutments are offered including Straight, Angled, UCLA, Healing, Cylinder, and Multi-unit. Restorations can be screw and/or cement-retained to the abutments. Laboratory aids, impression transfers, and pins facilitate creation and verification of the prosthetic restoration. A torque of 15 Nm is recommended for cover screws, coping screws, and healing abutments. A torque of 25 Nm is recommended for retention screws and all other abutments. Associated surgical instrumentation includes the alignment pin, fit gauges, hex drivers, thumb knob, removal carriers, expanders, and Piezoturgy® Handpiece inserts for site preparation, and the REX IPD removal/insertion tool.

The Piezoplant REX TL 1.8 implants are provided preassembled to an impression transfer; that may also function as a straight abutment, via a retention screw, to facilitate implantation. A cover screw is pre-packaged with each preassembled implant. These devices are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The assembled implant and included cover screw are provided sterile.

The Piezoplant System surgical instruments and restorative components are provided in a non-sterile condition and must be sterilized prior to use.

The REX TL 1.8 implant series has an external hex implant platform with a 4.1 mm diameter (4.1 mmID).

Indications for Use

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Contraindications

Do not use the Rex Piezoplant System in patients who suffer from any medical conditions that make surgery inadvisable or may be otherwise deemed to be a contraindication by the treating dental practitioner. Such conditions may include and not be limited to: heart disease, diabetes, arthritis, HIV positivity, puberty, pregnancy or breastfeeding, radiotherapy, chemotherapy, immunosuppressant therapy, paraneoplastic therapy, and psychiatric disorder. Do not use the Rex Piezoplant System in the presence of following conditions: uncontrolled bleeding disorders, uncontrolled diabetes, inadequate wound healing capacity, uncompleted growth of the maxilla or mandible, drug or alcohol abuse, xerostomia, weakened immune system, uncontrollable endocrine disorders, steroid use, titanium allergy, an insufficient quantity of bone volume (height and width) at the implant site, untreated periodontal disease (loosening of the teeth), untreated severe grinding or clenching of the teeth, infection at the operative site or in the neighboring teeth (pockets, cysts, granulomas), including major sinusitis, or poor hygiene of the mouth and teeth and low compliance (uncooperative or unmotivated).

Relative Contraindications

Caution should be exercised in the presence of the following: exposure to long-term use of opioids or bisphosphonate drugs, previously irradiated bone, diabetes mellitus, anticoagulation drugs, hemorrhagic diatheses, unfavorable anatomic bone conditions, temporomandibular joint disorders, tobacco use including moderate to heavy smoking, or an unbalanced relationship between the upper and lower teeth.

Warnings and Precautions

• Techniques required to place and restore dental implants are highly complex, requiring specialized knowledge. Practitioners must be trained in implantology and piezoelectric bone cutting techniques as well as insertion techniques of press-fit implants before using the Piezoplant System.

- The safe and effective use of implants and associated surgical and restorative devices may be achieved only if qualified surgeons perform the procedure per the instructions provided. Devices must be used as supplied. Modifications to implants and surgical instruments may result in serious injury or death. Restorative devices may only be modified as directed.
- A careful biomechanical study must be performed by the surgeon and restorative dentist to determine the optimal oral restoration for each patient. However, a one hundred percent implant success rate cannot be guaranteed.
- Poor surgical planning including failure to reconcile the actual dimensions of surgical instruments to the sizes in radiographic measurements may result in drilling beyond the intended depth. This may result in excessive bone damage and/or fracture of the implant and/or prosthetic components.
- Do not use Piezoplants in patients if the adequate implant position, sizes, or numbers needed to support functional and eventually parafunctional loading cannot be achieved.

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- Do not use Piezoplants in patients if the adequate implant position, sizes, or numbers needed to support functional and eventually parafunctional loading cannot be achieved.

• Failure to comply with the instructions contained in this document, including reuse of products marked as single-use, may cause harm to the patient, including risk of serious injury or death. Any serious incident that occurs in relation to these devices should be reported to Rex Implants Inc. and the relevant governing or regulatory authority in the US FDA or competent authority of the Member State in which the user and/or patient is established.

How supplied
Piezoplants are single-use products, provided in a triple bag, placed in a carton box and sterilized by gamma irradiation. Piezoplants are provided preassembled to a transfer, which may also function as a straight abutment, via a retention screw, to facilitate implantation. A cover screw is pre-packaged with each straight abutment and included cover screw are provided sterile and should be handled in a safe manner. All sterile products are labeled "STERILE." Do not use sterile products if the package is damaged or already opened. Do not use the sterile products if the expiration date on the label has passed. Do not clean, re-sterilize or reuse any sterile product. Due to the complex surface characteristics of the Piezoplants, only gamma radiation has been demonstrated to effectively sterilize these devices. Piezoplants should be stored in a clean, dry, dust-free, dark place at room temperature.

The Piezoplant System restorative components, surgical tray, and surgical instruments are provided non-sterile and must be sterilized prior to use per the instructions provided below. Piezoturgy® inserts are also provided non-sterile and must be cleaned and sterilized per the instructions for use provided with the device. All dental abutments and restorative devices are indicated as single use.

Cleaning/Reprocessing
The devices in the Piezoplant System provided non-sterile must be cleaned before initial use. Reusable devices must be cleaned between uses. The cleaning process should be performed immediately after use to prevent contaminants from drying onto the devices. While it is recommended that the following validated steps are included in a reprocessing protocol, the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for implants or devices not manufactured by Rex Implants.

Manual Cleaning/Disinfecting/Reprocessing Method
1. Rinse device in cold, potable tap water (< 43°C; <109°F) to remove debris and prevent coagulation of blood.
2. Prepare a solution of enzyme detergent* and potable tap water at pH 7, according to the manufacturer's instructions.
3. Place the device in a clean container. Add a sufficient amount of solution of enzyme detergent solution in the container to cover completely.
4. Leave the device immersed for 10 minutes at 40°C (104°F). This will reduce the organic residues. When immersed in the solution of enzyme detergent, gently brush any threaded parts and small grooves on the device using a toothbrush with soft bristles made of nylon until all visible contamination is removed.

5. Place the device in an ultrasonic bath containing enzymatic detergent solution at 40°C (104°F) for at least 10 minutes. This will reduce the organic compounds on the devices. After soaking in the ultrasonic bath, gently brush any threaded parts or grooves on the device.

6. Under running, warm, potable tap water and using a toothbrush with soft bristles made of nylon, clean the device thoroughly without damaging the surface. Do this until all visible traces of soil are removed. Carry out the final rinse with distilled water.

7. Finish cleaning and inspect the devices under an appropriate light source, paying attention to details that might cause debris to collect (e.g., threads, holes, slots) and if necessary repeat the cleaning cycle.

8. Inspect all devices for any signs of wear and tear. Do not use any device whose integrity is visibly compromised.

9. Dry the device in preparation for sterilization.
*Procedure validated with All-in-One 4 enzyme detergent.

Automated Cleaning/Disinfecting/Reprocessing Method
1. Perform a pre-cleaning by following steps 1 – 6 of the Manual Cleaning/Disinfecting/Reprocessing Method

2. Lay the pre-cleaned device in a metallic tray and place it in thermof ormation*.
NOTE: Place the devices in the washing machine so that dead zones do not arise and the water can properly drain. Also, make sure that the devices are properly held in place in the washing basket and cannot move during the washing process, as shocks could damage them.

WARNING: Avoid overloading. Overloading compromises cleaning effectiveness.

3. Set the following sequence and parameters applicable to the cleaning cycle:

- 1 min. Pre-wash with cold, potable water;
- 5 min. Wash with alkaline detergent* at 55°C ± 2°C (131°F);
- 1 min. Neutralization with proper solution** (1/10 cold water, 2/3 warm water);
- 1 min. Rinse with potable water (1/10 cold water, 2/3 warm water).

4. Follow current local regulations and current facility procedure for the safe disposal of devices; devices should be cleaned and sterilized before disposal.

5. During the post-operative healing period, it is critical to protect the implant from trauma and promote osseointegration by ensuring adequate clearance between the implant restoration and antagonistic teeth. This can be achieved by providing adequate clearance between the implant restoration and antagonistic teeth, fixed prosthetic bridge elements or removable prosthetic elements.

6. Providing instructions to the patient is essential for successful treatment. The patient must be made aware of any limitations of treatment, importance of oral hygiene, avoidance of contraindications, and potential risk of adverse effects. During the healing period a soft diet must be prescribed. Patients must be informed to consult a physician if any changes in implant performance occurs including bone resorption, loosening, and/or implant failure. In the presence of good oral hygiene, the expected lifetime of Piezoplants could range from 5 to 20 years depending on masticatory and parafunctional habits.

7. REX TL 1.8 implants may be restored only upon completion of the healing process, including at least 3 months of healing in high density bone and 6 months in low density bone.

8. The occlusal load on any Piezoplant should be similar to that of conventional implants. Avoid traumatic oral parafunctional contacts in the centric relation, right and left lateral, and protrusion.

9. The REX TL 1.8 Piezoplant cannot support a single crown in the molar region even after osseointegration is completed, but can support a single crown if placed elsewhere.

10. Due to the variety of third-party restorative devices available, Rex Implants cannot verify that all device combinations are safe and effective. Therefore, the use of restorative devices manufactured by Rex Implants is strongly recommended.

11. If custom abutments are used with implants in the REX TL 1.8 series, the angulation must be no greater than 15°.

12. After implant placement, if more than 40% of a Piezoplant surface is exposed (i.e. not surrounded by bone), the implant should be removed from the patient.

Potential adverse events
Potential adverse events must be communicated to the patient prior to surgery. Potential adverse events due to the use of dental implants may include: integration failure; integration rupture; wound dehiscence before graft; jaw bone fracture; the perforation of the following: maxillary sinus, inferior border of the mandible, labial and lingual bone walls, alveolar canal, and gingiva; abscesses, fistulas, suppuration, inflammation, radionecrosis, persistent pain, sensitivity reduction, paresthesia, hyperesthesia, excessive bone reduction requiring surgery, implant fracture, systemic infections, nerve lesions or other nerve damage, and vascular lesions or hemorrhaging, which at times may be serious especially in patients undergoing treatment of aortic aneurysm, aneurysms, or other vascular diseases.

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The Piezoplant System restorative components, surgical tray, and surgical instruments are provided non-sterile and must be cleaned and sterilized per the instructions for use provided with the device. All dental abutments and restorative devices are indicated as single use.

Cleaning/Reprocessing
The devices in the Piezoplant System provided non-sterile must be cleaned before initial use. Reusable devices must be cleaned between uses. The cleaning process should be performed immediately after use to prevent contaminants from drying onto the devices. While it is recommended that the following validated steps are included in a reprocessing protocol, the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for implants or devices not manufactured by Rex Implants.

Manual Cleaning/Disinfecting/Reprocessing Method
1. Rinse device in cold, potable tap water (< 43°C; <109°F) to remove debris and prevent coagulation of blood.
2. Prepare a solution of enzyme detergent* and potable tap water at pH 7, according to the manufacturer's instructions.
3. Place the device in a clean container. Add a sufficient amount of solution of enzyme detergent solution in the container to cover completely.
4. Leave the device immersed for 10 minutes at 40°C (104°F). This will reduce the organic residues. When immersed in the solution of enzyme detergent, gently brush any threaded parts and small grooves on the device using a toothbrush with soft bristles made of nylon until all visible contamination is removed.

5. Place the device in an ultrasonic bath containing enzymatic detergent solution at 40°C (104°F) for at least 10 minutes. This will reduce the organic compounds on the devices. After soaking in the ultrasonic bath, gently brush any threaded parts or grooves on the device.

6. Under running, warm, potable tap water and using a toothbrush with soft bristles made of nylon, clean the device thoroughly without damaging the surface. Do this until all visible traces of soil are removed. Carry out the final rinse with distilled water.

7. Finish cleaning and inspect the devices under an appropriate light source, paying attention to details that might cause debris to collect (e.g., threads, holes, slots) and if necessary repeat the cleaning cycle.

8. Inspect all devices for any signs of wear and tear. Do not use any device whose integrity is visibly compromised.

9. Dry the device in preparation for sterilization.
*Procedure validated with All-in-One 4 enzyme detergent.

Automated Cleaning/Disinfecting/Reprocessing Method
1. Perform a pre-cleaning by following steps 1 – 6 of the Manual Cleaning/Disinfecting/Reprocessing Method

2. Lay the pre-cleaned device in a metallic tray and place it in thermof ormation*.
NOTE: Place the devices in the washing machine so that dead zones do not arise and the water can properly drain. Also, make sure that the devices are properly held in place in the washing basket and cannot move during the washing process, as shocks could damage them.

WARNING: Avoid overloading. Overloading compromises cleaning effectiveness.

3. Set the following sequence and parameters applicable to the cleaning cycle:

- 1 min. Pre-wash with cold, potable water;
- 5 min. Wash with alkaline detergent* at 55°C ± 2°C (131°F);
- 1 min. Neutralization with proper solution** (1/10 cold water, 2/3 warm water);
- 1 min. Rinse with potable water (1/10 cold water, 2/3 warm water).

4. Follow current local regulations and current facility procedure for the safe disposal of devices; devices should be cleaned and sterilized before disposal.

5. During the post-operative healing period, it is critical to protect the implant from trauma and promote osseointegration by ensuring adequate clearance between the implant restoration and antagonistic teeth. This can be achieved by providing adequate clearance between the implant restoration and antagonistic teeth, fixed prosthetic bridge elements or removable prosthetic elements.

6. Providing instructions to the patient is essential for successful treatment. The patient must be made aware of any limitations of treatment, importance of oral hygiene, avoidance of contraindications, and potential risk of adverse effects. During the healing period a soft diet must be prescribed. Patients must be informed to consult a physician if any changes in implant performance occurs including bone resorption, loosening, and/or implant failure. In the presence of good oral hygiene, the expected lifetime of Piezoplants could range from 5 to 20 years depending on masticatory and parafunctional habits.

7. REX TL 1.8 implants may be restored only upon completion of the healing process, including at least 3 months of healing in high density bone and 6 months in low density bone.

8. The occlusal load on any Piezoplant should be similar to that of conventional implants. Avoid traumatic oral parafunctional contacts in the centric relation, right and left lateral, and protrusion.

9. The REX TL 1.8 Piezoplant cannot support a single crown in the molar region even after osseointegration is completed, but can support a single crown if placed elsewhere.

10. Due to the variety of third-party restorative devices available, Rex Implants cannot verify that all device combinations are safe and effective. Therefore, the use of restorative devices manufactured by Rex Implants is strongly recommended.

11. If custom abutments are used with implants in the REX TL 1.8 series, the angulation must be no greater than 15°.

12. After implant placement, if more than 40% of a Piezoplant surface is exposed (i.e. not surrounded by bone), the implant should be removed from the patient.

Potential adverse events
Potential adverse events must be communicated to the patient prior to surgery. Potential adverse events due to the use of dental implants may include: integration failure; integration rupture; wound dehiscence before graft; jaw bone fracture; the perforation of the following: maxillary sinus, inferior border of the mandible, labial and lingual bone walls, alveolar canal, and gingiva; abscesses, fistulas, suppuration, inflammation, radionecrosis, persistent pain, sensitivity reduction, paresthesia, hyperesthesia, excessive bone reduction requiring surgery, implant fracture, systemic infections, nerve lesions or other nerve damage, and vascular lesions or hemorrhaging, which at times may be serious especially in patients undergoing treatment of aortic aneurysm, aneurysms, or other vascular diseases.

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The Piezoplant System restorative components, surgical tray, and surgical instruments are provided non-sterile and must be cleaned and sterilized per the instructions for use provided with the device. All dental abutments and restorative devices are indicated as single use.

Cleaning/Reprocessing
The devices in the Piezoplant System provided non-sterile must be cleaned before initial use. Reusable devices must be cleaned between uses. The cleaning process should be performed immediately after use to prevent contaminants from drying onto the devices. While it is recommended that the following validated steps are included in a reprocessing protocol, the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for implants or devices not manufactured by Rex Implants.

Manual Cleaning/Disinfecting/Reprocessing Method
1. Rinse device in cold, potable tap water (< 43°C; <109°F) to remove debris and prevent coagulation of blood.
2. Prepare a solution of enzyme detergent* and potable tap water at pH 7, according to the manufacturer's instructions.
3. Place the device in a clean container. Add a sufficient amount of solution of enzyme detergent solution in the container to cover completely.
4. Leave the device immersed for 10 minutes at 40°C (104°F). This will reduce the organic residues. When immersed in the solution of enzyme detergent, gently brush any threaded parts and small grooves on the device using a toothbrush with soft bristles made of nylon until all visible contamination is removed.

5. Place the device in an ultrasonic bath containing enzymatic detergent solution at 40°C (104°F) for at least 10 minutes. This will reduce the organic compounds on the devices. After soaking in the ultrasonic bath, gently brush any threaded parts or grooves on the device.

6. Under running, warm, potable tap water and using a toothbrush with soft bristles made of nylon, clean the device thoroughly without damaging the surface. Do this until all visible traces of soil are removed. Carry out the final rinse with distilled water.

7. Finish cleaning and inspect the devices under an appropriate light source, paying attention to details that might cause debris to collect (e.g., threads, holes, slots) and if necessary repeat the cleaning cycle.

8. Inspect all devices for any signs of wear and tear. Do not use any device whose integrity is visibly compromised.

9. Dry the device in preparation for sterilization.
*Procedure validated with All-in-One 4 enzyme detergent.

Automated Cleaning/Disinfecting/Reprocessing Method
1. Perform a pre-cleaning by following steps 1 – 6 of the Manual Cleaning/Disinfecting/Reprocessing Method

2. Lay the pre-cleaned device in a metallic tray and place it in thermof ormation*.
NOTE: Place the devices in the washing machine so that dead zones do not arise and the water can properly drain. Also, make sure that the devices are properly held in place in the washing basket and cannot move during the washing process, as shocks could damage them.

WARNING: Avoid overloading. Overloading compromises cleaning effectiveness.

3. Set the following sequence and parameters applicable to the cleaning cycle:

- 1 min. Pre-wash with cold, potable water;
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4. Follow current local regulations and current facility procedure for the safe disposal of devices; devices should be cleaned and sterilized before disposal.

5. During the post-operative healing period, it is critical to protect the implant from trauma and promote osseointegration by ensuring adequate clearance between the implant restoration and antagonistic teeth. This can be achieved by providing adequate clearance between the implant restoration and antagonistic teeth, fixed prosthetic bridge elements or removable prosthetic elements.

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8. The occlusal load on any Piezoplant should be similar to that of conventional implants. Avoid traumatic oral parafunctional contacts in the centric relation, right and left lateral, and protrusion.

9. The REX TL 1.8 Piezoplant cannot support a single crown in the molar region even after osseointegration is completed, but can support a single crown if placed elsewhere.

10. Due to the variety of third-party restorative devices available, Rex Implants cannot verify that all device combinations are safe and effective. Therefore, the use of restorative devices manufactured by Rex Implants is strongly recommended.

11. If custom abutments are used with implants in the REX TL 1.8 series, the angulation must be no greater than 15°.

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Manual Cleaning/Disinfecting/Reprocessing Method
1. Perform a pre-cleaning by following steps 1 – 6 of the Manual Cleaning/Disinfecting/Reprocessing Method
2. Lay the pre-cleaned device in a metallic tray and place it in thermof ormation*.
NOTE: Place the devices in the washing machine so that dead zones do not arise and the water can properly drain. Also, make sure that the devices are properly held in place in the washing basket and cannot move during the washing process, as shocks could damage them.

WARNING: Avoid overloading. Overloading compromises cleaning effectiveness.

3. Set the following sequence and parameters applicable to the cleaning cycle:

- 1 min. Pre-wash with cold, potable water;
- 5 min. Wash with alkaline detergent* at 55°C ± 2°C (131°F);
- 1 min. Neutralization with proper solution** (1/10 cold

