

CLEANING AND STERILISATION MANUAL

PIEZOSURGERY® *touch*



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

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1 INTRODUCTION

Carefully read this manual before proceeding with the cleaning and sterilization operations, and always keep it within reach.

The words **WARNING**, **CAUTION** and **NOTE** contained in this document, carry special meaning and must be carefully reviewed. Depending on their degree of seriousness, the safety precautions are classified:

⚠ WARNING: Identifies conditions or practices that present a risk of serious injury or death to the patient and/or the user

⚠ CAUTION: Identifies conditions or practices that could result in minor injury or device damage

NOTE: Identifies special information to clarify or emphasize important instructions.

⚠ WARNING: To prevent potential serious injury to the user and the patient and/or this device or other equipments, read all the "Safety precautions" present in the manual with particular attention.

The purpose of this manual is to make the operator knowledgeable of the safety precautions, the installation procedures, and the instructions for a correct use and maintenance of the device and its accessories. Use of this manual for purposes other than those strictly tied to cleaning and sterilization of the device is forbidden.

The information and illustrations in this manual are updated as of the date of issue reported on the last page.

Mectron is committed to continuously update its products with possible modifications to device components.

In case you uncover discrepancies between

what described in this manual and the device in your possession, contact your Retailer or the After-Sales Service of Mectron for clarification and support.

LIMITATION ON THE NUMBER OF CLEANING AND STERILIZATION CYCLES:

Cleaning and sterilization cycles repeated over time have minimum effects on the instruments examined in this manual. The life expectancy of the products is usually determined by their consumption and by damages caused from their use.

⚠ WARNING: The operators who perform the cleaning and sterilization operations must be adequately protected and trained.

⚠ WARNING: Infections control.

First use: Reusable accessories (brand new or returned by service) and single-use accessories (diamond coated inserts) are delivered in NON STERILE condition and must be prepared prior the use by applying the procedures described in this manual.

Every Use: Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in this manual.

⚠ WARNING: Diamond coated inserts are SINGLE-USE.

The diamond coated inserts are intended to be used on an individual patient during a single surgical procedure and then discarded. The diamond coated inserts cannot therefore reprocessed since they cannot be cleaned properly. Bone and soil residues might remain adhered to the diamond coating even after cleaning and sterilization, and enter into oral cavity of another patient.

2 FLUSH FUNCTION

The FLUSH function allows to run a flushing cycle on the irrigation circuit of the handpiece(s) used during the treatment.

⚠ CAUTION: FLUSH function. The FLUSH function must be used after every patient treatment, before starting the cleaning and sterilization procedures. Failure to carry out flushing of the handpiece tubing will lead to salt crystallisation that can seriously damage the device.

⚠ WARNING: The "FLUSH" function does not substitute for the cleaning and sterilization procedures described

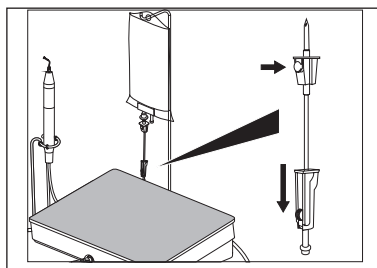
in this manual. After having carried out the "FLUSH" function, the cleaning and sterilization procedures must be followed meticulously in order to prepare the device accessories ready for the next patient and minimize any risk of patient-to-patient contamination.

⚠ CAUTION: The handpiece and the cord cannot be separated from one another.

Carry out a flushing cycle of the hydraulic circuit of the handpiece and its cord according to the following steps:

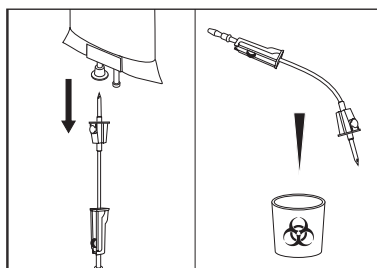
Close the air intake on the drip system;

1



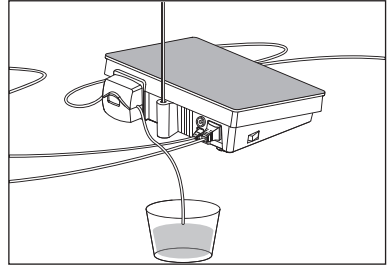
Disconnect the drip system from the physiological solution bag/bottle and from the peristaltic pump tubing. Dispose of the drip system following local regulations for proper disposal of contaminated materials;

2



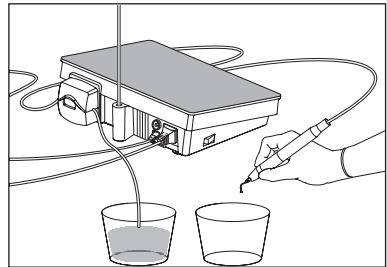
Immerse the end part of the peristaltic pump tube or the tube of the bone grafting kit, if used, in a receptacle or glass containing demineralized water or sterile water;

3



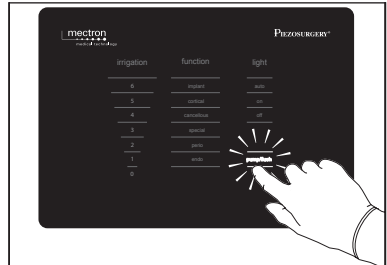
Place the handpiece with or without insert over a bowl to collect the demineralized/sterile water that will outflow during the flushing cycle;

4



To enter the flushing mode, select PUMP/ FLUSH on the keyboard: all the other selection options present on the display are disabled, and the PUMP/FLUSH writing flashes;

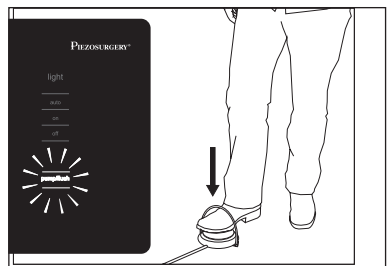
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NOTE: You can exit the cleaning mode by pressing on PUMP/FLUSH again or, alternatively, by waiting for at least 15 seconds. The FLUSH function is disabled and the keyboard is enabled again, and displays the last setting used;

6

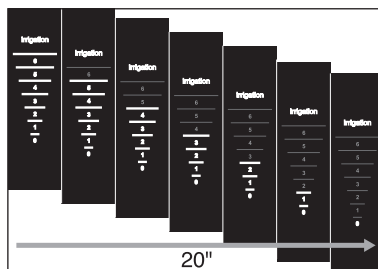
To make the FLUSH function start while the PUMP/FLUSH writing is flashing, press the foot pedal once and release it: PUMP/FLUSH stops flashing and the flushing cycle starts;



NOTE: The FLUSH function can be interrupted at any time by pressing the PUMP/FLUSH writing again or, alternatively, by pressing on foot pedal. The keyboard is enabled again, and displays the last setting used;

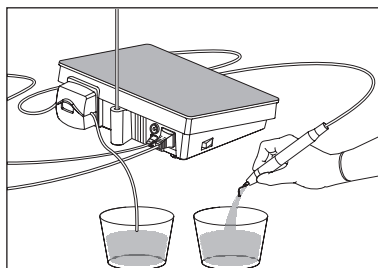
As soon as the peristaltic pump starts, the entire scale of values of the “irrigation” section lights up and during the liquid passage, the value of the irrigation shifts from 6 a 0 . The cycle lasts 20 seconds. Once it has ended, the keyboard is enabled again, and displays the last setting used;

7



To perform a flushing cycle of every handpiece, tube, or connector used during the same treatment, repeat the operations described previously, from point 6 onward.

8



3 CLEANING AND STERILIZATION

Important information on the cleaning procedures:

- Cleaning processes must immediately be carried out after each use. Do not allow contaminated tools, inserts and handpieces to dry prior to reprocessing;
- Mild neutral pH (pH 6-9) enzymatic detergents must be utilized for the removal of organic soil as blood and bone debris immediately after use;
- Never use alkaline detergents or detergents with a pH outside the range of 6-9 during the cleaning procedures;
- The final rinse before sterilization should be carried out by using demineralized water;
- Use running tap water whenever indicated in this manual;
- Do not use organic solvents such as acetone or isopropyl alcohol to clean the console, the handpiece and all the others instruments/accessories;
- Do not use metal brushes or scouring pad during cleaning procedures since these will damage the surface and finish of instruments;
- Use only soft-bristled, nylon brushes;
- Do not use pointed objects for cleaning;
- Cleaning agents must be completely rinsed from the instruments to prevent accumulation of detergent residue.

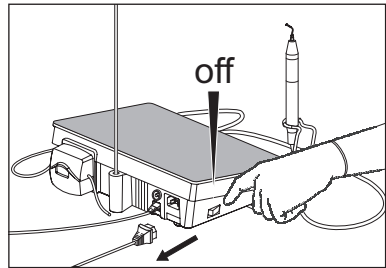
3.1 Disassembling of Parts

Disassemble device components before carrying out the cleaning procedures described in this manual.

⚠ WARNING: Switch the device off. Before carrying out the cleaning procedures described in the following paragraphs, turn the console off and disconnect it from the electrical power source

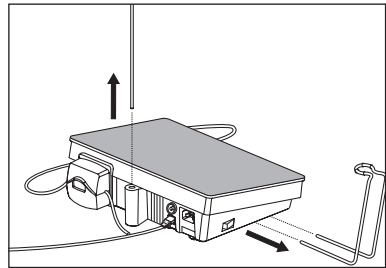
⚠ WARNING: Supplementary grounding cable. If present, disconnect the supplementary grounding cable before you perform the cleaning and sterilization procedures.

1



2

Remove the handpiece fixed holder and the irrigation bag support rod from the device console;

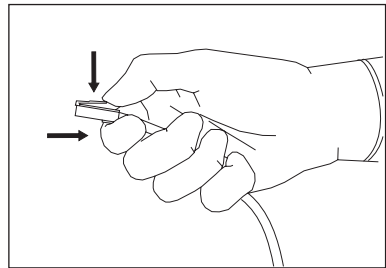


3

Disconnect the foot pedal from the console. While holding the foot pedal cord connector, press the release sleeve and pull it back to remove;

⚠ CAUTION: Do not attempt to screw or twist the cord connector during removal. The push/pull connector can be damaged by twisting.

⚠ CAUTION: To avoid damaging the foot pedal cord, hold only the connector when disconnecting the cord. Always hold the cord by its connector. Never pull on the cord itself.



Disconnect the handpiece/cord from the console;

⚠ CAUTION: To avoid damaging the handpiece, disconnect it by always holding onto the connector only. Never pull the cord.

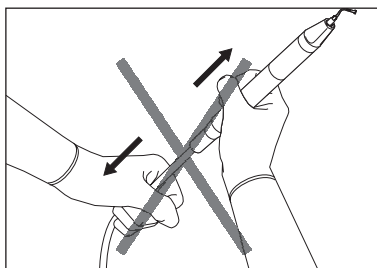
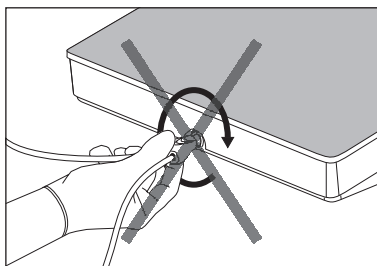
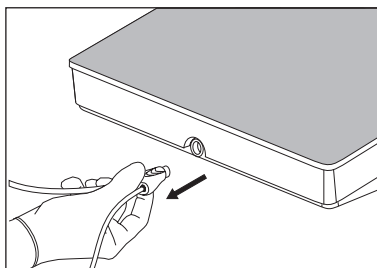
⚠ CAUTION: Do not attempt to unscrew or turn the connector when disconnecting the handpiece. The connector could get damaged.

⚠ CAUTION: The handpiece and cord cannot be separated.

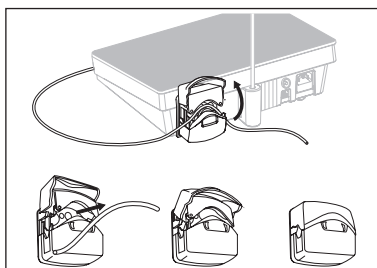
Remove the peristaltic pump tubing:

- Open the peristaltic pump head completely and remove the tube;

4



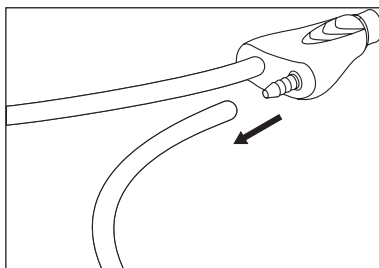
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CLEANING AND STERILIZATION

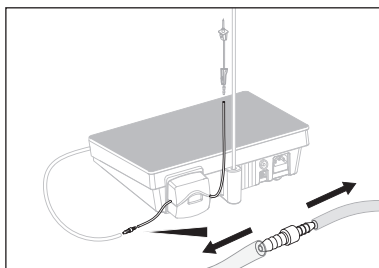
- Disconnect the pump silicon tube from the connector of the handpiece;

6



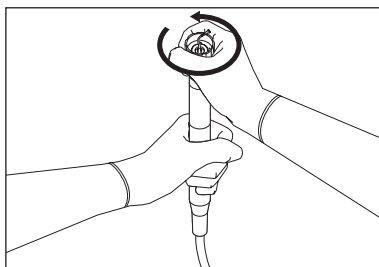
- If the bone grafting kit has been used, disconnect the tube-to-tube connector from the peristaltic pump tubing and from the tube of the bone grafting kit;

7



If present, unscrew the insert from the handpiece by using the torque wrench;

8



⚠ WARNING: During the tightening and removing operations, the user must pay particular attention to avoiding injury from inserts with sharp points and cutting edges.

3.2 Cleaning of the Console

⚠ WARNING: Switch the console off by means of the main power switch and disconnect it from the electrical power source.

⚠ WARNING: The device casing is not protected against penetration of liquids. Do not spray liquids directly onto the surface of the console. Moisture inside the console could cause damage.

⚠ WARNING: Do not sterilize the console. It will no longer function.

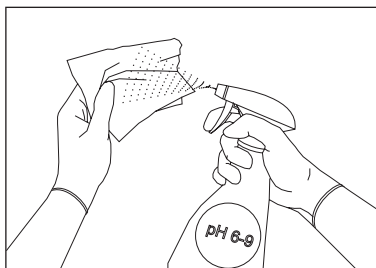
⚠ CAUTION: Do not use organic solvents such as acetone or isopropyl alcohol to clean the console. Some alcohol-based disinfectant solutions may be harmful, causing discoloration of and/or damage to plastic materials.

Clean and wipe console casing surfaces with a clean, soft lint free cloth, dampened with a mild surface disinfection agent, featuring a neutral pH (pH7), according to the manufacturer's specifications;

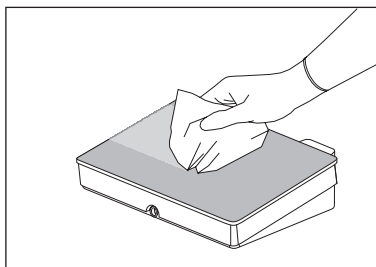
Allow the disinfectant solution to dry in the air or dry the console with a clean, non abrasive, lint free, cloth before using the device again;

Be sure to dry off the console after cleaning. Moisture inside the console could cause damage.

1



2



3.3 Cleaning of the Foot Switch

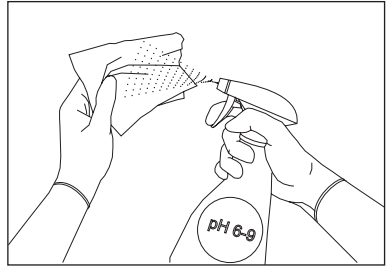
⚠ CAUTION: Do not sterilize the foot pedal. It will no longer function.

⚠ CAUTION: Foot pedal and electrical connector of the cord must NOT be cleaned under running water.

⚠ CAUTION: Do not immerge the foot pedal and its cord in liquids solutions.

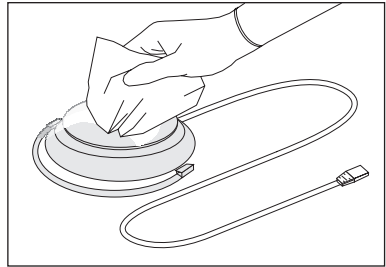
Wipe the foot pedal with a soft cloth moistened with a detergent/disinfectant solution, featuring a mild pH (pH 6-9);

1



Dry with a soft cloth and allow the foot pedal to dry completely before using again.

2



3.4 Cleaning of the Handpiece and its Cord

⚠ **CAUTION:** The handpiece and the cord cannot be separated from one another.

⚠ **CAUTION:** The procedure/s described in this paragraph must be always preceded by a flushing cycle of the liquid circuit carried out by means of the FLUSH Function described in Chapter 2 on page 2.

⚠ **CAUTION:** Do not clean the handpiece and its cord in ultrasonic cleaners or allow them to be fully immersed in any soaking solution.

⚠ **CAUTION:** Do not use hydrogen peroxide for cleaning the handpiece and its cord.

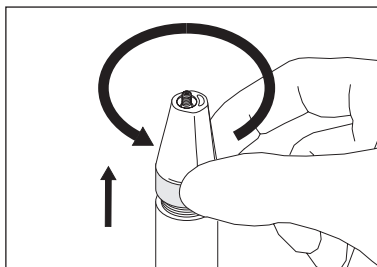
⚠ **CAUTION:** Disconnect the handpiece from the console exclusively by acting on its connector. Make reference to Chapter 3.1 on page 5.

3.4.1 Preparation

Unscrew and remove the front terminal from the handpiece;

NOTE: On the cone with LED light the metal ring cannot be separated from the cone in plastic;

1

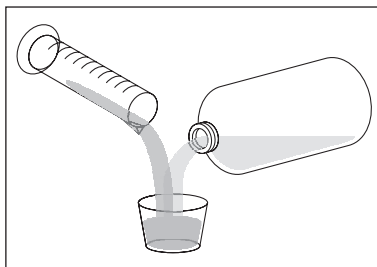


3.4.2 Cleaning Procedure

Prepare an enzymatic detergent solution^{a)} with pH 6-9, as per the instructions of the manufacturer;

⚠ **CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not recycle it.

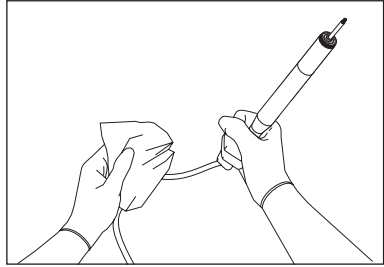
2



- a) Process validated by independent body with enzymatic detergent Cidezime[®] (Enzol[®]).

Clean the surface of the handpiece cord and connector using a clean, soft, lint free, cloth moistened with the prepared enzymatic detergent solution and, if need be, disinfect with no-aggressive disinfectant solution with neutral pH (pH7), according to the disinfectant's manufacturer;

3

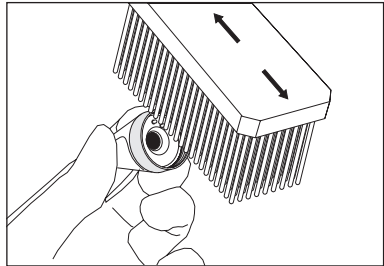
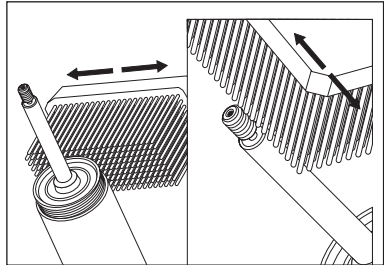


Use the enzymatic detergent solution and a clean soft bristled, nylon brush to gently scrub the external surface of the handpiece and the front terminal until all visible soil has been removed.

The following parts must be brushed meticulously:

- Threaded pin onto which the inserts are screwed;
- The visible parts adjacent to the threaded pin;
- The internal and external parts of the front terminal.

4



Thoroughly rinse the front terminal under running warm tap water and then under demineralized water to eliminate any residual detergent;

Hold the handpiece with its front end pointed downward;

Rinse thoroughly the front end and the surfaces of the external body of the handpiece under running warm tap water to eliminate any residual detergent;

Final Rinsing

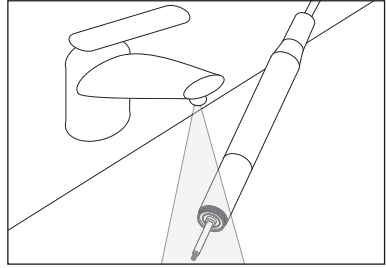
Hold the handpiece with its front end pointed downward;

Rinse thoroughly the front end and the surfaces of the external body of the handpiece under demineralized water.

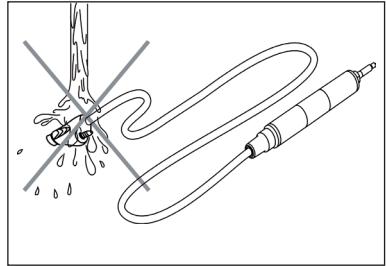
⚠ CAUTION: Do not rinse the handpiece cord connector under running water.

NOTE: Repeat steps 4, 5 and 6 until rinse de-mineralized water runs clear;

5



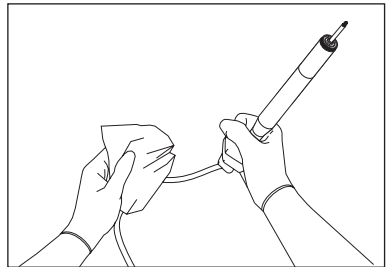
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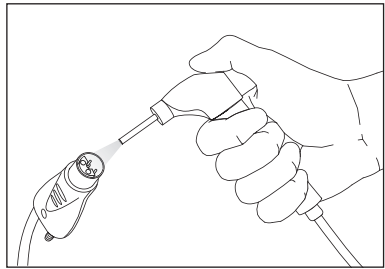
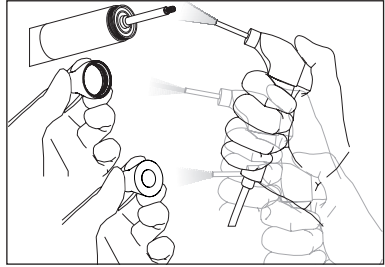
Remove any residual detergent on the handpiece cord by using a clean, soft, lint free cloth moistened with de-mineralized water;

Dry all handpiece parts and cord with a clean and lint-free towel;



Thoroughly dry all parts of the handpiece with cord, especially the electrical contacts, blowing on them with compressed air;

8



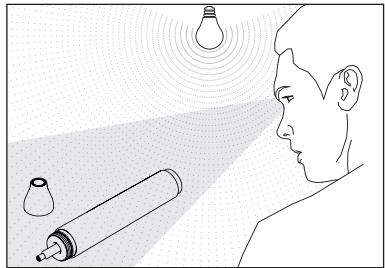
3.4.3 Inspection Prior Sterilization

All the handpiece parts must be inspected prior to sterilization;
Generally unmagnified visual inspection under good light conditions is sufficient;
All parts of the handpiece should be checked for visible soil and/or corrosion;
All parts of the handpiece must be visually inspected for damage or wear;
Particular attention should be paid to:

- Soil "traps" such as threaded parts;
- Cavities;
- Grooves;

Repeat cleaning if not visibly clean and re-inspect;
Remove damaged parts;

9



3.4.4 Packaging

The handpiece with its cord and the front terminal can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

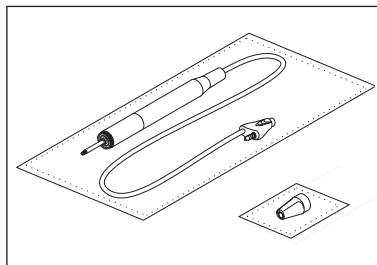
CAUTION: Do not pack the handpiece with an insert screwed on it.

CAUTION: Each component must be packed individually.

CAUTION: Ensure that the inner pouch is large enough to contain each component without stressing the seals or tearing the packaging.

The handpiece with its cord and the front terminal are ready for the sterilization process (refer to Chapter 4 on page 32).

10



3.5 Cleaning of the Inserts

WARNING: Diamond coated inserts are SINGLE-USE. The diamond coated inserts are intended to be used on an individual patient during a single surgical procedure and then discarded. The diamond coated inserts cannot therefore be reprocessed since they cannot be cleaned properly. Bone and soil residues might remain adhered to the diamond coating even after cleaning and sterilization, and enter into oral cavity of another patient.

CAUTION: Do not use hydrogen peroxide. Do not use hydrogen peroxide to clean the inserts.

WARNING: To prevent injury, reprocess inserts separately. Special caution is necessary due to the danger of injury and infection from handling soiled cutting tools. Healthcare personnel involved in device operation and cleaning must be appropriately protected. Handle sharp-edged and pointed instruments with care.

3.5.1 Cleaning Procedure

Prepare an enzymatic detergent solution^{b)} with pH 6-9, as per the instructions of the manufacturer;

⚠ CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

b) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

Place the insert horizontally in a clean container and add enzymatic detergent solution until the insert is covered completely;

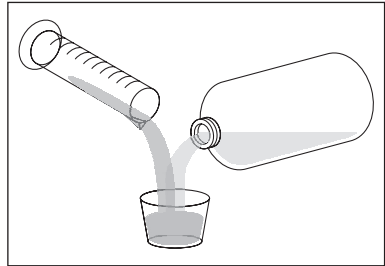
Let the insert soak for 10 minutes at 40 °C $\pm$ 2 °C. This procedure reduces the amount of blood, protein and mucous present on the insert;

Use a clean soft bristled nylon brush to gently scrub the all the surfaces of the insert until all visible soils has been removed;

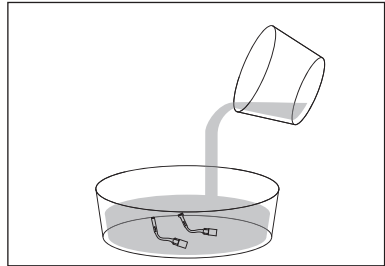
NOTE: Clean the following parts of the insert tips meticulously:

- Lumens and internal channel;
- Hard to clean areas such as cutting edges, particularly the small spaces between saw teeth;

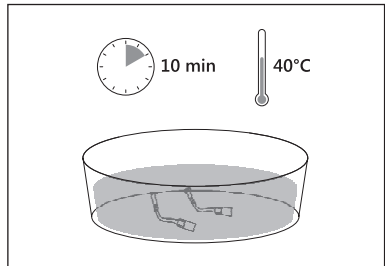
1



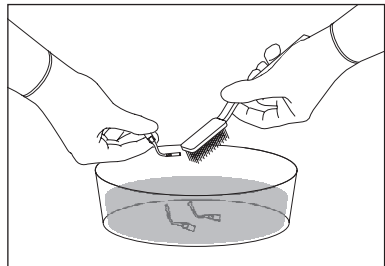
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3

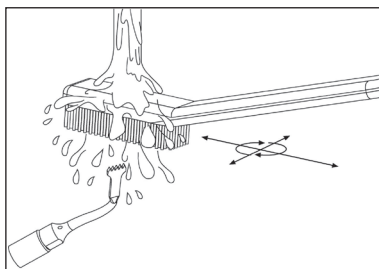


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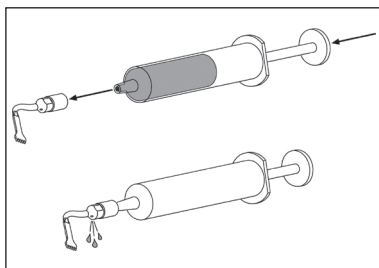
Remove the insert from the enzymatic soak;
Thoroughly rinse and scrub the insert tip with a soft bristled nylon brush under running tap water;
Repeat this procedure until all visible soils has been removed;

5



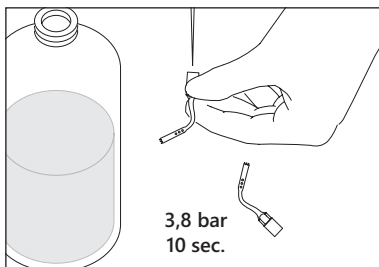
By using a disposable syringe inject and aspirate the enzymatic detergent solution into hard-to-reach areas (lumen/cannulae);
Repeat this operation three times for effective removal of soil from the inner lumen surface;

6



Flush the internal channel of the insert with demineralized water injected at a pressure of 3.8 bars for at least 10 seconds so as to remove any residues. It is possible to carry out this operation by using a single use syringe;

7



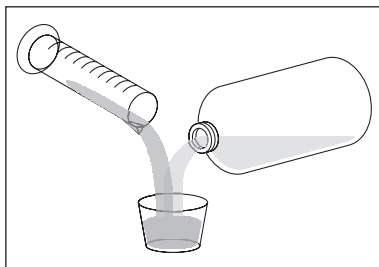
3.5.2 Ultrasonic Bath

Prepare an enzymatic detergent solution^{c)} with pH 6-9, as per the instructions of the manufacturer;

CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

c) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

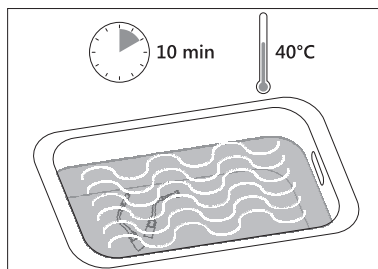
8



CLEANING AND STERILIZATION

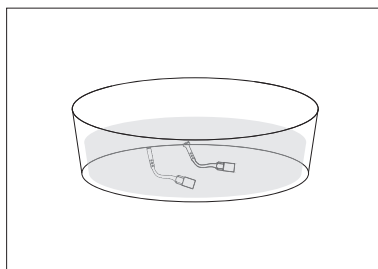
Place the insert tip/s in a mesh bottom stainless steel instrument tray;
Place the tray into the ultrasonic cleaner and ensure that the instruments in the bath, at 40°C, are submerged;
Sonicate for at least 10 minutes;

9



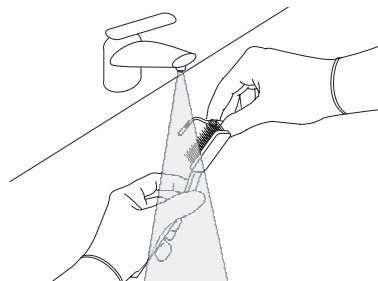
Remove the insert from the ultrasonic tank and rinse with demineralized cold water;

10



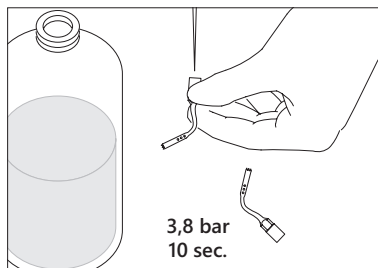
Scrub the inner and outer surfaces of the insert with a clean soft bristled nylon brush under running tap water;

11



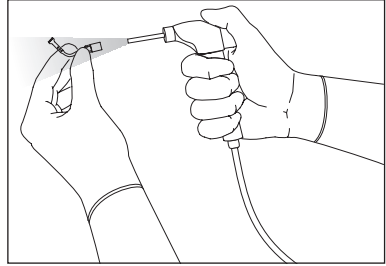
Rinse the insert under demineralised water;
Flush the internal channel of the insert with demineralized water injected at a pressure of 3.8 bars for at least 10 seconds so as to remove any residues;

12



⚠ CAUTION: Make sure that the insert is completely dry also internally before starting the sterilizing cycle. Use filtered compressed air to remove any moisture from the inner lumen. This will prevent the appearance of stains or patches on the surface or internal oxidizing of the insert.

13



3.5.3 Inspection Prior Sterilization

After the cleaning process inspect the insert for cleanliness, function and damage.

Generally unmagnified visual inspection under good light conditions is sufficient; All parts of the insert should be inspected for visible soil and/or corrosion and for damage or wear;

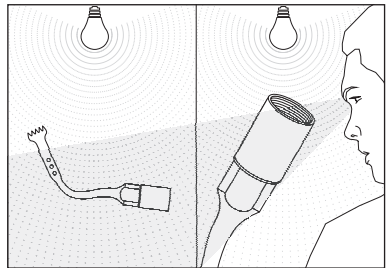
Particular attention should be paid to:

- Soil "traps" such as lumens, threaded parts;
- Recessed features (holes, cannulations);
- Sides of insert teeth;
- Cutting edges sharpness. In particular check edges for distortions/large nicks; edges that should be continuous;

Repeat cleaning if not visibly clean and re-inspect;

Remove damaged and defective inserts;

14



3.5.4 Packaging

The insert can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

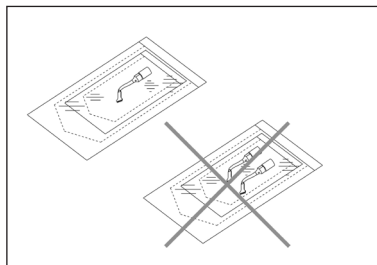
- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

CAUTION: The insert must be packed individually.

CAUTION: Ensure that the inner pouch is large enough to contain the insert without stressing the seals or tearing the packaging.

The insert is ready for the sterilization process (refer to Chapter 4 on page 32).

15



3.6 Cleaning the Torque Wrench

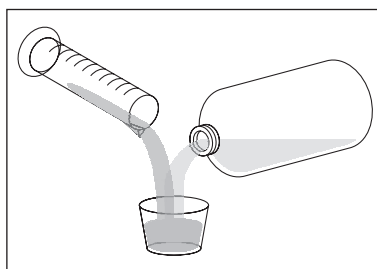
CAUTION: Do not use hydrogen peroxide. Do not use hydrogen peroxide to clean the torque wrench.

Prepare an enzymatic detergent solution^{d)} with pH 6-9, as per the instructions of the manufacturer;

CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

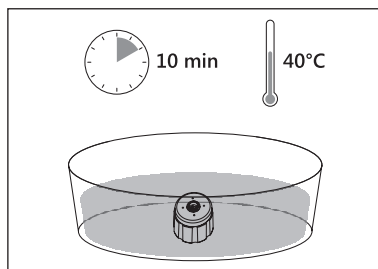
- d) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

1



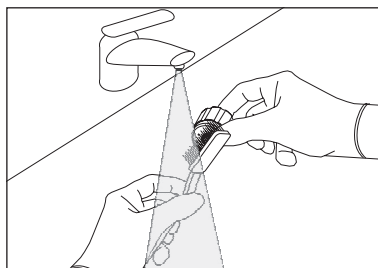
Lay the torque wrench in a clean container;
Add a sufficient amount of the prepared solution to the container to cover the torque wrench;
Soak the torque wrench in the detergent for 10 minutes at 40 °C;
This will reduce the amount of blood, protein and mucus from the torque wrench;

2



Remove the torque wrench from the enzymatic soak;
Use a clean soft bristled nylon brush to gently scrub the inner and the external parts of the wrench under running tap water until all visible soil has been removed;

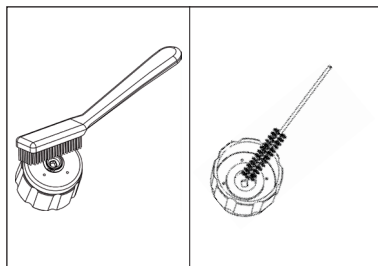
3



NOTE: The following parts must be brushed meticulously:

- External metal ring;
- Internal cavities, groves and crevices;

4



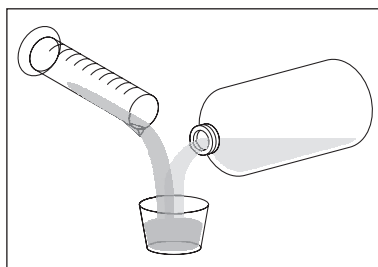
The procedures above must be repeated until rinse water runs clear;

3.6.1 Ultrasonic Bath

Prepare an enzymatic detergent solution^{e)} with pH 6-9, as per the instructions of the manufacturer;

5

CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

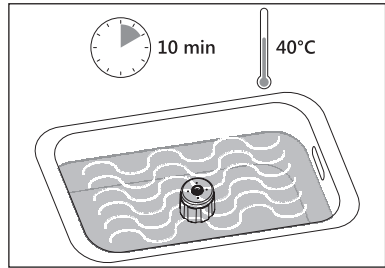


e) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

CLEANING AND STERILIZATION

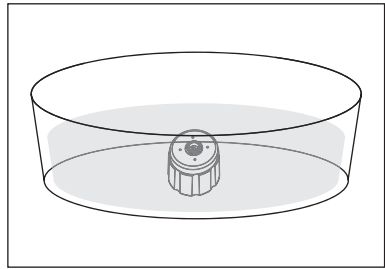
Place the torque wrench in a mesh bottom stainless steel instrument tray;
Place the tray in the ultrasonic cleaner;
Completely submerge the wrench in the cleaning solution, at 40°C, and sonicate for 10 minutes;

6



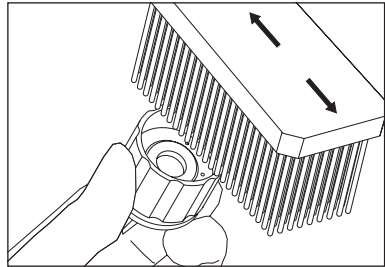
Remove the torque wrench from the ultrasonic cleaner and rinse thoroughly with demineralized cold water;

7



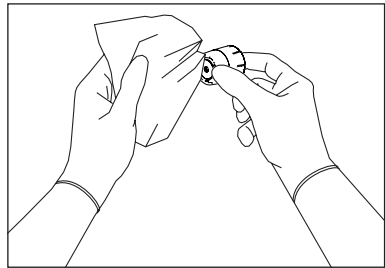
Final scrubbing/rinsing:
Use a clean soft bristled nylon brush to gently scrub the inner and the external parts of the wrench, then rinse thoroughly with demineralized cold water;

8



Dry the torque wrench with a clean lint-free cloth;
Use filtered compressed air to remove any moisture from cavities, grooves, crevices and other difficult to reach areas.

9



3.6.2 Inspection Prior Sterilization

After the cleaning process inspect the torque wrench for cleanliness, function and damage.

Generally unmagnified visual inspection under good light conditions is sufficient; All parts of the torque wrench should be inspected for visible soil and/or corrosion and for damage or wear;

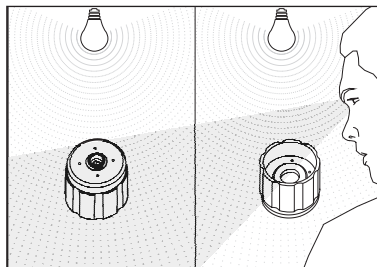
Particular attention should be paid to:

- Soil "traps" such as cavities and grooves;

Repeat cleaning if not visibly clean and re-inspect;

Remove damaged and defective torque wrenches;

10



3.6.3 Lubrication

Prior to sterilization the torque wrench must be lubricated with a commercial surgical grade instrument lubricant;

⚠ CAUTION: Alkaline detergents attack grease and seals in the tool. Use of alkaline detergents will wash grease out of the wrench, causing malfunctions and increasing wear. It is therefore important to lubricate the wrench after every cleaning procedure.

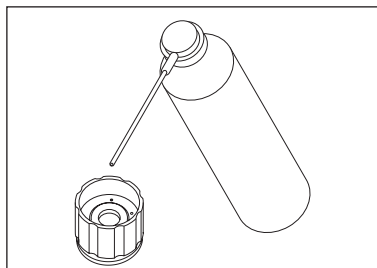
⚠ CAUTION: Do not use lubricants containing oil, petroleum or silicone based because they prevent direct contact of the surfaces with steam.

The lubricant must be applied by spraying directly on the internal peripheral contact surface of the torque wrench;

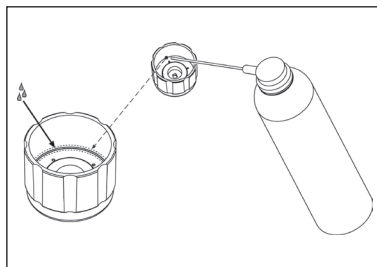
Remove the excess oil with a clean lint-free towel after spraying;

NOTE: As alternative method it is possible to apply 2 or 3 lubricant drops;

11



12



3.6.4 Packaging

The torque wrench can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

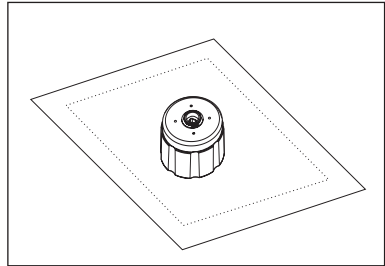
- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

CAUTION: The torque wrench must be packed individually.

CAUTION: Ensure that the inner pouch is large enough to contain the torque wrench without stressing the seals or tearing the packaging.

The torque wrench is ready for the sterilization process (refer to Chapter 4 on page 32).

15



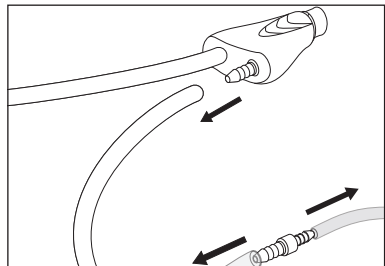
3.7 Cleaning the Peristaltic Pump Tubing

CAUTION: Do not use hydrogen peroxide. Do not use hydrogen peroxide to reprocess the peristaltic pump tubing/s.

NOTE: Disconnect the tube from the connector of the handpiece (see Chapter 3.1 on page 5).

If the bone grafting kit is used, disconnect the tube-tube connector from both tubes;

1

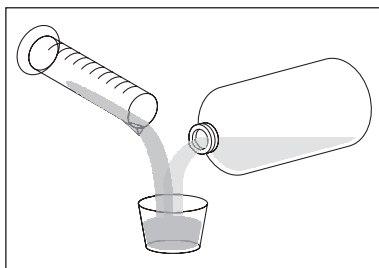


Prepare an enzymatic detergent solution^{f)} with pH 6-9, as per the instructions of the manufacturer;

⚠ CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

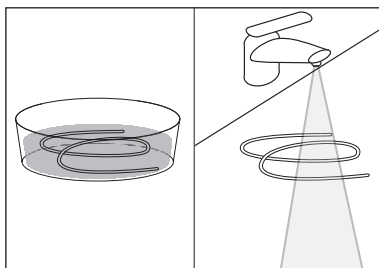
f) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

2



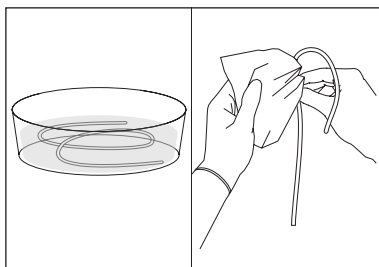
Immerse the peristaltic pump tube in the prepared enzymatic detergent solution; Rinse thoroughly under running tap water to eliminate any residuals of detergent;

3



Carry out a final rinsing with demineralized cold water and thoroughly dry it with a clean lint-free cloth; The connector is ready to be packed for the sterilization process (refer to Chapter 4 on page 32);

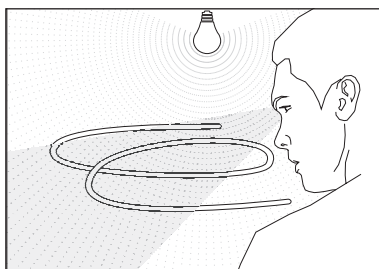
4



3.7.1 Inspection Prior Sterilization

After the cleaning process inspect the peristaltic tube for cleanliness (visible soil) and damage; Generally unmagnified visual inspection under good light conditions is sufficient; Repeat cleaning if not visibly clean and re-inspect; Remove damaged and/or defective tubes.

5



⚠ CAUTION: It is advisable not to exceed 8 sterilization cycles.

3.7.2 Packaging

The peristaltic pump tubing can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

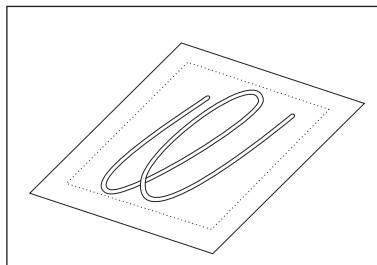
- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

CAUTION: The peristaltic pump tubing must be packed individually.

CAUTION: Ensure that the inner pouch is large enough to contain the peristaltic pump tubing without stressing the seals or tearing the packaging.

The peristaltic pump tubing is ready for the sterilization process (refer to Chapter 4 on page 32).

6



3.8 Cleaning the Tube-to-Tube Connector (Optional)

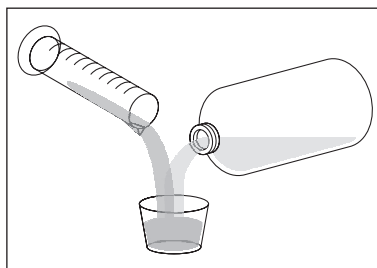
CAUTION: Do not use hydrogen peroxide. Do not use hydrogen peroxide to reprocess the peristaltic pump tubing/s.

Prepare an enzymatic detergent solution^{g)} with pH 6-9, as per the instructions of the manufacturer;

CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

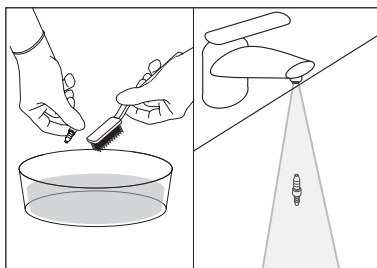
- g) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

1



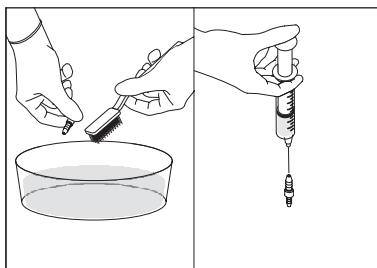
2

Use the enzymatic detergent solution and a clean soft bristled, nylon brush to gently scrub the inner and the external parts of the connector;
Rinse thoroughly under running tap water to eliminate any residuals of detergent from the external surface and from the internal channel;



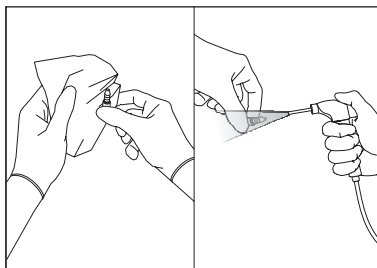
3

Carry out a final rinsing with demineralized cold water;
Use a disposable syringe for rinse the internal channel;



4

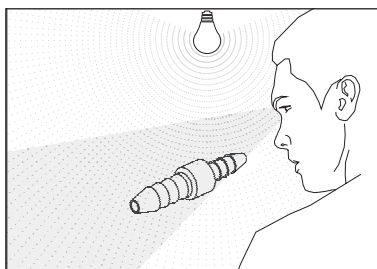
Dry thoroughly the connector with a clean lint-free cloth;
Use filtered compressed air to remove any moisture from internal channel;



3.8.1 Inspection Prior Sterilization

5

After the cleaning process, inspect the tube-tube connector for cleanliness (visible soil);
Generally unmagnified visual inspection under good light conditions is sufficient.



3.8.2 Packaging

The tube-tube connector can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

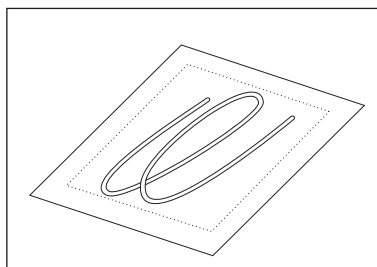
- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

⚠ CAUTION: The tube-tube connector must be packed individually.

⚠ CAUTION: Ensure that the inner pouch is large enough to contain the tube-tube connector without stressing the seals or tearing the packaging.

The tube-tube connector is ready for the sterilization process (refer to Chapter 4 on page 32).

6



3.9 Cleaning the Irrigation Bag Support Rod and the Fixed Handpiece Support

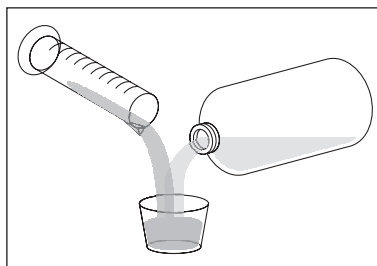
⚠ CAUTION: Do not use hydrogen peroxide. Do not use hydrogen peroxide to reprocess the peristaltic pump tubing/s.

Prepare an enzymatic detergent solution^{h)} with pH 6-9, as per the instructions of the manufacturer;

⚠ CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

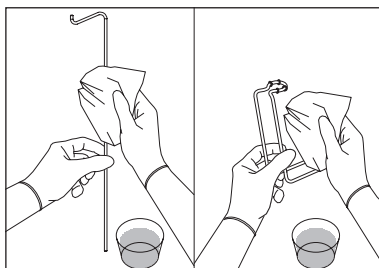
- h) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

1



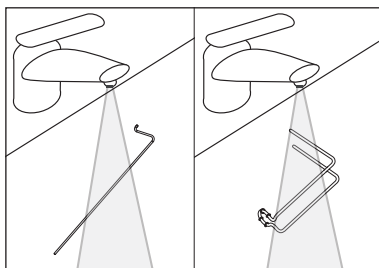
2

Clean the surfaces of the rod and of the handpiece holder using a clean, soft, lint free, cloth moistened with the prepared enzymatic detergent solution;



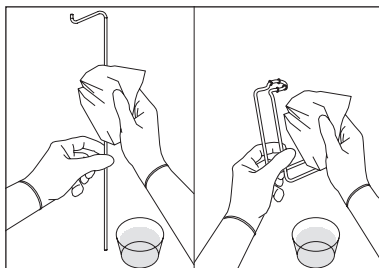
3

Rinse thoroughly under running tap water to eliminate any residuals of the enzymatic solution;
These components can be disinfected with a mild disinfectant solution prepared having a neutral pH (7);



4

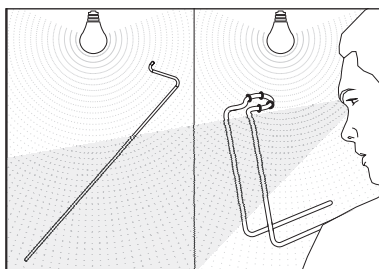
Rinse thoroughly under demineralized water to eliminate any residuals of the enzymatic and/or disinfectant solution/s;
Dry thoroughly them with a clean lint-free cloth;



3.9.1 Inspection Prior Sterilization

5

After the cleaning process, inspect the irrigation bag support rod and the fixed handpiece support for cleanliness (visible soil) and damage;
Generally unmagnified visual inspection under good light conditions is sufficient;
Repeat cleaning if not visibly clean and re-inspect;
Remove damaged and/or defective parts.



3.9.2 Packaging

The irrigation bag support rod and the fixed handpiece support can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

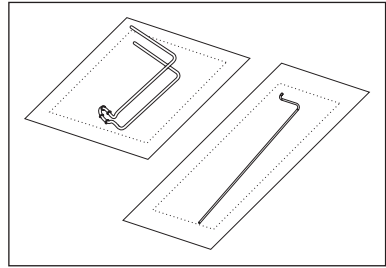
- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

CAUTION: These components must be packed individually.

CAUTION: Ensure that the inner pouch is large enough to contain each component without stressing the seals or tearing the packaging.

The irrigation bag support rod and the fixed handpiece support are ready for the sterilization process (refer to Chapter 4 on page 32).

6



3.10 Cleaning the Mobile Handpiece Support

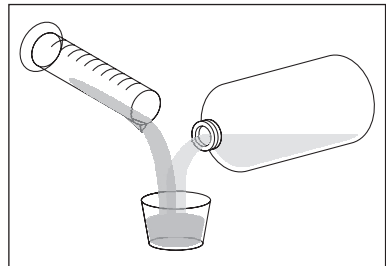
CAUTION: Do not use hydrogen peroxide. Do not use hydrogen peroxide to reprocess the peristaltic pump tubing/s.

Prepare an enzymatic detergent solutionⁱ⁾ with pH 6-9, as per the instructions of the manufacturer;

CAUTION: Once used, dispose of the enzymatic detergent correctly, do not recycle it.

- i) Process validated by independent institute with enzymatic detergent Cidezime® (Enzol®).

1



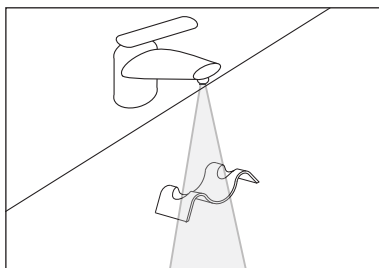
2

Immerse the mobile support of the handpiece in the prepared enzymatic detergent solution;
Remove the mobile support of the handpiece from the detergent solution and clean it using a clean, soft, lint free, cloth;



3

Rinse thoroughly under running tap water to eliminate any residuals of the enzymatic solution;
This component can be disinfected with a mild disinfecting solution prepared having a neutral pH (7);



4

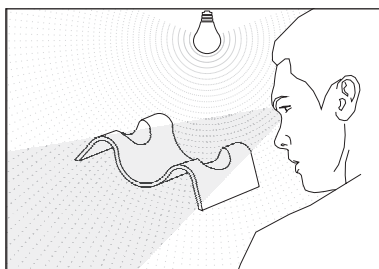
Rinse thoroughly under demineralized water to eliminate any residuals of the enzymatic and/or disinfectant solution/s;
Dry thoroughly them with a clean lint-free cloth.



3.10.1 Inspection Prior Sterilization

5

After the cleaning process, inspect the mobile support of the handpiece for cleanliness (visible soil) and damage;
Generally unmagnified visual inspection under good light conditions is sufficient;
Repeat cleaning if not visibly clean and re-inspect;
Remove damaged and/or defective parts;



3.10.2 Packaging

The mobile support of the handpiece can be sterilized by using a single-use medical steam sterilization pouch of the appropriate size;

IMPORTANT: The packaging for terminally sterilized instrument should meet the following requirements:

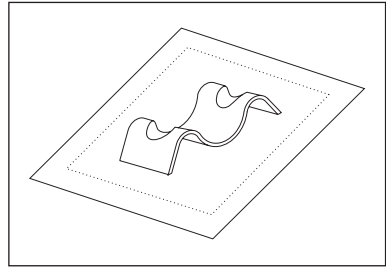
- Compliance with AAMI/ISO 11607-1;
- Legally marketed in the US;
- Suitable for steam sterilization;
- Grade appropriate for weight of instrument.

⚠ CAUTION: The mobile support of the handpiece must be packed individually.

⚠ CAUTION: Ensure that the inner pouch is large enough to contain the mobile support of the handpiece without stressing the seals or tearing the packaging.

The mobile support of the handpiece is ready for the sterilization process (refer to Chapter 4 on page 32).

6



4 STERILIZATION PROCEDURE

PIEZOSURGERY touch device's reusable components that can be sterilized:

- Handpiece with cord;

NOTE: The stainless-steel box supplied with the PIEZOSURGERY handpiece is intended exclusively for transportation, from the working area to the decontamination area and **NOT** for the sterilization process.

- Torque wrench;
- Insert tips;

⚠ WARNING: Diamond coated inserts are SINGLE USE ONLY. The diamond coated inserts are intended to be used on an individual patient during a single surgical procedure and then discarded. The diamond coated inserts must be sterilized only one time, prior first use.

- Peristaltic pump tubing;
- Tube-tube connector;
- Irrigation bag support rod and hand piece fixed support;
- Hand piece mobile support.

⚠ CAUTION: DO NOT STERILIZE THE CONSOLE. Console will no longer function.

⚠ CAUTION: DO NOT STERILIZE THE FOOT PEDAL. Foot pedal will no longer function.

⚠ CAUTION: When sterilizing multiple instruments in one autoclave cycle, ensure that the autoclave maximum load is not exceeded.

4.1 Sterilization Method

Carry out sterilization of the above reusable components exclusively by means of a pre-vacuum steam autoclaving.

⚠ WARNING: Risk of contamination. DO NOT use a gravity displacement autoclave to sterilize the PIEZOSURGERY touch sterilizable instruments. The operating cycle of a gravity displacement autoclave **DO NOT** ensure adequate sterilization of the lumens, cavities, recessed features of the instruments.

⚠ WARNING: Use exclusively a pre-vacuum autoclave to sterilize the PIEZOSURGERY touch sterilizable instruments.

⚠ CAUTION: Never use any other sterilization method, because of potential incompatibility with the materials used in the construction of the components.

⚠ CAUTION: DO NOT USE the following sterilization methods:

- Ethylene oxide sterilization
- Hot air sterilization
- Flash Autoclaving
- STERRAD sterilization
- STERIS system

or comparable sterilization systems

⚠ CAUTION: DO NOT sterilize the instruments by using:

- Hydrogen peroxide
- Peracetic acid system
- Formaldehyde sterilization
- Glutaraldehyde sterilization

or comparable sterilization solutions/system.

4.2 Minimum Recommended Steam Sterilization Parameters

The following table recommends minimum sterilization parameters that have been validated by Mectron S.p.A. to provide a 10^{-6} sterility assurance level (SAL).

IMPORTANT: These steam sterilization parameters, validated by independent laboratory, refer exclusively to the operating cycle of a PRE-VACUUM autoclave.

Cycle Type	Minimum Temperature	Minimum Exposure Time (Wrapped)	Minimum Dry Time
Pre-vacuum (3 times)	132 °C + 3 °C (270 °F + 5 °F)	4 min.	20 min.

⚠ CAUTION: Do not exceed 135°C (275°F).

⚠ CAUTION:

- The handpiece and the cord cannot be separated from one another;
- Do not operate or store the handpieces unless a drying cycle has been performed;
- Do not sterilize handpiece with an insert screwed on it;
- The handpiece and other accessories must not be assembled during sterilization;
- After sterilization, the handpiece should only be used again when it has cooled down to room temperature.
- The cooling process must not be accelerated;

- Never immerse the handpiece in a liquid to help it cool after sterilization, or product damage may result;
- After sterilization, verify functionality by operating the equipment prior to surgical use;
- Remove the handpiece from the sterilizer immediately after the sterilization cycle is complete or product damage may result;
- Upon completion of the sterilisation cycle, before connecting the handpiece cord to the device, make sure that the electrical contacts of the connector are perfectly dry. If necessary, dry the contacts by blowing air onto them with medical compressed air.

4.3 Storage

After sterilization instruments should be stored in the sterilization wrap in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions and handling.

A maximum shelf life for sterilized instruments should be defined by each health care facility.



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