

Dear Torq driver Customers

Thank you for choosing torq driver.

Please read the user manual carefully to ensure the appropriate use and maintenance of this product, and keep the enclosed warranty in a safe place.

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Chapter 1. Introduction

1.1 Indications for use

This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.

1.2 Outline

This driver is a digital implant torque driver which controls demanded speed and torque value automatically during dental implant practices. It can set and control speed (15, 30, 45, 60 RPM) and torque value (15, 20, 25, 30, 35 Ncm).

Also, enables a driver tip to rotate both clockwise and counterclockwise. The speed and torque value will be displayed. If actual loading value is higher than the set value, the device will automatically stop working which we call as a 'torque limit technic.'

1.3 Intended operator

This device can be used by only a licensed dentist.



Do not use the device other than intended purpose.

1.4 Check before use

- 1) Read this manual thoroughly
- 2) For use by dental professionals only
- 3) Do not use the device other than intended use.

Chapter 2. Safety (Cautions and Warning)

2.1 Danger

- 1) Only the specified lithium ion battery shall be used for this device. The use of the other type of battery is strictly forbidden.
- This product should be used only on predetermined standard charging adapter. Use of a different type of adaptor may result in damage to the device.

2.2 Warning

- 1) It shall not be used to the patients who were treated with cardiac pacemaker.
- 2) The handpiece head shall not be connected with other products except the other recommended products.
- 3) Do not use the torque driver as a manual ratchet. It may break inner gear.
- 4) Calibrate the torque driver before use.
- 5) Check the vibration, noise and heat before use. These must be check outside of patient's oral cavity. Contact your local representative for any malfunction.
- 6) Stop using immediately and request for repair to the representative if the operation of the torque driver is not usual.
- Do not touch the power cable and the product with wet hands. It may cause an electric shock.
- 8) Do not drop water or chemicals on the charging cradle of the torque driver. It may cause electric shock and damage on the electric circuit.
- Do not place the product near to explosive and inflammable material.
- 10) Do not disassemble or modify the torque driver.
- 11) Do not drop the product.
- 12) Please make sure to check beeping sound when you place the product onto a cradle socket. (Misplacement of the torque driver on to the cradle may result in the device not being charged, and the device may slip and be damaged.)
- 13) Stop using the torque driver and contact local representative immediately if there is internal water leakage on the torque driver as it damages the device.

- 14) Please be aware of heavy loading. Do not use it when final screw is placed.
- 15) Please keep any portable or RF communication devices away as it may interfere with the performance of device.
- 16) Please use the given cradle to charge the device. DO NOT USE any other similar ones.
- 17) Do not to place any other metal objects (Ex. Metal, coin, wire and plastic) inside of the charging cradle and the torque driver.

2.3 Caution

- Do not place or use the product under the direct sunlight, in a car during summer daytime. Never place the product near fire or fireplace.
- 2) Turn off the device when you replace handpiece head or screw driver with new one. It may cause damage of the product.
- 3) When you connect abutments using a screw driver tip, please check whether screw is correctly connected before using.
- 4) The maximum torque value may not be exerted when the battery is low. Charge the battery fully before use.
- 5) Any chemical or detergent on the torque driver may cause the change of color and deformation. Please remove it as soon as possible.
- It is strongly recommended to use the torque driver by wrapping the sanitized vinyl sheet to protect it from the contaminant and high humidity.
- 7) This device is intended only for indoor use.

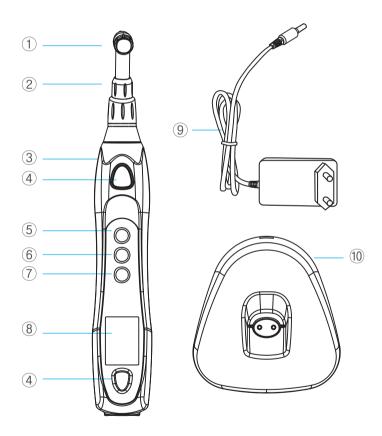
2.4 Notice

- 1) Wear the protective glasses and mask for your safety and health during use.
- 2) Additional training is not required to use this instrument.
- 3) The user is responsible for operating, maintaining and inspection.

Chapter 3. Specifications (Component Description)

3.1 Components of the product

1)Torque driver



| No. | Name | Description | | |
|-----|-------------------------|--|--|--|
| 1 | Chuck button | - Button to tight/un-tight screw drivers | | |
| 2 | Handpiece head | - Enables the driver tip to rotate. | | |
| 3 | Torque driver | - Where users holds the device. | | |
| 4 | Operating button | - Enables the device to operate. Motor runs only when the button is being pressed. (You can use both buttons depends on how you hold the device) | | |
| 5 | Power and torque button | the electric power turns ON/OFF when the button is pressed longer than 2 seconds. the torque value changes when the button is pressed shorter than 2 seconds. (When the device is turned ON) Torque value: 5, 10, 15, 20, 25, 30 and 35 Ncm. (Unit of 5Ncm) | | |
| 6 | CW and CCW button | Sets rotation direction. Calibration performs when the button is pressed longer than 2 seconds. | | |
| 7 | RPM button | - Sets RPM value. - RPM value: 15, 30, 45, 60 RPM | | |
| 8 | LCD panel | Displays current status and operation mode. | | |
| 9 | Charging adaptor | - Supplies power to the cradle | | |
| 10 | Charging cradle | - Charges battery | | |

3.2 Product performance

1) Torque driver

| Model name | TORQ DRIVER | |
|--------------------------|---------------------------------|--|
| Electrical specification | DC 7.4V, 360mAh | |
| Rotation speed (no load) | 15, 30, 45, 60 RPM | |
| RPM value accuracy | ±5 % | |
| Torque value | 5, 10, 15, 20, 25, 30, 35 [Ncm] | |
| Torque value accuracy | ±10 % | |
| Dimensions | 30mm(W) × 28mm(L) × 200mm(H) | |
| Weight | 150g | |

2) Handpiece head

| Screw driver | Screw driver shank ∅2.35mm, ISO1797-1 Type 1 | |
|--------------|--|--|
| Chuck type | Push Button Chuck | |
| Weight | 50g | |

3) Charging cradle

| Electrical specification | Input: 12 V, 1.0 A, Output: 8.4 V, 360 mA | |
|--------------------------|---|--|
| Dimensions | 105 × 111 × 51 mm [Width×Length×Height] | |
| Weight | 80g | |

3.3 Pictogram

| P _x | Federal law restricts this device to sale by or on the order of a dentist | | |
|-----------------------------|---|--|--|
| Community European | | | |
| 0120 | Notified Body | | |
| REF | Catalogue number | | |
| SN | Serial number | | |
| | Manufacturer | | |
| EC REP | Authorized representative in the European Community | | |
| Date of manufactured | | | |
| * | Keep dry | | |
| === | DC | | |
| | Class II Equipment | | |
| ፟ 大 | B type applied part | | |
| Caution | | | |
| Consult Instruction for use | | | |
| X | Do not dispose of with domestic waste | | |

3.4 Characteristics

- This device can be operated for approximately an hour in continual mode when it is loaded. (time period may vary depends on the conditions.)
- 2) Torquing value is between 5 to 35 Ncm.
- Calibration procedure can reduce torque value errors between the torque driver and Handpiece head.
- 4) There are three buttons. (torque control, CW/CCW, and RPM control)
- 5) You can operate torque button from 5Ncm to 35Ncm with increment of every 5Ncm. It can only work as POWER ON/OFF when you press it over 2 seconds.
- 6) CW and CCW button changes a rotation direction of Motor and can work as CALIBRATION function when you press it over 2 seconds.
- 7) RPM control changes the Motor speed.
- 8) Real-time torque value is displayed on LCD panel.

3.5 Environmental conditions (Storage, Relocation, Operation)

3.5.1 Storage conditions

- 1) Temperature: -10°C ~ +50°C
- 2) Humidity: 10 ~ 80%
- 3) Air pressure: 500hPa ~ 1060hPa

3.5.2 Relocation conditions

- 1) Temperature: -10°C ~ +50°C
- 2) Humidity: 10 ~ 80%
- 3) Air pressure: 500hPa ~ 1060hPa

3.5.3 Operation conditions

- 1) Temperature: +10°C ~ +35°C
- 2) Humidity: 30 ~ 80%
- 3) Air pressure: 700~1060 hPa



CAUTION

If you operate the product where the conditions are not met, malfunction may occur.

Chapter 4. Installation

4.1 Environmental condition

- Strongly recommend to meet these conditions when installing the product.
 - Temperature : 10 \sim 40 °C Humidity : 10 \sim 75 %
 - Pressure : 700 ~ 1060 hPa
- 2) There must be power source of 100V~240V, 50Hz~60Hz to install and use a charging cradle.
 - Temperature : 10 ~ 40 °C - Humidity : 10 ~ 75 % - Pressure : 700 ~ 1060 hPa

4.2 How to install

- 1) Make sure to insert an adaptor cord completely into a charging cradle socket when you connect them together.
- 2) Insert the torque driver correctly into charging cradle when charging the torque driver
- 3) Place charging cradle away from high humidity

Chapter 5. Operation (Description of Operation)

5.1 Check list before usage

- 1) Please check any damage of the device and battery status.
- 2) Please use exclusive Screw Driver Tip.
- 3) In order to prevent infection, please sterilize screw driver tips and the handpiece head for 30 minutes in 121°C before every usage to prevent any infection. (Please refer to the information provided by sterilizer manufacturer.)
- 4) Please replace the screw driver tip if it is rotten or worn.

5.2 How to operation

5.2.1 Charging battery



- 1) Connect adaptor cord to outlet.
- 2) Plug power cable to power.



3) Mount the torque driver correctly onto the cradle.



4) Orange LED light is on when charging starts.



- 5) LED light changes from orange to green when charging is completed.
- 6) Take out charging adaptor from outlet.

A CAUTION

- Please make sure to mount torque driver correctly onto the cradle as it may slip.
- Please make sure to observe LCD Panel when mounting torque driver. Please make sure LCD Panel faces front.
- Please make sure no liquid is into recharging socket and cradle.
- Contact local representative if LED light does not appear as it has trouble in electrical circuit.
- If debris gets on the product charging port, please remove the debris and cleaning, between product and charging cradle can cause erroneous contact.
- Be careful when you mount torque driver onto the cradle Cradling socket may be damaged.
- Do not touch the device with wet hands.
- Do not use the cradle to recharge other electrical device.
- You may need 60 minutes to fully recharge the device. It may vary depends on battery condition, temperature and environment
- You may feel warm in battery part of the Motor if you recharge the device for short time. It is recommended to charge for long time.
- \odot Do not place the cradle under direct sunlight and Recharge the battery in moderate temperature. (0 \sim 40°C)

5.2.2 Changing handpiece head

- 1) Handpiece head can be detached from torque driver. Twist and pull A Part to CCW direction.
- To tight torque driver and Handpiece head, please keep Handpiece head in alignment with torque driver and twist to CW

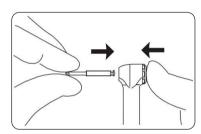




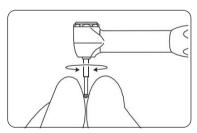
Please do not connect other brands' Handpiece head to torque driver as it may cause damage inside Handpiece head and circuit in torque driver.

5.2.3 Mounting the screwdriver(Attachment)

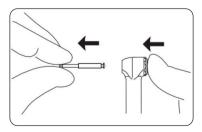
1) Press gently upper part to detach.



Lightly push the Chuck button, so screw driver tip can be connected easily.



Press the screw driver tip into axis direction to check whether the screw driver tip is safely connected.



You can easily separate the screw driver tip by lightly pushing the Chuck button.



A CAUTION

- Please turn off when you mount/dismount the screw driver
- Please use exclusive screw driver tip for implant abutment.
- Please check any transformation or axis alignment before
- Make sure to connect the tip correctly before use.
- Please clean and disinfect screw driver tip as it can cause malfunction and damage.
- Please keep the rotation speed and torque value recom mended by dental implant manufacturer.
- Please use proper screw driver tip from the surgical kit and it shall be qualified and registered by your authorities concerned.

5.2.4 Preparation before use



- 1) Press POWER button () over 2 seconds turn on the device.
- 2) Pressing POWER button ((1)) will set torque value from 5Ncm to 35Ncm, per 5Ncm. (5, 10, 15, 20, 25, 30, 35 Ncm)

Displays torque value



CAUTION

- Please clean Handpiece head and tip and replace with the new one when it is deformed.
- □ Calibration on Torque driver is necessary. No calibration prior to use may cause inaccurate torque value.

5.2.5 Calibration method

- 1) Calibration will start if you press operating button (calibration button)(()) for 3 seconds.
 2) LCD panel shows 'CAL' with beeping sound.
- 3) As calibration starts. Motor runs and it automatically calibrates torque value.
- 4) In 8 seconds, calibration will be completed.

5.2.6 Operation

- 1) the torque driver is operated when Driving button((")) is pressed and driving stops when the button is released.
- 2) Driving button() is on the top and bottom of the motor hand piece. Driving button() on the top is used when the torque driver is gripped with pen grasp method and the Driving button () at the bottom is used when it is gripped with palm up grasp method.



5.2.7 Reverse rotation

- 1) Pressing CW and CCW button(()) gently changes rotation direction.
- 2) The torque driver MUST NOT work when you change rotation direction. When CCW is set, LCD panel shows '(R)' and faster beep comes out than CW set.
- 3) When the torque driver runs, CCW cannot be set even if you press the button(()).
- 4) If you press the button again, CW is set and '(R)' on LCD panel will disappear.



5.2.8 Auto stop function

 Motor Handpiece stops automatically when the torque value is overloaded



CAUTION

- Do not use Torque Driver like manual ratchet as it damages inner gears.
- Please check the battery before use. Maximum torque value may not reachable if battery is not sufficient.
- Use of Torque Driver for a long time may cause heating and it will damage inner circuit and battery damage. Please cool it down in cooler place.

5.2.9. Auto power off

If the device does not run for 10 minutes, it stops automatically to save energy and prevent malfunction.

5.2.10 Auto presetting

When the device turns on, it automatically sets torque value that was set last time. When the device turns on, it automatically sets RPM value that was set 30 rom.

5.2.11 Changing the speed



- 1) You can select the rotation speed (15/30/45/60 rpm).
- 2) Set the rotation speed after turning on Torque Driver by pressing RPM button (RPM).
- 3) Rotation speed will be displayed on the top of LCD panel.



The default speed is 30rpm. If the user wants fast fastening and loosening, 45rpm or 60rpm can be used. However, before changing the rpm, please refer to the user manual of the abutment and follow the manufacturer's recommendation.

5.3 Cautions when using

- 1) Only qualified dentists or dental professionals shall use.
- Cannot be used to patients who were treated by Cardiac Pacemaker
- 3) Only use for intended purpose
- 4) Make sure AC cord is shielded.
- Always use the provided adaptor only. Do not use any other similar products.
- Power shall be from grounded outlet to prevent both device damage and electrical shock hazard.
- 7) Please keep the device away from water and do not use in dusty area.
- 8) Please do not use the device where inflammable gas is nearby.
- 9) Always make sure that authorized or qualified technician can dis-assemble/assemble.
- 10) Please do not place any heavy object near charging cable and keep away from heat.
- 11) Stop the device immediately and turn it off if it runs abnormally.
- 12) Make sure to sterilize Handpiece head and screw driver tip after each use.

5.4 Emergency stop

5.3.1 Auto stop function

1) When torque driver is overloaded, it automatically stops. Exceeded torque value does not load implant.

Chapter 6. Routine Maintenance

6.1 Manual cleaning

6.1.1 Handpiece head





- 1) Separate the Handpiece head connected in the Torque driver.
- 2) Prepare a cloth (preferably cotton) or soft brush moistened with isopropyl alcohol.
- Clean foreign substance on the entire surface of handpiece head and in the gaps with cloth or brush soaked in isopropyl alcohol for at 2 three minutes.
- 4) Repeat the cleaning process if foreign substance of handpiece head is found

6.1.2 Torque driver

- 1) Separate the Handpiece head connected in the Torque driver.
- 2) Prepare a cloth (preferably cotton) or soft brush moistened with isopropyl alcohol.
- 3) Clean foreign substance on the entire surface of Torque driver and in the gaps with cloth or brush soaked in isopropyl alcohol for at 2 three minutes.
- 4) Repeat the cleaning process if foreign substance of Torque driver is found.



CAUTION

After use, Please clean the soil before drying.

6.2 Inspection

- Inspect whether there is any foreign substance visible to the naked eve.
- 2) Repeat the cleaning process if foreign substance of Handpiece head and Torque driver is found.
- 3) Check the operating condition.
- 4) Repeat the above procedure for every single use.

6.3 Sterilization (Handpiece head)

The hand piece head should be sterilized after the cleaning. The recommended sterilization parameters are as below which are validated by the manufacturer.

| Cycle type | Pre-vacuum | |
|---------------|-------------------|--|
| Configuration | Wrap | |
| Temperature | 121 °C [249.8 °F] | |
| Exposure time | 30 minutes | |
| Dry time | 30 minutes | |

Chapter 7. Trouble Shootings

7.1 Cases

- Device is not turning on even though I pressed POWER ON/OFF button.
- The battery status is low or has not been charged for a long time.
 ⇒ Please charge the battery. If it still does not work, replace the battery with new one.
- 7.1.2 If the battery is not being charged.
- If the temperature of battery is too low or too high
 ⇒ If the temperature is lower than 0°C or higher than 40°C, battery
 charging may not work. The temperature may increase right after
 charging, but please contact your representative if it is overheated.
- 2) If the main body does not fit to the cradle.⇒ Please put the main body correctly onto the cradle.
- 3) If other electrical device is plugged into the charging cradle.

 ⇒ There is a high possibility that inner circuit may be damaged.

 Please contact local representative to repair. Please do not plug other products to the charging cradle because inner parts may be damaged.
- 7.1.3 Insufficient Power/Vibration
- 1) When screw driver tip is incorrectly connected to Handpiece head.
 - \Rightarrow Unscrew the tip and re-screw it correctly
- 2) When screw driver tip is bent or deformed.
 - ⇒ Replace with new driver tip.
- 3) When screw driver tip does not rotate due to tight connection with handpiecehead.
 - \Rightarrow Disconnect from handpiece head. Clean or replace screw driver tip with new one.
- 4) When torque or RPM value is lower than the set value.
 - ⇒ Check battery status.
- 5) When calibration does not work smoothly.
 - \Rightarrow Please check battery status. If the battery is low, please charge it.

Chapter 8. A/S

8.1 Accessories

| Handpiece head | Charging cradle | Charging adapter | |
|------------------|-----------------|------------------|--------|
| Transpicco ricad | | Type A | Type B |
| A-3 -5 | OCSTEM* | 19 | |

8.2 Information on After-Sale Service

- Manufacturer: MICRO-NX Co., Ltd.
- · Made in : Republic of Korea
- Address: 22 Maeyeo-ro 1-gil, Dong-gu, Daegu, 41059 Republic
 - of Korea
- Contact: +82-53-650-1000 / micronx@micronx.co.kr
- Homepage: www.micronx.co.kr

8.3 Warranty

- 1) Warranty period of the product
- Warranty Period: 1 year
- Battery : 6 months
- Torque driver: Cannot be warranted because it is a consumable.



Warranty cannot be applied for any default that is caused by mishandling of a consumer.

Chapter 9. Electromagnetic Compatibility

9.1 Electromagnetic emission

The product is suitable for use in an specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

| Emission Test | Compliance | Electromagnetic Environment Guidance | |
|---|------------|---|--|
| RF-emission CISPR 11 | Group 1 | The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. | |
| RF-emission CISPR 11 | Class A | The product is suitable for use in all establishments, including dom | |
| Harmonic emissions IEC 6100-3-2 | Class A | estic establishments and those directly connected to the public | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | low-voltage power supply net- work that supplies buildings used for domestic purpose. | |

9.2 Electromagnetic Immunity

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

| Immunity Test | IEC 60601- Level | Compliance Level | Electromagnetic Environment Guidance |
|---|--|--|---|
| Electrostatic discharge(ESD) IEC61000-4-2 | ± 6kV contact ± 8kV air | ± 6kV contact ± 8kV air | Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/bursts IEC61000-4-4 | ± 2kV for power supply lines ± 1kV for input/output lines | ± 2kV for power supply lines ± 1kV for input/output lines | Mains power quality should be that of a typical commercial and/or hospital environment. |
| Surge ± 1kV differential mode ± 2kV common mode | | ± 1kV differential mode ± 2kV common mode | Mains power quality should be that of a typical commercial and/or hospital environment. |

| Immunity test | IEC 60601- level | Compliance level | Electromagnetic environment guidance |
|---|--|--|--|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4- 11 | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% DIP IN UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% DIP IN UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | commercial or hospital | |

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9.3 Recommended separation distances between portable and mobile HF-communications equipment and the product

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – accord—

| Rated maximum output power of transmitter | Separation distance according to the frequency of transmitter in meter (m) | | | |
|---|--|--------------------------------|---------------------------------|--|
| in watts (W) | 150 kHz to 80 MHz d = 1.2√P | 80 MHz to 800 MHz d = 1.2√P | 800 MHz to 2.5 GHz d = 2.3√P | |
| 0.01 | 0.12 | 0.12 | 0.23 | |
| 0.1 | 0.38 | 0.38 | 0.73 | |
| 1 | 1.2 | 1.2 | 2.3 | |
| 10 | 3.8 | 3.8 | 7.3 | |
| 100 | 12 | 12 | 23 | |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Chapter 10. Disposal

10.1 Disposal guideline

- 10.1.1 Disposal of torque driver unit, charging cradle and charging adapter
- Follow your country specific laws, directives, standards and guidelines for the disposal of used electrical devices.
- Ensure that the parts are not contaminated on disposal.



10.1.2 Disposal of the packaging material

- All of packing materials can be recycled.
- Please send old packing materials to related companies for recycling.



The EU directive 93/42/EEC was applied in the design and production of this medical device.



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