JTS Drive Unit

Model: MLE3

For Use with
JTS Extendible Implants

Limb Lengthening Protocol &
Operation Manual
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1 JTS Extendible Implants

1.1 Glossary of Terms:

JTS MLE – Juvenile Tumor System Mobile Limb Extender

Drive Unit – A MLE, consisting of two main parts, a Power Unit and a Magnetic Coil

Power Unit – Mains Power Box

Magnetic Coil (or Coil) – External Electromagnetic Coil

Power Unit Cable – Connects Power Unit to mains supply

Directional Control Switch – Located on Power Unit, selects between ‘A’, ‘B’ and ‘Stop’

On/Off Switch – Located on the Power Unit, switches the system ‘On’ and ‘Off’

Coil Cable – Connects the Magnetic Coil to the Power Unit

1.2 Required for a Lengthening:

Lengthening of the JTS implant does not require surgical intervention and is usually performed in an outpatient setting. The following are required to perform a JTS lengthening:

A trained Health Care Practitioner – a suitably qualified Healthcare Practitioner who has completed the Stanmore JTS Drive Unit training course

A JTS MLE (Drive Unit) consisting of Power Unit, Coil, Coil Cable and Power Unit Cable

A JTS MLE Lengthening Protocol & Operation Manual (this document)

A copy of the Patient Specific Operation Drawing – This contains important information about settings to lengthen the JTS and also the maximum length achievable for the implant. Copies can be obtained from your local representative or by contacting Stanmore Implants directly

Mains power supply of either 115V or 240V

An examination table or chair – for the comfort of the patient

A patient requiring limb lengthening

A stethoscope – to enable the operator to hear the JTS Implant’s mechanism rotating and extending the Implant

A stop watch – to enable timing of the lengthening procedure and quantify the amount of lengthening achieved
1 JTS Extendible Implants

1.3 System Description:

An extendible prosthesis inserted in a skeletally immature patient as a part of a limb sparing treatment requires extending on a regular basis to keep pace with the growth in the contralateral limb. The JTS Drive Unit (JTS MLE) was developed to provide a non-invasive extending control mechanism for the JTS Extendible Implant. This Drive Unit produces a controlled expansion of the prosthesis without a need for surgical intervention.

There are two parts in the JTS system:

- **JTS Extendible Implant**
  A patient specific implant with a telescoping shaft connected through a gearbox to a disc magnet. The implant is surgically inserted into the patient as normal.

- **The JTS Drive Unit**
  After the surgery as the patient grows the JTS Drive Unit is used to extend the prosthesis by placing the limb with the implant into the Coil.

The JTS Drive Unit has two main elements, a cylindrical Coil and a Power Unit. When the Coil is energised a rotating magnetic field is generated which captures the implant magnet causing it to rotate in synchronisation. The rotary motion of the magnet is converted through a gearbox with a 13000:1 reduction into a linear motion causing the implant to extend in a very controlled manner.

The JTS Implant extends at 1mm every 4 minutes.
1.4 Patient Specific Operation Drawing:

At the time of surgery, the clinician is provided with a Patient Specific Operation Drawing, an example Operation Drawing is shown in section 3. These instructions must be used whenever the prosthesis is extended. Failure to do so may result in reversal of the growth or over extension of the prosthesis. The Operation Drawing contains the following important information:

- The location of the magnet inside the prosthesis
- The Direction Control setting, marked either, ‘A’ or ‘B’
- The maximum extension achievable from the prosthesis

Copies of the Patient Specific Operation Drawing can be obtained by contacting your local representative or Stanmore Implants directly

Not all devices in a similar skeletal location will lengthen on the same directional control setting. **The most up to date Patient Specific Operation Drawing must be consulted prior to attempting a lengthening to determine the Directional Control Setting, position of magnet and maximum permissible extension of the device.**

1.5 Magnetic Field Generation:

The magnetic field generated by the Drive Unit is concentrated in the inner space of the Coil itself with very little field on the outer surface of the Coil. The maximum value of the magnetic flux is less than 100 mille-Tesla RMS. In general, the field is very weak and therefore there are no special precautions required during operation of this equipment. However, it is recommended that keys, wallets, change or phones are not place within the Coil and the patients should remove these items from pockets prior to inserting their limb into the Coil.

When the implant is being extended there should be no noticeable discomfort for the patient, however the patient may notice slight vibrations, or mild stretching of the tissues surrounding the joint. It is recommended that extensions of 3 to 5 millimetres increments are targeted per session with sufficient time between extensions to allow soft tissues to recover from any mild stretching.
2 LIMB LENGTHENING PROTOCOL

2.1 Drive Unit Connections:

Ensure safe manual handling practices are observed as the Power Unit weight approximately 16 kg (35 pounds) and the Coil weights approximately 36 kg (80 pounds). These units are considered to both be 2 person lifts.

Coil Cable Connection
(Note: there is a keyway on the connector to aid insertion in the correct orientation. Once the connector has been inserted it is locked in place by snapping the clip over the connector)
2 Limb Lengthening Protocol

2.2 Before use:

Before using the equipment please ensure that:

- You have been suitably trained to use the Drive Unit. If you have not been trained in the Operation of the device do not attempt to use it. Contact your local representative or Stanmore Implants directly.
- The equipment, including all cables, are in good order and not damaged in any way. If any damage is visible do not attempt to use the device and contact your local representative or Stanmore Implants directly.
- The Coil must be placed on a level surface during use. Ensure that the manual handling safety precautions are observed whilst lifting the equipment since the Coil weighs approximately 36 Kg (80 pounds) and the Power Unit approximately 16 Kg (35 pounds). These units are considered to both be 2 person lifts.
- The Power Unit is suitably placed on a level surface. Ensure that proper electrical safety practices are observed during storing, setting-up and use of the equipment.
- All trip hazards associated with trailing cables are removed or minimised.
- A copy of the Patient Specific Operation Drawing is available.
- A copy of the Limb Lengthening Protocol & Operation Manual (this document) is available.
- Ensure that the Coil and Power Unit are clean, the Coil and Power Unit can be wiped down with Universal Wipes if required.
- The vents on the Power Unit are not obstructed.

2.3 Equipment Set Up:

When setting up the JTS Drive unit for use please ensure that:

- The equipment is adequately placed for the use as explained in the previous section.
- The Coil Cable is connected from the Coil into the socket in the front of the Power Unit.
- That the Directional Control Switch is set to ‘STOP’
- The ‘On/Off’ switch on the Power Unit is set to the ‘Off’ position.
- Plug the Power Unit Cable in at the back of the Power Unit and into a suitable power outlet.
2 Limb Lengthening Protocol

2.4 Patient Positioning:

When positioning the patient please ensure that;

- The patient has removed his/her shoes and socks
- The patient is comfortable either sitting or lying with their hips approximately the same height as centre of the Coil (it is recommended to have the patients limb adequately supported by cushioning at all times during the lengthening)
- The Patient Specific Operation Drawing is consulted for the location of the magnet within the JTS implant
- The patient’s limb is placed into the Coil from the front end of the Coil

The Coil is marked ‘FRONT’ and it is vitally important to insert the patients’ limb from this side

- The implant magnet is approximately centrally located within the Coil

**NOTE:** The front of the Coil is labelled ‘FRONT’ and this label must face the patient as the limb is inserted into the Coil

**NOTE:** The magnet contained within the JTS is approximately located within the centre of the Coil

**NOTE:** The precise position and the orientation of the magnet within the Coil is not absolutely critical but the magnet needs to be about 5 cm inside the Coil. In addition, there is no need for the patient to be absolutely still whilst the implant is being extended. Small movements will not impede the function of the device.
2 Limb Lengthening Protocol

2.5 Limb Lengthening Protocol:

1. Before lengthening the JTS Implant using the JTS MLE the patient must be assessed by a suitably qualified Health Care Practitioner to determine the amount of extension required for the session.

2. Ensure that the Directional Control switch on the Power Unit is set to the ‘Stop’ position.

3. Ensure that the ‘On’/’Off’ switch on the Power Unit is set to the ‘Off’ position.

4. Refer to the Patient Specific Operation Drawing to determine whether the JTS Implant lengthens on Directional Control setting ‘A’ or ‘B’.

5. Ensure that the patient’s limb containing the JTS Implant is correctly inserted into the Coil from the front as described in section 2.4 and ensure that the magnet contained within the JTS Implant is approximately centrally located in the Coil. The magnet position within the JTS implant is indicated on the Patient Specific Operation Drawing.

6. The amount of extension expected from a lengthening procedure is directly proportional to the amount of time that the implant is in the energised Coil.

   The Implant extends at 1mm every 4 minutes

To achieve a lengthening of 4mm the JTS Implant will have to be placed within the energised Coil for 16 minutes.

Guidance must be sought from a suitably qualified Health Care Practitioner to determine the amount of extension required for the session.

<table>
<thead>
<tr>
<th>Extension (mm)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (minutes)</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
<td>24</td>
<td>28</td>
<td>32</td>
<td>36</td>
</tr>
</tbody>
</table>

The above table shows how the extension of the JTS Implant increases with the time the Implant is inserted into the energised Coil. Extensions of 3-5mm, as highlighted above are typical and take 12-20 minutes.
2 LIMB LENGTHENING PROTOCOL

2.5 Limb Lengthening Protocol (Continued):

7. Turn on the mains power on the Power Unit by selecting the ‘On’ position on the ‘On/Off’ switch on the Power Unit. You should now be able to hear the internal fan running. Please note that this fan will run for approximately sixty seconds, it will only come on again if required during the lengthening procedure. If you do not hear the fan when the Power Unit is switched on please consult the Trouble Shooting section.

8. Referring to the Patient Specific Operation Drawing select the ‘A’ or ‘B’ setting on the Directional Control Switch to lengthen the JTS Implant. Selecting the opposite will reverse the mechanism shortening the implant. Once the direction and been selected start the stop watch. Once a direction has been selected on the Power Unit the Coil will emit a high pitched whine. If the high pitched whine is not audible consult the Trouble Shooting section.

9. By placing a stethoscope on the patient’s medial malleolus of the leg with the JTS implant you can hear the implant mechanism rotating. You should hear a soft mechanical whirring of the gearbox to indicate that the implant is lengthening. If you hear a soft buzzing/humming sound from the prosthesis (not the Power Unit) please turn the Power Unit off, stop the stopwatch and see the Trouble Shooting section.

10. The patient should feel no pain or discomfort during the lengthening, however the patient may experience some vibration and ‘tightening’ around the joint and this may temporarily affect the patients range of motion. Any reduction in range of motion should be alleviated by following the patient’s regular physio regime.

**If the patient experiences any pain, numbness or tingling stop the lengthening**

11. The JTS Implant will lengthen at about 1mm every 4 minutes and you should listen to the mechanism throughout the lengthening procedure.

12. JTS Implants tend to be lengthened about 3-5mm per session but guidance on the amount of extension required in a session must be sought from a suitably qualified Health Care Practitioner.
2 Limb Lengthening Protocol

2.6 Completion of Lengthening:

1. Once the desired amount of extension has been achieved turn the Directional Control Switch to the ‘Stop’ position and turn the main ‘On/Off’ switch on the Power Unit to the ‘Off’ position.

2. Ensure that there are no trip hazards associated with trailing cables from the Coil or Power Unit.

3. The patient can now remove their limb from the Coil.

4. The Power Unit and Coil should now be wiped down with Universal Wipes.

5. The Power Unit and Coil should now be disconnected, remove the Power Unit Cable from the mains power supply and rear of the Power unit, disconnect the Coil Cable from the Power Unit and place the Power Unit and Coil back into the flight case. Care must be taken to ensure that the Power Unit and Coil are placed in the correct orientation within the flight case.

Ensure that the manual handling safety precautions are observed whilst lifting the equipment since the Power Unit weighs approximately 16 Kg (35 pounds) and the Coil approximately 36 Kg (80 pounds).

These units are considered to both be 2 person lifts.

2.7 Trouble Shooting:

1. Fan not heard on start up or high pitch whine not heard from Coil once direction selected

   - Check all connections are secure, Power Unit Cable and Coil Cable
   - Make sure that mains power socket is functioning as expected
   - Once all connections have been checked if the fan is still not heard on power up Please stop the procedure and contact your local Representative or Stanmore Implants directly.

2. Buzzing/humming sound heard

   - If you hear a buzzing/humming sound coming from the JTS Implant (not the Power Unit) this means that the internal magnet is not coupled with the rotating magnetic field generated by the Coil and the JTS Implant is not extending as expected. In order to address this you should first:

     - Check the position of the patient’s limb within the Coil and ensure that the magnet is approximately centrally located in the Coil. Reposition the patient’s limb if necessary. Restart the extension by selecting either ‘A’ or ‘B’ on the Directional Control Switch
     - Once the JTS starts to lengthen restart the stopwatch
     - If this does not solve the problem the following steps can be worked through:
2.7 Trouble Shooting (Continued):

- Switch the Direction Control Switch to ‘Stop’ and leave it in that position for approx. 5 seconds.
- Then switch the Directional Control Switch back to either ‘A’ or ‘B’, as indicated on the Patient Specific Operation Drawing.
- This can be repeated up to 5 times or until you hear the soft mechanical whirring sound of the gearbox running.

3. Buzzing/humming sound heard – Step 2 failed to address the issue

- If the JTS Implant persists in not extending as expected, you may need to switch the Directional Control Switch using a reciprocating, forward and reverse motion to encourage the implant to commence or continue lengthening.

  **Note:** This forward and reverse motion must not be attempted until at least 1mm of extension has been achieved since implantation.

- Turn the Directional Control Switch to ‘Stop’ on the Power Unit.
- Turn the Directional Control Switch to the opposite direction (i.e. shorten the implant).
- Let the implant run in the opposite direction for about 5 seconds.
- Turn the Directional Control Switch to ‘Stop’ and then onto the correct Directional Control setting as indicated on the Patient Specific Operation Drawing and run for about 10 seconds.
- This action may need to be repeated to encourage the implant to commence or continue lengthening.
- Ensure that the stopwatch is restarted once the implant starts to extend.

4. Buzzing/humming sound heard – Steps 2 and 3 failed to address the issue

- If the JTS Implant still does lengthen as expected having completed steps 1 and 2 of Trouble Shooting you must consult a qualified Healthcare Practitioner to aid with patient stretching or possible manipulation of the limb.
- Have the patient remove their leg from the Coil and, under the supervision of a Qualified Healthcare Practitioner, complete their regular stretching exercises to help loosen the soft tissue surrounding the joint.
- Attempt to lengthen the JTS Implant following steps 2 and 3 outlined above.
- If the JTS Implant still fails to lengthen as expected some manipulation of the patient’s limb may be performed by a suitably qualified Healthcare Practitioner.
- A light longitudinal pull on the patient’s limb by a qualified Healthcare Practitioner may be attempted to try and reduce soft tissue tension surrounding the joint.
- Following limb manipulation attempt to lengthen the JTS Implant following Trouble Shooting steps 2 and 3 as outlined above.

If these Trouble Shooting measures fail to address the JTS Implant not lengthening please stop the procedure and contact your local representative or Stanmore Implants directly.
3 SAMPLE PATIENT SPECIFIC OPERATION DRAWING

STANMORE IMPLANTS WORLDWIDE
Telephone number: +44 (0) 20 8236 6500

SAMPLE OPERATION DRAWING

Patient name: PATIENT, Some
BMI: E. No: 000000
Surgeon: Dr Surgeon
Cp Date: Some Date
Hospital: Some Hospital

The JTTS® extendible implant is MRI UNSAFE - the implant or a patient with an implant in place must not be taken into an MRI environment.

Implant type: Distal Femoral Replacement
Type of fixation: Cemented Femoral Stem - Cemented Passive Tibia
Joint type: Extra-Small SMILES Rotating Hinge
Max Extension: 50mm (Do not over extend)
Material: CoCrMo – Ti – UHMWPE - HA
Side: Right

MINIMAL RESECTION OF TIBIAL CONDYLES

CEMENTED STEM
TAPERED Ø 6 > Ø7.5

Ø19 HA COLLAR

MAGNET & GEARBOX
EXTRA SMALL ROTATING HINGED PASSIVE Tibia

Ø15

Ø10.5 PASSIVE TIBIAL STEM

130

179

10

179

20

150

NOTES:
1. This implant contains a magnetically driven gearbox to remotely extend the implant post-operatively as the patient grows.
   - For this a Mobile Limb Extender - Model MLE3 is required.
   - Inset patient’s limb from the front of the machine ensuring the magnet (shown above) is centrally positioned within the device.
   - Turn the switch to POSITION ‘A’ to extend the device and POSITION ‘B’ to reverse it.
   - Allow 4 minutes to extend 1 mm and it is recommended that only 3 to 4 mm be extended at any one sitting. This allows soft tissue relaxation and reduces the possibility of overloading the gearbox.
   - Switch the drive off before removing the limb.
2. The magnet is made from NiFe alloy and is encased in a titanium casing sealed with adhesive. The gearbox is constructed from Stainless Steel parts coated with titanium nitride. The gearbox is lubricated with liquid paraffin.
3. The magnet and the gearbox are housed inside a silicone “O” ring sealed chamber.

DRAWN BY Some Designer DATE Some Date
4  WARNINGS AND PRECAUTIONS

Prior to carrying out any extension to a JTS Extendible implant ensure that you have the correct Patient Specific Operation Drawing available as this will indicate the correct setting for the drive unit to extend the implant.

To prevent reduced range of motion or discomfort to patients provide adequate physiotherapy to regain full range of motion before and after extending the prosthesis.

Avoid over extension of the prosthesis to prevent discomfort to the patient or cause reduced range of motion.

Ensure that full concentration is given whilst extending an implant to prevent trauma to the patient. Lack of concentration may lead to inappropriate implant extension.

After prolonged use of the MLE device the MLE may become warm to touch. Prevent long periods of continuous use.

This equipment must only be operated by a trained operator who is familiar with the controls and has read the manual. Untrained operators may lead to trauma to the patient. Please contact your local representative or Stanmore Implants for training.

Misuse of the equipment may lead to trauma to the patient.

Caution should be exercised to prevent spillage on, or misuse of the equipment to avoid electrical shock.

Perform regular service to prevent excessive electromagnetic field exposure which might lead to nerve stimulation.

Being an electromagnetic device ferromagnetic material near the Coil might become attracted. Avoid such materials near the Coil.

Being an electromagnetic device electromagnetic interference may be experienced by sensitive equipment in a hospital environment. Avoid close proximity with sensitive equipment.

The drive unit is heavy. To avoid the risk of damage, the drive unit must only be stored and transported in the supplied flight cases.

If the equipment is accidentally damaged ensure it is fully checked prior to use. Please contact your local representative of Stanmore Implants.

This equipment must be maintained / serviced regularly to ensure proper function. Any deterioration in function of the device may lead to trauma to the patient.

Do not open the Power Unit while it is connected to a mains supply as this could lead to an electric shock.

Do not clean the drive unit or the control box with any solvent

Ensure that the manual handling safety precautions are observed whilst lifting the equipment since the Power Unit weighs approximately 16 Kg (35 pounds) and the Coil approximately 36 Kg (80 pounds). These units are considered to both be 2 person lifts.

Ensure that the Coil is placed on a level surface during use.

Ensure that the Power Unit is placed on a level surface.

The JTS MLE is not suitable for use in an oxygen rich environment.

Only to be serviced/maintained by qualified personnel.

Ensure to position the equipment so that it is not difficult to disconnect the mains supply plug.

The main contraindication of the procedure is the size of the patient’s leg. The opening in the Coil is 16cm in diameter (approx. 50cm circumference), if the patient’s limb is bigger than this they will be unable to position the prosthesis correctly in the magnetic field.

Booster switch to only be used by qualified service personnel.

If the drive unit requires disposing of, contact Stanmore Implants.

WARNING: JTS Drive Unit only to be used with supplied Coil (Coll and drive unit must have matching serial numbers). Use of non-paired Coil may lead to trauma to the patient.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

WARNING: No modification of this equipment is allowed.

WARNING: The drive unit must only be used with an Stanmore Implants JTS non-invasive extendible implant.
5 Cleaning and Maintenance

- Routinely remove dust using a soft cloth. Do not use solvent of any kind. If required wipe the Drive Unit with Universal Wipes and allow it to dry naturally before use. The Drive Unit should be cleaned after each use and between patients.
- The equipment should be checked annually for performance, by an approved person. Please contact your local representative or Stanmore Implants directly for details.

6 Technical Specifications

Wiring schematics are available on request from Stanmore Implants Worldwide.

<table>
<thead>
<tr>
<th>MODEL:</th>
<th>MLE3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical Input Supply (230V Systems)</td>
<td>SINGLE PHASE 230 V, 50 Hz</td>
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<tr>
<td>Electrical Input Supply (115V Systems)</td>
<td>SINGLE PHASE 115 V, 60 Hz</td>
</tr>
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<td>Mains fuse rating:</td>
<td>Double T-5 Amps-AH</td>
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<tr>
<td>Secondary circuit fuse rating</td>
<td>T-1.6 Amps-AL</td>
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<tr>
<td>Max Power Consumption:</td>
<td>500VA</td>
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<tr>
<td>Net Weight of Coil:</td>
<td>36kg</td>
</tr>
<tr>
<td>Net Weight of Power Unit:</td>
<td>16kg</td>
</tr>
<tr>
<td>Electrical Classification:</td>
<td>Class 1</td>
</tr>
<tr>
<td></td>
<td>Coil – Applied Part –</td>
</tr>
<tr>
<td></td>
<td>Type B</td>
</tr>
<tr>
<td>Mode Of Operation:</td>
<td>Continuous</td>
</tr>
<tr>
<td>Maximum magnetic flux intensity:</td>
<td>100 milli-Tesla RMS</td>
</tr>
<tr>
<td>Means used to disconnect mains:</td>
<td>Mains plug</td>
</tr>
<tr>
<td>Operation Environmental Conditions (transport &amp; storage):</td>
<td>Temperature: 10°C - 32°C (-10°C - 50°C)</td>
</tr>
<tr>
<td></td>
<td>Humidity: 30% - 75% (10%-90%)</td>
</tr>
<tr>
<td></td>
<td>Atm. Pressure: 70.0kPa – 106.0 kPa (50kPa-106kPa)</td>
</tr>
<tr>
<td>Software Revision:</td>
<td>QF-133 Issue 2</td>
</tr>
<tr>
<td>Calibration &amp; Installation:</td>
<td>Installation, calibration and testing documentation available upon request.</td>
</tr>
<tr>
<td>Servicing:</td>
<td>Equipment only to be serviced and repaired by approved Stanmore Implants manufacturer. Work Instructions held by approved manufacturer.</td>
</tr>
</tbody>
</table>
7  LABEL  SPECIFICATION

Power Unit Main Label (230 V Systems)

Coil Main Label (230 V Systems)

Coil Main Label (115 V Systems)

Mains Power Label (230 V Systems)

Air Vent Label (115 V Systems)

Secondary Circuit Label

Coil Output Label
7 Label Specification

**Front Label**

- **Directional Control Switch Label**
- **Do Not Trash Label**
- **Stanmore Implants Label**

**Patient Specific Label**

- **Earth label**

**Instructions Label**

**INSTRUCTIONS:**
- Insert patient’s limb from the front of the coil ensuring the magnet shown in the Operations Instructions for the patient is centrally positioned within the coil.
- Turn the switch to POSITION ‘A’ or ‘B’ as indicated in the Operations Instructions to extend the prosthesis. It is possible to hold the prosthesis turning by placing a stethoscope on either the ankle or greater trochanter. The noise heard should be light gurgling or bubbling water, if the needle is pushed then this indicates that the magnet has stopped turning in which case refer to the Operations Manual.
- Allow 4 minutes to extend 1 mm and it is recommended that only 3 to 4 mm be extended at any one setting.
- Should it be necessary to reduce the length of the prosthesis turn the switch in the opposite direction again as instructed on the Operations Instructions. **DO NOT** shorten the implant unless it is absolutely necessary.
- Switch the drive off before removing the limb.
Special Instructions / Notes regarding the MLE3 JTS Drive unit and Electromagnetic compatibility (EMC) testing to EN60601-1-2:2007

The MLE3 has been tested regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure the MLE3 is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the MLE3.

As the MLE3 intentionally radiates electromagnetic energy to provide its intended function, it could in some cases interfere with the operation of other equipment. If the MLE3 is believed to interfere with the normal operation of other equipment, the user should try disconnecting the MLE3 from the mains supply (to establish if the MLE3 is the cause of the problem). If the MLE3 is found to interfere with other equipment, the user is encouraged to increase the physical distance between the MLE3 and the susceptible equipment.

Despite the testing of the MLE3 that has been undertaken, normal operation of the MLE3 can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the MLE3 is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the MLE3 is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

The MLE3 has been tested (and should be used only with) the Coil output cable supplied.

If the MLE3 is used with a cable other than the one supplied, this may result in increased emissions or decreased immunity of the MLE3 in relation to EMC performance.

It should be noted that the cables provided with the MLE3 should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

The MLE3 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the MLE3 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2, the MLE3 has an essential performance. This essential performance is that the Coil output should remain on.
### Guidance and manufacturer's declaration – electromagnetic emissions

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 2</td>
<td>The MLE3 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The MLE3 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
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<tr>
<td>IEC61000-3:2</td>
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<td></td>
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<tr>
<td>Voltage fluctuations / flicker</td>
<td>Completes</td>
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<tr>
<td>emissions</td>
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<tr>
<td>IEC61000-3:3</td>
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### Guidance and manufacturer's declaration – electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC61000-4-2</td>
<td>± 6 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient /</td>
<td>± 2 kV for power</td>
<td>± 2 kV for power</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>burst</td>
<td>supply lines</td>
<td>supply lines</td>
<td></td>
</tr>
<tr>
<td>IEC61000-4-4</td>
<td>± 1 kV for input /</td>
<td>input / output</td>
<td></td>
</tr>
<tr>
<td></td>
<td>lines</td>
<td>lines are not</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>applicaple</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV line(s) to</td>
<td>± 1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-5</td>
<td>line(s)</td>
<td>± 2 kV common mode</td>
<td></td>
</tr>
<tr>
<td></td>
<td>± 2 kV line(s) to</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>earth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dip, short interruptions and voltage variations on power supply input lines</td>
<td>≤ 5% U&lt;sub&gt;i&lt;/sub&gt; (&lt;95 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 0.5 cycle</td>
<td>≤ 5% U&lt;sub&gt;i&lt;/sub&gt; (&lt;95 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-11</td>
<td>40% U&lt;sub&gt;i&lt;/sub&gt;</td>
<td>40% U&lt;sub&gt;i&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(50 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 5 cycles</td>
<td>(60 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% U&lt;sub&gt;i&lt;/sub&gt;</td>
<td>70% U&lt;sub&gt;i&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(30 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 25 cycles</td>
<td>(30 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤ 5% U&lt;sub&gt;i&lt;/sub&gt;</td>
<td>≤ 5% U&lt;sub&gt;i&lt;/sub&gt;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(&lt;95 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 5 s</td>
<td>(&lt;95 % dip in U&lt;sub&gt;i&lt;/sub&gt;) for 5 s</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50Hz)</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>If incorrect operation occurs, it may be necessary to position the MLE3 further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.</td>
</tr>
<tr>
<td>Magnetic field</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*NOTE U<sub>i</sub> is the a.c. mains voltage prior to application of the test level.
### Guidance and manufacturer’s declaration – electromagnetic immunity

The MLE3 is intended for use in the electromagnetic environment specified below. The customer or the user of the MLE3 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the MLE3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance ($d$) $d = 1.2\sqrt{P}$</td>
</tr>
<tr>
<td>Radiated RF IEC61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$</td>
</tr>
</tbody>
</table>

Where $P$ is the maximum output power rating of the transmitter in watts ($W$) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres ($m$).

Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

![Interference symbol](image)

**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 and people.

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* Field 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 MLE3 is used exceeds the applicable RF compliance level above, the MLE3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the MLE3.

* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
### Testing Notes (EN60601 1-1-1:2007)

#### Recommended separation distances between portable and mobile RF communications equipment and the MLE3

The MLE3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MLE3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MLE3 as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 KHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>1.2</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in metres (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 800 MHz, the separation distance for 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 and people.

### Manufacturer Contact Details

<table>
<thead>
<tr>
<th>Company Information</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>If further information is required on Stanmore Implants’ devices or instrumentation please contact the Design Services Office:</td>
</tr>
<tr>
<td>Stanmore Implants</td>
<td>Tel: +44 (0) 20 8238 6500</td>
</tr>
<tr>
<td>Worldwide Ltd</td>
<td>Fax: +44 (0) 20 8953 0617</td>
</tr>
<tr>
<td>210 Centennial Avenue</td>
<td>E-mail: <a href="mailto:design.services@stanmoreimplants.com">design.services@stanmoreimplants.com</a></td>
</tr>
<tr>
<td>Centennial Park</td>
<td></td>
</tr>
<tr>
<td>Elstree</td>
<td></td>
</tr>
<tr>
<td>Hertfordshire</td>
<td></td>
</tr>
<tr>
<td>WD6 3SJ</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
</tr>
</tbody>
</table>