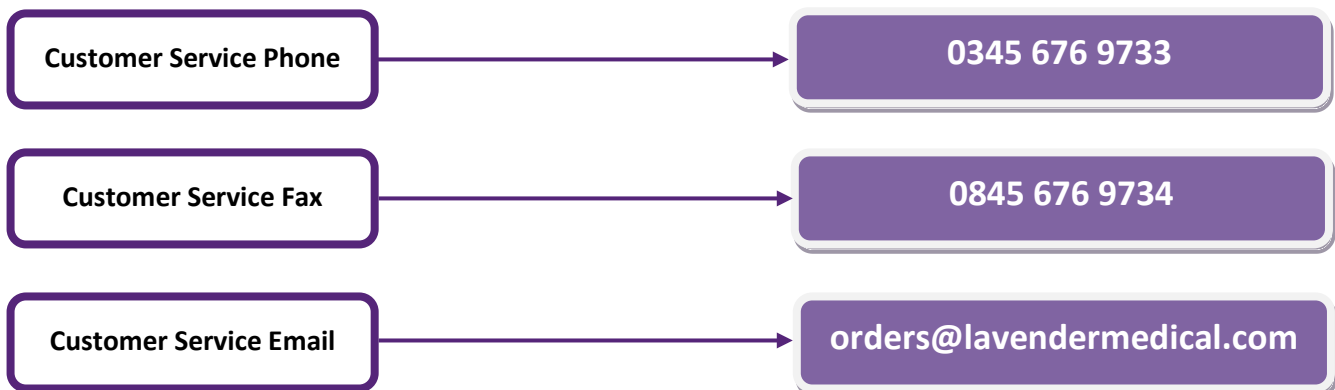




## Ordering Information

Orders can be placed using by one of the following methods or through your local Territory Managers

### Customer Services:



Hospital Name  
Hospital Address

PO: #

Dear Theatre Manager,

We have delivered to you the following sets on loan, please confirm by signature below that the following items have been delivered to you, and are complete (as per the enclosed Delivery Note). Please note if this Loan Set has been delivered by our courier, we would assume that you have agreed to all our T&C's if we have not heard from you within 1 working day of receiving the Loan Set.

**Loan Sets :**

- Set 1
- Set 2
- etc

You will find enclosed the following documents:

- ◆ Certificate of First Use by Lavender Medical Limited or the Decontamination Certificate
- ◆ Delivery Notes (On packaging of sets)
- ◆ Terms and Conditions of Hire Sets or Consignment Set
- ◆ Disclaimer for Surgeons
- ◆ Cleaning and Sterilisation Information for the Sets

You will need to return to us the following:

- ◆ Decontamination Certificate for Each Set
- ◆ Completed Product Usage Form
- ◆ Signed Delivery Note

Every precaution has been taken to deliver the set complete with any missing items clearly documented. However, it is your responsibility to make sure the set matches the Bill of Materials provided and to inform Lavender Medical within 24 hours of delivery on any missing items, if no response is provided it will be taken that the set is complete as per the Bill of Materials. Please see General Terms and conditions. Please note if this Loan Set has been delivered by our courier, we would assume that you have agreed to all our T&C's if we have not heard from you within 1 working day of receiving the Loan Set.

Kind Regards,

Lavender Medical Team

**Confirmation of Delivery:**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Position: \_\_\_\_\_

Date: \_\_\_\_\_

*(please sign and return)*

## Dear Customer,

Thank you for using the Lavender Medical Set Service. Please find enclosed the loan or consignment set you have ordered. The set has been fully inspected before dispatch and is sealed complete. If you have any questions or enquiries regarding the set(s) you have received please contact us on **0345 676 9733** or [info@lavendermedical.com](mailto:info@lavendermedical.com).

### Our Responsibility to You:

- The set is fully checked for functionality;
- The set is supplied complete as per packing list;
- The Set is supplied to you with new or, if used, with a decontamination certificate from the previous hospital;
- The set is supplied with any necessary documentation; and
- The set is supplied with product specification and operating techniques when available.

### Your Responsibility to Us:

- All sets must be cleaned and decontaminated following every procedure;
- All sets must be sterilised and returned with a decontamination certificate at the end of the agreement. We reserve the right to charge an additional £600 administration fee for any set returned not ;
- All sets must be returned with a completed Product Usage Form;
- All set replenishments can be organised through your Lavender Medical account manager, at [orders@lavendermedical.com](mailto:orders@lavendermedical.com) or by calling 0345 676 9733;
- All implants removed from set boxes must be returned in the same box they arrived in;
- We are required by European procedures to have complete batch code traceability on all our products. All products are checked by batch codes before dispatch and on return. Any products found to differ from the original batch codes will be charged to the customer.

**For further information please refer to our terms and conditions in this pack.**

**Thank you for using Lavender Medical Sets**

**Yours faithfully,**

**Lavender Medical Team**

# Overview of Terms and Conditions for Lavender Medical Loan Sets

**This is in addition to Lavender Medical's general terms and conditions and is for your reference only. All T&C apply unless agreed otherwise.**

- Loan sets are charged on a sale or return basis. Any items missing on return will be invoiced. This includes both instrumentation and consumables.
- All loan sets are liable to a hire charge in line with our current price list, available on request. All items used are charged at full list price.
- Our sets should not be defaced in any manner including adding stickers/ writing to non-removal ink. Should an item be defaced the Customer will be responsible for the cost of repair/ replacement
- Loan sets are chargeable per procedure. If a set is booked for more than one operation date all subsequent replenishments will carry an additional charge.
- If there is more than 7 days between procedures a second full loan charge will apply.
- Extension to agreed loan periods can be charged for as additional day's loan
- Collection will be the next working day after the operation date.
- Following the operation it is the customer's responsibility to clean and decontaminate all instrumentation, all Loan sets returned must be sterilised and returned with a completed decontamination certificate.
- Failure to provide a valid decontamination certificate will result in a £600 processing charge as we will consider these instrument sets to be contaminated.
- To avoid invoicing discrepancies, the Product Usage Form supplied must be completed and returned with a completed decontamination certificate.
- The Medical Devices Directive requires complete batch traceability for all our products and we have procedures in place to ensure compliance. To maintain batch code traceability all implants removed from cases must be returned into the same case they arrived in.
- Any implants returned with batch codes differing to those issues will be charged at list price.
- As a Loan Service we take all reasonable measures to ensure all sets are supplied complete. However, on occasions where there are any items known to be missing, this will be highlighted on the checklist.
- Any items not reported as missing upon receipt of the set and prior to return and/or not returned to Lavender Medical Limited will be invoiced.

## Loan Set Charges

Loan set charges are for the standard hire period of 3 days. Each additional day of hire will be charged at £150 per day. Loan charges are at the absolute discretion of the company.

### Product Group

### Charge

All Orthopedic Sets unless otherwise agreed	£600
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- If there is another procedures on another day a second full loan charge will apply.
- Extension to agreed loan periods can be charged for as additional day's loan
- Failure to provide a valid decontamination certificate will result in a £600 processing charge as we will consider these instrument sets to be contaminated.

NB All prices are exclusive of VAT

## Terms and Conditions for the Loan Sets – Lavender Medical Limited

### October 2021 EDITION

#### 1. INTERPRETATION

1.1 The following definitions and rules of interpretation apply in these conditions.

**Charges: the charges payable by the Customer for the hire of the Loaned Goods.**

**Company:** Lavender Medical Limited (CRN: 6828106).

**Contract:** any contract between the Company and the Customer for the sale and purchase of the Loaned Goods, incorporating these conditions, and any supplemental conditions relevant to the arrangements between the Company and the Customer.

**Customer:** the person, firm or company who purchases the Loaned Goods from the Company.

**Decontamination Certificate:** the certificate confirming the Loaned Goods have been decontaminated and are sterile.

**Delivery Point:** the place where delivery of the Loaned Goods is to take place under condition 5.

**Guidelines on Cleaning and Sterilisation:** the guidance provided by the Company relating to the cleaning, sterilisation and decontamination of the Loaned Goods.

**Implants:** the orthopaedic implants for osteosynthesis applications which may be made available by the Company to the Customer.

**Instruments:** the instruments for osteosynthesis applications which may be made available by the Company to the Customer.

**Loaned Goods:** any Loaned Goods agreed in the Contract to be hired to the Customer by the Company (including any part or parts of them), as detailed in the Schedule and bill of materials and including without limitation the Instruments and/or the Implants.

**Loan Period:** the period commencing when the Customer takes possession of the Loaned Goods on hire (including Saturdays Sundays and Bank Holidays) and ending upon the happening of any of the following events: (i) the physical return of the Loaned Goods by the Customer into the Company's possession; or (ii) the physical repossession or collection of Loaned Goods by the Company;

**Liability:** liability for any and all damages, claims, proceedings, actions, awards, expenses, costs and any other losses and/or liabilities;

**Price List:** the price list of the Company which will be updated annually in line with the prices charged by suppliers for the Loaned Goods and which will be made available to Customers annually when updated.

**Procedure:** an operation or other medical procedure for which the Loaned Goods are intended to be used.

**Product Usage Form:** the product usage form to be completed by the Customer.

**Quotation:** the quotation provided by the Company to the Customer for the supply of the Loaned Goods, which may be a specific quotation for a specific order, or any other arrangement or agreement between the Company and the Customer.

- 1.2 A reference to a law is a reference to it as it is in force for the time being taking account of any amendment, extension, application or re-enactment and includes any subordinate legislation for the time being in force made under it.
- 1.3 Condition headings do not affect the interpretation of these conditions.

## **2. APPLICATION OF TERMS**

- 2.1 Subject to any variation under condition 2.3 the Contract shall be on these conditions to the exclusion of all other terms and conditions (including any terms or conditions which the Customer purports to apply under any purchase order, confirmation of order, specification or other document).
- 2.2 No terms or conditions endorsed on, delivered with or contained in the Customer's purchase order, confirmation of order, specification or other document shall form part of the Contract simply as a result of such document being referred to in the Contract.
- 2.3 These conditions apply to all Loaned Goods hired by the Company and any variation to these conditions and any representations about the Loaned Goods shall have no effect unless expressly agreed in writing and signed by a director of the Company. The Customer acknowledges that it has not relied on any statement, promise or representation made or given by or on behalf of the Company which is not set out in the Contract. Nothing in this condition shall exclude or limit the Company's Liability for fraudulent misrepresentation.

## **3. ORDERS AND ACCEPTANCE**

- 3.1 Each order or acceptance of a Quotation for Loaned Goods by the Customer from the Company shall be deemed to be an offer by the Customer to hire the Loaned Goods subject to these conditions.
- 3.2 No order placed by the Customer shall be deemed to be accepted by the Company until a written acknowledgement of order is issued by the Company or (if earlier) the Company delivers the Loaned Goods to the Customer.
- 3.3 The Customer shall ensure that the terms of its order are complete and accurate.
- 3.4 Any Quotation is given on the basis that no Contract shall come into existence until the Company despatches an acknowledgement of order to the Customer. Any Quotation is valid for a period of 30 days only from its date, provided that the Company has not previously withdrawn it.
- 3.5 If the Customer wishes the Company to consider exercising its discretion to hire the Loaned Goods in an emergency on humanitarian grounds and before a purchase order can be formally presented to the Company with a purchase order number, the Customer shall notify the Company of this and provide reasonable details in relation to the request which shall be promptly submitted to the Company. If the Company agrees to supply the Loaned Goods the on the basis of the request, then:-
- 3.5.1 the Customer undertakes to provide an official purchase order and purchase order number within 48 hours of the submission of the request;
  - 3.5.2 the Loaned Goods delivered will be delivered subject to these terms and conditions and on no other basis; and
  - 3.5.3 payment of the Charges will fall due in accordance with these terms whether or not the Customer provides an official purchase order.

- 3.6 In placing an order, accepting a Quotation, or making an emergency request, the Customer warrants that the Loaned Goods shall be used:-
- 3.6.1 for their intended purpose, reasonably and not improperly;
  - 3.6.2 in accordance with all national and international laws or relevant codes of practice or codes of conduct applicable to the Loaned Goods; and
  - 3.6.3 in accordance with the instructions for use provided by the manufacturer of the Loaned Goods or, if there are no such instructions for use, in accordance with any instructions for use issued by the Company.
- 3.7 The Loaned Goods are supplied with a surgeons notice ("the Surgeon's Notice"). The Customer undertakes to bring the Surgeon's Notice to the attention of any surgeon who will use the Loaned Goods.

#### **4. DESCRIPTION**

- 4.1 The quantity and description of the Loaned Goods shall be as set out in the Company's Quotation or acknowledgement of order.
- 4.2 All samples, descriptive matter, specifications and advertising issued by the Company and any descriptions or illustrations contained in the Company's catalogues or brochures are issued or published for the sole purpose of giving an approximate idea of the Loaned Goods described in them.

#### **5. DELIVERY**

- 5.1 The Company will arrange for delivery of the Loaned Goods to, and shall arrange for collection of the Loaned Goods from, the Customer or as otherwise agreed with the Customer in writing. The Loaned Goods will be delivered on the day before the Procedure and will be collected on the day following the Procedure, at such times as are agreed with the Customer. The Customer may request and the Company may agree to deliver the Loaned Goods and collect the Loaned Goods longer before or after the Procedure, but the Company reserves the right to charge the Customer an additional Charge in respect of the extended period during which the Loaned Goods are in the Customer's possession. If the Loaned Goods are not ready for collection at the agreed time then the Company reserves the right to Charge the Customer for an additional day's hire in accordance with condition 7.3.
- 5.2 The Charges are exclusive of delivery and collection fees unless the Loaned Goods.
- 5.3 If the Company's performance of its obligations under the Contract is prevented or delayed by any act or omission of the Customer, its agents, subcontractors, consultants or employees, the Company shall not be liable for any costs, charges or losses sustained or incurred by the Customer arising directly or indirectly from such prevention or delay.
- 5.4 The Customer will inspect the Loaned Goods on delivery and notify the Company as soon as reasonably possible of any missing items. If missing items are not notified promptly to the Company, and in any event within 24 hours of delivery the Loaned Goods will be deemed to have been properly delivered and the Customer will be liable for any Loaned Goods not returned to the Company.
- 5.5 Any Liability of the Company for non-delivery of the Loaned Goods shall be limited to replacing the Loaned Goods within a reasonable time or issuing a credit note at the pro rata Contract rate against any invoice raised for such Loaned Goods.



- 5.6 Subject to the other provisions of these conditions the Company shall not be liable for any indirect or consequential loss (which includes, without limitation, pure economic loss, loss of profits, loss of business, depletion of goodwill and similar loss), costs, damages, charges or expenses caused directly or indirectly by any delay in the delivery of the Loaned Goods.
- 5.7 The Customer shall provide at the Delivery Point and at its expense adequate and appropriate equipment and manual labour for unloading the Loaned Goods.

## **6. RISK AND TITLE**

- 6.1 The Loaned Goods are at the risk of the Customer from the time of delivery.
- 6.2 Risk in the Loaned Goods will not pass back to the Company from the Customer until the Loaned Goods are back in the physical possession of the Company which for the purposes of these Conditions shall be when the Company collects the Loaned Goods from the Customer. This shall apply even if the Company has agreed to cease charging for the Loaned Goods.
- 6.3 Ownership of the Loaned Goods remains at all times with the Company. The Customer has no right, title or interest in the Loaned Goods except that they are hired to the Customer.
- 6.4 The Customer must not deal with the ownership or any interest in the Loaned Goods. This includes but is not limited to selling, assigning, mortgaging, pledging, charging, securing, hiring, withholding, exerting any right to withhold, disposing of and/or lending.
- 6.5 The Customer shall insure the Loaned Goods on such reasonable terms and for such reasonable risks as the Company may specify including but not limited to theft, fire, flood, explosion, vandalism or malicious damage and other usual risks covered by the medical profession. The proceeds of any such insurance shall be held by the Customer in trust for the Company and be paid to the Company on demand. The Customer must not compromise any claim in respect of the Loaned Goods and/or any associated insurance without the Company's written consent.
- 6.6 The Customer's right to possession of the Loaned Goods shall terminate immediately if:-
- 6.6.1 the Customer has a bankruptcy order made against him or makes an arrangement or composition with his creditors, or otherwise takes the benefit of any statutory provision for the time being in force for the relief of insolvent debtors, or (being a body corporate) convenes a meeting of creditors (whether formal or informal), or enters into liquidation (whether voluntary or compulsory) except a solvent voluntary liquidation for the purpose only of reconstruction or amalgamation, or has a receiver and/or manager, administrator or administrative receiver appointed of its undertaking or any part thereof, or documents are filed with the court for the appointment of an administrator of the Customer or notice of intention to appoint an administrator is given by the Customer or its directors or by a qualifying floating charge holder (as defined in paragraph 14 of Schedule B1 to the Insolvency Act 1986), or a resolution is passed or a petition presented to any court for the winding-up of the Customer or for the granting of an administration order in respect of the Customer, or any proceedings are commenced relating to the insolvency or possible insolvency of the Customer; or

6.6.2 the Customer suffers or allows any execution, whether legal or equitable, to be levied on its property or obtained against it, or fails to observe or perform any of its obligations under the Contract or any other contract between the Company and the Customer, or is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 or the Customer ceases to trade; or

6.6.3 the Customer encumbers or in any way charges any of the Loaned Goods.

6.7 The Customer grants the Company, its agents and employees an irrevocable licence at any time to enter any premises where the Loaned Goods are or may be stored in order to inspect them, or, where the Customer's right to possession has terminated, to recover them.

6.8 On termination of the Contract, howsoever caused, the Company's (but not the Customer's) rights contained in this condition 6 shall remain in effect.

## 7. PRICE

7.1 Unless otherwise agreed by the Company in writing, the Charges for the Loaned Goods shall be the Charges set out in the Quotation or acknowledgement of order which shall be based on the Charges specified in the Price List. A copy of the Price List has been made available to the Customer and further copies can be made available on request. The Company may require an initial payment on account in advance of the Customer hiring the Loaned Goods.

7.2 The Charges for the Loaned Goods are quoted to the Customer per Procedure. If Loaned Goods are required for more than one Procedure, any subsequent additions or replenishments to the Loaned Goods will carry an additional Charge as detailed in the Price List and as notified by the Company to the Customer in writing.

7.3 All Loaned Goods will be collected on the working day following the Procedure, or otherwise in accordance with the arrangements agreed with the Customer. If Loaned Goods are not ready for collection by the Company at the required time, the Company will charge the Customer an additional Charge for each day the Loaned Goods remain unavailable for collection. The additional Charge will be based on the daily charge rate of the Company in force at that time. as detailed in the Price List.

7.4 The Company may agree to extend the Loan Period. The Customer will be charged an additional Charge for every day the Loan Period is extended. Such daily Charge will be notified to the Customer by the Company and will be based on the daily charge rate of the Company in force at that time.

7.5 The parties agree that the Company may review and increase its Charges for reasons including but not limited to, increases in the minimum wage, additional employment liabilities or other liabilities imposed on the Company by legislation.

7.6 The Loaned Goods are made available to the Customer on a sale or return basis. If the Customer fails to return the Loaned Goods (or any part thereof) or the Loaned Goods are returned in such a condition which means they cannot, in the reasonable opinion of the Company, be loaned to other customers in the future, the Company shall invoice the Customer for the full replacement value of the Loaned Goods (or relevant part thereof).

7.7 The Charges shall include the costs of standard delivery but shall be exclusive of any value added tax and the costs of delivering the Loaned Goods by any other means than standard delivery all of which amounts the Customer shall pay in addition when it is due to pay for the Loaned Goods, unless these are specifically included in the Quotation. Standard

delivery for these purposes means delivering the Loaned Goods on the date requested by the Customer provided the Company is notified before 3.00pm GMT on the day prior to the date delivery is required and delivery will take place at any time during normal working hours (9.00am-5.00pm).

## **8. PAYMENT**

- 8.1 Subject to condition 8.4, payment of the Charges is due in pounds sterling within 30 days of the date of the Company's invoice to the Customer for the Loaned Goods.
- 8.2 Time for payment shall be of the essence.
- 8.3 No payment shall be deemed to have been received until the Company has received payment in full in cleared funds.
- 8.4 All payments payable to the Company under the Contract shall become due immediately on its termination despite any other provision.
- 8.5 The Customer shall make all payments due under the Contract in full without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise.
- 8.6 If the Customer fails to pay the Company any sum due pursuant to the Contract, the Customer shall be liable to pay interest to the Company on such sum from the due date for payment at the annual rate of 4 % above the base lending rate from time to time of the Bank of England, accruing on a daily basis until payment is made, whether before or after any judgment.
- 8.7 For the avoidance of doubt all Charges will remain due and payable irrespective of whether a Procedure is cancelled or the Loaned Goods are not used by the Customer.

## **9. CARE OF LOANED GOODS**

- 9.1 The Customer shall:-
- 9.1.1 not interfere with the Loaned Goods, their working mechanisms or any other parts of them and shall take reasonable care of the Loaned Goods and only use them for their proper purpose in a safe and correct manner in accordance with any operating and/or safety instructions provided or supplied to the Customer.
  - 9.1.2 notify the Company immediately after any fault breakage, loss and/or damage to the Loaned Goods;
  - 9.1.3 take adequate and proper measures to protect the Loaned Goods from theft, vandalism, misuse, damage and/or other risks;
  - 9.1.4 notify the Company of any change of its address and upon the Company's request provide details of the location of the Loaned Goods;
  - 9.1.5 permit the Company at all reasonable times and upon reasonable notice to inspect the Loaned Goods including allowing access to any property where the Loaned Goods are situated;
  - 9.1.6 keep the Loaned Goods at all times in its possession and control and not part with control of the Loaned Goods and not remove the Loaned Goods from the country where the Customer is located and/or the country where the Company is located without the prior written consent of the Company; and
  - 9.1.7 not continue to use Loaned Goods where they have been damaged and will notify the Company immediately if the Loaned Goods are involved in an accident resulting in damage to the Loaned Goods, other property and/or injury to any person.

- 9.2 Prior to the collection of the Loaned Goods by the Company the Customer shall ensure the Loaned Goods are cleaned, sterilised and decontaminated in accordance with the Guidelines for Cleaning and Sterilisation. Following completion of the necessary cleaning, sterilisation and decontamination procedures, the Customer will complete and provide to the Company, when the Loaned Goods are collected, a valid Decontamination Certificate. The Decontamination Certificate will confirm that the Customer has fully and properly cleaned, sterilised and decontaminated the Loaned Goods in accordance with the Guidelines for Cleaning and Sterilisation. The Customer acknowledges that the Loaned Goods will be made available to other Customers in the future and in doing so the Company will rely on the valid Decontamination Certificate as proper evidence that the Loaned Goods have been fully and properly cleaned, sterilised and decontaminated. The Customer agrees to indemnify the Company against any claims, losses, demands, actions, proceedings and costs (including legal fees) it incurs as a result of the Customer failing to carry out its responsibilities properly in respect of cleaning, sterilising and decontaminating the Loaned Goods.
- 9.3 If the Customer fails to provide a valid Decontamination Certificate, then the Company will Charge the Customer an additional fee of £600.00 plus VAT in respect of the decontamination, sterilisation and cleaning procedure the Company will be required to undertake in respect of the Loaned Goods.
- 9.4 The Product Usage Form will be completed by the Customer and be given to the Company (or its representatives) when the Loaned Goods are collected.
- 9.5 The Medical Devices Directive 93/42/EEC requires that complete batch code traceability is maintained for all Loaned Goods. The Customer acknowledges and agrees that in order to maintain batch code traceability all Loaned Goods removed from cases must be returned and made available for collection in the same cases in which they were delivered. Any Loaned Goods returned with batch codes differing to those issued or not returned in the same case in which they were delivered, will be charged for and the Customer will be invoiced for such items at the list price of those items in place at that time.
- 9.6 The Customer will pay to the Company the full replacement cost (at the list price of those items in place at that time) of any Loaned Goods which are lost or stolen or damaged beyond economic repair.
- 9.7 It is the Customer's responsibility to make sure that the Customer and all other parties who use the Loaned Goods during the term of the Contract are properly instructed in their safe and correct use.

## 10. BREAKAGE

- 10.1 The Customer shall be responsible for all expenses, loss and/or damage suffered by the Company arising from any breakage of the Loaned Goods due to the Customer's negligence, misdirection and/or misuse of the Loaned Goods.
- 10.2 Subject to condition 10.1 the Company will at its own cost carry out all routine maintenance and repairs to the Loaned Goods. Maintenance and repairs will be undertaken when the Loaned Goods are in the possession of the Company.
- 10.3 The Customer must not repair or attempt to repair the Loaned Goods unless authorised to do so in these Conditions or in writing by the Company.

## **11. LOSS OR DAMAGE TO THE LOANED GOODS**

- 11.1 The Customer will pay to the Company the full replacement cost of any Loaned Goods which are lost, stolen and/or damaged beyond economic repair during the Loan Period (this includes non-removable marker pens or stickers) The replacement value will be replacement value of the Loaned Goods at the date the Company is notified of the loss, theft or damage.
- 11.2 The Customer shall pay the rental charges for the Loaned Goods up to and including the date it notifies the Company that the Loaned Goods have been lost, stolen and/or damaged beyond economic repair. Thereafter the Company shall be entitled to invoice the Customer for the full replacement value of the lost, stolen and/or damaged Loaned Goods, in accordance with condition 11.1.

## **12. THE COMPANY'S RESPONSIBILITIES**

- 12.1 Prior to the Loan Period the Company will fully inspect the Loaned Goods to ensure the Loaned Goods are functional and fit for purpose.
- 12.2 The Loaned Goods supplied will be detailed in the delivery note and bill of materials provided with the Loaned Goods upon delivery of the Loaned Goods.
- 12.3 The Loaned Goods will be supplied to the Customer with a valid Decontamination Certificate to verify that the Loaned Goods have been fully and properly cleaned, sterilised and decontaminated.
- 12.4 Loaned Goods can be supplied will information and documentation required for proper use of the Loaned Goods. This will include product specifications and operating techniques when available. If required, the Company will provide technical representation (i.e. an officer of the Company will be made available to provide technical representation) provided the Customer notifies the Company in advance of the Procedure and in any event no less than 24 hours before the Procedure is scheduled to take place that technical representation or other technical information is required.
- 12.5 The Company will use all reasonable endeavours to ensure that Loaned Goods which are part of a set, and provided as a complete set. If any items are known to be missing this will be highlighted to the Customer in bill of materials.

## **13. TERMINATION**

- 13.1 The Loaned Goods shall be loaned for a minimum of one Procedure. The parties shall agree between them the period of hire and neither the Customer nor the Company shall be entitled to terminate the Contract before the expiry of that period unless agreed with the other party.
- 13.2 After the period specified in condition 13.1, the Contract shall automatically terminate unless the parties agree to extend the Loan Period in writing.

## **14. DEFAULT**

- 14.1 If the Customer:-
- 14.1.1 fails to make any payment to the Company when due without just cause;
  - 14.1.2 breaches the terms of the Contract and, where the breach is capable of remedy, has not remedied the breach within 7 days of receiving notice requiring the breach to be remedied;

- 14.1.3 persistently breaches the terms of the Contract;
- 14.1.4 provides incomplete, materially inaccurate or misleading facts and/or information in connection with the Contract;
- 14.1.5 pledges, charges or creates any form of security over any Loaned Goods;
- 14.1.6 ceases to trade;
- 14.1.7 is unable to pay its debts within the meaning of s123 of the Insolvency Act 1986, proposes to compound or makes an arrangement with or convenes a meeting of, its creditors or applies for an interim moratorium in respect of claims and/or proceedings, ceases or threatens to cease to carry on business, enters into voluntary or compulsory liquidation, has a resolution passed or a petition presented for its winding up, has a receiver, administrator or administrative receiver appointed or proposed to be appointed over all or any of its assets, any attachment order/arrestment is made against the Customer, any distress/diligence, execution or other legal process is levied on any property of the Customer or the Customer takes or suffers any similar action in any jurisdiction;
- 14.1.8 appears reasonably to the Company to be about to suffer any of the above events;
- 14.1.9 then the Customer's right to the hire of the Loaned Goods shall terminate immediately and the Company shall have the right, without prejudice to any other remedies, to exercise any or all of the rights set out in the condition below.

14.2 If any of the events set out in condition 14.1 above occurs in relation to the Customer then:-

- 14.2.1 the Company may enter, without prior notice, any premises of the Customer (or premises of third parties with their consent) where any Loaned Goods may be and repossess any Loaned Goods;
- 14.2.2 the Company may immediately cancel, terminate and/or suspend without Liability to the Customer the Contract and/or any other contract with the Customer; and/or
- 14.2.3 all monies owed by the Customer to the Company shall immediately become due and payable.

14.3 Any repossession of the Loaned Goods shall not affect the Company's right to recover from the Customer any monies due under the Contract and/or any damages in respect of any breach which occurred prior to repossession of the Loaned Goods.

14.4 Upon termination of the Contract the Customer shall immediately:

- 14.4.1 Arrange for the cleaning, sterilisation and decontamination of the Loaned Goods in accordance with the Guidelines on Cleaning and Sterilisation and make the Loaned Goods available for collection by the Company together with a valid Decontamination Certificate; and
- 14.4.2 pay to the Company all arrears in respect of the Loaned Goods and any other sums payable under the Contract.

## 15. **LIMITATION OF LIABILITY**

15.1 The following provisions set out the entire financial Liability of the Company (including any liability for the acts or omissions of its employees, agents and sub-contractors) to the Customer in respect of:-

- 15.1.1 any breach of these conditions; and
- 15.1.2 any representation, statement or tortious act or omission including negligence arising under or in connection with the Contract.
- 15.2 All warranties, conditions and other terms implied by statute or common law are, to the fullest extent permitted by law, excluded from the Contract.
- 15.3 Any defective Loaned Goods must be returned to the Company for inspection if requested by the Company before the Company will have any Liability for defective Loaned Goods.
- 15.4 The Company shall have no Liability to the Customer if, without just cause, any monies due in respect of the Loaned Goods have not been paid in full by the due date for payment.
- 15.5 The Company shall have no Liability for additional damage, loss, liability, claims, costs or expenses caused or contributed to by the Customer's continued use of defective Loaned Goods after a defect has become apparent or suspected or should reasonably have become apparent to the Customer.
- 15.6 The Customer shall give the Company a reasonable opportunity to remedy any matter for which the Company is liable before the Customer incurs any costs and/or expenses in remedying the matter itself. If the Customer does not do so the Company shall have no Liability to the Customer.
- 15.7 The Company shall have no Liability to the Customer to the extent that the Customer is covered by any policy of insurance arranged as a result of the Contract and the Customer shall ensure that the Customer's insurers waive any and all rights of subrogation they may have against the Company.
- 15.8 Nothing in these conditions excludes or limits the Liability of the Company:-
- 15.8.1 for death or personal injury caused by the Company's negligence; or
  - 15.8.2 for any matter which it would be illegal for the Company to exclude or attempt to exclude its Liability; or
  - 15.8.3 for fraud or fraudulent misrepresentation.
- 15.9 Subject to condition 15.8:-
- 15.9.1 the Company's total Liability in contract, tort (including negligence or breach of statutory duty), misrepresentation, restitution or otherwise, arising in connection with the performance or contemplated performance of the Contract shall be limited to the Contract Charges; and
  - 15.9.2 the Company shall not be liable to the Customer for loss of profit, loss of business, or depletion of goodwill in each case whether direct, indirect or consequential, or any claims for consequential compensation whatsoever (howsoever caused) which arise out of or in connection with the Contract.

## 16. ASSIGNMENT

- 16.1 The Company may assign the Contract or any part of it to any person, firm or company.
- 16.2 The Customer shall not be entitled to assign the Contract or any part of it without the prior written consent of the Company.



## 17. **FORCE MAJEURE**

The Company reserves the right to defer the date of delivery or to cancel the Contract or reduce the volume of the Loaned Goods ordered by the Customer (without liability to the Customer) if it is prevented from or delayed in the carrying on of its business due to circumstances beyond the reasonable control of the Company including, without limitation, acts of God, governmental actions, war or national emergency, acts of terrorism, protests, riot, civil commotion, fire, explosion, flood, epidemic, lock-outs, strikes or other labour disputes (whether or not relating to either party's workforce), or restraints or delays affecting carriers or inability or delay in obtaining supplies of adequate or suitable materials, provided that, if the event in question continues for a continuous period in excess of 120 days, the Customer shall be entitled to give notice in writing to the Company to terminate the Contract.

## 18. **GENERAL**

- 18.1 Each hire of an item of Loaned Goods shall form a distinct Contract which shall be separate to any other Contract relating to other Loaned Goods.
- 18.2 The Customer shall be liable for the acts and/or omissions of its employees, agents, servants and/or subcontractors as though they were its own acts and/or omissions under this Contract.
- 18.3 The Customer agrees to indemnify and keep indemnified the Company against any and all losses, lost profits, damages, claims, costs (including legal costs on a full indemnity basis), actions and any other losses and/or liabilities suffered by the Company and arising from or due to any breach of contract, any tortious act and/or omission and/or any breach of statutory duty by the Customer.
- 18.4 Each right or remedy of the Company under the Contract is without prejudice to any other right or remedy of the Company whether under the Contract or not.
- 18.5 If any provision of the Contract is found by any court, tribunal or administrative body of competent jurisdiction to be wholly or partly illegal, invalid, void, voidable, unenforceable or unreasonable it shall to the extent of such illegality, invalidity, voidness, voidability, unenforceability or unreasonableness be deemed severable and the remaining provisions of the Contract and the remainder of such provision shall continue in full force and effect.
- 18.6 Failure or delay by the Company in enforcing or partially enforcing any provision of the Contract shall not be construed as a waiver of any of its rights under the Contract.
- 18.7 Any waiver by the Company of any breach of, or any default under, any provision of the Contract by the Customer shall not be deemed a waiver of any subsequent breach or default and shall in no way affect the other terms of the Contract.
- 18.8 The parties to the Contract do not intend that any term of the Contract shall be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person that is not a party to it.
- 18.9 These conditions and the Contract constitute the whole agreement between the parties and supersedes all previous agreements between the parties relating to its subject matter.
- 18.10 This Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with English law, and the parties submit to the exclusive jurisdiction of the English courts.



**19. COMMUNICATIONS**

19.1 All communications between the parties about the Contract shall be in writing and delivered by hand or sent by pre-paid first class post, or sent electronically:

19.1.1(in case of communications to the Company):

19.1.1.1 to its registered office or such changed address as shall be notified to the Customer by the Company;  
or

19.1.1.2 to its email address provided on the Quotation or such changed email address as shall be notified to the Customer by the Company; and

19.1.2(in the case of the communications to the Customer) to the registered office of the addressee (if it is a company) or (in any other case) to any address (including any email address) of the Customer set out in any document which forms part of the Contract or such other address as shall be notified to the Company by the Customer.

19.2 Communications shall be deemed to have been received if sent by pre-paid first class post, two days (excluding Saturdays, Sundays and bank and public holidays) after posting (exclusive of the day of posting) or if delivered by hand or electronically, on the day of delivery.

**LAVENDER MEDICAL LIMITED METALLIC INTERNAL FIXATION DEVICES**  
**ATTENTION OPERATING SURGEON**

**DESCRIPTION**

Lavender Medical distributes a variety of internal fixation devices intended to aid in the alignment and stabilisation of fractures to the skeletal system. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal, healthy bone or to withstand stress placed upon the device by full or partial weight bearing, particularly in the presence of non-union, delayed union or incomplete healing. The use of external support (e.g., walking aids, braces) is recommended as a part of the treatment. The surgeon is to be thoroughly familiar with the implant, the method of application, instruments and the surgical procedure. In all cases sound orthopaedic practice is to be followed and the surgeon must select a type of internal fixation device appropriate for the treatment. The patient is to be warned of the risks involved in the use of the device as listed, including the possible adverse effects.

The patient is to be made fully aware and warned that the device does not replace normal, healthy bone, and that the device can break as a result of stress, activity or weight bearing. The patient is to be warned that failure to follow post-operative care instructions can cause failure of the device or the treatment. Senility, mental illness, alcoholism and other conditions may cause the patient to ignore certain necessary limitations and precautions in the use of the internal fixation device, leading to failure or other complications.

**INDICATIONS**

1. Fresh fractures.
2. Osteotomy.
3. Revision procedures where other treatments or devices have failed.
4. Arthrodesis.
5. Joint Replacements

**CONTRAINDICATIONS**

1. Active infection.
2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections.
3. Patients with mental or neurological conditions who are unwilling or incapable of following post-operative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, tests are to be made prior to implantation.

**SUGGESTIONS CONCERNING PARTIAL WEIGHT BEARING AND NON-WEIGHT BEARING ORTHOPAEDIC APPLIANCES AND RECONSTRUCTIVE IMPLANTS (Prepared by the Orthopaedic Surgical Manufacturers Association - USA)**

The use of metallic surgical implants has given the surgeon a means of bone fixation and helps generally in the management of fracture and reconstructive surgery. However, these implants are intended only to assist healing and are not intend to replace normal body structures. Metallic bone fixation devices are internal splints which align the fracture while normal healing occurs.

The size and shape of bones and soft tissue places limitations on the size and strength of implants. If there is delayed union or non-union of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue. Therefore it is important that immobilisation of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. All metallic surgical implants are subject to repeated stresses in use which can result in metal fatigue. Factors such as the patients weight, activity level and adherence to weight bearing, or load bearing instructions have an effect on the load and number of cycles to which the implant is subjected.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but also must be aware of the mechanical and metallurgical aspects of surgical implants. Post-operative care is extremely important. The patient should be warned that non-compliance with post-operative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the device.

The following are specific warnings, precautions and adverse effects which should be understood by the surgeon and explained to the patient. Warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

## **WARNINGS**

1. Correct selection of the implant is extremely important. The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimise risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing.
2. These devices can break when subjected to the increased loading associated with delayed union or non-union. Internal fixation devices are load sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to early breakage.
3. **CORROSION.** Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fracture of implants. Thus, every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws in a bone plate.

## **PRECAUTIONS**

1. **SURGICAL IMPLANTS MUST NEVER BE RE-USED.** An explanted metal implant should never be re-implanted, even though the device may appear undamaged it may have small defects and internal stress patterns which may lead to early breakage.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metallic implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant. Intraoperative fracture of the screws can occur if excessive force (torque) is applied while seating bone screws into position.
3. **REMOVAL AFTER FRACTURE HEALING.** Metallic implants can loosen, fracture, corrode, migrate, cause pain or stress shield bone even after a fracture has healed, particularly in young, active patients. If an implant remains implanted after complete healing it can actually increase the risk of re-fracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate post-operative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
4. **ADEQUATELY INSTRUCT THE PATIENT.** Post-operative care and the patients ability and willingness to follow instructions are one of the most important aspects of successful fracture healing. This is particularly important should the device be used to treat an unstable fracture, such as intertrochanteric or subtrochanteric. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing, or load bearing, have been implicated in premature loosening, migration, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture under normal weight bearing, or load bearing, in the absence of complete bone healing. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk during post-operative rehabilitation. The patient must be warned to inform any other medical practitioner who may treat him in the future of the presence of the implant.

#### **POSSIBLE ADVERSE EFFECTS**

1. Non-union or delayed union which may lead to breakage of the implant.
2. Bending or fracture of the implant. Loosening and/or migration of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Limb shortening due to compression of the fracture or bone resorption.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.

#### **STERILITY**

1. Metallic internal fixation devices which are supplied in the sterile condition are clearly marked "STERILE" on the packaging.
2. Metallic internal fixation devices which are supplied in the non-sterile condition must be sterilized prior to surgical use. These devices may be sterilized by using high temperature steam (autoclaving). The sterilization process must be

properly validated and routinely controlled. The sterility of devices sterilized by this method is the responsibility of the user.

3. Metallic internal fixation devices which were originally supplied in the sterile condition, but whose sterility has been compromised due to the packaging having been inadvertently damaged or opened may be re-sterilized using the method described in (2) above.

## Schedule

### Loaned Goods

- Please see **Page 2** of the document pack for full list of goods.