Stanmore Implants

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*Field Safety Notice PR 1629460*

**21 December 2017**

## Field Safety Notice

**FSCA identifier**: Field Safety Notice – **PR 1629460**

**Type of Action**: Field Safety Corrective Action

**Description:** Instructions for Use related to locking screw mechanism introduced in the Minimally Invasive Grower (MIG) component were not made available

**Product Name** Custom Made Implant Systems with Minimally Invasive Grower (MIG) component

**Lot #:** Custom Implants with MIG component manufactured between March 2007 - October 2014.

Dear Distributor/Healthcare Provider/Surgeon,

On 21 December 2017, Stanmore Implants Worldwide Limited (SIW, the manufacturer) initiated a voluntary Field Safety Corrective Action for the product referenced above. The intent of this letter is to list all known hazards potentially associated with this action and list the risk mitigation factors.

### Issue

In March 2007, the Minimum Invasive Grower (MIG) component with locking mechanism was utilised with custom made long bone replacement implants for limb salvage procedures of skeletally immature or juvenile patients, to prevent unintended changes in the length of the device. However, Instructions for Use (IFU) was not updated to clarify the function of locking mechanism and warnings related to the locking screw until October 2014, resulting in potential lack of awareness of the locking mechanism and its function during that time.

The devices implanted after October 2014 were accompanied with the updated IFU. The additional language included in the IFU can be found highlighted on page 2 of attachment 2, under section "Minimally Invasive Grower – Device Extension".

### Potential Hazards/Harms:

For implant systems with MIG component implanted prior to October 2014, the IFUs did not include information clarifying the function of locking mechanism and warnings related to the locking screw. The following potential hazards are identified resulting from the lack of such information:

- Misinformation-Lack of Instructions for Use
- Unintended change in length of implant

The aforementioned hazards may result in one or more of the following harms:

1. Complications associated with a delay in surgery (less than 15 minutes) in order to inquire or clarify the function of the locking feature
2. Pain due to excessive limb length discrepancy
3. Instability and impaired function due to excessive limb length discrepancy
4. Unplanned extension surgery (Minimally Invasive) to alleviate the hazardous situation
5. Revision surgery to alleviate the hazardous situation to implant an alternate system or additional components such as C collars

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**Risk Mitigation:**

Due to the nature of the custom implants with MIG component, revision procedures (extensions) are expected during the growth phase of the patient to lengthen the prosthesis and adjust for the patient's growth. The procedures are intended to be minimally invasive where a small incision provides access to the growing mechanism's key and also the locking screw. Such procedures would allow for the correction of any unintended changes in the length of the implant and also allow to properly secure the system with the locking screw (Refer to attachment 2). In cases where minor or slow changes in length occur, some palliative measures such as orthotics or external shoe lifts may mitigate the leg length discrepancy without surgical intervention.

In the occurrence that any of the affected products were released to your facility, please follow the below advice:

1. Circulate the IFU appended as attachment 2 and this Field Safety Notice internally to all interested/affected parties.
2. Make all relevant personnel aware of the locking mechanism and the warnings added to the IFU associated with the locking screw.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Please replace your existing copy of the MIG IFU with the one appended as attachment 2 and review additional warnings highlighted on page 2, under section "Minimally Invasive Grower – Device Extension".
5. Inform SIW if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that SIW can inform the recipients appropriately).*
6. Complete the attached acknowledgement form (attachment 1) to confirm receipt of the updated IFU. (*Please complete this form even if you already have the current IFU. This will preclude the need for SIW to send any reminder notice)*
7. Please inform SIW of any adverse events.
8. Return the completed Field Safety Notice acknowledgement form to the SIW Representative noted in the acknowledgement form.

Stanmore Implants Worldwide Limited maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Notice may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact your local Sales Representative.

Yours Sincerely,

Amit Agrawal
Senior Manager, Regulatory Affairs & Compliance
210 Centennial Avenue,
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Attachments:
1. Acknowledgement Form
2. Instructions for Use

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Attachment 1

**STANMORE IMPLANTS WORLWIDE LIMITED**
**FIELD SAFETY NOTICE ACKNOWLEDGMENT FORM**

**21 December, 2017**

NAME:

ADDRESS:

CITY, STATE ZIP,

POSTCODE:

| | |
|---|---|
| **FSCA identifier**: | Field Safety Notice – **PR 1629460** |
| **Type of Action**: | Field Safety Corrective Action |
| **Description:** | Instructions for Use related to locking screw mechanism introduced in the Minimally Invasive Grower (MIG) component were not made available |
| **Product Name** | Custom Made Implant Systems with Minimally Invasive Grower (MIG) component |
| **Lot #:** | Custom Made Implants with MIG component manufactured between March 2007 to October 2014 |

I confirm that I have received the IFU appended as attachment 2 and have reviewed the additional warnings included on page 2 of the document, under section "Minimally Invasive Grower – Device Extension".

_____ _____

Customer (Signature) Date

_____

Customer Name (PRINT)

Please email this signed and dated form to Amelia.Wiltshire@stryker.com

Stanmore Implants

# Minimally Invasive Grower – Instructions For Adjustment

## 1. Minimally Invasive Grower - Device Description

A typical minimally invasive grower is shown below in Fig. 01. The extending section consists of a telescoping outer shaft, an inner sliding piston, a screw with an integral gearwheel, a worm with a hexagon hole, and a smaller locking screw. To extend the mechanism a 'T' handle hex key is used. Prior to extending the prosthesis, the locking screw must be disengaged.

The Patient Specific Operation Drawing must be consulted to identify the location of the extension port and locking screw.

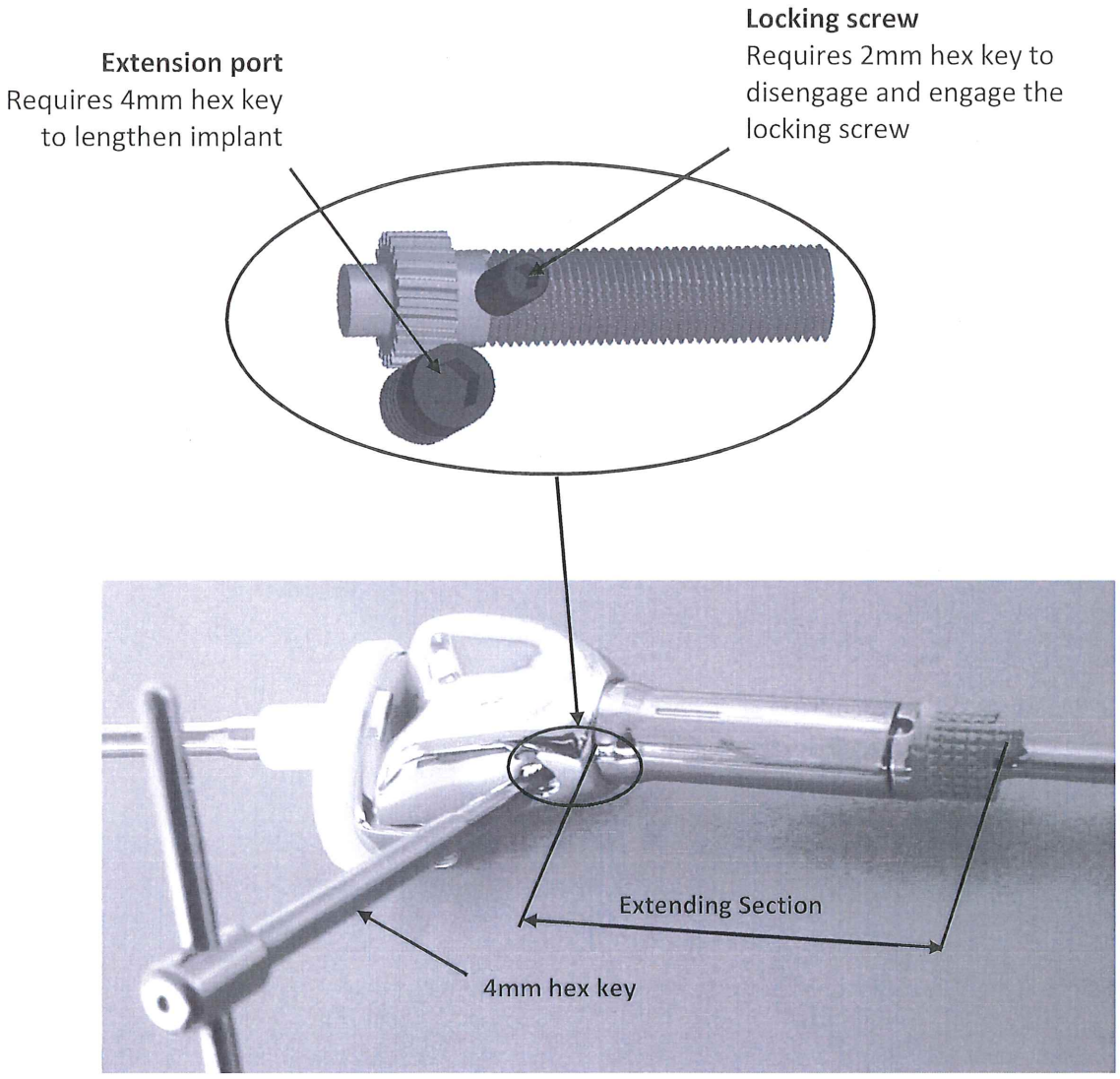


Fig. 01 - Minimally Invasive Grower

## 2. Minimally Invasive Grower - Device Extension

2.1 Before the extension mechanism is operated, refer to the Patient Specific Operation Drawing detailing the location of the Extension Port and the Locking Screw. These are both in close proximity to each other and a single incision is normally all that is required.

2.2 Using a 2mm hex key, disengage the Locking Screw without fully removing (one full counter-clockwise rotation will suffice)

⚠ Warning — If the Locking Screw is fully removed from the device or over turned, the mechanism may fail to extend.

2.3 The implant is extended using the 4mm hex key; this is inserted into the extension port and turned in a clockwise direction

2.4 10 x full 360° clockwise turn of the 4mm hex key will extend the prosthesis by 1mm

2.5 Once the implant has been extended to the desired length, the Locking Screw must be re-tightened (clockwise rotation) to engage and lock the extending mechanism.

⚠ Warning — If the Locking Screw is not fully engaged and the mechanism locked, there could be a tendency for unintentional extension.

## 3. Minimally Invasive Grower - Device Assembly/Disassembly

The minimally invasive growing implant has certain design characteristics to ensure that the implant is correctly assembled and will function as expected.

3.1 The gearbox mechanism (worm and gearwheel) is designed to disengage by pulling the telescopic components apart once the 2mm Locking Screw has been disengaged. This disassembly may be required during implantation or revision. Figure 02 below Outlines a detailed breakdown of components in this device.

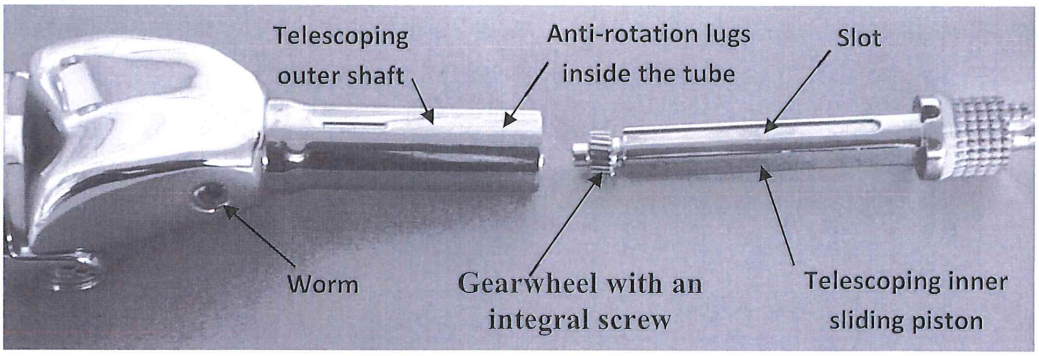


Fig. 02 Minimally Invasive Grower components

3.2 In order to dismantle the device the 2mm Locking Screw must be first disengaged and removed. During dismantling of this device, the telescopic inner sliding member should slide apart without any problems. However, for small diameter shafts it is possible that the gearwheel catches the anti-rotation lugs inside the telescoping outer tube. In this situation, push the telescopic components together and extend the prosthesis by at least 25 mm using 'T' handle hexagon key. Having done this the inner sliding member should slide apart without any problems.

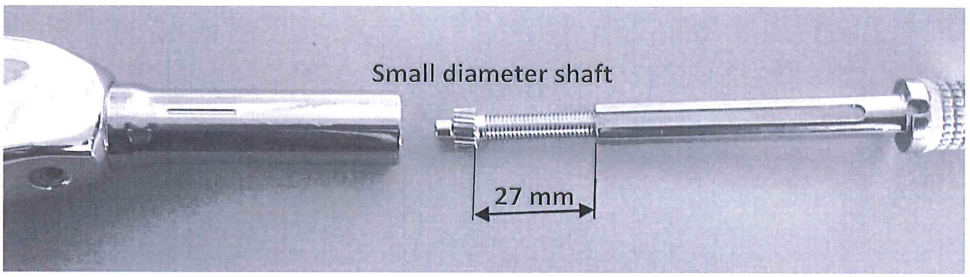


Fig. 03 Minimally Invasive Grower with small diameter shafts

3.3 In assembling the device ensure that the lead screw is fully screwed into the inner sliding member and then insert it into the outer shaft ensuring anti-rotation lugs are properly engaged in the slot. In small diameter shafts, it is possible that the gearwheel catches the anti-rotation lugs preventing its assembly. In this situation, unwind the screw by at least 27 mm, as shown in figure 3 above, before engaging telescopic parts together. Once the gearbox mechanism has engaged turn the key anticlockwise and reduce the extension to zero.

3.4 To ensure the gearbox mechanism is properly engaged, turn the worm using hexagon key and gently push the telescoping components together. On extending the prosthesis, a delayed response may be encountered due to the screw taking up the gap to support the load.

3.5 A fully assembled growing prosthesis can be extended by one clockwise turn of the hexagon key to advance the prosthesis by 0.1 mm. For example, to extend the prosthesis by 1 mm turn the key by ten full turn. Once the device has been correctly assembled the 2mm Locking Screw must be reengaged.

3.6 In some patients, where there is no compressive force on the device, during the extending procedure it is possible that the gearbox mechanism becomes disengaged. Therefore, by applying a compressive force during extension the gearbox remains fully engaged.

3.7 Applying the recommended assembly and disassembly procedure as defined above, this particular device will perform to its planned application. At no time, any of the parts should forcibly be put together or separated. Failure to do so may result in malfunction of the mechanism.

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