

Minimally Invasive Grower Lengthening Protocol



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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.

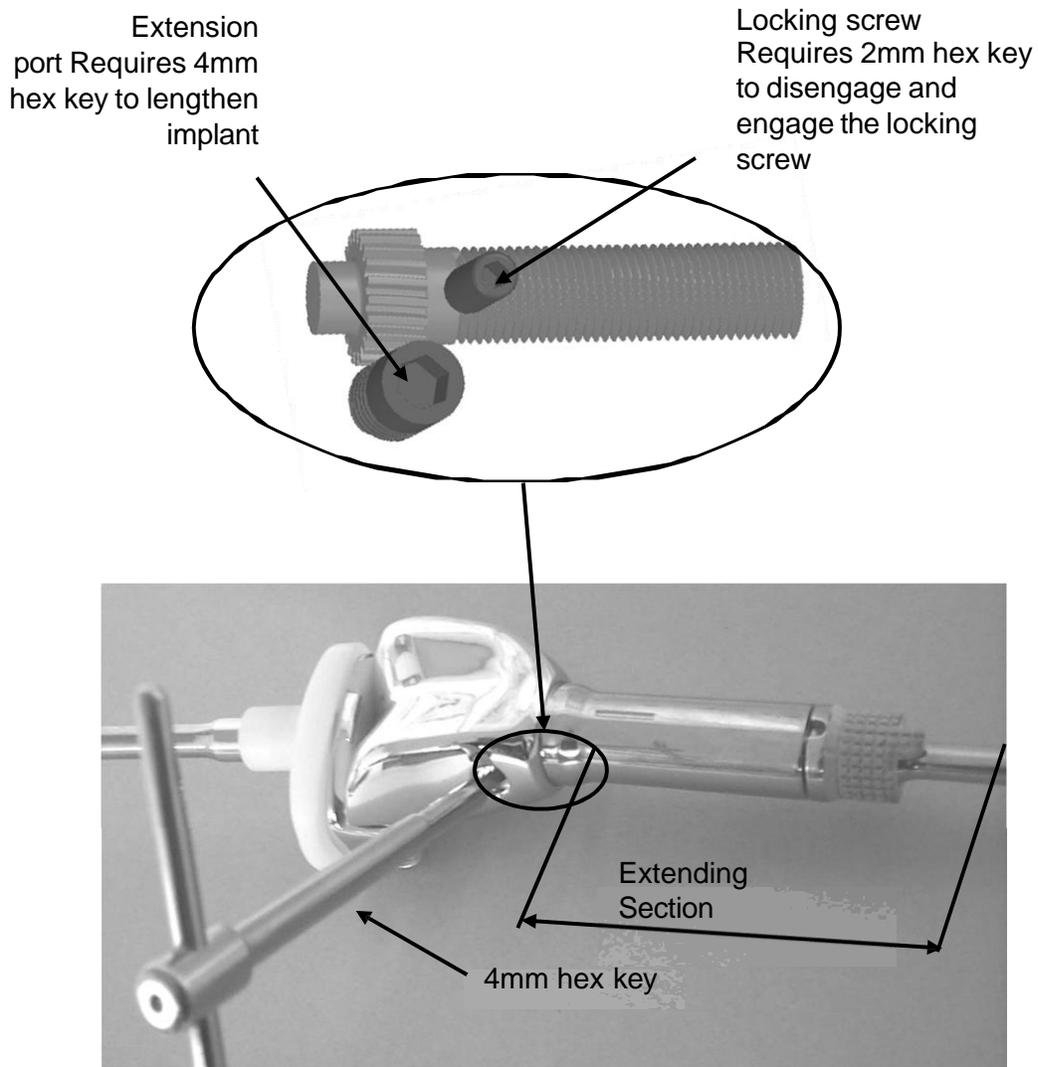


Fig. 01 - Minimally Invasive Grower

2. Minimally Invasive Grower - Device Extension

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



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

3. The implant is extended using the 4mm hex key; this is inserted into the extension port and turned in a clockwise direction
4. 10 x full 360° clockwise turn of the 4mm hex key will extend the prosthesis by 1mm
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.



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.

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.

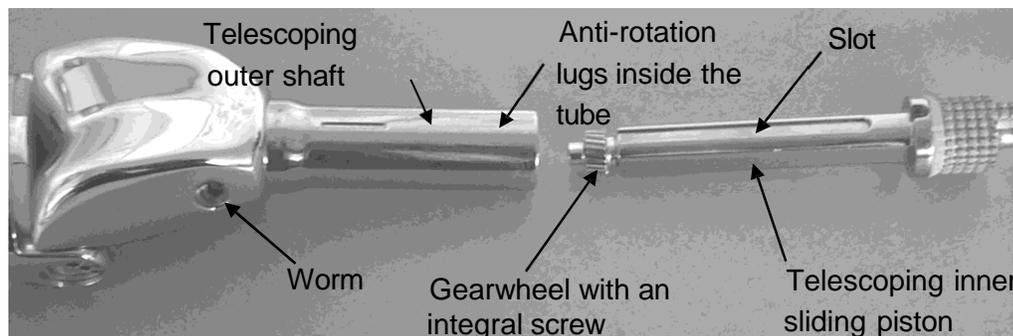


Fig. 02 Minimally Invasive Grower components

- 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.

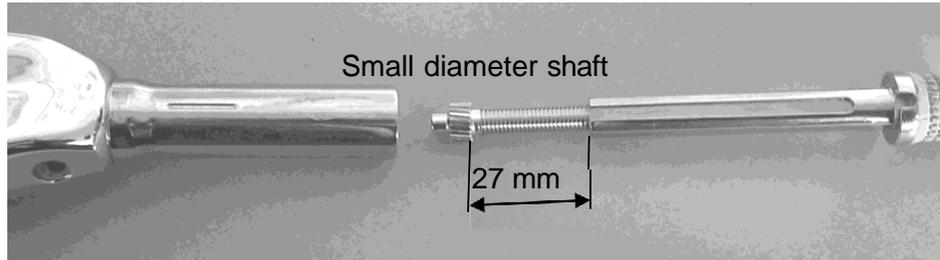


Fig. 03 Minimally Invasive Grower with small diameter shafts

- 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.
- 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.
- 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.
- 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.
- 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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