APPENDIX 1

ASSEMBLY OF THE TWO PROSTHETIC COMPONENTS

The assembly of the two components of a PFM-Revision 2nd generation stem (Revitan straight stem) stem is realised with a torque wrench providing a constant tightening force. It is performed in a different manner depending on the strategy selected by the surgeon. Assembly in one stage (extrafemoral) if an endofemoral approach was chosen or an intrafemoral assembly in two stages in situ, after implantation of the distal component with the help of a proximal temporary component if a femoral flap was performed.

NB: The torque wrench is also used for the tightening and untightening of the safety nut.

PRINCIPLE OF OPERATION AND DIRECTIONS FOR USE OF THE TORQUE WRENCH

The operating principle of the torque wrench key is based on using a cutting blade to split a polyethylene pin, the diameter of which has been determined such that it is always necessary to exert a torque of about 10 Nm to achieve this splitting.

Thanks to the new system composed of PE shear pins, the torque wrench doesn’t need to be recalibrated and offers a high level of safety to the user.
1. **Loading of the torque wrench.**

- Remove the cover (a) of the torque wrench (fig. 5, 6 and 7).
- Unpack the loader (b). The polythelene loader holds 6 shear pins. In practice, during each maneuver (torque), it is recommended to split 2 pins. With a shear pin loader it is thus possible to apply a torque three times (under normal conditions, 2 times are required during the assembly).

   *NB: A shear pin loader is packed with each proximal component of the implant. The shear pins should not be resterilised.*

2. Place the pins into the recesses of the torque wrench and turn the loader to free the shear pins.

3. Remove the lock of the loader.
4. Put the cover back in place and lock it in position “Lock”.

5. After use, unlock the cover by pushing the button.

6. Turn the cover to the “Open” position.

7. Remove the cover and extract all the “remaining” shear pins from the recesses.
ASSEMBLY OF THE STEM IN ONE STAGE (EXTRAFEMORAL)

1. Position the definitive proximal component
Before starting with the assembly of the two implant components, position the proximal component onto the morse taper of the distal component by hand and set the desired antetorsion of the proximal component. This step must be done before any assembly force is applied to the stem. Once the antetorsion is chosen, push the two parts together by hand to give them stability before continuing with the assembly.

2. Screw on the stem tensioner
Screw the threaded rod of the tensioner onto the threaded part of the morse taper. To screw on the tensioner, hold it in the hand so that the threaded rod protrudes from the tensioner. Alternatively, the threaded rod can be removed out of the tensioner, screwed onto the threaded part of the morse taper and eventually the tensioner is reassembled. Tighten by hand the nut of the stem tensioner.

3. Assembly of the proximal component
Hold firmly the stem tensioner and tighten the assembly of the two components with the torque wrench. For this process the request of assistance is strongly recommended. Further, don’t use the stem holder to maintain the implant in order to keep control of the antetorsion of the proximal component.

4. Screw on the conical nut
Finally the conical nut is screwed onto the threaded part of the morse taper with the help of the setting instrument and tightened with the torque wrench. For the tightening, the implant is placed into the stem holder for an easier control of the rotational stresses.
ASSEMBLY OF THE STEM IN TWO STAGES (INTRAFOEMORAL)

1. Assembly of the temporary proximal part and implantation of the definitive distal component
After wedging in the definitive distal component, further trial reductions can be carried out if necessary by changing the sizes of the proximal trial part and changing its antetorsion (up to +/-30°).

2. Position the definitive proximal component
Before starting with the assembly of the two implant components, position the proximal component onto the morse taper of the distal component by hand and set the desired antetorsion of the proximal component. This step must be done before any assembly force is applied to the stem. Once the antetorsion is set, push the two parts together by hand to give them stability before continuing with the assembly.

3. Screw on the stem tensioner
Screw the threaded rod of the tensioner onto the threaded part of the morse taper. To screw on the tensioner, hold it in the hand so that the threaded rod protrudes from the tensioner. Alternatively, the threaded rod can be removed out of the tensioner, screwed onto the threaded part of the morse taper and eventually the tensioner is reassembled. Screw tight by hand the nut of the stem tensioner.

4. Assembly of the definitive proximal component and screw on the conical nut
Hold firmly the stem tensioner and tighten the assembly of the two components with the torque wrench. For this process the request of assistance is strongly recommended. Finally the conical nut is screwed onto the threaded part of the morse taper with the help of the setting instrument and tightened with the torque wrench. When tightening the conical nut, neutralise the torsion stresses caused by the torque wrench exerting counter-pressure on the neck in the opposite direction to the tightening by hand or with the specially provided handle positioned over the neck of the implant.
APPENDIX 2

REMOVAL OF A PFM-REVISION 2\textsuperscript{nd} GENERATION (Revitan Straight Stem)

The possibility of extraction must be provided for every implant. Although this statement is true, it is nevertheless often difficult to fulfil it. In particular, a cementless stem can be very demanding to extract when it is not loosened. In the PFM-Revision 2\textsuperscript{nd} generation (Revitan Straight system), the development of disassembly instruments for the proximal component allows to some extent to overcome this disadvantage as its removal is always possible without difficulties. On the other hand, the extraction of the distal component is often demanding, especially if it is well osteointegrated or has a long stem.

INDICATIONS

The removal of a PFM-Revision 2\textsuperscript{nd} generation (Revitan Straight stem) can involve the proximal part or the entire implant.

REMOVAL OF THE PROXIMAL PART

The distal part of the implant is stable but it is necessary to remove the proximal part in order to:

- Change the proximal component to replace it mostly with a higher one for reasons of a secondary subsidence of the implant (fig. 1). Less frequently the antetorsion has to be modified (recurrent dislocation).
- Allow articular access either to carry out cleansing of the joint cavity (sepsis) or to work on the cup (changing it or placing an anti-dislocation device).

Example attached. Bipolar loosening: revision with PFM revision stem and St. Nabor cup. Radiography after 6 months: significant subsidence of femoral stem. Expanded trochanterotomy and replacement of the proximal component with a component of greater height with extra-long neck. The distal component, which had not loosened, was left in place.

![Figure 1](image_url)
REMOVAL OF BOTH COMPONENTS

Two different situations can be identified:

- There is a loosening with abnormal mobility of the implant: in this case, removal of the stem does not pose any problems. The stem can be removed in one piece using a simple extractor (fig. 2).
- In absence of a loosening, the implant should be extracted in two stages: removal of the proximal part and then removal of the distal part.

Example attached. Revision of PFM revision stem and dual-mobility cup, for repeated bipolar loosening (radiography after 3 years). Revision, pseudarthrosis of trochanter major: simple removal, monobloc, of the femoral stem (distal component, 200 mm in length) which was replaced by a shorter stem with a large diameter. Replacement of dualmobility cup with a cementless St. Nabor cup.

NB. The stem is not loosened but it is necessary to remove it in order to carry out cleansing of the medullary canal (sepsis) or because of secondary subsidence, which cannot be compensated by changing the proximal part.

FEMORAL APPROACH(ES)

Expanded trochanterotomy.

If it is intended to remove only the proximal component, articular access is strongly recommended in the form of an expanded trochanterotomy at the lateral cortex up to the point at which the proximal and distal components join (fig. 3).

Perform a digastric trochanterotomy, preserving the insertions of the musculus vastus lateralis at the base of the greater trochanter.
If it is intended to remove both components of the prosthesis (proximal and distal components), apart from any loosening, two options are available to the surgeon:

- **Lateral flap.** If the stem is short (length of distal component 140 mm), create a lateral flap, with a length of between 15 and 20 cm (fig. 4B).
- **Expanded trochanterotomy or flap and diaphyseal partition line.**

  If the stem is long (length of distal component 200 mm): after having performed an expanded trochanterotomy or a flap, use an oscillating saw to create a diaphyseal partition line (fig. 4A).

  Creation of a femoral flap is the most reliable option and it is worth bearing in mind that if the implant has not loosened it is always easier to remove a short stem.

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**Endofemoral route.**

If the stem is loose, endofemoral access alone is possible with care being taken to eliminate obstacles at the level of the greater trochanter.

Choosing endofemoral access requires wide lateral and posterior opening of the greater trochanter.
REMOVAL OF THE PROXIMAL COMPONENT (2nd GENERATION)

N.B. The disassembly of the PFM-R 2nd generation (Revitan Straight) is performed following an analogous process as with the first generation stem (PFM-R), with the sole difference that the instruments changed somewhat due to the presence of a thread at the level of the shoulder.

For the disassembly of a proximal component of the first generation different instruments are required and available in a separate instrument set.

DISASSEMBLY INSTRUMENTS

1. The torque wrench is in the “Lock” position.

2. Removal of the conical nut with the torque wrench.

3. Screwing the disassembly sleeve onto the distal implant component, using the setting instrument (see fig. 6b).
4. Screw the disassembly instrument into the thread on the shoulder of the proximal component.

5. The threaded rod with T-handle is screwed into the disassembly instrument (a) which is positioned over the threaded sleeve (c). By firmly turning, the threaded sleeve, and thus the distal implant component is pressed downward; and pressure is exerted simultaneously on the proximal component with the disassembly instrument.

NB. If the decoupling cannot be achieved by this simple tightening, hit a sharp blow with a mallet on the handle of the threaded rod.

6a. Decoupling of the proximal component.
6b. Removal of the disassembly sleeve using the setting instrument.

NB. Protect the morse taper with a compress if the removal of the distal part is not envisaged.
DISASSEMBLY OF THE PROXIMAL COMPONENT (1st GENERATION)

Warning! For the implants of 1st generation, the absence of a thread in the proximal zone of the female morse taper, entails the necessity for a specific ancillary instrument in order to disassemble the proximal component.

Placement of the threaded sleeve (fig. 7)
Unscrew the security nut with the wrench suited for this purpose or with the torque wrench, from the new range. Position the cylindrical threaded sleeve of one diameter smaller than the security nut.

NB. The threaded rod, which will be later used for the disassembly, is based on this threaded sleeve (see fig. 9a). During its placement, it is not necessary to lock it.

Placement of the disassembly instrument (fig. 8)
The disassembly instrument is a connection taper positioned over the neck, which should be oriented in order to direct the engraved pointer to the shoulder of the implant.

Warning! The disassembly instrument should correspond to the implanted proximal component and there are 3 different disassembly instruments:

- **P1** is for P1 former model (old A1.P1)
  Ref. 010079013
- **P1** is for P1 new model
  Ref. 010079007
- **P2 - P2.5 - P3** for the 3 other instruments
  Ref. 010079008
Disassembly of the proximal component
The threaded rod with handle (ref. 0100079009) is screwed into the disassembly component and is positioned over the threaded sleeve (fig.9a).
The tightening has a decoupling effect on the proximal component by means of the connection taper, which is positioned over the neck.

During the decoupling, it is sometimes required to control the rotational forces with the help of the sleeve based on the morse taper (fig.9b).

If the decoupling cannot be achieved by this simple tightening, hit a sharp blow with a mallet on the handle of the threaded rod.

Once the proximal component has been removed, proceed with a careful cleansing of the medullary cavity and protect the morse taper with a compress if the removal of the distal part is not envisaged.

Removal of the distal component
The removal of the distal component is done after having removed the proximal component. It is performed with the extraction instrument (01.00079.011) (fig.10a) that is screwed onto the connection taper and the slap hammer. This allows striking with sharp taps in the axis of the distal component (fig.10b).

If the distal stem cannot be extracted from the femur with a few hammerblows additional measures have to be taken, like longitudinal osteotomies, a window, a flap or the introduction of flat chisels along the stem to facilitate the extraction of the distal component.