

Addendum to IFU 00021 Rev.0

PANTHEON PFR – Proximal Femoral Replacement

Intended Purpose: Hip Articular Prostheses to be used as part of the the modular Pantheon Proximal Femur Reconstruction (PFR) for the reconstruction of the proximal femur in case of severe proximal femoral bone loss in complex primary and revision hip surgery (due to infection, fracture, failed total hip prosthesis) or in case of bone tumor.

The following Implantable Medical Devices (IMD):

- **PANTHEON proximal Body Flat**
- **PANTHEON Proximal Body Smooth**
- **PANTHEON Salvage cementless stem HA coated**
- **PANTHEON Salvage cementless stem**
- **PANTHEON Salvage cemented stem**
- **PANTHEON cortical plates**
- **PANTHEON salvage plates**
- **PANTHEON bridging collars**
- **PANTHEON shaft**

have not been evaluated for safety and compatibility in the MR environment.

They have not been tested for heating, migration, or image artefact in the MR environment.

The safety of the devices in the MR environment is unknown. Known risks of exposing implant devices to the MR environment include displacement, torque, and radio frequency induced heating. Implant devices may also create image artefacts in MR scans.

Scanning a patient who has these devices may result in patient injury.