



**Tender Committee**  
**Orthopaedic Implants Tender**  
**MOLDAVIA**

The 3rd of May 2019

*Subject : Hip Prosthesis / Range of Femoral Heads / Additional information*

Dear Committee members,

In addition to my previous letter dated current April 25<sup>th</sup> I am pleased to give you hereunder some more information about femoral heads on the market.

Our standard range of CoCr femoral head offers the diameters 28, 32, 36 and 40 with 4 different lengths of neck usually classified as S, M, L and XL. This range is an international standard to cover the requirements of hip arthroplasty and complies with the norms on the market. The entire range is CE marked and also FDA approved.

To allow a wide range of combinations between components of hip prosthesis and then allow a perfect reconstruction of anatomy, the femoral heads could be used with standard stems and lateralized stems.

In addition to this, Signature Orthopaedics propose beyond the standard XLPE liners an entire range of lateralized XLPE liners that could be use in specific cases where surgeon may need this option to restore perfectly the anatomy of patients.

All those products are CE approved and available on demand on a routine basis.

In unlikely case of patient demanding a custom head, like I wrote in my previous letter, Signature Orthopaedics is in position to propose and produce custom head based on surgeon specific. In this case the component could be propose as a custom implant which do no required the CE mark. This is a usual situation for us as we do a lot of custom implants for example for tumor cases; In such situation as Signature Orthopaedics is ISO13485 and complies with the 93/42/EEC annex 2 directive we have agreement to produce custom implants.

With my Best Regards

Olivier PERNOIS

Signature Orthopaedics France

Director

A handwritten signature in black ink, appearing to read "Olivier Pernois", is written over the printed name and title.