

# SmartPeg Development Policy

SmartPegs are delicate measurement tools. In order for them to function properly, they are manufactured to exact dimensions, ensuring a close fit to the implant. Osstell offers more than 50 different types of SmartPegs, and together they fit more than 100 implant systems.

When a new implant is to be added to the SmartPeg Reference List, Osstell first checks to determine whether an existing SmartPeg Type can be used, see Step 1. If this is the case the implant may be added to the SmartPeg Reference List, see Step 3. If a current SmartPeg Type cannot be used a new one needs to be developed, see Step 2.

## Step 1: Checking Whether an Existing SmartPeg Can be Used

In order to start the investigation of whether an existing SmartPeg Type can be used for the implant the following is needed:

### 1. Implant Blueprints

Osstell needs dimensional information about the implant. Implant blueprints are preferable (see blueprint samples on page 2).

As a minimum the following is needed:

- Dimensions of the implant head
- Dimension tolerances
- Angles
- Dimensions of the internal geometry: Size and depth of the implant threads and minimum length of the implant threads.

Osstell and the Implant Company normally exchange Non-Disclosure Agreements if blueprints are sent. A template for a Non-Disclosure Agreement is available from Osstell. Other useful information may also be submitted, such as the recommended bone level etc. See address under section "Contact Information".

### 2. Two Implant Samples

At least two samples of each available platform are needed. They should be of standard length, approximately 15 mm. See address under section "Contact Information".

### 3. Investigation Fee

An investigation fee of 500 EUR/implant is to be paid to Osstell by the Implant Company.

## Step 2: Developing a New SmartPeg Type

If an existing SmartPeg Type cannot be used and a new one needs to be developed, the Implant Company and Osstell will share the development costs. This requires a minimum order of 500 pcs of SmartPegs by the Implant Company. These SmartPegs can be used for clinical studies and such. After the SmartPeg Type has been developed it will be added to the SmartPeg Reference List, see Step 3.

## Step 3: Adding the Implant to the SmartPeg Reference List

Please note that a Change Agreement concerning product changes is needed for implants that are added to the SmartPeg Reference List. A template for a Change Agreement is available from Osstell.

## Contact Information

Email: [support@osstell.com](mailto:support@osstell.com)

Phone: +46 (0)31 723 5561

For samples, agreements, and printed information, please use the address below. Mark the item for the attention of Support.

Osstell AB  
Att: Support  
Stampgatan 14  
SE-411 01 Gothenburg  
SWEDEN

Sample blueprints: At a minimum, the following dimensions are needed:

