

## **1. Framework**

Since last September 1st 2009, all hip, knee and shoulder total joint replacements prosthesis are class III medical devices according to article 1 of European Directive 2005/50/EEC. As a consequence, to allow the placing on the market of those medical devices, their manufacturers have to follow a conformity assessment procedure required for this class.

These manufacturers have proceeded to new classifications for the main part of the products presented in their catalogue. However, some older references were not submitted to these procedures. As a consequence for the latter, placing on the market of complete joint replacement system or of spare pieces is now impossible.

Moreover, spare parts of total joint replacements prosthesis used for a partial change can't be considered as a custom made device.

This situation turns out blocking when a surgeon needs to get a spare part of such a system to realise a partial replacement of an already implanted system. When possible, partial change of an implanted system is of interest for the patient because the surgical procedure being more limited remains less traumatic than the one necessary for a total replacement.

## **2. Dispensation for placing on the market of non CE marked medical device**

Use of a non CE marked medical device in France is possible, apart from a biomedical investigation framework, after obtaining of an exemption issued by the **National Agency of Medicine and Health Product Safety (ANSM)**.

Article R.5211-19 of French Public Health Code, adapting point 13 of Article 11 of Medical Device European Directive 93/42/EEC, makes provision for, on "duly justified demand", the authorization by the ANSM Director, within the framework of exemption and interest for public health, the placing on the market and putting into service of a medical device which has not been submitted to conformity assessment procedures.

In this legal context, ANSM could accept the deliver of an exemption for articular implants manufacturers having received requests from surgeons for partial replacement of implants which elements are no more CE marked.

ANSM will publish a list of dispensation for joints replacement systems issued on his internet website.

## **3. How to get a dispensation**

### **3.1. Criterias**

This particular procedure is reserved to :

- Spare parts of total joint replacement systems not any more CE marked and being previously placed on the market in France.
- Pieces already packaged or to pieces manufactured according to technical specifications mentioned in the technical file followed for the manufacture of previous CE marked pieces..
- Partial change of already implanted systems, excluding *de novo* implantation or complete implant replacement.

### **3.2. Procedure**

Manufacturer send an initial demand to get an annually authorization delivered by ANSM. This authorization will be extended after assessment of an annual statement of implantations as long as the need of this dispensation can be established.

Manufacturer is allowed, with justification, to present the initial authorization request anytime before the surgeon demand.

The initial demand deposit should include the following elements:

- Copy of Declaration of conformity with covered commercial reference names joined with the last CE certificate related to the joint replacement system and a copy of the latest version of instruction for use.
- A document intended to be delivered as an addendum to the instructions for use , mentioning:
  - o Strictly restricted use of the element for a partial replacement of an already implant system

- Product delivering is under a dispensation procedure
- Absence of a valid CE marking for the product
- Adverse event reporting commitment towards the manufacturer or ANSM for incidents or risk of incidents linked to use of the or these elements according to article L.5212-2 of the French Public Health Code.
- A statement justifying the necessity for exemption, mentioning:
  - Time period during which the or these elements have been placed on the market
  - Number of the or these elements implanted in France during this period
  - Justification of the lack of CE marked equivalent solutions in terms of elements for articular prosthesis
  - An estimated re intervention rate (based on post market survey figures or estimates) and as a consequence the estimated number of elements necessary per year.
  - Any information concerning the remaining stock available and, notably, the use-by date of these medical devices

If appropriate, for newly manufactured devices, a declaration testifying that manufacturing process is compliant with requirements of latest version of previously CE marked technical file.

ANSM will send a confirmation letter after assessment of these elements. A list of all exemptions delivered will be published on its website.

Manufacturer will send, every year just before expiry date of dispensation, a summary of all elements delivered within the framework of this procedure with a demand of prorogation of the exemption for the next 12 months if wanted.

### **3.3. Device delivery**

Implants will be delivered only on a duly justified demand of a surgeon. This demand should mention the reason (clinical aspects) for the use of these spare parts and the expected related benefit for the patient.

Elements should not be deposit previously to any specific demand in the healthcare facility, as usually done for other implant systems. They shall be provided only after request from a healthcare facility.

Already packaged implants shall be delivered with the addendum instructions for use. For the implants not yet packed, the package shall not include the CE marking but all the information needed to identify the implant and the manufacturer. They will be delivered with the instructions for use and the addendum.