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R.E.A. 211053 di Verona
C.C.I.A.A. VR n. 01346810235
C.F. 01346810235
P. IVA 02042700233
Cap. Soc. € 850.000,00 i.v.

Field Safety Notice

Commercial name of the affected product: CEMOVER

FSCA-identifier (date): 12th September 2011

Date: 12th September 2011

Details on effected device:

CEMOVER DEVICE, see the website: www.tecres.it.

CEMOVER is a disposable sterile device used for the removal of PMMA bone cement mantle in revision procedures of cemented prosthesis. Bone cement removal is achieved removing gradually defined portions, extracting them from proximal part.

The device consists of PMMA cylindrical metamers joined by a metal connection to create a sort of candle. The candle is cemented inside the medullary canal where residual bone cement is present adhered to the bone. Following polymerization, the device becomes fixed to the new fresh cement and the old residual cement. Using supplied instruments, it is possible to remove segmentally the cement from the medullary canal.

Description of the problem:

In a case, during surgery, a portion came out wrongly leaving part of the portion itself inside the femoral canal. Due to this, cement debris fell into the threaded hole of the next portion and the surgeon was not able to remove the other portions.

Advice on action to be taken by the user:

For this reason we decided to update to the instructions for use for stating, besides to follow the IFU carefully, as follow:

A. To achieve an adequate fixation:

1. low viscosity cement should be used;
2. the device shall be inserted inside the fresh cement soon (the cement shall be still "liquid");
3. the position of the limb shall be directed downward, so to favour the introduction of the fresh cement and to avoid the leakage from the medullary canal: in this way the fresh cement will completely fill the cavity and when the device will be introduced the complete fixation of all the segments of the device will be favoured.

B. To achieve a correct removing of all the parts of the candle:

1. the debris must be removed by an accurate cleaning by pulsed lavage;
2. in case of difficulties to remove the debris by pulsed lavage the use of the another instrument supplied in the Cemover kit (Cemover plug remover staff) can solve it.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action to ensure effectiveness of the corrective action.



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