



**PEAK
PRESSURE
RELEASE
SYSTEM**

**RESORBABLE
CEMENT
RESTRICTOR**

BIO MED
Biomaterials

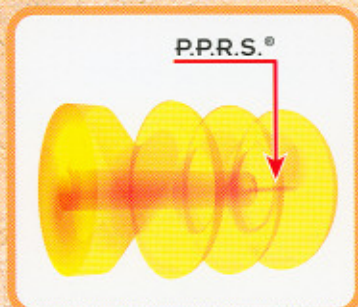
GENERAL

The C~plug® is a resorbable bone cement plug. Its specific design and composition confer many advantages to the device. Not only does it fulfil a standard cement restrictor's requirements but brings about two major advantages. Reduced pressure distal to the plug through a Peak Pressure Release System®

(PPRS®) and the possibility to use a larger size plug. The C~plug® is manufactured from a neutral biocompatible compound composed of 50% gelatine, 30% glycerol and 20% H₂O. It is a sterile single use device and must be stored at a temperature below 30°C (86°F). Re-sterilisation should not be attempted.

ADVANTAGES OF THE C~PLUG®

- Allows for the use of larger plugs.
- Effectively stops cement flow beyond the plug.
- Efficiently protects the medullary canal distal to the plug.
- Reduces pressure distal to the plug from 3 MPa to 300 millibars through the PPRS®.
- Confers greater resistance to displacement.
- Facilitates cement pressurisation with current cementing techniques.
- Gives a clear-cut cement interface.



- Creates a homogeneous cement mantle around the implant.
- Is totally resorbed within a few days.
- Reduces the amount of polyethylene used in arthroplasties.
- Eliminates a potential risk of polyethylene debris in the medullary canal.
- Makes revision surgery easier as there is no plug to remove.
- Eliminates instrument incidents.
- Allows for easier and more precise positioning.

PERFORMANCES

The C~plug® has been evaluated and has evidenced a higher degree of resistance to displacement and a greater ability to restrict cement penetration than currently available devices.

The incorporated PPRS® reduces the pressure distal to the plug from an average 3MPa to 300 millibars,

thereby limiting the risk of a fat embolism and avoiding marrow content being forced into the vascular system during insertion.

Larger C~plugs® can be used in order to obtain a tighter fit.

INSTRUMENT SET

Surgeons tend to place larger plugs to obtain a tighter fit especially when using new cementing techniques. If this enhances clinical results and reduces plug displacement, it can also lead to instruments remaining blocked in the canal.

The C~plug® instrument set has been redesigned so as to allow for such a choice and avoid such incidents. With standard instrument sets the plug carrier that has to be used with a larger plug is also larger. It has a nominal diameter larger than the measured canal; therefore it can remain entrapped due to the specific visco-elastic characteristics of bone.

The base of any C~plug® carrier has a diameter smaller than a plug or trial size one size larger and therefore cannot remain entrapped.



When inserted it will easily pass, as it will always be smaller than the predetermined canal diameter, even when using a larger plug.

INSTRUCTIONS FOR USE

techniques may differ slightly

When templating for the size of the stem prosthesis also predetermine both the depth and the diameter for the C-plug®. The depth should correspond to the

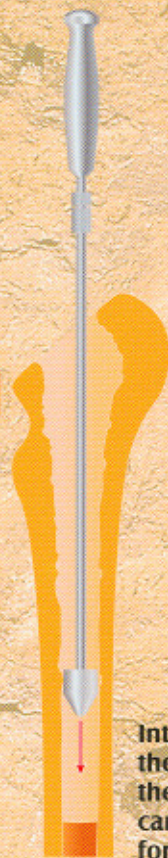
length of the stem prosthesis to be used + 2 1/2 cm. [This will leave 1 cm between the distal tip of the stem and the proximal end of the restrictor].

1



Select the sizing trial that corresponds closest to the templating observations. Attach it to the instrument rod.

2



Introduce the trial into the medullary canal and check for a proper fit.

3



Mark the depth with the sliding index as described above.

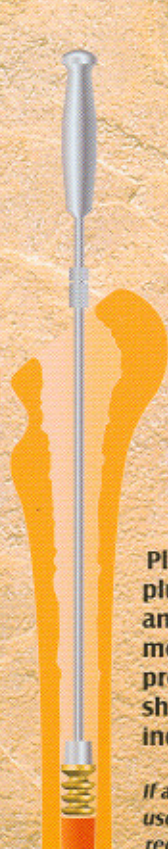
4



Select the appropriate C-plug®, either corresponding to the trial or one size larger. Attach the plug carrier corresponding to the plug to be effectively used.

Example: If the canal size has been pre-determined and confirmed as being 12 mm, use the carrier 12. If using a plug size 12. If a larger plug is preferred, in this case a size 14, then one must also use the corresponding plug carrier, a size 14.

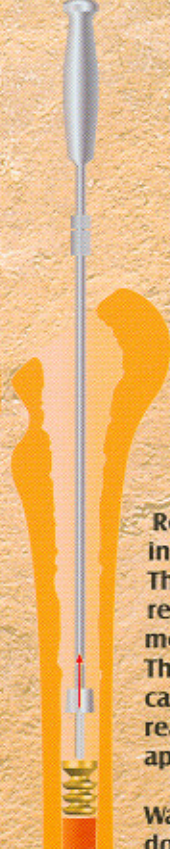
5



Place the corresponding plug on the plug carrier and introduce into the medullary canal to the pre-determined depth shown by the sliding index.

If a larger size plug is being used gentle hammering may be required.

6



Remove the instrument. The plug will remain put in the medullary canal. The medullary canal is then ready for cement application.

Warning :
do not unscrew



ORDERING INFORMATION

C~plugs® are available in 6 sizes.

Standard Product	Order reference	Size - diameter
C~plug®	CP 08	8 mm
C~plug®	CP 10	10 mm
C~plug®	CP 12	12 mm
C~plug®	CP 14	14 mm
C~plug®	CP 16	16 mm
C~plug®	CP 18	18 mm
Instrument set	CPS 01	

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