

UNIVERSAL CEMENT RESTRICTOR

MANUFACTURER - DISTRIBUTOR:

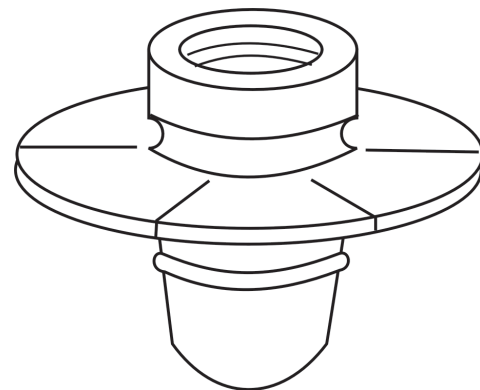
permedica S.p.a.

via Como, 38/39 - IT23807 Merate (Lc) - ITALY

REGISTERED TRADEMARK:



QUALITY CERTIFICATION:



INTENDED PURPOSE

The UNIVERSAL Cement Restrictor is a device intended for use in cemented total or partial hip and knee replacement operations when intramedullary stems fixation is required.

The aim of the device is to seal the medullary canal in order to prevent distal cement migration during the prosthetic implantation phase, while favoring at the same time even cement distribution around the component and guaranteeing appropriate pressurization and trabecular bone penetration at the implant site.

TECHNICAL DATA

DESIGN:

Circumferential tab split into 8 petals to allow adaptation to all anatomical conditions; metal wire with radiographic reference function; central thread for tool positioner engagement.

MATERIALS:

Ultra High Molecular Weight Polyethylene (UHMWPE) without calcium stearate - ISO5834/1/2
Wire: medical grade stainless steel AISI 316L - ISO5832/1

STERILIZATION:

Method: Ethylene Oxide (EtO) or irradiation (Beta or Gamma rays - nominal dose 25 kGy) in vacuum.

Valdity: 5 years (Beta/Gamma sterilized products) - 10 years (EtO sterilized products).

PACKAGING:

Outer: rigid carton box, with polypropylene protection film;

Inner: double bi-laminated polyamide/polyethylene plastic envelope vacuum packed (Beta/Gamma sterilized products).
Double paper/plastic envelope (EtO sterilized products).

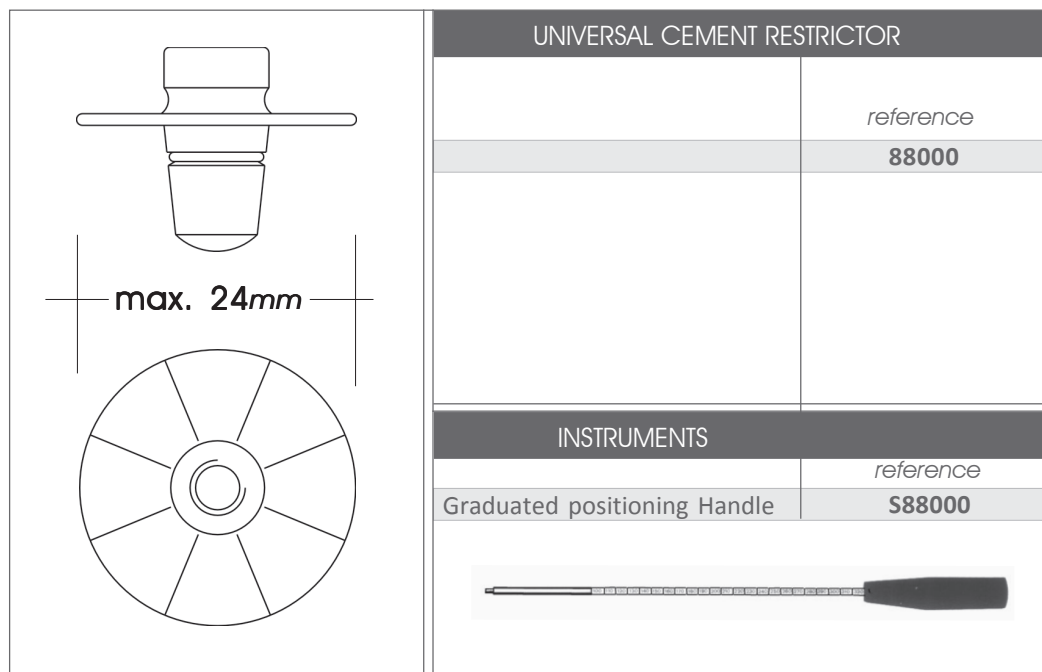
Identification labels reporting all necessary information regarding the product can be found both on the outer or inner package; extra detachable labels for application to the clinical chart are enclosed.

DEVICE CLASSIFICATION:

Class IIb as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendments.

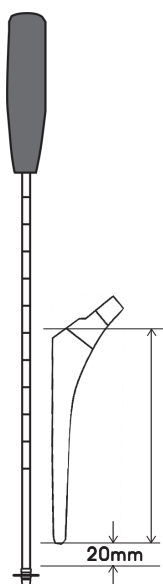
PRODUCT TECHNICAL INFORMATION SHEET

AVAILABLE SIZES

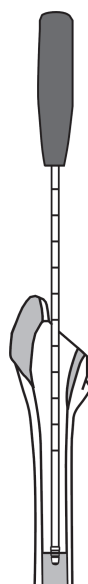


IMPLANTATION PROCEDURE

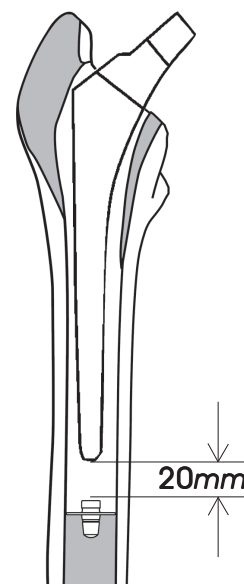
For device positioning into the medullary canal, screw the Cement Restrictor onto the Graduated Positioning Handle.



Determine the depth for device insertion referring to the length of the prosthesis, leaving max. 20mm. between the the distal tip of the stem.



Insert the Restrictor to the desired depth and remove the Positioning Handle by unscrewing.



Fill the medullary canal with bone cement and insert the prosthesis.