



INSTRUCTION MANUAL

1-DEFINITION

K'Ball® universal is a single use, non invasive Class 1 MD designed to prevent inward migration of the protruding K'wire. It protects the patient, the surgeon and hospital staff from K'wire's sharp end, especially when several pins are handled in a small space. **K'Ball®** fits all K'wires ranging 0.6 to 2 mm Ø.

2- MATERIALS

Spherical shell: POM C- **insert:** PTFE –**Hexagonal headless screw:** 316L stainless steel L

3- IMMOBILIZATION OF THE PIN

a- Using the MSF screwdriver tighten the screw powerfully until the K'wire is firmly immobilized.

b- The tightening torque applied on the screw is proportional to the Ø of the pin used, so the smaller the pin's Ø e.g. 0.6 mm the greater will be the tightening torque applied. Furthermore the handle of the MSF screwdriver has a 7° knurled surface allowing a better grip of the tool in gloved hand.

c- SUR.GICAL PROTOCOL

A 4 steps surgical protocol video is available at page 3 of our web site www.michaelsfrance.fr

4- INDICATIONS

K'Ball® universal is mainly indicated to prevent inward migration of the K'wire.

5 - SIDE EFFECTS

6 - known allergy to metals.

7 - WARNING

a- K'Ball® universal MD must be in conformity with the manufacturer directives, according to which the managing Director is only authorized to proceed to self-certify the CE declaration of conformity. Furthermore the **K'Ball® MD** must be performed by a surgeon who has assimilated the surgical procedure.

b- If a defect or a malfunction is detected on a **K'Ball® MD**, it must be replaced and reported to the manufacturer.

8- Lot

A lot number "0 to 9" indicating the year of manufacturing may be embedded on the outer surface of the **K'Ball®** e.g. (I) which stands for 2021. At the end of each decade e.g. 2030 the countdown will be set back to 0.

9 – WASH & DECONTAMINATION

K'Ball® universal must be washed, decontaminated and sterilized before being used. Considering that a wide variety of detergents and fluids are available on the market, and considering that Michael'S France does not possess expertise to evaluate suitability and compatibility of each and every products, therefore, as indicated on page 3 of our web-site **The Chemical Compatibility Chart** indicates the product the most.

10 – DELIVERY

a- K'Ball® universal is supplied non-sterile in an 11 translucent disposable dispenser inappropriate for sterilization procedure and storage.

11- WATER TEMPERATURE

Michael'S France asserts that **K'Ball® MD** withstands immersion in water heated at 196°F / 91.11°C

12- DISCLAIM OF LIABILITY

Michael'S France disclaims all responsibility as to the type of washer/disinfector equipment, consumables or cycle process, being understood that it is up to each decontamination and sterilization team to determine which equipment, consumable or parameters are the most appropriate to their need.

13- STERILIZATION PROCESS

PROCESS	Cycle	Temperature	Exposure time	Bar
Steam	Prion Gravity	250°F (121°C)	30 min	2
Steam	Prion Gravity	270°F (132°C)	15 min	2
Steam	Pre Vacuum	270°F (132°C)	10 min	2
Steam	Pre Vacuum	272°F (133.2°C)	4 min	2

14 –WARRANTY

a- K'Ball® universal must be discarded after removal. Breaching this rule may invalidate the manufacture's warranty.

b- Never use **K'Ball®** to extract the pin.

15- PACKAGING

K'Ball® universal are supplied non sterile in an 11 translucent disposable dispenser.

16- Aphtalate: **K'Ball®** is Aphtalate free.