



122 avenue de la République
75011 Paris - FRANCE -
Tel/Fax: + 33 (0)1 48 05 11 00
E-Mail: contact@dentak.com

CE 0124

This product exclusively applies to professionals of medicine, (dental surgeons, facial maxillary surgeons, stomatologists)



Notice of K-System

DESCRIPTION

The device called trephine bone crushing drill (FTBO) consists of a trephine tube comprising at its forepart teeth and a drill blade set which is suitable to be fitted and exchanged early on the trephine tube. The device is fitted on a contra angle or a hand-piece turning at low speed. The core extracted by the trephine is immediately crushed by the blade. The bony crushing fills up gradually the trephine tube. The trephine drill is uncoupled from the contra angle, the blade drill is removed from the trephine tube and the latter is then fitted on a syringe adapted for its ulterior injection. The K-SYSTEM is available in various sizes. These sizes offered by DENTAK have been elaborated in order to come up to all the indications when an autogenous crushed bone graft is necessary in the dental / oral / facial fields.

INDICATIONS

The indications where an autogenous crushed bone graft is necessary in periodontal and dental implant surgeries (Bone removal simultaneously with the preparation of the area receiving the implant, immediate implantation, SUMMERS technique, sinus lift procedure)

CONTRA-INDICATIONS

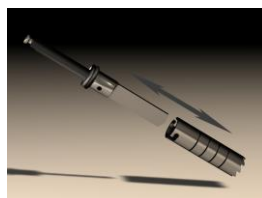
All the usual contra-indications linked to bone graft. K-SYSTEM has not been designed to be used during orthopedic procedures. Its use is restricted to dental / oral / facial procedures.

V5-E-07/03/07

OPÉRATIVE PROTOCOL



Check the steadiness of the trephine fitting on the blade. Fit the FTBO on a contra angle or a hand piece and try to pull slightly the tool out to check if it is in the right position. Check imperatively the rotation direction of the FTBO before use. An inverted rotation direction could unpair the trephine tube from the blade drill. Drill at the level of the donor site imperatively under external irrigation and at low speed (500 rpm max). Do not drill beyond the 11mm mark



Remove the FTBO from the contra angle and disassemble the trephine tube from the blade drill



Fit the trephine tube on the syringe



Inject the crushed bone at the level of the recipient site.

RECOMMENDATIONS FOR USE

Check before each use whether the instruments are in good conditions. The used of ruined blades causes an increasing risk of bone heating.
Never fit a sole blade on the contra angle or handpiece.
Never connect a trephine tube and a drill blade with a different diameter.

CLEANING DISINFECTION AND STERILIZATION

K-SYSTEM components must be cleaned, disinfect and sterilized between each patient use.

Cleaning

After use scrub dirt and other debris from all the K-SYSTEM components and wipe clean with a cotton swab or cloth.

Disinfection

Immerse all the K-SYSTEM components in an ultrasonic cleaner containing detergent disinfectant. It is essential that disinfectant products be used scrupulously in conformity with the manufacturer's instructions. A meticulous rinsing with water must be carried out after disinfection.

Inspection

After cleaning and disinfection visually inspected all the components for the cleanliness and working conditions.

The used of ruined blades causes an increasing risk of bone heating.

Sterilization

Insert K-SYSTEM components into an autoclavable pouch and seal it. The recommended sterilization is autoclave at 135 °C for 20 minutes. The recommended number of sterilization cycles before disuse is 250 cycles

SYMBOLS

LOT

Lot number



Sterilizable at 135°C at steam during 20 minutes

REF

Commercial reference of the product

NON STERILE

Non sterilized