

Dental Drill Instructions For Use

Indications

Intra-Lock® dental drills are for use to perforate the tissue or bone and create the osteotomy, or hole, where Intra-Lock® dental implant(s) will be placed.

Material

Intra-Lock® dental drills are manufactured from Stainless Steel.

How Supplied







Intra-Lock® dental drills are provided sterile (by gamma radiation) and are intended for single patient use only.

The label on the package provides the lot number, product description, catalog reference number and expiration date. To ensure sterility, dental drills must be used before the end of the expiration date indicated on the outer package label.

Prior to using Intra-Lock® dental drills, inspect the package and labeling for integrity. If the package has been opened, damaged or the device has been contaminated or exceeded the expiration date before the first use, it may be sterilized according to the instructions provided below.

Sterilization



Dental drills may be sterilized using a full cycle pre-vacuum steam sterilization at a temperature of 132°C (270°F) for an exposure time of 4 minutes.

Note: These instructions have not been validated to reprocess dental drills for use with multiple patients. After use on any patient, the dental drill may include extensive tissue and/or bone debris and therefore require more extensive cleaning and sterilization techniques. If dental drills are reused, the user or reprocessing facility must validate the parameters they utilize, which must include an inspection for potential wear and damage incurred to the dental drill from the previous use.

Drilling Technique

Warning: Osseous drilling can generate detrimental heat that may cause thermal bone necrosis and subsequent failure of the dental implant to osseointegrate. It is critically important that all bone-cutting procedures are CONDUCTED AT SLOW SPEEDS. Profuse, internal and/or external irrigation is mandatory.

The slow-speed, highly irrigated drilling procedure is conducted while angling the dental drill such that the direction of the drill bisects the ridge. The dental drill should also be held vertically, avoiding a mesial or distal cant. Depth gauge/alignment components can be periodically inserted into the osteotomy site to monitor the angle of penetration. Successively larger drills are used until the desired diameter is achieved. Drilling is performed with a precise, up and down pumping action. The drill angle is maintained in

order to preserve the concentricity of the hole, while the pumping action allows for incremental depth penetration and periodic cleansing of the flutes.

It is recommended to drill a Pilot Hole when the bone is of high density using a "Lancer" Pilot drill extending to a depth of 8 mm.

Caution: Federal law restricts this device to sale by or on the order of a licensed dentist or physician.



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