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Dental Surgical Instrument

DSI FIXTURE & SCREW REMOVER KIT










INSTRUCTIONS FOR USE

DESCRIPTION

The device is intended for use in removing failed implanted fixture and/or fractured screw from the implanted fixture.

CONTENT

Type		H (mm)	Ref:
x2 Fixture remover screw	Ø 1.6 / 1.8	22.0	FRD-01
x2 Fixture remover screw	Ø 2.0 / 2.5	22.0	FRD-02
Fixture remover screw	Narrow	22.0	FRD-03
Ratchet extension	Ø 6.0	16.0	RE-02
Handpiece condenser	Ø 6.0	24.0	SDADP-01
Turning Handle		11.0	TH-03
Wrench Long		110.0	SDWRH-02
Remover Drill	0.8	32.5	D-REM08
Remover Drill	1.3	32.5	D-REM13
Reverse Drill	0.8	30.0	D-RED08
Reverse Drill	1.3	30.0	D-RED13
Tap Drill	0.8	30.0	TD-08
Tap Drill	1.3	30.0	TD-13
Flat Tip Driver	2.5	26.0	FTD-01
Turning Handle		15.4	TH-01

Guide Holder		-	GH-01
Drill Guide External Mini		12.0	G-EM
Drill Guide External Regular		12.0	G-ER
Drill Guide Octa Internal		12.0	G-OI
Drill Guide Hex Submerged		12.0	G-HS
Drill Guide TSV 3.7/4.1		12.0	G-TSV
Drill Guide Tri-Lobe		12.0	G-TRI
Drill Guide Submerged Narrow		12.0	G-SN

HOW TO USE

Removing Fixture

Drill the Fixture Remover Screw counterclockwise to fix the remover to the implanted fixture. Keep drilling counterclockwise to remove the fixture.

** In case the Fixture Remover Screw cannot be separated from the fixture due to excessive torque "cold welding". Contact the company for the refills.*

- Turning Handle (TH-03) and Wrench-Long are used to turn Fixture Remover Screw manually.
- Ratchet Extension is used to extend the length of Fixture Remover Screw when the surgical site is not accessible.
- Handpiece Condenser is used to connect Fixture Remover Screw to the implant engine.

Removing the fractured screw

1. Connect Drill Guide to Guide Holder.
 2. Fix the Drill Guide to the fixture and turn Remover Drill counterclockwise to remove the fractured screw.
 3. In case the fractured screw cannot be removed using Remover Drill, insert Reverse Drill into the Drill Guide and turn it counterclockwise with enough irrigation to form a hole onto the fractured screw. Insert Tap Drill to the hole and turn it counter clockwise to remove the fractured screw (Recommended Speed: under 80 RPM.)
- Guide Holder is used to fix the Drill Guide to the fixture in order to avoid too much movement of Remover, Reverse and/or Tap Drills while drilling.
 - Drill Guide is used with Guide Holder to avoid too much movement of Remover, Reverse and/or Tap Drills while drilling.
 - Turning Handle (TH-01) is used to drill manually.
 - Flat Tip Driver is used to remove the fractured screw in case of fractured one-piece implant or damaged hex of abutment. **Before place and turn Flat Tip Driver counterclockwise to remove the screw, form a slot using a bur.*

STORAGE AND TRANSPORTATION CONDITIONS

The device should be kept during storage and transportation at room temperature in dry place. Keep the device out of direct sunlight and avoid heavy materials placing on the device.

WARNING

- For efficient and safe use of this device, the surgeon should be sufficiently trained and have enough experience in surgical operation technique related to these instruments.
- The surgeon is responsible for making reasonable judgement on deciding which instrument and surgical technique to use for a special purpose considering condition of individual patient.

CAUTIONS

- The surgeon should be well acquainted with suitable precautions against problems that may occur during an operation.
- Excessive drilling can cause injury during surgical operation.

PRECAUTIONS

- The surgeon should inform the patient of the risks associated with surgery.
- Inspect each device to ensure they are not damaged.
- All instruments must be sterilized prior to use.
- The device should be used by sufficiently trained surgeon.
- The device should not be modified or used against the [Indications for Use] stated in this document.

POSSIBLE ADVERSE EFFECTS

Allergy to metallic material, inflammation and/or infection caused by carelessness.

CONTRAINDICATION

- Do not use for the patients with active or suspected infection, immune deficiency history, steroid treatment, bleeding disorder, endocrine diseases, osteomyelitis or other acute diseases and the patients receiving radiation therapy on the cranium or having gingival diseases or severe oral hygiene problems unless the surgeon make reasonable judgement that the surgery with the device is safe for the patients under appropriate control.
- Do not use for any patient who is not suitable for surgery including the patients with allergy to metallic material.

CLEANING & STERILIZATION

The subject devices, surgical instruments, are reusable after cleaning and sterilizing. They must be cleaned before reuse. Following these recommended instructions for cleaning.

1) Cleaning:

- ① Disassemble the device where possible.
- ② Remove body fluids or blood with flowing water.
- ③ Cleanse the device thoroughly using suitable brushes in flowing water until foreign

substances are removed. (do not use metal brushes or steel wool).

④ Cleanse the device with surgical instrument cleaner according to the instructions provided by the manufacturer of the cleaner.

⑤ Rinse the device in flowing water or distilled water for 20 seconds three times.

⑥ Air-dry or wipe the device with clean cloth and alcohol to prevent from water spot.

2) Pre-Cleaning:

① Follow the same instructions from ④ to ⑥ of Cleaning.

3) Sterilization:

Dental Surgical Instruments is supplied NON-STERILE.

They must be sterilized by the end user after and prior to use.

Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps or pouches) should be used.












MATERIAL

Stainless Steel, Tungsten Carbide, Silicone ring, Plastic Box.

PACKAGING

The device is packaged in KIT.

Ref: SD-FSR

Consult instructions for use		Manufacturer	
Caution		Reference / Article number	
Non-sterile product		Batch Code	
Temperature limitation		Date of manufacture	
Keep away from rain		Symbol for "Use by Prescription only"	
Keep away from sunlight			

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.