Rev.2 08/2015-E

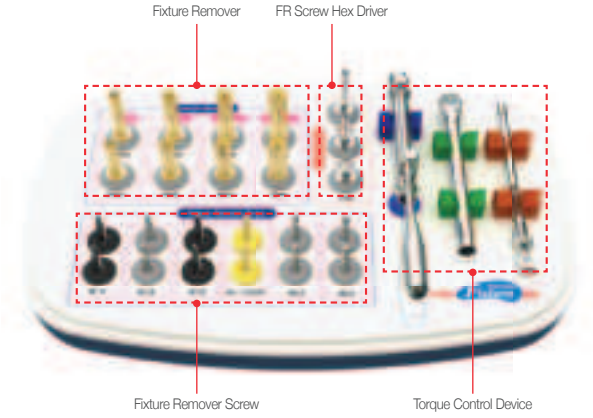
Neo FR Kit
User Guide

DENTAL

Neo Biotech
Satisfaction to Dentists

Product description

This product is a fixture remover kit consisting of dental implant surgical tools (drills, surgical tools, drivers) manufactured from medical device materials such as stainless steel.



Intended use

This product is a surgical tool designed to remove implants that were stopped during the implantation due to excessive torque or implants whose surrounding bones have been damaged. After removing the implant, a new implant with the same diameter can be immediately implanted.

Preservation

Store at room temperature in a dry location away from direct light.

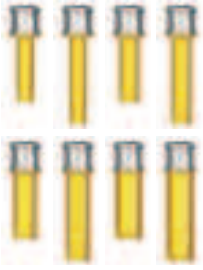
How to Prepare Before Use

1. Prior to using this product, the clinician must completely understand the condition, performance, and function of the product.
2. Use only after raising any doubts and verifying any issues with the manufacturer.
3. For the procedure, a plan must be first established, based on checking the patient's oral condition and accurate judgments.
4. After taking into consideration the condition of the patient, tools appropriate for the procedure must be prepared.

Components

1 Fixture Remover

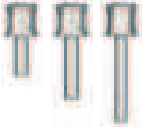
This is used in combination with a fixture remover screw, and is used to remove the implant by directly applying removing torque



	Product Name	Length
Narrow	FR315	15mm
	FR320	20mm
Regular	FR415	15mm
	FR420	20mm
Wide (Ø5)	FR515	15mm
	FR520	20mm
Wide (Ø6~8)	FR615	15mm
	FR620	20mm

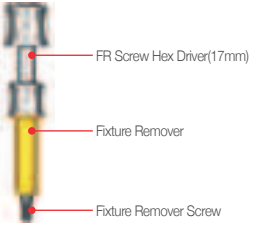
2 FR Screw Hex Driver

This is used when the fixture remover screw needs to be affixed to, or removed from, the implant.



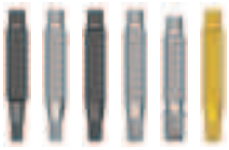
Product Name	Length
HDF1607	7mm
HDF1612	12mm
HDF1617	17mm

<HDF1617 is used when removing the FR screw from the fixture remover>



3 Fixture Remover Screw

This is connected to the screw hole inside the implant to be removed. It is connected to the implant and the fixture remover to allow the implant to be removed.



Product Name	Screw size
FRS14	M1.4
FRS16	M1.6
FRS18	M1.8
FRS172	1-72UNF
FRS20	M2.0
FRS25	M2.5

* "M" means a metric screw, and the number stands for the size of the external diameter of the screw

4 Torque Control Device

This can be used by connecting the fixture remover or the FR screw hex driver. It is used to apply to, or measure from, the connected surgical tool an exact amount of torque.

Product Name	Screw size
TW80400	80Ncm/400Ncm

Instruction for use

1. Before using the surgical tool, sterilize and disinfect the components based on our recommended steam sterilization conditions.
2. Completely remove the prosthesis connected to the implant that needs to be removed.
3. After selecting the fixture remover screw that is the appropriate size for the size of the screw hole inside the implant that needs to be removed, connect it to the FR screw hex driver and apply a torque of 40~80Ncm to the implant. (Figures 1, 2)

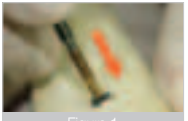


Figure 1

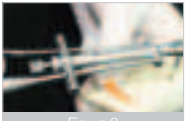


Figure 2

* Recommended tightening torque according to the Fixture remover screw size is as follows

<Fixture remover screw Guide Torque>

Screw	Spec.	Recommended Torque (Ncm)	Screw	Spec.	Recommended Torque (Ncm)
FRS14	M1.4	60	FRS172	1-72UNF	80
FRS16	M1.6	80	FRS20	M2.0	80
FRS18	M1.8	80	FRS25	M2.5	80

4 Rotate the fixture remover connected to the fixture remover screw attached to the implant in a counterclockwise direction as far as possible then, using the torque control device, apply torque in the removal direction (counterclockwise) until the implant rotates. (Figures 3, 4)


Figure 3

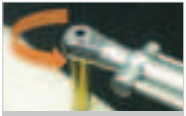


Figure 4

* The maximum torque based on the fixture size is as follows

<Fixture removing torque>

Fixture Size	Remover	Screw	Maximum Torque(Ncm)
Narrow	FR315 or FR320	FRS14	200
		FRS16	250
		FRS18 / FRS172	300
		FRS20	350
Regular	FR315 or FR320	FRS18 / FRS172	300
		FRS20	350
	FR415 or FR420	FRS18 / FRS172	300
		FRS20	350
Wide (Ø5)	FR415 or FR420	FRS20	350
		FRS25	400
	FR515 or FR520	FRS20	350
		FRS25	400
Wide (Ø6~8)	FR515 or FR520	FRS20	350
		FRS25	400
	FR615 or FR620	FRS20	350
		FRS25	400

5 Optional procedure

If the implant cannot be removed even after the fixture removing torque has been applied, remove the fixture remover from the implant and, using the round bur, remove a minimum amount of the bone surrounding the upper part of the implant. Then retry the step "number 4." **(Figures 5, 6)**


Figure 5


Figure 6

6 Attach a vise to the lower part of the removed implant (Figure 7). After connecting the torque control device to the fixture remover, rotate clockwise in order to separate from the implant. **(Figures 8, 9)**

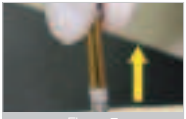


Figure 7

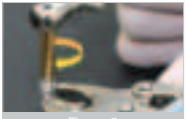


Figure 8

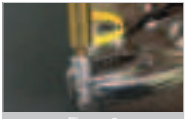


Figure 9

Separate all of the fixture remover screws connected to the removed implant by rotating them counterclockwise, using the FR screw hex driver. **(Figures 10, 11)**

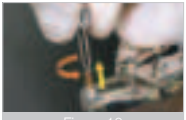


Figure 10

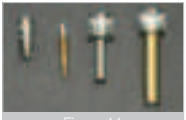
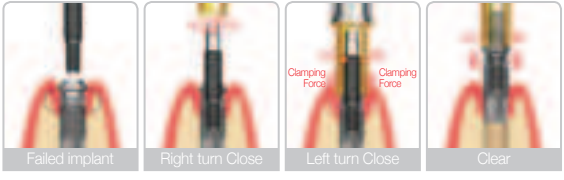


Figure 11

<Fixture removing mimetic diagram>



Failed implant | Right turn Close | Left turn Close | Clear

Precaution for use

1. The product must be used only after the user becomes completely familiar with the proper methods of use.
2. When selecting the size of the fixture remover screw, the precise size of the screw hole inside the implant that needs to be removed must be verified. If not, incomplete fixation of the fixture remover screw to the implant may cause the screw to become damaged or fractured before the implant can be removed
   (If a fixture remover screw is used that is too small for the size of the screw hole inside the implant, connection can be forced. Accordingly, when the proper size is unknown, start from the largest size fixture remover screw and go down until the proper size fixture remover screw to connect is selected.)
3. When selecting the size of the fixture remover, it is recommended that a size bigger than the diameter of the upper part of the implant be selected. If a smaller size is used, it may not be able to properly receive the removing torque, making it difficult to remove the implant.
4. When affixing the fixture remover screw, it must be affixed using the recommended amount of torque. If not, the fixture remover screw may fracture, bend, or it may simply rotate between the implant and the fixture remover.
5. A fixture remover screw and fixture remover must be used one time only as the fixture remover screw and fixture remover may bend or fracture if reused. Accordingly, reuse is prohibited.
6. When the maximum removing torque is exceeded in the course of using the fixture remover, there is a risk that the surgical tool will be damaged, or the implant will be shattered or bone fractured. Accordingly, caution should be taken not to exceed the maximum removing torque.
7. If 60 Ncm or a higher amount of torque is applied when removing the implant, the implant must be removed with adequate irrigation in order to prevent any overheating.
8. When using the torque control device together with surgical tools, if torque is applied before they are completely connected, the product performance may be reduced or the product may be damaged. Accordingly, use only after they are properly connected.
   (Such as a fixture remover, or FR Screw hex driver)

How to Sterilize

1. Because the product is a non-sterilized medical device, select either a pre-vacuum or a gravity autoclave. (Plastic products must not be sterilized at or above 170°C (338°F)
2. Before sterilization, the inner wrapper must be removed from the tray. Assembled components must be separated in order to improve the efficiency of sterilization.

3. Using surgical wrap, wrap the tray, seal with autoclave tape, and sterilize.

<Recommended Steam Sterilization Conditions >

	Cycle Type	Temperature	Pressure	Exposure Time	Dry Time
KIT, Instrument	Pre-vacuum[1][2]	132 °C	2 bars	3 minutes	30 minutes
		270 °F	28.5 psi		
KIT, Instrument	Gravity[1]	121 °C	1 bars	40 minutes	30 minutes
		250 °F	14.5 psi		

In order to effectively carry out high-pressure steam sterilization, the use of biological indicators at a regular interval must be considered. (Dry heat sterilization or chemical sterilization is not recommended.)

① Minimum time and temperature conditions for steam sterilization to reach the sterilization guarantee level of 10^{-6}

② If regional or national sterilization requirements are stricter than the conditions provided above, they must be followed.

If the above sterilization conditions are exceeded, it is possible that the plastic and components may be damaged. The sterilization device must be adjusted to ensure that the recommended temperatures are not exceeded.

How to Wash after Use

Surgical Tools

1. After the procedure ends, detach all surgical tools from the tray, soak them in alcohol, and rinse them using conventional means.
2. After washing by using distilled water or flowing water and rinsing, remove any traces of blood or foreign objects remaining. Use a syringe or pipe cleaner for areas that are difficult to wash.
3. Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using tap water and, after ten minutes of ultrasound washing, rinse using tap water for three minutes.
4. Completely remove the moisture using a dry cloth or a warm-air circulator.

KIT Tray

1. Remove all visible foreign objects using distilled water or flowing water and a soft brush. For areas that are difficult to clean, use a syringe or pipe cleaner.
2. Following the instructions of the cleaner manufacturer, dilute the enzyme cleaner using tap water and soak for one minute. Afterwards, using a soft brush, remove any foreign objects remaining on any part.
3. After washing, rinse for three minutes using tap water to remove the remaining enzyme cleaner.
4. Completely remove the moisture using a dry cloth or a warm-air circulator.
5. Organize the dry surgical tools in the kit case and sterilize, following the sterilization procedure. (At this time, refer to the colors to make the setup easy.)

How to Store and Maintain after Use

1. All surgical tools that were used must be immediately detached, washed, and dried, after the procedure, then stored at room temperature.
2. Do not store in a soiled area or where there is a risk of infection.
3. This product is a non-sterilized medical device. Accordingly, it may be used only after sterilizing in an autoclave before and after any procedure. (See How to Sterilize)

Precaution

1. Only dentists who have completed implant procedure education and training courses can use this product.
2. For each patient, a procedure plan must be established, based on a treatment plan after testing and analyzing for whole-body ailments, infectious disease, whether they are receiving treatment for other ailments, and whether there is any oral lesion.
3. The surgeon must use the product only after becoming completely familiar with how to use the product and the relevant warnings, and must select products that fit the treatment plan.
4. Before each procedure, the tools must be examined for wear and tear.
5. Any external contact with the surfaces is prohibited.
6. Improper selection of the patient or procedure may cause failure of the implant or post-surgical bone loss around the implant.
7. Hydrogen peroxide is prohibited for disinfection and washing, as it could damage or discolor the TIN coating, laser markings, or colors.

Contraindication

1. Patients with serious internal ailments: endocrinal ailments such as diabetes or hypertension, circulatory ailments, and ailments related to the blood, organ, or immune systems.
2. Patients receiving high-level radiation treatment for malignant tumors or other reasons.
3. Patients who have unsuitable jaw relations or problematic occlusions.
4. Patients with dry mouths.
5. Patients with unrestored teeth who maintain bad oral health conditions.
6. Patients with acute inflammatory ailments and patients who are at risk of infection.
7. Pregnant patients.
8. Smokers.
9. Patients with blood clotting conditions or with severe cardiac ailments.
10. Children aged 16 years or younger.
11. Patients who are allergic to titanium or stainless steel.
12. Patients without ordinary wound-healing function.

13. Patients who are taking other drugs.
14. Patients who are vulnerable to physical and mental stress due to temporary use of a specific medication.
15. Patients who are emotionally unstable, such as due to alcohol addition, drug abuse, neurological ailments, or mental ailments.
16. Patients who have unrealistic expectations regarding the treatment.

Side effect

1. Using surgical techniques in a skillful manner minimizes the occurrence of complications.
2. Paresthesia due to nerve damage or malocclusion, infection, edema, hypodermic bleeding, pain, or opening of the sutures, ulcer in the soft tissues, and other localized adverse reactions may occur.
3. Localized and general allergic reactions.

Label Symbols

Symbol	Definition	Symbol	Definition
REF	Catalog Number	CONSULT INSTRUCTIONS FOR USE	Consult instruction for use
LOT	Batch Code	STERILE R STERILIZED USING IRRADIATION	Sterilized Using irradiation
	Date of manufacture	Rx only Prescription only	Prescription Only
	Manufacturer	DO NOT REUSE	Do not re-use
CAUTION, CONSULT ACCOMPANYING DOCUMENTS	Caution, consult accompanying documents	DO NOT USE IF PACKAGE IS DAMAGED	Do not use if package is damaged
NON STERILE	Non-Sterile		

* This product is a non-sterilized medical device.

Compatibility List for FR Kit

2010.12.03

Corporation	Implant System	Implant Diameter	Internal Thread Size	Solution Kit Compatibility	Note
Nobel Biocare	Branemark System MK III Groovy NP Ø3.3mm		M1.6x0.35P	YES	
	Branemark System MK III Groovy RP Ø3.75mm		M2.0x0.4P	YES	
	Branemark System MK III Groovy RP Ø4.0mm		M2.0x0.4P	YES	
	Branemark System MK III Groovy WP Ø5.0mm		M2.5x0.45P	YES	
	NobelSpeedy System MK III Groovy NP Ø3.3mm		M1.6x0.35P	YES	
	NobelSpeedy System MK III Groovy RP Ø4.0mm		M2.0x0.4P	YES	
	NobelSpeedy System MK III Groovy WP Ø5.0mm		M2.0x0.4P	YES	
	NobelSpeedy System MK III Groovy WP Ø6.0mm		M2.5x0.45P	YES	
	NobelReplace Straight Groovy NP Ø3.5mm		M1.8x0.35P	YES	
	NobelReplace Straight Groovy RP Ø4.0mm		M2.0x0.4P	YES	
	NobelReplace Straight Groovy WP Ø5.0mm		M2.0x0.4P	YES	
	NobelSpeedy Replace NP Ø3.5mm		M1.8x0.35P	YES	
	NobelSpeedy Replace RP Ø4.0mm		M2.0x0.4P	YES	
	NobelSpeedy Replace WP Ø5.0mm		M2.0x0.4P	YES	
	NobelSpeedy Replace 6.0 Ø6.0mm		M2.0x0.4P	YES	
	NobelReplace Tapered NP Ø3.5mm		M1.8x0.35P	YES	
	NobelReplace Tapered RP Ø4.3mm		M2.0x0.4P	YES	
	NobelReplace Tapered WP Ø5.0mm		M2.0x0.4P	YES	
	NobelReplace Tapered 6.0 Ø6.0mm		M2.0x0.4P	YES	
	NobelActive 3.5 Ø3.5mm		M1.54	SPECIAL ORDER	
Straumann	Standard Ø3.3 RN		M2.0x0.4P	YES	
	Standard Ø4.1 RN		M2.0x0.4P	YES	
	Standard Ø4.8 RN		M2.0x0.4P	YES	
	Standard Ø4.8 WN		M2.0x0.4P	YES	
	Standard Plus Ø3.3 NN		No Inspection	M1.6 or M1.8	verify
	Standard Plus Ø3.3 RN		M2.0x0.4P	YES	
	Standard Plus Ø4.1 RN		M2.0x0.4P	YES	
	Standard Plus Ø4.8 RN		M2.0x0.4P	YES	
	Standard Plus Ø4.8 WN		M2.0x0.4P	YES	
	Tapered Effect Ø3.3 RN		M2.0x0.4P	YES	
	Tapered Effect Ø4.1 RN		M2.0x0.4P	YES	
	Tapered Effect Ø4.8 RN		M2.0x0.4P	YES	
	Bone Level Implant Ø3.3 NC		No Inspection	M1.6 or M1.8	verify
	Bone Level Implant Ø4.1 NC		No Inspection	M1.6 or M1.8	verify
	Bone Level Implant Ø4.8 NC		No Inspection	M1.6 or M1.8	verify
3i Biomet	Certain® Internal Ø3.4		No Inspection	M1.6 or M1.8	verify
	Certain® Internal Ø4.1		No Inspection	M1.6 or M1.8	verify
	Certain® Internal Ø5.0		No Inspection	M1.6 or M1.8	verify
	Certain® Internal Ø6.0		No Inspection	M1.6 or M1.8	verify
	External Ø3.4		M2.0x0.4P	YES	
	External Ø4.1		M2.0x0.4P	YES	
	External Ø5.0		M2.0x0.4P	YES	

Compatibility List for FR Kit

2010.12.03

Corporation	Implant System	Implant Diameter	Internal Thread Size	Solution Kit Compatibility	Note
	External Ø6.0		M2.0x0.4P	YES	
Zimmer (Screw-Vent)	Screw Advent Implant Ø3.3		1-72UNF(M1.854x0.353P)	YES	
	Screw Advent Implant Ø3.7		1-72UNF(M1.854x0.353P)	YES	
	Screw Advent Implant Ø4.7		1-72UNF(M1.854x0.353P)	YES	
	Tapered Screw Advent Implant Ø3.7		1-72UNF(M1.854x0.353P)	YES	
	Tapered Screw Advent Implant Ø4.7		1-72UNF(M1.854x0.353P)	YES	
	Tapered Screw Advent Implant Ø6.0		1-72UNF(M1.854x0.353P)	YES	
	Advent Implant Ø3.7 (Ø4.5 Platform)		1-72UNF(M1.854x0.353P)	YES	
	Advent Implant Ø4.7 (Ø4.5 Platform)		1-72UNF(M1.854x0.353P)	YES	
	Advent Implant Ø4.7 (Ø5.7 Platform)		1-72UNF(M1.854x0.353P)	YES	
Zimmer (Swissplus)	Straight Swissplus Implant Ø4.1		M2.0x0.4P	YES	
	Straight Swissplus Implant Ø4.8		M2.0x0.4P	YES	
	Tapered Swissplus Implant Ø3.7 (Ø3.8 Platform)		1-72UNF(M1.854x0.353P)	YES	
	Tapered Swissplus Implant Ø3.7		M2.0x0.4P	YES	
	Tapered Swissplus Implant Ø4.8		M2.0x0.4P	YES	
Zimmer(Spline)	Spline Twist Implants 3.75mmD		1-72UNF(M1.854x0.353P)	YES	
	Spline Twist Implants 5.0mmD		1-72UNF(M1.854x0.353P)	YES	
	Spline Reliance Cylinder Implants 3.25mmD		No Inspection		
	Spline Reliance Cylinder Implants 4.0mmD		1-72UNF(M1.854x0.353P)	YES	
	Spline Reliance Cylinder Implants 5.0mmD		1-72UNF(M1.854x0.353P)	YES	
Astra	OsseoSpeed 3.0S		M1.4x0.3P	NO	
	OsseoSpeed 3.5S		M1.6x0.35P	YES	
	OsseoSpeed 4.0S		M1.6x0.35P	YES	
	OsseoSpeed 4.5		M2.0x0.4P	YES	
	OsseoSpeed 5.0		M2.0x0.4P	YES	
	OsseoSpeed 5.0S		M2.0x0.4P	YES	
Keyston Dental (Lifecore)	PrimaConnex Internal Connection Tapered Implants Ø3.5		M1.8x0.35P	YES	
	PrimaConnex Internal Connection Tapered Implants Ø4.1		M1.8x0.35P	YES	
	PrimaConnex Internal Connection Tapered Implants Ø5.0		M1.8x0.35P	YES	
	PrimaConnex Internal Connection Straight Implants Ø3.3		M1.8x0.35P	YES	
	PrimaConnex Internal Connection Straight Implants Ø4.0		M1.8x0.35P	YES	
	PrimaConnex Internal Connection Straight Implants Ø5.0		M1.8x0.35P	YES	
	RENOVA RBM Tapered Implants Ø3.75		M1.8x0.35P	YES	
	RENOVA RBM Tapered Implants Ø4.5/4.75		M1.8x0.35P	YES	
	RENOVA RBM Straight Implants Ø3.75		M1.8x0.35P	YES	
	RENOVA RBM Straight Implants Ø4.5/4.75		M1.8x0.35P	YES	
	RESTORE Small Diameter Ø3.3		1-72UNF(M1.854x0.353P)	YES	
	RESTORE Regular Diameter Ø3.75 & Ø4.0		M2.0x0.4P	YES	
	RESTORE Small Diameter Wide Diameter Ø5.0 & Ø6.0		M2.5x0.45P	YES	
	STAGE-1 system Ø3.3 (RDS)		M2.0x0.4P	YES	
	STAGE-1 system Ø4.1 (RDS)		M2.0x0.4P	YES	

Compatibility List for FR Kit

2010.12.03

Corporation	Implant System	Implant Diameter	Internal Thread Size	Solution Kit Compatibility	Note
	STAGE-1 system Ø4.8 (RDS)		M2.0x0.4P	YES	
	STAGE-1 system Ø4.8 (WDS)		M2.0x0.4P	YES	
	STAGE-1 system Ø5.5 (WDS)		M2.0x0.4P	YES	
	STAGE-1 system Ø6.3 (WDS)		M2.0x0.4P	YES	
MIS	MISTRAL Internal Octagon System Ø3.75		M2.0x0.4P	YES	
	MISTRAL Internal Octagon System Ø4.1		M2.0x0.4P	YES	
	MISTRAL Internal Octagon System Ø4.8		M2.0x0.4P	YES	
	Mis Biocom Internal Ø3.3		1-72UNF(M1.854x0.353P)		
	Mis Biocom Internal Ø3.75		1-72UNF(M1.854x0.353P)		
	Mis Biocom Internal Ø4.2		1-72UNF(M1.854x0.353P)		
	Mis Biocom Internal Ø5.0		1-72UNF(M1.854x0.353P)		
	Mis Biocom Internal Ø6.0		1-72UNF(M1.854x0.353P)		
	Mis Seven Internal Ø3.75		1-72UNF(M1.854x0.353P)		
	Mis Seven Internal Ø4.2		1-72UNF(M1.854x0.353P)		
	Mis Seven Internal Ø5.0		1-72UNF(M1.854x0.353P)		
	Mis Seven Internal Ø6.0		1-72UNF(M1.854x0.353P)		
	Mis Lance Internal Ø3.75		1-72UNF(M1.854x0.353P)		
	Mis Lance Internal Ø4.2		1-72UNF(M1.854x0.353P)		
	Mis Lance Internal Ø5.0		1-72UNF(M1.854x0.353P)		
Dentsply	Ankylos internal Ø3.5		M1.8x0.35P	YES	
	Ankylos internal Ø4.5		M1.8x0.35P	YES	
	Ankylos internal Ø5.5		M1.8x0.35P	YES	
	Ankylos internal Ø7.0		M1.8x0.35P	YES	
	Xive S internal Implant Ø3.0		M1.6x0.35P	YES	
	Xive S internal Implant Ø3.4		M1.6x0.35P	YES	
	Xive S internal Implant Ø3.8		M1.6x0.35P	YES	
	Xive S internal Implant Ø4.5		M1.6x0.35P	YES	
	Xive S internal Implant Ø5.5		M1.6x0.35P	YES	
	Xive TG External Implant Ø3.4		No Inspection	NO (M1.4x0.3P)	verify
	Xive TG External Implant Ø3.8		No Inspection	NO (M1.4x0.3P)	verify
	Xive TG External Implant Ø4.5		No Inspection	NO (M1.4x0.3P)	verify
	Frialit Internal Implant Ø3.4		M1.6x0.35P	YES	
	Frialit Internal Implant Ø3.8		M1.6x0.35P	YES	
	Frialit Internal Implant Ø4.5		M1.6x0.35P	YES	
	Frialit Internal Implant Ø5.5		M1.6x0.35P	YES	
	Frialit Internal Implant Ø6.5		M1.6x0.35P	YES	
CAMLOG	CAMLOG Root Line Ø3.8		M1.6x0.35P	YES	
	CAMLOG Root Line Ø4.3		M1.6x0.35P	YES	
	CAMLOG Root Line Ø5.0		M2.0x0.4P	YES	
	CAMLOG Root Line Ø6.0		M2.0x0.4P	YES	
	Maestro External implants Ø3.5		No Inspection		

Compatibility List for FR Kit

2010.12.03

Corporation	Implant System	Implant Diameter	Internal Thread Size	Solution Kit Compatibility	Note
Biohorizons	Maestro External implants Ø4.0		M2.0x0.4P		
	Maestro External implants Ø5.0		M2.0x0.4P		
	Maestro External implants Ø6.0		M2.0x0.4P		
	Biohorizons Internal Ø3.5		No Inspection	1-72UNF(M1.854x0.353P)	verify
	Biohorizons Internal Ø4.0		No Inspection	1-72UNF(M1.854x0.353P)	verify
	Biohorizons Internal Ø5.7		No Inspection	1-72UNF(M1.854x0.353P)	verify
SPI Implant	SPI Internal Implant Ø3.5		M1.4x0.3P	No	
	SPI Internal Implant Ø4.5		M1.6x0.35P	YES	
	SPI Internal Implant Ø5.0		M1.6x0.35P	YES	
	SPI Internal Implant Ø6.0		M1.6x0.35P	YES	

Remover
Fixture

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Satisfaction to Dentists

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