

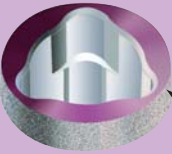
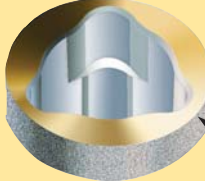
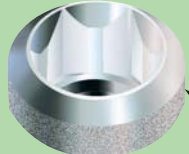
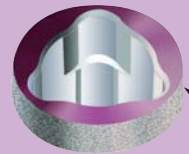
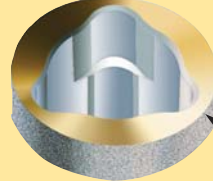
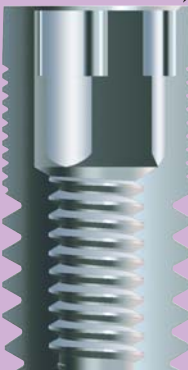
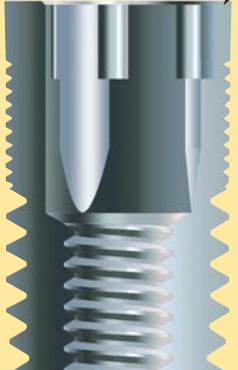

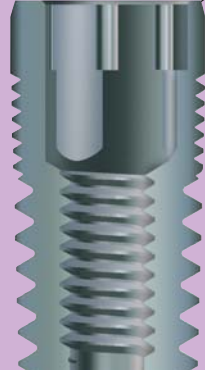

**Implant Direct Receives FDA Marketing Approval to Claim Surgical Compatibility**  
 Implant Direct's 510(k) Approved Submission States: "The Spectra-System consists of seven implants with external thread configurations consisting of double lead threads over the body of the implant and 2mm-2.5mm of quadruple lead mini-threads near the coronal portion of the implant. ... The seventh implant of the Spectra-System, the RePlant, matches the tapered body dimensions and tri-lobe platform of the Nobel Biocare Replace Tapered implants and therefore can be inserted utilizing Nobel Biocare drills."

**WARNING of Potential Fracture of 3.5mmD RePlant Implants Because of Thin Walls**  
**Nobel Replace Drilling Protocol for Dense Bone specifies use of their Bone Tap for the 8mm and 10mm Length Implants and their Dense Bone Drills for the 13mm and 16mm Implants**

The RePlant Implant outside diameter and internal tri-lobe dimensions match the Nobel Tapered Replace Implants, and as a result, share the inherent design weakness of that implant, with the walls only being 0.009" thick at the tops of the tri-lobes. The thinnest part of the walls of the 4.3mmD RePlant are also relatively thin, being only 0.012". Although the RePlant is made of Titanium Alloy, which adds about 20% to the strength of each implant, there is still a risk of implant fracture when inserting RePlant implants using Nobel Replace surgical instruments, including those recommended for dense bone. Nobel's dense bone surgical protocol recommends use of the bone tap for 8mm and 10mm length implants and use of their dense bone drills (slightly wider diameter) for the 13mm and 16mm Tapered Replace Implants. The threads of the RePlant implant are designed for self-tapping insertion, having a vertical cutting groove extending half way up the length of the implant. Even considering the increased strength compared to the Nobel Replace implant, and the improved thread design, the risk of fracture of a 3.5mmD and 4.3mmD RePlant implant still exists in very dense bone. This risk can be eliminated, and initial stability optimized for all qualities of bone by adhering to the following surgical protocols for soft, medium and dense bone. It should be noted that although the design of the RePlant threads do not match that of the Replace implant, use of Nobel RePlace bone taps in dense bone, as specified by Nobel for insertion of the 8mm and 10mm Tapered Replace implants, will slightly expand the socket and reduce the amount of bone that the self-tapping RePlant needs to cut through, thereby reducing the insertion torque compared to insertion in an untapped socket.



**Implant Direct's Surgical Protocol for insertion of RePlant Implants with NobelReplace Instruments:**

- TYPE 4 BONE:** In soft bone, only enlarge the socket using Nobel's recommended intermediate drill for the specific diameter implant, followed by self-tapping insertion using the RePlant Aluminum Fixture-mount to protect the implant.
- TYPE 2-3 BONE:** In medium density bone, enlarge the socket using the recommended final drill for the specific diameter implant, followed by self-tapping insertion using the RePlant Aluminum Fixture-mount to protect the implant.
- TYPE 1 BONE:** Use NobelReplace's dense bone surgical protocol. **Optional Protocol:** Insert RePlant self-tapping using the RePlant Aluminum Fixture-mount as a safety gauge. If it strips, unscrew the implant using NobelReplace insertion tools, resize the socket using NobelReplace's dense bone surgical protocol and re-insert the RePlant Implant.

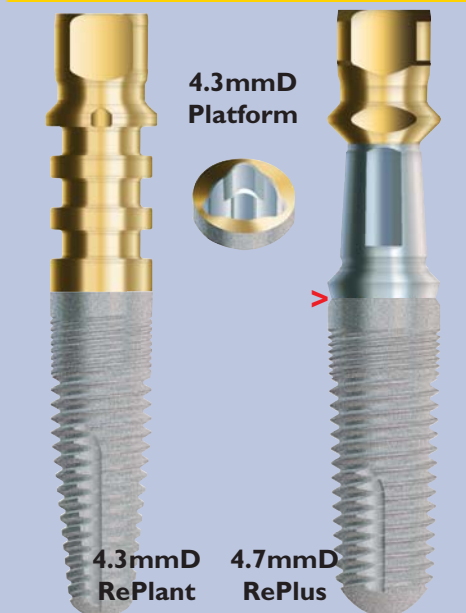
3.5mmD Platform	4.3mmD Platform	3.7mmD Platform	3.5mmD Platform	4.3mmD Platform
				
Wall Thickness 0.009"	Wall Thickness 0.012"	Wall Thickness 0.018"	Wall Thickness 0.013"	Wall Thickness 0.020"
				
Replace/RePlant 3.5D	Replace/RePlant 4.3D	ScrewPlant 3.7D	RePlus 3.7D	RePlus 4.7D

## RePlant, RePlus and ScrewPlant Implants from Implant Direct Made from Titanium Alloy for Increased Strength/ Designed for Self-tapping Insertion

Implant Direct's 3.5mmD RePlant Implant requires about 20% more force (12.88in/lbs vs. 10.90in/lbs) to fracture compared to Nobel Biocare's 3.5mmD Replace Tapered Groovy Implant. The difference is due strictly to the use of stronger Medical Grade Titanium Alloy compared to CP Titanium.. RePlant and Replace implants have the same dimensions with the 3.5mmD implants having a wall thickness of only 0.009" (thickness of two human hairs) and the 4.3mmD implants having a wall thickness of only 0.012". Nobel's TiUnite surface will not form on the Alloy, thus necessitating the use of the weaker CP Titanium but Nobel uses Ti Alloy for it's HA coated Replace Implants. Implant Direct's RePlus Implants match the platforms of the 3.5mmD, 4.3mmD and 5.0mmD RePlant and Replace implants but have the same outside diameters and evenly tapered body design of the ScrewPlant and other Spectra-System implants. This improved design allows for insertion in an undersized socket in soft bone for increased stability. The top 0.3mm of each RePlus implant tapers in to the smaller diameter 3.5mmD, 4.3mmD and 5.0mmD platforms. The wider diameters provide increased strength and the transition to the narrower platform creates room for thicker soft tissue considered by some to be an advantage in the esthetic zone.

 Replace CP Ti 0.009" Wall	IMPLANT	Wall Thickness	Torque in/lbs	Torque N-Cm	Mode of Failure
		3.5mmD Replace	0.009"	10.90	123.20
	3.5mmD RePlant	0.009"	12.88	145.50	Implant Fractured
 RePlus Ti Alloy 0.013" Wall	RePlant 3.5mm Al. Fixture-mount Strips to Protect Implant		5.85	66.1	Tri-lobe Stripped
	3.7mmD RePlus	0.013"	15.75	178.00	Implant Fractured
	3.7mmD Screw Plant	0.018"	16.03	181.10	Hex Stripped

### The Even Taper of the RePlus Implant along with the use of Straight Drills allows a Soft-bone/Hard-bone Surgical Protocol that Provides Greater Initial Stability in Soft Bone



Surgical Protocol for RePlant - insert Self-tapping using Aluminum Fixture-mount			
Implant Size and Type	Test Media Balsa or Oak	Socket Preparation	Insertion Torque
Nobel Replace 4.3mmD	Balsa Wood Soft Bone	Nobel 4.3 Drill No Bone Tap	2.25in/lbs 25.4Ncm
Nobel Replace 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill Bone Tap	2.10in/lbs 23.73Ncm
Nobel Replace 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill No Bone Tap	18.65in/lbs 210.7Ncm
ID RePlant 4.3mmD	Balsa Wood Soft Bone	Nobel 3.5 Drill No Bone Tap	3.30in/lbs 37.3Ncm
ID RePlant 4.3mmD	Balsa Wood Soft Bone	Nobel 4.3 Drill No Bone Tap	1.90in/lbs 21.5Ncm
ID RePlant 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill Bone Tap	3.05in/lbs 34.5Ncm
Fixture-Mount 4.3mmD	Test To Failure		10.12in/lbs 114.1Ncm
ID RePlant 4.3mmD	Oak Wood Hard Bone	Nobel 4.3 Drill No Bone Tap	11.81in/lbs 133.5Ncm
ID RePlus 4.7mmD	Balsa Wood Soft Bone	ID 3.8mmD No Bone Tap	3.91in/lbs 44.2Ncm
ID RePlus 4.7mmD	Oak Wood Hard Bone	ID 4.4/3.8mmD No Bone Tap	6.35in/lbs 71.8Ncm

