Limitations of Zimmer Dental’s TM Implant

Zimmer Dental has launched a version of the Screw-Vent® with a porous, non-threaded midsection made of what they call Trabecular Metal, claiming it is “THE BEST THING NEXT TO BONE™.” Zimmer Dental’s marketing claims it is the “first dental implant to offer a mid-section with up to 80% porosity” and reports that “human clinical studies of this Trabecular Metal Dental Implant began in 2010, data collection will continue in the coming years.”

The concept of bone ingrowth with porous surfaces on dental implants is not new. The TPS surface treatments were popular in the 1980’s and 1990’s with Straumann and IMZ implants but soft tissue complications following exposure eventually contributed to their replacement with blasted and etched surfaces.

The now obsolete Innova implant with a beaded, porous surface was first introduced in the 1980’s. In fact, all press-fit implants other than Bicon, have faded from the scene because of the clinical observations that achieving initial stability, critical for osseointegration, is best achieved with implants having threads over the entire length. Optimizing initial stability in soft as well as dense bone allows for immediate loading in not only full arch splinted implants for “Teeth-in-1Day” procedures but also for free-standing single tooth replacements, even in soft bone of the maxilla. This has become a reality by varying the size of the socket depending on the density of the bone, optimizing stability by placing a tapered screw implant into an undersized socket prepared with straight step drills (G. Niznick: Achieving Osseointegration in Soft Bone. Oral Health August 2000). In the last decade, there has been an evolution to further optimize stability by improving thread design and surface area with progressively deeper threads towards the apex and adding micro-threads near the top of the implant. Improving the self-tapping features of implants with long vertical grooves eliminated the need for bone taps when used in conjunction with dense bone drilling procedures. Double-lead threads on the body with quadruple-lead micro-threads with two vertical cutting grooves extending half-way up the implant, were introduced in 2006 by Implant Direct (Niznick Pat. # 7,677,891). Further refinements came in 2008 with the introduction of the ReActive tri-lobe and Legacy3 internal hex implants, adding progressively deeper, flat-based buttress threads. In 2009, the Legacy2 implant was launched with deeper buttress threads, and with three vertical cutting grooves extending 2/3rds the way up from the apex, further facilitating self-tapping insertion. In 2013, Implant Direct will introduce the InterActive Implant with micro-grooves above micro-threads to further optimize surface area and facilitate soft tissue attachment should the top of the implant become exposed. As shown below, not all screw implants are the same.
“Product” section of the Recall Notice cites limitations for use of the 4.1mm TM Implant not required with 4.1mm Screw-Vent Implant:

“The 4.1mmD Trabecular Metal Implants are intended to be splinted to additional implants when used in the posterior region.”

“Reason for Recall” section of the Recall Notice states:

“The Zimmer Dental voluntary device recall resulted from an investigation into the February 2012 complaint involving an apical tip of a 4.1mmD Trabecular Metal Implant which separated from the implant assembly during surgery on a patient with a dense (Type D1) thick, inferior border.”

“Action” section of the Recall Notice states:

“Zimmer sent an Urgent Medical Device notification letter dated April 24, 2012, with an attached Technical Bulletin listing precautions present in the new Information for Use sent to distributors and customers via E-mail and FED EX. Notifications identified the issue and risks found with the device listing responsibilities, precautions and procedural precautions.”

Change in Surgical Protocol in Dense Bone

Zimmer Dental’s added “precautions” to reduce torque on the apical threads during insertion was to recommend use of a 3.8mmD straight drill as a final drill in dense bone for the 4.1mmD TM Implant rather than the 3.8/3.4mmD step drill originally recommended for both the 4.1mmD TM Implant and Tapered Screw-Vent. In contrast to the straight drill, the step drill design creates a smaller diameter in the apical section of the osteotomy to allow thread for the tapered threaded apex of both implants (shown below by overlaying a 3.8mm straight drill over the tapered body of the 4.1mm Tapered Screw-Vent). Given that the TM Implant lacks the threads of the Screw-Vent, over-sizing the apical area of the socket to minimize or eliminate torque on the apical threads during insertion could further compromise initial stability critical for osseointegration and essential for immediate loading. Dentists may not be able to determine from the resistance they encounter during drilling that the dense bone protocol should be followed.