ULTRATOOTH
by BIODENT



ULTRATOOTH BY BIODENT

The Ultratooth *Handbook*

Ultratooth Training & Catalogue

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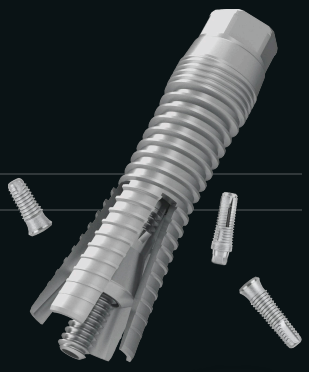
01

Introduction



01

Immediate Loading in Full Functional

Ultratooth is the only implantable dental device that has been cleared by the US FDA for immediate loading in full function at the time of placement, since 1994.

02

Preserves Original Emergence Profile

Ultratooth preserves the original emergence profile of the tooth, which is essential in the esthetic zone.

03

Prevents Coronal Bone Loss

Due to the Eiffel Tower design, the coronal bone loss typically seen in screws of cylindrical type implants does not occur. Thus, being able to maintain the original emergence profile over time.

04

Increase Bone Density

Histological studies show bone density and quality improves due to the compaction of the surrounding bone when expansion occurs (“Oscillating Effect”).

05

Greater Surface Area

The surface area of an Ultratooth is 30% more than a typical equal size screw implant due to the integration of the internal sides of its pods.

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01 — INTRODUCTION

Welcome letter from the Inventor



SARGON LAZAROF D.D.S.
INVENTOR OF THE ULTRATOOTH TECHNOLOGY

We appreciate your interest in this new major advancement in dental implantology. We believe that restorations on implants can, and should be, fabricated with virtually the same methods taught in dental schools for fixed restorations on natural tooth abutments. It should be noted that the traditional definition of “abutment” has been the “prepared tooth” (“prep”) that anchored or held the restoration (retainer) in the case of a fixed partial denture (“bridge”).

In the past, the word “abutment” as it pertained to implantology, described many machined components of varying shapes and sizes that rarely resembled, nor functioned like, a traditional “prep”. Often, dentists and dental technicians became overwhelmed by all these component parts that appeared so different from our traditional restorative techniques and esthetic standards.

The Ultratooth system utilizes restorative techniques that are already familiar to all dentists. We use a minimum number of components with which the doctor and laboratory can design and fabricate custom anatomical abutments or “preps,” both for provisionalization and for final restorations. We have all but eliminated the need for soft tissue retraction in most impressions where subgingival restoration margins are necessary. The Ultratooth is designed with a proprietary external hex morse taper which makes abutment and screw loosening or fractures a thing of the past. By using this system, a dentist can confidently do a cement restoration and not worry about retrievability for screw loosening or fractures.

All our products are manufactured in the United States under the highest quality FDA standards and the most modern methods for manufacturing precision tolerance surgical devices and instrumentation. Compliance to the strict guidelines of the Good Manufacturing Practices of the FDA is continuously being adhered to by our operations staff.

As you become familiar with the significant advantages of the Ultratooth system, you will see the added benefits you can bring to your patients. We will be here supporting you and your staff in a harmonious, friendly manner.

Ultratooth welcomes the opportunity to bring you into this new dimension of treatment capability.



Sargon Lazarof D.D.S.

INVENTOR OF THE ULTRATOOTH TECHNOLOGY

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01 — INTRODUCTION

Technical Specifications



STANDARD

3.8 mm BODY DIAMETER

PRODUCT CATALOG NUMBER	IMPLANT BODY LENGTH	IMPLANT COLLAR DIAMETER	IMPLANT BODY DIAMETER	IMPLANT ABUTMENT LENGTH	IMPLANT COLLAR LENGTH
3910UT	10 mm	4.14 mm	3.8 mm	3 mm	1.3 mm
3913UT	13 mm	4.14 mm	3.8 mm	3 mm	1.3 mm
3916UT	16 mm	4.14 mm	3.8 mm	3 mm	1.3 mm

NOTE

ULTRATOOTH implants are precision machined from Titanium Alloy (Ti 6Al 4V), surface blasted with aluminum oxide, and acid etched.



WIDE

4.8 mm BODY DIAMETER

PRODUCT CATALOG NUMBER	IMPLANT BODY LENGTH	IMPLANT COLLAR DIAMETER	IMPLANT BODY DIAMETER	IMPLANT ABUTMENT LENGTH	IMPLANT COLLAR LENGTH
3910UTW	10 mm	5.14 mm	4.8 mm	3 mm	1.3 mm
3913UTW	13 mm	5.14 mm	4.8 mm	3 mm	1.3 mm
3916UTW	16 mm	5.14 mm	4.8 mm	3 mm	1.3 mm

NOTE

The Ultratooth expands 1.5 mm on all sides at full expansion.

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02 — DIAGNOSIS & TREATMENT PLANNING

02

Patient Selection & Evaluation

> Patient evaluation and selection prior to implant surgery is perhaps the most important aspect of implant treatment. If the patient has not had a physical evaluation within two years, a complete medical evaluation is recommended. Additionally, a comprehensive health questionnaire should be completed by the patient and reviewed by the practitioner. It is recommended that the pre-surgical patient evaluation include:

01 A determination of general and oral health, including an oral hygiene evaluation of the patient's past habits and current clinical status should be made. A clinical assessment of oral hygiene history is important not only in determining qualification for dental implants to be used, but the type of prosthetic restoration as well. Habits such as bruxing should be considered during treatment planning as this increases the load on the implants. Existing infectious periodontal problems, abnormal bone conditions, and/or bite registry should be evaluated and corrected either before, or coincident with, implant placement. An oral condition or tendency that could adversely affect natural teeth (including tobacco usage and heavy alcohol consumption) will have a negative effect on implant success, including bone quality and soft tissue effects. An assessment should be made as to whether the patient can physically and psychologically withstand anesthetic, surgical, and postsurgical treatments associated with implant placement. A medication assessment is essential, including the use of aspirin and over-the-counter anti-inflammatory and analgesic drugs. In addition, a history of substance abuse which is often difficult to identify, can pose an enormous problem in treatment. Generally, practitioners should not place implants in these patients. Any of these situations or combinations may contraindicate the use of dental implants.

02 The practitioner should assess the patient's motivation towards good dental implant care. The patient should be encouraged to practice good oral hygiene and be willing to learn and practice the oral hygiene techniques necessary for implant maintenance and subsequent long-term success.

03 Comprehensive oral examination coupled with panoramic and periapical radiographs is essential. This evaluation should determine anatomic landmarks, such as the maxillary sinus or mandibular canal, adequacy of bone quality, quantity and anatomy for dental implant placement. The practitioner may also consider one or more of the following diagnostic aids: tomogram, cephalogram, radiographic guide, or a C.T. Scan.

04 Assessment of the patient's diet. Suggestions for dietary supplements several weeks prior to implant placement may be required.

05 Diagnostic casts for evaluation of occlusion and mandibular movements. Record as necessary on quality articulating equipment.

06 Diagnostic wax-ups, try-ins, and surgical guides to assist accurate placement of implants relative to the desired prosthetic goal and anatomic limitations.

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Indications

The Ultratooth is designed for use in either partially or fully edentulous mandibles and maxillae, as a final or intermediary abutment(s) or fixed or detachable prosthesis, and for use in support of free-standing restorations with or without the involvement of adjacent dentition.

Contraindications

GENERAL MEDICAL CONTRAINDICATIONS:

Customary general contraindications associated with elective surgery should be observed. These include, but are not limited to: significant vascular impairment to the implant site; metabolic bone disease; clotting disorders; current treatment with therapeutic agents that may have an effect on the surgical site, surrounding tissue, or normal healing responses (i.e. drug therapy or substance abuse, chemotherapy, radiation therapy, chronic steroid treatment, anticoagulant therapy); or other metabolic or physical disorders that interfere with bone growth, maintenance or wound healing.

POSSIBLE CONTRAINDICATIONS:

- Chronic bleeding problems (blood dyscrasias)
- Certain cardiac and vascular diseases
- Chronic renal disease
- Treatment with corticosteroids
- Treatment with chemotherapeutic agents
- Metabolic bone or connective tissue diseases
- Diabetes (uncontrolled)
- Psychological impairment
- Bruxing/abnormal clenching
- Tobacco usage
- Poor patient oral hygiene
- Patients taking osteoporosis medication (ex. Fosamax, Boniva etc.)
- Pregnant women (only as an emergency procedure)

TEMPORARY CONTRAINDICATIONS:

- Systemic infections
- Local oral or respiratory infections

ANATOMIC OR PATHOLOGIC CONTRAINDICATIONS:

- Insufficient alveolar bone width and height to surround the implant with at least one millimeter or bone, both buccally and lingually to the most superior cervical aspect of the implant body.
- High mandibular neurovascular canal 2mm proximal to the osteotomy.
- Malignancies
- Adjacent tooth infections

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Warnings

- Age: 18 years or older
- Improper techniques can cause implant failure, loss of bone, and injury to the neurovascular structures.
- No attempt should be made to alter or modify the implant body or threaded area of the abutment. Use only genuine Ultratooth abutments to restore an Ultratooth.
- Biodent implants are intended to be used only with the specifically designed bone drills and surgical instrumentation provided in the Ultratooth Trial Kit and the Universal Kits. Additionally, Ultratooth abutments and prosthetic attachments must be seated completely and radiographs should be taken to verify the seating of all components used in the restoration phase of the implants. Other abutment systems will not fit the Ultratooth Hex.
- Ultratooth implants and instrumentation must not be altered in any way. They are designed for use with the Ultratooth system abutments and attachments supplied only by Biodent Inc. Abutments and attachments supplied by other companies might not be made to the exact specifications and standards of the Ultratooth System, and use of them may lead to implant failure, implant abutment failure, prosthesis failure, and/or loss of bone.
- The use of electro-surgical or laser instruments around metallic implants and their abutments is discouraged due to the electric and/or heat conductivity of the substrate metal.
- Implant mobility, bone loss, or infection may indicate implant failure. Any implant that appears to be failing should be treated as soon as possible. If the removal of the implant is deemed necessary, unscrew the expansion screw (several reverse turns will release the tension on the expansion mechanism), and push down on the expansion screw with the screwdriver to reposition the expansion nut. Then the implant driver should be attached, and the implant unscrewed. The soft tissue should be curetted from the implant site and the site allowed to heal in the same manner as an atraumatic natural tooth extraction. If necessary, bone grafting can be used.
- If the implant becomes contaminated in any way, the implant must not be used. The implant must not ever be cleaned or re-sterilized for use in another patient. Do not attempt to decontaminate the implant by any in-office method.
- Do not allow intra-oral procedures to transmit heat to the implant body and surrounding bone. Ample external and internal irrigation is necessary for cooling to prevent this type of problem.

> Do not use acrylic resins around fresh surgical sites because it causes sensitivity. Some implant sites have an inflammatory reaction which will cause softening of bone and ultimately loosening of the Ultratooth.
> **Only composite resins are recommended for immediate provisionalization**

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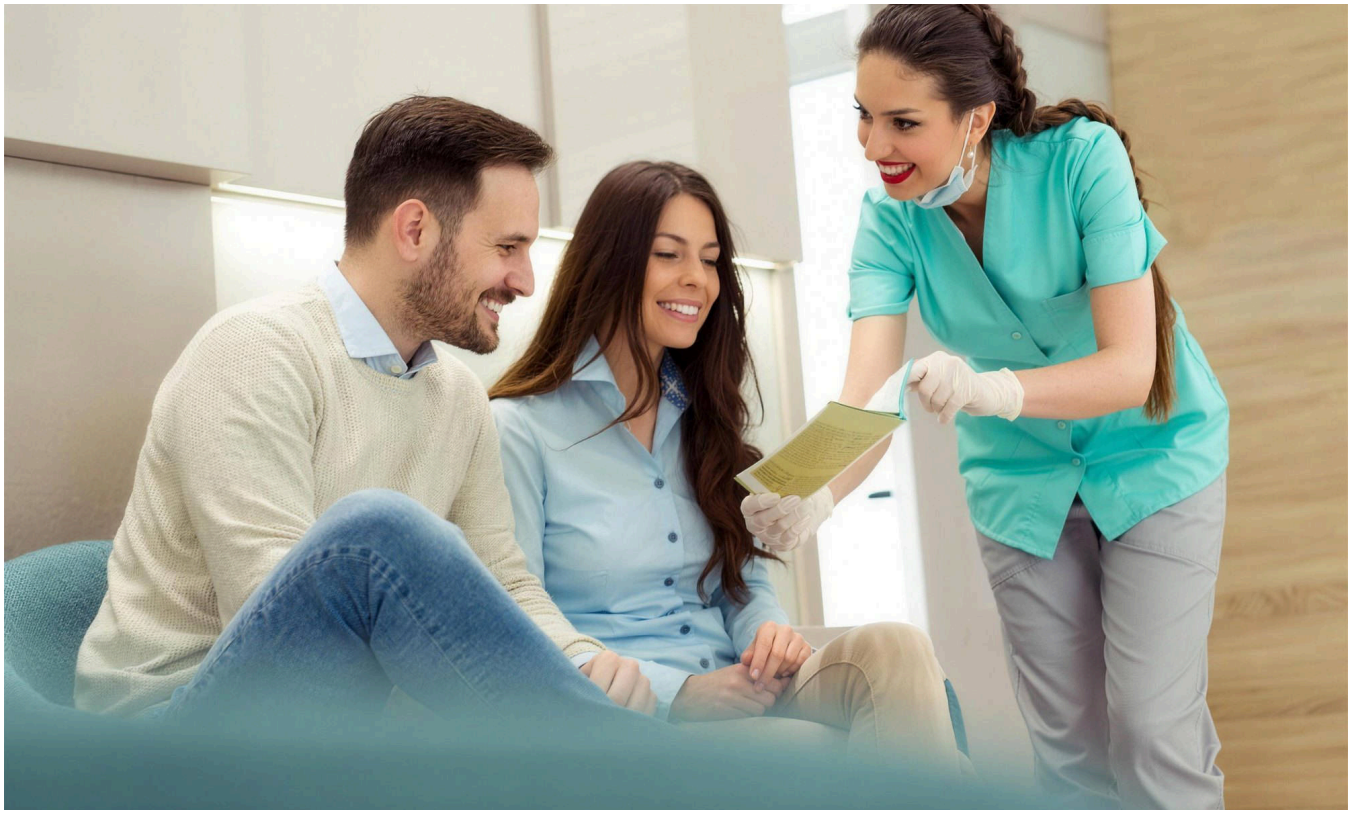
Precautions

The surgical techniques required to place endosseous implants require highly specialized and complex procedures. Although these techniques are described in this Manual, formal training in placement of such implants is strongly recommended. Practitioners should attend study courses to prepare themselves in established techniques of oral implantology.

It is essential to determine the local anatomy and suitability of the available bone. Adequate radiographs, direct palpation, and visual inspection of the prospective implant site are necessary prior to implant treatment.

Patient Education

Assure that the patient has been well educated regarding the implant procedure, and that expectations of the prosthetic result are acceptable to the patient. In addition, discuss home care and implant maintenance with the patient. A signed informed consent for treatment is recommended.



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03 — SURGICAL PROCEDURE

What's in my Box?

03





UT ABUTMENT SCREW



UT CARRIER

Can be used as Impression Post and Final Abutment



UT SCREW CAP

Seals the top of the ULTRATOOTH



ULTRATOOTH



UT PROVISIONAL ABUTMENT

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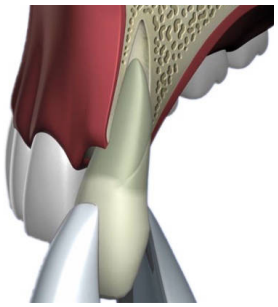
03 — SURGICAL PROCEDURE

Closed Procedure

Step 1

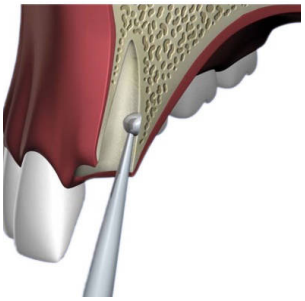
Extract tooth as a-traumatically as possible preserving original contour of the hard and soft tissue.



> **NOTE**
> Use of periotomes or elevators facilitate an atraumatic extraction.

Step 2

All fibrous and cystic tissue must be curetted.



> **NOTE**
> Use of Ultrasonic Scaler (for socket debridement) and a laser (one that doesn't damage the surrounding bone) for socket disinfection are recommended.

Step 3

Using the Universal One-Step Drill (#4085) penetrate the palatal wall of the socket. Initially (A) enter at a slight angle and then (B) upright the drill to correct angle and begin drilling.



> **NOTE**
> Recommended drill speed is 1500 RPM

> **NOTE**
> Since all anterior teeth are replaced with a 13 mm or 16 mm Ultratooth for immediate loading, the Universal One-Step Drill (#4085), for the 13 mm Ultratooth, and the Universal One-Step Drill Long (#4085L), (for the 16 mm Ultratooth), respectively, are always drilled to the hub.

> **WARNING**
> After initial penetration through the notch the drill must drop down easily through the spongy bone. If it feels like you are going through hard bone, you are possibly perforating through the palate. Upright your drill further.

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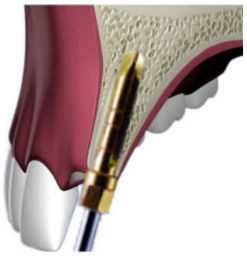
Step 5

Using your Final Drill Short (#4040T) for the 13 mm Ultratooth, drill to the hub to go the desired depth and direction of the implant site.

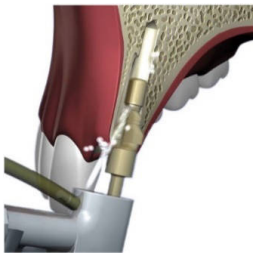


> **NOTE**
> Use the Final Drill Long (#4042T) for the 16 mm Ultratooth.

> **NOTE**
> If placing a wide Ultratooth, use the Final Drills Short (for 13 mm Ultratooth) or Long (for 16 mm Ultratooth) followed by the Final Drill Wide (#4080T). Take the Final Drill Wide (#4080T) to the top of the hub to get extra length when placing a 16 mm Ultratooth Wide.

Step 6

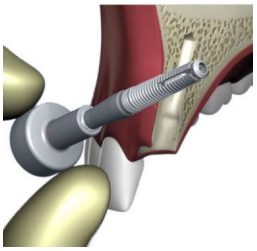
The Emergence Profile Counterbore Drill (#4050W) is used to remove hard and soft tissue tags from the future abutment position.



> **NOTE**
> Drive the Emergence Profile Counterbore past its wings to the hub.

Step 7

The Hand Wrench (#6055) is used to remove the Ultratooth from its' packaging and to initially drive the Ultratooth into the surgical site.



> **NOTE**
> The Hand Wrench (#6055) is Morse Tapered so when you engage the top of the Ultratooth Carrier it will not fall when carrying Ultratooth to patient's mouth.

> **NOTE**
> Once you begin driving the Ultratooth with force by hand, use the Implant Driver Short (#6040IS) inside the Hand Wrench (#6055) to ensure the Morse Taper does not cause your Hand Wrench (#6055) to get stuck to the top of your Ultratooth Carrier (#3970UT).

Step 8

After the Ultratooth is initially driven in, use the UT Hex Driver (#6025UT) to remove the UT Abutment Screw (#7160UT) first.

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Step 9

The UT Hex Driver (#6025UT) is again used to lift the UT Carrier (#3970UT) by loosening the UT Screw Cap (#3965UT) of the Ultratooth. The UT Carrier and UT Screw Cap are then both removed.

> **NOTE**
> To finish driving the Ultratooth, use the base of the Fixture Driver (#6045UT) and your Ratchet (#6051).

Step 10

Once the Ultratooth is fully seated to the bottom of the boar, you will use the Expansion Screwdriver (#6005) to initiate the expansion of the pods by hand.



Step 11

Then using the Torque Wrench (#6053), set at 20 Newtons, you will finish expanding the pods of the Ultratooth.

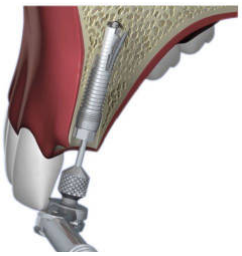
> **NOTE**
> The head of the internal expansion screw is the first seal point of the Ultratooth.



Step 12

After 20 Newtons of force the head of the Torque Wrench (#6053) will automatically break, keeping you from over expanding the Ultratooth.

> **NOTE**
> If you do try to over-expand the Ultratooth, the tip of the Expansion Screwdriver (#6005) will bend before any damage can occur to the internal screw of the Ultratooth.



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Step 13

The UT Screw Cap (#3965UT) is then hand tightened (or with 10 Newtons of force) back on the top of the Ultratooth. This establishes the secondary seal point by using an internal morse taper.

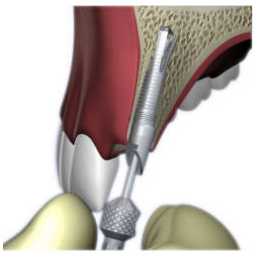
Step 14

The UT Carrier (#3970UT) can be prepared into an abutment outside of the oral cavity. The prepped abutment is then placed on the Ultratooth and the UT Hex Driver (#6025UT) is used to tighten the UT Abutment Screw (#7160UT). This is the third seal point due to the proprietary hex morse junction.



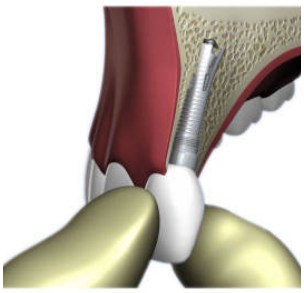
Step 15

The abutment can be refined using a diamond drill with adequate irrigation.



Step 16

At this point either the provisional or final crown can be cemented and used in full function.



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03 — SURGICAL PROCEDURE

Ultratooth Placement Chart

What minimum size Ultratooth to use where.

Maxillary molars

TOOTH NO. **1, 2, 3, 14, 15, 16**

EXTRACTION SOCKET

13 mm wide



EXTRACTION SOCKET — COMMENTS

If placement is in the palatal root, do not immediately load. Graft the remaining root sockets and make a custom healing abutment with composite. If there is sufficient bone between the roots to place a 10 mm wide, it can be immediately loaded.

RESTORATIVE OPTIONS

Ideal abutment would be the carrier prepped or the fixed abutment. If there is a vertical limitation, use the top of the implant. The small abutment can be used to add length to the top of the implant. If the lab is adjusting the small abutment, only horizontal cuts can be used to adjust length, for the purpose of transferability.

ADDITIONAL NOTES

No standard-diameter implants should be used for these teeth unless they are bicuspidized. If there is less than 10 mm of bone and you are using the Ultratooth to lift the floor of the sinus, you need a minimum of 7 mm of bone.

HEALED SITE

10 mm wide

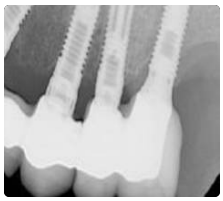


All bicuspids

TOOTH NO. **4, 5, 12, 13, 20, 21, 28, 29**

EXTRACTION SOCKET

13 mm standard



EXTRACTION SOCKET — COMMENTS

A 10 mm wide can be used if the bicuspid root is small and is entirely obliterated after preparation.

RESTORATIVE OPTIONS

As for maxillary molars: the carrier prepped or the fixed abutment; the small abutment can add length (horizontal cuts only).

ADDITIONAL NOTES

Sometimes a wider implant is undesirable because you need at least 2 mm of bone both buccally and lingually, unless you leave room on one side and graft the other so there is still blood flow to form additional bone.

HEALED SITE

10 mm standard

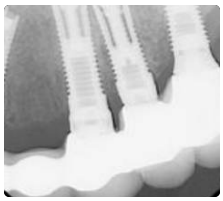
NO RADIOGRAPH

Canines

TOOTH NO. **6, 11, 22, 27**

EXTRACTION SOCKET

16 mm standard



EXTRACTION SOCKET — COMMENTS

To prevent the need for angled abutments, make sure the final direction is parallel to the extracted tooth.

RESTORATIVE OPTIONS

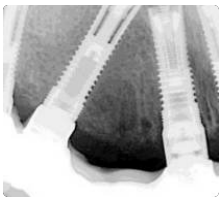
Carrier, fixed abutment, or small abutment. Anything with severe angulation can use a waxing sleeve to make a custom abutment.

ADDITIONAL NOTES

Always use at least a 16 for canines if placed as a single tooth in lateral excursions. The floor of the nose (bone) is approximately 2 mm that you can use to lock the implant in. If you place a 13, use it for cosmetic purposes only and do not put it in lateral excursions.

HEALED SITE

16 mm standard



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03 — SURGICAL PROCEDURE · PLACEMENT CHART (CONTINUED)

Maxillary anterior teeth

TOOTH NO. 7, 8, 9, 10

EXTRACTION SOCKET

13 mm standard



EXTRACTION SOCKET — COMMENTS

Never use a 10, because the crown-to-root ratio won't be sufficient.

RESTORATIVE OPTIONS

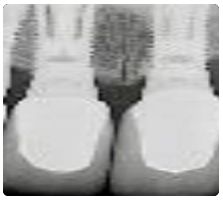
The carrier or the small abutment.

ADDITIONAL NOTES

If using the small abutment, finish the crown on the flat part of the implant past the hex so the crown doesn't spin.

HEALED SITE

13 mm standard

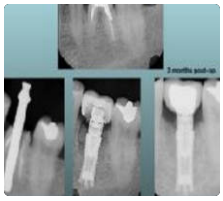


Mandibular molars

TOOTH NO. 17, 18, 19, 30, 31, 32

EXTRACTION SOCKET

13 mm wide



EXTRACTION SOCKET — COMMENTS

Can only be immediately loaded if placed between the mesial and distal roots (furcation area).

RESTORATIVE OPTIONS

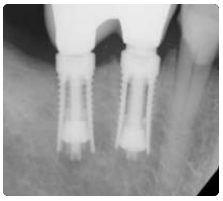
Fixed abutment, carrier, or small abutment.

ADDITIONAL NOTES

Same as maxillary molars. Always stay at least 2 mm away from the mandibular canal. When placing between roots in extraction sockets, it is easier to prep the osteotomy before extracting the roots.

HEALED SITE

10 mm wide

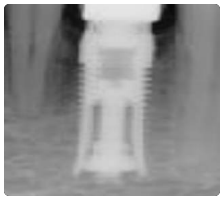


Mandibular anterior teeth

TOOTH NO. 23, 24, 25, 26

EXTRACTION SOCKET

13 mm standard



EXTRACTION SOCKET — COMMENTS

In extraction sockets the Ultratooth is placed more upright in a lingual position, since the lower anterior teeth have a severe labial angulation.

RESTORATIVE OPTIONS

Use the small abutment.

ADDITIONAL NOTES

Always use the small abutment. This is also the only area where a 4-unit bridge is acceptable (23–26): use two 13UT in the laterals with a 4-unit bridge and immediate load.

HEALED SITE

13 mm standard



NOTE

This chart gives the minimum size ULTRATOOTH needed to be able to immediately load **IN FULL FUNCTION** at placement. When there is insufficient bone quantity (TYPE IV) and quality, you can still place the ULTRATOOTH and let healing occur for the next 3 to 4 months before putting full functional load on it.

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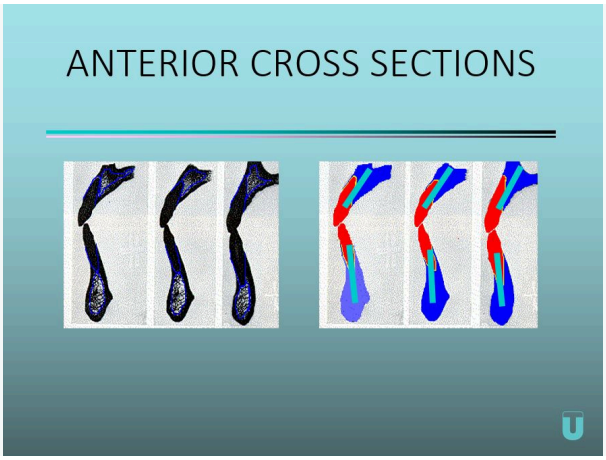
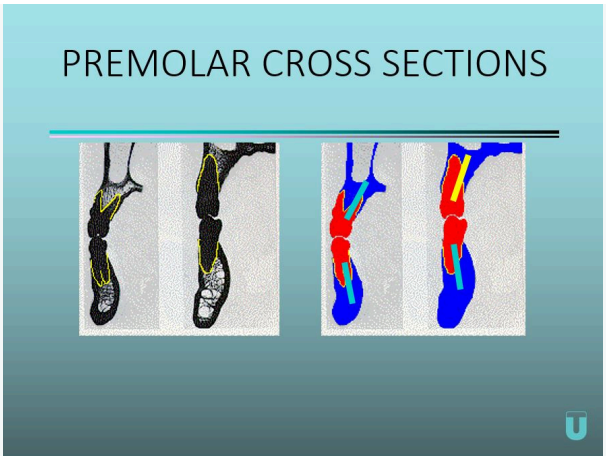
03 — SURGICAL PROCEDURE

Cross Section

ANTERIOR CROSS SECTIONS



PREMOLAR CROSS SECTIONS



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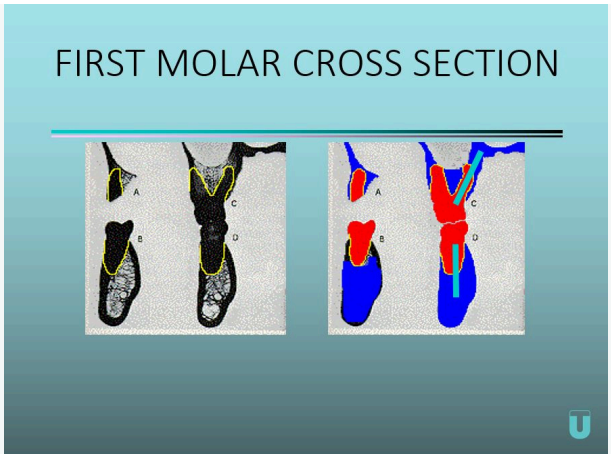

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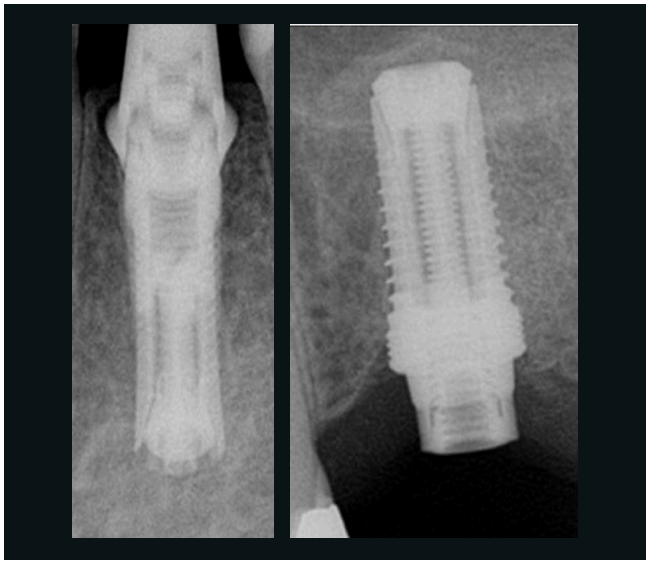
03 — SURGICAL PROCEDURE

Expansions

TYPE I EXPANSION



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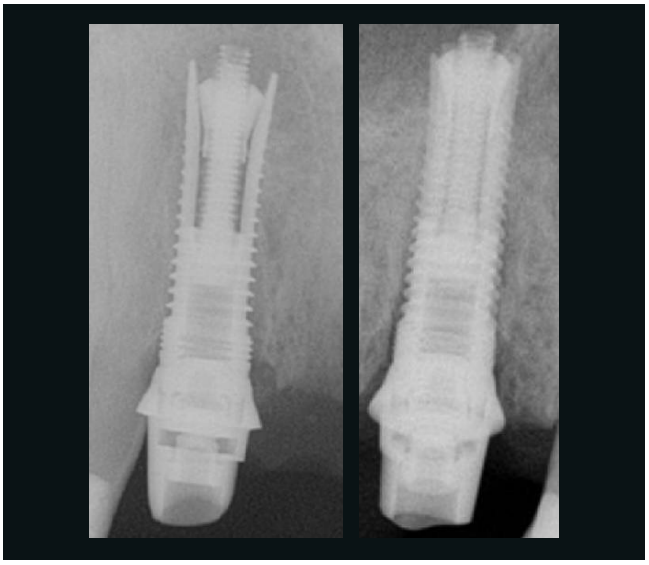
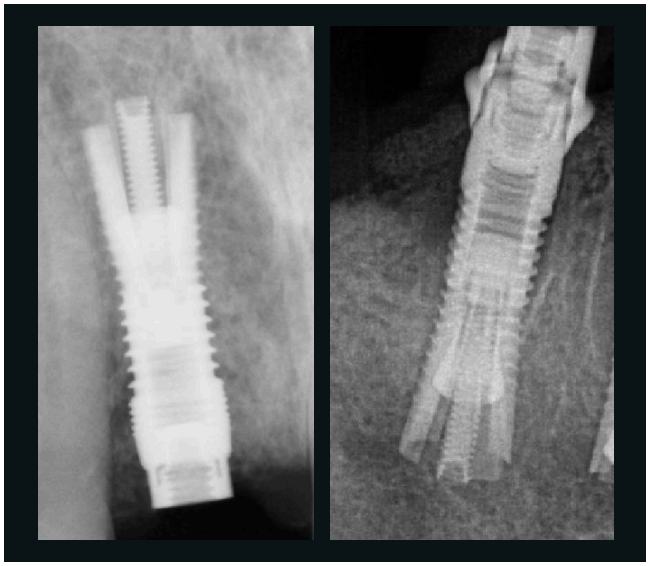
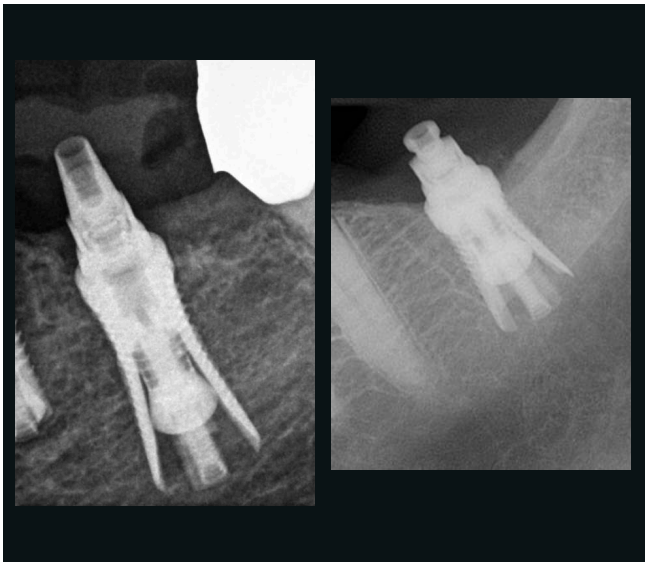


TYPE III EXPANSION



TYPE IV EXPANSION



> Do not load in full function when placing in TYPE IV bone.

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04 — RESTORATIVE PROCEDURES

Preparing the UT Carrier into a Final Abutment

04

Using the Ultratooth Carrier (#3970UT) you can prepare it into your final abutment and take an impression of the prepped abutment to send to the lab for a regular final crown to cement on the Ultratooth.



01

Prepare the Ultratooth Carrier (#3970UT) outside of the patient's mouth.



02

Use a piece of silicone to seal off the top of the abutment prior to taking your impression.



03

Wrap cord around the margin of the prepared UT Carrier (#3970UT).



04

Surround your abutment with impression material.



05

Take final impression and send to a lab to make a regular crown.

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04 — RESTORATIVE PROCEDURES

Taking Implant-Level Impressions



01

First you will remove the Ultratooth Carrier (#3970UT) from the top of the Ultratooth.



02

Snap on the UT Transfer Cap (#7056UT) on the top of the Ultratooth to take your impression.



03

The UT Transfer Cap (#7056UT) will remain in your impression once it is removed from the patient's mouth.



04

Send your impression with the Ultratooth Implant Analog (#7305UT) snapped into the transfer cap and the UT Carrier (#3970UT) for your lab to prep and make into your final abutment and crown.

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04 — RESTORATIVE PROCEDURES

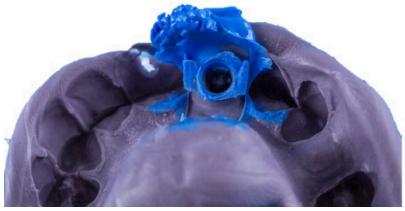
Using UT Carrier as Impression Post and Final Abutment



01

Make sure your UT Carrier (#3970UT) is seated properly on the Ultratooth and secured with the UT Abutment Screw (#7160UT) before you take your impression.

> **NOTE**
> Seal off the top of the UT Carrier (#3970UT) prior to taking an impression.



02

Take your impression ensuring you capture the ridges of the UT Carrier (#3970UT).



03

Use the UT Hex Driver (#6025UT) to screw the UT Carrier (#3970UT) and UT Abutment Screw (#7160UT) onto the Ultratooth Implant Analog (#7305UT).



04

Place these into the impression and send to lab to fabricate the final abutment and crown.

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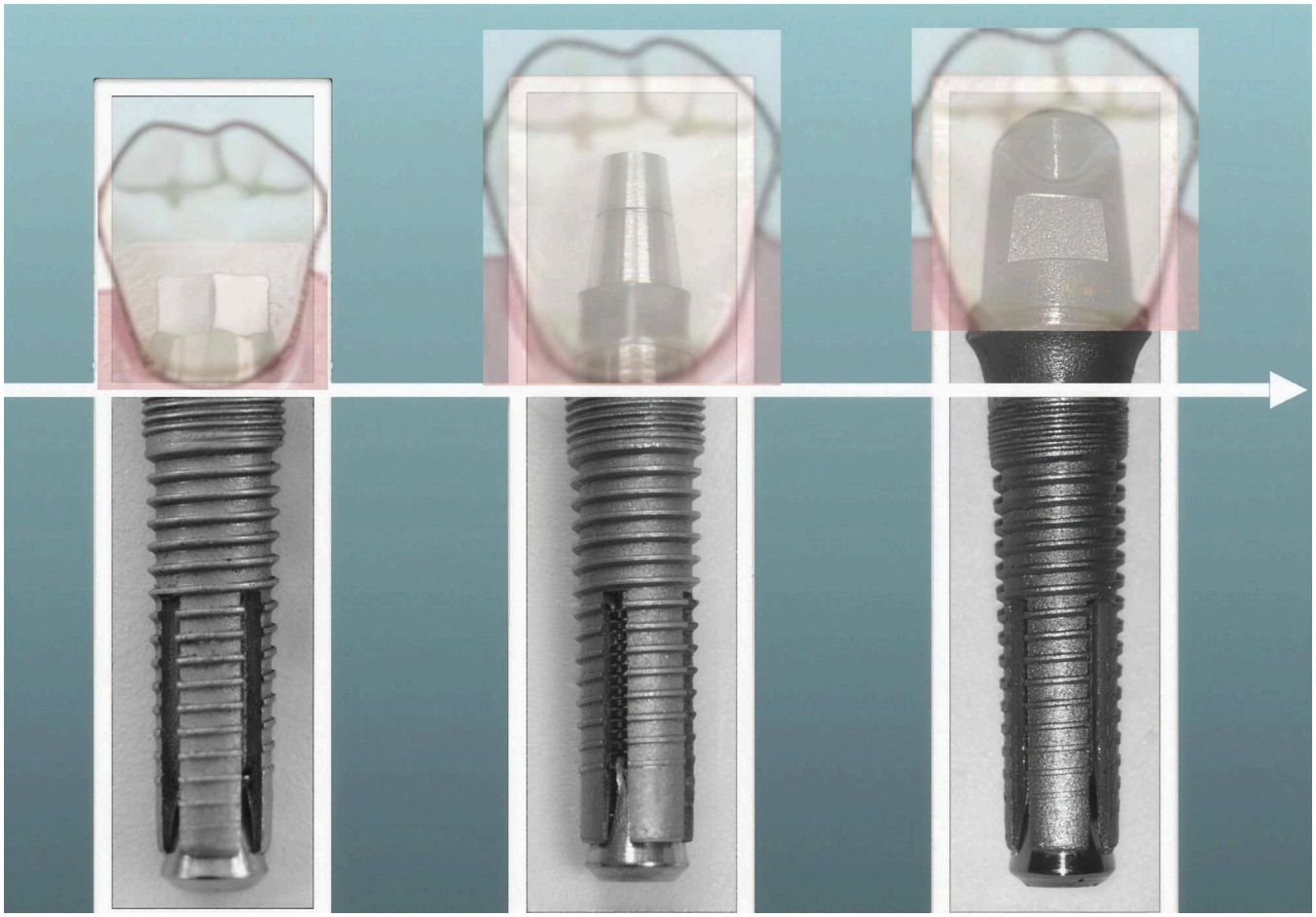
04 — RESTORATIVE PROCEDURES

Finishing Crowns



NOTE

The top 3 mm of the Ultratooth is an abutment.

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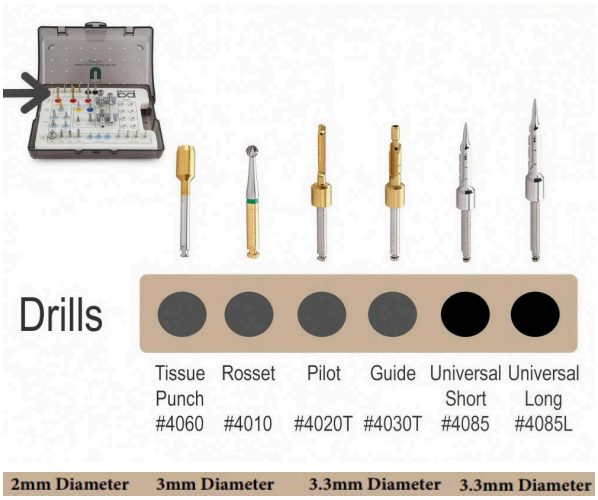
05 — PRODUCT INFORMATION

05

Universal Surgical Kit



BIODENT UNIVERSAL KIT
#9011



DRILLS



FINAL DRILLS

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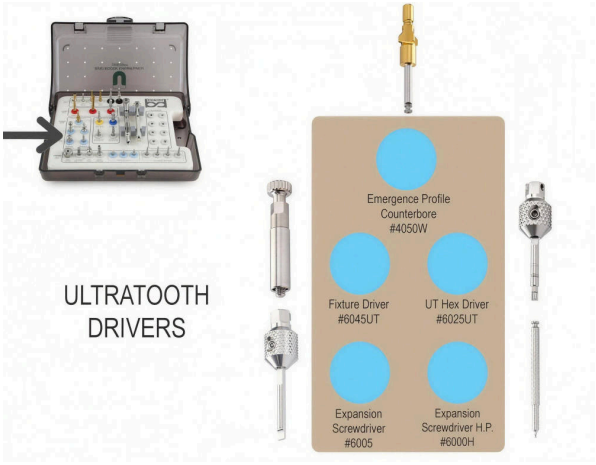
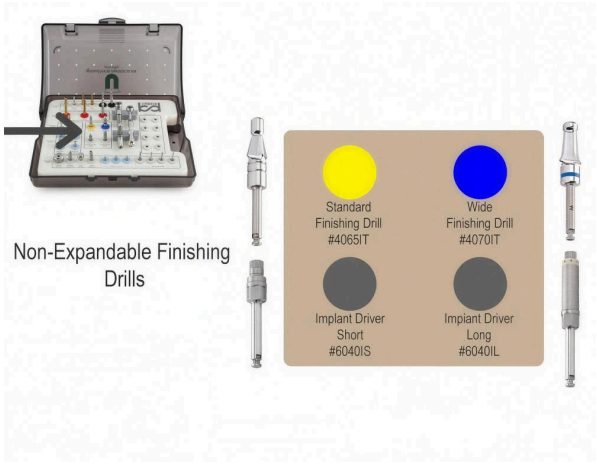
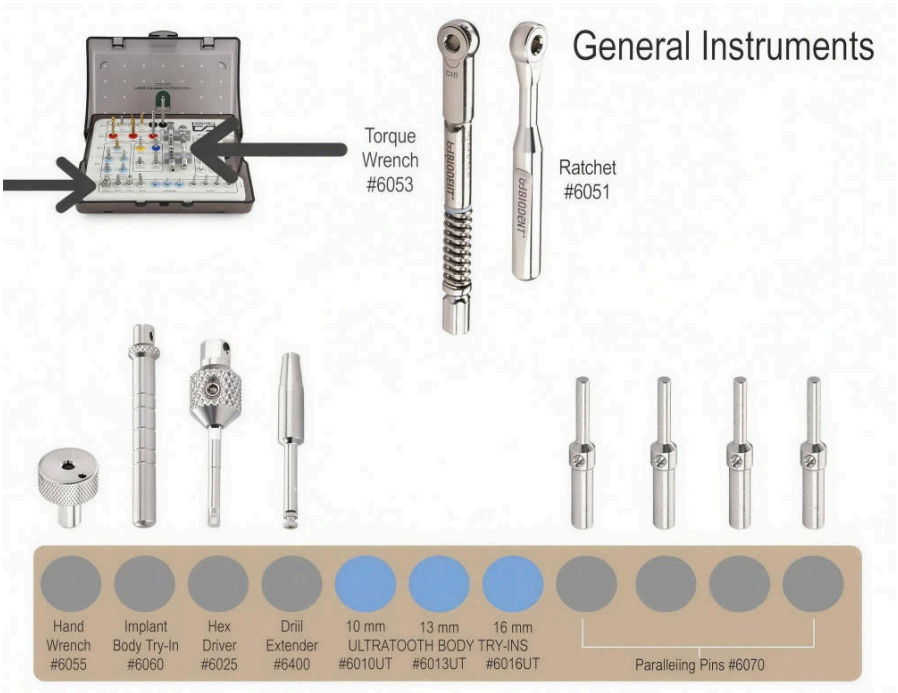


ULTRATOOTH DRIVERS



NON-EXPANDABLE FINISHING DRILLS



GENERAL INSTRUMENTS

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05 — PRODUCT INFORMATION

Surgical Components

SURGICAL DRILLS

IMAGE	ITEM NO.	DESCRIPTION
	4060	4mm Tissue Punch
	4010	Rosette Drill
	4020	2mm Pilot Drill
	4030	3mm Guide Drill
	4040	Final Drill-Short
	4042	Final Drill-Long
	4080	Final Drill-Wide
	4050W	Emergence Profile Counterbore Drill
	4085	Universal Drill
	4085L	Universal Drill Long

SURGICAL INSTRUMENTS

IMAGE	ITEM NO.	DESCRIPTION
	6000H	Screwdriver Handpiece
	6005	Screwdriver Assembly
	6020H	Hex Driver Handpiece
	6045UT	UT Implant Driver Assembly
	6055	Hand Wrench
	6060UT	UT Try-ins
	6060	Implant Body Try-in
	6400	Drill Extender
	6025UT	UT Hex Driver Assembly

GENERAL INSTRUMENTS

IMAGE	ITEM NO.	DESCRIPTION
	6053	Torque Wrench
	6051	Ratchet

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05 — PRODUCT INFORMATION

Restorative Components

IMAGE	ITEM NO.	DESCRIPTION
	**3970UT**	Ultratooth Carrier
	**7044UTS**	Ultratooth Small Abutment
	**7047UT**	Ultratooth Prepped Abutment
	**7050UT**	Ultracera Abutment **NOTE:** Ultratooth must be placed 3 mm deeper to seat this abutment properly.
	7056UT	Ultratooth Transfer Cap
	**7045UT**	Ultratooth Provisional Abutment
	**7160UT**	Ultratooth Abutment Screw
	**3965UT**	Ultratooth Screw Cap
	**7305UT**	Ultratooth Implant Analog
	**7401UT**	Ultratooth Small Abutment Analog
	**7307UT**	Ultratooth Abutment Analog
	**7210UT**	Ultratooth Waxing Sleeve Non-Hexed
	**7220UT**	Ultratooth Waxing Sleeve Hexed

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05 — PRODUCT INFORMATION

ULTRASNAP



ULTRASNAP is the newest addition to the ULTRATOOTH family. This innovative and game-changing over-denture attachment system will enable ULTRATOOTH providers to deliver **immediate detachable over-dentures** for their patients.

While traditional over-denture attachments wear over time, ULTRA-SNAP is designed to survive the life of the dental prosthesis without any changing of worn parts.

ULTRASNAP PREMIER QUALITIES INCLUDE THE FOLLOWING:

- Innovative and patented "SNAP" Technology
- Treats Up To 40° Angle Correction Between Implants
- Three Male Abutments for high, medium, and low levels of retention
- Low Vertical Height
- Long lasting results for your patients







ULTRASNAP PATIENT PROCESS

VISIT 1	VISIT 2	VISIT 3	VISIT 4
Took Full Mouth Impressions For New Dentures And Placed 8 Ultratooth Implants.	Bite Registration	Final Denture Try-In Appointment	Final Delivery Of Overdentures, Ultrasnap Attachments Were Picked Up Chairside.

Patient's Work Was Completed In A Total Of 4 Visits In 3 Weeks

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05 — PRODUCT INFORMATION

Removal Protocol

> If the Ultratooth is fully integrated and there is an infection being caused by an adjacent tooth, then simply doing an RCT on the adjacent tooth will save the Ultratooth and the area will heal.

If the Ultratooth was placed in an infected site before placement, then please follow the instructions below on removal.

01 Remove the restorative components on the Ultratooth using the UT Hex Driver **by turning them all counter clockwise**.

   a. First the abutment screw will be removed.

   b. Second, the abutment (carrier) can be removed by unscrewing the UT Screw Cap with the UT Hex Driver so the abutment will disengage the Morse Taper and lift off the Ultratooth.

   c. Lastly, the UT Screw Cap will be removed.

02 Once you are at the internal portion of the Ultratooth, you will use your Expansion Screwdriver, and begin turning the internal expansion screw counterclockwise to break the integration**. You will immediately stop unscrewing once you feel resistance, which means you have unscrewed the internal cone to the end of the internal screw.** Then take a mallet or instrument and tap on your screw driver until the screwdriver pushes the expansion screw and the expansion cone down. Which will result in the pods no longer being supported.

03 Then you can either use a 5 mm trephine drill for the standard Ultratooth or a 6 mm trephine drill for the wide Ultratooth to remove the implant safely.

AFTER THE ULTRATOOTH IS REMOVED, PLEASE STERILIZE AND SEND BACK TO HEADQUARTERS AT:

Biodent Returns
685 Cochran Street Suite 200
Simi Valley, CA 93065

Once we receive the Ultratooth and the Implant Removal Questionnaire filled out, we will send you a complimentary replacement Ultratooth.

****Please note we only approve 2 complimentary replacements for clinical failures per customer****

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05 — PRODUCT INFORMATION · INSTRUCTIONS FOR USE

Instructions for Use

ULTRATOOTH™ · SARGON® IMPLANT SYSTEM
IFU **INV/MAN/INS10 · REV Y**

The procedures and guidelines presented in these pages are neither a substitute nor replacement for formal training. The judgment, skill, and training required to place and restore dental implants is complex. Formal training in surgical placement and prosthetic restoration of the ULTRATOOTH™, a Sargon® Implant System technology (collectively "ULTRATOOTH™") is a requirement.

All Sargon Implants are trademarked as ULTRATOOTH™ and manufactured and distributed by BIODENT™. FDA-Device Registration No: 2085360. This product is protected under one or more of the following U.S. Patents: 8,828,066; 8,696,720; 9,055,985; 5,681,167. For more information, please visit: www.biodentinc.com/patents

01 Patient selection and evaluation

Patient evaluation and selection prior to implant surgery is perhaps the most important aspect of the implant treatment process. If the patient has not had a physical evaluation within two (2) years, a complete medical evaluation is recommended. Additionally, a comprehensive health questionnaire should be completed by the patient and reviewed by the practitioner.

02 Indications for use

The BIODENT™ System is designed for use in either partially, or fully edentulous mandibles and maxillae, as a final or intermediary abutment(s) for fixed or detachable prostheses, and for use in support of freestanding restorations with or without the involvement of adjacent dentition.

03 Contraindications

GENERAL MEDICAL CONTRAINDICATIONS

Customary general contraindications associated with elective surgery should be observed. These include, but are not limited to: significant vascular impairment to the implant site; metabolic bone disease; clotting disorders; current treatment with therapeutic agents that may have an effect on the surgical site, surrounding tissue, or normal healing responses (i.e. drug treatment, anticoagulant therapy); or other metabolic or physical disorders that interfere with bone growth, maintenance or wound healing.

POSSIBLE CONTRAINDICATIONS

- Chronic bleeding problems (blood dyscrasias)
- Certain cardiac and vascular diseases
- Chronic renal disease
- Treatment with corticosteroids
- Treatment with chemotherapeutic agents
- Metabolic bone or connective tissue diseases
- Diabetes (uncontrolled)
- Psychological impairment
- Bruxing/abnormal clenching
- Tobacco usage
- Poor patient oral hygiene
- Patients taking osteoporosis medication (ex: Fosamax, Boniva, etc.).
- Pregnant women (only as an emergency procedure)

TEMPORARY CONTRAINDICATIONS

- Systemic infections
- Local oral or respiratory infections

ANATOMIC OR PATHOLOGIC CONTRAINDICATIONS

- Insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone, both buccally and lingually to the most superior cervical aspect of the implant body.
- High mandibular neurovascular canal 2mm proximal to the osteotomy.
- Malignancies
- Adjacent tooth infections

04 Warnings

WARNINGS

- Age: 18 years or older
- Improper techniques can cause implant failure, loss of bone, and injury to the neurovascular structures.
- No attempt should be made to alter or modify the implant body or threaded area of the abutment. Use only genuine BIODENT™ abutments to restore the Ultratooth™.
- BIODENT™ Implants are intended to be used only with the specifically designed bone drills and surgical instrumentation provided in the BIODENT™ Surgical Kit. Additionally, BIODENT™ abutments and prosthetic attachments must be seated completely and radiographs should be taken to verify the seating of all components used in the restoration phase of the implants. BIODENT™ Implants are not compatible with other prosthetic systems.
- BIODENT™ implants and instrumentation must not be altered in any way. They are designed for use with the BIODENT™ System abutments and attachments supplied only by BIODENT™. Abutments and attachments supplied by other companies might not be made to the exact specifications and standards of the BIODENT™ System, and use of them may lead to implant failure, implant abutment failure, prosthesis failure, and /or loss of bone. The use of electro-surgical or certain laser instruments around metallic implants and their abutments is discouraged due to the electric and/or heat conductivity of the substrate metal.

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05 — PRODUCT INFORMATION · INSTRUCTIONS FOR USE (CONTINUED)

- Implant mobility, bone loss or infection may indicate implant failure. Any implant that appears to be failing should be treated as soon as possible. If the removal of the implant is deemed necessary, unscrew the expansion screw (several reverse turns will release the tension on the expansion mechanism), and push down on the expansion screw with the screwdriver to reposition the expansion nut. Then the implant driver should be attached, and the implant unscrewed. The soft tissue should be curetted from the implant site and the site allowed to heal in the same manner as an atraumatic natural tooth extraction, grafting of bone may be performed if necessary. If the implant is partially integrated use the above procedure to remove the bone from internal surface of pods and then use a trephine drill that fits the diameter of the upper portion of the implant to remove the implant. The drill will cause the legs to collapse since they no longer are supported with bone on the inside surface.
- If the implant becomes contaminated in any way, the implant must not be used. The implant must never be cleaned or re-sterilized for use in another patient. Do not attempt to decontaminate the implant by any in-office method. Reuse of a single use device that has come in contact with blood, bone, tissue, body fluids or other contaminants may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Do not allow intra-oral procedures to transmit heat to the implant body and surrounding bone. Ample external and/or internal irrigation is necessary for cooling to prevent this type of problem.

05 Precautions

The surgical techniques required to place endosseous implants require highly specialized and complex procedures. Although these techniques are described in the Sargon Technical Manual, formal training in placement of such implants is strongly recommended. Practitioners should attend study courses to prepare themselves in established techniques of oral implantology. It is essential to determine the local anatomy and suitability of the available bone. Adequate radiographs and Tomograms, direct palpation, and visual inspection of the prospective implant site are necessary prior to implant treatment. A Cad – generated surgical guide is highly recommended.

06 Device description

The Sargon Immediate Load Implant® is a root-form screw-type dental implant made from titanium alloy (Ti6Al4V). The unique design of this implant provides expansion capability at the implant's apical end that is activated by the surgeon after placement by inserting a screwdriver into the channel of the implant and torquing the expansion screw to 20 Newton cm^2.

The implant is assembled from three titanium parts: the implant body, the expansion screw, and the expansion cone. The implants have body diameter (3.8mm, 4.8), lengths (10mm, 13mm, and 16mm) with a Hex/Bevel head for Morse Taper Seal. There is also a Screw Cap that is designed to seal the top of the implant once the implant is expanded.

ULTRATOOTH™

The Ultratooth™ is a one-piece implant and abutment combination includes:

39XXUTX	implant	**3965UT**	screw cap
3970UT	UT Carrier	**7160UT**	UT abutment screw
7045UT	UT provisional Abutment		

There is no abutment/implant interface to leak, cause irritation or loosen. A Prep-able extension abutment can be used when additional retention for a tooth restoration is desired. Impression techniques are identical to those of the immediate fixed abutment (IFA). With the Ultratooth™ an optional impression post can be used for transfer purposes. This economical approach to single tooth immediate loading is now available in 3 lengths and two diameters: 16mm (#3916UT), 13mm (#3913UT), 10mm (#3910UT), and in 3.8 and 4.8 mm diameters. Please refer to CUS/TRN10 for details on Ultratooth™ Handbook for specification, placement and restoration.

BIODENT™ NON-EXPANDABLE IMPLANT

A non-expandable (screw type) line of implants is available with internal connection abutment system. These come in 8, 10, 13, 16 mm lengths and 3.8 diameter. The Non-expandable Is a one-piece implant and abutment combinations includes

38XXI	Non expandable implant	**3970IC**	IC Carrier
3960I	IC Cover Screw	**7160**	Abutment screw

See CUS/TRN 20 Non expandable Implant chart.

IMPORTANT

ALL IMPLANT LENGTHS ARE MEASURED FROM THE THREADED AREA AND DO NOT INCLUDE THE HEAD PORTION OF THE IMPLANTS SINCE THE HEAD AND COLLAR OF THE IMPLANTS CAN BE PLACED BELOW BONE LEVEL ADDING TO THE LENGTH OF THE IMPLANT. PLEASE MAKE SURE ANY MEASUREMENT IS MADE FROM THE CORRECT PART OF THE IMPLANT DURING PLACEMENT SINCE IMPROPER MEASUREMENT COULD CAUSE THE IMPLANT TO BE PLACED DEEPER THAN NECESSARY CAUSING GENERAL PERFORATIONS AND NERVE DAMAGE IN THE MANDIBLE.

NOTE: A surgical template must be used to avoid positioning errors. Before opening the sterile packaging of the Ultratooth™ implant, place the appropriate size Ultratooth™ body try-ins into the completed osteotomy. The body try-in shows the exact position of both the implant and its abutment. By using the try-in, the operator can now make a length correction if necessary. If any angulation problems exist, proceed with the standard Ultratooth™ implant and custom abutments for angulation corrections.

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05 — PRODUCT INFORMATION · INSTRUCTIONS FOR USE (CONTINUED)

07 Sterilization, storage & caution

STERILIZATION

All BIODENT™ Implants are provided STERILE and intended for single use only. The method used for sterilization is Gamma radiation. For expiration of sterility please see label on implant package.

STORAGE

To ensure implant packaging integrity, store between 20 Celsius to 25 Celsius

CAUTION

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

08 Surgical placement procedure

01 The use of a surgical guide of the doctor's design preference is recommended to facilitate proper location and angulation of the implant.

02 Create an elevated gingival tissue flap over the implant site to expose the bone ridge.

03 With copious irrigation by sterile water (chilled if possible), mark and flatten the area with a **ROSETTE DRILL** (catalog #4010) to create a surgical table at the crest of the ridge. This surgical table should be at least 2mm wider than the implant.

Note: A radiograph may be taken with the pilot drill in place to confirm depth and direction. When placing more than one implant, place a **PARALLEL PIN** (catalog #6070) into the completed pilot osteotomy and proceed to the next implant site. Align the pilot drill parallel to the previous pin when available bone permits and drill the next osteotomy.

04 Using the 2mm diameter **PILOT DRILL** (catalog #4020); first penetrate the cortical bone, then drill into the spongy bone to a depth of 4 to 5mm.

05 Place the guide portion of the **GUIDE DRILL** (catalog #4030) into the prepared site and drill to the same depth drilled by the pilot drill. Do not generate heat at a fast-drilling speed.

The **UNIVERSAL ONE-STEP DRILL** (catalog #4085, 4085L) may be used by sufficiently experienced surgeons to replace Steps 3–5 listed above.

06 Use the **FINAL DRILL** (catalog #4040, #4042 or 4080 for wide) to penetrate to the line corresponding to the length of the selected implant.

07 To prepare the crestal portion of the osteotomy for the collar of the implant, use the Emergence Profile **COUNTERBORE DRILL** (catalog #4050). Drill to the length of the implant collar - 1mm. This drill should be used in cases where the Ultratooth™ head portion is being placed below bone level.

08 The implant is attached to a carrier, which is held by the implant holder in a blister pack. This design is to ensure sterility during shipment and storage while allowing easy placement onto the Implant Driver. After removing from the box, peel off the Tyvek cover to open the blister pack. Pull back holder from the blister pack. You may use the **HAND WRENCH** (catalog #6055) or **IMPLANT DRIVER** (catalog #6045UT) with the latch type connection to engage the carrier to remove the implant from the holder.

09 Drive the implant in as far as needed, you may use a ratchet (catalog #6051) if bone resistance indicates the need. All BIODENT™ implants are self-tapping.

10 You may use the Ultratooth™ **HEX DRIVER** (catalog #6025UT) to unscrew and remove the implant holder from the implant. In case of Ultratooth™, the holder may still be holding onto the implant due to the friction fit. Instead of pulling it apart by force, use the same driver to unscrew the screw cap. This will lift the holder from the implant. Then Continue unscrewing to remove screw cap as well.

11 Insert the **SCREWDRIVER** (catalog #6005) into the head of the implant expansion screw and finger-turn it clockwise to draw the expansion mechanism up into the implant. As the mechanism rises, the body of the implant expands into the walls of the surgical site. Use the **TORQUE WRENCH** (catalog #6053) to tighten the expansion screw to 20 Newton/cm² (reference catalog #6053 IFU for more information on the torque wrench)

12 With good bone quality and quantity, tightly screw on the screw cap on the implant after expanding the implant. This ensures a primary seal from bacterial infiltration into the implant.

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05 — PRODUCT INFORMATION · INSTRUCTIONS FOR USE (CONTINUED)

09 Surgical finishing options

01 For Non-Expandable Implants: Install the **HEALING COLLAR** (catalog #'s 3942I, 3944I, 3942IW, 3944IW) or **COVER SCREW** (catalog #3960I) of appropriate length. For Ultratooth™ (UT) Implants you may prepare the holder as the final abutment and install it on the implant and place a provisional crown if indicated. You can also use the holder as a transfer-type impression post and use the provisional abutment (enclosed within the implant sterile Blister package) for provisionalization. The lab can prepare the holder as the final abutment and use it to fabricate the final prosthesis.

02 Place a temporary restoration on implants that are in good quality bone. Implant in soft bone can be left unloaded to heal. A healing collar or a cover screw can be placed on all non-expandable implants. Appropriate antibiotic coverage is recommended post-surgically.

10 Surgical follow-up

If the Ultratooth™ is placed without follow-up observation, it could have the same prognosis for success as do many other conventional implants. However, the Ultratooth™ success rate can be improved by allowing for early detection of an ailing implant through follow-up observation. By having regular patient follow-up visits shortly after surgery, healing can be assessed and if initial stability has not been sustained, the problem can be addressed by re-expansion of the implant to 20 Newton/cm²

Requirements

- Do radiograph to ensure component seating.
- Always tighten the expansion screw to 20 Newton/cm/2
- Always activate the expansion mechanism.

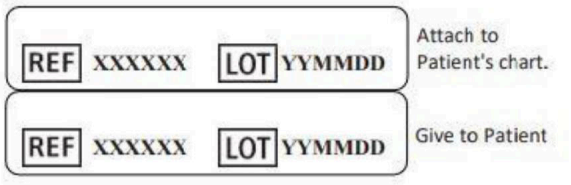
11 Do not

- DO NOT immediately load implants that have been placed in poor quality bone density such as 3D and 4D bone without experienced evaluation of the ability of the bone to support the load. NOTE: Experience has shown that 3D bone can often accommodate loading, while 4D bone should never be loaded immediately. Incremental loading is appropriate under these conditions.
- DO NOT immediately load implants that are involved in the floor of the sinus.
- DO NOT use any abutment system other than the BIODENT™
- DO NOT use any Methyl-methacrylate to provisionalize any newly placed implants, since it will cause inflammation and rejection of the implant in patients with sensitivity to Methyl-methacrylate

12 Symbol definitions

STERILE R	Sterilization by irradiation
	Do not reuse
	Caution, consult accompanying documents
	Consult instructions
	Void if package is damaged
Rx	Caution! U.S. Federal Law restricts this device to sale by or on the order of dentist.
REF	Catalog Number
LOT	Batch Code and Date of Manufacture are the same.
	Use by
	Manufacturer
2	Do not re-sterilize
	Storage Temperature (20° Celsius to 25° Celsius)

PATIENT LABEL:



EC REPRESENTATIVE · CE 2460



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