GTR/GBR Product Catalog

IMTEC CORPORATION

Creating Simple Solutions through Digital Technology

IMTEC Corporation

IMTEC Corporation is committed to the advancement of dental science and dental implant technology. The company, through ongoing research, has developed a wide range of dental products currently in use by clinicians throughout the world.

The IMTEC Hexed-Head dental implant system was first developed by Ronald A. Bulard, D.D.S. in 1986. IMTEC Corporation was incorporated by Dr. Bulard and E.S. Gillespie, D.D.S. in 1990. From its inception, the company's implant system and related technology have been developed based on simplicity and technical accuracy.

IMTEC has sponsored a host of clinical and university studies with protocols of selected studies having been reviewed and accepted by the American Dental Association (ADA). Additional studies are currently ongoing at major universities around the world.

The IMTEC System

Great care is taken in the selection of materials, production methods, sterilization and packaging of IMTEC dental implants and associated components. Strict inspection procedures have been established to ensure all IMTEC products are in compliance with an array of regulatory standards.

IMTEC Corporation's products are manufactured under registered ISO 9001 and ISO 13485 quality systems. In addition, by meeting the stringent European standard (EN46001) for medical devices, IMTEC has been authorized to utilize the CE mark. This demonstrates the company's manufacturing excellence and concerns for patient safety. By following the FDA's Good Manufacturing Practices (GMP) and by adhering to additional rigorous medical device regulations, IMTEC dental products have been accepted by the Food and Drug Administration (FDA) to be marketed and sold in the United States.

Unless otherwise noted, all implants and components are precision machined with Computer Numerical Controlled (CNC) machine tooled. Critical dimensions are held within +/-.0005" (5 µ) accuracy. IMTEC dental implants are produced from surgical grade titanium.

Quality Control

Quality Assurance at IMTEC Corporation meets the rigid specifications of the medical device regulations. Many of the critical dimensions are subject to 100% inspection during various stages of production.

Packaging

IMTEC Corporation's dental implants and sterile components utilize packaging configurations that have been validated to provide clean, sterile barriers for a duration of at least five years. Each sterile device includes a removable patient chart label for future referencing and simplified record keeping. Dental instrumentation and components are provided non-sterile.

Commitment

Our commitment at IMTEC is to provide the dental profession with state of the art, cost effective dental implants and associated products, coupled with competent, reliable customer service. We stand ready to serve you at all times. Please visit our user friendly website at www.imtec.com, or call our toll free number, 800-879-9799 today.

IMTEC Limited Warranty

IMTEC Corporation warrants to the dental professional who purchases its products that all reasonable care has been taken in the choice of materials, method of manufacture, coating and packaging. IMTEC Corporation shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of its products. The foregoing warranty, as conditioned and limited, is in lieu of and excludes all other warranties, whether expressed or implied, including but not limited to any implied warranties of merchantability or fitness-for-use, and of any other obligation on the part of the seller. IMTEC neither assumes, nor authorizes any other person to assume for it any additional liability or responsibility in connection with its products. No agent, employee or representative of IMTEC has any authority to bind IMTEC to any affirmation, representation or warranty concerning its products and any such representation or warranty shall not be enforceable by the buyer. Liability under this warranty is limited to replacement of any product which shall appear to IMTEC Corporation to have been defective in materials, manufacture or packaging. Damage to any IMTEC Corporation product through misuse, neglect, accident or failure to follow recommended procedures or instructions for use or by modification by the buyer or user voids any IMTEC warranty. Product replacement under IMTEC's warranty shall be effected by promptly contacting IMTEC at the phone numbers provided. Nothing in IMTEC's warranty shall be construed to extend the rights or remedies of a patient into whom an IMTEC product is implanted. CAUTION: United States laws restrict the sale of any IMTEC product or device to licensed physicians, dentists or dental specialists. Use by any other person is strictly prohibited.

Shipping Policy

Shipments are made freight collect or prepaid by IMTEC with the shipping costs added to the customer's invoice. Priority shipping options are available at the customer's expense. Clinicians are cautioned not to accept packages with exterior damage. If there are shortages or questions, please notify the company within ten days.

Return Policy

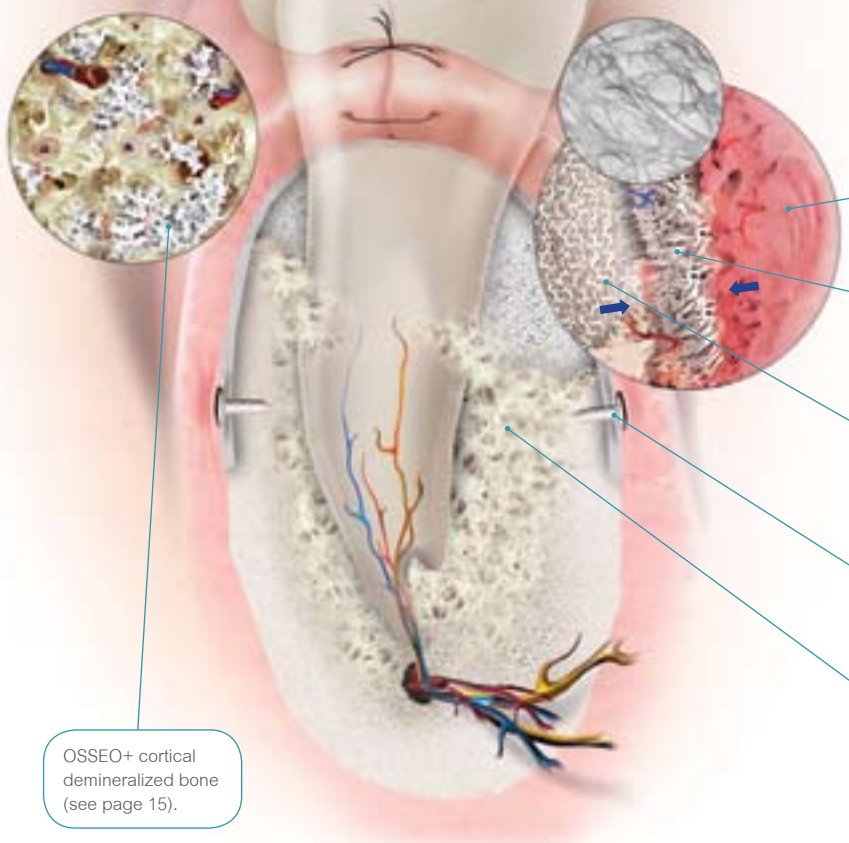
A return goods authorization (RGA) number is mandatory when returning any product to IMTEC. An RGA number can be obtained by calling your IMTEC sales representative within 30 days of the invoice date. No cash refunds. A 15% restocking fee will be applied to all returned items.

Contents

Dynamics of Bone Regeneration

Guided tissue regeneration procedures have gained professional acceptance and are now routinely utilized in the repair of periodontal and bony defects. Bioactive chemicals are activated when a defect is created (extraction, surgical intervention, etc.), stimulated or activated when a defect is created (extraction, surgical intervention, etc.), stimulated (decortication), or enhanced (bone and/or tissue grafts/augmentation). The area that is (decortication), or enhanced (bone and/or tissue grafts/augmentation). The area that is delineated by the walls of the defect, the surface of the defect (e.g. the root of the tooth), the fill material and the barrier membrane constitute a unit that acts like a biological incubator.

The biochemical messages are received by mesenchymal stem cells that reside within the bone marrow. These cells are multipotential precursors that can transform into bone, ligament or cementum. Once activated, the mesenchymal stem cells migrate into the defect and are chemically inspired to proliferate and to preferentially differentiate. IMTEC products play vital roles in the regeneration process.



Soft connective tissue grows and adheres to the IMTEC BioSorb Collagen Resorbable Membrane.

The IMTEC BioSorb matrix orientation of preferred collagen fiber enhances tensile strength making it much stronger than first generation collagen membranes.

The bone regeneration site is packed with synthetic fill material or the patient's bone. The soft connective tissue is separated from this area with the BioSorb membrane.

The IMTEC ZorbTac complements BioSorb, resulting in a resorbable membrane stabilization system.

This illustration demonstrates the regeneration of bone.

OSSEO+ cortical demineralized bone (see page 15).

Why IMTEC's GTR/GBR Products?

IMTEC provides a quality, cost effective and comprehensive system that offers a variety of products that strive toward the ultimate goal of clinician and patient satisfaction.

Quality

IMTEC quality system meets and exceeds regulations set by several worldwide regulatory authorities. From the selection of raw materials to the sterilization of the final product, IMTEC operates under the guidelines of FDA, MDD and ISO 13485 quality systems and is also authorized to use the CE mark.

Cost Effective

IMTEC provides affordable dental systems by simplifying the techniques and components necessary for success. This makes the use of IMTEC GTR/GBR products cost effective, and also makes ordering simple and efficient.

Comprehensive System

The IMTEC GTR/GBR systems are designed to be completely self-supported. The clinician saves time and money by ordering all necessary instruments and materials from one source.

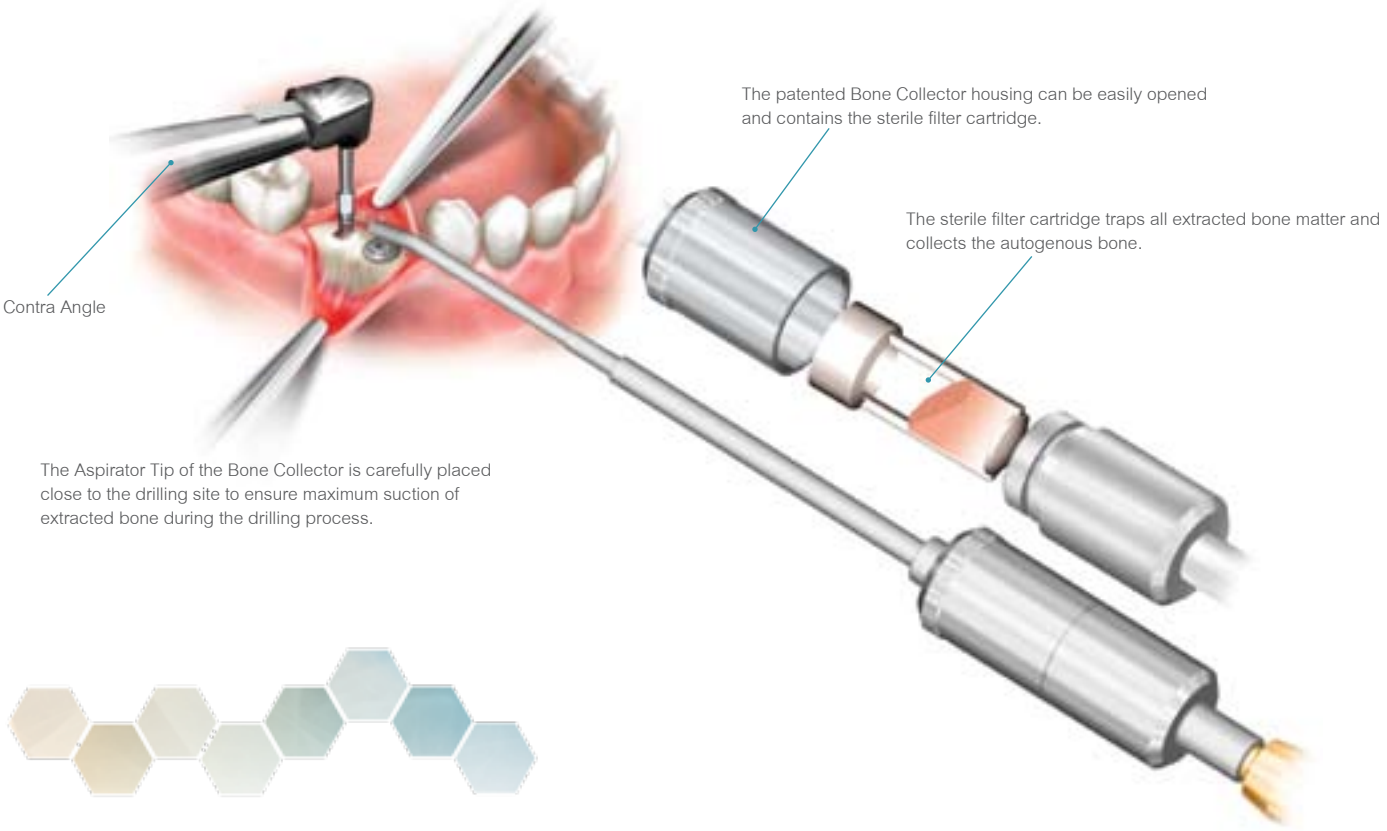
Variety

IMTEC focuses on providing a variety of products within each system. Porous, non-porous, osseo and perio membranes are available as well as resorbable and non-resorbable tacks, so the clinician is able to choose a product that is suitable for each specific case.

Satisfaction

All of the elements above contribute to the overall effectiveness of the IMTEC quality policy to continuously improve quality, value and customer satisfaction.

Surgical Protocol for the Bone Collector™ System

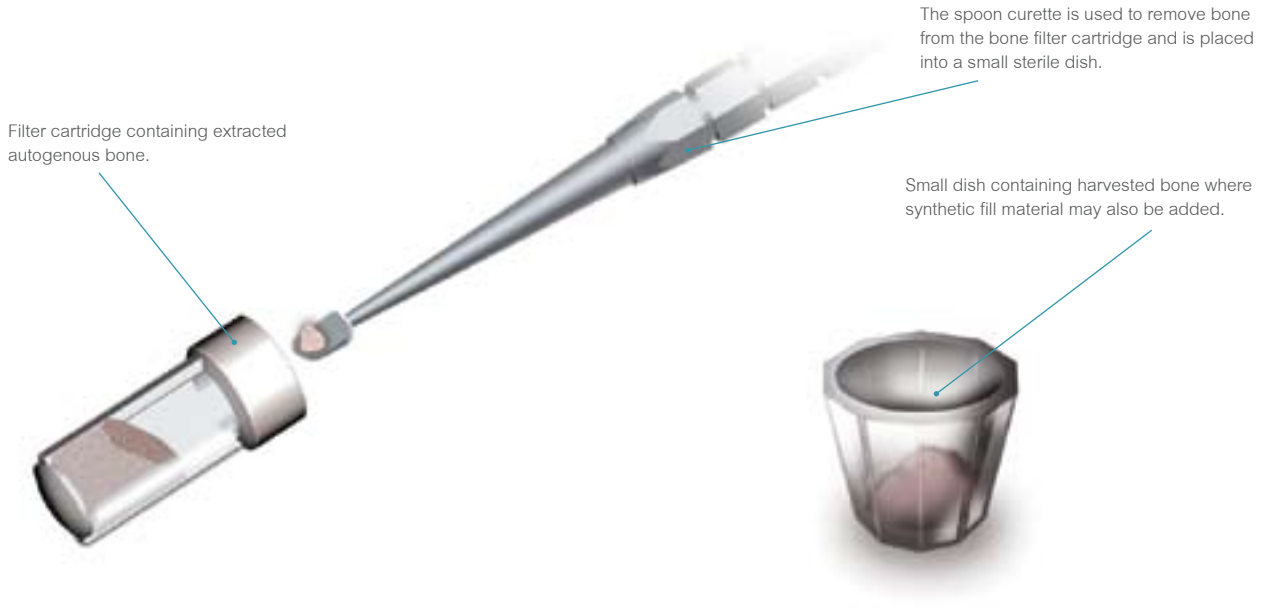


There is a wide variety of particulate grafting materials which can be used as a matrix for new osseous regeneration as well as an intermediate space maintainer in the GTR/GBR procedure. They fall into general categories of autogenous, synthetic, allograft or treated animal bone. IMTEC Corporation promotes the use of transplanted autogenous bone when practical. The matrix should be applied in the least invasive method. Healthy, naturally autogenous bone may be simply and quickly harvested for immediate use with the IMTEC Bone Collector System.

A conservative, full thickness flap procedure is accomplished in the retromolar or other available site. The cortical and medullary bone can then be removed by use of a slow drilling procedure or with Rongeurs. The Bone Collector instrument is easily introduced into the suction line with an internal filter and suction tip in place. The system's aspirator tip is held in close proximity to the surgical site which draws all extracted bone matter into the suction system where it is retained in the inline filter. When the bone harvesting process is complete, the bone collector housing is then separated. The filter cartridge and trapped bone material are then recovered. Normal surgical suction can then be resumed by the clinician.

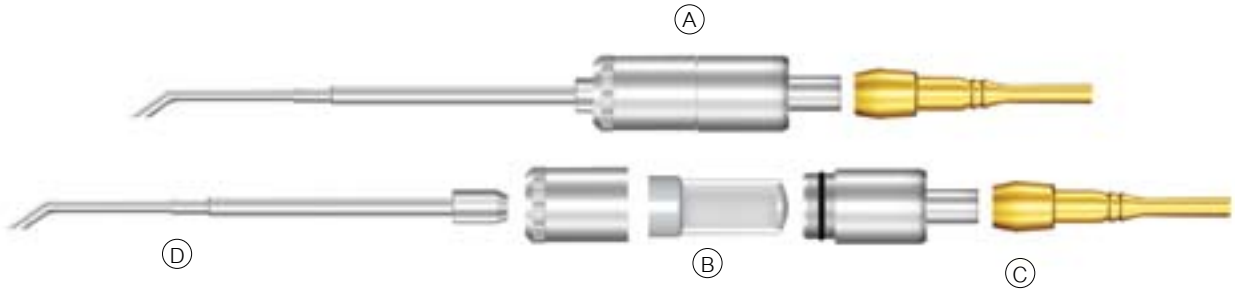
The autogenous bone is removed from the filter cartridge and placed into a small, sterile container by use of a gentle scooping motion. It is now ready for placement into any area where bone regeneration is desired. At the discretion of the clinician, the recovered bone may be combined with any number of synthetic or treated foreign bone materials to enhance mass or growth features in the placement site.

When the particulate grafting material has been satisfactorily placed in the desired area, a mechanical barrier should be applied to conserve the graft anatomy and to prevent epithelial invagination.



IMTEC Bone Collector™ System and Filter Cartridges

	Item	Catalog #
A	Bone Collector Housing	9100
B	Filter Cartridge, Sterile	9110
C	Surgical Suction Adapter	9105
D	Aspirator Tip	9160



Surgical Protocol for GTR/GBR System

IMTEC Corporation features a Guided Tissue/Bone Regeneration (GTR/GBR) System that includes:

1) A simplified technique to harvest bone fill material
2) An advanced physical barrier membrane
3) A final mechanical stabilizer

Professional applications of this advanced technique as related to oral cavities include repair of periodontal and implant bony defects as well as lateral and vertical bone mass enhancement.

Steps for Repair of Hard Tissue Defect

STEP ONE

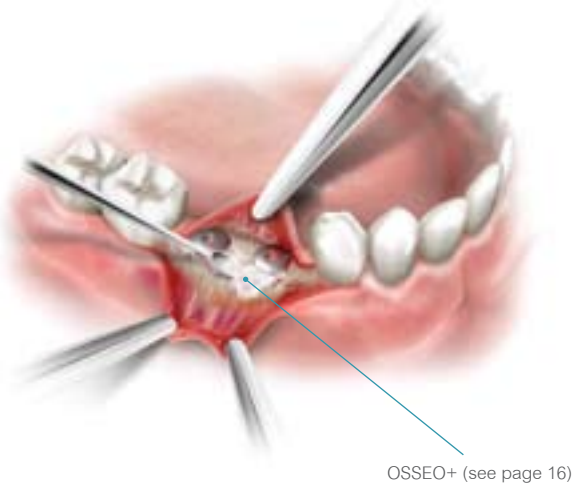
The prosthesis is removed and a full thickness flap reflected to allow adequate access to the tissue defect. Reattach the phase I healing abutment.

STEP TWO

Remove all granulated tissue. (Care must be taken not to damage the implant surface.)

STEP THREE

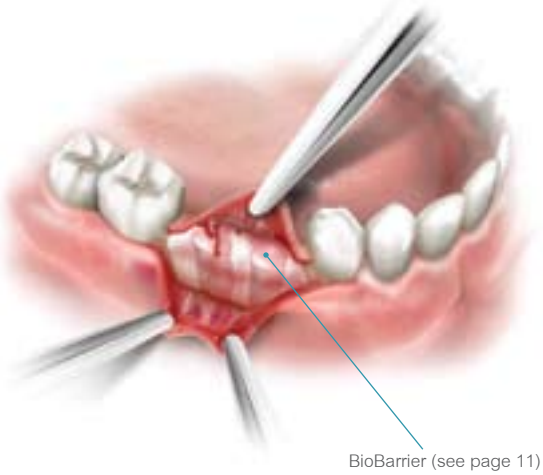
The bone fill material is placed into the defect site and contoured to approximate ideal anatomy.



OSSEO+ (see page 16)

STEP FOUR

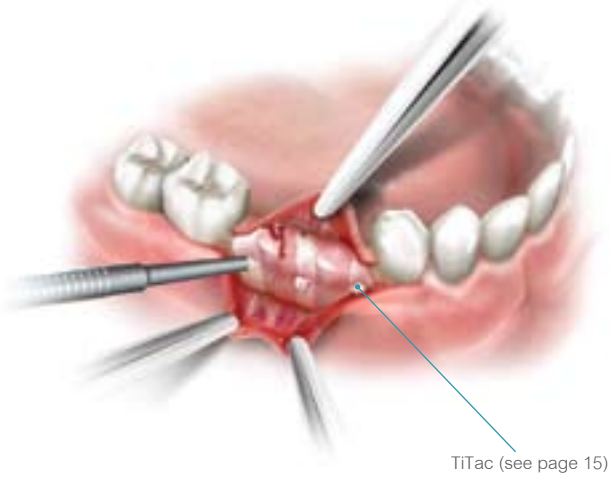
The chosen membrane is trimmed to the desired shape and adapted into position.



BioBarrier (see page 11)

STEP FIVE

The membrane and bone fill material are stabilized in position using bone tacks.



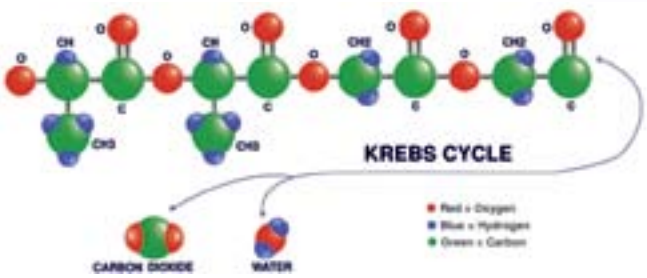
TiTac (see page 15)

STEP SIX

The flap is rejoined with a standard suture procedure. Primary closure is recommended. If a non-resorbable membrane is used then the membrane should be removed before placement of the final prosthesis.

Membranes

When the IMTEC resorbable membranes and tacks are used and their mechanical properties are no longer needed, they are absorbed and reduced to carbon dioxide and water and then completely removed from the body via the Krebs Cycle.



Collagen Resorbable Membranes

BioSorb®

Type 1 Bovine Achilles Tendon

Technological advances have led to the creation of BioSorb. The BioSorb membrane's handling characteristics are so advanced that the membrane handles like soft tissue. The membrane is fully resorbed in 26 to 38 weeks.

Tensile Strength

The BioSorb® membrane dramatically enhances tensile strength by creating a matrix that consists of long, interwoven collagen fibers. The fibers form a network much stronger than first generation collagen membranes.

Suture Pullout Strength

The BioSorb® membrane has been designed to increase suture pullout strength, a desired property of all membrane barriers. Its long oriented, cross-linked collagen fibers form an organic meshwork that is extremely favorable for suturing.

BioSorb® Membranes

The BioSorb membrane maintains its structual integrity for 26-38 weeks.

Item Size	Catalog #
15 x 20mm	BIO1520-6
20 x 30mm	BIO2030-6
30 x 40mm	BIO3040-6

Synthetic Resorbable Membranes

BioCellect™

Resorbable Homopolymer Lactic Acid

The BioCellect synthetic membrane provides a true barrier during the regenerative process of surgical management and treatment of peridontal defects. The membrane is composed of a biocompatible, metabolically resorbable homopolymer of lactic acid. This allows the membrane to aid in regeneration and integration of the tissue components in guided tissue regeneration procedures.

The true barrier of the BioCellect membrane is obtained by its unique bi-axial design. One side is compressed into a true film barrier that helps prevent epithelial cells from penetrating. The porous design on the other side provides a scaffold that promotes growth of bone into the membrane. The membrane is ultimately metabolized to carbon dioxide and water via the Krebs Cycle and does not need to be removed after periodontal healing has occurred.

BioCellect™ Perio Membranes

BioCellect Perio membranes maintain their structual integrity for 4-8 weeks.

Item Size	Catalog #
15 x 20mm	PERIO1520
20 x 30mm	PERIO2030

BioCellect™ Osseo Membranes

BioCellect Osseo membranes maintain their structual integrity for 12-16 weeks.

Item Size	Catalog #
15 x 20mm	OSSEO1520
20 x 30mm	OSSEO2030

PTFE Non-Resorbable Membranes

BioBarrier™

Pure Polytetrafluoroethylene

BioBarrier membranes consist of proprietary pure polytetrafluoroethylene (PTFE). PTFE is a long chain of fluorocarbon polymers which have been scientifically established as a generally non-reactive, biocompatible material. The BioBarrier membrane sold by IMTEC satisfies each of the five generally accepted requirements of a tissue guided barrier:

- Tissue Regeneration
- Clinical Manageability
- Absence of Cell Penetration
- Biocompatibility
- Stability

Ovoid

Ⓐ

Ⓑ

Poncho

Skirt

Ⓒ

Ⓓ

BioBarrier™ Membranes

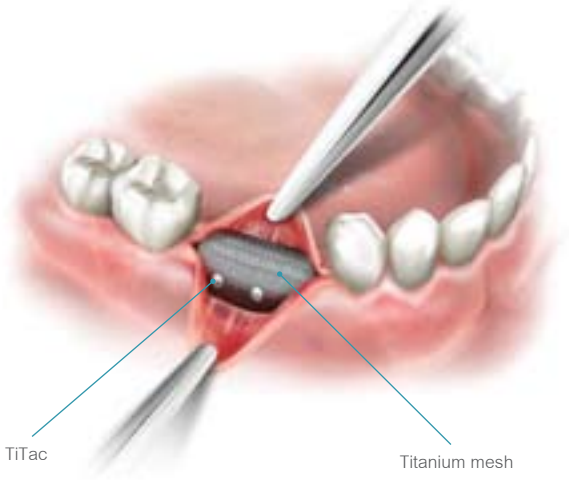
"P" denotes porous material 5µm, 0.125mm thick.

"NP" denotes non-porous material, 0.185mm thick.

	Item Size	Catalog #	
Ⓐ	17 x 25mm, ovoid	1725P	1725NP
Ⓑ	34 x 25mm, ovoid	3425P	3425NP
Ⓒ	10 x 18mm, poncho	1018P	1018NP
Ⓓ	18 x 25mm, skirt	1825P	1025NP

Titanium Mesh

Expanded CP Titanium



Patients who cannot be treated with dental implants because of inadequate alveolar bone can become candidates for implant placement following bone enhancement. The ridge augmentation method using IMTEC Titanium Mesh is particularly suitable for the repair of both localized and extensive alveolar ridge defects. While other types of barrier membranes are appropriately used for minor tissue deficiencies, fabricated titanium mesh can be molded to act as a scaffold for defects found during the reconstructive process.

Titanium Mesh has characteristics that permit exchange of fluids, is malleable for three dimensional adaptation, readily fixed in place with titanium bone screws or tacks and is visible by radiograph. The mesh is shaped to retain bone augmentation materials, surgically placed and held in place with retaining tacks for the time period required for new bone development, normally six to eight months. The mesh may then be surgically removed, as indicated prior to further surgical procedures.

The expanded Titanium Mesh gives exceptional compression resistance. The tenting properties of the mesh make it ideal for protection of the graft material. Membranes may also be used in conjunction with the Titanium Mesh.

Titanium Mesh

- Protection for the graft site
- Precision expanded C.P. Titanium Foil
- Thickness 0.10mm
- Pore size 0.03mm
- Membrane support
- Tissue Support

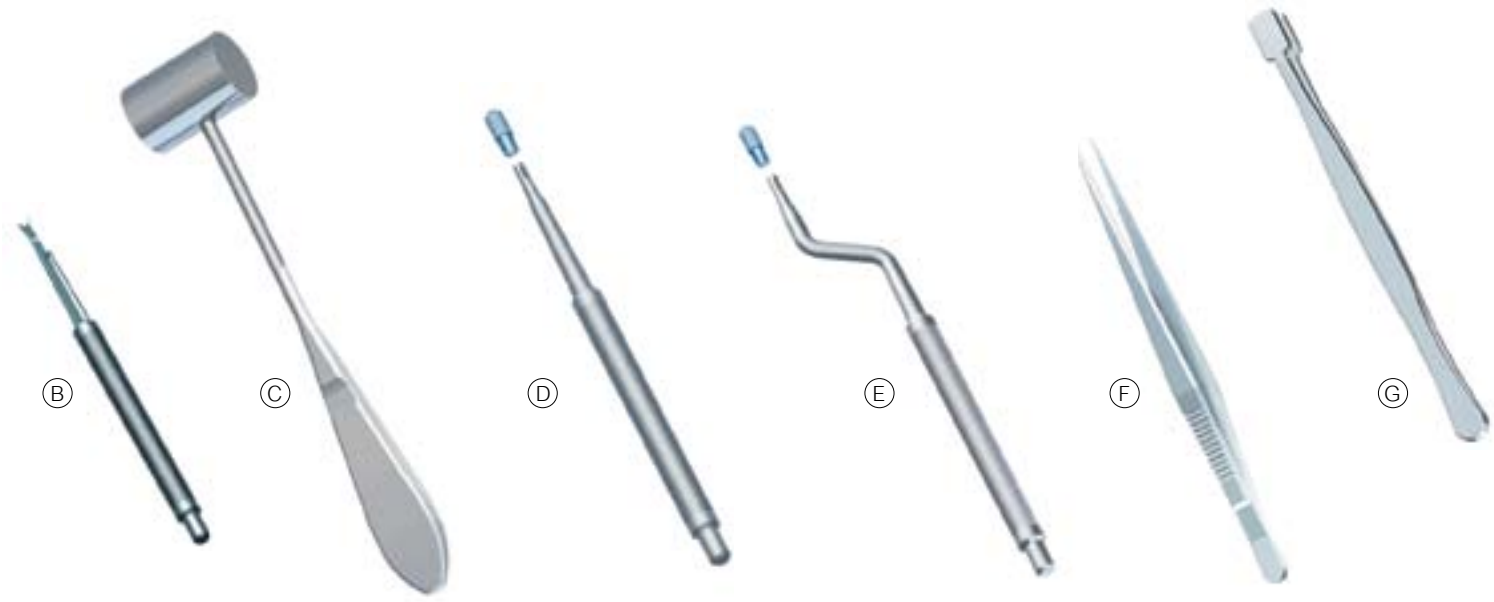
Item	Catalog #
Titanium Mesh (34 X 25mm), Sterile	3425TI

Bone Tack System

Bone Tack Instrumentation Kit

Complete Kit includes the following surgical instruments.

	Item	Catalog #
A	Bone Tack Instrumentation Cassette (organizer only)	1307
B	Membrane Stabilization Instrument	9535
C	Tack Mallet	9525
D	Bone Tack Instrument	9500
E	Angled Bone Tack Instrument	9510
F	Titanium Surgical Forceps	1200
G	Membrane Forceps	9530
H	Bone Tack Instrumentation Kit	9502



Additional Accessories

Item	Catalog #
Autoclavable Tack Holder	9575

Resorbable Bone Tack System

70/30 copolymer of L-Lactide / DL-Lactide

ZorbTac™

The IMTEC ZorbTac is a safe resorbable tack providing a membrane stabilization that eliminates the need for a second surgery. ZorbTac is composed of biocompatible copolymers. When the tack's mechanical properties are no longer needed, they're absorbed and reduced to carbon dioxide and water via the Krebs Cycle.

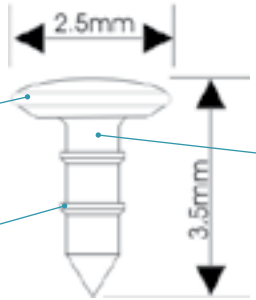
ZorbTac tacks maintain their structual integrity for 12-16 weeks.

ZorbTac™

Item	Catalog #
ZorbTac - 2 tacks/sterile package	ZTAC
	1-4 packs
	5-24 packs
	25+ packs

Item	Catalog #
ZorbTac Pilot Drill (not shown)	9509

- Used for initial penetration of bone
- Drill diameter (.91mm)



The dome shaped head of ZorbTac snaps into the Bone Tack Instrument and makes insertion and stabilization efficient and simple.

Designed with two barbs, ZorbTac has a wide diameter that provides a more secure and stabilized contact with the bone site.

ZorbTac is composed of a 70/30 copolymer of L-Lactide / DL-Lactide and is available in the length of 3.5mm.

Non-Resorbable Bone Tack System

Titanium

TiTac™

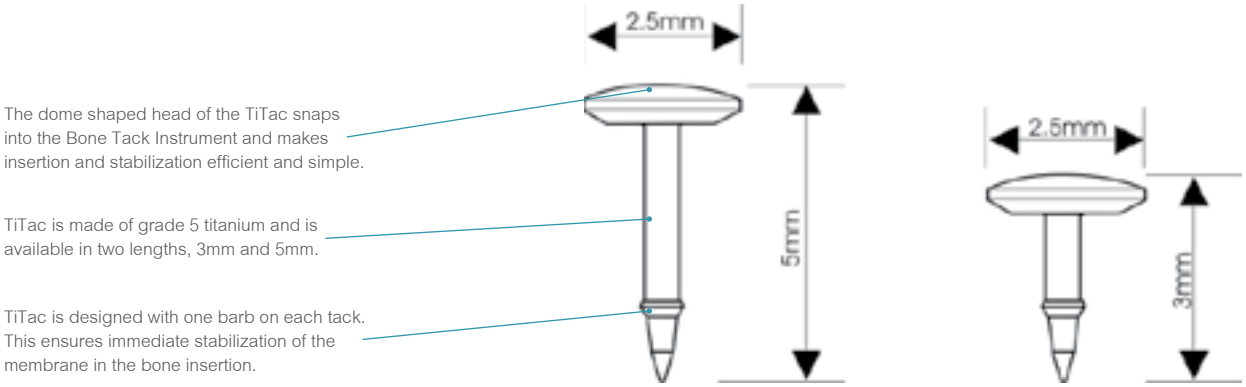
TiTac is a titanium tacking system that allows for simplified stabilization of a membrane. The TiTac may be placed without the use of a pilot drill*. At the clinician's discretion, TiTac may be removed.

TiTac™

Item	Catalog #
3mm tack, quantity of 5 - non-sterile	9503
5mm tack, quantity of 5 - non-sterile	9505

Item	Catalog #
TiTac Pilot Drill (not shown)	9515

- May be used for initial penetration of dense cortical bone
- Drill diameter (0.52mm)



*NOTE: In some instances a pilot drill may be needed for drilling dense cortical bone.

IMTEC

OSSEO™+

Cortical Demineralized Bone

Processing Treatment

For patients lacking proper bone structure, IMTEC Corporation now offers cortical demineralized bone. Cortical demineralized bone is produced for use in the reconstruction of maxillary or mandibular defects, or to assist in regeneration of bone tissue to maximize the potential for implant success.

To incorporate cortical demineralized bone material into bone regeneration procedures, mix the bone tissue with the patient's blood to form a loose paste, then insert the paste into the required areas according to the IMTEC bone/tissue regeneration protocol.

IMTEC cortical demineralized bone is derived from qualified donors, free from risk factors and disease according to U.S. FDA guidelines. A multi-stage processing system is used to ensure the product is pure and free from contaminates. No foreign substances are added to the material, resulting in the final product being classified (by the U.S. FDA) as a tissue.

The Processing treatment begins by cleaning cortical bone grafts of adherent tissue. The cleaned grafts are exposed to a series of solutions listed below and ground to the proper size, .125mm to .850mm sized particles. The particles are then exposed to a washing process consisting of a hydrochloric acid bath wash. The hydrochloric acid bath reduces the levels of calcium in the tissue to less than eight percent (typically less than 1%), which is recommended for a high degree of success. Cortical demineralized bone is then packaged, freeze-dried, and exposed to gamma irradiation. Irradiation step is performed with the graft in the final package to ensure the highest safety standards are achieved.

The preparation of bone grafts involves soaking and rinsing in the following solutions to clean and aid in inhibiting bacterial growth:

- Antibiotics
- Hydrogen Peroxide
- Alcohol
- Sterile water
- Allowash ®

Allowash ® is a patented process of LifeNet, Inc. and is licensed for use by Community Tissue Services.

The patented Allowash ® Treatment is extremely effective against viruses and bacteria. The technique consists of three different chemicals used to effectively remove cellular elements from musculoskeletal tissue while maintaining structural integrity.

Tests And Processing Information

The following tests are performed by Community Tissue Services on bone grafts:

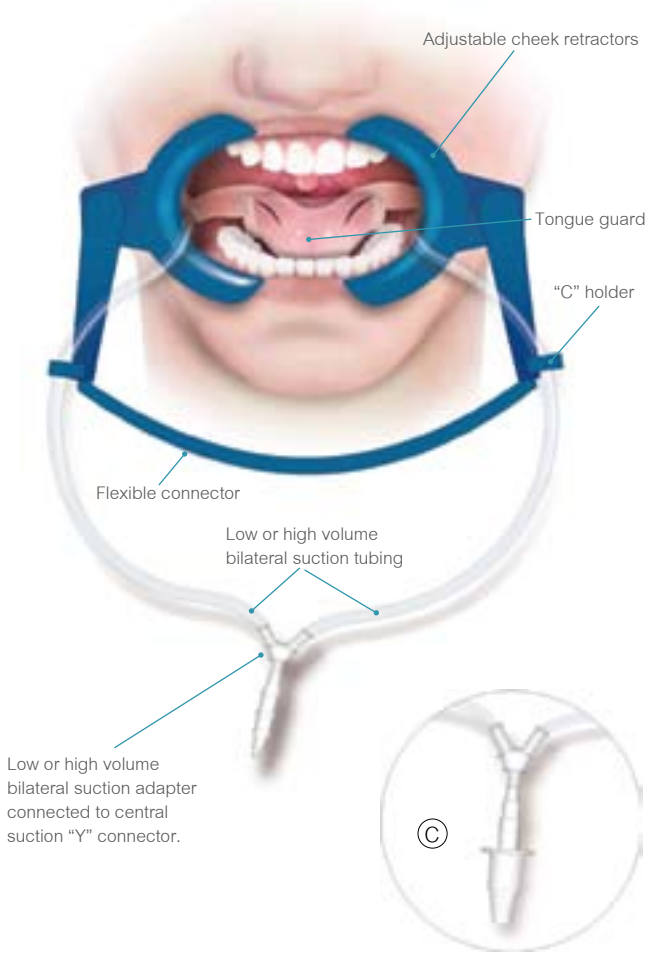
Serological Tests	Performed by Community Tissue Services	Required by AATB	Required by FDA
Hepatitis B Core Ab Total	*		
Hepatitis B Surface Ag	*	*	*
Hepatitis C Virus Ab	*	*	*
HIV 1/2 Ab	*	*	*
HTLV-I/II Ab	*	*	
RPR/STS or FTA	*	*	
HIV RNA NAT	*	*	
HCV RNA NAT	*	*	

- As of October 2004, CTS completed HIV RNA NAT and HCV RNA NAT back testing of inventory with available samples.
- The Gamma Irradiation process performed by Community Tissue Services is an added step to decrease the potential bacterial and viral risks to the patient.

IMTEC Cortical Demineralized Bone

Item Size	Catalog #
.5cc	OSSP05
1.0cc	OSSP10
2.0cc	OSSP20
5.0cc	OSSP50

IMTEC Dry Field System



The IMTEC Dry Field System is specially designed to retract the tongue and lips of the patient while the clinician performs IMTEC surgical or prosthetic protocols. The unique design of the system allows for a dry field that is achieved by suction tubes and fully exposes both dental arches for unparalleled access.

The complete system is flexible and adjustable for the patient's comfort. The IMTEC Dry Field System saves chair time and reduces salivary contamination during implant placement.

System includes:

- (2) Cheek retractors
- (1) Flexible connector
- (1) Tongue guard
- (2) Bilateral suction tubes
- (1) Central suction "Y" connector with low volume adapter

High volume bilateral suction adapter sold separately.

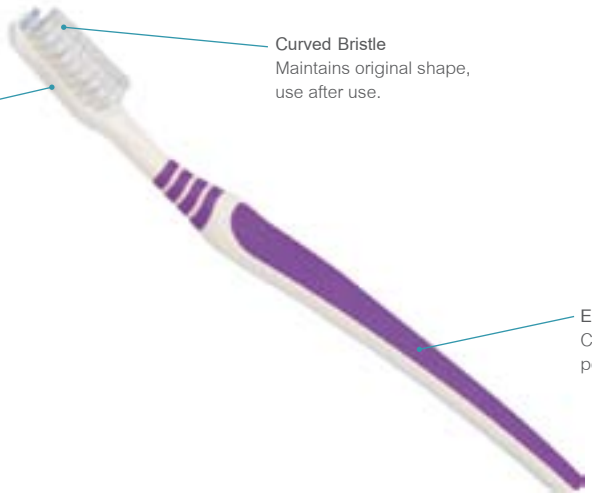
IMTEC Dry Field System

	Item	Catalog #
Ⓐ	IMTEC Dry Field System - Large (*Single use provided sterile)*	300-701
Ⓑ	IMTEC Dry Field System - Small (*Single use provided sterile)*	300-700
Ⓒ	High volume bilateral adapter	300-411

ACCESS™ Oral Care

The Implant Toothbrush with Curved-Bristle Memory!

Unique curved bristles with built-in memory provide the optimum position for aggressively cleaning abutment surfaces at the gum line. They have the required integrity to remove plaque and debris from implant prosthetics while gently stimulating the surrounding soft tissue.



Curved Bristle
Maintains original shape, use after use.

Surround Brush
Designed to gently clean around implant supported and natural teeth.

Easy-Grip Handle
Comfortable to hold. Ensures proper attack position for maximum plaque removal.

ACCESS™ Toothbrush

Item	Catalog #
ACCESS Toothbrush, Bristle Density #1 (hard) Available in assorted primary colors.	6008-12
ACCESS Toothbrush, Bristle Density #2 (medium) Available in assorted pastel colors.	6009-12

IMTEC™ Membrane & Tack Comparison Chart

The IMTEC™ Guided Tissue/Bone Regeneration System is designed to accommodate a clinician's tissue engineering needs.

Membranes	Resorbable	Non-Resorbable	Composition	Time as an effective barrier
BioSorb (Collagen)	•	—	Type 1 Bovine Achilles Tendon	26 - 38 weeks
BioCellect Perio (Synthetic)	•	—	Resorbable Homopolymer Lactic Acid	4 - 8 weeks
BioCellect Osseo (Synthetic)	•	—	Resorbable Homopolymer Lactic Acid	12 - 16 weeks
BioBarrier - Porous (PTFE*)	—	•	Pure Polytetrafluoroethylene	Must be removed
BioBarrier - Non Porous (PTFE*)	—	•	Pure Polytetrafluoroethylene	Must be removed

Membranes / Tissue Support				
Titanium Mesh	—	•	CP Titanium	Must be removed

Tacks				
ZorbTac	•	—	70/30 L-Lactide/DL-Lactide Copolymer	12 - 16 weeks
TiTac	—	•	Grade 5 Titanium	**

** Material: Proprietary pure Polytetrafluoroethylene. (PTFE)*

*** May be removed at the clinician's descretion.*

Technical/Clinical Assistance

International clinicians should contact an authorized IMTEC distributor or the company at www.imtec.com

- Telephone orders are accepted at: 800-879-9799 or 580-223-4456
- Customer Service fax numbers: 800-986-9574 or 580-223-4561
- Office Hours are 8:00 AM - 6:00 PM Monday-Friday Central Standard Time
- Technical Assistance: 800-879-9799 or 580-223-4456
- International customers may contact IMTEC by phone 800-897-9799 or 580-223-4456
- All major credit cards accepted
- All prices are subject to change without notice
- All graphics are by way of illustration only (Not responsible for typographical errors)
- For more information online please visit **www.imtec.com**

Orders placed after 3:30 PM Central Standard Time will be processed the following business day.

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