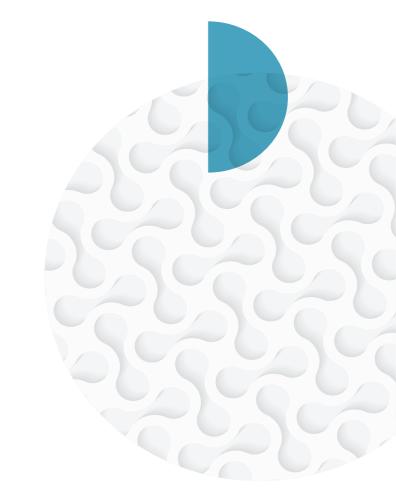
INNOVATIVE BONE

SOLUTION







INNOVATIVE BONE

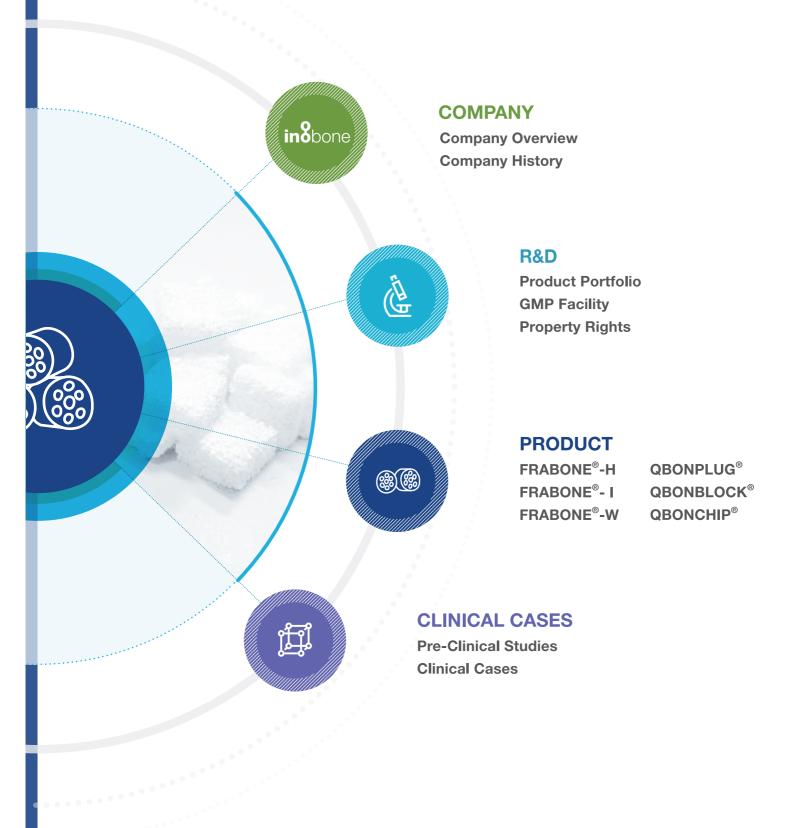
SOLUTION

Inobone Co., Ltd. aims to be a world top leader in the field of hard and soft tissue regeneration, including bone graft substitute, through world-class research and development to provide innovative solutions for improving human health.



in8bone

CONTENT





Inobone Co., Ltd.

Inobone Co., Ltd. aims to be a world top leader in the field of hard and soft tissue regeneration, including bone graft substitute, through world-class research and development to provide innovative solutions for improving human health.

The development of diverse healthcare industries in modern society has greatly improved the quality of human life. However, many developed countries are entering an aging society, and as a result, more and more people are easily exposed to musculo-skeletal diseases and accidents.

In the case of bone graft for the treatment of musculo-skeletal diseases and accidents, autogenous bone graft is still considered as a golden standard but the use of autogenous bone involves the inconvenience of obtaining through secondary surgery and the amount is very limited. In case of allograft and xenograft, the application is limited due to virus infections and immune rejection and also for religious reasons.

Although synthetic bone graft have excellent stability in preclinical testing, there has been limited clinical consensus on their use and limited expansion of the market. In the future, however, the use of synthetic bone will become a major trend due to the development of excellent synthetic bone free from virus infection and immune rejection

Inobone Co., Ltd. has developed FRABONE® & QBON®, a new type of synthetic bone graft material that overcomes the existing limitations, based on its own high-purity bioceramics and world-class bone substitute research and development. Both products have been acknowledged for their technology and received the **NET** (**New Excellent Technology**) from the Ministry of Health and Welfare of Korea. At present, these innovative products have received much attention in orthopedics, neurosurgery and dental markets.

Company History





2019

• ISO 13485:2016 certification





2018

- Launched FRABONE®-W
- Launched FRABONE®-C







2017

- Relocated company
- Launched FRABONE®-H
- Launched FRABONE®-I







2016

- NET Award for QBON®
- R&D work for Wedge Bone under TIPS







2015

- ISO 13485:2003 certification
- NET Award for FRABONE®







2014

- Launched FRABONE®
- Obtained KGMP approval





2013 ~ 2011

- Joined SCH University's Business incubator Tenants
- INOBONE and SCH to co-develop bone substitutes





2010

• INOBONE Co. Ltd. was established







R&D

Product Portfolio GMP Facility Property Rights

Product Portfolio

WORLD-CLASS



each surgical site



GMP Facility

Manufacturing facilities



▲ Raw material synthesis process



▲ Molding process



▲ Extrusion process



▲ Sintering process

Clean room facilities



▲ Air shower



▲ Coating process



▲ Washing process



▲ Packaging process

Intellectual property rights

Certification

INOBONE Co., LTD has been certified a research institute, ISO 13485:2016 and GMP quality, and for the first time in a bone graft material, it has been awarded NET (New Excellent Technology) certificate by the Ministry of Health and welfare as an innovative new technology.



Certificate of GMP Certification No.: KCL - ADB - 1187



Research Institute
No. 20414112047



Certificate of CE
Certificate No: 2195-MED-1935301



ISO 13485:2016



Certificate of NET 99th certificate of New Excellent7 Technology



Certificate of NET 124th certificate of New Excellent Technology

Patent

Inobone Co., Ltd. has various patents through continuous technology investment and development to secure international technology competitiveness.



Trademark Registration



Trademark Registration



Design Registration



Patent (KR)



Patent (KR)



Patent (KR)



Patent (US)



Patent (GE)



FRABONE®

FRABONE® has achieved the distinction of being accredited as a "New Excellent Technology" (NET) by the Korean Ministry of Health and Welfare In 2015





FRABONE -H

FRABONE®-H is a synthetic bone void filler made of micro-channeled biphasic calcium phosphate (BCP) granules and coated with hyaluronic acid (HA)



FRABONE-I

FRABONE®-I is an injectable synthetic bone void filler made of micro-channeled biphasic calcium phosphate (BCP) granules coated with hyaluronic acid (HA)



FRABONE®-W

FRABONE®-W is a synthetic bone substitute that is composed of micro-channeled biphasic calcium phosphate (BCP) granules mixed with HAp (60%) and β – TCP (40%) in a wedge type



FRABONE® has achieved the distinction of being accredited as a "New Excellent Technology" (NET) by the Korean Ministry of Health and Welfare In 2015

Design concept of **FRABONE**®

Human Cortical Bone Mimic Design

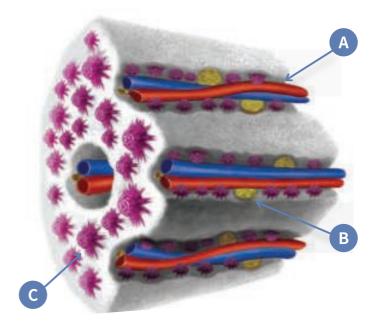
FRABONE® canal structure

FRABONE® imitates Haversian canal of human cortical bone

Regeneration process

FRABONE® canal structure is filled up with vessels and now bone materials, resulting in faster regeneration.

- A Blood vessels
- B Osteoclast
- Osteoblast
- * International Patent: PCT / KR2011 / 05509 · USA, Germany



Design concept of **FRABONE**®

Human Cortical Bone Mimic Design

Advantage & Positioning

Similar to the human bone

Just like human bone in structure, strength & porosity

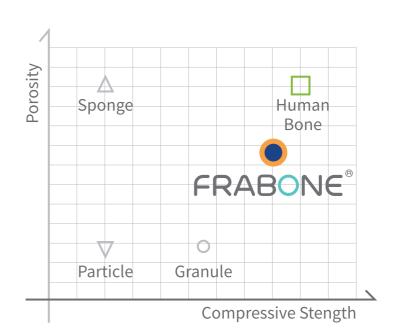


Haversian canals & macro-pores for angiogenesis and osteogenesis Submicron-pores for fast biodegradation



High purity bio - ceramics Ideal HAp / β - TCP ratio







FRABONE®-H is a synthetic bone void filler made of microchanneled biphasic calcium phosphate(BCP) granules coated with hyaluronic acid(HA).

The HA coating is a water-soluble polymer, which acts as a temporary binding agent for the granules.

After implantation the binder is absorbed leaving behind only the highly porous Frabone granules thus allowing the infiltration of new blood vessels and new bone materials, resulting in faster bone regeneration.

Indications

FRABONE®-H is a bone void filler intended for use as a synthetic bone implant material for orthopedic, dental and neurosurgical applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure.

FRABONE®- H

Advantages



Easy to Use

FRABONE®-H is packaged in pouch for easy use. Hyaluronic acid water-soluble coating as a binder



Human Bone Mimic Design

Similar to human bone in structure, strength & porosity



Fast bone regeneration

Haversian canals & micro / Micro pores for angiogenesis and osteogenesis



High biocompatibillity

High purity and ideal HAp & β -TCP (60/40) ratio Coated with hyaluronic acid

Features

Properties	FRABONE®-H
Granule Diameter	0.7mm, 3.0mm
Unit weight	1.0g, 3.0g, 5.0g, 10.0g, 20.0g, 30.0g
Product Type	Granular Bone Void Filler
Composition	Hydroxyapatite, Beta-tricalcium Phosphate, Hyaluronic Acid
Mechanism of Action	Osteoconductive, Biocompatible, Bioactive, Bioresorbale
Indication of Use	Orthopedics & Neurosurgery
Granule Channel Number	3-16
Granule Channel Diameter	100~300μm

FRABONE®- H

Order Information < Orthopedic / Neurosurgical >







Produ	ct Code	Unit Weight (g)	Granule Size (dxh, mm)
	070300	3.0	0.7 x0.7
OGFBT	070500	5.0	0.7 x0.7
OGFDI	071000	10.0	0.7 x0.7
	072000	20.0	0.7 x0.7
OGFBT	300100	1.0	3.0 x 2.0
	300300	3.0	3.0 x 2.0
	300500	5.0	3.0 x 2.0
	301000	10.0	3.0 x 2.0
	302000	20.0	3.0 x 2.0
	303000	30.0	3.0 x 2.0

Instruction For Use



Check the labels for the right amount for appropriate use before opening the packaging



Carefully open the pouch







Produ	ct Code	Unit Weight (g)	Granule Size (dxh, mm)
0.651	070025	0.25	0.7 × 0.7
OGFI	070050	0.5	0.7 × 0.7



Hydrate the granules with saline. Let it stand for 20-30 seconds to let the sticky coating swell



Apply the granules on the bone defect area using a spatula

^{*} FRABONE®-H can be also used without using saline, it will be hydrated upon contact with the fluids found on the implant site such as blood.

^{*} Over mixing with physiological saline can weaken the viscosity of FRABONE®-H



FRABONE®-I is an injectable synthetic bone void filler made of micro-channeled biphasic calcium phosphate (BCP) gran-Ules coated with hyaluronic acid(HA).

The HA coating is a water-soluble polymer, which acts as a temporary binding agent for the granules. After implantation the binder is absorbed leaving behind only the highly porous Frabone granules thus allowing the infiltration of new blood vessels and new bone materials, resulting in faster bone regeneration.

Indications

FRABONE®-I is a bone void filler intended for use as a synthetic bone implant material for orthopedic, dental and neurosurgical applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure.

FRABONE®- I

Advantages



Easy to Use

FRABONE®-I is packaged in a syringe type designed for easy use.





Human Bone Mimic Design

Similar to human bone in structure, strength & porosity



Fast bone regeneration

Haversian canals & Micro / Macro pores for angiogenesis and osteogenesis



High biocompatibillity

High purity and ideal HAp & beta -TCP (60 / 40) ratio Coated with hyaluronic acid

Features

Properties	FRABONE®-I
Granule Diameter	0.7mm
Unit weight	0.25g, 0.50g, 3 g
Product Type	Injectable Granules / Syringe
Composition	Hydroxyapatite, Beta-Tricalcium Phosphate, Hyaluronic Acid
Mechanism of Action	Osteoconductive, Biocompatible, Bioactive, Bioresorbable
Indication of Use	Dental
Granule Channel Number	3
Granule Channel Diameter	100~300μm

FRABONE®- I

Order Information < Dental >







Product Code Unit Weight (g)		Granule Size (dxh, mm)	
DOF	070025	0.25	0.7 × 0.7
DGFI	070050	0.5	0.7 × 0.7

Instruction For Use



Unscrew the outer cap (Be careful not to remove the inner cap)



Hydrate FRABONE®-I with saline water by using plunger (pull & push 1~2times)







Produ	ct Code	Unit Weight (g)	Granule Size (dxh, mm)
DCEDT	070100	1.0	0.7 × 0.7
DGFBT	070300	3.0	0.7 × 0.7



Remove the saline water by pushing the plunger gently and wait 20 seconds for suitable hydration



Unscrew the inner cap and inject FRABONE®-I at the implant site

 $^{^{\}star}$ Over mixing with physiological saline can weaken the viscosity of FRABONE®-I



FRABONE®-W is a synthetic bone substitute that is composed of micro-channeled biphasic calcium phosphate (BCP) granules mixed with HAp (60%) and β – TCP (40%) in a wedge type.

This product maintains excellent porous structure and excellent compressive strength, which overcomes limitations of bone substitute used in conventional orthopedics and neurosurgical surgery.

Indications

FRABONE®-W is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the tibia, ankle and foot, such as:

- Opening wedge osteotomies of the bones of the foot
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Evans Lengthening osteotomy or Calcaneal Z osteotomy
- Metatarsal/Cuneiform arthrodesis

FRABONE®-W

Advantages



Easy to Use

FRABONE®-W is packaged in pouch for easy use Each-type design make it easy to handling



Human Bone Mimic Design

Similar to human bone in structure, strength & porosity



Fast bone regeneration

Haversian canals & Micro / Macro pores for angiogenesis and osteogenesis



High biocompatibillity

High purity and ideal HAp & beta -TCP (60 / 40) ratio

Features

Properties	FRABONE®-W
Product Type	Wedge, Truncated cone, Mat
Composition	Hydroxyapatite, Beta-Tricalcium phosphate
Mechanism of Action	Osteoconductive, Biocompatible, Bioactive, Bioresorbable
Indication of Use	Orthopedics & Neurosurgery
Pore Size	100~300 um

FRABONE®- W

Order Information < Orthopedic / Neurosurgical >

<Wedge type>

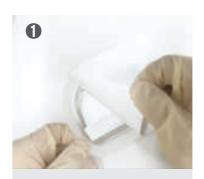






Produ	ct Code	Wedge Size (L x W x H, mm)
	0745	35 x 45 x 7
OWIDI	1045	35 x 45 x 10
	1345	35 x 45 x 13

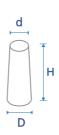
Instruction For Use



Check the labels for appropriate use before opening the packaging

<Truncated cone type>





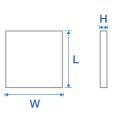
Produ	ct Code	Wedge Size (d x D x H, mm)
OWFBT	1014	10.5 x 13.5 x 37

2

Carefully open the pouch

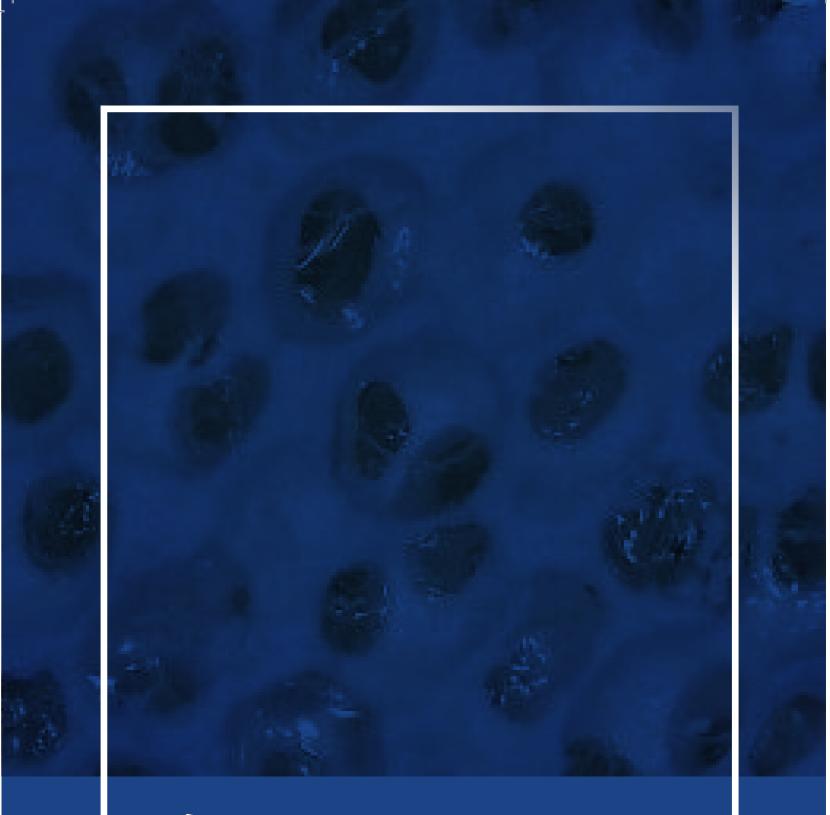
<Mat type>





Produ	ct Code	Wedge Size (L x W x H, mm)
OMFBT	0545	45 x 45 x 5
OMFBT	0514	45 x 14 x 5







PRODUCT

QBONPLUG®
QBONBLOCK®
QBONCHIP®

QBON®



QBON® has achieved the distinction of being accredited as a "New Excellent Technology" (NET) by the Korean Ministry of Health and Welfare in 2016





QBONPLUG®

QBONPLUG® is a unique type dental bone plug with a highly porous hydrogel structure having a tooth-shaped matrix with BCP bone graft inserted inside providing not only hemostasis and pain relief but also fast bone formation and extracted socket preservation



QBONBLOCK®

QBONBLOCK® is a block type synthetic bone graft whose frame is composed of biphasic calcium phosphate (BCP) applying high porosity and ECM - like hydrogel technology, leading to fast bone formation



QBONCHIP®

QBONCHIP® is a chip type synthetic bone graft whose frame is composed of biphasic calcium phosphate (BCP) applying high porosity and ECM - like hydrogel technology, leading to fast bone formation



QBON® has achieved the distinction of being accredited as a "New Excellent Technology" (NET) by the Korean Ministry of Health and Welfare in 2016

Design concept of **QBON**®

Human Cancellous Bone Mimic Design

QBON® frame structure

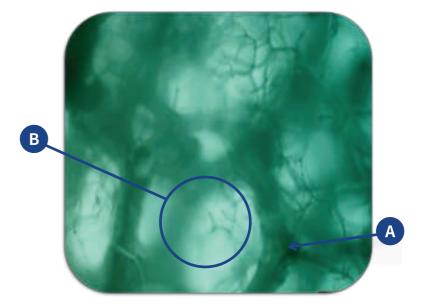
QBON® imitates human cancellous bone & ECM-like structure

Regeneration process

The osteocyte is rapidly activated in the ECM - like grating structure, then the interconnected porous structure of the cancellous bone causes neovascularization, resulting in faster regeneration

- A Cancellous bone frame
- B ECM-like structure

* International Patent: PCT / KR2011 / 05509 · USA, Germany



Design concept of **QBON**®

Human Cancellous Bone Mimic Design

Advantage & Positioning

Similar to the human bone

Just like human bone in structure, strength & porosity



Fast bone regeneration

ECM - like structure for easy osteocyte adhesion Macro-pores mimicking human cancellous bone for osteogenesis

Excellent bio - compatibility

High purity bio - ceramics Ideal HAp $/ \beta$ - TCP ratio





QBONPLUG® is a plug-type synthetic bone substitute designed to be used for socket preservation, which forms the most ideal frame structure for excellent cell attachment and differentiation, leading to rapid bone regeneration.

QBONPLUG® is a biodegradable controlled human cancellous bone mimic synthetic bone graft with uniform lattice structure of 100 ~ 300 micro-meter diameter, combined with porous hydrogel technology. It promotes attachment and differentiation of osteoblast by adding a high purity beta-TCP to the porous mimicking ECM structure.

Indications

QBONPLUG® is a plug-type synthetic bone substitute intended for use as socket preservation leading to new bone formation.

QBONPLUG®

Advantages



Easy Implant Surgery

Allows impant surgery in case of alveolar bone resorption with fast bone formation.



Human Bone Mimic Design

Similar to cancellous bone structure with ECM-like hydrogel matrix



Socket preservation & bone formation

Acts as a scaffold for new bone formation and it easy for socket preservation.



Membrane is not required

Does not need membrane application on the extraction socket.

Features

Properties	QBONPLUG®
Unit Volume	0.6 ~ 2.7 cc
Product Type	Synthetic bone plug
Composition	Hydroxyapatite, beta-Tricalcium phosphate, Hydrogel
Mechanism of Action	Osteoconductive, Biocompatible, Bioactive, Bioresorbable
Indication of Use	Dental
Porosity	80~85%
Pore Diameter	50 ~ 300 μm

QBONPLUG®

Order Information < Dental >

<Moral>





Product Code		Unit Volume (cc)	Plug Size (d x w x h)
DDODD	ML	2.5	19.5 x 14.0 x 12
DPQBP	ММ	1.4	16.5 x 11.5 x 9.5

Instruction For Use



Check the labels for appropriate use before opening the packaging



Carefully open the pouch

<Pre-Moral>





Product Code		Unit Volume (cc)	Plug Size (d x h)	
DPQBP	PL	2.7	28 x 13	
	РМ	1.4	23 x 10.5	



Apply the bone plug on the extraction socket

 $[\]star$ Use premolar or molar bone plug depending on the type of tooth extracted.





CLINICAL CASES

Pre-Clinical Studies Clinical Cases

Biological interactions

FRABONE®

Enhanced bone regeneration invivo with FRABONE® in a rabbit model implanted in the femur head.

Bone formation was prolific through the channel and in-between the granule.



Lateral channel Section

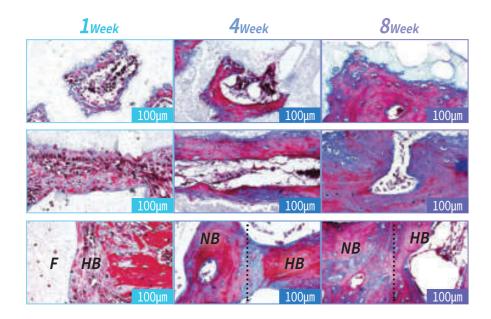
Significant increase in osteogenesis observed in lateral channel section.

Longitudinal channel section

Accelerated osteo-genesis process in several inner canals of FRABONE®.

Interface

Direct bonding with NB(New Bone) and HB(Host Bone) in the Defected areas.



* Masson's Trichorme stained FRABONE® implanted bone areas. F(FRABONE®), HB (Host Bone), NB(New Bone).

Research result

FRABONE® showed excellent result in pre - clinical research. FRABONE® proved to be outstanding in early osteogenesis process, and bone defects were filled with new bone similar to the natural bone structure

Orthopedic Surgery

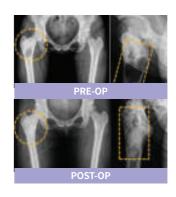
Clinical cases

Osteofibrous dysplasia

A 33 years old female was diagnosed with right hip pain. Radiaographs and CT scan revealed fibrous dysplasia in femoral intertrochanter area.

Window was opened at the anterolateral of the proximal femur fibrous dysplasia lesions and the lesion tissues were removed with a curet under direct vision. FRABONE® was grafted at the femoral intertrochanter defect. No internal fixation was used to support the operated bone. At month 6, the patient had recovered well with no complaints and had returned to work. Radiological and clinical observations revealed that FRABONE® ensured bone regeneration without complication.

After 12 months the X-Ray shows that the void created after the removal of fibrous tissue was filled with newly regenerated bone through the intergranular and intragranular porosity.





Osteotomy

In two separate patients, one, aged 57 years old female with severe walking pain with mechanical locking (catching pain) of knee joint and the other, 60 year old female, with the same problem were treated.

The first patient was diagnosed with medial meniscus root tear and the second patient with medial meniscus posterior horn complex tear. Both of them had severe medial compartment osteoarthritis and varus deformity. After arthoscopic partial mesiscectomy and synovectomy an opening wedge high tibial osteotomy was performed with 1mm and 3 mm size Frabone, respectively. Tibia was stabilized using locking screw mechanism. FRABONE® ensured bone regeneration within the bone void. No pain and post operative complication was observed.

After 5 months the X-Ray shows that the void created after the osteotomy was filled with regenerated bone through the inter and intra granular porosity of FRABONE®





Orthopedic Surgery

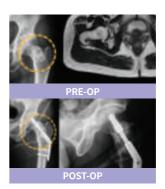
Clinical cases

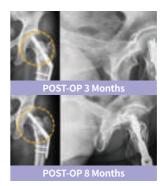
Simple bone cyst

A 50 years old female was diagnosed with right hip pain. Radiographs and MRI scan revealed bone cyst in femoral intertrochanter area. The cyst was removed by curettage from the anterolateral of the proximal femur.

FRABONE® was grafted at the defect in femoral intertrochanter and femur neck. Due to the weak femur neck an additional support implant was used to stabilize the hip joint. At month 8, the patient had recovered well with no complaints and had returned to work. Radiological and clinical observations revealed that FRABONE® ensured bone regeneration without complication.

After 8 months the X-Ray shows that the void created after the removal of cyst was filled with newly regenerated bone. The fixation of implant helped to stabilize the femur neck and prevent premature fracture while the void after the cyst removal is being regenerated with the help of FRABONE®.



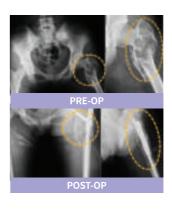


Simple bone cyst with fracture

A 15 years old female was treated with right hip fracture after a trauma. Raiographs and CT scan reveal the fracture caused due to bone weakening for a bone cyst formation.

The fracture was treated after the cyst removal by curettage from the anterolateral of the proximal femur. FRABONE® was grafted at the femoral intertrochanter defect. The fractured femur neck was stabilized by support implant and hip joint activity was restored. At month 8, the patient had recovered well with no complaints and had returned to work. Radiological and clinical observations revealed that FRABONE® ensured bone regeneration without complication.

After 5 months the X-Ray shows that the FRABONE® loaded bone fracture zone was filled with newly regenerated bone. The fixation implant helped to stabilize the hip joint and prevent premature fracture and ensured patients mobility.





Orthopedic Surgery

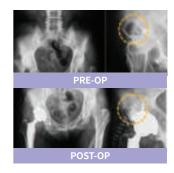
Clinical cases

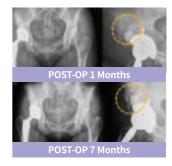
Avascular Necrosis

A 69 years old female was treated for right hip pain. Radiographs and CT scan reveal the bone necrosis near acetabulum. The hip joint needs replacement and a total hip replacement operation was done with bone grafting for the replacement of bone with necrosis.

Bone undergone necrosis was removed by curettage from the pelvis. FRABO-NE® was grafted at the pelvis defect. Artificial hip joint was installed in place with proper fixation. At month 7, the patient had recovered well with no pain and complication. Radiologically and clinically revealed that FRABONE® ensure bone regeneration without complication.

After 8 months the X-Ray shows that the void created after the removal of cyst was filled with newly regenerated bone. The fixation of implant helped to stabilize the femur neck and prevent premature fracture while the void after the cyst removal is being regenerated with the help of FRABONE®.





Dental Implant

Clinical cases

Dental Implant

A patient with dental caries and inflammation on multiple teeth was treated. Both of the maxillary molar area had insufficient bone. After extraction of affected teeth a maxillary sinus lift operation was planned before the dental prosthesis application.

FRABONE® was used for the maxillary sinus lift procedure. No inflammatory response was observed and the bone healing progressed gradually. After 4 months no bone absorption occurred and hardening was observed. After 6 months of initial implantation the cavity was fully regenerated with newly formed bone observed under biopsy and microscopical analysis. Dental prosthesis was fixed on the elevated maxillary sinus and stable implant performance was observed postoperatively without any failure or complication.

FRABONE® was applied for maxillary sinus lift up and observed for 6 months, after which the cavity formed by removal of tooth was fully regenerated as shown in the biopsy data. Application of dental prosthesis on the elevated maxillary sinus was performed successfully after 6 months.

