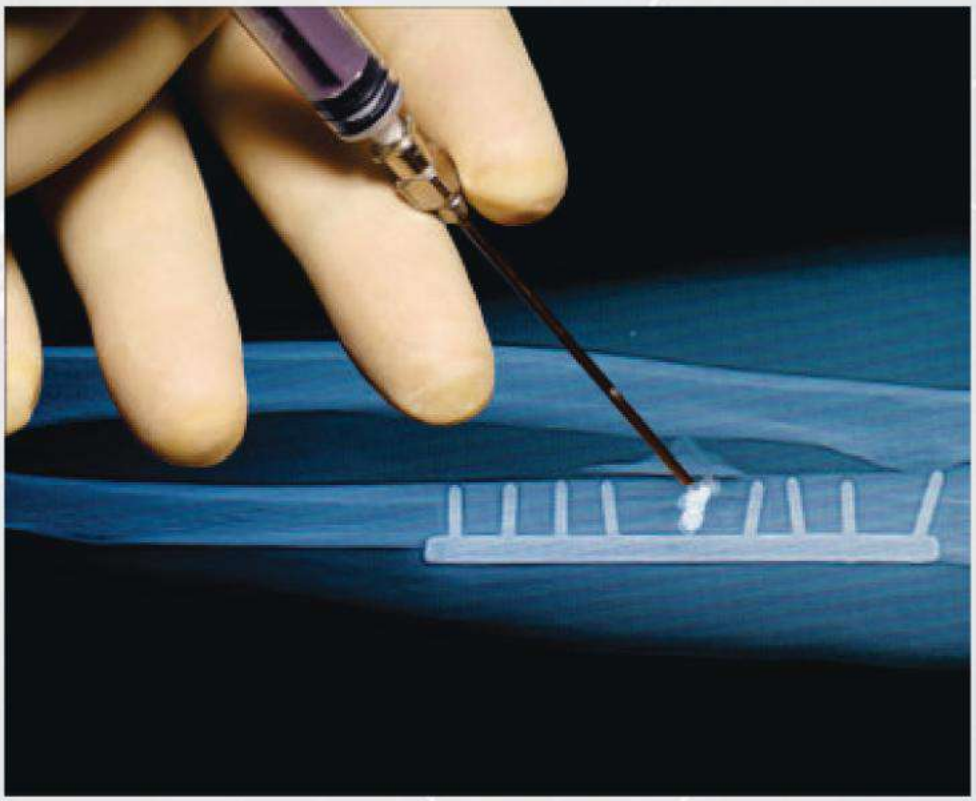
RIOSTIN Synthetic HA Powder SHAP

Prevent non union of fractured bone



In 15-20% cases the bone ends of fractured bone do not unite and non union/ delayed union occurs.

It is equally common in all types of cases. Whether it is closed reduction, open reduction with screw plates or nailing. There are variety of causes such as clot formation, interposition of soft tissue between ends of bone.

TAVAS® brings you HA powder to be injected between and around ends of broken bones.

in all cases of open or closed reduction. This will improve the environment around the fracture and increase chances of healing by providing an environment of Calcium & Phosphate ions the building blocks of bone. It will increase activity of Osteoclasts and osteoblasts in the vicinity of fractured bone ends.

Closed injection of HA powder can be repeated after 7-20 days depending upon X-ray visualisation of bone healing activity / callus. If callus is not visible after three weeks. Repeat injection of HA Powder is recommended.

The quality of TAVAS® HA powder is that it will not diffuse around and will remain coalesced as injected for prolonged period.

You may expect a significant reduction in non union cases.

Put the powder on plastic petri dish

add sterile distilled water & mix with spatula

Make paste to a flowable consistancy.

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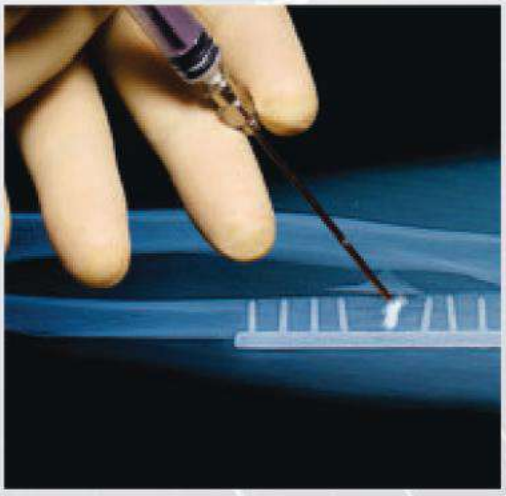
Load the paste into the syring from open wide end of barrel.



Inject under C-arm visualization between and around ends of bone. Depending upon the fracture you may have to use 10-50 gms of powder.

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RIOSTIN Natural hydroxyapatite with natural collagen.

INTRODUCTION

Conventional bone grafting is done with autologous bone graft from iliac crest, which is still the gold standard. However, it involves another operative procedure, longer operating time and more trauma to the patient. The donor site becomes painful after healing.

TAVAS has developed xenograft in the name of RIOSTIN. It is natural Hydroxyapatite with natural collagen and with naturally occurring trabecular pattern. It is very useful for bone repair and replenishment. It can be used in weight bearing areas.

One should remember that results of use of RIOSTIN may be inferior to autologous bone.

DESCRIPTION

RIOSTIN is made of natural low crystalline Hydroxyapatite with collagen. It is available in form of granules, dowels and blocks. The shape can be changed by using Gigli saw and bone nibblers.

The information, given here, is not exhaustive and is for guidance only. The surgeon is best advised to use the method, which his own practice and discretion dictate to be best for the patient.

INDICATIONS

RIOSTIN is indicated in almost all the places where a bone graft is required. Following are some of the indicative uses specialty wise.

Neurosurgery: Lumber & cervical fusion, vertebral reconstruction, cranial reconstruction and other types of reconstructions.

·Orthopedic Surgery: Lumber & cervical fusion, vertebral reconstruction, cranial reconstruction and other types of reconstructions, Cavity filling, osteotomy reconstructions, non union fracture and filling the gaps in cases of bone loss due to trauma.

·Plastic Surgery: Maxillofacial reconstructions, bony augmentation, hand surgery & cavity filling.

·Dental Surgery: Maxillofacial reconstruction surgery, periodontics, orthodontics and other areas requiring a bone graft.

·Other Specialties: Where a bone graft is required.

CONTRAINDICATIONS

Presence of infection whether local or general, prohibits all kind of implantation procedures. Open wounds will not respond well with bone grafting surgeries.

Poor general health and metabolic deficiencies will not produce desired results.

Above mentioned contraindications are general. The surgeon must evaluate the individual patient for the risks involved.

WARNINGS

Collapse of RIOSTIN is a possibility.
Do not re sterilize RIOSTIN.
Only blocks with weight bearing line should be used for weight bearing areas.
The slot line on the block should be parallel with weight bearing axis of the body.

METHOD OF USE

RIOSTIN implantation is an implantation procedure. It carries a greater risk of infection because of large surface area. It is advisable to take all precautions necessary for an implantation procedure. Some of the points are given below:
a. It should be first procedure in the morning.
b. There should be minimum number of people inside the
theatre (4persons). No scrub nurse
c. There should be minimum movement inside OT.
d. Procedure should be as fast as possible 20-50 minutes.
e. Use disposable mops only (it is a must)
f. Use disposable drapes.
g. Use incise drapes on incision sites.
h. Only 2-4 procedures in a day.
i. The grafting material should be opened only just before implantation.
j. Minimum handling of graft material.
k. Use skin staplers for skin closure.
After opening the site of implantation, obtain good hemostasis of the area. Scrap the walls of the cavity/defect. Remove all soft tissue from the cavity or defect. Harvest some bone and bone marrow from the same site by scraping and shallow drilling in the cavity. Incorporation of patients own bone and bone marrow provides BMP's for bone healing and improves results. Larger cavity size needs larger percentage of patients own bone. Fill gap with RIOSTIN blocks or granules. Cover the gap with soft tissue. Gelatine foam sponge may be used to cover the granules and to prevent spilling of granules. Calcium phosphate cement (RIOSTIN CP Cement) may also be used to secure the granules and top the cavity.

COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical

RI STIN Natural hydroxyapatite with natural collagen.

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procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

Some complications specific to RI STIN are following

* Collapse of block: There must be secondry arrangements to prevent damage due to collapse of block

* Fracture of RI STIN

* Lack of integration

The medical literature is full of hazards and complications associated with use of Calcium Hydroxyapatite. Some of the major hazards are infection, extrusion of grafted material, serous discharge, serous collection, hemorrhage, skin erosion and migration.

Granules 10cc pack

0.5-0.9 mm average particle size

0.9-1.9 mm average particle size

1.8-5.0 mm average particle size

Granules 1cc pack

0.5-0.9 mm average particle size

0.9-1.9 mm average particle size

1.8-5.0 mm average particle size

Chips 10cc pack

5x 15 mm average chip size

Blocks Average Block size and qty

30 x 15 x 6 mm 1no.

30 x 15 x 7 mm 1no.

30 x 15 x 8 mm 1no.

30 x 15 x 9 mm 1no.

30 x 15 x 10 mm 1no.

30 x 15 x 12 mm 1no.

30 x 15 x 14 mm 1no.

30 x 15 x 16 mm 1no.

30 x 15 x 18 mm 1no.

30 x 15 x 20 mm 1no.

Dowel Average Dowel size and qty. One

Dia 8, length 10 mm

Dia 10, length 12 mm

Dia 12, length 19 mm

Dia 13, length 19 mm

Dia 14, length 19 mm

Dia 15, length 19 mm

Dia 12, length 5 mm

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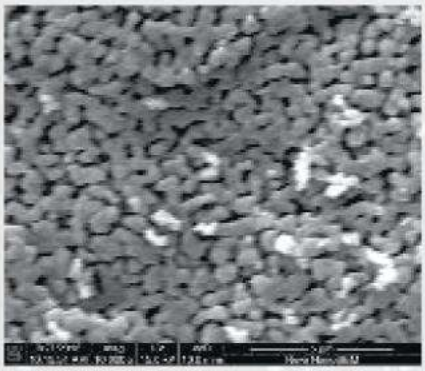
RIOSTIN Modified Hydroxyapatite

Modified Hydroxyapatite

TAVAS® Hydroxyapatite products are world renowned and have successful user experience of more than 16 years.

Modified hydroxyapatite is a combination of HA 40% (hydroxyapatite) & ß-TCP (beta-tricalcium phosphate) is 60%. It consists of nano crystal agglomerates.

It has excellent osteo-conductive properties bordering to the level of osteo-inductive property. With this material bone healing is very fast.



Microstructure of as-synthesized Modified HA block

Granules 10cc Pack

0.1-0.4 mm average Particle Size

0.4-0.9 mm average Particle Size

0.8-1.8 mm average Particle Size

1.8-3 mm average Particle Size

Granules 1cc Pack

0.1-0.4 mm average Particle Size

0.4-0.9 mm average Particle Size

0.8-1.8 mm average Particle Size

Blocks Average Block size & quantity

1 x 0.5 x 0.5 cm 20 nos.

1 x 1 x 2 cm 5 nos.

1 x 1.5 x 2 cm 3 nos

2 x 2.5 x 0.3 cm 1 no.

2 x 2.5 x 0.5 cm 1 no.

Supplied ready to use Gamma-ray sterilized in double peel open packaging.

TAVAS®

RIOSTIN Synthetic Hydroxyapatite

Synthetic Hydroxyapatite

TAVAS® Hydroxyapatite products are world renowned and have successful user experience of more than 16 years.

Synthetic Hydroxyapatite is a pure naocrystalline HA. Nano crystals mimic biological HA, present in our human body.

Here healing is faster than other macrocrystal HA available from other sources.. It consists of nano crystal agglomerates.

It has excellent osteo-conductive properties.

Granules 10cc Pack
0.1-0.4 mm average particle size
0.4-0.9 mm average particle size

Granules 1cc Pack
0.1-0.4 mm average particle size
0.4-0.9 mm average particle size

Blocks Average Block size and quantity
1 x0.5 x 0.5 cm 20 nos
1 x 1 x 2 cm 5 nos.

Dowel
These dowels are made of nano crystalline HA with absorbable fibers. These are very strong due to fibers.

Average Dowel size
Dia 12 length 14 mm
Dia 14 length 16 mm
Dia 16 length 18 mm
Dia 18 length 20 mm
Dia 20 length 22 mm

Injectable HA nano crystalline powder
This powder is to be mixed with sterile distilled water to make an injectable paste. It can be injected through a thick needle (14 gauge) to the site. useful for non-union of bone.

Synthetic HA Powder SHAP

Soft Synthetic HA
This unique HA granule becomes soft like sponge on wetting with saline or water. It can be molded like putty. It can be easily used to fill cavities.

Soft Granules 10 cc pack
0.8-1.8 mm average particle size
1.8-3 mm average particle size

Soft Granules 1cc pack
1 cc packaging has 4 small packaging for dental use. One 1/4 packaging is more than sufficient for one dental socket filling after extraction. By virtue of being soft like sponge it will be held in place & will not wash out.

0.8-1.8 mm average particle size

Soft Carve-able blocks
These blocks when wet with saline or water can be carved using sharp blade.
1 x 1.5 x2 cm 3 nos
2 x 3 x3 cm 1 no.

MADE IN INDIA

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