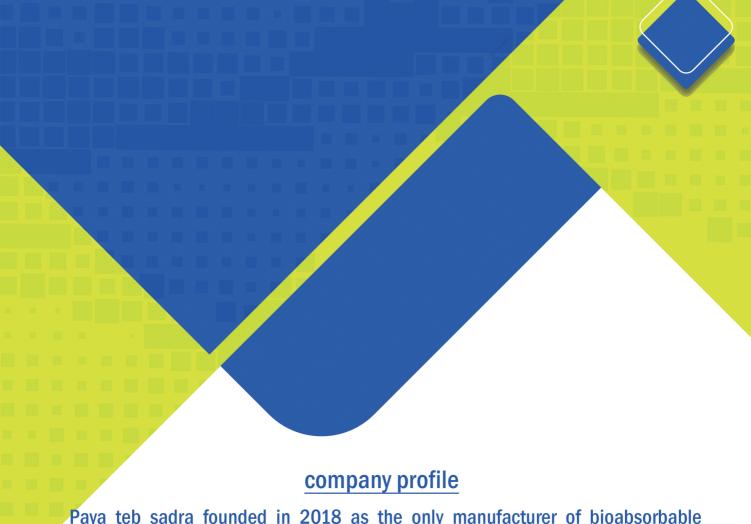


Design, Formulation, mechanical and chemical advantages of PAYA TEB Sadra

Always at the edge of orthopedics!

www.Payatebs.com

Edition 2025



Paya teb sadra founded in 2018 as the only manufacturer of bioabsorbable implants in the Middle East.

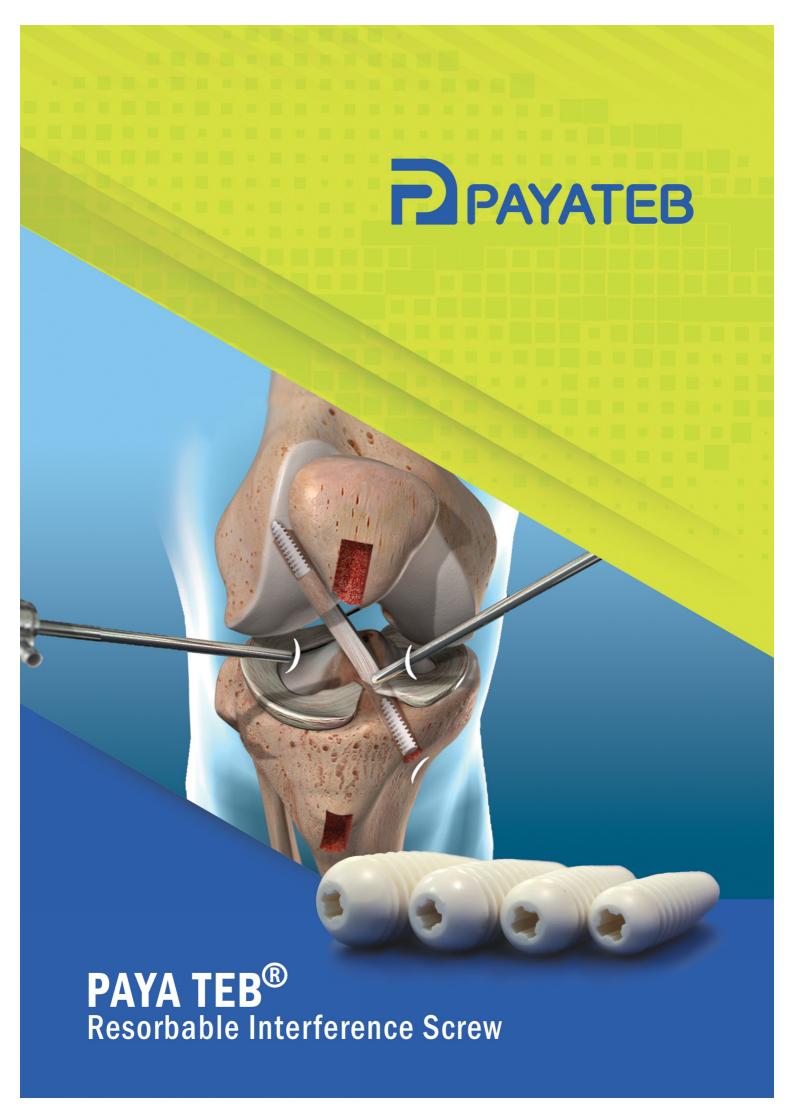
As a High-Tech company, we benefit the license manufacturing agreement with a well-known multi national orthopedic device manufacturer with more than 20 years of experience in the area of various medical devices. Our manufacturing facility is ISO 13485 certified (by KIWA CERMET ITALY) and located in Pardis (15 km East of Tehran). Our facility consist of following sub production systems including:

Clean Room Class ISO 7 (1class 10.000)
SC Cleaning system
Super Precision Laser Systems
Special Gas Storage System
Vacuum Medical Packaging Line

Our goal is to provide the local market as well as the market in neighboring countries with high quality and at reasonable prices. We have started with the manufacturing of bioabsorbable interference screw to be used in soft tissue fixation and ACL reconstruction surgeries in particular and there are few new products pending registration.

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PAYA TEB SADRA

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Distributor area:



Philosophy

Bioabsorbable interference screws are used extensively in orthopaedic procedures and they are frequently used for graft fixation in ACL reconstruction. Like titanium screws, these screws secure the ACL graft, but they offer the added potential benefits of allowing magnetic resonance imaging (MRI), decreasing stress shielding from gradual transfer of load during degradation and theoretically minimizing the difficulty of revision surgery as there are no implants to remove. Numerous studies analyzing clinical outcomes after use of bioabsorbable screws have demonstrated graft stability throughout screw resorption.

In general, commercially available biodegradable interference screws used in clinical practice are chemically based on degradable polymers, but nowadays a trend to use biodegradable composite materials using the same synthetic biodegradable polymers as matrix reinforced with biodegradable ceramics could be observed. One of the approved biocermics is tricalcium phosphate which is used in order to reduce the foreign body reaction and increase osteoconduction and mechanical properties of the biodegradable composite materials.

Why PAYA TEB®?

PAYATEB as an innovative interference screw was designed in order to ameliorate fixation without damaging the graft based on clinical experience, retrieval analysis of some failed screw and finite element simulation.

At PAYA TEB, we have designed a conical shape screw which is tapered at the distal end and cylindrical at the proximal end. The clinical performance of PAYA TEB interference screw is assured by the combination between the clinical technique, screw design and biodegradable PLLA BTCP composite material properties which guarantees the integrity of the screw during insertion, the tissue regrowth, and the stability of fixation.

PAYA TEB® Aims:

BIOTURN™ was designed to fulfill two core aims:

- 1. provide appropriate mechanical properties necessary for ligament reconstruction
- 2. Ensuring a regulated resorption and osteointegration to form architectural bone through hydrolysis.

Design, Formulation, mechanical and chemical advantages of PAYA TEB®

Design and Mechanical Advantages



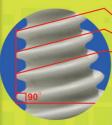
- Immediate thread location at the distal end to ensure easy insertion of screw into the bone tunnel.
- Conical shape with taper design at the distal tip, maintains easy tightening.





low profile and close threads to gain 30% more contact between graft and screw which is leading to the higher bone-tendon-screw grip.





Semi-reverse threads to ensure easier insertion while screw tightening.





Round thread edges to minimize the risk of graft cutting while screw tightening.

Formulation, Chemical and Biological Advantages

- Composite formulation consists of 70% PLLA reinforced by 30% Beta Tri Calcium Phosphate
- No circumstantial foreign body reaction caused by low PH in the bone tunnel and surrounding tissue.
- No tibial tunnel widening caused by low PH as BTCP basic properties neutralizing the PLLA acidity in the bone tunnel and surrounding tissues.
- High osteoconductivity maintained by BTCP content.

PAYATEB

130 13485 Certified Company







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PAYATEB



PAYATEB

FIRMFIX® FEMORAL FIXATION SUSPENSORY DEVICE



Injury to the anterior cruciate ligament (ACL) is regarded as critical to the physiological kinematics of the femoral-tibial joint, its disruption eventually causing long-term functional impairment. Both the initial trauma and the pathologic motion pattern of the injured knee may result in primary degenerative lesions of the secondary stabilizers of the knee, each of which are associated with the early onset of osteoarthritis. Consequently, there is a wide consensus that young and active patients may profit from reconstructing the ACL. Several factors have been identified as significantly influencing the biomechanical characteristics and the functional outcome of an ACL reconstructed knee joint. These factors are:

- (1) individual choice of autologous graft material using either patellar tendon-bone grafts or quadrupled hamstring tendon grafts,
- (2) anatomical bone tunnel placement within the footprints of the native ACL.
- (3) adequate substitute tension after cyclic graft preconditioning
- (4) graft fixation close to the joint line using biocompatible graft fixation materials that provide an initial fixation strength exceeding those loads commonly expected during rehabilitation.

Why FIRMFIX®?

 $\mathsf{FIRMFIX}^{\circledR}$ is specially designed to achieve the following benefits:

- Optimum mechanical resistance
- Excellent biocompatibility
- Safety use: optimal visibility device
- Adapted range to different tunnel's length

FIRMFIX® Aims:

FIRMFIX [®] ligament attachment system aims to provide an optimal solution for trans-osseous fixation of the transplant for the ligament reconstruction.

FIRMFIX® (continuous loop) first aim is to solve the problems caused by manually tied open loops and any problems which could contribute to tunnel widening.

FIRMFIX® Charectristics:

FIRMFIX® is a fixation system with cortical support which consists of a 1.6 mm diameter braided continuous loop in Ultra High Molecular Weight Polyethylene (UHMWPE), a titanium button made of Ti- Al-6-4V ELI alloy along with traction sutures of coated UHMWPE braid in two different colors.

Loop Sizes Table

Reference	Length of the Loop	
AS-15	15 mm	
AS-20	20 mm	
AS-25	25 mm	
AS-30	30 mm	
AS-35	35 mm	
AS-40	40 mm	

Advantages:

Knotless UHMWPE Loop braided and bonded to achieve maximum tensile strength The average measured ultimate force to failure is 1800 - 2000 N

Testing protocols and indicative results

Loop Length	Test Name	Protocol	Maximum Displacement	Cycle Readings
25 mm	Cyclic tensile Fatigue	0-200 N 1HZ 1500 Cycle	0.03 mm	Displacement is Measured at every 300 Cycle

Loop Length	Test Name	Protocol	Average Tensile Force at Break
25 mm	Ultimate Force to Failure	0-2000 N 1HZ	1800-2000 N



Titanium plate made of Ti- Al-6-4V ELI alloy precisely machined polished and anodized to guarantee that no sharp angle is left on the surface or around the corners of the plate.





 1.6 mm diameter braided continuous loop in Ultra High Molecular Weight Polyethylene (UHMWPE), ensure the highest required breaking strenght (1800-2000) N





Two traction threads made of silicone coated UHMWPE which enables user to see the threads easily during surgery.

Silicone coating will provide extra strenght as well as super easy pass of thread through the bone tunnel.



Adjustable Femoral Fixation Device

Maximize Fixation

Minimize Displacement

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Characteristics

The Pull-n-Fix Adjustable Femoral Fixation Device provides ultra-low displacement as well as ultra-strong fixation.

In addition, the Pull-n-Fix ACL Reconstruction Suspensory Device incorporates:

- Double UHMWPE 3 mm tape loop design to help protect the graft during loop reduction.
- The self-locking adjustment, which maximizes graft in tunnel and requires minimal force to reduce loop.
- A low profile titanium button (12.5 X 4.5 mm), which is compatible with common extension devices
- Double USP 5 traction suture to assist with controlled button flip.
- •Simple surgical technique requires minimal instrumentation
- •Optimal combination of biologic healing and mechanical integrity





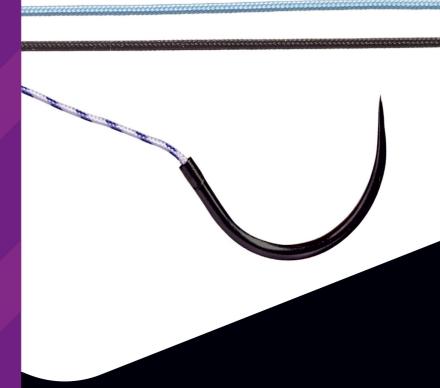






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FirmFiber® is a non-absorbable braided sterile surgical suture prepared from fibers of ultra high molecular weight, long-chain linear polyethylene.

Characteristics

- Special suture braid construction for ultra low profile and max strength
- Inter-locking core technology provides all fiber configurations with a sturdy core within center of the suture to act as a backbone for better knot tying and handling characteristics
- Excellent strength: stronger than steel on a weighted basis
- High flex strength
- More abrasion resistance when compared to polyester
- Vibrant tracer colors with tri-axial patterns for enhanced visibility

FirmFiber is designed and manufactured in USP 2 & USP 5 sizes with and without needles in order to fulfill the needs of all ranges of indications and techniques.



Distributor's Area

