



NORM SPINE SYSTEM

Vertebroplasty Set

Vertebraplasti Seti



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“Spine System” spinal vertebrada kompresyon sonucu oluşabilen kırıklardan ileri gelen, uzun süreli ve güçten düşüren ağrıları olan hastaların bu rahatsızlığını giderebilmek amacı ile tasarlanmış bir sistemdir. Kırıkların tedavi edilmesi amacıyla vertebranın içine kemik çimentosu enjekte edilmesi söz konusudur ve sonuçlar hastalarda mobilitenin yeniden elde edilmesi, belirgin ölçüde ağrının giderilmesi yönündedir.

Sistem, ileri derecede ağrı yapan vertebral kırıkların tedavisinde kullanılan yenilikçi bir minimal invaziv tedavi prosedürüdür. Kemik çimentosunun bölgeye uygulanmasında kullanılacak “needle” ile bir arada bulunan enjeksiyon cihazından oluşur ve dijital fuloroskopi ile bilgisayarlı aksiyal tomografi kombinasyonu ile görüntülenir. Bu uygulama ağrının ortadan kaldırılmasını belirler ve uygulamaya tabi olan hastaların normal faaliyetlerine dönmelerini sağlama imkanı sunar. Bu türde bir uygulama osteoporoz ve vertebral metastazdan kaynaklanan ağrıların tedavisinde en uygun sonuçları vermektedir.

“Spine System” is designed to perform percutaneous vertebroplasty, a procedure that offers relief to patients suffering prolonged and debilitating pain from compression fractures in the spinal vertebrae. It involves injecting bone cement into the vertebrae to stabilize fractures, and results in significant pain relief and restoration of mobility in patients.

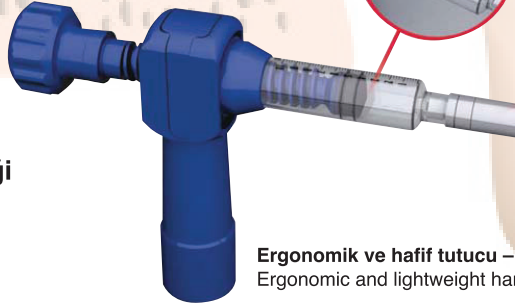
It is an inventionist minimally invasive therapeutic procedure for the treatment of the painful vertebral fractures. It consists of bone cement in the injection through a needle, introduced with the combined guidance of CAT (Computerized Axial Tomography) and digital fluoroscopy. That determines a reduction of the pain and allows the ability of retrieving the mobility for the normal activity to the patients that have involved to this procedure. Such procedure gives optimal results in the treatment of the pain caused from osteoporosis and vertebral metastasis.



Biopsi Giriş Seçeneği
Biopsy Needle Option

Gücün direkt geçişi – Vertebranın güvende olması, kontrol edilebilir tedavi süreci
Direct transmission of power – Safety Of the vertebra, controlled feedback on effect

Luer tip kilitlemeli konektör – pratik ve sızma riski taşımayan bağlantı
Luer-Lock special connector - Quick, leak free connection



Steril – tek kullanımlık – patentli
Sterile - Single use – Patented

Ergonomik ve hafif tutucu – Güvenli, kolay ve kontrollü uygulama
Ergonomic and lightweight handle - Safe, simple, controlled insertion



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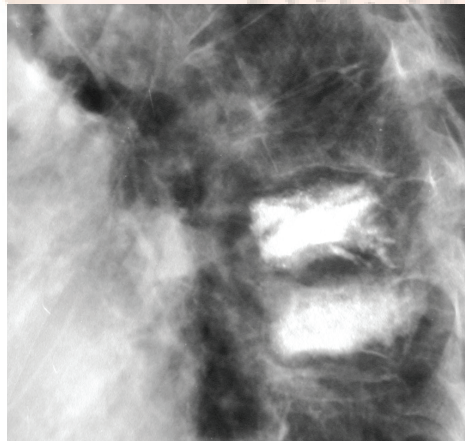
NVPK01 NORM Vertebroplasty Kit
NVPK01 NORM Vertebroplastî Kiti



NVPK01GN NORM Vertebroplasty Kit Gauge Needle
NVPK01GN NORM Vertebroplastî Kiti - Giriş İğnesi



NVPS02 NORM Vertebroplasty Set
NVPS02 NORM Vertebroplastî Seti
NVPS02 - GN NORM Vertebroplasty Set - Gauge Needle
NVPS02 - GN NORM Vertebroplastî Seti - Giriş İğnesi





1403 Sokak No: 3 Balgat 06520 Çankaya Ankara / TÜRKİYE
Tel : +90 (312) 284 00 80 (pbx)
Fax : +90 (312) 285 30 93
Web : www.normltd.net



CE
NB 2292
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Number of Certificate
85044

VERTEBROPLASTY SET- STERILE

The front vertebral cannulle gauge neddle with round steel core and holder

The inside the streil cannulle needle for vertabraplasty (this cannulle needle is tasked to drill vertabral body during to the vertebaplasty)

A. Presentation

1. Each box is sterilized with ethylene oxide and below spesifications.

- 1.a. diameter 2.4mm
- 1.b. lenght 100mm
- 1.c diameter 3mm
- 1.d. lenghts 100mm, 150mm and 200mm

B. Contents

1. Osteo introducers set and gauge canulle needle is made from medical grade stainless steel.

C. Instruction for use

1. The use of medical device must be performed by a doctor that has experience on the execution of the producure of percutaneous vertabraplosty.
2. The round steel core of gauge needle is fixed through the pedicle into the injured vertebra.
3. The cannulle is removed after fixed the gauge needle
4. All compenent are for single-use, the used device must be diposed, re-use of single device creates a potential risk of patient and/or user.
5. It is suitable for surgical hammer.

D. Preparation

Prepare the medical equipments and medication for local or general anesthesia

E. Method and Procedure for use

- a. Find the approaching spot of pedicle with wire pin and mark the point with a pen.
- b. Puncture up to 5mm of the vertebral body passing through the pedicle with bone marrow needle.
- c. Pull out the needle from the Bone marrow needle.
- d. Push the guide wire into the bone marrow needle up yo $\frac{3}{4}$ of vertebral body.
- e. Remove the Bone marrow needle except fort he guide wire.
- f. Through the guide wire, push the Cannula and Expander from the starting point of vertebral body to 3mm.
- g. Remain the Cannula only and remove the Guide wire and Expander.
- h. Ream with the bone drill to the end of callous bone of vertebral body through the Cannula.
- i. Remove the spacer and the filled the cement with cement filler through into cannulle.

Cannulle Diameter	Cannulle Lenght	Cement Capaticy
2.4 mm	100 mm	0,28ml
3.0 mm	100 mm	0,51ml
3,0mm	150mm	0,76ml
3,0mm	200mm	1,02ml

F. Indication

It is use to aid in the insertion of the bone cement into body cavities.

G. Contraindication

Infection, Pregnancy, Metal illness

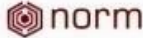








H. Cautions

- a. Do not disassemble, repair and reconstruct except the experts.
- b. Use of medical devices is only fort he educated and certified person
- c. All components are for single-use and do not reuse.
- d. Used products during the operation should be disposed regarding as the correct procedure and those must be fallen into disuse.
- e. Please observe the restriction
- f. The doctors should check procedure with C-arm for constant and complete syrgical during the operation.
- g. The expiry date must be controlled before the use.
- h. Do not use if any part of the package is damaged.
- i. Do not sterilized the use part for re-use.

I. Storage

- a. Do not expose the product directly to the sun, too high/low temperature and humidity.
- b. Do not keep the products at the place includes ion like salinity.
- c. avoid the place for chemicals and containing gas.

J. Expiry Date 3 years from the date of E.O sterilization

		PRODUCT NAME			
REF: Catalog Number		STERILE EO			
/.....		Metod Of Sterilization Ethylene Okside		Read Usage Instructions	
					
Don't Use if Packet Is Please Damaged		Single use		Expired Date	
LOT-.....					
Lot Number		Product Barkod Number			
 NORM TIBBİ ÜRÜNLER İTH.İHR.SAN. VE TİC.LTD.ŞTİ. 1403.Sokak No : 3 Balgat/Ankara Tel: +90 312 284 00 80 Faks: +90 312 285 30 93 Web : www.normltd.net - E_mail : info@normltd.net					
Manufacture					

Executive Summary

Balloon Kyphoplasty is a minimally invasive percutaneous method for stabilizing the spine. NOVA helps to restore some of the height lost with fracture and reduce the angle of the deformity. It offers a good alternative for patients who fail to respond to the traditional approaches of bedrest, analgesics, and back braces. By inflating the Balloon in the vertebral body, a space is created which facilitates the insertion of bone cement using the Cement and Bar. The major benefits of are the significant reduction in back pain and increase patients functional abilities, allowing a return to the previous level of activity.

DESIGN PHILOSOPHY and DEVICE DESCRIPTION

The opening and closing switch controls inflow condition of fluid to preserve expanding and shrinking of the balloon. The pressure mode lever makes it possible for convenient surgery to select pressurization modes, such as bulk micro pressurization and depressurization. The pressure handle is an innovative device to pressurize push or turn of the handle generates bulk or micro pressure for more stable and accurate vertebral recovery. Scale marks of the measuring vessel helps to predict amount of required bone cement with measuring amount of injected fluid. The pressure gauge indicates applied pressure for vertebral recovery. The maximum allowable pressure of surgery is 300 psi. the balloon recovers intact vertebral morphology and makes a cavity to cement by injected fluid from the pressurizer after insertion at damaged vertebral body.

Minimally Invasive Spine Surgery

Fast Pain

Relief Safe Delivery of Bone Cement User

Friendly Approach Local Anesthesia

Fast Recovery

Indications

Vertebral Compression Fracture

Osteoporosis

Metastatic Bone Tumor

Contraindications

Infection of the fractured vertebra

Severe hemorrhagic diathesis

Known allergies to the cement

Pregnancy

ASA score of 4

Marketing History

