ORDIN DE PLATA NR.: 1199 TIP.DOC. 1

DATA EMITERII:25 februarie 2022

PLATITI: 560-00 LEI: Cinci Sute Sasezeci lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.

CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. suc."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) Institultul de Medicina Urgenta IMSP

CONTUL DE PLATI/CODUL IBAN
MD55VI022510300000002MDL
CODUL FISCAL :1003600152606 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.

CODUL BANCII:
:VICBMD2X :

DESTINATIA PLATII:Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1643979315681 din 28.02.2022

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:25/02/2022

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

L.S. (semnatura electronica)

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2022.02.25 16:18:57 EET
Reason: MoldSign Signature
Location: Moldova

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. **8506** din **28.04.2021**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albişoara, 16/1, ap.(of.) 7, mun. Chişinău, Republica Moldova.**

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

1. POIATA VITALIE 33,40 %

2. NASEDCHIN ALEXANDR 33,30 %

3. KOJEVNIKOV DMITRII 33,30 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Mikron Makina Sanayi ve Ticaret Ltd. Şti.
Company Address	: İvedik OSB Mah. Ağaç İşleri Sanayi Sitesi 1372. Sk. No:31 Yenimahalle ANKARA / TURKEY
Manufacturing Site (Branch Office)	: Dağyaka Mah. Dağyaka Cad. No:38 Kahramankazan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-Sterile Spinal Screw Rod System - Class IIb Sterile Cervical & Lomber Peek Cages - Class IIb Non-Sterile Corpectomy Cages - Class IIb Sterile Cervical Mobile Disc Prosthesis - Class IIb Non-Sterile Plates - Class IIb Non-Sterile Bone Plates & Bone Screw - Class IIb
GMDN	: 37272, 43084, 38161, 34170, 46647, 56642, 35685, 58446, 48011, 61325, 32854

Product Types are attached.

Certificate Number	: M.2017.106.8497
Report Number	: MD.3468.YB
Initial Assessment Date	: 22.05.2017
Registration Date	: 07.06.2017
Recertification Assessment Date	: 20.12.2019
Reissue Date / No	: 15.04.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

This document containing 3 (three) pages is the Annex of the Certificate with the number M.2017.106.8497 and with the registration date of 07.06.2017 and with the re-issue date 15.04.2020 issued for "Mikron Makina Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

LIST OF PRODUCTS	GMDN
Non-Sterile Spinal Screw Rod System	
MSFX -MIKRON SPINAL STABILISATION POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILISATION POLYAXIAL CANNULATED-CEMENTED SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MONOAXIAL CANNULATED-CEMENTED SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLYAXIAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION MULTIFUNCTIONAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION MONOAXIAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR CANNULATED-CEMENTED MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR CANNULATED-CEMENTED MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION ROD	58446
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR ROD	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CERVICAL CONNECTOR ROD	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CONNECTOR HOOK	48011
MSFX -MIKRON SPINAL STABILIZATION MULTIAXIAL TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION LATERAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION EXTENSION CONNECTOR FOR 1 ROD	58446
MSFX -MIKRON SPINAL STABILIZATION EXTENSION CONNECTOR FOR 2 ROD	58446
MSFX -MIKRON SPINAL STABILIZATION MULTIAXIAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDICULAR HOOK SMALL	61325
MSFX -MIKRON SPINAL STABILIZATION PEDICULAR HOOK OFSET	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK LEFT ANGLED	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK RIGHT ANGLED	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK OFSET LEFT/RIGHT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK LEFT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK RIGHT	61325
MSFX-MIKRON SPINAL FIKSATION INTERSPINOUS U DEVICE	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL POSTERIOR POLIAXIAL SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ROD	58446
THORACOLUMBAR POSTERIOR POLIAXIAL SCREW TITANIUM SELF TAPPING	37272
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTO FOR 1 ROD	58446
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTOR FOR 2 ROD	58446
THORACOLUMBAR POSTERIORLINK CONNECTOR TITANIUM AXIAL	58446
THORACOLUMBAR POSTERIORLINK CONNECTOR TITANIUM AXIAL 2	58446
MSFX-MIKRON SPINAL STABILIZATION POLYAXIAL HEMISPHERICAL SCREW	37272
MSFX-MODULER RIGID PLATE SMALL	46647
MSFX-MODULER RIGID PLATE LARGE	46647
MSFX-MODULER RIGID PLATE SACRUM	46647
MSFX-MODULAR DOUBLE SIDED DYNAMIC PLATE SMALL	46647
MSFX-MODULAR DOUBLE SIDED DYNAMIC PLATE LARGE	46647
MSFX- MODULAR SEMI RIGID PLATE SMALL	46647
MSFX- MODULAR SEMI RIGID PLATE LARGE	46647
MSFX-MIKRON SPINAL STABILIZATION SPHERICAL CONNECTOR	61325
MSFX-MIKRON SPINAL STABILIZATION SPHERICAL CROSS CONNECTOR	61325
POLYAXIAL CONNECTOR CLAMP	58446
MIDDLE CONNECTOR CLAMP	58446
CONNECTOR CLAMP	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SCREW + Setscrew	37272
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SPONDYLOLISTHESIS SCREW + Setscrew	37272
MSFX-MIKRON SPINAL STABILIZATION PEDIATRIC ROD	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC ROD CONNECTOR	58446
MSFX- MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC LAMINAR CONNECTOR	48011
MSFX- MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC PEDICUL HOOK	48011
MSFX- MODULAR DYNAMIC PLATE SMALL	58446
MSFX-MODULAR DYNAMIC PLATE LARGE	58446
MSFX-MODULAR DYNAMIC PLATE SMALL	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SPONDYLOLISTHESIS SCREW + Setscrew	37272
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC TRANSVERSE CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC ROD CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC LATERAL CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC AXIAL CONNECTOR	58446
MSFX- MIKRON SPINAL STABILIZATION MONOAXIAL HOOK TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION HIGH FLEX LUMBAR EXPANDABLE PEEK CAGE	38161
MSFX- MIKRON SPINAL STABILIZATION ANTERIOR TITANIUM PLATE CORPUS RIGHT	46647
MSFX- MIKRON SPINAL STABILIZATION ANTERIOR TITANIUM PLATE CORPUS LEFT	46647
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR TRANSVERSE CONNECTOR	58446
MSFX- SPHERICAL TRANSVERSE CONNECTOR SCREW TO SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION SPHERICAL CONNECTOR PEDIATRIC SCREW TO SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION TRANSVERSE LINK AXIAL	58446
MSFX- MIKRON SPINAL STABILIZATION PEDIS TRANSVERSE LINK PEDIATRIC	58446
MSFX- MIKRON SPINAL STABILIZATION SACRAL CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION SACRAL MULTIAXIAL CONNECTOR	58446

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. 2292

This document containing 3 (three) pages is the Annex of the Certificate with the number M.2017.106.8497 and with the registration date of 07.06.2017 and with the re-issue date 15.04.2020 issued for "Mikron Makina Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

MSFX-MIKRON SPINAL STABILIZATION SACRAL-ILIAC SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR AGRAF PLATE	61325
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR TRANSVERSE CONNECTOR	58446
Sterile Cervical & Lumbar Peek Cages	
MSFX-MIKRON SPINAL LUMBAR FUSION PEEK CAGE	38161
MSFX-MIKRON SPINAL LUMBAR FUSION PEEK CAGE ANGLED	38161
MSFX-MIKRON SPINAL STABILIZATION MINIMAL INVASIVE TLIF CAGE	38161
MSFX -MIKRON SPINAL STABILIZATION HIGH FLEX LUMBAR EXPANDABLE PEEK CAGE	38161
MSFX MIKRON SPINAL STABILIZATION HIGH FLEX EXPANDABLE CERVICAL PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION TLIF CAGE	38161
MSFX- MIKRON SPINAL FIXATION BANANA CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION TLIF CAGE ANGLED	38161
MSFX- MIKRON SPINAL FIXATION BANANA CAGE ANGLED	38161
MSFX MIKRON SPINAL STABILIZATION HIGH FLEX EXPANDABLE TLIF PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL BLADED PEEK CAGE & ANATOMICAL SURFACE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL PEEK CAGE & ANATOMICAL SURFACE	38161
Non-Sterile Corpectomy Cages	
MSFX- MIKRON SPINAL STABILIZATION LUMBAR CORPECTOMY CAGE	38161
MSFX- MIKRON SPINAL STABILIZATION LUMBAR CORPECTOMY CAGE ANGLED	38161
MSFX- MIKRON SPINAL STABILIZATION CERVICAL CORPECTOMY TITANIUM CAGE	38161
MSFX- MIKRON SPINAL STABILIZATION CERVICAL CORPECTOMY TITANIUM CAGE ANGLED	38161
MSFX- MIKRON SPINAL STABILIZATION CORPECTOMY CAGE SCREW	38161
Sterile Cervical Mobile Disc Prosthesis	
MOBILE CERVICAL DISC PROSTHESIS	43084
Non-Sterile Plates	
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE	61325
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE SCREW- REVISION	37272
Non-Sterile Bone Plates & Bone Screw	
CLAVICLE DISTAL LOCKING PLATE	46647
CLAVICLE SHAFT LOCKING PLATE	46647
CLAVICLE HOOK LOCKING PLATE	46647
HUMERUS PROXIMAL LOCKING PLATE	46647
HUMERUS DISTAL MEDIAL LOCKING PLATE	46647
HUMERUS DISTAL LATERAL LOCKING PLATE	46647
HUMERUS DISTAL POSTEROLATERAL LOCKING PLATE	46647
ULNA PROXIMAL LOCKING PLATE	46647
SMALL BROAD LOCKING PLATE	46647
SMALL NARROW LOCKING PLATE	46647
RADIUS PROXIMAL LOCKING PLATE	46647
RADIUS DISTAL VOLLARE LOCKING PLATE	46647
RADIUS DISTAL DORSAL LOCKING PLATE	46647
PELVIS RECONSTRUCTION STRAIGHT LOCKING PLATE	46647
PELVIS RECONSTRUCTION CURVED LOCKING PLATE	46647
TIBIA DISTAL MEDIAL LOCKING PLATE	46647
TIBIA DISTAL ANTEROLATERAL LOCKING PLATE	46647
FIBULA DISTAL LOCKING PLATE	46647
SMALL METAPHYSEAL LOCKING PLATE	46647
SEMITUBULAR LOCKING PLATE	46647
KALKANEUS LOCKING PLATE	46647
ULNA DISTAL LOCKING PLATE	46647
RECONSTRUCTION SHAFT LOCKING PLATE	46647
ULNA PROXIMAL HOOK LOCKING PLATE	46647
SMALL(MINI) FOOT LOCKING PLATE	46647
SMALL (MINI) FOOT STRAIGHT LOCKING PLATE	46647
SMALL HAND LOCKING PLATE	46647
SMALL HAND STRAIGHT LOCKING PLATE	46647
LARGE NARROW LOCKING PLATE	46647
LARGE BROAD LOCKING PLATE	46647
FEMUR PROXIMAL LOCKING PLATE	46647
FEMUR PROXIMAL NECK LOCKING PLATE	46647
FEMUR PROXIMAL TROCHANTER LOCKING PLATE	46647
FEMUR DISTAL LOCKING PLATE	46647
TIBIA PROXIMAL LATERAL LOCKING PLATE	46647
TIBIA PROXIMAL MEDIAL T LOCKING PLATE	46647
TIBIA PROXIMAL MEDIAL L LOCKING PLATE	46647
TIBIA DISTAL LATERAL LOCKING PLATE	46647
LARGE METAPHYSEAL LOCKING NARROW PLATE	46647
LOCKING SELF TAPPING CORTICAL SCREW	37272
LOCKING SELF DRILLING SCREW	37272
LOCKING SELF TAPPING CANCELLOUS SCREW	37272
HEXAGONAL UNLOCKED SELF TAPPING CORTICAL SCREW	37272
HEXAGONAL UNLOCKED SELF TAPPING CANCELLOUS SCREW	37272
CANNULATED FULL GROVED SCREW	37272
CANNULATED CANCELLOUS SCREW	37272
ANKLE SCREW	37272
HEXAGONAL LOCKING SELF DRILLING CANNULATED SCREW	37272
LOCKING SELF TAPPING CORTICAL SCREW	37272
UNLOCKED SELF TAPPING CORTICAL SCREW	37272
TROCAR KIRSHNER WIRE	35685
WASHER SMALL	56642
WASHER MEDIUM	56642

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

This document containing 3 (three) pages is the Annex of the Certificate with the number M.2017.106.8497 and with the registration date of 07.06.2017 and with the re-issue date 15.04.2020 issued for "Mikron Makina Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

WASHER LARGE	56642
WASHER EKSTRA EKSTRA LARGE	56642
WASHER EKSTRA LARGE	56642
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL ELASTIC NAIL RADIUS/ULNA/FEMUR/TIBIA/HUMERUS NOT CANNULATED TEN ELASTIC NAIL SCREW	37272
TEN ELASTIC NAIL AND CAP SMALL	37272
TEN ELASTIC NAIL AND CAP ORTA	37272
TEN ELASTIC NAIL AND CAP LARGE	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL TIBIA CANNULATED ANATOMIC NONCOATED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL LOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC NONCOATED FIXED COMBINE CURVED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED LONG PROXIMAL TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL NECK/CONDILLAR LOCKING IMPLANTS ALL INSTRUMANTATION, ROUGHSHOD BLADE SCREW	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED LONG PROXIMAL TITANIUM	32854
NAIL LOCKING SCREW PROXIMAL-DISTAL-SHAFT	37272
END CAP EXTRA SMALL	37272
END CAP SMALL	37272
END CAPI ORTA	37272
END CAP LARGE	37272
END CAP EXTRA LARGE	37272
END CAP EXTRA LARGE	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC NONCOATED FIXED CURVED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL UNLOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC UNCOATED FIXED CURVED TITANIUM	32854

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

This is to certify that

Quality Management System
for Medical Devices

of

MİKRON MAKİNA
SANAYİ VE TİCARET LİMİTED ŞİRKETİ

İVEDİK ORGANİZE SANAYİ BÖLGESİ MAH. AĞAÇ İŞLERİ SANAYİ SİTESİ. 1372. SOK. NO:31
YENİMAHALLE - ANKARA / TÜRKİYE

MANUFACTURING SITE: **DAĞYAKA MAH. DAĞYAKA CAD. NO:38 KAHRAMANKAZAN ANKARA / TÜRKİYE**

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to;

SPİNAL VE TRAVMA İMPLANTLARI, AMELİYAT EL ALETLERİ VE
GENEL EL ALETLERİ TASARIMI ÜRETİMİ VE DAĞITIMI

DESIGN, MANUFACTURE AND DISTRIBUTION OF SPINAL & TRAUMA IMPLANTS,
SURGICAL INSTRUMENTS AND GENERAL INSTRUMENTS

ISO 02 848 1089	Feb. 11, 2021	Mar. 3, 2022
Certificate No.	*Date of this Certificate*	**Next Audit Due Date*
Mar. 4, 2020	Mar. 3, 2022	
Date of Initial Registration	*Certification Expiry Date*	*Managing Director / Director*

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

MİKRON MAKİNA - MSFX LUMBAR PEEK CAGES
INSTRUCTION FOR USE (IFU)

GENEL
Omurgada lomber birleştirme implantı olarak kullanılan " MSFX PLIF PEEK Kafesler ve MSFX TLIF kafesler "3 boyutlu, hemen hemen dikdörtgen formunda, batkın özelliği olan bir yüzeye sahiptir. 3 boyutlu eğimli yapıya sahip olan üst ve alt yüzeyler, superior ve anferior vertebral organlar arasındaki bağlama özelliğine yardımcı olurlar. Bu implantlar titanyum alaşımlı (Ti-6A1-4V ELI) ve PEEK-Optima / EVONİK PEEK malzeme kullanılarak imal edilirler.
Boyun ve omur gövdeleri arasında kaynamada basit ve etkin bir yöntemdir. Anteriordan girişim ve servikal diskektomi'yi takiben aşağıdaki durumlarda kullanılabilir;
Disk mesafelerinin prolabe olmasında
Disk fıtıklaşmasında
Mekanik instabilitede
Posterior elemanları kalsifikasyonunda
Osteokondrosis
Spinal dar kanalda

Bileşen	Malzeme	Spesifikasyon
Cage Body	PEEK	ASTM F2026
Titanium markerları	Titanyum Alaşımı (Ti6Al4V-ELI)	ISO 5832-3 / ASTM F136
Titanium çiviler	Titanyum Alaşımı (Ti6Al4V-ELI)	ISO 5832-3 / ASTM F136

Table 1. MSFX Lomber PEEK Kafes Bileşenleri

İmplantlar sterile olarak piyasaya sunulur.EO sterilizasyon methodu kullanılır.
El aletleri de kullanım öncesinde temizlenmeli ve steril edilmelidir.

MALZEME
MSFX Lomber PEEK Kafeslerin ana yapısı PEEK (Polyetereterketon, ASTM F2026'ya göre)dan üretilmiştir.Ürünün markerları ve çivileri Ti6Al4V-ELI'den üretilmiştir.
Ürünün çivileri ve bıçak mekanizması aynı şekilde titanyum alaşımdan üretilmektedir.

MRI GÜVENLİK BİLGİSİ
İmplantlar MR uyumludur.

KULLANIM AMACI
Hareketsiz ve etkinliği olan yer açmak için
Ameliyat sonrası erken dönemde biomekanik stabilite için
Mükemmel ve etkinliği kanıtlanmış kemik füzyon istendiğinde
Basit, güvenilir ve benzerlerine göre ucuz bir yöntem istendiğinde

EN DİKASYONLAR
MSFX Lomber PEEK Kafesler, 6 haftalık ameliyat dışında bir tedavi görmüş ancak boyun ve/veya kol ağrısı çeken hastalar için , servikal disk çıkarıldıktan sonra spinal füzyon için stabiliteyi sağlamak için uygun vertebra kısıma implante edilir.
MSFX Lomber PEEK Kafesler, servikal omurganın dejeneratif disk hastalığı (DDD) olan ve tek disk seviyesinde eşlik eden radiküler semptomları olan iskeletsel olarak olgun hastalarda kullanım için endikedir. DDD, hasta öyküsü ve radyografik çalışmalar ile doğrulanan diskin dejenerasyonu ile diskojenik ağrı olarak tanımlanmaktadır.

MSFX Lombar PEEK Kafesleri, servikal omurgada intervertebral vücut füzyonunu kolaylaştırmak için kullanılır ve anterior bir yaklaşımla yerleştirilir ve otojen kemik ile doldurulur. Innesis, MSFX Lumbar PEEK Kafesleri ek fiksasyon ile kullanılacaktır.

POTANSİYEL TERS ETKİLER
1. Implantın yer değiştirmesi
2. İmplantın kırılması
3. İmplantın vucüt ile etkileşime girmesi
4. Etraftaki organlara baskı uygulaması
5. Spinal deformasyon
6. Enfeksiyon
7. Kemik kırılması
8. Psödoarthrosis
9. Nörolojik fonksiyonların yitirilmesi
10. Hematom oluşması
11. Omurganın hareketliliğini kaybetmesi
12. Ölüm

UYARILAR
1- Lomber Peek kafesler her zaman açılmamış ambalajlarında saklanmalı, kullanım öncesinde STERİL ürünlerde ambalajların zarar görüp görmediği kontrol edilmelidir. 2- Ürün ambalajı açılmadan önce etiket bilgileri konrol edilmeli, (ölçü, lot no, steril bilgileri v.s.) sterizasyon geçerlilik tarihi geçmiş implanlar kesinlikle kullanılmamalıdır, ambalajı açmak için kullanılan alet, ürün yüzeyine zarar verecek şekilde temas ettirilmemelidir. 3- Her implantın kullanım öncesinde zarar görmemiş olduğundan emin olunmalı (ezik, çizik, darbeli v.s.) 4- İmplantlar sadece bir kullanımlık olup tekrar kullanımı katiyetle yasaktır. 5-Hastaya implantların etkileri ve yan etkileri hakkında bilgi verilmelidir. Hasta kendisine takılan implantın sınırları, yüklenmenin sınırları, hareket alanı ve müsaade edilen aktivitesi hakkında bilgilendirilmeli ve ameliyatlı bölgede oluşan beklenmedik değişimi hemen doktora bildirmesinin gerekliliği konusunda uyarılmalıdır. Hasta, MR çekilmesi esnasında bünyesinde implant bulunduğunu ilgili operatöre belirtmesi gerektiği konusunda bilgilendirilmelidir. 6- Opere edilen implanta ait izlenebilirliğin sağlanabilmesi için hastanın kalıcı belgelerine implant ambalajı üzerinde bulunan tanımlayıcı etiketten birisi yapıştırılmalıdır.7-İmplantları tek kullanımlıktır ve yeniden birbaşka hasta üzerinde kullanılamaz.8-İndikasyonlar, kullanılacak implantın ölçülerinin seçimi ve kullanılacak olan implantasyon yöntemi ve bunların sorumluluğur.

İMPLANT SEÇİMİ
Hastalar için implantların uygun ebadının , şeklinin ve tasarımın seçimi operasyonun başarısı için kritiktir.
Metalik cerrahi implantlar kullanımda tekrarlayan strese ve implantların dayanma gücü hastanın kemik şekline ve ebadına uygun tasarımın uygulanması ile sınırlıdır .Eğer hasta seçiminde ,uygun implantın yerleştirilmesi hususunda üstün bir özen gösterilmez ise , operasyon sonrasında implant üzerindeki yük minimize edilecek şekilde yönetim sağlanamazsa ; İmplant üzerindeki yük ,iyileşme süreci tamamlanmadan metal yoğunluğuna ,kırılmalara ,bükülmelere ve implantın gevşemesine sebep olabilir veya implant iyileşme sağlanmadan çıkarılabilir. .

İMPLANTIN ÇIKARILMASI VE İMHASI
En iyi sonuç için, implantların çıkarılmasınd , implante edilirken kullanılan MSFX markalı el aletleri kullanılmalıdır.
MSFX Lomber PEEK Kafesler , kalıcı implantlardır. Eğer doktor kararı ile çıkarılması gerekirse aynı el aletleri kullanılarak çıkarılabilir.
Bu sabitleme sistemi normal iyileştirme süreci esnasında, operasyon bölgesini sabitlemek amacıyla dizayn edilmiştir.Kemiğin stabilizasyonu sonrasında , implantın fonksiyonu kalmamış olabilir ve, implantın yerleştirilmesinde kullanılan el aletleri kullanılarak ,implant çıkarılabilir .İmplantın çıkarılmasında son karar doktora ve hastaya bağlıdır. Çoğu hastada ,implantın çıkarılması önerilir .Eğer implant çıkarılmaz ise aşağıdaki komplikasyonlar oluşabilir.1-Korozyon , bölgesel enfeksiyon veya ağrı 2-İmplantın yer değiştirmesi , yaralanmaya sebep olabilir 3-Postoperative travmdan dolayı yaralanma riski 4-Eğilme , gevşeme ve kırılma , eğer bu durumlar yaşanırsa implantın çıkarılması zorlaşır 5-Ağrı ,rahatsızlık ve implantın varlığına karşı hassaiyet 6-Artan enfeksiyon riski 7-Kuvvete bağlı kemik kaybı İmplantlar operasyon sonrasında kırılmalar , yeniden kırılmalar ve komplikasyonlar oluşmadan uygun şekilde çıkarılmalıdır.
*İmplantın imhası için hastane kurallarına uyunuz.

EL ALETLERİ
Ürün ile kullanıcak el aletleri Mikron Makina tarafından sağlanır.

TEMİZLİK VE DEKONTAMİNASYON
Manuel bir temizlik ve dezenfeksiyon işleminden, bir ultrasonik banyo kullanıldığında, genel olarak kaçınılmalıdır ve otomatik bir yıkama işlemine nazaran daha az etkili olduğundan, sadece makineli bir işlem mevcut olmadığında kullanılmalıdır.
Bunun dışında manuel işlem, özellikle de çok kirli aletlerde, makineli hazırlığa destek olarak kullanılabilir.
Tavsiye edilen donanım: Ticari, tıbbi ürünler için izinli alkalik temizlik maddeleri (pH değeri 9-11) veya kombine temizlik-dezenfeksiyon maddesi (örneğin ECOLAB firmasından Sekusept® Aktif 2%).

STERİLİZASYON
Ürünler piyasaya steril olarak sunulur.
Sterilizasyon yöntemi EO'dur.

PAKETLEME
İmplantlar ve seteler steril olarak markete sunulur.
PET-G kullanılarak , laklı tyvek ile paketleme , ultrasonik yıkamadan sonra AYALAB'da yapılır. Validasyon çalışması mevcuttur.

SAKLAMA / RAF ÖMRÜ
*İmplantları oda sıcaklığında normal basınç altında , temiz ve kuru tutunuz.
Ref. : Sıcaklık 22° ± 5 , Nem < %70
*Güneş Işığından uzak tutunuz
**İmplanların raf ömrü , üretim tarihinden itibaren 5 yıldır.
**İmplanların raf ömrü , üretim tarihinden itibaren 5 yıldır.

KULLANILAN SEMBOLLER/PİKTOGRAMLAR

Üretici	Üretim Tarihi
Lot No	Son Kullanma Tarihi
Katalog No	Steril
Tekrar Kullanılmaz	Zarar Görmüş Ambalajlı Ürün Kullanılmaz
Miktar	Güneş Işığından uzak tutunuz
Kullanma Talimatına bakınız	Sıcaklık Sınırlaması

Mikron Makina Sanayi ve Ticaret Ltd. Şti Notified Body UDEM'in denetimi ile AT sertifikasını ve Technical Universal Verification Belgelendirme ve Eğitim Hizmetleri Ltd. Şti tarafından verilen ISO 13485:2016 sertifikalarına kullanma hakkına sahiptir ve üretimine de belirtilen ilgili standartlar doğrultusunda devam etmektedir.ISO 13485:2016 Certificate No:4136
Medikal Cihaz Direktifi EK II of 93/42/EEC
Sertifika No: M.2017.106.8497
CE 2292

ÜRETİCİ:Mikron Makina Sanayi Ticaret Limited Şirketi
İvedik O.S.B Ağaç işleri San.Sitesi 1372.Sok.No:31 Pk.06370
Ostim -Yenimahlle ANKARA / TURKİYE
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MİKRON MAKİNA - MSFX LUMBAR PEEK CAGES
INSTRUCTION FOR USE (IFU)

GENERAL

The MSFX Lumbar PEEK Cages (MSFX PLIF Cages and MSFX Lomber TLIF Cages) are lumbar intervertebral devices made from PEEK Optima (per ASTM F2026), to be implanted into appropriate lumbar vertabral sectionto help provide stability for spinal fusion after a diseased lomber disc producing neckand/or arm pain is removed during spinal decompression for patients who have had six weeks of non-operative treatment. The devices are provided in various sizes andshapes to fit in specific anatomies, as well as optional blade system to strenghten the device's position in the implanted spot. An inner chamber is incorporated in the device's design to accomodate bone graft, in order to better support fusion

Components	Material	Spesification
Cage Body	PEEK	ASTM F2026
Titanium markers	Titanium alloy (Ti6Al4V-ELI)	ISO 5832-3 / ASTM F136
Titanium spikes	Titanium alloy (Ti6Al4V-ELI)	ISO 5832-3 / ASTM F136

Table 1. Component of MSFX Lumbar PEEK Cages

The System is equipped with components which are provided **Sterile**. Implants are provıded sterilized by EO Sterilization method .
Instruments should be cleaned and sterılızed prıor to use.

MATERIAL

The main bodies of MSFX Lumbar PEEK Cages are manufactured from PEEK (Polyetheretherketone, per ASTM F2026), with markers and spikes inserted in them made from Ti6Al4V-ELI.
These spikes, the blade mechanism and the markers are all made from the same titanium alloy (Ti6Al4V-ELI).

MRI SAFETY INFORMATION

The implants are MR compability .

INTENDED USE

MSFX Lumbar PEEK Cages are made to be implanted into appropriate vertebral section to help provide stability for spinal fusion after a diseased lomber disc producing neck and/or arm pain is removed during spinal decompression for patients who have had six weeks of non-operative treatment.
MSFX Lumbar PEEK Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the lomber spine with accompanying radicular symptoms at one disc level . DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.
MSFX Lumbar PEEK Cages are used to facilitate intervertebral body fusion in the lomber spine and are placed via an anterior approach and packed with autogenous bone. Innesis , MSFX Lumbar PEEK Cages are to be used with supplemental fixation.

INDICATIONS

The MSFX Lumbar PEEK Cages are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment.
The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

CONTRAINDICATIONS

Contraindications include, but are not limited to:
• Any case needing to mix metals from different components.
• Any case not described in the indications.
• Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
• Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
• Any patient unwilling to co-operate with postoperative instructions.
• Fever or leukocytosis.
• Infection, local to the operative site.
• Mental illness.
• Morbid obesity.
• Pregnancy.
• Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
• Signs of local inflammation.
• Suspected or documented metal allergy or intolerance.
These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
Contraindications of this device are consistent with those of other spinal systems.

POTENTIAL ADVERSE EFFECTS

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/ or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function,
10. Haemorrhage of blood vessels and/or hematomas.
11. Loss of or increase in spinal mobility or function.
12. Death.

WARNINGS

1-Implants should always be kept in unpacked original packs
2-The information involved in the label such as (size, lot no, sterilization details etc) should be controlled before unpacking th product. The tool to be used to open the pack should not give damage to the product surface.
3-Each implant should be controlled strictly to determine whether it was damaged (crushed, scratched, broken etc.) before use.
4-Due to material triedness, the implants are for only single use. NEVER LET THEM TO BE USED FOR THE NEXT TIME.
5-The patient should be informed about the effects and side effects of the implants. The patient should have the information regarding to the limits, loading limits, movement space and the permitted activity of the fixators and should also be warned o notify th edoctor if any unexpected change occurs in operated part of his body.
6-In order to follow up the operated implant, the informative permanent documents of the patient should also bear one of the descriptive labels on the package of respective fixators.
7- Original Mikron Makina Surgical Instruments shall be used during implantation of MSFX branded Spinal Implants.

SELECT OF IMPLANT

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PRECAUTIONS

MSFX Lumbar PEEK Cages are only available to be used by the expert surgeons, who are familiar with the surgery technique specific to the product. The products are designed in the manner of comforming to each other so MIKRON branded fixators should never be combined or used with other branded products; these products are only to be operated wit respective hand tools.
The user should particularly pay attention to that point:
1-To select the correct instrument is rather important. The implants should be selected depending on individually type type size of each patient. While this selection is being described, the anatomic and and biomechanical factors uch as tha age, activity, weight, bone and muscle structure of the patient should be taken into consideration. In the event of any incorrect implant chosen, may be loosen situation,the schanz nails may be bended or the bone may be cracked.
2-An excessive bending ,twisting or form deterioration shoul be avoided in application.
3-Since the implants have the limited keeping capacity, excessive pressure to be occured due to the weight of the patients should be avoided. The unexpected results may occure if the said matter is not considered seriously.
4-Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence.
5-Obese, malnourished, and/ or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.PHYSICIAN NOTE:
Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patients.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects.
The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

REMOVAL OF IMPLANT & DISPOSAL IMPLANT REMOVAL

For the best results, the same type of MSFX branded instruments as used for implantation should be used for implant removal purposes.
If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the The MSFX Lumbar PEEK Cages are not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:
• The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
• Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
• Pain or abnormal sensations due to the presence of the implants.
• Infection or inflammatory reactions.
• Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.
**Please apply disposal procedure for implants accordance with hospital rules.

SURGICAL TOOLKITS

CLEANING AND DECONTAMINATION

All instruments and **implants** must be disassembled (if applicable) and cleaned using cleaners before sterilization and introduction into a sterile surgical field .Cleaning and disinfecting of instruments can be performed with aldehydefree solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.
NOTE: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.
All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

The implants are supplied STERILE to market .
Sterilization method : EO Sterilization

PACKAGING

The implants are supplied STERILE. Sterile products are packed by AYALAB after ultrasonic washing process (For packing, PET-G and tyvek are used)
Validastion process is present.

STORAGE / SHELF LIFE

*Keep the implants dry and clean @ room temprature under normal atmospheric pressure.
*Keep away sun light
**Shelf life is 5 years after machining date.Do not use after the use-before-date.

USED SYMBOLS / PICTOGRAMS

MİKRON MAKİNA - MSFX LUMBAR PEEK CAGES
INSTRUCTION FOR USE (IFU)

Manufacturer 	Date of Manufacturer 
Batch No 	Use by Date 
Catalogue Number 	Sterile 
Do not Reuse 	Do not use if packing is damage 
Quantity QTY: xx	Keep away sunlight 
Consult instruction for use 	Temperature Limit 

MIKRON Makina Sanayi ve Ticaret Ltd. Şti. has right to use the TS EN ISO EC certificate by the audit of Notified Body -UDEM- and 13485:2016 certificate by the audit of KGS Certification and also continue his manufacturing according to the related standarts.
ISO 13485:2016 Certificate No: 110511

Medical Devices Directive ANNEX II of 93/42/EEC Certificate No: M.2017.106.8497

CE 2292

MANUFACTURER: Mikron Makina Sanayi Ticaret Limited Şirketi
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