NEW AGE

IMPLANTING VALUES



Mini Fragment

Locking Plate System

FDA

DRUG LICENSE INDIAN FDA

CE

CE CERTIFICATE

ISO 13485:2016 Medical Devices

ISO 13485:2016

ISO 9001:2015

ISO 9001:2015

GMP Quality

GMP QUALITY

About NewAge Medisys Limited

NewAge Medisys Limited is an ISO 13485: 2016 & CE Certified manufacturer and supplier of the widest range of surgical implants including Trauma system, Spine system, Hip system and it's instruments.

We are engaged in manufacturing and exporting of orthopaedic implants with a passion to make available best quality and précised implants to surgeons & patients.

At NewAge Medisys Limited, we don't emphasize on figures, but are devoted to continuous research & development and pledged to enforce ultra modern improvements on varieties of orthopaedic implants. Each orthopaedic implant that we manufacture is made with cutting edge technology and exceptional quality standards which are clinically proven.

We take extreme pride in our experts and dedicated team that makes sure quality is never compromised.

We are equipped with the latest automated technology CNC, VMC and Swiss-Type Sliding Head machines imported from countries like South Korea and Taiwan.

Many importers from the Middle East and Latin America sell our products under their brands. This itself is a testimony to acceptances of our core competencies in quality control, product design & development, computer aided manufacturing, prototyping and packaging.

With next generation orthopaedic implants, we are deliberately becoming a leader in the medical implants market.

WHAT MAKES US EXCEPTIONAL THAN OTHERS:

- Premium Quality.
- Maintaining exceptional Quality standards.
- Manufacturing implants with cutting edge technologies.
- Constant product innovation in design inputs.
- Commitment & determination.
- Prompt delivery.
- After-sales service.
- Easy Communication.



Certification & Inspection

Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on **Medical Device Regulation - (Council Regulation 2017/745)**

Certificate No.: CE-6961

Manufacturer

Name : NEWAGE MEDISYS LIMITED

Address : PLOT NO B 1, SURVEY NO 275, GALAXY INDUSTRIAL ESTATE, BEHIND TULSI METAL, SHAPAR VERAVAL, RAJKOT, GUJARAT – 360024, INDIA

Product : DESIGN AND DEVELOPMENT OF ORTHOPAEDIC IMPLANTS & INSTRUMENTS (more detail as per Appendix I & III)

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on **Medical Device Regulation -(Council Regulation 2017/745)**

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	21st April 2025
1st Surveillance Audit Due	20th April 2026
2nd Surveillance Audit Due	20th April 2027
Certificate Expiry (subject to the company maintaining its system to the required standard)	20th April 2028

Authorised Signatory

Page 1 of 4

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



Certification & Inspection

Certificate of Registration

This is to certify that the
Quality Management System for Medical Devices
of

NEW AGE IMPLANTING VALUES

NEWAGE MEDISYS LIMITED

at

PLOT NO B 1, SURVEY NO 275, GALAXY INDUSTRIAL ESTATE, BEHIND TULSI METAL, SHAPAR VERAVAL, RAJKOT, GUJARAT – 360024, INDIA

has been independently assessed and is
compliant with the requirements of:

ISO 13485:2016

For the following scope of activities:

DESIGN AND DEVELOPMENT OF ORTHOPAEDIC IMPLANTS & INSTRUMENTS

Certificate Number: UQ - 2025042135

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	21st April 2025
1st Surveillance Audit Due	20th April 2026
2nd Surveillance Audit Due	20th April 2027
Certificate Expiry	20th April 2028

Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



Certification & Inspection

Certificate of Compliance

Certificate Number: UQ - 2025042134

This is to certify that

NEW AGE IMPLANTING VALUES

NEWAGE MEDISYS LIMITED

at

PLOT NO B 1, SURVEY NO 275, GALAXY INDUSTRIAL ESTATE, BEHIND TULSI METAL, SHAPAR VERAVAL, RAJKOT, GUJARAT – 360024, INDIA

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of **"Good Manufacturing Practice"** as laid down by **"World Health Organisation"** which has been in conformance to the requirements of

WHO-GMP

SCOPE:- DESIGN AND DEVELOPMENT OF ORTHOPAEDIC IMPLANTS & INSTRUMENTS

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	21st April 2025
1st Surveillance Audit Due	20th April 2026
2nd Surveillance Audit Due	20th April 2027
Certificate Expiry	20th April 2028

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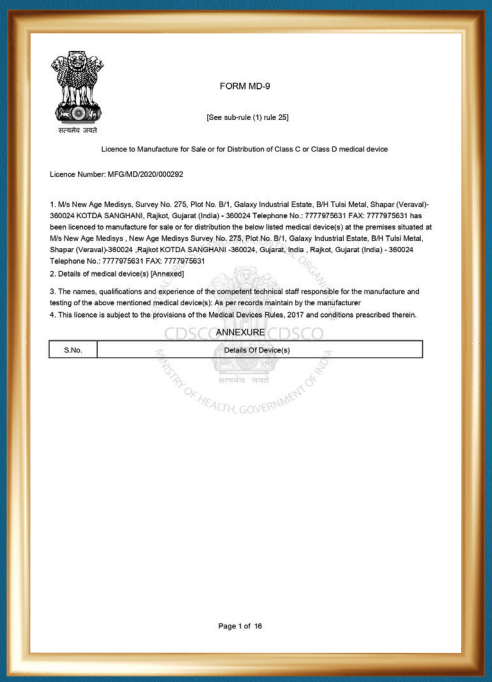
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2020/000292

1. M/s New Age Medisys, Survey No. 275, Plot No. B/1, Galaxy Industrial Estate, B/H Tulsi Metal, Shapar (Veraval)-360024 KOTDA SANGHANI, Rajkot, Gujarat (India) - 360024 Telephone No.: 7777975631 FAX: 7777975631 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s New Age Medisys , New Age Medisys Survey, No. 275, Plot No. B/1, Galaxy Industrial Estate, B/H Tulsi Metal, Shapar (Veraval)-360024 ,Rajkot KOTDA SANGHANI -360024, Gujarat, India , Rajkot, Gujarat (India) - 360024 Telephone No.: 7777975631 FAX: 7777975631
2. Details of medical device(s) [Annexed]
3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)

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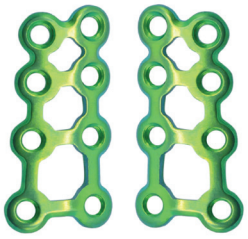
1.5mm Mini Fragment Locking Plate System

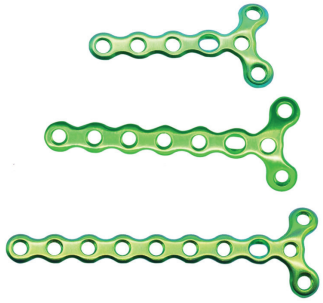
Size (Holes)	Reference Number Titanium	Size (Holes)	Reference Number Titanium
	Left		Right
8	2901.08	8	2902.08

1.5mm Mini Strut Locking Plate (Oblique-Angled)



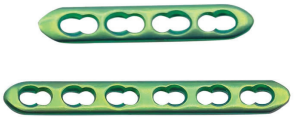
1.5mm Mini Y Locking Plate

Size (Holes)	Reference Number Titanium
3	2903.03
4	2903.04
5	2903.05
6	2903.06
7	2903.07



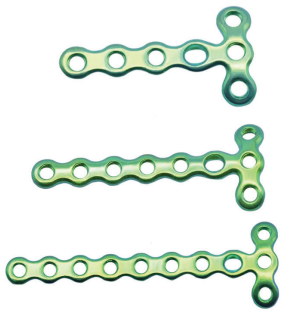
Size (Holes)	Reference Number Titanium
4	2904.03
5	2904.04
6	2904.05
7	2904.06
8	2904.07

1.5mm Mini Straight Locking Plate



1.5mm Mini Fragment Locking Plate System

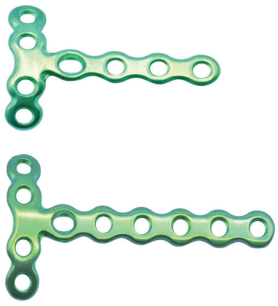
1.5mm Mini T Locking Plate (Head Hole 3)



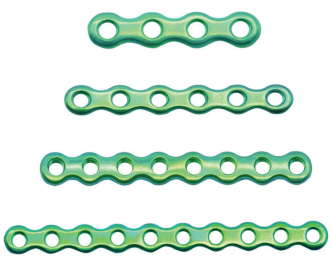
Size (Holes)	Reference Number Titanium
3	2905.03
4	2905.04
5	2905.05
6	2905.06
7	2905.07

1.5mm Mini T Locking Plate (Head Hole 4)

Size (Holes)	Reference Number Titanium
3	2906.03
4	2906.04
5	2906.05
6	2906.06
7	2906.07



1.5mm Mini Reconstruction Locking Plate

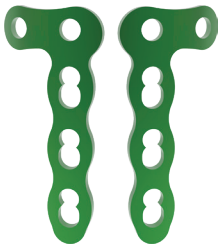


Size (Holes)	Reference Number Titanium
4	2907.04
5	2907.05
6	2907.06
7	2907.07
8	2907.08
9	2907.09
10	2907.10
11	2907.11
12	2907.12

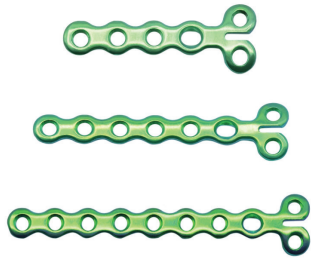
1.5mm Mini Fragment Locking Plate System

Size (Holes)	Reference Number Titanium	Size (Holes)	Reference Number Titanium
	Left		Right
3	2908.03	3	2909.03
4	2908.04	4	2909.04
5	2908.05	5	2909.05
6	2908.06	6	2909.06
7	2908.06	7	2909.06

1.5mm Mini L Locking Plate



1.5mm Mini Condylar Locking Plate



Size (Holes)	Reference Number Titanium
3	2910.03
4	2910.04
5	2910.05
6	2910.06
7	2910.06

Size (Length)	Reference Number Titanium
6mm	2911.06
8mm	2911.08
10mm	2911.10
12mm	2911.12
14mm	2911.14
16mm	2911.16
18mm	2911.18

1.5mm Wise-Lock Screws, Self Tapping, (Star Head)



1.5mm Mini Fragment Locking Plate System

1.5mm Cortical Screws, Self Tapping, (Star Head)



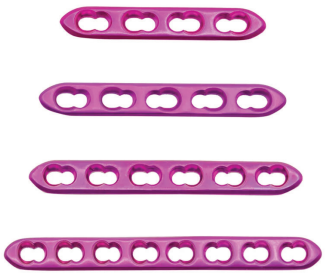


Size (Length)	Reference Number Titanium
6mm	2912.06
8mm	2912.08
10mm	2912.10
12mm	2912.12
14mm	2912.14
16mm	2912.16
18mm	2912.18

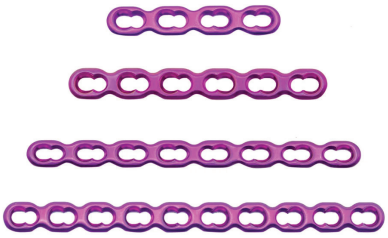
2.0mm Mini Fragment Locking Plate System

2.0mm Mini Straight Locking Plate

Size (Holes)	Reference Number Titanium
4	2913.04
5	2913.05
6	2913.06
7	2913.07
8	2913.08



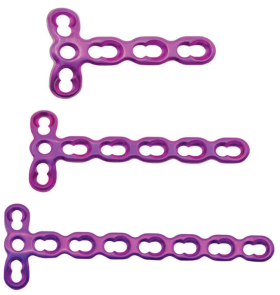
2.0mm Mini Adaptation Locking Plate



Size (Holes)	Reference Number Titanium
4	2914.04
5	2914.05
6	2914.06
7	2914.07
8	2914.08
9	2914.09
10	2914.10
11	2914.11
12	2914.12

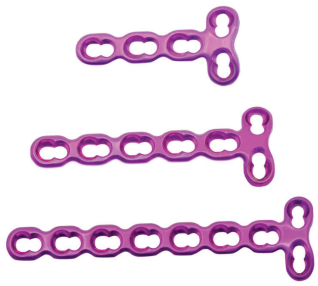
2.0mm Mini T Locking Plate

Size (Holes)	Reference Number Titanium
3	2915.03
4	2915.04
5	2915.05
6	2915.06
7	2915.07



2.0mm Mini Fragment Locking Plate System

2.0mm Mini T Reconstruction Locking Plate



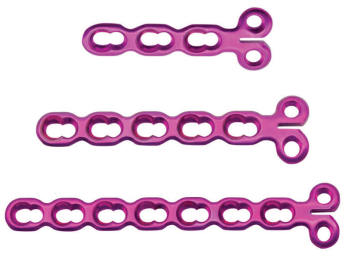
Size (Holes)	Reference Number Titanium
3	2916.03
4	2916.04
5	2916.05
6	2916.06
7	2916.07

2.0mm Mini Y Locking Plate



Size (Holes)	Reference Number Titanium
3	2917.03
4	2917.04
5	2917.05
6	2917.06
7	2917.07

2.0mm Mini Condylar Locking Plate

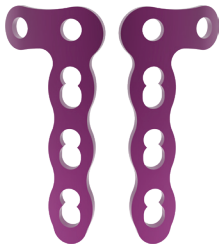


Size (Holes)	Reference Number Titanium
3	2918.03
4	2918.04
5	2918.05
6	2918.06
7	2918.07

2.0mm Mini Fragment Locking Plate System

Size (Holes)	Reference Number Titanium	Size (Holes)	Reference Number Titanium
	Left		Right
3	2919.03	3	2920.03
4	2919.04	4	2920.04
5	2919.05	5	2920.05
6	2919.06	6	2920.06
7	2919.06	7	2920.06

2.0mm Mini L Locking Plate



2.0mm Wise-Lock Screws, Self Tapping, (Star Head)





Size (Length)	Reference Number Titanium
6mm	2921.06
8mm	2921.08
10mm	2921.10
12mm	2921.12
14mm	2921.14
16mm	2921.16
18mm	2921.18

Size (Length)	Reference Number Titanium
6mm	2922.06
8mm	2922.08
10mm	2922.10
12mm	2922.12
14mm	2922.14
16mm	2922.16
18mm	2922.18

2.0mm Wise-Lock Screws, Self Tapping, (Star Head)

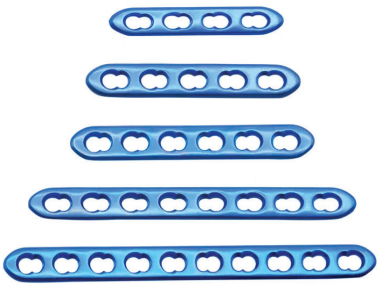




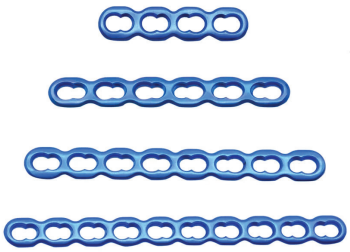
2.4mm Mini Fragment Locking Plate System

Size (Holes)	Reference Number Titanium
4	2923.03
5	2923.04
6	2923.05
7	2923.06
8	2923.07

2.4mm Mini Straight Locking Plate



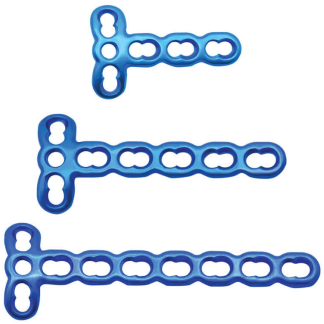
2.4mm Mini Reconstruction Locking



Size (Holes)	Reference Number Titanium
4	2924.04
5	2924.05
6	2924.06
7	2924.07
8	2924.08
9	2924.09
10	2924.10
11	2924.11
12	2924.12

Size (Holes)	Reference Number Titanium
3	2925.03
4	2925.04
5	2925.05
6	2925.06
7	2925.07

2.4 mm Mini T Locking Plate



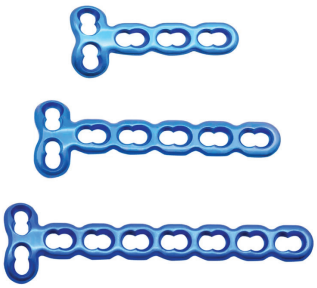
2.4mm Mini Fragment Locking Plate System

2.4mm Mini Y Locking Plate



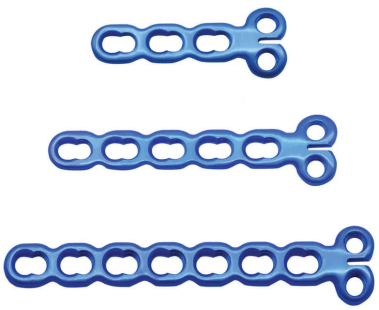
Size (Holes)	Reference Number Titanium
3	2926.03
4	2926.04
5	2926.05
6	2926.06
7	2926.07

2.4mm T Locking Plate



Size (Holes)	Reference Number Titanium
3	2927.03
4	2927.04
5	2927.05
6	2927.06
7	2927.07

2.4mm Mini Condylar Locking Plate

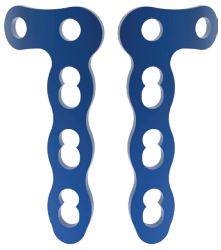


Size (Holes)	Reference Number Titanium
3	2928.03
4	2928.04
5	2928.05
6	2928.06
7	2928.07

2.4mm Mini Fragment Locking Plate System

Size (Holes)	Reference Number Titanium	Size (Holes)	Reference Number Titanium
	Left		Right
3	2929.03	3	2930.03
4	2929.04	4	2930.04
5	2929.05	5	2930.05
6	2929.06	6	2930.06
7	2929.06	7	2930.06

2.4mm Mini L Locking Plate



2.4mm Wise-Lock Screws, Self Tapping, (Star Head)





Size (Length)	Reference Number Titanium
6mm	2931.06
8mm	2931.08
10mm	2931.10
12mm	2931.12
14mm	2931.14
16mm	2931.16
18mm	2931.18

Size (Length)	Reference Number Titanium
6mm	2932.06
8mm	2932.08
10mm	2932.10
12mm	2932.12
14mm	2932.14
16mm	2932.16
18mm	2932.18

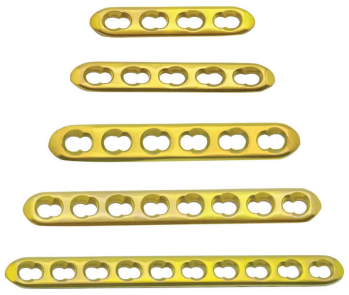
2.4mm Cortical Screws, Self Tapping, (Star Head)





2.7mm Mini Fragment Locking Plate System

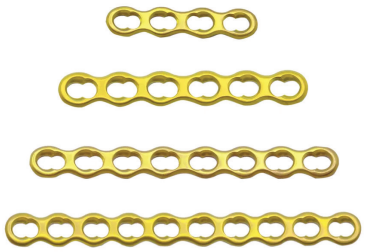
2.7mm Mini Straight Locking Plate



Size (Holes)	Reference Number Titanium
4	2933.03
5	2933.04
6	2933.05
7	2933.06
8	2933.07

Size (Holes)	Reference Number Titanium
4	2934.04
5	2934.05
6	2934.06
7	2934.07
8	2934.08
9	2934.09
10	2934.10
11	2934.11
12	2934.12

2.7 Mini Reconstruction Locking Plate



2.7 Mini T Locking Plate

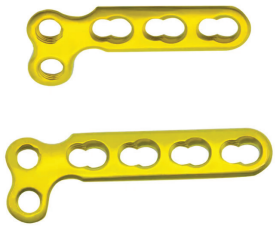


Size (Holes)	Reference Number Titanium
3	2935.03
4	2935.04
5	2935.05
6	2935.06
7	2935.07

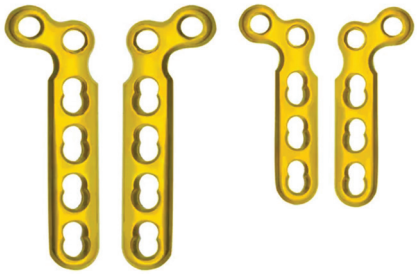
2.7mm Mini Fragment Locking Plate System

2.7 Mini L Locking Plate

Size (Holes)	Reference Number Titanium	Size (Holes)	Reference Number Titanium
	Left		Right
3	2936.03	3	2937.03
4	2936.04	4	2937.04
5	2936.05	5	2937.05
6	2936.06	6	2937.06
7	2936.06	7	2937.06



2.7 Mini Locking Oblique L Plate



Size (Holes)	Reference Number Titanium	Size (Holes)	Reference Number Titanium
	Left		Right
3	2938.03	3	2939.03
4	2938.04	4	2939.04
5	2938.05	5	2939.05
6	2938.06	6	2939.06
7	2938.06	7	2939.06

Size (Holes)	Reference Number Titanium
3	2940.03
4	2940.04
5	2940.05
6	2940.06
7	2940.07

2.7 Mini Condylar Locking Plate



2.7mm Mini Fragment Locking Plate System

2.7mm Wise-Lock Screws, Self Tapping, (Star Head)



Size (Length)	Reference Number Titanium
6mm	2941.06
8mm	2941.08
10mm	2941.10
12mm	2941.12
14mm	2941.14
16mm	2941.16
18mm	2941.18

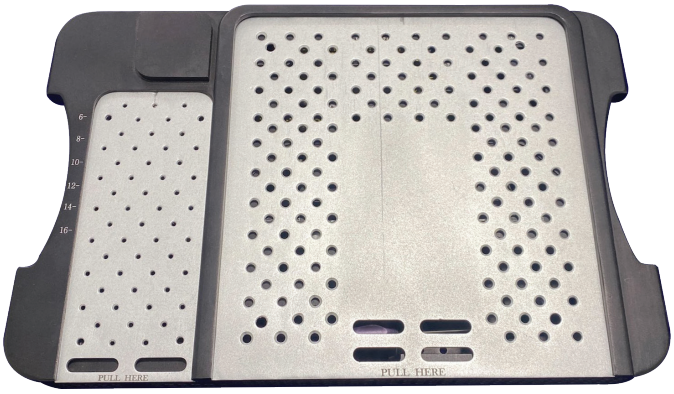
2.7mm Cortical Screws, Self Tapping, (Star Head)



Size (Length)	Reference Number Titanium
6mm	2942.06
8mm	2942.08
10mm	2942.10
12mm	2942.12
14mm	2942.14
16mm	2942.16
18mm	2942.18

Mini Fragment Locking Plate System

Mini Fragment Locking Plate System Instrument Set





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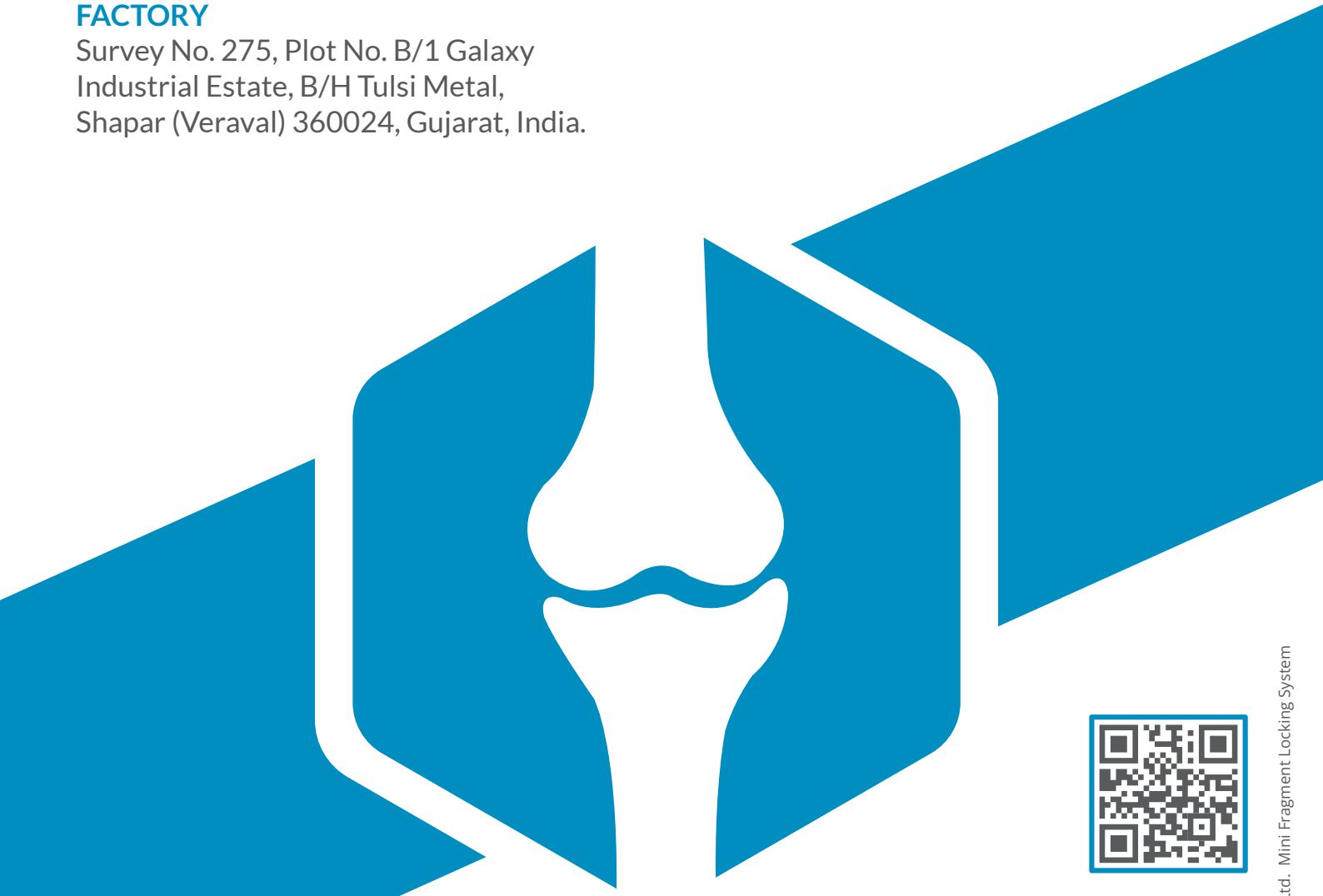

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