For the Attention of the Operating Surgeon:

IMPORTANT INFORMATION

ON THE DEPUY SYNTHES

MatrixNEURO™ CRANIAL PLATING SYSTEM, STERILE

DESCRIPTION

The DePuy Synthes MatrixNEURO Cranial Plating System consists of plates, burr hole covers, and meshes that come in a variety of shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with DePuy Synthes MatrixNEURO screws. System components are manufactured in either titanium or titanium alloy and are intended for single use only.

INDICATIONS

The DePuy Synthes MatrixNEURO Cranial Plating System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery, reconstructive procedures, and selective Orthognathic surgery of the maxilla and chin.

CAUTIONS

- DePuy Synthes recommends pre-drilling in dense bone when using 5 mm screws. Always drill with the proper level of irrigation and use the power tool manufacturer's recommended drilling speed to minimize the risk of necrosis or over-drilling.
- Use only a 1.1 mm drill bit for pre-drilling.
- Cut the implant close to the edge of the screw holes to protect soft tissue from trimmed edges.
- Excessive and repetitive bending of the implant increases the risk of implant breakage.
- When using plates, ensure countersink holes are facing upward.
- Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.
- After implant placement is complete, irrigate and apply suction for removal of debris potentially generated during implantation.

WARNINGS

- The MatrixNEURO Cranial Plating System is not intended for use in patients who are not yet skeletally mature. Resorbable fixation products should be considered as an alternative.
- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.

POSSIBLE ADVERSE EVENTS

- Loosening, bending, or breakage of the device.
- Non-union or delayed union which may lead to breakage of the implant.
- Pain, discomfort or abnormal sensation due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Infection, nerve damage and pain.

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MR INFORMATION

The MatrixNEURO Cranial Plating System has not been evaluated for safety and compatibility in the MR environment. The MatrixNEURO Cranial Plating System has not been tested for heating or migration in the MR environment.

INSTRUCTIONS FOR USE

It is anticipated that the DePuy Synthes MatrixNEURO Cranial Plating System will be used as follows:

- Expose area to be fixated via standard surgical approach (e.g. coronal incision, etc.)
- Select implant
- Size implant (if required)
- Contour implant (if required)
- Position implant
- Pre-drill screw holes (optional)
- Secure implant
- Close

Refer to the MatrixNEURO Cranial Plating System Technique Guide for complete instructions for use.

STERILIZATION

These devices are offered STERILE only. Resterilization of the sterile device may only be performed if the device has been opened, but not used. Resterilization of the sterile device should not be performed if the device packaging is damaged upon receipt or if the device has been contaminated with blood, tissue and/or bodily fluids/matter.

Note: Prior to resterilization, process the opened but unused, unsoiled implant as follows:

Cleaning – Manual Method

Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9.

1. Rinse device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the device.
2. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
4. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to clean the device. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly-made, clean solution.
5. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels.
6. Visually inspect device.
7. Perform a final rinse on device using DI or PURW water.
8. Dry device using a clean, soft, lint-free cloth or clean compressed air.

Cleaning – Mechanical Method: Ultrasonic

Equipment: ultrasonic cleaner, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9.

Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

Pre-clean method (Pre-clean method must be performed prior to ultrasonic mechanical method listed below.)

1. Rinse device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the device.
2. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
4. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to clean the device. Clean device under water to prevent aerosolization of contaminants.

   Note: *fresh solution is a newly-made, clean solution.*
5. Rinse device thoroughly using cold or warm tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels.
6. Visually inspect device.

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Ultrasonic process: (Pre-cleaning steps 1 – 6 should occur prior to this step.)

7. Prepare a fresh detergent solution using a neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.

   Note: *fresh solution is a newly-made, clean solution.*

8. Clean DePuy Synthes device ultrasonically for a minimum of 15 minutes.
9. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels.
10. Visually inspect device.
11. Perform a final rinse on device using DI or PURW water for a minimum of 15 seconds.
12. Dry device using a clean, soft, lint-free cloth or clean compressed air.

Cleaning – Mechanical Method: Mechanical washer

Equipment: Ultrasonic cleaner, washer/disinfector, various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9.

Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

Pre-clean method (Pre-clean method must be performed prior to mechanical washer method listed below.)

1. Rinse soiled device under running cold tap water for a minimum of one minute. Use a soft-bristled brush to clean the device.
2. Manually clean device for a minimum of two minutes in a freshly prepared neutral pH enzymatic or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Use a soft-bristled brush to clean the device. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly-made, clean solution.
3. Rinse device using cold to lukewarm running tap water for a minimum of one minute. Use a syringe, pipette or water jet to flush lumens and channels.
4. Prepare a fresh detergent solution using a neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: fresh solution is a newly-made, clean solution.
5. Clean DePuy Synthes device ultrasonically for a minimum of 15 minutes.
6. Rinse device for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. DI or PURW water must be used for final rinse.
7. Visually inspect device.

Mechanical Washer process: (Pre-cleaning steps 1 – 7 should occur prior to this step.)

8. Process device using the following cycle parameters.

Cycle	Minimum Time (minutes)	Minimum Temperature/ Water	Type of Detergent
Pre-wash	2	Cold tap water	N/A
Wash I	2	Cold to warm tap water	Neutral enzymatic pH between 7 and 9
Wash II	5	Warm tap water (>40ºC)	Detergent with pH between 7 and 9
Rinse	2	Warm DI or PURW (>40ºC)	N/A
Dry	40	90ºC	N/A

The following parameters are for the resterilization of the individual sterile device:

Method	Cycle	Minimum Temperature	Minimum Exposure Time	Minimum *Dry Time
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 Minutes	20 Minutes

These parameters are validated to sterilize only these devices. The manufacturer's validated sterilization parameters and the autoclave manufacturer's operating instructions should be followed. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, FDA cleared sterilization wrap, pouches, or containers should be used by the end-user for packaging terminally sterilized devices. The manufacturer's instructions for use for the sterilization wrap, pouches, or containers are to be followed.

**Synthes recommends a minimum dry time of 20 minutes for this device when sterilized using the parameters recommended above. However, because dry time can be influenced by various factors such as autoclave performance, sterilization load, sterilization wrap/package materials, steam quality, varying cool-down time, and environmental conditions, adequate drying of this device should be verified by visual inspection.*

CAUTION:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Manufactured by:

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Note: For recognized manufacturer, refer to the product label.