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510K
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P **NNACLE**

Surgical Technique Guide



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System Components



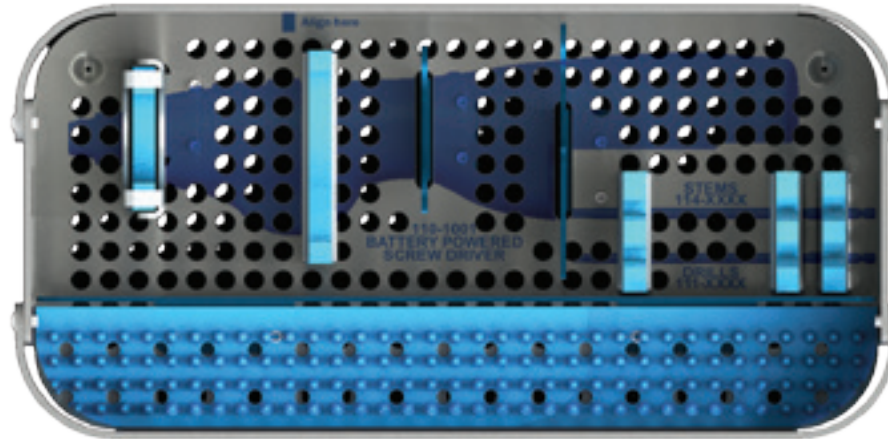
110-1001 Pinnacle Battery Powered Screw Driver



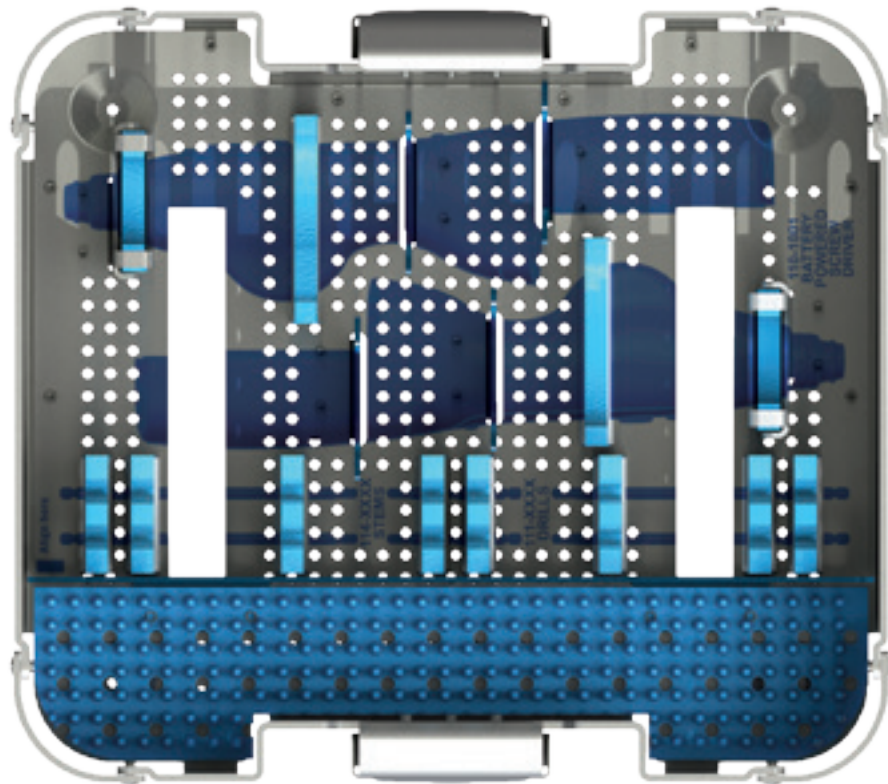
110-1000-SP
110-1000-SP-02



Replacement Battery, Sterile
Replacement Battery, Sterile, 2-Pack



110-1011 – Pinnacle Sterilization Tray, 1BPS



110-1012 – Pinnacle Sterilization Tray, 2BPS

System Components



DRIVER STEMS	SHORT (37mm)	MEDIUM (53mm)	LONG (83mm)
1.2mm	114-1215	114-1221	114-1233
1.6mm	114-1615*	114-1621	114-1633
2.0mm	114-2015	114-2021	114-2033



0.9mm TWIST DRILLS	SHORT	EXTENDED
4mm STOP	111-0940	111-0941
5mm STOP	111-0950	111-0951
6mm STOP	111-0960*	111-0961
8mm STOP	111-0980	111-0981



1.2mm TWIST DRILLS	SHORT	EXTENDED
4mm STOP	111-1240*	111-1241
5mm STOP	111-1250	111-1251
6mm STOP	111-1260	111-1261
8mm STOP	111-1280	111-1281



1.6mm TWIST DRILLS	SHORT	EXTENDED
4mm STOP	111-1640	111-1641
5mm STOP	111-1650	111-1651
6mm STOP	111-1660	111-1661
8mm STOP	111-1680	111-1681*

* Indicates that driver stem or twist drill is shown

TOTAL LENGTHS:		
	SHORT	EXTENDED
4mm STOP	42mm	78mm
5mm STOP	43mm	79mm
6mm STOP	44mm	80mm
8mm STOP	46mm	82mm



Driver Overview

The OSTEOMED Pinnacle Driver is a handheld, cordless, software driven, battery operated driver for high speed insertion of screws and drilling of pilot holes. The device software is optimized for driving OSTEOMED 1.6mm bone screws in lengths from 4mm to 6mm. The software is also capable of driving OSTEOMED 2.0mm bone screws in lengths from 5mm to 18mm, and 1.2mm bone screws in lengths from 4mm to 6mm. The device operates in the forward and reverse directions. A sterile, single use battery powers the device and is intended for use solely with the Pinnacle Driver.

Material

The Pinnacle Driver (p/n 110-1001) is made from various grades of stainless steel, aluminum, silicone, PEEK, gold plated brass, and plastic. Accessories are made from various grades of stainless steel. The driver uses one lithium metal replacement battery pack (p/n 110-1000). The battery housing containing the battery is made from various grades of plastic and gold plated brass. The battery is provided sterile packaged via gamma.

Clinical Indications

The Pinnacle Driver is intended for driving screws and for drilling into bone, in conjunction with cranial surgical procedures.

Contraindications

The Pinnacle Driver is contraindicated in patients where there is insufficient bone or poor bone quality.

Warnings:

- BATTERY MUST BE REMOVED FROM THE PINNACLE DRIVER BEFORE CLEANING AND STERILIZING THE HANDPIECE. DO NOT ATTEMPT TO RE-STERILIZE THE BATTERY.
- THE STERILE PACKAGED BATTERY IS SINGLE USE ONLY. DO NOT REUSE.
- Do not immerse the Pinnacle Driver in any solution. Immersing will render the device inoperable.
- Do not modify the Pinnacle Driver.
- If the device becomes too warm to hold comfortably during normal operation, discontinue use of the device.
- Do not use the Pinnacle Driver in poor quality bone. Use of the Pinnacle Driver to insert screws in soft bone or diseased bone may result in stripping of the bone after full insertion.
- The Pinnacle Driver can only be used with OSTEOMED screws and accessories. Failure to do so may result in damage to the device or accessories. Do not attempt to use the Pinnacle Driver to apply power to a bone tap.
- Do not attempt to advance a fully seated screw using the Pinnacle Driver, as it can result in stripping of the screw cruciform. Use an alternate (i.e., manual) driving mechanism for adjusting screws or fully seating screws if the Pinnacle Driver does not function as desired.
- When driving bi-cortical screws, the torque limiting software may prevent full insertion of the screw as the screw tip approaches the second cortical layer. In this situation, after the motor operation delay concludes, the Pinnacle Driver can be used to then fully seat the screw.
- Do not attempt to insert screws with the hand piece in **DRILL** mode (mode switch illuminated **BLUE**) or to drill pilot holes with the hand piece in **DRIVE** mode (mode switch illuminated **GREEN**) to ensure optimal operation of the Pinnacle Driver. In **DRILL** mode, the torque limiting software will not be activated to fully seat screws.

Cautions

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OSTEOMED instruments or implants. Inspect all components preoperatively to assure utility. Alternate insertion or fixation methods should be available intraoperatively.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques for driving screws and drilling pilot holes.
- Carefully inspect the Pinnacle Driver and battery prior to use. Devices which are faulty, leaking, emitting malodor or discoloration, damaged, or suspect should not be used. Immediately contact your local OSTEOMED representative for replacement.
- OSTEOMED recommends the use of OSTEOMED products in a sterile environment.
- Eye protection should be worn when using the Pinnacle Driver.
- Drill using the appropriately sized pilot drill. Use irrigation when drilling pilot holes. Discontinue use of the handpiece if it becomes too warm after continuous use.
- Do not activate more than one button at a time.

Operating Instructions

1. Align the battery contacts and dovetail slots of the battery with the mating dovetail boss on the hand piece. Fully insert the battery until an audible snap is heard and the battery adjoins the battery contact face of the hand piece.

Caution: Do not apply excessive force when inserting the battery. Do not touch battery contacts.



2. At battery insertion, the mode switch will illuminate green, and the hand piece will be ready to use.

Note: If the mode switch does not illuminate, remove the battery, re-insert, and ensure complete insertion.

Mode Switch Color Summary Table

Color	Mode	Comments
Green	● DRIVE	Indicates Pinnacle Driver is powered, operational, and in DRIVE mode
Blue	● DRILL	Indicates Pinnacle Driver is powered, operational, and in DRILL mode
Flashing Red	● FAULT	Indicates Pinnacle Driver is powered, but not functioning properly.



3. If mode switch immediately illuminates a flashing red, remove the battery and replace with a new, unused battery and repeat battery insertion. If the mode switch again illuminates a flashing red, this indicates the device is in a FAULT mode. Immediately contact your local OSTEOMED representative for replacement.



Operating Instructions (Cont.)



4. After selecting the appropriate size driver stem or pilot drill accessory, pull the collet towards the hand piece, insert the driver stem or drill, rotate the hex shank until aligned with the mating feature of the collet, then fully seat it in the collet. Release the collet to allow it to spring forward into a locked position, and ensure the accessory is properly captured by gently pulling it away from the collet. Use caution when inserting or changing accessories to avoid activation of the buttons.

Note: Only OsteoMed Hex Shank Accessories may be used with the driver. It will be operational if the accessory is inserted before or after battery insertion.

5. To drive screws, ensure the mode switch is illuminated green, indicating DRIVE mode, and confirm a driver stem is locked into position in the collet.



6. Load the desired screw by aligning the driver stem tip with the screw head and pushing down to engage the screw.



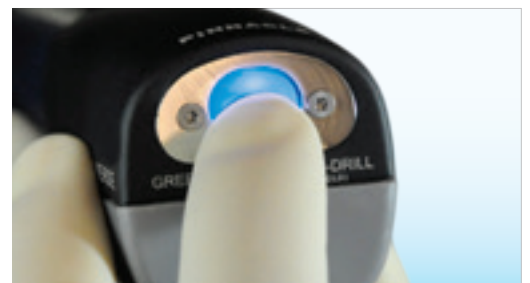
Operating Instructions (Cont.)

7. Position the screw in the desired location on the bone and push the forward button. The Pinnacle Driver will rapidly insert the screw and the torque limiting software will halt motor operation when the screw is fully seated. Release pressure from the forward button and gently rock the hand piece from side to side to disengage the driver stem tip from the fully seated screw head.



8. To remove screws (if necessary), engage the driver stem tip with the screw head and push the reverse button. If the screw does not reverse, help initiate screw removal by rotating the hand piece counter-clockwise while holding down the reverse button.

9. To drill pilot holes, press and hold the center of the mode switch button for at least 2 seconds until the mode switch illuminates blue, indicating DRILL mode, and confirm a pilot drill accessory is locked into position in the collet.



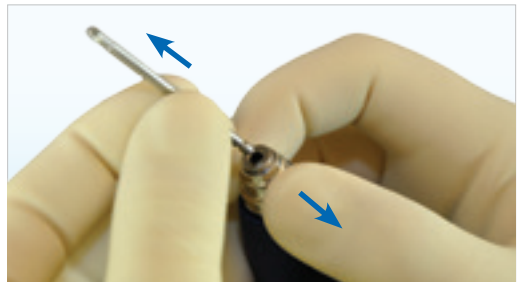
10. Position the drill in the desired location and push the forward button. The Pinnacle Driver will rapidly activate the drill. Use a “peck” technique by slowly advancing the drill bit, and then removing it from the bone to allow substrate chips to be removed, preventing jamming or breaking of drill bits. Use irrigation if necessary in dense bone. Continue until the desired pilot hole depth is achieved. If necessary, use the reverse button to aid in removing the drill from the bone.

Operating Instructions (Cont.)

- 11.** To change the hand piece back to DRIVE mode from DRILL mode, push down on the center of the mode switch button for at least 2 seconds until the mode switch illuminates green. Alternatively, the hand piece can be changed to DRIVE mode by removing and then re-inserting the battery.



- 12.** To remove the OsteoMed Hex Shank Accessory, pull back on the collet and hold depressed while pulling the accessory away from the handpiece.



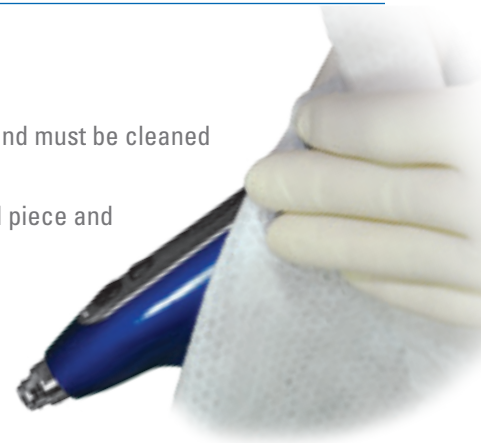
- 13.** To remove the battery, squeeze the ribs on either side of the battery and pull away from the hand piece while holding the driver firmly with the other hand.



Operating Instructions (Cont.)

Cleaning

- The Pinnacle Driver and OSTEOMED Hex Shank Accessories are supplied NON-STERILE and must be cleaned and sterilized prior to surgical use.
- After patient use, and removing the disposable battery, wipe down the exterior of the hand piece and OsteoMed Hex Shank accessory to minimize debris drying on them.
- Complete the device cleaning per Automated Cleaning Method as outlined below.
Note: Do not use abrasive cleaners.
- Do not immerse or submerge the Pinnacle Driver in any liquid.
- Do not ultrasonically clean the Pinnacle Driver.
- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer’s user instructions (manual and/or automated cleaning, etc.) and recommendations for chemical detergents.
- Automated Cleaning may be performed with Pinnacle Driver and OSTEOMED Hex Shank Accessories inside the Pinnacle Sterilization Case or out of the Pinnacle Sterilization Case.



Automated Cleaning Method

Cycle	Duration	Water/Temperature	Detergent Type and Concentration (or equivalent)
Pre-Wash 1	3 minutes	Cold tap water	N/A
Wash 1	5 minutes	Hot tap water (55°C)	TecWash III (pH 7.0-9.5) 1 oz/gallon
Wash 2	10 minutes	Hot tap water (60°C)	TecWash III (pH 7.0-9.5) 1 oz/gallon
PURW Rinse	1 minute	DI water (10°C)	N/A
PURW Rinse	10 minutes	DI water (93°C)	N/A

Operating Instructions (Cont.)

Sterility

- The Pinnacle Driver and OSTEOMED Hex Shank Accessories are provided NON-STERILE and are sterilizable by steam sterilization (autoclaving).
- Sterilization of the Pinnacle Driver can be achieved wrapped by itself (no case), or within an Aesculap container. Sterilization of the OSTEOMED Hex Shank Accessories can be achieved inside the Pinnacle organizational tray inside an Aesculap or other cleared containers.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect accessories prior to sterilization per standard hospital procedures. The following sterilization parameters must be used:

Pre-Vacuum Steam Sterilization

Sterilization Case:	Hand piece Only (No Case)	1-Driver Case (110-1011)	2-Driver Case (110-1012)
Minimum Temperature:	270° F (132° C)	270° F (132° C)	
Cycle	4 minutes	4 minutes	
Minimum Dry Time:	30 minutes	30 minutes	
Minimum Open Door Time:	N/A	N/A	
Minimum Cool-Down Time:	N/A	N/A	
Configuration	Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques.	Unwrapped using a rigid sterilization container (Aesculap – 510(k) K053389 or equivalent)	
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.			
Note: Biological indicator of <i>G. stearotherophilus</i> was used in sterilization validation.			
Note: If the specified wrap is not available, only FDA cleared wraps should be used to wrap the subject device.			

Pinnacle Driver Battery Overview

The OSTEOMED Pinnacle Driver battery (p/n 110-1000) is a sterile, single use battery provided to power the Pinnacle Driver. The battery is provided sterile packaged in 1-pack (p/n 110-1000-SP) or 2-pack (110-1000-SP-02) configurations. This battery is intended for use solely with the Pinnacle Driver (p/n 110-1001) provided by OSTEOMED.

Sterility

The Pinnacle Driver battery is provided STERILE by exposure to gamma irradiation. DO NOT RE-STERILIZE. The battery is for one-time, single-patient use only. DO NOT USE IF STERILE PACKAGING IS OPENED OR DAMAGED. The expiration date of the battery is provided on the individual battery packaging label. DO NOT USE PAST THE EXPIRATION DATE TO AVOID RISK OF INFECTION.

Warnings:

- **DO NOT RE-STERILIZE THE BATTERY. DO NOT ATTEMPT TO RECHARGE THE BATTERY.**
- **Single-use only. The battery is provided sterile. DO NOT REUSE.**
- **Do not put the battery into fire or heat it. If exposed to direct heat, the insulator in the battery may be damaged, which may cause heat generation, smoke emission or ignition.**
- **Do not use or leave the battery near a high heat source such as a fire or heater. Such high temperature may cause damage and result in heat generation, smoke emission or ignition of the battery.**
- **Do not dip or wet the battery in water or other liquid. This may result in the battery being discharged with an abnormal current and voltage, which may result in heat generation, smoke emission or ignition of the battery.**
- **Do not immerse the battery. Immersing will render the battery inoperable.**
- **Do not apply heavy force, drop, crush, or throw the battery. Strong impact may damage the battery resulting in heat generation, smoke emission or ignition of the battery.**
- **Do not use the battery for a purpose other than those specified. Otherwise, its performance may be lost and its service life may be shortened. Depending on the equipment in which the battery is used, excessively high current can flow through the battery, possibly damaging it and leading to leakage, heat generation, smoke emission or ignition.**
- **If the battery leaks and the electrolyte gets into the eyes, do not rub them. Rinse the eyes with clean running water and immediately seek medical attention. Otherwise, eye injury may result.**
- **If you notice any malodor, heating, discoloration, deformation, or any other physical change to the device, remove the battery from the hand piece and avoid using the battery. Using the battery in such a state may result in heat generation, smoke emission or ignition.**
- **If the battery leaks or emits a malodor, take it away from any fire immediately. The electrolyte may catch fire, which may cause heat generation, smoke emission or ignition.**

Cautions

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Battery must be removed from the Pinnacle Driver before cleaning and sterilizing the driver itself.
- Do not use the battery if the packaging or the battery appears opened or damaged, as sterility may be lost.
- Do not use the battery if there is foreign material in the packaging.
- Do not use excessive force when inserting the battery into the device. If the battery does not insert easily into the device, remove it and re-insert. Failure to properly insert the battery into the device can result in damage to the driver and/or the battery.
- Do not use or leave the battery in direct sunlight or high temperatures as high temperature may cause performance loss and/or the life of the battery may be shortened.
- If the battery is rusty, exhibiting malodor, heating, or any other defect before using the battery, do not use the battery. Contact OSTEOMED.
- If the battery leaks and its electrolyte contacts the skin or clothes, wash the skin with tap water right away.
- Reference the Pinnacle Driver Instructions for use (9461) regarding the battery installation and removal from the Pinnacle Driver so as not to mishandle and waste the battery.

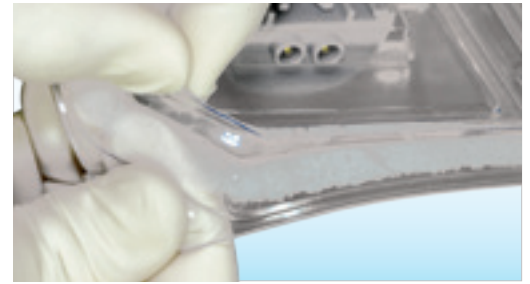


Pinnacle Driver Battery Instructions

1. After removing the plastic tray from the black shelf box, use the “Peel Here” corner to remove the Tyvek® lid.

Bend back the ribbed corner of the tray with one hand and pull back the corresponding corner of the plastic lid slowly.

The sterile batteries will now be accessible.



2. Align the battery contacts and dovetail slots of the battery with the mating dovetail boss on the hand piece. Fully insert the battery until an audible snap is heard and the battery adjoins the battery contact face of the hand piece, and confirm it is locked in place by gently pulling on the battery.

Caution: Do not apply excessive force when inserting the battery. Do not touch battery contacts.



3. At battery insertion, the mode switch will immediately illuminate green, and the handpiece will be ready to use.

Note: If the mode switch does not illuminate immediately, remove the battery, re-insert, and ensure complete insertion.



4. If the mode switch illuminates a flashing red, remove the battery and replace with a new, unused battery and repeat battery insertion. If the mode switch again illuminates a flashing red, this indicates the hand piece is not functioning properly. Immediately contact your local OSTEOMED representative.



5. To remove the battery, squeeze the ribs on either side of the battery and pull away from the hand piece while holding the driver firmly with the other hand.



Pinnacle Driver Battery Pack Disposal

- Observe the general environmental regulations applicable to battery disposal. Do not attempt to recharge a used battery.
- Always follow local regulations for the disposal of Lithium metal battery packs and electronics.
- Do not discard batteries in regular trash; they should be recycled properly.
- Before disposing of the battery pack or cells, insulate any exposed terminals with adhesive tape or similar materials to prevent short circuits.

Technical Specifications

Classification:

Self-contained power electrical power source. Complies with IEC 60086-4, ANSI/AAMI ES60601-1:2005(R) 2012/A1:2012, CSA c22.2 No. 60601-1:14

Power Rating: 8V, 550 mAh

Type: Primary (non-rechargeable), Lithium metal

Chemistry: Lithium Nickel Cobalt Oxide

Operating Conditions: Temperatures between 50°F - 95°F
Relative humidity non-condensing between 30% - 75%
Atmospheric pressure between 76 kPa - 106 kPa
Only operate at altitudes below 3000m
For indoor use only

Shipping and Storage Conditions:
Temperatures between -4°F - 140°F
Relative humidity non-condensing between 20%-95%
Atmospheric pressure between 50 kPa – 106 kPa

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Customer Service: (800) 456-7779

Manufactured By:
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2361 McGaw Ave.
Irvine, California 92614 USA
Telephone: (800) 652-6204



Pinnacle Ordering Information

Pinnacle Driver: 110-1001

Single Sterile Battery Pack: 110-1000-SP

Double Sterile Battery Pack: 110-1000-SP-02

Pinnacle Single Sterilization Tray: 110-1011

Pinnacle Double Sterilization Tray: 110-1012

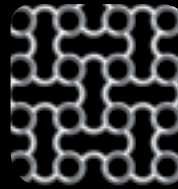
Hex Shank Driver Stems: 114-XXXX

Hex Shank Twist Drills: 111-XXXX

OsteoMed Products



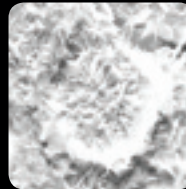
DuraKnife



OsteoMed Mesh



Fast-Flap



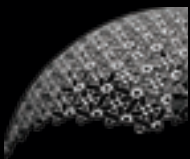
OsteoVation



OsteoDriver 2



Profile Zero



OsteoForm Mesh



SmartFlex



OsteoMatch



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