Surgical Technique



Rhausler Inc.



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I. System Overview

The PLAGE Anterior Cervical Fusion System is an integrated plate and cage design offering a new approach for ACDF procedures.

The one-piece titanium implant, translational design, and textured surface combine to provide flexibility, speed of insertion, and an environment that promotes fusion.

The PLAGE device allows for flexibility in the surgical technique. This guide reviews three options:

Option 1 - Dual-Drill Guide

- **Option 2** Universal Drill Guide
- **Option 3** Free-hand with screwdriver

Implant Features:

- Single piece, Titanium implant reduces the opportunity for breakage and micro movement
- Large implant surface for reduced implant resorption
- Low-profile implant tabs
- Acid-etched Titanium surface reduces migration and promotes bony on-growth
- Thin implant sidewall allows for post-operative fusion visibility
- Slotted screw holes allow for translational movement

II. Indications and Contraindications:

Indications and Intended Use

PLAGE Anterior Cervical Fusion System is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Contraindications

- Patients with a systemic infection, with a local inflammation at the bone site or with readily progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis.
- Patients with known allergies to metals.
- Patients with mental illness or who are resistant to following post-operative activity restrictions.
- Patients where the available implant sizes are unsuitable for their anatomy.
- Other medical conditions that would preclude or outweigh the potential benefits of spinal surgery.



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Warnings/Potential Adverse Events

Warnings

- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- US Federal law restricts this device to sale by or on the order of a physician.
- If needed, all metal implants and instruments or fragments thereof can be located by means of an X-Ray.
- This device may not be used with components from other manufacturers.
- Do not use implants made from dissimilar metals in contact with the titanium alloy Ti6 Al 4V PLAGE implant components; otherwise, galvanic corrosion may occur.
- Implants and instruments are provided non-sterile and must be sterilized prior to use.
- This device provides temporary stabilization during the development of spinal fusion. It is not intended to be the sole means of spinal support. No spinal implant can withstand body loads without the support of bone. In this event, Implant bending, loosening, disassembly, or breakage(s) will occur.
- Use without a bone graft or in cases that develop into a non-union will not be successful.
- Testing has not been performed to assess the safety and compatibility of PLAGE Implants in a Magnetic Resonance Environment. The PLAGE implants have not been tested for heating or migration in the MR environment.

Potential Adverse Events

- Infection.
- Non-union, delayed union, or mal-union, which can lead to loosening or breakage of the implants.
- Loss of fixation.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Fracture of the vertebral bodies.
- Post-operative change in spinal curature, loss of correction, height, and/or reduction.
- Dural tears, persistent CSF leakage, meningitis.
- Loss of bladder control or other types of urological system compromise.
- Nerve damage due to surgical trauma.
- Spinal bone fracture, resorption, damage, or necrosis.
- Loss of or increase in spinal mobility or function.
- Scar formation.
- Vascular damage, including possible paralysis.
- Inability to perform daily activities.
- Death.

Re-operation may be needed to treat some of the potential adverse events. General surgical risks should also be explained to the patient.

Precautions

Precautions

Device Performance. Metallic supplemental fixation systems are internal splints which align the vertebral bodies during the fusion process. If there is delayed fusion or non-fusion, the implant can eventually break due to metal fatigue. Based on fatigue testing results, the physicians/surgeon should consider the levels of implantation, patient, weight, patient activity level, and other patient conditions which may impact performance of the system. Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

<u>Surgical implants must never be re-used</u>. Even though the device appears undamaged, it may have all small defects and internal stress patterns which could lead to breakage. Re-use also presents biological hazards associated with disease transmission and immune/allergy issues, some of which could cause severe illness or be fatal.



<u>Correct handling of the implant is extremely important.</u> Contouring of metallic implants must be avoided. Caution should be taken not to over-tighten threaded components, including implants, instruments, and implant/instrument interfaces.

Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fracture healing. The patient must be made aware of the limitations of the implant and that physical activity and full load-bearing have been implicated in premature loosening, bending or fracture of supplemental fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under weight-bearing or load-bearing in the absences of complete boney healing (fusion). Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spinal fusion, as are patients with poor muscle and bone quality and/or nerve paralysis. Use of allograft material may not give as good a result as pure autograft.

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III. Surgical Technique



1. Patient Positioning and Exposure

Place the patient in the supine position and bolster the intrascapular region to maintain the head in slight extension. The use of a head halter attached to an outrigger for traction may also be helpful. The shoulders are taped pulling inferiorly to allow better visualization of the lower cervical spine on fluoroscopy.

Exposure and Incision

The operative fluoroscopy C-arm is positioned at a 45-degree angle above the patient to function both as an ether screen and to provide intraoperative images. The surgeon selects a right- or left- sided approach to the cervical spine. (Fig. 1)



Retraction and Distraction

Once the skin incision (transverse or oblique) and anterior soft tissue dissection have been performed, allowing visualization of the pathologic levels, a cervical self-retaining soft tissue retractor (such as the Caspar Cervical Retractor System) is used to maintain exposure to the vertebral column to easily identify appropriate levels to operate.

After identification of the appropriate disc space is confirmed via x-ray, a cervical vertebral distraction system (such as the Caspar Cervical Distraction System) may be used to enhance access to the disc space. The distraction pins are placed slightly offset of the midline, the cranial pin slightly to the right and the caudal pin slightly to the left in the vertebral bodies adjacent to the disc. The distractor is placed over the pins, and gentle distraction is applied. (Fig. 2)



2. Discectomy and Endplate Preparation

With the disc space distracted, a complete discectomy is performed using curettes, pituitary Rongeurs and Kerrisons to remove all disc material and cartilage to expose the posterior longitudinal ligament. A high-speed drill, Kerrison and/or curette can be used to remove the posterior disc and osteophytes to achieve neural decompression. *The disc fragment and/or the posterior longitudinal ligament are removed as preferred.* (Fig. 3)



In select cases, a partial corpectomy or undercutting of the posterior vertebral body margins is necessary for a complete decompression of the spinal cord and exiting nerve roots. The intervertebral disc space is prepared for the PLAGE implant by removing the cartilage endplate, exposing the bony endplate and shaping the superior and inferior bony margins in a parallel or slightly lordotic fashion. (Fig. 4)

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3. Implant Insertion

The PLAGE Anterior Cervical Fusion System comes in a variety of sizes. The cervical implants are made of medical grade titanium alloy Ti6A14V and are available in a range of sizes from 5 mm to 10 mm in height and 15x14 and 17x16 mm deep and wide. The PLAGE implant can be placed with two locking bone screws.

Implant Sizing

Once the disc space has been prepared, the appropriate size and height of the PLAGE implant can be determined by inserting one of the color-coded Trials (Trials D-3100 thru D-3105). (Fig. 5)

Once the appropriate size and height of the implant has been determined, select the corresponding color-coded Rasp. The Rasp (D-3000 thru D-3005) is used to roughen and expose the end plates, and prepares them for the placement of the corresponding sized PLAGE implant. (Fig. 6)

Note: All Trials, Rasps, Drill Guides and PLAGE implants are color-coded to PLAGE height. Rasps are 1 mm deeper than implant.



PLAGE Trial Sizes					
Height (mm)	Item No.	Color			
5	D-3100	Silver			
6	D-3101	Blue			
7	D-3102	Copper			
8	D-3103	Green			
9	D-3104	Violet			
10	D-3105	Gold			

PLAGE Rasp Sizes					
Height (mm)	Item No.	Color			
5	D-3000	Silver			
6	D-3001	Blue			
7	D-3002	Copper			
8	D-3003	Green			
9	D-3004	Violet			
10	D-3005	Gold			

Note:

Slap Hammer The Slap Hammer (C-7150) can be attached to the proximal end of the Holder Impactor Tool (D-3200), Trials and Rasps to assist in their removal from the vertebral body if necessary.

Option 1: Dual-Drill Guide





Color-Coded Dual Drill Guides

The Color-Coded Dual Drill Guides (D-2465 thru D-2780) (Fig. 7) can be attached to the appropriate color coded PLAGE^m implant using the (C-3201) Drill Guide Holder.

Implant Preparation & Insertion

Secure the color-coded Dual Drill Guide from the implant caddy with the Dual Drill Guide Holder (D-3201) (Fig. 7) then screw in the Dual Drill Guide Holder and Guide into the corresponding color-coded implant. (Fig. 8)

Note: If implanting the 5 mm standard implant (D-1465) use Dual Drill Guide (D-2465) variant. See appendix for Dual Drill Guide variant on page 18.

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Use the packing block (C-7085) to support the implant while packing the graft window with bone or alternate materials. (Fig. 9)

Use the Bone Graft Impactor Tool (D-3203) to impact the bone in the implant graft window prior to implanting.



Once firmly attached, the Implant can be inserted into the disc space. It is now ready to drill the pilot holes and to place the bone screws. (Fig.10)

Note: If desired, the Mallet (D-7058) can be used to tap the Drill Guide Holder (C-3201) to aid in placement of the PLAGE implant.



The appropriate length Twist Drill is selected (10, 12, 14, and 16 mm lengths are available) to match the corresponding length of the self-tapping bone screws.

The twist drill can be attached to the Handle for AO Shafts (C-7028). The twist drill is then placed in one side of the Dual Drill Guide and drilled until it no longer advances in the guide. (Fig. 11)

The opposite side of the guide is then drilled and the twist drill is removed and disposed of according to hospital protocol for Single Use Items.



Bone Screw Loading The associated length bone screw is selected and retrieved with the Locking Clocked Screwdriver (C-7026

with the Locking Clocked Screwdriver (C-7026, Optional C-7025). (Fig. 12)

Note: See Bone Screw Loading on pages 19-20 for instructions on securing the bone screw to the One-Step Locking Screwdriver.

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Bone Screw Placement and Locking

The bone screw is then screwed through the drill guide until the screwdriver bottoms out and is two finger tightened. Lock the screw. (Fig. 13)

Note: See Bone Screw Locking instructions on page 21 for information on how to lock the PLAGE bone screws.

The screwdriver is removed and the second bone screw is then placed through the drill guide in the same manner and removed. (Figs. 14)



The Dual Drill Guide Holder with the Dual Drill Guide is also unscrewed and removed. The screwdriver can be reinserted for further tightening or locking of the bone screw cam if not done in previous step. (See Technique for Screwdriver C-7025 or optional C-7026).

Note: In the event a hole becomes stripped, an oversized 4.5 mm Diameter Unicortical Locking Self-Tapping Oversized Screw may be utilized to insure adequate cervical PLAGE compression. Oversized bone screws are available in 10, 12, 14, and 16 mm lengths.



Unlocked

PL-AGE Screw Locking Mechanism



Locked

The PLAGE Screw incorporates a screw locking mechanism to prevent screws from backing out.

Note: If the locking ring is loose, then locking cam is not locked. See Bone Screw Locking instructions on page 21

Option 2: Universal Drill Guide



Implant Preparation & Insertion

Select the appropriate sized PLAGE Implant, using the Holder/Impactor Tool (D-3200). (Fig. 15)

Use the packing block (C-7085) to support the implant while packing the graft window with bone or alternate materials.

Use the Bone Graft Impactor Tool (D-3203) to impact the bone in the implant graft window prior to implanting.



Using the Holder/Impactor Tool (D-3200) place the implant in the disc space. (Fig. 16)

Note: If desired, the Mallet (C-7058) can be used to tap the Holder/Impactor Tool to aid in placement of the PLAGE implant.

Note: After the implant is inserted in the disc space, the Holder/Impactor Tool (D-3200) may be removed prior to attaching the Universal Drill Guide (tC-7052)

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Universal Drill Guide

The Universal Drill Guide (C-7052) with Nylon Depth Stop Spacers, available in 10, 12, 14 and 16 mm, can be used as a drill guide to vary the bone screw placement angle. Fluoroscopy can be used to verify the correct bone screw angle desired prior to drilling and after placement in the implant.

Insert Depth Spacer (C-7053) into Universal Drill Guide (C-7052). Next, tighten the adjuster to secure the spacer between the adjuster and the drill guide body. (Fig. 17)



The Universal Twist Drill is placed in the Universal Drill Guide and the distal tip is placed in one of the screw holes. (Fig. 18)

The Universal Twist Drill is then driven by the Handle for AO Shafts (C-7028). Drill until the drill bottoms out into the PLAGE screw hole and use the same technique for the second screw hole. Twist drill is removed and disposed of according to hospital protocol for Single Use Items.

Repeat the steps from the, 'Option 1: Dual Drill Guide', for bone screw loading placement and locking, pages 11 –12.

Note: See Bone Screw Locking Instructions on page 21 for information on how to lock the PLAGE bone screws.

Option 3: Free-hand with Screwdriver



Implant Preparation & Insertion

Select the appropriate sized PLAGE Implant, using the Holder/Impactor Tool (D-3200). (Fig. 19)

Use the packing block (C-7085) to support the implant while packing the graft window with bone or alternate materials.

Use the Bone Graft Impactor Tool (D-3203) to impact the bone in the implant graft window prior to implanting.



Using the Holder/Impactor Tool (D-3200) place the implant in the disc space. (Fig. 20)

Note: If desired, the Mallet (C-7058) can be used to tap the Holder/Impactor Tool to aid in placement of the PLAGE implant

Note: After the implant is inserted in the disc space, the Holder/Impactor Tool (D-3200) may be removed.

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Awl (C-7036)

By selecting a self-drilling, self-tapping bone screw, the screw placement and cam locking can be completed by using the Locking Clocked Screwdriver (C-7026, Optional C-7025). (Fig. 21)

Note: Care should be taken if it is deemed that the cortical bone is extremely hard. In that case the 12 mm Awl, can be used first to penetrate the cortical bone prior to the screw placement of a self-drilling self-tapping bone screw.

Bone Screw Placement and Locking

The bone screw is then screwed through the implant tab until the screwdriver bottoms out and is two finger tightened. Lock the screw. (Fig. 22)

Note: See Bone Screw Locking Instructions on page 21 for information on how to lock the PLAGE bone screws.

4. Verification of Final Implant Placement





Verification of Final Implant Placement

Visually confirm that bone screws are fully seated within the PLAGE implant tabs, and that the locking ring is in the locked position. (Fig. 24)

It is recommended that the final AP and lateral radiographs are obtained.

The final AP image should confirm the midline placement of the device.

The final lateral image should confirm adequate bone screw placement within the PLAGE tabs, and desired coverage of the implant interbody portion was achieved within the disc space. (Fig. 23)

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Appendix: Dual Drill Guide Variant



The 5 mm Dual Drill Guide (C-2465) is only used with 5 mm PLAGE (D-1465). Prior to using the 5 mm Dual Drill Guide one must first insert the implant using the Holder/ Impactor tool (D-3200). (Fig. 25)



Once the implant is inserted, place Drill Guide over the implant. Note, the 5 mm Dual Drill Guide does not screw into the PLAGE 5 mm implant. Repeat steps listed in Dual Drill Guide section for use of twist drills, and insertion of bone screws. (Fig. 26)

Appendix: Bone Screw Selection and Loading



Bone Screw Selection

The type of bone screw selected by the surgeon dictates the specific surgical technique and instrumentation used. Fluoroscopy verifies screw angle, length, and placement. The bone screws should not violate the adjacent disc spaces or project into the spinal canal to compress the spinal cord or nerve roots.

With the cervical PLAGE implant in place, the surgeon selects the appropriate twist drill, or Awl for preparing the bone screw pilot holes.

Bone Screw Loading

Here are important steps to avoid complications when using the (C-7026) Locking Clocked Screwdriver.

 Prior to loading the Screwdriver, be sure that the outer locking mechanism is pulled up flush to the handle

- When engaging the bone screws in the screw caddy, bring the hex end of the Screwdriver to the selected bone screw at a 45-Degree angle while holding the back end of the handle with one hand (Fig. 27)
- Rotate the Driver to a perpendicular position (straight up) and rotate the handle while pushing down lightly to engage the hex in the screw
 - Be sure that the hex of the Driver is fully engaged into the bone screw
- Slide the outer locking shaft down until it seats flush on the bone screw. A slight twist of the shaft may be required to fully seal.

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Appendix: Bone Screw Locking



Once fully engaged, use your free hand to engage the locking mechanism into the bone screws Locking Cam. This is achieved by lightly pushing down and rotating the 4-pronged wheel until the hex of this outer locking mechanism is fully engaged into the hex of the screw Locking Cam.

Re-engaging the Screwdriver

When the surgeon re-engages the Screwdriver back into the bone screw which has been already placed into the PLAGE implant ready for final tightening and locking, there are a few steps to keep in mind.

It can be difficult to re-engage the screwdriver into the bone screw if it is not positioned coaxial to the head of the bone screw (aligned straight in). It also is critical that the Retractor arms or any instruments placed in the wound do not interfere when attempting to place the Screwdriver into the bone screw. Any sideward pressure will cause the screwdriver NOT to cleanly engage the Bone screw. If any part of the Retractor is interfering with the Screwdriver placement, you MUST hold the retractor away from touching or in any way interfering with the Screwdriver shaft.



Once the Screwdriver is fully engaged into the bone screw (while continuing to avoid any lateral pressure / interference) the Locking Shaft needs to be lightly pushed down and rotated into the Cam Mechanism and once fully engaged, the Locking Mechanism needs to be rotated clockwise 1/16th of a turn to lock the bone screw in place. Note: At least 1/3 of the bone screw head (depending on the angle of placement) must be past the top of the plate's screw hole ridge and not fully tightened into the bottom of the implant PRIOR to engaging the locking cam. Once the cam is locked, you can further tighten the bone screw into the implant.

There are three (3) confirmations to confirm that the Locking Cam is locked.

- FIRST, the surgeon will feel a tactile click once the Locking Shaft is rotated 1/16th of a turn (usually hears a click as well).
- The SECOND is the black dashes on the Cam no longer line up with the four cuts in the head of the screw.
- The THIRD is to use a small probe or dissector, push side to side on the cam ring and, if there is no movement of the cam ring, the Bone Screw is locked.

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Appendix: Implant Removal



Cervical PLAGE Removal

With the cervical vertebral column section containing the PLAGE implant being clearly exposed using a cervical soft tissue retractor, use the Locking Clocked Screwdriver (C-7026) to unlock the bone screw locking mechanism by a 1/16 rotation counterclockwise (see section "Technique Self-Retaining One-Step Locking Screwdriver"). Remove each bone screw using the screwdriver by turning the bone screw counterclockwise until the bone screw is completely disengaged from the vertebral body and implant.

Repeat this for the remaining bone screw and properly dispose of the bone screws and implant when completed. If the bone screw cannot be removed using the Self-Retaining One-Step Locking Screwdriver, a Screw Extractor Tool is used. The Screw Extraction Tool is loaded into the Handle for AO Shafts and the distal tip is placed into the center of the bone screw and turned counterclockwise, backing out the bone screw.

Bone Screw Removal Tool (C-7031)

If the bone screw cannot be removed using the Locking Clocked Screwdriver (C-7026), a Screw Extraction Tool (C-7031) is used.

The screw Extraction Tool is loaded in to the Handle for AO Shafts (C-7028), and the distal tip is placed in to the center of the bone screw and turned counterclockwise, backing out the bone screw. Once the bone screw is removed, the bone screw must be properly discarded.

IV. Implant Options

Face View





Top View



Item No.	Implant Description	Foot Depth (mm)	print Width (mm)	Height (mm)	Implant Lordotic Angle (°)	Plate Lordotic Angle
D-1165	PLAGE, Lordotic 13x14x5mm, Silver, 0° SML	13	14	5	4	0
D-1166	PLAGE, Lordotic 13x14x6mm, Blue, 0° SML	13	14	6	4	0
D-1167	PLAGE, Lordotic 13x14x7mm, Copper, 0° SML	13	14		4	0
D-1168	PLAGE, Lordotic 13x14x8mm, Green, 0° SML	13	14		4	0
D-1169	PLAGE Lordotic 13x14x9mm, Violet, 0° SML	13	14	9	4	0
D-1170	PLAGE Lordotic 13x14x10mm, Gold, 0° SML	13	14		4	0
D-1275	PLAGE Lordotic 13x14x5mm, Silver, 6º SML	13	14		4	6
D-1276	PLAGE, Lordotic 13x14x6xmm, Blue, 6° SML	13	14	6	4	6
D-1277	PLAGE, Lordotic 13x14x7mm, Copper, 6° SML	13	14		4	6
D-1278	PLAGE, Lordotic 13x14x8mm, Green, 6º SML	13	14		4	6
D-1279	PLAGE, Lordotic 13x14x9mm, Violet, 6º SML	13	14		4	6
D-1280	PLAGE, Lordotic 13x14x10mm, Gold, 6° SML	13	14		4	6
D-1465	PLAGE, Lordotic 15x14x5mm, Silver, 0° STD	15	14		4	0
D-1466	PLAGE, Lordotic 15x14x6mm, Blue, 0° STD	15	14		4	0
D-1467	PLAGE, Lordotic 15x14x7mm, Copper, 0° STD	15	14		4	0
D-1468	PLAGE, Lordotic 15x14x8mm, Green, 0° STD	15	14		4	0
D-1469	PLAGE, Lordotic 15x14x9mm, Violet, 0° STD	15	14		4	0
D-1470	PLAGE, Lordotic 15x14x10mm, Gold, 0° STD	15	14		4	0
D-1575	PLAGE, Lordotic 15x14x5mm, Silver, 6º STD	15	14		4	6
D-1576	PLAGE, Lordotic 15x14x6mm, Blue, 6º STD	15	14		4	6
D-1577	PLAGE, Lordotic 15x14x7mm, Copper, 6° STD	15	14	7	4	6
D-1578	PLAGE, Lordotic 15x14x8mm, Green, 6° STD	15	14		4	6
D-1579	PLAGE, Lordotic 15x14x9mm, Violet, 6° STD	15	14		4	6
D-1580	PLAGE, Lordotic 15x14x10mm, Gold, 6° STD	15	14	10	4	6

Item No.	Bone Screw Description	Diameter (mm)	Total Length (mm)
C-6010	PLAGE 4.0x10 mm Self-Tap Screw, Silver		
C-6012	PLAGE 4.0x12 mm Self-Tap Screw, Light Blue		12
C-6014	PLAGE 4.0x14 mm Self-Tap Screw, Magenta	4	14
C-6016	PLAGE 4.0x16 mm Self-Tap Screw, Light Green		16
C-6110	PLAGE 4.0x10 mm Drill-Tap Screw, Copper		
C-6112	PLAGE 4.0x12 mm Drill-Tap Screw, Dark Blue	4	12
C-6114	PLAGE 4.0x14 mm Drill-Tap Screw, Pink		
C-6116	PLAGE 4.0x16 mm Drill-Tap Screw, Gold		
C-6210	PLAGE 4.5x10 mm Self-Tap Screw, Green	4.5	10
C-6212	PLAGE 4.5x12 mm Self-Tap Screw, Teal	4.5	12
C-6214	PLAGE 4.5x14 mm Self-Tap Screw, Grape	4.5	14
C-6216	PLAGE 4.5x16 mm Self-Tap Screw, Sea Green	4.5	





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