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Boston Scientific

AMS 700™ with MS Pump™ Inflatable Penile Prosthesis

Patient Guide

BSC (Patient Guide with Card, Custom Template 11.25 x 8), Patient Guide, MB, AMS 700, en, 51491645-01A

Perforation

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www.bostonscientific.com

CE 2797

2024-12

51491645-01

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Implanting
Surgeon: _____
Surgeon Telephone: _____
Hospital: _____

For additional information see IFU on website: www.IFU-BSCI.com

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MRI safety information:
This person is implanted with an AMS 700 IPP, an Inflatable Penile Prosthesis, and can safely undergo an MRI exam only under very specific conditions. Scanning under different conditions may result in injury or device malfunction. Full MRI safety information is available in the physician IFU, which can be obtained at www.IFU-BSCI.com or by calling +1-888-272-1001.

This device is MR Conditional to 3.0 Tesla

Security Screening: The metal in your device may be detectable.

To request a new card:
Please contact the Patient Liaison at:
U.S. Toll Free: +1-800-328-3881, Option 2

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Place Rear Tip Extender label here if used.

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300 Boston Scientific Way
Marlborough, MA 01752 USA
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Guide Outside Cover

Implant Card

AMS 700™ with MS Pump™ Inflatable Penile Prosthesis

Important Physician Information
This person has an AMS 700 with MS Pump Inflatable Penile Prosthesis (IPP) implanted to treat erectile dysfunction.

Patient Name: _____
Patient Telephone: _____
Implant Date: _____

Boston Scientific

Drawing 51491645

Black (K) ΔE ≤5.0 / CMYK Image

Design: The AMS 700 IPP is a fluid-filled system (see **Figure 1**). It consists of three components: a reservoir, a pair of cylinders, and a pump, as shown in **Figure 1**. Kink resistant tubing connects the components. All components contain silicone.

To inflate: Grasp the tubing above the valve block with one hand. Using the other hand, squeeze and release the pump bulb quickly and firmly. Then squeeze and release the bulb several times until the cylinders fill with fluid and become erect. Do not squeeze the deflation button while squeezing the bulb.

To deflate: Grasp the tubing above the valve block with one hand. Using the other hand, place the thumb and forefinger on opposite sides of the valve block. Squeeze the deflation button for about 4 seconds, and then release it.

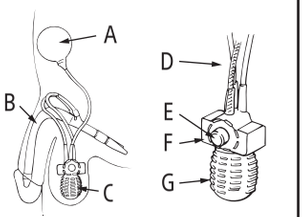

Figure 1: AMS 700 with MS Pump; pump assembly.

A. Reservoir
B. Cylinders
C. Pump
D. Tubing
E. Deflation Button
F. Valve Block
G. Pump Bulb

Place AMS 700 IPP Cylinder or preconnected system label here.

Place AMS 700 IPP Reservoir label here.

Place AMS 700 IPP Accessory Kit label here.

Place AMS 700 MS Pump label here, if a preconnected system was not used.

AMS 700™ with MS Pump™ Inflatable Penile Prosthesis

Patient Guide

Introduction

The AMS 700 with MS Pump Inflatable Penile Prosthesis (IPP) is used to treat chronic, organic, male erectile dysfunction (impotence). The AMS 700 IPP is designed to provide the patient with control over the erect and flaccid states of their penis.

Once implanted, the AMS 700 IPP is not visible. The device consists of three components connected by tubing, as shown in **Figure 1**: a reservoir, two cylinders, and the MS Pump. The AMS 700 IPP is available with an antibiotic treatment of rifampin and minocycline HCl, named InhibiZone™ (IZ). The reservoir, implanted in the pelvic area near the bladder, holds fluid until the patient decides to inflate the cylinders. Two cylinders reside side-by-side in the shaft of the penis. The pump, implanted in the scrotum, consists of a pump bulb and a deflation button as shown in **Figures 1 and 2**. The pump inflates and deflates the cylinders by moving fluid from the reservoir to the cylinders. When the cylinders fill with fluid, the penis becomes erect.

The pump bulb is round and is at the bottom of the pump. The deflation button is above the pump bulb on the rectangular valve block, as shown in **Figure 1**.

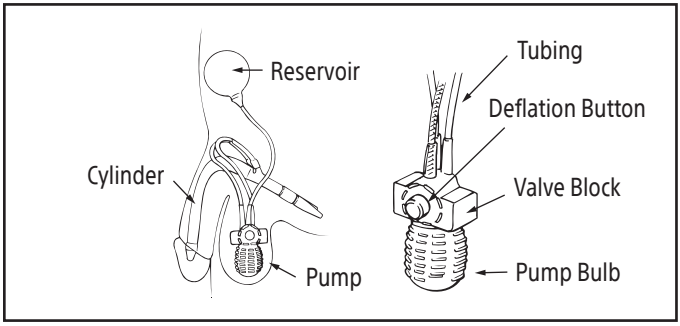

Figure 1: AMS 700 IPP with MS Pump; pump assembly.

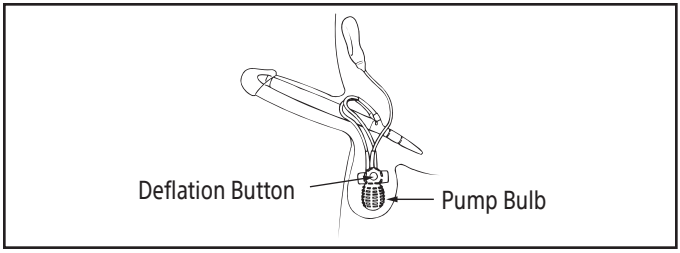

Figure 2: AMS 700 IPP with MS Pump inflated.

Indications for Use

The AMS 700 IPP is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence).

Contraindications

- The implantation of this device is contraindicated in patients who have active urogenital infections or active skin infections in the region of the surgery.
- The implantation of the InhibiZone version of this device is contraindicated in patients with known allergy or sensitivity to the drugs rifampin or to minocycline HCl or other tetracyclines.
- The implantation of the InhibiZone version of this device is contraindicated in patients with systemic lupus erythematosus (SLE) because minocycline HCl has been reported to aggravate this condition.

What to expect after surgery

Your doctor will give you instructions on positioning your penis and the required care during your healing period. After using the restroom, carefully position your penis, per your doctor's instruction.

You may experience pain or discomfort at the surgical area after your surgery and when you first use your device. In most cases, the pain goes away within a few weeks of surgery. However, some patients have reported lasting pain. Contact your doctor if pain lasts longer than expected or is severe, as this may require either surgical or non-surgical treatment.

Recovery times vary from patient to patient. It is important to follow post-operative instructions from your doctor. You will be able to return to work and everyday activities at the discretion or direction from your doctor. After three to six weeks your doctor may show you how to inflate and deflate your device and talk with you about when you can start using it.

Most doctors recommend that you wait four to six weeks before having sex. This time allows your incision site to heal and helps your body to adapt to your device. You will probably have an appointment with your doctor during the recovery period to be sure you are healing properly. At your doctor's discretion, you may have follow-up visits after the surgery. After your doctor says you can begin using your AMS 700 IPP, follow the operating instructions.

During the recovery time and after, take care to avoid trauma to the pelvic or abdominal area. Always keep in mind that you have had a surgical implant and carefully choose your activities. Trauma, such as falling or sports, may damage the device or the nearby area. Use of injection therapy in the pelvic or abdominal area, or additional treatment in that area, may also damage the device. Always inform your doctor and dentist about your device before any medical procedures, so they can take appropriate precautions.

After you are healed, continue to have yearly contact with your doctor to evaluate the device. The AMS 700 IPP is not a lifetime implant. The device will be subject to wear through normal daily use which will vary by patient. It is possible that parts of the system may require replacement or removal over time.

The AMS 700 IPP has been tested after 1,000 inflations and 1,000 deflations, which is based on 2 uses of the device per week for 10 years.

How to use my AMS 700 IPP

Inflation

When you squeeze and release the pump bulb, the fluid moves from the reservoir, through the pump and into the cylinders. When the cylinders fill with fluid, the penis becomes erect.

1. Feel for the MS Pump in your scrotum.
2. Grasp the tubing above the valve block with one hand, to hold the pump in place.
3. Initially, squeeze the pump bulb **quickly** and **firmly**, and then release it to activate the pump, as shown in **Figure 3**.

   The remaining pump bulb squeezes can be slower. Releasing allows the inflation bulb to refill with fluid. Continue to alternate squeezing and releasing until the cylinders fill with fluid and become erect. Full erection may take multiple squeezes of the pump bulb. Be sure to talk to your doctor for the optimal number of squeezes.

Note: Do not squeeze the deflation button while squeezing the pump bulb.

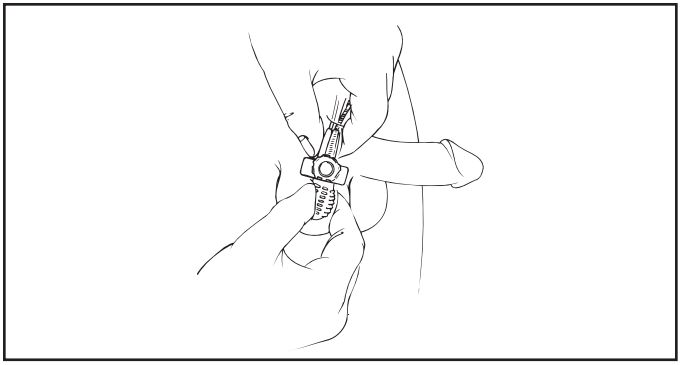

Figure 3: View of the MS Pump in the scrotum during inflation.

Deflation

When you squeeze the deflation button for about four seconds the fluid begins to leave the cylinders and return to the reservoir. After about four seconds release the deflation button and the cylinders will return to their deflated position. The penis becomes soft (flaccid).

1. Feel for the MS Pump in your scrotum.
2. Grasp the tubing above the valve block with one hand, to hold the pump in place.
3. With your other hand, locate the raised deflation button on the valve block.
4. To effectively squeeze the deflation button, you must place a thumb and forefinger on opposite sides of the valve block, as shown in **Figure 4**.

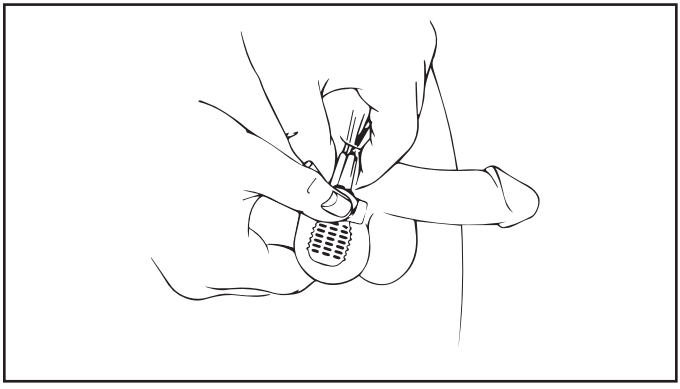

Figure 4: View of the MS Pump in the scrotum during deflation.

5. Squeeze the deflation button for about four seconds and then release. The cylinders will continue to deflate and your penis will become soft (flaccid).

Note: Do not squeeze the deflation button while squeezing the pump bulb.

6. After the cylinders have deflated, you may squeeze your penis to make it more flaccid.

What symptoms indicate that I should contact my doctor?

As with any surgery, there is the possibility that complications may develop. You should contact your doctor immediately if any of these symptoms occur:

- Change in skin color, such as redness, near an incision or implant area
- Fever
- Hives or rash
- Problems with urination
- Pus coming from the incision or head of the penis
- Severe or lasting pain
- Swelling near an incision, the scrotum or the penis

Adverse events

Patients reported the following adverse events during a clinical study (conducted from 1995-01-31 to 2002-10-24) for the AMS 700 IPP without InhibiZone:

- Blood in urine (Hematuria)
- Bruising at or near the urinary and genital organs (Urogenital ecchymosis)
- Collection of blood outside of blood vessel (Urogenital hematoma)
- Cylinder bulge (Cylinder aneurysm)
- Decreased penile sensation
- Dizziness
- Dry mouth
- Device in an inappropriate position (Device malposition)
- Device inflates on its own (Auto-inflation)
- Device malfunction, such as leaks, incomplete inflation or deflation
- Device moved from original location (Device migration)
- Infection

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- Inflammatory disease affecting joints (Rheumatoid arthritis)
- Joint pain
- Low grade fever
- Pain or discomfort during urination (Dysuria)
- Patient dissatisfaction
- Pelvic pain
- Penile curvature
- Problems with ejaculation
- Problems with healing at an incision area
- Problems with memory function
- Problems with sexual function
- Problems with skin sensation such as prickling, numbness, feeling of pins and needles (Paresthesia)
- Problems with urination
- Scar tissue around the reservoir (Reservoir encapsulation)
- Scrotal tissue attached to the pump
- Skin redness (Urogenital erythema)
- Swelling or stiffness
- Swelling, redness or raised tissue, at or near the urinary or genital organs (Urogenital edema)
- Urinating more than usual (Urinary frequency)
- Weakness
- Wearing down of tissue around the device (Erosion/Extrusion)
- Other*

*Patients reported the following "Other" adverse events during the clinical study, and each occurred in less than 0.5% of patients:

- A headache, often accompanied by nausea and sensitivity to light and sound (Migraine)
- An infection in any part of the urinary system, the kidneys, bladder, or urethra (Urinary tract infection)
- Back pain
- Decreased sexual desire
- Depression
- Downward angle of the penile head (Glans hypermobile - dorsally)
- Extreme sensitivity to light (Photosensitivity reaction)
- Eye disorder
- Eye pain
- Feeling off balance (Vertigo)
- Hair loss (Alopecia)
- Inability to control bowel movements (Fecal incontinence)

- Inability to pull back the penile foreskin (Phimosis)
- Kidney stone (Kidney calculus)
- Pain in the upper abdomen and just below the ribs (Epigastric pain)
- Poor control of glucose levels in the blood (Diabetes mellitus)
- Scar tissue (Fibrosis)
- Skin infection (Cellulitis)
- Sudden and urgent need to urinate (Urinary urgency)
- Thickening of the skin
- Tissue death (Necrosis)

Patients reported the following adverse events during this clinical study which may be associated with the use of this product:

- Bleeding
- Blood clot in a blood vessel (Thrombosis)
- Blood vessel problem (Vascular compromise)
- Curved or bent penis during erection (Ventral chordee)
- Decreased blood flow to an organ or tissue that may cause a change in skin color (Ischemia)
- Exposure to harmful material (Biohazard)
- Formation of a sore (Ulceration)
- Inflammatory disease affecting joints (Non-Rheumatoid Arthritis)
- Injury of the bladder, penis, nerve, or urine pathway from the bladder
- Injury to a blood vessel (Vessel trauma)
- Pain that does not go away or is severe
- Penile cylinder crossing over from one side of the penis to the other (Cavernosal Crossover)
- Prolonged surgery due to device issue
- Small area of inflamed tissue (Granuloma formation)
- Small piece of the device found in the body
- Swelling (Seroma)

Risks associated with the implantation of the AMS 700 IPP device

Warnings

- Not quickly treating erosion may cause it to get worse, leading to infection and further injury.
- If an allergic reaction develops to an AMS 700 IPP treated with InhibiZone, a doctor should remove the device and start appropriate treatment.
- Implantation of a penile prosthesis may result in a curved or scarred penis.

- Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection associated with a prosthesis.
- Pre-existing abdominal or penile scarring or tissue tightening may make surgical implantation more complicated or impractical.
- The implantation of a penile prosthesis will make natural or spontaneous erections impossible.
- The implantation of a penile prosthesis may make some erectile dysfunction treatment options impossible.
- Carefully consider with a doctor the risks and benefits of the device regarding sensitivity to silicone.

Precautions

- Occasionally, parts of the device move in the body, such as a cylinder, pump, or reservoir.
- Removal of a device without quick replacement may complicate a future implant surgery.
- For proper inflation and deflation, the patient will need adequate manual dexterity and strength.
- Certain psychological conditions or abnormal brain function, such as dementia or memory loss, may prevent the patient's successful operation of the device.
- Physical injury to the pelvic or abdominal areas may result in damage to the device and surrounding tissue which may require device replacement or another type of surgery.
- Use of injection therapy will damage the device.
- InhibiZone does not replace normal antibiotic protocols. Continue to use medications prescribed by a doctor.
- Patients should tell their doctor if they are taking methoxyflurane to carefully monitor kidney function, because when combined with InhibiZone it can increase the potential for kidney damage.
- Patients should tell their doctor if they are taking warfarin because an ingredient in InhibiZone can slow blood clotting time.
- Patients should tell their doctor if they are taking thionamides, isoniazid, or halothane because when combined with an ingredient in InhibiZone it can increase the potential for liver damage.
- Any risk from the InhibiZone antibiotics on male fertility is unknown and must be weighed against the benefit of using an InhibiZone-treated device to reduce the risk of infection.

Materials

The AMS 700 IPP with and without InhibiZone utilize the same materials with the same surface areas. AMS 700 IPP with InhibiZone (including reservoir, pump, and two cylinders), regardless of configuration, contains ≤ 33 mg rifampin (CAS # 13292-46-1) and ≤12 mg minocycline HCl (CAS # 10118-90-8) which represents less than 2% of an oral dose exposure for a complete course of rifampin or minocycline HCl with the maximum dose calculated for the most common device configuration's average content plus one standard deviation.

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. The tubing plug and Keith needles are made of stainless steel and therefore may contain cobalt, defined as CMR 1B in a concentration above 0.1% weight by weight.

The following tables describe the materials that have long-term contact with patient tissue as part of the implanted device. The physician may use either Quick Connect Window Connectors or Suture-Tie Connectors to connect the device. **Table 1** describes device materials if the physician uses Quick Connect window connectors, and **Table 2** describes device materials if the physician uses Suture-Tie connectors.

Table 1: Implantable Materials in AMS 700 IPP System plus AMS 700 IPP Accessory Kit (if using Quick Connect window connectors)

Implantable Material	Patient Contacting Surface Area (sq cm)	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone	614	92.87
Expanded PTFE	33.50	5.07
Polyamide	0.03	Trace
316 Stainless Steel[1]	0.52	0.08
Polyacetal	13.09	1.98
Total Implantable	**661.14**	**100**

[1]Implantable stainless steel is attributable to the tubing plug included in the AMS 700 IPP Accessory Kit. The tubing plug is used to plug component kink resistant tubing in the event of revision surgery when the physician decides to preserve and maintain that component.

Table 2: Implantable Materials in AMS 700 IPP System plus AMS 700 IPP Accessory Kit (if using Suture-Tie connectors)

Implantable Material	Patient Contacting Surface Area (sq cm)	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone	614	94.56
Expanded PTFE	33.50	5.16
Polyamide	0.03	Trace
316 Stainless Steel[1]	0.52	0.08
Polysulfone	1.27	0.19
Total Implantable	**649.32**	**100**

[1]Implantable stainless steel is attributable to the tubing plug included in the AMS 700 IPP Accessory Kit. The tubing plug is used to plug component kink resistant tubing in the event of revision surgery when the physician decides to preserve and maintain that component.

Contains cobalt: CAS No. 7440-48-4; EC No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in concentration above 0.1% weight by weight.

Based on animal studies, the European Commission has classified cobalt as a substance that may cause cancer or interfere with normal reproduction. However, research shows that metal alloys containing cobalt used in medical devices do not cause an increased risk of these effects in humans. The patient is advised to speak with his doctor if he has any questions about the device materials.

Frequently asked questions

Below are answers to some of the more frequent questions about a penile prosthesis. Talk to your doctor about any additional questions you may have.

Will I have to take any precautions before undergoing future medical procedures?

It is important to tell your doctor that you have an AMS 700 IPP to prevent damage to the device or injury to the surrounding areas.

Can I go through security screening?

When you walk through security screening, the metal in your device may set off a metal detector. Since the AMS 700 IPP has minimal metal, it should not set off a metal detector. However, if detected, report that

you have a medical device. Carry the Implant Card for the AMS 700 IPP because it identifies you as a recipient of a medical device.

If you do not have an Implant Card, please ask your doctor or visit our website at:
https://www.bostonscientific.com/en-US/patients/health-conditions/mens-urology-resources/pru-reply-card.html

What should I do if the cylinders are difficult to inflate, or if they won't inflate?

Reset the pump by following these steps:

1. Squeeze the deflation button to refill the pump bulb.
2. Reactivate the pump with a **HARD, QUICK** squeeze of the pump bulb.
3. Inflate the device normally.

If this doesn't resolve the problem,

1. Squeeze the sides of the valve block to refill the pump bulb.
2. Squeeze the deflation button for 2-4 seconds to reset the lock-out mechanism.
3. Reactivate the pump with a **HARD, QUICK** squeeze of the pump bulb.
4. Inflate the device normally.

Do not squeeze the deflation button and pump bulb at the same time.

Do not squeeze the ends of the valve block while squeezing the pump bulb at the same time.

Where can I get more information about my AMS 700 IPP?

Your first resource is your doctor. Your doctor is most familiar with your medical situation and can work with you to achieve optimal results from the AMS 700 IPP. You can also call Boston Scientific at +1-800-328-3881, or visit our website at www.bostonscientific.com

Reservoir Location Information

Medical journal articles were reviewed in 2022 to evaluate the surgical placement of the AMS 700 reservoir in either the pelvic area near the bladder or in another location chosen by the doctor (known as ectopic reservoir placement). Seventy articles described reservoir location from more than 9,000 patients and from that total, over 6,000 patients had a reservoir placed in another location (ectopic reservoir placement). Levels of satisfaction and the number of complications were similar, no matter the reservoir location.

The medical journal article review identified the following possible adverse events (AEs) for either reservoir location:

- Device inflates on its own (Auto-inflation)
- Wearing down of tissue around the device (Erosion)
- Device moved from original location (Migration or herniation)
- Infection
- Reservoir malfunction such as leaks, incomplete inflation or deflation
- Pain
- Feeling the reservoir under the skin (Palpability)
- Reservoir in an inappropriate position (Reservoir malposition)
- A second surgery may be required to reposition or remove the reservoir (Reservoir revision or removal)

Ectopic reservoir placement may not have regulatory approval in all markets.

MRI Safety Information 

Table 3 provides the MRI parameters for patients with an AMS 700 IPP with MS Pump. The patient may be safely scanned under these conditions regardless of cylinder type/size, reservoir type/size, RTEs, connector type, or if there is a tubing plug implanted. Failure to follow these conditions may result in injury.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Table 3: MR Conditional Labeling

Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact that extends approximately 36 mm from the device.

Reporting serious incidents

Report any serious incident that occurs in relation to this device to your healthcare provider, to Boston Scientific and to the relevant local regulatory authority for medical devices in your country. For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (https://www.tga.gov.au).

Related professional use documents: 51491574, 51873615.

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Symbol definitions

REF	Catalog number
	Use by date
LOT	Lot Number
UDI	Unique Device Identifier
	Magnetic Resonance Conditional
	Legal Manufacturer
	Contains hazardous substance

REF

This document is applicable to the following products:

720182-01	72404174	72404242	72404264	72404283
720185-01	72404175	72404243	72404265	72404284
72401850	72404209	72404244	72404266	72404285
72403872	72404230	72404250	72404267	72404286
72404010	72404231	72404251	72404268	72404287
72404011	72404232	72404252	72404269	72404288
72404012	72404232-10	72404252-10	72404271	72404289
72404013	72404233	72404253-12	72404272	72404291
72404014	72404233-12	72404253	72404273	72404292
72404043	72404234	72404255	72404274	72404293
72404155	72404234-14	72404256	72404275	72404294
72404156	72404235	72404257	72404280	72404300
72404161	72404236	72404258	72404281	72404301
72404162	72404237	72404260	72404282	72404302
72404171	72404238	72404261	72404282-10	72404302-10
72404172	72404239	72404262	72404283-12	72404303
72404173	72404241	72404263	72404284-14	72404303-12
72404305	72404306	72404307	72404308	72404310
72404320	72404321	72404322	72404323	72404324
72404325	72404326	72404330		